

**MULTI-ETHNIC STUDY
OF ATHEROSCLEROSIS
(MESA)**

**Manual of
Operations**

March 2017

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1. Overview

This manual describes the protocol for identifying, documenting, and classifying incident and recurrent endpoint events and deaths in the MESA cohort. It describes the protocol for the administration of Follow-up Calls, as they are the primary mechanism for events surveillance.

MESA identifies possible events primarily by participant self-report. Participants may report events at clinic visits or through interim follow-up telephone calls, or they may contact the field center directly, after the occurrence of an event.

The events of primary interest to MESA are:

- Myocardial infarction (MI)
- Angina
- Congestive heart failure (CHF)
- Peripheral vascular disease (PVD)
- Stroke
- Transient ischemic attack (TIA)
- Deaths due to cardiovascular diseases (CVD), subcategorized

In addition, MESA records revascularization procedures, catalogues all discharge diagnoses for hospitalizations and records International Classification of Diseases (ICD) codes for all deaths due to non-cardiovascular causes.

MESA staff document possible events through review and abstraction of medical records and death certificates, interviews, questionnaires, and other procedures. At least two physicians review each event's case materials, and its data are analyzed by computer algorithm (for MI events only) that uses standardized criteria to assign a final classification. Differing diagnoses between two reviewers are resolved, and a selected number of cases may be reviewed by the entire MESA Morbidity and Mortality (M&M) Committee for quality assurance purposes. A more detailed description of the review process can be found in Section 5.

2. Identification of Possible Events

The primary means of identifying possible events in MESA is participant self-report via post-baseline contacts (Follow-up Calls) conducted by telephone. Field center staff may also learn of potential events in other ways: participants may notify the clinic when they experience an event; a MESA examination may identify a possible event; investigation of one event may identify another event; National Death Index (NDI) search could identify a death; or field center staff may learn of a participant's death through an obituary or other public notice.

2.1 Events Identified by Follow-Up Phone Call

A trained interviewer administers a standardized interview by telephone to the participant at scheduled intervals between clinic visits (see *Appendix D.1, Follow-Up Phone Call*). The interviewer asks participants if they have had any new diagnoses of MI, angina, CHF, PVD, stroke, or TIA, and whether these involved inpatient or outpatient treatment. The interviewer also asks the participants to identify all hospitalizations and initial nursing home admissions that have occurred since their last field center contact, in addition to any relevant procedures or tests. Follow-up staff refers all possible events to events surveillance staff for investigation.

During the course of follow-up, staff may also identify deaths, which are also referred to surveillance staff for investigation. As closeout for non-hospitalized deaths for which CVD is indicated as a possible primary or contributory cause, an interviewer makes a follow-up phone call to the participant's next-of-kin or other knowledgeable proxy to identify circumstances surrounding the death.

2.2 Events Identified by Other Methods

2.2.1 Events Identified by Participant Notification

Participants are asked to notify the Field Center if they are hospitalized or receive a diagnosis of CVD from their personal physician. This request is reiterated to participants during each clinic visit and follow-up phone call. In addition, newsletters sent out to participants remind them to contact the field center should they be hospitalized or diagnosed with CVD. If a participant identifies a potential event, then surveillance staff will obtain the proper information from the participant and/or the participant's proxy.

2.2.2 Events Identified Through MESA Clinic Visits

Prior to clinic visits, staff asks participants questions, similar to those asked during the interim contact interview, related to new diagnoses of CVD and hospitalizations/nursing home admissions. If the participant identifies a potential event during the field center visit, surveillance staff collects available data about that event during the clinic visit.

2.2.3 Events Identified Through Investigation of Another Potential Event

While the Field Center staff is investigating an event, they may discover another possible event. If that new event happened on the same day (for outpatient events) or during the same hospitalization (for hospitalized events) then that new event may become part of the already existing investigation. The Field Center may edit the events forms (ex/Initial Notification) to include the new information. Alternately, the Field Center may choose to open a new investigation for the newly identified event. In the case that the Field Center opens a new investigation, and the events end up being connected, they will be linked during the review process by the physician reviewers.

2.2.4 Events Identified Through a National Death Index (NDI) Search

According to its web site, “The National Death Index (NDI) is a central computerized index of death record information on file in the State vital statistics offices. Working with these State offices, NCHS established the NDI as a resource to aid epidemiologists and other health and medical investigators with their mortality ascertainment activities.”

Periodically, the Coordinating Center will search the NDI for participants with whom the study has lost touch. The Field Centers will then be notified of these deaths so that additional information can be obtained and so that the death can go to physician review.

A Field Center may itself search the National Death Index (NDI) for deaths in their subject pool if the Field Center needs to use the NDI as a way to obtain death certificates. If the NDI identifies a subject as having died (previously unknown to the FC), the Field Center can immediately attempt to contact the subject/proxy to get more information. Any information obtained from the NDI should be retained in the subject’s record. The Field Center must go through an application process (which involves the IRB at the Field Center’s own institution) in order to begin receiving NDI information. The application and additional information can be found at the NDI web site:

National Death Index
Division of Vital Statistics
National Center for Health Statistics
3311 Toledo Road, Room 7316
Hyattsville, Maryland 20782
(301) 458-4444
email: ndi@cdc.gov
Web site: <http://www.cdc.gov/nchs/r&d/ndi/ndi.htm>

2.2.5 Events Identified by the Field Center through an Obituary or Other Public Notice

Periodically, a Field Center may come across an obituary or other public notice pertaining to a subject in the MESA study. The Field Center should immediately attempt

to contact the subject/family to get more information. The Field Center should retain the public notice in the subject's record. Any information that surveillance staff obtain regarding a potential event should be followed up on, regardless of source.

2.3 Notification of the Coordinating Center

When a potential event is identified, Field Center staff complete and scan an *Initial Notification of Potential Event/Death* form. Scanning the form into the database alerts the Coordinating Center of the potential event(s). This helps the Coordinating Center track event investigations that are in process, and triggers the next events collection steps for field center staff.

3. Events Investigation

Surveillance and Events staff may consist of coordinators, nurses, medical records technicians, and other professionals. These staff members are trained to determine a potential event's eligibility for investigation and to gather information required for its validation. A schema showing the flow of data collection and forms used is provided in Figure 3.1. For more detailed descriptions on how to complete individual forms, please see Appendix D.

Consent

During the MESA Field Center clinic visits, participants provide consent for MESA staff to access their medical records as needed in the future. However, most often this consent will only be valid for a stated period of time. If the participant's consent expires, surveillance staff must send the participant a new medical release form to obtain further permission to access medical records as needed.

Please Note:

The lifespan of participant written consents and HIPAA signatures differ. HIPAA signatures are valid in perpetuity. Therefore, it is *NOT* necessary to re-obtain HIPAA signatures. On the other hand, written consents are valid for a limited duration. The length of time a signed consent form is valid varies by municipality and individual institutions. A participant written permission to release medical records must be re-obtained when consent expires. To ensure you are maintaining up-to-date medical releases for your field center's participants, be sure to familiarize yourself with any local (i.e., city, county, or state) rules governing the length of time a signed release is considered valid. Also, check with the major hospitals in your area to become aware of any specific policies they may have regarding a signed medical release form's expiration. Note that policies at individual hospitals may vary with respect to allowing Field Center staff access to the records themselves. Institutional Review Board (IRB) approval may be needed to access some records. Field Centers are encouraged to contact their institution's HIPAA official to ensure that their consent practices are appropriate.

Foreign Language Records

It is plausible that MESA participants may have medical events occurring outside of the country. If it is feasible to obtain foreign records, particularly if the record language can be easily translated (such as Spanish or Chinese), then an attempt should be made. Medical records for deaths or CVD events should definitely be sought. If foreign governments/institutions are not cooperative in providing the records, participant families should be approached to obtain the information. Field Centers should inform participants in advance to bring back medical records if they leave the country.

Methods of Data Collection

Field center staff submit most information using the Electronic Data Collection software (EDC). See Section 7.2 for more information. However, staff must also submit selected parts of the medical record. These may include electrocardiograms (ECGs), catheterization reports, treadmill results, chest x-ray (CXR) reports, and other pertinent procedure and diagnostic documentation. Such records must be photocopied, scanned and then transmitted to the Coordinating Center electronically. See Section 7.1.

Staff must properly blind the photocopies. Your center may require that this be done before they are scanned and transmitted.

Prevalent (Pre-baseline) Disease

Although MESA participants were intended to be free of baseline cardiovascular disease, surveillance may identify events that occurred prior to baseline. These will not undergo an investigation. A Local Cardiac MD reviewer will document prevalent disease in the MESA database for all endpoints of interest (MI, angina, CHF, PVD, stroke, TIA); if the endpoint in question is stroke or TIA, the Local Cardiac MD reviewer must refer to the MESA stroke/TIA Criteria outlined in Section 4 of this manual. The Events Data Management software allows the Field Centers to enter in this information, automatically updating the participant's disease status to 'prevalent' for the relevant endpoint. Field Center staff must consult with a physician reviewer from their site prior to entering information regarding prevalent disease into the software.

Recurrent Events

MESA does review "recurrent events." These potential events should be investigated the same as incident events.

3.1 Initial Notification

The Field Center notifies the Coordinating Center about potential events by completing an *Initial Notification of Event/Death* form in the EDC. This form should be submitted immediately after the center learns of the potential event(s). The Field Center should not wait to obtain medical records before submitting this form.

This form allows the Field Center to select multiple types of events that may have occurred. Multiple events occurring during a single hospital stay belong to the same investigation and should all be reported on the same *Initial Notification*. Multiple events may be reported on the same *Initial Notification* form (thus grouping them as a single investigation) if they occurred on the same day or if they occurred within 30 days and are, in the judgment of the Abstractor, related to the same condition. It does not matter if the potential events are in or out of hospital, as long as the Abstractor feels that the incidents are clearly related. Only one *Initial Notification of an Event/Death* is to be completed for each investigation. If it is unclear whether two events should be marked on the same *Initial Notification*, you should submit two *Initial Notifications* to start two investigations or consult your PI.

3.2 Eligibility

After the Coordinating Center has been notified of the potential events via the *Initial Notification* form, the Field Center begins to obtain the necessary information to complete the investigation. See Section 3.3 Methods. After medical records have been obtained, the Field Center must complete the *Events Eligibility* form in the EDC to see if the potential event(s) contained in this investigation qualify for review. Whenever possible, the Field Center Abstractor should be the staff member who completes the *Events Eligibility* form, although the Events Coordinator (if trained) may fill out the form

if the form is then approved by the Abstractor. If the participant was hospitalized and transferred between care facilities, the field center must complete a separate *Events Eligibility* form for each admission.

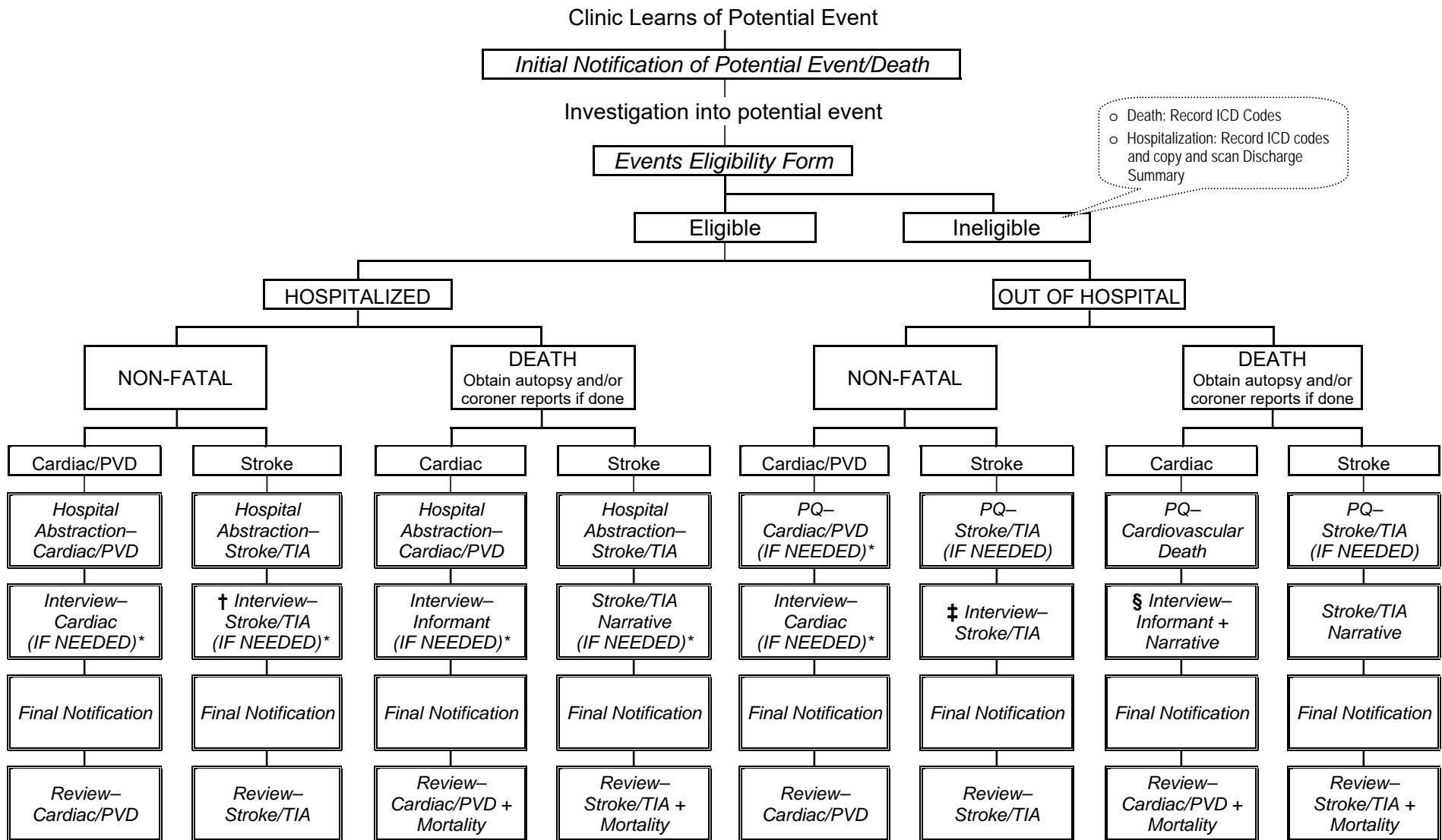
3.2.1 Eligible Events

If the investigation yields an eligible event, then the Field Center proceeds with the investigation. Figure 3.1 on the following page indicates which forms should be completed for each type of eligible event noted on the *Events Eligibility* form. Please see Appendix D for detailed instructions for each individual form.

3.2.2 Ineligible Events

If no events in the investigation are eligible for review, then the Field Center staff should complete a *Final Notice* form. They should mark on the *Final Notice* form all procedures/tests that were done and scan the Discharge Summary (if a Discharge Summary isn't available, please scan other summary documentation). Other materials do not need to be scanned, and any already-scanned materials do not need to be deleted. No additional forms are necessary.

Figure 3.1 MESA Events Forms Flow Chart



- Death: Record ICD Codes
- Hospitalization: Record ICD codes and copy and scan Discharge Summary

* "IF NEEDED" does not require an override if you do not submit that form.

† Interview needed if hospital records inadequate; add Narrative if needed; do proxy Narrative in place of Interview if ppt is incapacitated.

‡ Interview required; add Narrative if needed; do proxy Narrative in place of Interview if ppt is incapacitated.

§ Narrative required; be sure to scan the sheet, regardless of whether it contains a narrative or not

3.3 Methods

You will need a recent (6–12 months) signed consent in order for most centers to release records. Make sure you are aware of local municipality and/or hospital regulations regarding the length of time a signed consent remains valid.

Consent needs to be year specific. Do not use month reported by participant.

You will need to have a separate *Hospital Abstraction* form completed by the Central Abstractor for each eligible hospitalization within the event investigation. If a participant is transferred to another hospital without first being discharged home, a separate form must be completed for any subsequent qualifying hospitalization.

If appropriate and useful to the site, the following two-step method of requesting medical records may be utilized as an alternative to help limit the amount of PHI requested to the “minimum necessary,” and save time and effort for both the hospital medical records and MESA staff:

- 1) Request item 1 from the list of in-patient admissions records below.
 - Upon receipt of the Discharge Summary and ICD codes, determine eligibility for cardiac/peripheral vascular disease investigation.
- 2) If event is ineligible, proceed to complete event as “Ineligible Non-CVD.”

or

- 2) If event is eligible, request the additional records for items 2-10 from the list of in-patient admissions records list below.

In-patient admission records to be requested:

1. When an over-night hospitalization has been reported, send an initial request for the **Discharge Summary/Last Physician’s Progress Note** (if discharge summary was not done) AND the **Discharge Summary ICD-10 (or ICD-9) Diagnostic and Procedure Codes** (also called Physician’s Attestation) for all over-night admissions from the date of the last follow-up interview to the date of the current follow-up. (If participant hospitalization Encounter Summaries are available select the dates appropriate for record requests.)

2. **History and Physical** (including pre-operative if available)

3. **Emergency Physician’s Notes** (including EMS Report and ECG tracing, if available)

4. **Physician’s Consults**

5. **Physician’s Progress Notes**

6. **Laboratory Report** with Patient Values, Normal Ranges, and Collection Times

7. **Imaging Reports** including:

- Chest X-rays
- CT/MRI/MRA

- Ultrasounds (including Doppler)
 - Echocardiograms
- 8. Cardiac Procedures** including:
- 12-Lead ECG Tracings (including EMS reports) – no rhythm strips needed
 - Cardiac Surgical Reports (including CABG)
 - Angiogram/Angioplasty/PTCA/PCI Reports **with** Hemodynamic Log/Procedure Report
 - Cardiac Stress Tests Summary (such as Myocardial Perfusion, Bruce Protocol, Cardiolite). No ECGs or worksheets from stress tests needed
- 9. Arterial Vascular Procedures** including:
- ABI (Ankle-Brachial-Arm Index)
 - Doppler/Ultrasound Studies
 - Vascular Surgical Reports
 - Angiogram/Angioplasty Reports **with** Hemodynamic Log/Procedure Report
- 10. Autopsy/Coroner Report**

Blind the following list of items on all documents using the Acrobat software's redaction feature or a China marker.

Do blind:

1. Name and initials: patient (participant), and relatives only
2. Patient address
3. Hospital: name, address, phone number
4. Addresses other than the patient (participant)
5. Telephone numbers: patient (participant), spouse, physician, and all others
6. Place of employment: address, and phone number only
7. Insurance company information: address, phone number, and policy number only
8. Social security # of the patient (participant)
9. Medicaid/Medicare number
10. Month and day of birthday (if age is 89 or older, blind year as well)
11. Medical record number if it uses the social security number.
12. Web addresses
13. Device serial numbers

Do not blind:

1. Race
2. Sex
3. Marital Status
4. Admission date
5. Discharge date
6. Dates of procedures and events

3.4 Nonfatal Events**3.4.1 Nonfatal Hospitalized**

If a participant reports any hospitalization, surveillance staff requests records as detailed in 3.3. A recent signed consent is required by most hospitals in order to release records (see earlier in this section for more information about consents). Once the record is received, surveillance staff matches the reported hospitalization to the actual record and, if discrepancies are found, re-contacts the participant to resolve these. If the event involved a transfer to another hospital or other health-care facility, surveillance staff obtains all pertinent records from all institutions. Transfers are considered together as one potential investigation.

Surveillance staff reviews the ICD-9-CM codes and, if necessary, the discharge summary, to complete the *Events Eligibility* form, which identifies whether the hospitalization is eligible for further record abstraction. (Please see Table 3.1 on the following page for a list of eligible ICD codes.) Whenever possible, the Field Center Abstractor should be the staff member who completes the *Events Eligibility* form, although the Events Coordinator (if trained) may fill out the form if the form is then approved by the Abstractor. A computerized cross-check at the Coordinating Center of the *Events Eligibility* form, with the data collected on the Follow-Up Phone Call or the *Initial Notification of Potential Event/Death* Form, serves as a means of verifying that all reported hospitalizations have been assessed for eligibility. If the investigation is 'eligible' for cardiac, a *Hospital Abstraction* form must be completed by the Central Cardiac Abstractor (see Appendix D.5 for further information). If the investigation is eligible for stroke, all collected records must be reviewed by the Central Stroke Abstractor (see Appendix D.6 for further information).

Table 3.1 shows ICD-9 codes eligible for further investigation/abstraction.

Table 3.1
Eligible Hospital Abstraction Codes*¹

	ICD-9 Code¹	Description
Procedures	36	Operation-heart vessels
	37	Operation-heart and pericardium
	38	Operation-incision, excision, occlusion of vessels
	39	Other operation on vessels
	84.1	Leg amputation
	88.5	Cardiac catheterization
Diagnoses	402	Hypertensive heart disease
	410	Acute MI
	411	Acute CHD
	412	Old MI
	413	Angina
	414	Other CHD
	425	Cardiomyopathy
	427	Cardiac dysrhythmias
	428	Heart failure
	429	Ill-defined heart disease
	430	Subarachnoid hemorrhage
	431	Intracerebral hemorrhage
	432	Other brain hemorrhage
	433	Occlusion/stenosis of precerebral arteries
	434	Occlusion of cerebral arteries
	435	TIA
	436	Other CVA
	440	Atherosclerosis
	441	Aortic aneurysm
	443.8	PVD (specified)
443.9	PVD (unspecified)	
518.4	Acute pulmonary edema	

*Include all decimals, unless otherwise specified

¹ICD-10 Equivalents will be incorporated when ICD-10 is implemented

NOTE: If a medical record is eligible for stroke abstraction by having an ICD-9 cerebrovascular procedure code 38–39 or diagnosis codes 430–436, surveillance staff will send the hospital record to the Central Abstractor in Minnesota. If the medical record

is eligible on the basis of any other ICD-9 code, the Central Cardiac Abstractor abstracts pertinent data at the field center using the *Hospital Abstraction: Cardiac/PVD* form. If a participant experiences both a cerebrovascular and cardiac event, both sets of forms must be completed. If the hospital records are unavailable or do not provide adequate information to assess the event's eligibility, a *Cardiac/PVD Interview* or *Interview for Stroke/TIA Symptoms* may need to be administered.

Screening Codes

For charts that include ICD-9 procedure code 35 or diagnosis codes 250, 390–459, 745–747, 794.3, 798-799, the abstractor reads the discharge summary looking for evidence of eligible conditions. If a possible condition is noted, the chart is also considered eligible.

If the chart is not eligible for abstraction, the abstractor simply records the ICD-9 codes on the *Events Eligibility* form, scans the discharge summary, and transmits this documentation to the Coordinating Center. See Section 7.1 for how to scan records.

The Field Center must also complete a *Final Notification* form indicating the reason that the event is ineligible. If the Field Center realizes early on that the event never happened (participant was never hospitalized) or is a duplicate of another investigation, they may delete the *Initial Notification* from the database. Once an *Event Eligibility* form has been submitted, however, the Field Center must continue on and submit a *Final Notice*, marking 'Not an Event' as the type.

3.4.2 Nonfatal Outpatient Events

Participants may also report outpatient diagnoses for outcomes of interest to MESA. These will most likely be in cases of angina, CHF, PVD, and TIA but are also possible in cases of MI or stroke. In addition to diagnoses, MESA wants to capture the occurrence and results of certain outpatient cardiovascular procedures. If there is an outpatient cardiac diagnosis or procedure, the Field Center will first request records (both physician notes and procedure reports). If the obtained information is not sufficient, then the Field Center will send a *Physician Questionnaire: Cardiac/PVD* to the participant's treating physician. If staff believes additional information on symptoms is needed to ascertain the cardiac outpatient event (this is rarely needed), a *Cardiac/PVD Interview* is administered with the participant or appropriate proxy. All pertinent records are noted on the *Final Notice* form. All of these records should be scanned if the case is eligible for review. If the case is not eligible for review, the procedures should be marked on the *Final Notice*, but not scanned.

If a non-fatal outpatient TIA or stroke is reported, surveillance staff requests all records and conducts the *Interview for Stroke/TIA Symptoms* with the participant, adding the *Stroke/TIA Narrative* if needed to provide a full picture of the event. (If the requested medical records are insufficient, then the staff should also send a *Physician Questionnaire: Stroke/TIA* to the appropriate physician.) If the participant is incapacitated and thus unable to respond coherently to the *Interview*, then the staff should administer the *Stroke/TIA Narrative* (not the *Interview*) to an appropriate proxy or informant.

NOTE: Emergency Room visits are considered ‘outpatient’ for MESA unless the participant is subsequently admitted to the hospital. If the patient is admitted to the hospital through the ER, the event is considered ‘hospitalized’. The ER and ambulance records will be considered as part of the hospital record at large.

NOTE: Nursing Home stays are also considered ‘outpatient’ events. However, nursing home records are of limited interest. Information from nursing homes should only be obtained for limited instances such as the first admission for chronic care or death. Other nursing home records, such as stays in a rehabilitation center located in the same hospital, short-term rehabilitations after hospitalization, or long-term chronic care stays that are permanent are not of interest and do not need to be obtained.

3.5 Fatal Events

Events staff completes an *Events Eligibility* form for all participant deaths. Whenever possible, the Field Center Abstractor should be the staff member who completes the *Events Eligibility* form, although the Events Coordinator (if trained) may fill out the form if the form is then approved by the Abstractor. This includes obtaining the ICD-10 codes of the primary and any secondary causes of death listed on the death certificate. Typically, surveillance staff can obtain these from the appropriate Health Department, but, if necessary, a MESA nosologist codes the causes. Events staff should not assign codes themselves.

Using the *Events Eligibility* form, surveillance staff reviews the ICD-10 codes of all deaths to determine eligibility for further investigation. Deaths requiring investigation are all those with the following codes:

<u>Underlying Cause:</u>	
I** (except I60-I69)	Cardiovascular disease
E10-E14	Diabetes
J81	Pulmonary edema
R96,R98,R99	Ill-defined
R07	Chest pain
<u>Any Listed Cause:</u>	
I20-I23	Acute CHD
I60-I67, G45-G46	Acute stroke

3.5.1 Hospitalized Deaths

Eligible hospitalized fatal events will be eligible for hospital record abstraction (described above), in which case surveillance staff performs a hospitalization investigation as well as an investigation of the fatal event. If the in-hospital death is not eligible based on the discharge ICD-9 codes but is eligible based on the death certificate codes, surveillance staff still undertakes a hospital investigation. If an eligible in-hospital death has an autopsy, surveillance staff copies the autopsy report and submits it to the Coordinating Center as part of the event’s case packet. The events staff may also attempt

to interview the participant's proxy to obtain more information using the *Informant Interview* or *Stroke Narrative* (depending on the type of death) if the information from the hospital is insufficient. These forms are on an "if needed" basis.

3.5.2 Out-of-Hospital Deaths

Eligible out-of-hospital deaths, which include deaths in the emergency room, nursing homes, dead-on-arrivals, and participants admitted without ever showing vital signs, require a different kind of investigation. For possible out-of-hospital stroke deaths (ICD-10 I60–I67 or G45–G46), surveillance staff identifies a physician to whom to send a *Physician Questionnaire: Stroke/TIA*. Events staff should also request records from the physician at this time. Staff also identifies an informant to be administered the *Stroke/TIA Narrative* form (do not administer the *Interview for Stroke/TIA Symptoms*). For possible cardiac deaths (i.e., deaths eligible for investigation per at least one non-cerebrovascular ICD-10 code), surveillance staff contacts at least one informant (e.g., spouse or next-of-kin listed on the death certificate or proxy identified on the clinic tracking form) to interview using the *Informant Interview* form. Staff also identifies one physician (e.g., participant's personal physician or the one certifying the death) to whom a *Physician Questionnaire: Cardiovascular Death* form is sent. **Again, request records at the same time.** If staff subsequently identifies a better informant or physician, an additional interview is conducted or an additional questionnaire is sent to this person. Staff may need to make multiple contacts to complete collection of these forms. If an eligible out-of-hospital death has an autopsy or coroner report, staff scans and transmits it to the Coordinating Center as part of the event packet.

3.6 Final Notification

After the Field Center staff has completed their investigation, they will complete and submit a *Final Notification* form in the EDC, unless it has been completed by the Central Abstractor. This form will tell the Coordinating Center what type of event(s) the Field Center believes are included in that investigation. There must only be one *Final Notification* form for each investigation, but multiple eligible event types (from that investigation period) may be marked. Investigations are not considered complete until all documentation for both cardiac and stroke has been submitted. Do not complete a *Final Notice* until all documentation is in the system. Once a *Final Notice* is received by the Coordinating Center, it is considered complete and ready to be sent to the M&M Physician Reviewers for classification.

NOTE: If an investigation contains both eligible and ineligible events, do not mark the "ineligible events" choice on the form. Only mark this option on the *Final Notice* if there are no eligible events.

4. MESA Criteria for Events

Each potential event is reviewed and classified using standardized criteria.

A reviewer's classification of an event applies only to the specific hospitalization or outpatient situation under review. Unless the review is for death, a reviewer should not be concerned if there is a history of prior incident events identified in the records or in MESA reviews. Each event should be judged separately as "Definite," "Probable," or "No/Absent" for a new incident event.

4.1 Criteria for Non-Fatal Events

Nonfatal events include **MI, resuscitated cardiac arrest, angina, congestive heart failure, peripheral vascular disease (PVD), stroke, and TIA**. In addition, MESA records revascularization procedures. MESA is purposefully not identifying asymptomatic coronary or ventricular disease as an endpoint because of concerns about potential bias.

4.1.1 Criteria for Myocardial Infarction

The criteria for myocardial infarction (MI) include information about chest pain, cardiac enzymes, and ECGs. The MESA MI criteria have been adapted from the Atherosclerosis Risk in Communities (ARIC) Study. The source for the ARIC criteria is: "ARIC Protocol 3, Surveillance Component Procedures, Version 4.0" (October 1997).

Chest pain: Chest pain is defined as an episode of ischemic pain, tightness, pressure, or discomfort in the chest, arm, or jaw. Other atypical pains identified as due to coronary ischemia may qualify. If there is a clear non-cardiac cause, chest pain is considered to be absent. Duration of pain is not considered part of the chest pain criteria.

Enzyme criteria: Table 4.1 on the next page shows the enzyme criteria in the absence of Coronary Artery Bypass Grafting (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA). Equivocal is between "above normal" and "twice the upper limit of normal," and abnormal is greater than "twice the upper limit of normal." When (non-CABG or non-PTCA) muscle trauma is present, enzymes are downgraded to equivocal.

Enzymes collected during the 48 hours following a CABG or PTCA will be classified differently from the scheme described in Table 4.1 on the next page. For PTCA, levels of CK or MB above three times the upper limit of normal (ULN) within 48 hours of the procedure will be categorized as abnormal. MB will take precedence over CK if both are available. These abnormal enzymes would not be "downgraded to equivocal" on the basis of the procedure. Similarly for CABG, levels of MB above five times the ULN within 48 hours of the procedure will be categorized as abnormal. Total CK will not be used for post-CABG enzymes. These abnormal enzymes would not be "downgraded to equivocal" on the basis of the surgical procedure. After 48 hours, the standard enzyme criteria would again apply.

Other new measures such as myoglobin or MB subforms may need to be added in the future and will be added as necessary with the same criteria for equivocal (between "above normal" and "twice the upper limit of normal") and abnormal (greater than "twice the upper limit of normal").

Table 4.1
MESA Algorithm to Classify Cardiac Enzymes as Abnormal, Equivocal or Normal

Enzyme Value	There is (a) no known muscle trauma/ hemolysis and (b) no PTCA or CABG in past 48 hours*	Muscle trauma/ liver/ hemolytic disease exists
CK-MB = present where present or absent	Abnormal	Equivocal
CK-MB $\geq 2x$ ULN (upper limit of normal)	Abnormal	Equivocal
CK-MB** $\geq 10\%$ Total CK, if no ULN is given	Abnormal	Equivocal
Total CK $\geq 2x$ ULN and LDH $\geq 2x$ ULN	Abnormal	Equivocal
LDH1 : LDH2 > 1	Abnormal	Equivocal
LDH1 $\geq 2x$ ULN if LDH2 is missing	Abnormal	Equivocal
Total CK $\geq 2x$ ULN or LDH $\geq 2x$ ULN	Equivocal	Normal
Normal < Total CK < 2x ULN and Normal < LDH < 2x ULN	Equivocal	Normal
5% Total CK < CK-MB** < 9% Total CK or CK-MB “weakly present”	Equivocal	Equivocal
Normal < CK-MB < 2x ULN	Equivocal	Equivocal
Normal < LDH1 < 2x ULN	Equivocal	Equivocal
Data present, but insufficient for above criteria	Incomplete	Incomplete
Normal < Troponins < 2x ULN	Equivocal	Equivocal
Troponins > 2x ULN	Abnormal	Abnormal
Troponins < ULN	Normal	Normal
CK-MB < ULN	Normal	Normal
All other results	Normal	Normal

*PTCA—abnormal in first 48 hours requires Troponins or LDH1 or CK or CK-MB > 3x ULN; equivocal requires 1-3x ULN.

CABG—abnormal in first 48 hours requires Troponins or LDH1 or CK-MB > 5x ULN; equivocal requires 1-5x ULN

**CK and CK-MB must be in same units for this criterion.

ECG criteria:

The following ECG tracings are identified by the Field Center and scanned:

- a. The first two codable ECGs after admission;
- b. The last codable ECG recorded before discharge; and
- c. The last codable ECG recorded on day 3 (or the first ECG thereafter) following admission or an in-hospital event.

The Coordinating Center provides the scanned ECG's to the Events Review Committee. Committee members (Physician Reviewers) will review the ECG's and classify them in to the categories listed below using clinical criteria.

In addition, MESA will do a central reading of ECG's. This will only be done on events reviewed by the committee for MI, to provide a more standardized serial ECG interpretation that includes the baseline exam ECG as well as the hospital ECG's. Criteria for standardized coding at the ECG Reading Center are provided in Appendix A. These criteria are based on the modification of Minnesota rules for serial ECG's.

MI Criteria: Table 4.2 on the following page shows the diagnostic categories of MI according to the ECG criteria, enzyme categories, and chest-pain history.

Table 4.2
MESA Diagnostic Criteria for Hospitalized MI

ECG Pattern *	Abnormal	Equivocal	Incomplete	Normal
Evolution of Major Q-Wave	Definite MI	Definite MI	Definite MI	Definite MI
Evolution of ST <u>Elevation</u> with or without Q-wave Or New LBBB	Definite MI	Probable MI	Probable MI	No MI
Evolution of ST-T <u>Depression</u> /inversion alone Or Evolution of Minor Q-waves alone	Definite MI	Probable MI	No MI	No MI
Single ECG with Major Q-Wave Or Single ECG with LBBB, described as new	Definite MI	Probable MI	No MI	No MI
Normal, Absent, Uncodable, other	Probable MI	No MI	No MI	No MI

ECG Pattern *	Abnormal	Equivocal	Incomplete or Missing	Normal
Evolution of Major Q-Wave	Definite MI	Definite MI	Definite MI	Definite MI
Evolution of ST <u>Elevation</u> with or without Q-wave Or New LBBB	Definite MI	Probable MI	No MI	No MI
Evolution of ST-T <u>Depression</u> /inversion alone Or Evolution of Minor Q-Wave alone	Probable MI	No MI	No MI	No MI
Single ECG with Major Q-Wave Or Single ECG with LBBB, described as new	Probable MI	No MI	No MI	No MI
Normal, Absent, Uncodable, other	Probable MI	No MI	No MI	No MI

* CERC equivalent ECG categories are listed in Appendix A. (These are for central ECG coding and not for Reviewer definitions.)

4.1.2 Criteria for Resuscitated Cardiac Arrest

A category of resuscitated cardiac arrest is an additional non-fatal outcome. This diagnosis is reserved for patients who were in full arrest (asystole or ventricular fibrillation and pulseless) and who underwent cardio-pulmonary resuscitation (including cardioversion) successfully. Cardiac arrest secondary to non-cardiac conditions, such as respiratory arrest, should not be classified as resuscitated cardiac arrest. Because post-arrest enzymes are difficult to interpret, in general, attempts to classify MI will not be made in patients with resuscitated cardiac arrest. Patients who never awaken and go on to die during a subsequent hospitalization would not qualify for the diagnosis of resuscitated cardiac arrest. Patients who never awaken and go on to die will be classified according to their cause of death (see Section 4.2).

To classify an event as a Resuscitated Cardiac Arrest, all of the criteria below must be met:

- a. The absence of a clear-cut non-cardiac cause. Presence of cardiac symptoms (e.g., chest pain) is confirmatory but not necessary.
- b. The person must have lived at least 24 hours after resuscitation.

4.1.3 Criteria for Angina

The MESA criteria for both inpatient and outpatient angina were adapted from the Women's Health Initiative (WHI). In MESA, angina is a symptomatic event generally involving ischemic chest, left arm, or jaw pain, though the symptoms may be "atypical." Atypical anginal symptoms can include shortness of breath, exertional dyspnea, epigastric discomfort, and back pain, in addition to pain that is isolated to the arm or the jaw. Physician adjudicators categorize angina events as "definite," "probable," and "no Angina" based on clinical judgment. In addition, reviewers record the criteria met during the hospitalization or outpatient medical visit:

- a. Physician diagnosis of angina and receiving medical treatment for angina (e.g., nitrates, beta-blockers, or calcium-channel blockers)
- b. CABG surgery or other revascularization procedure
- c. 70% or greater obstruction of any coronary artery per angiography
- d. Horizontal or down-sloping ST-segment depression or abnormal ST elevation of ≥ 1 mm on exercise or pharmacological stress testing with pain
- e. Scintigraphic or echocardiographic stress test positive for ischemia
- f. Resting ECG shows horizontal or down-sloping ST depression or abnormal ST elevation ≥ 1 mm with pain that is not present on ECG without pain

Reviewers check all criteria that apply. This approach has the advantage of easily permitting a range of analyses based on definitions of angina that include "soft" criteria (#a only) or various types of "hard" criteria (#b–f). In general, the original report of the procedure should be reviewed rather than accepting references in discharge summaries to the results of diagnostic or therapeutic procedures. However, if an original full report is not available, convincing reference to the procedure results in the discharge summary is acceptable.

Given its difficult diagnosis, Angina must retain a stringent criteria standard. All of the following guidelines below should be followed:

- a. Clear and thorough documentation of symptoms is needed to identify an event as “definite Angina.” Even if a test such as an ETT lists “Angina” or “chest pain” as its indication, Angina should not be ruled unless there is additional, explicit information from the physician regarding symptoms. Likewise, a test showing positive ischemia or the performance of a further procedure (e.g., catheterization) is not enough to rule for Angina if other MESA criteria are not met.
- b. Only code an event as Angina if it is distinct from an MI.
- c. Reviewers should not Angina as part of pain symptoms of an MI.

Angina will require clinical symptoms to be considered a MESA Event. If there is only a physician diagnosis/treatment, then the diagnosis cannot be ‘definite.’ If there is more than just a physician diagnosis, then the reviewer can assign ‘definite’ instead of ‘probable.’

Unstable angina: There is no formal separate classification for unstable angina. The suggested definition is “non-elective admission (discharge) to the hospital for acute angina and not codable as definite or probable MI.”

Revascularization: Revascularization will be documented on its own, as a category separate from other events. In cases where revascularization was performed without clinical symptoms, the Reviewers will record the revascularization, but not record angina. A reviewer’s classification of revascularization applies only to the specific hospitalization or outpatient situation under review. A reviewer should not be concerned if there is a history of prior revascularization(s) identified in the records or in MESA reviews.

4.1.4 Criteria for Congestive Heart Failure (CHF)

The MESA criteria for CHF were adapted from the WHI. MESA identifies both inpatient and outpatient diagnoses of heart failure. Physician reviewers categorize CHF events as “definite,” “probable,” and “no CHF.” A diagnosis of “definite” or “probable” CHF requires clear and thorough documentation of symptoms, as asymptomatic disease is not a MESA endpoint. (A ruling of “definite” requires more than a physician diagnosis.) Reviewers record the adapted MESA criteria for CHF met:

- a. CHF diagnosed by physician, and patient receiving medical treatment for CHF (e.g., diuretics, digitalis, vasodilators, beta-blockers, or ACE inhibitors)
- b. Pulmonary edema/congestion, by CXR
- c. Dilated ventricle or poor left ventricular function (e.g., low ejection fraction or wall motion abnormalities), by echocardiography, radionuclide ventriculogram (RVG)/multigated acquisition (MUGA), or other contrast ventriculography, or evidence of left ventricular diastolic dysfunction.

Reviewers will check all criteria that apply. This approach has the advantage of easily permitting a range of analyses based on definitions of heart failure that include "soft" criteria (#a only) or various types of "hard" criteria (#b–c).

In general, the reviewer should examine the original report of a procedure rather than accept references to results of the diagnostic or therapeutic procedures in discharge summaries. If an original full report is not available, convincing reference to the procedure results in the discharge summary is acceptable.

4.1.5 Criteria for Claudication or Peripheral Vascular Disease (PVD)

The MESA criteria for claudication have been adapted from the WHI. Claudication is a symptomatic event and in MESA refers to only the lower body—typically exertional leg pain relieved by rest. Outpatient records of claudication will not be sought in MESA unless they include a major outpatient diagnostic procedure such as angiography or angioplasty. Physician adjudicators categorize potential MESA PVD events as “definite,” “probable,” and “no PVD” based on clinical judgment. A ruling of “definite PVD” requires more than a physician diagnosis. Good documentation of symptoms is needed. Even if a test such as a Doppler lists “PVD” or “claudication” as its indication, PVD should not be ruled unless there is information documenting symptoms or treatment for PAD.

Physician adjudicators also subclassify PVD as:

- a. Lower extremity claudication
- b. Atherosclerosis of arteries of the lower extremities
- c. Arterial embolism and/or thrombosis of the lower extremities
- d. Abdominal aortic aneurysm

Reviewers also record the PVD criteria met:

- a. Ultrasonographically- or angiographically-demonstrated obstruction or ulcerated plaque ($\geq 50\%$ of the diameter or ≥ 75 of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below
- b. Absence of pulse by Doppler in any major vessel of the lower extremities
- c. Exercise test that is positive for lower extremity claudication
- d. Surgery, angioplasty, or thrombolysis for peripheral vascular disease
- e. Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene
- f. Exertional leg pain relieved by rest and at least one of the following: (1) claudication diagnosed by physician AND (2) ankle-arm blood pressure ratio ≤ 0.8
- g. Surgical or vascular procedure for abdominal aortic aneurysm
- h. Doppler, angiogram, CT, or MRI examination positive for abdominal aortic aneurysm

4.1.6 Criteria for Stroke and TIA

All potential cerebrovascular events are classified as “stroke,” “transient ischemic attack” (TIA), or “not a cerebrovascular event.” All events classified as stroke will be further classified by type: subarachnoid hemorrhage, intraparenchymal hemorrhage, other hemorrhage, brain infarction, or unknown. Criteria for TIA, stroke, and type of stroke are

provided below. Criteria for infarct subtype are provided in *Appendix B*. Symptomatic retinal infarction should be classified as "brain infarction" but requires documentation by an ophthalmologist. "Brain Infarct Subtypes" should also be coded for a symptomatic retinal infarction.

TIA

One or more episodes of focal neurologic deficit

AND

Lasting more than 30 seconds

AND

Complete resolution of focal neurologic deficit within 24 hours

AND

No clinically relevant lesion on brain imaging*

OR

Brain imaging not done

AND

None of the following features: clonic jerking, conjugate eye deviation, prolonged focal seizure with spread, scintillating scotoma, headache with nausea and vomiting, or immediately-preceding head trauma

Stroke

Rapid onset of neurologic deficit, headache, or meningismus

AND

Neurologic deficits not secondary to brain trauma (closed head injury), tumor, infection (e.g., encephalitis or meningitis), or other non-vascular cause. (But clinical evidence or suspicion of embolic stroke secondary to SBE *would* be counted as stroke)

AND

Clinically relevant lesion on brain imaging*

OR

Duration greater than 24 hours

OR

Death within 24 hours

* Clinically relevant lesion on brain imaging: Imaging finding judged to be consistent with signs and symptoms regardless of timing of brain imaging (i.e., less or greater than 24 hours), regardless of stroke type (i.e., with or without blood), and regardless of imaging technique (i.e., cranial computed tomography [CT scan] or cranial magnetic resonance imaging [MRI]).

4.1.6.2. Criteria for Stroke Types**Subarachnoid Hemorrhage (SAH)**

Clinical presentation with sudden onset of a headache, meningismus, loss of consciousness, or coma. Focal neurologic deficit may also be present.

AND

Consistent imaging findings with blood mainly in the subarachnoid space (basal cistern or convexity) or isolated intraventricular hemorrhage

OR

Cerebral fluid bloody or xanthochromic on direct non-traumatic examination

OR

Surgical or autopsy evidence of subarachnoid hemorrhage

Intraparenchymal Hemorrhage (IPH)

Clinical presentation of focal neurologic deficit; coma may be present

AND

Consistent imaging findings with mainly intraparenchymal, dense hemorrhage

OR

If no imaging, cerebral spinal fluid bloody or xanthochromic on direct non-traumatic examination

OR

Surgical or autopsy evidence of intraparenchymal hemorrhage

Other Hemorrhage (OH)

Insufficient data to classify subarachnoid or intraparenchymal hemorrhage

AND

Imaging shows blood in the parenchyma, subarachnoid space, or both

OR

Cerebrospinal fluid bloody or xanthochromic on direct non-traumatic examination

OR

Surgical or autopsy evidence of blood in parenchyma, subarachnoid space, or both

Brain Infarction (INF)

Not meeting criteria for SAH, IPH, or OH

AND

Clinical presentation of focal neurologic deficit; coma may be present

AND

Consistent imaging findings without clinically relevant lesion or with clinically relevant mainly non-hemorrhagic lesion or hemorrhagic lesion indicating a hemorrhagic infarction

OR

Surgical or autopsy evidence of brain infarction

Other Stroke Type (OS)

Not meeting criteria for SAH, IPH, OH, INF.

[Examples: venous thrombosis with bleed, arterial dissection.]

Unknown Stroke Type

Insufficient data to classify type as SAH, IPH, OH, INF, or OS

[Examples: No work-up was done.]

4.2 Criteria for Deaths

Deaths are classified, using criteria provided below, into the following fatal event categories:

- a. Atherosclerotic CHD Death, with sub-classifications of “definite fatal MI,” “definite fatal CHD,” and “possible fatal CHD”
- b. Stroke Death
- c. Other Atherosclerotic Disease Death (non-coronary/non-stroke)
- d. Other Cardiovascular Disease Death
- e. Non-Cardiovascular Disease Death

Those in categories a, c, and d are categorized according to timing from onset of last episode of symptoms to death (<5 min, 5 min to 1 hr, 1 to 24 hr, >24 hr, unknown). They are also classified as to most important mechanism(s) thought to cause death (more than one may apply):

- a. Primary arrhythmic death: death <5 minutes without preceding symptoms of ischemia or heart failure
- b. Secondary arrhythmic/mechanical death: death with preceding symptoms of ischemia or heart failure, but not directly due to shock or low output state
- c. Congestive heart failure – death due to shock or low output state, including prerenal azotemia
- d. Cardiac procedure such as CABG, angioplasty or stent
- e. Hemorrhage from thrombolytic therapy
- f. Unknown or uncertain

4.2.1 Criteria for Atherosclerotic Coronary Heart Disease Death

Requires the absence of known non-atherosclerotic or non-cardiac cause of death.

Definite Fatal MI

Any in-hospital death that meets criteria for MI

OR

Out-of-hospital death with a documented MI within previous 28 days

Definite Fatal CHD

Does not qualify as a “definite fatal MI”

AND

Chest pain within previous 72 hours

OR

History of CHD

Possible Fatal CHD

Does not qualify as “definite fatal MI” or “definite fatal CHD”

AND

Underlying cause of death included in: ICD-10 codes I20–I25, I46, I51.6, R96, or R98–R99

4.2.2 Criteria for Stroke Death

- a. Stroke occurrence and type determined by stroke event adjudication: subarachnoid hemorrhage, intraparenchymal hemorrhage, other hemorrhage, brain infarction, other stroke type, or unknown stroke type
- b. Mechanism of death is recorded as due to critical brain injury or as secondary to complications such as infections (lungs, urine, skin), pulmonary embolism, or arrhythmia. Critical brain injury can be lethal either because of the size of the infarct or bleed with herniation, or because of the location in the brain stem.

4.2.3 Criteria for Other Atherosclerotic Disease Death

If not codable, as above, reviewers can assign “Other Atherosclerotic Disease Death” based upon clinical judgment. Such criteria would include: complications of aneurysm, ischemia of any organ or limb leading to death, etc.

4.2.4 Criteria for Other Cardiovascular Disease Death

If not codable, as above, reviewers can assign “Other Cardiovascular Disease Death” based upon clinical judgment. Such criteria would include: pulmonary embolism, valvular heart disease, etc.

4.2.5 Criteria for Other Death

None of the above causes of death assigned, or a strong history of a likely cause of death that is not CHD.

Use official ICD-10 code (usually indicated on the death certificate)

5. Events Review and Classification

5.1 Important Definitions

Prevalent (Pre-Baseline) events: MESA participants were intended to be free of prevalent cardiovascular disease. However, surveillance may identify events that occurred before Baseline. These will undergo partial abstraction, local review (clinical judgment), and database documentation of prevalent disease, so as to be excluded during analysis. Full abstraction and committee review will not be required. Prevalent events of previous MI, Angina, CHF, PVD, Stroke, or TIA will be recorded. Prevalent events will be based on clinical events, not diagnostic testing alone (e.g., not MI by ECG only).

Recurrent Events: MESA will review ALL eligible events. This will include recurrent events. Events will be reviewed regardless of when the participant became prevalent for that endpoint (i.e. before or after baseline).

Transfers and events within 30 days: Transfers will be considered a single event, and, where appropriate, hospitalizations within 30 days for the same event may also be grouped in a single investigation. If the Field Center chooses to initiate separate investigations for each event, then they may mark investigations as possibly linked in the events software. This will notify the CC, who will inform the Physician Reviewer. The Reviewer will see both investigations simultaneously and have the opportunity to link them together.

Procedure-related events: The MESA M&M Committee classifies events as procedure-related or not. For CHF, procedure-related might be subdivided into IV fluids or other. This classification requires clinical judgment and will be determined at Review.

CHF or cardiac arrest as a cause of death: MESA classifies CVD deaths according to the underlying cause of death. CHF is treated as a mechanism of death rather than a cause of death, so no one can die of CHF. The causes of death are the underlying causes of CHF (ischemic, valvular, hypertension, alcoholic, etc.). Similarly, no one can die of a cardiac arrest. Information about mechanism of death and time between onset of symptoms and death is classified or recorded.

Aborted MI: Because most people who receive thrombolytic therapy have elevations of enzymes and ECG changes, MESA does not include a separate category for aborted MI.

For more term definitions, please see Appendix F: Glossary of Terms.

5.2 Reporting of Event Type (by Field Center Events Staff)

Based on information collected as part of the Field Center (FC) events surveillance process (including interviews, hospital records, ICD-9 and ICD-10 codes assigned by the hospital, physician questionnaires, autopsy reports, *Events Eligibility* form, and any other available medical information), the FC Events Coordinator or Abstractor types the (morbid or fatal) potential event into one of the following categories:

- Hospitalized Cardiac/PVD non-fatal
- Hospitalized Cardiac death
- Hospitalized Stroke/TIA non-fatal
- Hospitalized Stroke death
- Out-of-Hospital Cardiac/PVD non-fatal
- Out-of-Hospital Cardiac death
- Out-of-Hospital Stroke/TIA non-fatal
- Out-of-Hospital Stroke/TIA death
- Other (prevalent/pre-baseline, Non-CVD non-fatal event, Non-CVD death, insufficient data to classify, not an event) THESE ARE NOT ELIGIBLE FOR REVIEW BUT REQUIRE DOCUMENTATION.

It is important for the Events Coordinator and the Abstractor to communicate regarding each possible event. For cardiac hospitalizations, the Abstractor should be the person to decide what type of event is contained within the investigation. The Events Coordinator records the type on the *Final Notice* form. The CC uses this information to assign the event to the appropriate Physician Reviewer (see Review Process, Section 5.3).

5.3 Review Process

The MESA Morbidity and Mortality (M&M) Committee Members are divided into two subgroups for the purpose of events Physician Review: the Cardiac Subgroup and the Stroke Subgroup. The Cardiac Subgroup is responsible for reviewing events typed on the *Final Notification of Event/Death* form as Hospitalized Cardiac/PVD non-fatal, Hospitalized Cardiac death, Out-of-Hospital Cardiac/PVD non-fatal, or Out-of-Hospital Cardiac death. The Stroke Subgroup reviews all events typed as Hospitalized Stroke/TIA non-fatal, Hospitalized Stroke death, Out-of-Hospital Stroke/TIA non-fatal, or Out-of-Hospital Stroke death. Some cases may require review by both subgroups to determine all the final endpoints. The Coordinating Center will assemble and disseminate all review packets to the appropriate Physician Reviewers. (Detailed descriptions of how to complete the review forms themselves may be found in Appendix D.)

A reviewer's classification of an event applies only to the specific hospitalization or outpatient situation under review. Unless the review is for death, a reviewer should not be concerned if there is a history of prior incident events identified in the records or in MESA reviews. Each event should be judged separately as "Definite," "Probable," or "No/Absent" for a new incident event.

Reviewers will have three weeks (from when they receive the packet) to review all investigations, regardless of whether they are the Local or Central Reviewer. When there are reviews by committee, the Coordinating Center will send out packets at least two weeks in advance of the scheduled meeting.

Note: Because reviewers may need to resolve disagreements even after they enter their individual reviews online, the reviewers should not discard the paper review packet for any investigation until they see the investigation ID drop off all lists found on their online review website. This indicates that the review has been accepted in the database.

5.3.1 Local Review

All investigations that are to be reviewed by the *cardiac* subgroup (all eligible investigations except Stroke/TIA) will be reviewed at the Field Center where the potential event occurred. This Local Review will occur once for every eligible investigation and will occur simultaneously with the Central Review. A review packet will be sent to the assigned Physician Reviewer at the Field Center directly from the Coordinating Center. There is no Events Coordinator involvement during the review phase. The Reviewer will complete an online review form that will be submitted to the Coordinating Center. The results will be compared to the results from the Central Review (see 5.3.2). Disagreements will be resolved according to the procedures detailed in 5.3.4. On occasions when case distribution across FC's is uneven, two Central Reviewers may be assigned (rather than one Local and one Central).

There will be no Local Reviews of cerebrovascular investigations. The Coordinating Center will send these cases to centralized *cerebro* subgroup members only.

5.3.2 Central Review

All investigations that are to be reviewed by cardiac reviewers (all eligible investigations except cerebro) will be reviewed by a randomly selected Physician Reviewer (not from the Field Center where the investigation originated). Reviewers that are not affiliated with a Field Center will only be assigned investigations to review as a 'Central Reviewer'. Central Reviewers will complete online review forms, like the Local Reviewers. This review will occur simultaneously with the Local Review. The results will be compared by the Coordinating Center and any disagreement resolved as stated in section 5.3.4. On occasions when case distribution across FC's is uneven, two Central Reviewers may be assigned (rather than one Local and one Central).

All Stroke/TIA investigations will be centrally reviewed by two physicians (in lieu of one local review plus one central review). These two reviews will occur simultaneously, and any disagreement will follow the Disagreement Resolution process detailed below.

5.3.3 Requesting Additional Records

Reviewers should observe the following guidelines when confronting review packets for which additional records may be desired.

A. Please do not submit a temporary or provisional online review. Wait until you are satisfied that any issues involving records/criteria have been resolved. Our system will allow you to submit a second (changed) online review if necessary, but we discourage you from entering a temporary review while you await the resolution of a question, since this can alter interim reports about review data.

B. Look at Page 1 of the review packet's Summary Report to see if there is a note regarding availability of records. If a Field Center has determined that certain records were unobtainable, a note will indicate this.

C. If no such note appears, then it may be possible for the FC to request more records. Recognize, however, that a lack of medical records might not have been a FC or CC oversight. In some cases, the Field Center may not have requested medical records if they felt the Physician Questionnaire was sufficient.

D. If you would like the CC to ask the FC to request additional records, please send your request via the Comment box in the online review form.

(D1) Please clearly state that you are asking the CC to obtain more records (i.e., rather than "more records needed," write "Ask FC to obtain more records"). Whenever possible, mention the specific procedure/test reports that interest you--this greatly increases the success of our requests. If you want an interview done, please state that specifically.

(D2) It is important to send requests via the Comment box (rather than simply contacting your own site's coordinator) since the CC needs to coordinate records for both the local and central reviewers assigned to a review. We encourage communication with your coordinators from a training and quality control perspective, but we need information requests to be routed centrally.

(D3) If additional records are not available, you have the option of submitting no review but using the Comment box to declare that you think the investigation should be redesignated "Insufficient Information to Classify." In rare cases, you could request that the case go to committee if you think another physician might be able to diagnose the event.

(D4) Please do not mark the "No Event or Revascularization" bubble at the top of the online review form if you feel there is a lack of information or records. "No Event or Revascularization" should be marked only if you are confident in ruling that the patient did not experience any of the conditions or procedures described on the review form. Please see your Reviewer Manual if you have any additional questions about the criteria for the "No Event or Revascularization" category.

(E) On the rare occasion that you request that a case go to committee, please send your request via the Comment box. Please do not enter results into the online form. Please state in the Comment field why you want the committee to see the case.

5.3.4 Committee Review

Occasionally investigations will be reviewed by the entire Cardiac or Cerebro subgroup. This is done to ensure quality control. When a subgroup reviews cases together, the review form results may be recorded by hand and entered online back at the Coordinating Center. Data may also be entered directly online at the meeting. There is no resolution protocol for committee decisions. All results from a committee review are considered final, unless the committee agrees upon individuals to make the diagnosis.

At the events ascertainment process start-up, all available cases will be reviewed and classified by the entire M&M Committee for training and consistency purposes. A selected number of random cases will be reviewed by the entire committee each subsequent year for quality control purposes. Physician Reviewers may also request specific cases be brought before the entire committee.

5.3.5 Disagreement Resolution

The M&M committee has decided that all conflicting endpoint diagnoses (not revascularization) must be resolved by a “Third Reviewer” or, if necessary, by the committee as a whole.

NOTE: There is no need to resolve discrepant angina or TIA results if the participant is prevalent (at baseline) or incident already for MI or Stroke, respectively (or if both reviewers agreed that MI or Stroke was ‘definite’ for the investigation under review).

The third reviewer diagnosis will be considered final. If the two reviewers cannot agree, they will notify the Coordinating Center and another reviewer will be assigned to act as the final reviewer (this is called an “Adjudication” review) and will complete an online review for only the endpoint(s) in question. This independent Adjudication reviewer may discuss the case with the first two reviewers. The Adjudication reviewer will enter his/her decision online, and this will be considered the final diagnosis for that endpoint. (See Appendix D for detailed information on how to complete the online review forms.) For criteria marked under non-conflicting endpoint rulings, the local reviewer’s criteria selections will be the default selections for the Third Review record in the MESA database. If two central reviewers were the original reviewers (no local reviewer), then the central review that was entered most recently will be the source of the default criteria selection in the Third Review record.

The process of resolving morbidity and/or mortality review disagreements is now automated. Immediately after the completion of the two initial reviews, any disagreements are instantly brought to the last reviewer’s attention. Conflicting responses from the stroke and/or mortality form are displayed. After reviewing the item(s) of disagreement, the reviewer can choose from the following options to resolve the investigation:

- 1. Change my review to agree with other reviewer.**

This option will alter the second reviewer’s responses to match that of the first reviewer. Since the second review has been changed to match the first review, the case is resolved and the need for a third review is averted.

2. Return to my review to update.

This option allows the last reviewer to revisit his review to make revisions. If both the morbid and mortality reviews are in disagreement, this option will return the reviewer to the morbid review form before proceeding to the mortality review form. If differences exist only in the mortality reviews, this option will return the reviewer directly to the mortality review form. If the last reviewer's modifications result in agreement, the investigation is resolved and the need for a third review no longer exists. If disagreements still exist after the revision of the morbid and/or mortality reviews, the last reviewer will be presented with the same 3 options again.

3. Leave my review as it is and forward to other reviewer for 'third review'.

If review disagreements are detected and the last reviewer does not wish to amend their review to agree with the first reviewer, the last reviewer may opt to send the investigation to 'third review'. A third review requires both reviewers to collaborate on the investigation to ultimately come to a single evaluation for the event. By selecting this option, an automated e-mail message is sent to the first reviewer informing him of the third review. The reviewer assigned with the 3rd review will have the investigation appear in the "Final" review section of their on-line review queue.

After collaborating with the other reviewer on the final review, the reviewer assigned the third review must enter the review online. The on-line third review form displays the responses from both reviewers. For the disagreeing items, one reviewer's responses are displayed in red. The other reviewer's responses are shown in blue. Review items in agreement are grayed-out and locked out from editing. After submitting the third review, the investigation is resolved and no additional action is required.

NOTE: An automated computer review algorithm for certain events (e.g., MI) will be developed at the Coordinating Center based on the MESA criteria for event classification. The results of the computer review will be compared to the central review on a pilot basis to assess validity of the algorithm. If validated, the computer algorithm may serve as the second reviewer for clear-cut events when feasible. The computer algorithm will also be used as a quality control procedure throughout the events surveillance process to ensure that reviewers are adhering to MESA criteria for event classification and are not drifting over time.

5.3.6 Reviewer Responsibilities

Reviewers are responsible for doing several things:

- Review investigations and have the results entered online within two weeks of receipt of the investigation review packet.
- Contact the Events Data Coordinator at the Coordinating Center if there is any problem or missing information via the comments field on the Online Review Forms.
- Communicate with other Reviewers (when necessary) to resolve disagreements and submit results within two weeks of notification of disagreement by the CC.
- Act as a tie-breaker when two other Reviewers can not agree.
- Communicate to the Coordinating Center any data disparity that they encounter when reviewing the review packet via the comments field on the Online Review Form.
- Link investigations when appropriate.
- Oversee Events activities at their own Field Center.

The Coordinating Center will support all review activities. All questions or concerns with the process should be relayed directly to the Events Data Coordinator at the Coordinating Center. Events Coordinators at each Field Center will have no direct involvement in the Review Process. Abstractors at each Field Center will also have no direct involvement in the Review Process (unless they are also a Physician Reviewer).

6. Quality Control

6.1 Introduction

The M & M Committee has decided that **Cardiac Abstraction will be the focus of the MESA Events Quality Control (QC) program.**

The Pilot/Baseline round of the QC program will occur in April 2004. At that time, all six field centers will transcribe their February 2004 Cardiac Abstraction certification forms onto newly-provided QC abstraction forms. The scores for this pilot round will then form the baseline against which future QC rounds are compared (every six months).

It was noted that differing staff administered the Informant Interview and Stroke/TIA Interview forms at different sites, and it was agreed in 2012 that interviewers would be certified in the administering of these forms. The recommended protocol for certification is given in section 6.3.

6.2 Quality Control Activity

Summary: QC protocol for maintaining consistent and adequate abstraction of hospital charts for cardiac events in MESA.

Frequency: Every 6 months. Pilot/Baseline in April 2004, followed by next QC abstraction in October 2004.

(1) Send charts to Coordinating Center

Three (3) Field Centers—chosen by the Coordinating Center—will send one blinded (and page numbered) chart to the Coordinating Center every six (6) months (i.e., each FC sends only one chart every year). The Events staff at the Coordinating Center will send a copy of the blinded charts to each Abstractor.

(2) Complete QC Abstractions

Every Abstractor will complete three (3) QC charts every six (6) months. Paper hardcopy QC forms will be sent by the CC to the individual Abstractors. (QC forms have different underlying TELEform codes than the standard *Cardiac Abstraction* forms; the standard forms cannot be used for the QC abstractions.) Completing a ‘chart’ includes completing as many Abstraction forms as needed for that record. (Some charts may require multiple forms due to transfers.)

(3) Scanning QC forms

The Field Center will scan the QC forms within one (1) month of receiving the QC forms and charts. QC forms are verified and submitted in the same manner as other TELEforms.

(4) Reporting Results

The Coordinating Center will produce a report on the percent of disagreement between the individual Abstractors from all centers. This report will loosely quantify disagreement between abstractors. The aim would be to obtain a disagreement rate similar or lower to the baseline established by the pilot in April 2004. This report will be reviewed by the M&M Chair, the Events Director at the CC, and the CC representative to the QC committee.

(5) Field Center Feedback

The M&M Committee Chair and the Events Director at the CC will decide if further training or discussion with the Abstractors is warranted. A conference call to go over disagreements may occur when deemed necessary. Feedback letters to the Abstractors and their PI's will come from the QC Committee at the request of the M&M Chair and CC Events Director.

(6) Additional Training

If additional training or discussion is warranted, the Abstractors should have a conference call to discuss answers on the form. If there is great concern over multiple QC activities, then discussion with individual PI's or an Abstraction Training meeting for all abstractors can be considered. If there is concern regarding one particular Abstractor, then the QC Committee will act at the request of the M&M Chair and CC Events Director. Action to be determined on a case by case basis.

6.3 QC Protocol for Certification in Administration of Informant Interview and Stroke/TIA Interview Forms

- Read Appendix D.11 (Informant Interview) and D.12 (Stroke/TIA Interview) of the Events Manual of Operations.
- Practice each interview form on volunteers as necessary depending on previous interviewing experience (at least five times).
- For Certification on interview forms, conduct and audiotape three sets of interviews on three different volunteers. For Re-certification (interviewers who are already certified for follow-up or exam interviews), complete one set. For review purposes, responses must be coded on paper forms.
- Send completed forms with the recordings to the study certifier (Ms. Joel Hill) for review and certification. Electronic copies of the form and audio file are preferred.
- If the first set of tapes is not satisfactory based on the performance and quality review by the study certifier, additional tapes maybe requested.

7. Events Data Management

Section 7 provides instructions and protocols for the preparing and scanning of medical records. It also provides instructions for all functions of the Events Data Management Software program, including how to “match” forms with investigations, among many other functions.

7.1 Medical Records

After the Field Center has identified a new investigation, they should take the steps necessary for collecting records from hospitals/facilities. For detailed instructions see Section 3.3. All records and narratives will be scanned into a single PDF file and uploaded onto a secure server. The file can then be edited as necessary by the Field Center and Central Abstractors.

NOTE: It is helpful to review the Discharge Procedure codes, as well as the Discharge Summary, ER Notes, H and P, etc., to determine which procedures should be found in the record, such as ECGs, CXRs, Echos, etc.

7.1.1 Preparing Records

Once all records are received and any necessary narratives are completed, the following steps should be taken to prepare them for scanning. Since some sites have special requirements for maintaining patient confidentiality, blinding may occur at one of several places in this process for hospitalized events: before or immediately after scanning, or after Central Abstractor has completed abstraction.

1. Site does a preliminary, brief, review of the chart for completeness/appropriateness
2. Only relevant pages should be scanned (for example, do not include a colonoscopy report).
3. Sites that must blind records before transmission and are not using the Adobe Pro PDF software to blind records will blind them directly on paper at this point.
4. Site scans records onto their scanning station computer as an Adobe Acrobat Pro PDF file, taking care to scan documents in the order listed on the *Final Notice* form, with the exception that the ICD Code sheet should be scanned first, behind the coversheet.
 - a. Prior to scanning, complete a cover-sheet (found at the back of this section) and place it on top of the chart to be scanned. Number the entire packet in the bottom right corner, calling the coversheet page 1.
5. Sites that must blind records after scanning but before transmission, and *are* using the Adobe Pro PDF software to blind records will blind the scanned files on their scanning station computer at this point.

6. If there are records that are unobtainable even though mentioned in the record, enter an Investigative Note into the Event record and make a note to the Central Abstractor on the coversheet.
 7. The site uploads the records as a PDF file onto a secure server (ie. as usual). This is done automatically by the EDC software upon login.
 8. If the site receives CD records, or other electronic records, it will contact the Coordinating Center to determine the best method for incorporating them into the MESA system. CC staff will assist if files need to be translated from one format to another.
- ❖ NOTE: All ineligible and out-of-hospital events must be blinded before they are uploaded to the EDC.

7.1.2 Central Abstracting

The Central Abstractors will monitor the online Events Tracking list to identify new events for abstraction. After the Central Abstractor reviews the documents for a hospitalized investigation, they will contact the Field Center with next steps.

- If the scanned chart is complete, the Central Abstractor will complete a *Hospital Abstraction* form in the EDC. Documents not needed for Physician Review will be deleted.
- If more records are needed, the site will be asked to request the additional records. This request is also sent to the Event Coordinator at the Coordinating Center. If the requested records are received, the site will scan and merge the pages with the original scanned PDF.

After the *Hospital Abstraction* form is complete, the Central Abstractor will tell the site to blind the remaining pages that remain in the PDF on the secure server and complete the *Final Notice*.

7.1.3 Merging PDF files

If additional pages need to be added to an already existing PDF document, the following steps should be taken:

- Scan the additional pages as a new PDF and notify the Event Coordinator at the Coordinating Center as well as the Central Abstractor.
- A coversheet is not required, but allowed. If a coversheet is not used, the investigation ID and hospital code should be placed on the first page.
- After the Event Coordinator has processed the additional pages, the site will be notified so that they can merge the pages with the original scanned chart.

To merge:

- Open both PDF files located on the secure server.

- Click and drag the new pages into the original PDF.
- New pages should be placed at the end of the chart, unless instructed otherwise by the Central Abstractor.
- Once all pages are merged, delete any duplicate files from the server so that only one file per investigation remains.

After merging is complete, contact the Central Abstractor to let them know that the additional pages have been added to the chart.

7.1.4 Hospital Transfers

If a participant is transferred from one facility to another, all records must be obtained. When assembling the chart for scanning, the separate facilities should be grouped. This means that all records from the first admission appear at the beginning of the chart, followed by the records from subsequent admissions. For these cases, place the hospital code in the **upper left corner** of each page. The entire chart will still be numbered in the bottom right corner.

7.1.5 Updating the *Final Notice*

The *Final Notice* must accurately indicate what documents exist for an investigation. Please verify that all documents are correctly indicated on this form. Even if an investigation is ineligible for adjudication, please indicate what tests and/or procedures were performed. If the investigation is ineligible, you do not need to scan the documents, but do mark them on the form. For ineligible events, only the discharge summary needs to be scanned.

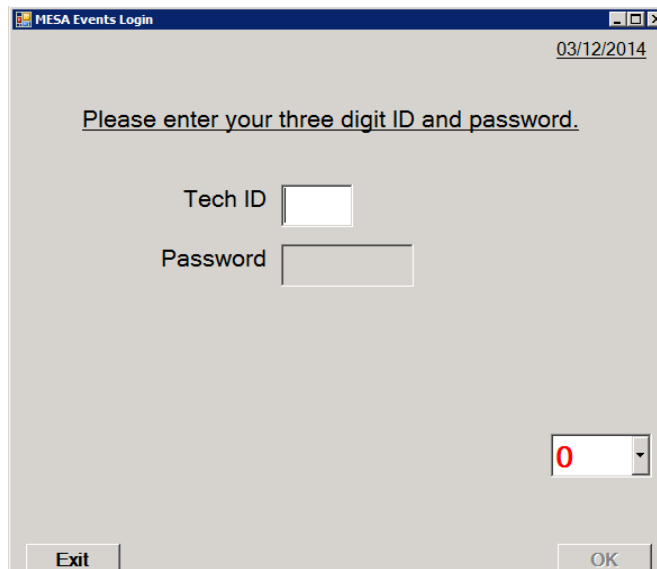
For Hospitalized events, the Central Abstractor will mark on the coversheet the final inventory of records that will go to adjudication. Use the coversheet to complete the *Final Notice* in the EDC.

7.1.6 Submitting the *Final Notice*

The LAST step in any investigation is completing the *Final Notice* in the EDC. Do NOT submit this form until ALL supporting documentation for the investigation has been successfully submitted. The Coordinating Center considers any investigation for which we have received a *Final Notice* to be closed. ‘Closed’ investigations are used to create Events Review Packets, as well as produce data reports. If the information is not complete when the *Final Notice* is submitted, then the Field Center will most likely receive a call from the CC asking that any inconsistencies or missing info be rectified.

7.2 MESA Events Electronic Data Collection Software (EDC)

1. Start the EDC by double-clicking on the MesaEvents.rdp icon on your desktop.
2. Log in using the User Name and Password sent separately (don't forget the domain "chscc\" in the user name). Then enter your Tech ID and Password.



- The Events Participant List will include any participants from your site. You can restrict the list to view one cohort or only new investigations using the drop-down menu in the upper right.

Participant ID	DOB	Enroll Date	Current Status
9900001	AAAAAAF Female	01/01/1960	01/01/2013 Yes
9900002	AAAAAAM Male	01/01/1960	01/01/2013 Yes
9900003	AAAAAAF Female	01/01/1960	01/01/2013 Yes
9900004	AAAAAAM Male	01/01/1960	01/01/2013 Yes

- Select a Participant ID to begin entering a case.
- The Events Investigations List screen will appear. Any investigations previously initiated for that participant will be seen here. To begin a new investigation, click the “Create New Investigation” button in the upper left corner and confirm the action. Note that new investigation numbers will begin at 50, regardless of the last old investigation number. To edit an existing investigation that is not marked as Complete, click on an investigation ID from the list.

Participant ID: 9900001 AAAAAAF

Create New Investigation

Investigation ID	Date	Event Type	Status
990000150		Non-CVD	
990000120	01/01/2013	Out-of-hosp. Cardiac/PVD (non-fatal)	Complete
990000120	01/01/2013	Out-of-hosp. Cardiac/PVD (non-fatal)	Complete
990000123	01/23/2013	Non-CVD	
990000131	02/01/2013	Hosp. Cardiac/PVD (non-fatal)	
		Hosp. Cardiac Death	
990000121	02/12/2013	Non-CVD	Complete
990000128	03/01/2013	Hosp. Cardiac Death	
990000130	04/01/2013	Non-CVD	Complete

- This will take you to the Events Investigation Summary screen.

Participant ID: 3000000 **MMMMMM** **Investigation ID:** 30000001 **Event Date:** 10/08/2001

Events identified in this Investigation: Non-CVD

Form Name	Status	Edit Date	Tech ID	Hosp/Num
Initial Notification	Complete	01/04/2002	382	
Events Eligibility	Complete	06/27/2002	382	
Cardiac - Hosp. Abstraction	Not Done			
Stroke - Hosp. Abstraction	Not Done			
Cardiac - Phys. Questionnaire	Not Done			
Cardiac - Phys. Quest. Death	Not Done			
Stroke - Phys. Questionnaire	Not Done			
Informant Interview	Not Done			
Stroke - Informant Interview	Not Done			
Final	Complete	08/06/2003	382	

Document Type	Edit Date	Hospital	Page	Import Date	Exclude
Other	07/03/2007		1	07/06/2007	

 View Participant Information:
 View/Edit Investigation Notes:
 Create Event Document Labels (Avery 5160):

- To view a medical record image click on its name in the lower box. A separate viewing window will appear.
- For new investigations, click the “Initial Notification” button to enter the rest of the info for the Initial form, and then click “Save” to save your data and return to the Investigation Summary screen.
- You can enter data for the rest of the forms from the Investigation Summary screen. Click on the form you want to fill out, and a dialog box will appear with a list of forms for that investigation.

- To start a new form, click inside the window on the “NEW- Click here to enter...” text. To edit an existing form, click on the number you want and the form will appear. (The Final and Stroke informant Interview forms will take you directly to the form without the list dialog box).

MESA Events Eligibility List

Participant ID: 9900001 Acrostic: AAAAAAF

Invest ID: 990000150

<u>Hospital Code</u>	<u>Admit Date</u>
NEW- Click here to enter a NEW Eligibility. -	

Close

- Enter the data on each page of the electronic form, and click the “Next Page” button in the lower right corner to save that data and continue. If you click the “Quit” button in the upper right corner, you will return to the Investigation Summary screen without saving the data from that page, but data on earlier pages will already be saved.
- To add Investigation Notes, click the “View/Edit Investigation Notes” button at the bottom of the Investigation Summary screen.
- Completing the Final form indicates that you have completed the investigation, so please do not enter the data on the Final form until you are finished entering all the other information for the case.

MESA Clinical Event
Coversheet

Participant ID: _____

Hospital Code: _____

Tech ID: _____

Total # of Pages (including coversheet): _____

Scan Date: _____

Cardiac

Cerebrovascular

Ineligible

Notes for Abstractor:

Notes for Field Center:

Appendix A: ECG Reading Center Protocol

A.1 Protocol

A.1.1 Introduction

The ECG Reading Center (CERC) for MESA will be reading the MI ECG's that the Field Centers submit to the Coordinating Center. This set of readings will be compared against the clinical reads that the Physician Reviewers make during the Review Process. Any discrepancies between the two readings will be noted. The Coordinating Center will run the MI algorithm with the results from the ECG Reading Center. Cases where the MI diagnosis differs between the Physician Reviewers and the Reading Center will be adjudicated.

A.1.2 Protocol Description

A.1.2.1 Collection/Submission of ECG's

Field Centers will obtain ECG's as part of the event investigation process. All investigations that contain events that are eligible for review by a physician reviewer require that pertinent medical records and other documentation be submitted to the Coordinating Center. Which ECG's should be scanned for hospitalized events is described on the *Hospital Abstraction: Cardiac/PVD* form and the corresponding question by question instructions (Appendix D.5). All ECG's should have the date and time clearly indicated on them and must be legible after scanning. The Field Centers are responsible for checking that the ECG's they scan meet these requirements.

After documentation of the event (including ECG tracings) is scanned in to the database by the Field Center, image files are sent electronically to the Coordinating Center where they are retained for Review and Reading Center purposes. These image files will be sent by the Coordinating Center to the Reading Center in batches.

NOTE: The Field Centers should not send hard copies of the ECG tracings to either the Coordinating Center or the ECG Reading Center.

A.1.2.2 Clinical Review of ECG's

After an investigation has been completed, it is prepared for Review by the Coordinating Center. An 'Event Packet' is sent to the assigned Physician Reviewers for them to review for endpoints. Any "definite" or "probable" MI diagnoses require that the ECG's for that investigation be read by the reviewing physician and coded. The clinical classifications are modified from the Minnesota rules for serial ECG's. The physician completes the Cardiac/PVD Review form online and the Coordinating Center receives the data.

A.1.2.3 Transmission to Reading Center

The Coordinating Center will electronically send image files to the Reading Center of all ECG's for investigations with a "definite" or "probable" MI. Clinical classification will not be sent to the Reading Center with the images. The Reading Center will not receive any information regarding chest pain or enzyme values.

A.1.2.4 Computerized Read by Reading Center

The Reading Center will code the ECG's by computer using the criteria in Table A.2 (see below). The codes are electronically transmitted back to the Coordinating Center.

A.1.2.5 Comparison at Coordinating Center

After the Coordinating Center receives the computer classifications back from the Reading Center, it will be run through the MI algorithm. If the diagnosis obtained in this fashion is different from the Physician Reviewers diagnosis, than the cases will be adjudicated. The Reading Center and M&M committee will adjudicate the event to determine whether an MI occurred. Notification and documentation of this adjudication will be the responsibility of the Coordinating Center.

A.1.2.6 Adjudication

If a case requires adjudication, the Coordinating Center will request a copy of the participant's Baseline ECG from the Reading Center. This ECG will be sent (along with the entire Events packet) to a cardiologist on the M&M Committee. This doctor will determine if the case needs to be re-classified. The cardiologist will enter their diagnosis in online as a 'Final' entry.

A.2 Reading Center Criteria

A.2.1 Modified Minnesota Code rules for Evolving ECG patterns for the classification of Acute MI

The following Table A.2 indicates the criteria that will be used by the ECG Reading Center to classify MESA events thought to be MI's.

ECG Pattern	Cardiac Enzymes			
	Abnormal	Equivocal	Incomplete or Missing	Normal
H1. –MC Serial Change Q1, Q4, Q7	Definite MI	Definite MI	Definite MI	Definite MI
H2. –MC Serial Change Q2, Q3, Q5, or Q6 OR STE Serial Change STE1,STE2, STE R1,or STE R2 OR Serial Change LBBB*	Definite MI	Probable MI	Probable MI	No MI
H3. ST-T1 throughST-T7 OR R1ST-T to R7 ST-T OR Q8	Definite MI	Probable MI	No MI	No MI
H4. Other ECGs, ECG absent or Uncodable	Probable MI	No MI	No MI	No MI
H5. Single ECG with diagnostic Q wave (MC 1.1.xor 1.2.x[except 1.2.6 or 1.2.8] OR LBBB[MC 7.1.1]	Definite MI	Probable MI	No MI	No MI

Cardiac Pain Absent**Cardiac Enzymes**

ECG Pattern	<u>Abnormal</u>	<u>Equivocal</u>	<u>Incomplete or Missing</u>	<u>Normal</u>
H1. –MC Serial Change Q1, Q4, Q7	Definite MI	Definite MI	Definite MI	Definite MI
H2. –MC Serial Change Q2, Q3, Q5, or Q6 OR STE Serial Change – STE2, STE R1, STE R2 OR Serial Change LBBB*	Definite MI	Probable MI	No MI	No MI
H3. ST-T1-ST-T7 OR R1ST-T-R7 ST-T OR Q8	Definite MI	Probable MI	No MI	No MI
H4. Other ECGs, ECG absent or Uncodable	Probable MI	No MI	No MI	No MI
H5. . Single ECG with diagnostic Q wave (MC 1.1.xor 1.2.x[except 1.2.6 or 1.2.8] OR LBBB[MC 7.1.1]	Probable MI	No MI	No MI	No MI

A.2.2 Definitions of Terms

EVOLVING Q WAVE PATTERNS

Evolving Q1: No Q-code in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code (Minnesota Code 1-1-1 through 1-2-5 plus 1.2-7) OR any code 1-3-X or 1-2-6 in baseline ECG followed by a record with any code 1-1-X.

Evolving Q2: An equivocal Q-code (Minnesota Code 1-2-8 or any 1-3 code) and no major ST-segment depression in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code PLUS a major ST-segment depression (Minnesota code 4-1-X or 4-2) and 100% increase in ST depression

Evolving Q3: An equivocal Q-code (Minnesota Code 1-2-8 or any 1-3 code) and no major ST-segment depression in prior study ECG or first ECG in event set of ECG(s) followed by a record with a Diagnostic Q-code PLUS a major T-wave inversion (Minnesota Code 5-1 or 5-2) and 100% increase in T-wave inversion

Evolving Q4: An equivocal Q-code and no ST-segment elevation in prior study ECG or first ECG in event set of ECG(s) followed by a record with a diagnostic Q-code PLUS ST-segment elevation (Minnesota code 9-2) and 100% increase in STE

Evolving Q5: No Q-code and neither 4-1-X nor 4-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS 4-1-X or 4-2 and 100% increase in ST depression

Evolving Q6: No Q-code and neither 5-1 or 5-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS a 5-1 or 5-2 100% increase in T-wave inversion

Evolving Q7: No Q-code and no 9-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS a 9-2 and a 100% increase in STE.

Evolving Q8 Evolving Q5: No Q-code and neither 4-1-X nor 4-2 in prior study ECG or first ECG in event set of ECG(s) followed by a record with an equivocal Q-code PLUS 4-1-X or 4-2 and 100% increase in ST depression

EVOLVING LBBB

New left bundle branch block (code 7-1-1, with the QRS duration increasing by at least 20 ms from less than 120 ms to ≥ 120 ms.)

EVOLVING ST ELEVATION

Evolving STE 1: No 9-2 in prior ECG or first ECG in event set of ECG(s) and 9-2 in at least 2 leads of a following event ECG with 100% increase in STE in both leads

Evolving STE 2: 9-2 in prior ECG or first ECG in event set of ECG(s) with a 100% increase in STE in at least 2 leads.

Evolving STE 3: 9-2 and no 5-1 or 5-2 in prior ECG in first ECG in event set of ECGs and

appearance of 5-1 or 5-2 with 100% increase in T-wave inversions. in at least 2 leads.

Evolving STE R1: Reversal of evolving STE 1.

Evolving STE R2: Reversal of evolving STE 2.

EVOLVING ST-T DEPRESSION/INVERSION

Evolving ST-T1: Either 4-0 (no 4-code), 4-4 or 4-3 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-2 or 4-1-2 or 4-1-1 and 100% increase in ST segment depression.

Evolving ST-T2: Either 4-2 or 4-1-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-1-1 and 100% increase in ST segment depression

Evolving ST-T3: Either 5-0, 5-4 or 5-3 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-2 or 5-1 and 100% increase in T-wave inversion.

Evolving ST-T4: Code 5-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-1 and 100% increase in T-wave inversion

Evolving ST-T5: Code 4-1-1 in prior ECG or first ECG in event set of ECG(s) followed by a record with 4-1-1 and 100% increase in ST depression.

Evolving ST-T6: Code 5-1 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-1 with 100% increase in T wave inversion.

Evolving ST-T7: Code 5-2 in prior ECG or first ECG in event set of ECG(s) followed by a record with 5-2 with 100% increase in T wave inversion.

Evolving ST-T R1 through ST-T R7 = the reverse of ST-T1 to ST-T7, respectively.

APPENDIX B: Brain infarct subtype classification

Appendix B provides the information necessary for completing Question 6 of the Stroke/TIA Review Form.

B.1 Introduction

During the Review Process, Stroke Physician Reviewers determine what type of stroke a participant may have had. If the participant is thought to have experienced a 'brain infarct', further classification is required. The Stroke Physician Reviewer will select the first, second and third choice for the diagnosis.

- First choice of Subtype: reflection of strict adherence to the subtype algorithm in manual Appendix B. If the first choice selected is 1, 2, 3, 4 or 5, responses to the second and third choice are not allowed. To ensure this rule is enforced, the second and third subtype fields are conditionally deactivated.
- Second choice of Subtype: allows for some loosening of the criteria and is an attempt to reduce the number of cases classified as "Unknown." A code of 1, 2, 3, 4 or 5 should be used for the second choice if any evidence exists in the records to support such a code. If the first choice subtype is 6, 7, or 8, a response to the second choice is required, even though it might still be 6 or 8.
- Third choice of Subtype: allows for a choice if the first choice is "more than one." The third choice would only be used if the first choice equals 7 (unknown, multiple).

This appendix describes how to differentiate between brain infarct subtypes.

B.2 Criteria

B.2.1 Large Vessel Extra-cranial Atheroembolic (LVe)

B.2.2 Large Vessel Intra-cranial Atheroembolic (LVi)

Extra-cranial: carotid artery, vertebral artery

Intra-cranial: distal internal carotid artery, distal vertebral artery, MCA, ACA, PCA, basilar

History and Examination Evidence of atherosclerosis:

Past history of TIA in the same vascular territory

OR

History of coronary artery or peripheral vascular disease

OR

Evidence of large artery atherosclerosis, such as carotid or femoral bruits or diminished pulses

AND

Vascular Imaging Studies:

Arteriography (catheter, CTA, or MRA) reveals occlusion, stenosis of 50% or more of an appropriate, large, extracranial or intracranial artery, and possibly occlusion of an appropriate stem, division, or branch artery

OR

Carotid Duplex demonstrates stenosis of 50% or more of an appropriate extracranial artery

OR

Transcranial Doppler demonstrates absent or abnormal flow velocities in the intracranial vessel

OR

Postmortem examination consistent with atherosclerosis

B.2.3 Cardioembolic (CE)**Cardiac history or examination reveals one of the following:**

Note: Studies include echocardiography (transthoracic, transesophageal, and contrast), ultra-fast cardiac CT, cardiac MRI, inpatient cardiac monitoring, Holter monitoring, and post-mortem examination. Not all need be used.

HIGH-RISK source for emboli: mechanical prosthetic heart valve, atrial fibrillation, sick sinus syndrome, myocardial infarction within 4 weeks, left ventricular thrombus, dilated cardiomyopathy, akinetic left ventricular segment, left atrial thrombus, atrial myxoma, infective endocarditis

OR

MEDIUM-RISK source for emboli: myocardial infarction >4 weeks and <6 months, congestive heart failure, left ventricular aneurysm, hypokinetic left ventricular segment, atrial flutter, bioprosthetic heart valve, mitral stenosis without atrial fibrillation, nonbacterial endocarditis

OR

LOW-RISK source for emboli: mitral valve prolapse, mitral annular calcification, atrial septal defect, patent foramen ovale, or interarterial septal aneurysm(s) in other vascular territories.

B.2.4 Small Vessel (Lacunar) (SV)

Must have all of the following:

Traditional “lacunar syndromes” findings- pure motor hemiparesis, sensorimotor stroke, ataxic hemiparesis, dysarthria-clumsy hand syndrome, or pure sensory stroke

AND

No aphasia, apraxia, or other cognitive deficits related to stroke, except if localization is established to be in the thalamus.

AND

No seizures or alteration of consciousness

AND

Minimal or no headache

AND

Clinically relevant infarct** on brain imaging no greater than 2.0cm in diameter either in a subcortical structure or in the brainstem in the territory of a small penetrating artery

OR

Postmortem examination reveals a small, deep infarction in the territory of a penetrating brain artery

** Clinically relevant infarct on brain imaging- Imaging finding judged to be consistent with signs and symptoms, regardless of timing of brain imaging (less than or greater than 24 hours) and regardless of imaging technique (CT or MRI)

B.2.5 Acute Ischemic Stroke of Other Known Etiology (O)

Arteriography shows specific, non-atherosclerotic vascular pathology

OR

Specialized testing (such as hematologic, serologic, or histologic examinations) demonstrating evidence of an underlying cause

OR

Post-mortem examination demonstrates arterial occlusion of specific etiology

B.2.6 Ischemic Stroke of Unknown Cause (no probable etiology determined despite complete workup):

Clinical criteria consistent with diagnosis as described below:

Variable onset or course of symptoms

AND

Findings do not fit the pattern of a previously described subtype

AND

CT/MRI demonstrates a bland or hemorrhagic infarction

AND

Vascular imaging shows no significant abnormalities

AND

Carotid duplex and transcranial Doppler are normal

AND

Arteriography demonstrates no significant abnormalities

AND

Cardiac testing demonstrates no source for embolism (see cardioembolic clinical criteria)

AND

Specialized testing, if done, reveals no etiology

OR

Postmortem demonstrates infarction but no specific vascular pathology

B.2.7 Ischemic Stroke of Unknown Cause (more than one likely etiology and single most likely etiology cannot be determined):

Findings fit equally well the patterns of more than one of the following subtypes: large vessel atherothromboembolic, cardioembolic, small vessel (lacunar), acute ischemic stroke of other etiology.

B.2.8 Ischemic Stroke of Unknown Cause: (workup is incomplete):

No likely source for stroke determined because the workup is incomplete (i.e., a usual, careful evaluation, including an arterial or cardiac imaging study or specialized testing that should have determined the most likely cause of stroke, was not performed).

To be classified as “Complete,” an Ischemic Stroke Subtype Work-Up requires the completion of four medical tests:

- **Brain Imaging:** Head CT or Head MRI
- **Extracranial Vascular Imaging:** Carotid Doppler or MRA / CTA / Conventional Angiogram
- **Intracranial Vascular Imaging:** Transcranial Doppler or MRA / CTA / Conventional Angiogram
- **Cardiac Assessment:** Echocardiography *AND* Initial EKG

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APPENDIX C

General Instructions for Administration and Completion of Events Forms

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APPENDIX C: General Instructions for Administration and Completion of Events Forms

C.1 General Interviewing Instructions

C.1.1 General Interviewing Information

1. Interviewer bias is any preference or inclination that creates a systematic difference between responses obtained by different interviewers. It can be affected by:
 - respondent's perception of the interviewer and his/her reaction to that
 - interviewer's perception of the respondent and his/her reaction to that
2. Characteristics of a good interview
 - 2.1 The interviewer creates a friendly, but businesslike atmosphere.
 - 2.2 The respondent is at ease. Keep these factors in mind:
 - The respondent may view a female interviewer as less threatening.
 - The respondent may view a much older interviewer as judgmental.
 - 2.3 The interviewer obtains the answer to the question that is asked by:
 - Proper use of probes.
 - Repeating a question rather than interpreting it.
 - 2.4 The interviewer obtains clarification of confusing answers.
 - 2.5 The interviewer gives only neutral responses to the respondent's answers.
 - 2.6 The interviewer accurately records responses.
- 3.0 Specific skills required for interviewers
 - 3.1 The ability to ask questions at the correct pace and in a conversational tone.
 - 3.2 A thorough knowledge of the questions and response categories (this will keep the interview flowing smoothly).
 - 3.3 Knowledge of how and when to use probes.
 - 3.4 The ability to think as an interviewer and to temporarily put aside other roles (e.g., researcher, health care provider).
 - 3.5 The ability to maintain a positive attitude about the interview (this lets the respondent know that the interview is important).
 - 3.6 The ability to keep some level of control over the interview process (e.g., by rewarding the respondent for answering questions but not for other behavior).

3.7 Additional interviewer attributes:

- Mobility (for personal interviews)
- Flexibility over schedule
- Neat, pleasant, professional appearance
- Not too timid, not too aggressive

4.0 Interviewer training

4.1 Training must cover all aspects of the interview, including:

- Introducing yourself
- Handling people who are reluctant "at the door"
- Obtaining consent
- Answering questions
- Obtaining privacy for the interview
- Setting respondent at ease
- Administering the interview
- Ending the interview

4.2 Role playing, using both standard and problematic situations, is an important aspect of training and allows trainees to discuss and solve problem that could arise in an interview with a respondent.

C.1.2 Interviewing Techniques

1. Standardized Interviewing Technique

1.1 MESA is a collaborative study being conducted through six field centers located throughout the United States. The goal of this collaboration is to produce a study that represents 6600 people throughout the country rather than 1100 from each of six smaller, geographically-scattered areas.

1.2 In order to produce data that can be considered collaborative, MESA study designers must develop and use standardized approaches to train interviewers and collect information about respondents. Standardization is achieved by using scripts in training, training supervisors centrally, establishing qualifications for supervisors, reviewing collected data, taping and reviewing interviews, and, finally, observing interviewers in the field.

1.3 Trainers will use scripts to teach probing techniques and to determine if interviewers are following skip patterns in the forms and adhering to the protocol. All **clinic** interviews will be taped. Interviewers will be trained to introduce taping to the study respondent and to secure his/her agreement. The Interviewer Supervisor will systematically review tapes to determine if questions are asked as written. Interviewers will be trained to avoid leading or providing answers for the study respondent.

- 1.4 The study is further standardized by using centralized training for interview supervisors and, where possible, for interviewers. We will initially train local interviewer supervisors; they, in turn, will train new, on-site personnel as needed. Supervisors will be in touch with each other and will share tapes to determine protocol adherence.
2. Retaining Study Participants and Engaging Other Respondents (e.g. relatives, proxies, and other informants)

The reinitiation of contact with the study participant and the first contact with the study respondents will be by telephone. Because telephone contact can make it easy for the respondent to decline, interviewers will be trained in effective telephone technique. They will also be taught to overcome respondents' objections and deal with difficult situations, some of which are described below.

 - 2.1 **Suspicion about the project.** Relatives, proxies, and other informants may not be aware that NIH is doing a study in the community and may seem suspicious. Your thorough understanding of the study will help to allay the respondent's fears or suspicions. You must learn to put the respondent at ease and to establish the legitimacy of your call.
 - 2.2 **Handicaps.** If a respondent has a disability, you must determine its severity and if it will prevent the respondent from completing in the interview. If the respondent has a person who can act as a proxy, you will need to secure their agreement to participate with the study respondent. If no such person exists, thank the study respondent and terminate the interview. Code the result appropriately and provide notes so that your supervisor can evaluate the case.
 - 2.3 **Difficulty in understanding the questions.** Some of your calls will be with persons who have difficulty understanding your questions. Read questions slowly and distinctly and allow the respondent adequate time to answer. Repeat questions, if necessary, but be careful not to insult the respondent by suggesting that he/she does not understand.
 - 2.4 **Focusing the interview.** Some respondents will welcome the opportunity to talk to a neutral person about their health and family problems. In doing so, they may stray from the questions asked. You must know when to allow a respondent time to elaborate and when to re-focus him/her on the question. Control the interview, but do not alienate the respondent.
 - 2.5 **Leading the respondent.** Some respondents will give answers that they believe you and/or the government **expect**; and they may expect you to help them with answers rather than give their own opinions or information. We are trying to gather objective data. Reassure the study respondents that there are no wrong or right answers. Encourage them to respond out of their experience and their knowledge.

- 2.6 **Diffusing sensitive questions.** Some respondents may hesitate or decline to answer questions they consider intrusive or sensitive (e.g., questions about death of a loved one). Your professional handling of a sensitive issue can help to alleviate their fears. The more secure you feel about the confidentiality of the study, the more apt you will be to give a sense of security to the study respondent. However, if all else fails, you may simply offer them the option to decline answering a specific question.
- 2.7 **Encouraging the respondent.** The respondent be clear about what is involved in the process of recruitment. Encourage both family members and respondent to raise questions or concerns about the study. Encouraging them to ask questions, and your thorough and thoughtful responses to those questions, will help to alleviate their concerns.

C.1.3 The Interview

The following procedures are recommended for a successful interview:

1. Prior to the visit prepare all materials (e.g., appropriate forms, identification, stamped self-addressed envelopes) that will be necessary for the interview.
2. The interviewer should confirm the appointment with the respondent to avoid confusion
3. Find an area where both you and the respondent can talk and write comfortably with minimal distractions.
4. Make sure that the respondent understands the questions and that you are interpreting the responses accurately. Do this by restating what you think the respondent is telling you or asking him/her to restate the question you are asking. At the same time, be careful not to impose your interpretations on the interview questions or the respondent's comments.
5. Convey your interest in the respondent's thoughts and feelings, but do your best to keep him/her focused on the interview questions. When the respondent strays from a question, try to use what he/she is saying to redirect the conversation back to the interview questions. Give positive reinforcement for direct answers. If necessary, set time limits at the outset of the interview to encourage the respondent to stay on track.
6. Respondents may try to convince you to answer certain questions for them. Let the respondents know that you are interested in **their** answers.
7. Be aware of any hearing and vision impairments and their effects on the respondent's understanding of the interview questions. If necessary, read the interview questions to respondents who have visual impairments or limited reading ability.
8. Communicate with other interviewers and the project director to share ideas about how to deal with difficult situations and to agree on consistent

explanations for questions that are frequently misunderstood by respondents.

9. Encourage, but do not force, respondents to answer to all questions.
10. If persons other than the respondent are present during the visit, address the respondent directly and do not encourage conversation with other parties. If necessary, ask that you and the respondent be left alone for a brief time to complete the questionnaire.
11. Be able to adapt to interruptions. Let the respondent know that you are willing to continue the interview after the interruptions are completed.
12. Make the interview a positive experience for the respondent. React favorably to answers and give compliments, when appropriate.

C.1.4 Overcoming Difficult Questions

The following are examples of, and suggested responses to, questions you may encounter.

1. Relatives, Proxies, and Other Informants:
 - ***"How do I know you and the survey are legitimate?"*** If the respondent is concerned about the legitimacy of the survey, repeat your introduction, remind him/her about participant's involvement in the study, and offer to mail a brochure if necessary. Suggest that s/he call the number on the brochure for information and verification. Also point out that local health officials are aware of the survey, and offer to mail to the respondent a reproduction of newspaper clippings and/or endorsements. **If you make a home visit, always wear your identification badge.**
 - ***"What's this survey about?"*** Explain that we have interviewed and examined approximately 6600 randomly selected people in six communities in the United States to collect data about their health. The data we collect will help the U.S. National Institutes of Health and local area health professionals to better understand the factors associated with heart and blood vessel diseases.
 - ***"I don't want to buy anything."*** Explain that we are not selling anything. We are doing an important research study and all the tests will be done free of charge.
 - ***"Where did you get my name?"*** Explain that the participant involved in MESA provided their name as a primary contact during their clinic visit. If applicable, remind that respondent that he/she was sent a letter about this selection process.

2. All Respondents:
 - ***"Will this affect the participant's medical care?"*** Explain that we are doing research and that the study will not affect any medical care the participant now receives. The clinic is only gathering data, not doing diagnostic work. Also explain that **all information** is held in strict confidence and that public reporting of the findings of this study will contain only statistical information.
 - ***"How long will it take to complete?"*** Explain that the interview this day will take about xx minutes.
 - ***"I don't drive and do not have a friend who can bring me."*** Offer free transportation. Explain that we will send a taxi to take him/her to and from the clinic appointment(s).
 - ***"I do not have the time"*** or ***"I am going to be in Florida for the next few months"*** or ***"I cannot take time off from work."*** Explain that the appointment can be scheduled when he/she has time. Explain that we also have weekend appointments for people who cannot come to the clinic during the week.

C.2 Instructions for Online Review Forms

C.2.1 Introduction

The Review Forms (completed by MESA Physician Reviewers) are the only Events forms to be completed online. Due to the inconsistent availability of Field Center scanners (and the widespread ease of using the internet), it was decided that the web would be utilized as the primary means for Events Review. The MESA Physician Reviewers, who are spread across the country, will go to the MESA Internal website to enter all their review diagnoses. They do not need to be on a MESA computer to do this.

Because reviewers may need to resolve disagreements even after they enter their individual reviews online, the reviewers should not discard the paper review packet for any investigation until notified by the Coordinating Center, which will send out a periodic list of closed reviews whose packets may be discarded.

C.2.2 Getting to the Forms

This section describes how to locate and log onto the secure website where the online review forms are located.

C.2.2.1 Internet Site

Open a session of an internet browser (preferably Internet Explorer). Go to the MESA website at <http://www.mesa-nhlbi.org>.

Once the main page has loaded, click on 'Internal Site' from the menu down the left-hand side of the page. You will be prompted for a user name and password. If you do not know either of these two things, please contact the MESA Webmaster at the Coordinating Center.

When you have entered the Internal Site, select ‘Online Forms’ from the menu down the left-hand side of the page. There will be a list of online forms to choose from. Select ‘Events Review’. This will bring you to the login screen for Event Reviews.

NOTE: The MESA website is designed and tested using recent versions of Internet Explorer. It is strongly recommended that you use this browser when accessing the MESA website.

C.2.2.2 Logging in

After clicking on ‘Events Review’ you will be presented with a login page. Please enter the Reviewer ID (physician who completed the form). If someone other than the Reviewer is entering the information into the forms, s/he should enter her/his Data Entry ID in the second box. If the Reviewer is entering his/her own results, then fill in the Data Entry ID field with the Reviewer ID, also. Both the Reviewer ID and the Data Entry ID (both required fields on the forms themselves) will auto-complete for the rest of your session after you successfully log in.

NOTE: Please contact the Events Data Director at the Coordinating Center if you do not know a Reviewer or Data ID.

After logging in, Reviewers will get a list of investigations that they have “open” (i.e., any investigations that still require a Review Form to be completed). Unauthorized ID’s will not be able to gain access to this site. Only the physician reviewing any specific investigation will have access to its corresponding review forms.

The list will contain the investigations assigned to that Physician Reviewer, categorized by type of review (ex/Local vs. Central). This list of investigations will remain posted until the Coordinating Center sends the next set of cases to be reviewed. The Reviewer may take as many sessions to complete his/her list as needed. Investigations that have been completed and submitted to the CC will no longer appear bolded in the list. Even, un-bolded investigations, may be revised and resubmitted, which will replace the earlier submission with the most recent one.

Alongside each investigation number appears a text box that includes any comment that the Physician Reviewer made previously by filling in the review form’s “Reviewer Comments” box. Scroll down to see multiple comments; if the investigation review in question also required a Mortality Review Form, then Review Comments may appear from that form as well.

C.2.3 Completing the Review Forms

Pre-baseline endpoints should not be entered on the review form. If a reviewer has information about a pre-baseline event, it should be conveyed to the Coordinating Center through a note in the “Comment” field, clearly distinguishing between pre-baseline and post-baseline dates.

C.2.3.1 Selecting an Investigation

In order to complete the review forms for an investigation, click on the investigation for which you wish to complete a review. The morbid form (Cardiac/PVD or Stroke/TIA)

will appear first. For death cases, the Mortality Review Form will be available after the morbid form has been submitted.

When the Reviewer opens up the online review form, the top right-hand portion of the form will be already filled in with the Participant ID, Investigation ID and type of review. Please verify that this information is correct before proceeding.

If the header information is complete, proceed to complete the form. The question by question instructions for each review form are separate from this document.

If the investigation in question has already been reviewed by the other committee (Cardiac or Stroke Committee), the results of that prior review will appear on the Summary Report included in the review packet.

For mortality reviews, only the committee associated with the cause of death should complete the mortality form for combination cardiac/cerebro cases. Answering “yes” to “Did the patient die?” on the morbid review form will trigger a prompt that asks the reviewer whether the Cardiac or Stroke committee should be the one to fill out the Mortality Review Form. If the reviewer choose his/her own committee, then the Mortality Form will appear automatically after clicking on the submit button in the morbid form. But if the reviewer chooses the other committee, then he/she will not need to fill out the Mortality Review Form (instead, a message will automatically be sent to the Coordinating Center so that the Mortality Review is assigned to the appropriate committee). If a reviewer has any doubt about which committee should do the Mortality Review Form, he/she may communicate questions to the Coordinating Center by using the “Send Comment” box in the morbid review form.

C.2.3.2 Linking Investigations

As of February 2004, reviewers will submit a separate review form for each individual investigation even when a participant’s multiple investigations are identified as “linked”-- part of a single, continuous incident (e.g., a single CHF or angina experience that spans different investigations). Even though individual reviews are submitted, the reviewer should still use the linking boxes on each review form to list the two-digit Investigation ID of the other linked investigation(s); this information will be stored in the database for reference at the time of analysis and will not substitute for submitting a separate, individual review form for each investigation. Reviewers may add notes in the “Comments” box to clarify any issue (e.g., that the current CHF endpoint is linked to a preceding event but the current angina endpoint is not).

The Coordinating Center will send to reviewers all investigations within 30 days of another investigation involving the same participant. For example, investigations dated 3/4/03, 3/25/03, and 4/25/03 will all be sent to review together (and only once all records have been gathered for all three). If the reviewer believes the investigations should be linked, then two or more may be linked.

Field Center staff may indicate to the Coordinating Center when they feel that two or more different investigations are representative of the same occurrence of one or more endpoints. If the reviewing physician agrees, then s/he may “link” the investigations together. It is helpful to discern whether linked investigations exist because it is an issue

that will affect how endpoint episodes are counted (e.g., whether a participant is said to have had one or two CHF events).

Reviewer disagreements about linking will not be sent to Third Review for resolution. Instead, reviews will be designated as final in the database according to the protocols already in place for reviews without disagreements (local review accepted, unless two central reviews are done, in which case the later review is accepted since it was presumably done with the knowledge of any late developments).

C.2.3.3 Selecting Answers

Entering Dates: For endpoints marked “definite” or “probable,” you will need to enter a diagnosis/procedure date, or else the submitted review will not be accepted. The format for entering dates is MM/DD/YYYY. For example, you must enter 03/07/2002 (rather than 3/7/02) for March 7, 2002. If the program ever seems to prevent you from placing your cursor in a date box, try re-clicking on the endpoint selection and then placing/clicking the cursor in the date box.

De-activating sections: To prevent conflicting data, choosing certain responses on the review form will automatically de-activate other choices on the form. For example, if you indicate that there is ‘No MI’, the rest of the MI section will not allow you to select answers. On the Mortality Review Form, the cerebro sections will not allow answers if the death is cardiac in nature.

Clearing the Form: You may clear all the information off of the form by clicking the ‘Clear Entire Form’ button at the end of the form. If you wish to clear only a section, click the subsection ‘Clear’ buttons (e.g., the button marked ‘Clear MI Section.’)

C.2.3.4 Submitting the Form

Not Submitting: If you do not wish to submit the form you have been working on, you may click the ‘Investigations’ button at the end of the form to return to the list of investigations needing review without submitting the review (any selections already entered in the review will **not** be saved for your later use). You may also send comments, but no data. Please see below.

Packet Problems: If at any time missing data or errors are discovered with an investigation, or in the online forms, you may note the problem in the comments box at the end of the form. There are two ways that this information gets emailed to the Events Data Director: (1) the review form is completed and submitted, or (2) the comments only are submitted. To send a comment without completing the form, write in the comments box and then click ‘Send Comments’ (any selections already entered in the review will **not** be saved for your later use).

Submitting a Completed Form: When all review information has been entered, click the ‘Submit’ button to send the review to the Coordinating Center. Once this button has been clicked, the review data has been sent. You will see a ‘Thank You’ message on the screen confirming this. When you return to the list of investigations needing review, that investigation will appear as submitted (no longer in bold type). If you wish to change your diagnosis after you have submitted data, click on the investigation again (even though it is not in bold type) and make your changes. Be sure that the entire form

appears as you wish it to appear, and then click 'Submit' to send your corrections to the Coordinating Center (i.e., do not clear the form and then submit only the one or two changed selections).

For investigations that include death, the reviewer must also complete a Mortality Review Form in addition to the regular review form. The Mortality Review Form can be accessed only after the regular review form has been successfully submitted. When the regular review form is successfully submitted, the "Thank You" screen will appear indicating that the submission was indeed successful. At the bottom of that screen, for fatal investigations, there will automatically appear a button called "Mortality Review Form for XXXXXXXXXX." Clicking on that button will take the reviewer to the Mortality Review Form, which can then be completed. If the reviewer does not choose to complete the Mortality Review Form directly after completing the regular review form, then s/he can later return to the Mortality Review Form only by first re-opening the regular review form and resubmitting it, which will generate the Mortality Review Form button again. (Note: any changes made to the regular review form during the re-opening process **will** replace previous entries.)

Investigations will remain on the list of investigations needing review until the Coordinating Center confirms that you have successfully submitted all of your assigned cases. When the CC sends the next set of packets, they will clear the list and post the new assignments.

C.2.4 Disagreements

When physicians disagree on a diagnosis, then the event must be resolved. This arbitration procedure is explained in Section 5 of the manual, "Events Review and Classification." When the final diagnosis has been determined, this information must be submitted to the Coordinating Center via the website.

The Reviewer submitting the final (resolved) review will be referred to as the "Third Reviewer." Even though the third reviewer may be one of the physicians who initially entered a local or central review, the final (resolved) review is entered not by updating an initial review but by creating a third review. If discussion among the initial reviewers cannot resolve the disagreement, then the third review will be assigned to a new reviewer. When a third review is assigned, the initial reviewers will not be able to change their original local or central review. When ready to submit the final (third) review, the third reviewer logs in to the review form section of the MESA website as usual. In advance, the Coordinating Center will have designated the disputed investigation as no longer an initial review (local or central) but rather a final review. The new final assignment will appear on the web list of both original reviewers (or just the new reviewer's list), but only one of the reviewers needs to complete the final review. The review submitted most quickly will be recorded in the database as the single, resolved review.

The third reviewer will select the investigation that needs resolution and confirm that 'Third Reviewer' is selected as the type of review (in top right of first page). The review form(s) will open with all the answers from the first two Reviewers showing, though distinguishable from each other. The third reviewer will be prompted to fill out only those sections of the review form that involve disputed endpoints. For endpoint sections with no initial disagreement, the third reviewer database entry will eventually default to

the local reviewer's criteria/procedure selections. If two central reviewers were the original reviewers (no local reviewer), then the third reviewer database entry will eventually default to the central review that was submitted most recently (on the assumption that it was completed with the most updated knowledge of the investigation). As usual, the third reviewer who did complete the Final review will be able to change/update the review until the Coordinating Center removes it from that reviewer's list.

C.2.5 Final Data

There is likely to be more than one set of answers for the sub-questions on the Review Forms, even if the physicians agree on the diagnosis. All of this data will be retained by the Coordinating Center. However, for the purpose of data analysis there will only be one "final" set of data. What information constitutes the "final" data follows the algorithm below:

Type of Review = Final... This is ALWAYS the "final" data. If the case is reviewed by committee then there is only one set of data. If there is a disagreement over a diagnosis, then the data entered on the final review form will be considered "final".

Type of Review = Local... This is the default data. This set is used when there are no disagreements in diagnosis. When there are disagreements, this data is used for all questions other than the ones in dispute.

Type of Review = Central... This data is always secondary to Local and Final Reviews. This data serves as a quality control check for the Local Reviews.

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**APPENDIX D: MESA EVENTS FORMS INSTRUCTIONS
(QUESTION BY QUESTION)**

D.1 Follow-up Phone Call Forms

D.1.1 General Information

Introduction

At the end of each Exam, each participant is asked to notify the clinic if any change occurs in his/her health, especially involving a hospitalization, nursing home admission, or diagnosis of myocardial infarction (MI), angina, congestive heart failure (CHF), peripheral vascular disease (PVD), stroke or transient ischemic attack (TIA). Clinic staff also informs each participant that they will contact him/her by telephone at a regular interval (Follow-up Calls) to ask some questions regarding his/her health since the previous telephone interview.

Administering the Forms

Be sure to match non-English speaking participants with like-speaking interviewers. The Contact Log contains preprinted information about the participant's language preference in the upper right-hand corner of the form.

Use of Proxy

If a participant is not able to do the interview (e.g., due to a medical problem), a proxy may be used. A proxy is a relative or other knowledgeable contact. If the participant has died, the proxy may complete the questionnaire for the period between the last Exam and the date of death.

The proxy may or may not be someone previously designated as a contact by the participant. For example, the participant may have designated his/her spouse as a primary contact, but the participant's son or daughter actually ends up being the person to complete the questionnaire. This is fine, as long as the new person is knowledgeable regarding the participant's medical condition, procedures of interest, etc.

When contacting a proxy, the interviewer should be sure to record dates, times, and explanatory notes for each contact on the *Contact Log*. Eight attempts to contact a proxy should be made over a two-week period during different times of the day. If no contact is made, repeat in four weeks.

Motivation

The surveillance phone interview in MESA serves several purposes:

- To ascertain whether participants have experienced any potential events
- To update participants' tracking data including their address, phone number, and contact information
- To update participants' vital status
- To obtain information regarding participants' general health and health care treatment since their last MESA telephone Follow-up call (not since clinic visit)
- To obtain detailed information about specific medical conditions that participants have been reported (by a physician) to have since their last MESA telephone Follow-up call (not since clinic visit)

- To obtain detailed information about any procedures or hospitalizations participants have had since their last MESA telephone Follow-up call (not since clinic visit)

Forms

Several forms are involved in completing the *Follow-up Phone Call*. Each is described in detail in later sections.

- Contact Log
- Contact Cover Sheet
- General Health
- Participant Tracking
- Specific Medical Conditions (as needed)
- Other Admissions (as needed)
- Specific Medical Procedures (as needed)

Mode of Administration

All forms are interviewer-administered to MESA participants over the telephone. If the participant prefers to relay this information in person, or for some reason is unable to complete the interview by phone, a home or clinic visit may be scheduled.

Timing of Questionnaire Administration

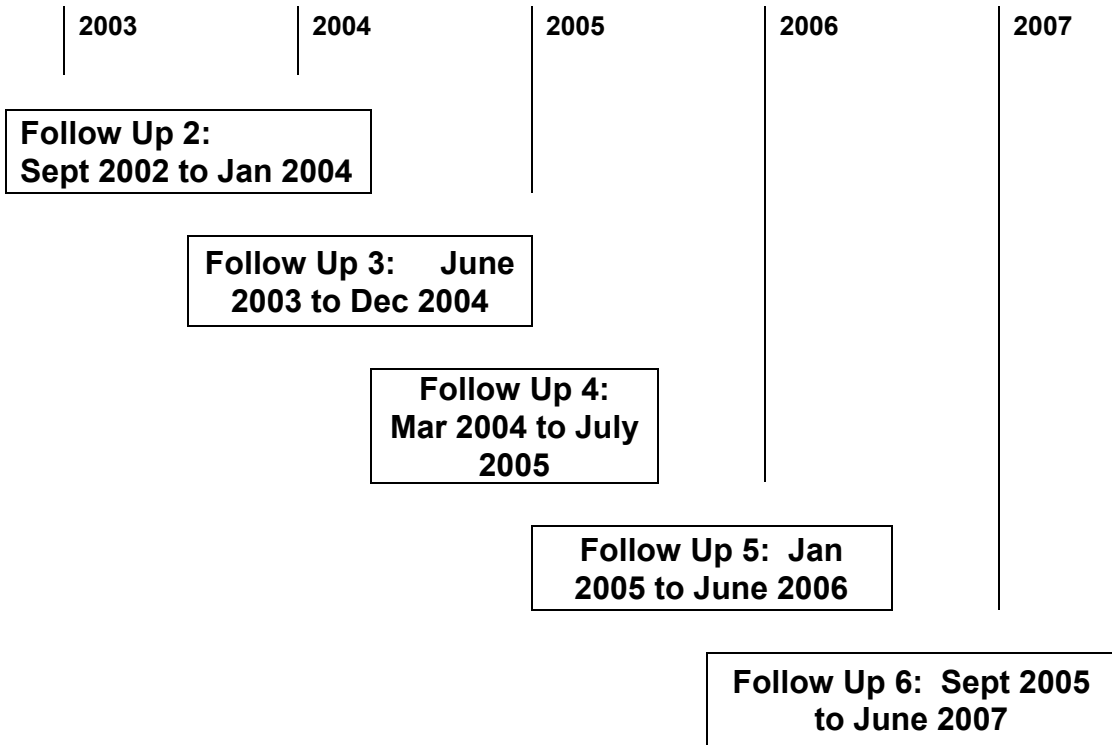
There are six (6) Follow-up Calls scheduled for the MESA study. The scheduling of the Follow-up Calls is no longer correlated with the scheduling of Exams. Each Follow-up call is now scheduled at a regular interval after the previous Follow-up call. The Exams are on an independent schedule, but the Follow-up calls will continue to be used to schedule participants for their upcoming MESA exams. The Coordinating Center will provide a software update to the MESA Administration database that will provide a program to identify participants who are due for their follow-up call. Specifically, given a user-specified window of time, the program will list all participants who require a follow-up phone call interview within that time window.

At minimum, this program should be run once each month to identify participants who should be contacted in the upcoming month. The Coordinating Center recommends running this program mid-month for all participants whose follow-up phone call is due in the following calendar month (e.g., running the program on June 15 for all participants due for a follow-up phone call in July). This allows you to prepare for the number of calls you'll need to make in a given month and possibly get a head start on calls due in that month by calling participants due for a follow-up early in the month during the final days of the previous month, but still within the target window for the call.

Table D.1.1

The following table shows the schedule for all currently anticipated MESA Follow-up Calls.

Note: A participant’s Follow-up Calls had previously been scheduled relative to his/her Exam visits, but that is no longer the case. Now each Follow-up Call will be made relative to the time when the participant’s previous Follow-up Call occurred.



Each field center should run its scheduling program frequently and systematically enough that you ensure (a) that calls are made within their target window and (b) that no participants are missed due to “gaps” between designated “end date” of the previous time the program was run and the designated “start date” for the current run.

Telephone interviewers doing Follow-up Calls should now be sure to tell each participant that the interviewer is seeking information about conditions, admissions, and procedures that occurred since the previous Follow-up Call (not since other MESA contact, such as an Exam or an unscheduled call to do gather information about a specific, already-discovered event). To ensure the collection of accurate information, the telephone interviewer should tell the participant the date of the previous Follow-up Call and should remind him/her of that date as often as necessary during the call.

For each participant identified by the program as due for a Follow-Up Phone Call, four forms, which include the following information, are generated:

Contact Log Form

- Space to track the calling history of contact attempts
- Space to indicate each contact attempt's pending status code

General Health Form

- Space to record participant's general health status since his/her last MESA telephone Follow-up call (not since clinic visit).
- Space to record if participant has had specific procedures, hospital/nursing home admissions, or diagnoses of interest to MESA since his/her last MESA telephone Follow-up call (not since clinic visit).

Participant Tracking Form

- Current tracking information (including address, phone number, current contacts)
- Space to record updated tracking information reported by the participant
- Space to record proxy contact information if interview is obtained by proxy (or to indicate proxy is a "contact" already defined by participant)

Contact Cover Sheet

- Space to record the final contact status code
- Space to record the participant's status code which defines both his/her vital status and his/her study status

The target follow-up contact date for each participant is nine to 12 months after his/her last Exam. Ideally, the earliest contact date is one month before the target date and the latest contact date is one month after the target date. If the clinic has made concerted efforts to obtain this information within the target window, could not do so, but is able to obtain the information outside the target window, this is acceptable. However, all reasonable efforts should be made to contact the participant and obtain the information within the target window.

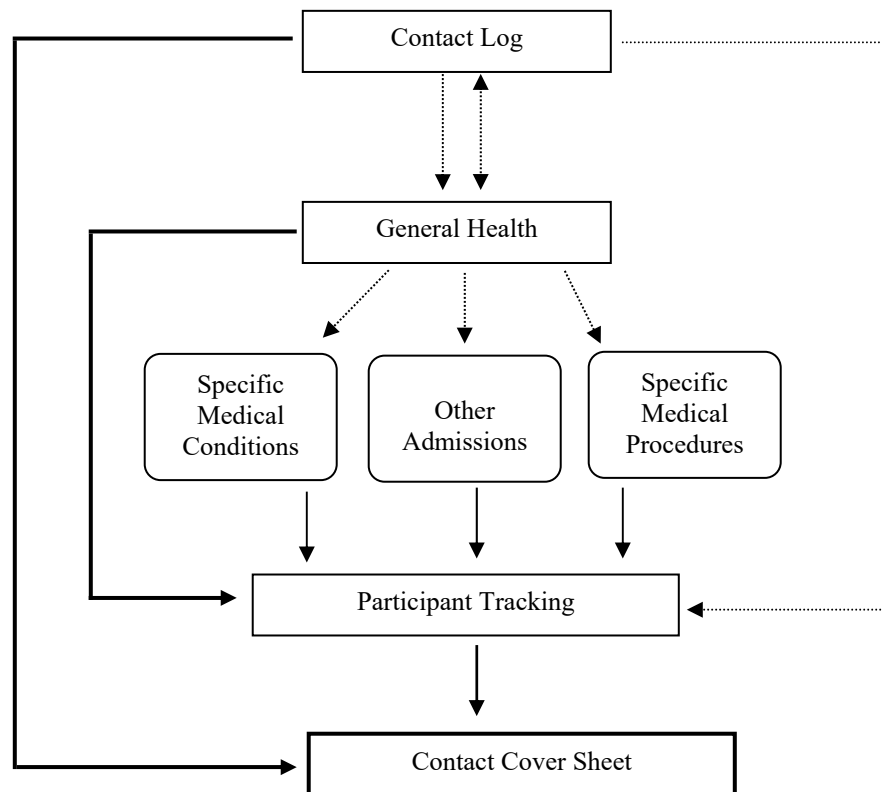
Details on Administration of Forms

The following chart briefly outlines the order in which the forms for the MESA Follow-up Phone Call 1 are generally administered. Key points to remember are:

- A *Contact Log* and *Contact Cover Sheet* are completed for ALL participants for whom contact is attempted.
- A *General Health* (or *General Health—Death*) and *Participant Tracking* form are completed for all participants with whom contact is made and who consent to an interview.
- A *Specific Medical Conditions, Other Admissions, or Specific Medical Procedures* form is completed only for those participants who indicate a corresponding potential event on the *General Health* form.

Each of these forms is described in greater detail in later sections of this document.

Figure D.1
MESA Follow-Up Phone Calls
Forms Administration



- a. Initiate a *Contact Log* for all participants to track call attempts.
- b. If contact is made, begin *General Health* interview, following “introductory” script.
- c. If participant (or proxy) indicates s/he would prefer you call at another time, end the call and record on the *Contact Log*.
- d. Repeat steps b and c until interview completed.
- e. If responses on *General Health* interview indicate *Specific Medical Conditions*, *Other Admissions*, and/or *Specific Medical Procedures* form(s) needed, complete as appropriate.
- f. If contact is made, regardless of whether participant/proxy indicates potential events requiring adjudication, review *Participant Tracking* information and update as necessary.
- g. Update final contact and participant statuses on *Contact Cover Sheet* for ALL participants even if no contact was made.

No Follow-up Call forms should be filled out for a potential event discovered through other means other than a Follow-up Call. Instead, proceed directly to *Initial Notification*.

Note: If a field center discovers a potential event through means other than a Follow-up Call (e.g., unscheduled notification by the participant during an Exam), then it is not necessary to fill out Follow-up forms for that potential event (*General Health*, *Specific Medical Conditions*, *Other Admissions*, *Specific Medical Procedures*). Likewise, do not add the new potential event to a previous Follow-up form (e.g., a *General Health* form completed a week earlier) because doing so will confuse the date-tracking function in the Events software. Instead, you should use the discovered information to submit an *Initial Notification* immediately and then begin gathering the appropriate documentation for a full investigation.

D.1.2 Contact Log

The *Contact Log* is used to document calling history and assign a “pending” call status code for each contact attempt. Preprinted on the form are the participant’s ID, acrostic, language preference, telephone number, enrollment (or Visit 1) date, date of last Follow-up Call, and the target window for the contact.

NOTE: This form is for field center administrative purposes only and is not scanned into the local MESA database.

At each contact attempt, record your Interviewer ID or initials and call attempt date, circle the day of the week, and record the time of the contact. A minimum of eight calls should be attempted at different times of the day before a participant is declared unreachable. MESA would prefer to have no unreachable participants. At the end of each contact attempt, record the applicable pending code from the available list of codes on the top half of the page. Assigning a pending code is very important, as the code may be necessary for determining the final contact status code in the event the participant is ultimately not successfully contacted.

Pending codes are:

Code	Category	Explanation
0	Contact not yet initiated	Default code already in MESA database.
1	Unlisted phone number	Number for this participant is unlisted. Interviewer should call the participant’s designated Contact 1 (and Contact 2, if necessary) to obtain a phone number for the participant.
2	Phone disconnected or out of service	Telephone number for this participant is incorrect or the number has been disconnected. Interviewer should call the participant’s designated Contact 1 (and Contact 2, if necessary) to determine if this is a temporary disconnection, and, if possible, obtain another phone number at which the participant can be reached.
3	Busy signal/no answer	Telephone is busy or no answer and there is no answering machine at the number. Another contact attempt should be made within the hour. If five attempts result in no answer, determine if the number is correct or if an alternate phone number is available for the participant.
4	Left message on answering machine or with person	Telephone number for this participant is presumed to be correct, but an answering machine, or someone else, is reached. Record details in the “Comments” section for this contact.
5	Person busy, call back	Telephone number for this participant is correct, but the participant is temporarily unavailable. Person answering phone has information about participant's availability and when the participant may be re-contacted. Record date to call again in the “Comments” section for this contact.

D.1.3 General Health

D.1.3.1 Introduction

Once the participant is contacted, the interviewer begins by reading the printed script in the “Introduction” section of the *General Health* form. However, the interviewer must be flexible and able to deviate from the script if necessary.

Some follow-up calls will involve the scheduling of an upcoming Exam (the date and time are filled in on Page 3 at the end of the *General Health* form), while other calls do not involve such scheduling. Be aware of whether you will need to schedule an Exam during the call.

At several times during the follow-up call, it may also be important that you clarify for the participant that you are interested in information dating from the participant’s last *MESA Follow-Up phone call* (not “since last contact with MESA,” which may have been an Exam or some sort of unscheduled interim phone call). Refer to the participant’s *Contact Log* to verify the date of the previous *Follow-up* call. We do not want to collect information that the participant already reported during the previous *Follow-up* call, but we also do not want the participant to omit any information in the false belief that, for example, s/he should not describe anything prior to a recent Exam.

Refer to notes on the *Participant Contact History* form to check for duplicate information.

If this is a proxy interview for a living participant, do the entire form, substituting the participant’s name for “you.” If this is a proxy interview for a deceased participant, use the alternate version (*General Health- Death*) to conduct the interview. Please see D.1.4.5 for more information about the *General Health- Death* form.

Begin the interview with “Introduction” section. (Script passages are in **bold**.)

Hello, my name is _____ and I’m calling to follow-up with _____ about MESA, a medical study in which s/he is currently enrolled. Is _____ available?

If no, say: **When would it be convenient to call back?** When time to call back is indicated, follow with: **Thank you, I will call again.** Record time to call back in the “Comments” line of the *Contact Log*.

Note: If you find out at this point that the participant is deceased, offer condolences, and then determine the date and location of death. Find out if this is an appropriate proxy and if this is a convenient time to talk, and if so, continue with the interview by proxy, using the *General Health-Death* form. If you do not have a *General Health-Death* form on hand, you may continue using the regular *General Health* form if you feel comfortable doing so (remember, though, to note on the *Contact Cover Sheet* that the participant has died). At the end of the interview, inform the respondent of the possible need for someone from the MESA staff to contact a family member at a later date for more information, and ask when would be the best time to call. Record this information in the “Comments” line of the *Contact Log*.

In addition to the “Comments” line of the *Contact Log* and Question 3 (alive/deceased) on the *Contact Cover Sheet*, you may use the optional *Death Information* form to record

the date, cause, and location of death. The *Death Information* form is a non-scanned form designed to facilitate communication between the interviewers and the Events staff so that a death investigation can begin. When finished filling out the *Death Information* form, the interviewer should give it to the Events staff. The *Death Information* form was created because neither the *General Health* form or the *General Health-Death* form has a specific way to record a death. The interviewers must communicate well with the Event staff to ensure that no deaths are overlooked.

Complete an *Initial Notification of Potential Event/Death* form to begin the death investigation process. See Appendix D.2 - Initial Notification of Potential Event/Death for more information about completing this form. If you are aware that the participant is deceased in advance, you may conduct any required events interviews during the same phone call.

If yes, (participant comes to phone), say: **Hello, participant name, this is _____ with the MESA study.**

I'm calling to see how you have been since we last saw you and to update our MESA records. Do you have a few minutes to speak on the phone now?

If no, say: **When would it be convenient to call back?** Record this information in the "Comments" section of the Contact Log and conclude with: **Thank you, I will call again.**

If yes, say: **We'd like to gather information about your general health and specific medical conditions that you may have had since our last telephone interview with you on _____ . I will ask you some questions about your health since the last time we had a telephone interview with you on _____ . I want to focus on what happened from _____ (date of last Follow-up Call) until today.**

NOTE: Once you actually begin the interview, enter the interview date in the "Date" field in the upper right-hand corner of the form. The participant's Member ID and Acrostic have been pre-printed on the form.

Read each question, pausing slightly between each of the response categories. If necessary, repeat the question or response categories.

D.1.3.2 Item by Item Instructions

NOTE: The following instructions are for Follow-up Phone Call 2 and on. Follow-up Phone Call 1 contains additional questions, which will not apply after that Follow-up cycle is complete. The numbering of questions will be different. (Please see Section D.1.4.3 for instructions for the additional Follow-up 1 questions.)

(Question 1) General Health

Would you say, in general, your health is (read all the response categories EXCEPT "Unsure") **Excellent, Very Good, Good, Fair, or Poor?**

Fill in circle next to the participant's response and go on to the next question. If participant is unsure of his/her response, fill in circle next to "Unsure." Go to Question 2.

(Question 2) Symptoms

Since our last telephone interview with you on _____, have you had any of the following symptoms? (Read each symptom, but NOT the responses. Responses are “Yes,” “No,” and “Unsure.”)

- **Discomfort or pain in your chest**
- **Shortness of breath**
- **Pain in your legs**

Fill in circle next to the participant’s response and go to Question 3.

(Question 3) Contact with health system

Since our last telephone interview with you, have you at any time seen a doctor or other health care professional? (Circle “Yes” or “No”)

Since our last telephone interview with you, have you had an overnight stay in a hospital or nursing home? (Circle “Yes” or “No”)

Did the participant answer “Yes” to either part of Question 3 above (seen a health professional or overnight stay)? (Do NOT read the responses. Fill in bubble for “Yes,” “No,” or “Unsure.”)

A “health professional” can also be a practitioner of non-Western medicine (e.g., an acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.

If YES, go to Question 4a.

If NO, or UNSURE, skip to “END.”

The participant is asked in both Question 3 and Question 6 whether he/she has been hospitalized. This information is purposely requested twice. Question 3 is a gateway question that determines whether subsequent questions will be asked at all. Question 6 asks specifically about hospitalizations not related to a condition documented in Question 5 and the *Specific Medical Conditions* form.

(Question 4) Symptom Diagnosis

(Question 4a) Has your doctor or health professional told you that you had one of the following since our last telephone interview with you? (Read each diagnosis, but NOT the responses. Responses are “Yes,” “No,” and “Unsure.”)

- **High blood pressure**
- **Diabetes**
- **High cholesterol level**

Be sure that the participant understands that he/she is being asked if he/she had *any* of the three conditions (or any combination of them).

A “health professional” can also be a practitioner of non-Western medicine (e.g., an acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.

As each diagnosis is read, if response is YES, ask: **Was this a new diagnosis since our**

last telephone interview with you on _____? (Do NOT read the responses. Responses are “Yes,” “No,” and “Unsure.”) If necessary, remind the participant of the date of his/her last Follow-up call with MESA. Only diagnoses made since this date should be recorded as “Yes.” Old diagnoses (prior to enrollment date) are recorded as “No.”

If YES to any item in Question 4a, go to Question 4b.

If NO or UNSURE to all items in Question 4a, go to Question 5.

(Question 4b) Did the doctor recommend any new or different treatments?

(This question could apply to one or more treatments for high blood pressure, diabetes, or high cholesterol.)

If response is YES, ask: **What treatments were recommended?** Do not prompt for specific responses. Mark all that apply. You need not distinguish which conditions the treatment was for or the names of specific medications. If an “other” treatment is reported, fill in the circle for “Other, specify:” and write treatment reported in the box provided.

If NO or UNSURE, go directly to Question 5.

(Question 5) Event Diagnosis

Since our last telephone interview with you, has your doctor or health care professional told you that you had any of the following? (Read each diagnosis, but NOT the responses. Responses are “Yes,” “No,” and “Unsure.”)



NOTE: This is a crucial question for finding events. Read slowly and be certain the participant understands. Definitions of the following events are provided in Appendix F: Glossary of Terms and in the Cardiac Abstraction section of the Events Manual (see D.5.6). If the participant is not sure what a particular condition is, it is acceptable to provide the definition. If necessary, remind the participant of the date of his/her last Follow-up phone call with MESA. Only diagnoses made since this date should be recorded as “Yes.”

- **A myocardial infarction or heart attack**
- **Angina pectoris or chest pain due to heart disease**
- **Heart failure or congestive heart failure**
- **Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries**
- **Atrial fibrillation**
- **Deep vein thrombosis or blood clots in your legs**
- **A transient ischemic attack (TIA) or mini-stroke**
- **A stroke**
- **Blockage to the carotid artery**
- **Lung abnormality or nodule**
- **Cancer**

If YES, complete a *Specific Medical Conditions* form for each item with a “Yes” response. Determine if a participant was told that he/she had one of the conditions on

more than one occasion—you must complete a separate *Specific Medical Conditions* form for each occasion.

You should complete all *Specific Medical Conditions* forms in their entirety before resuming the *General Health* form at Question 6.

If NO or UNSURE to all items, go to Question 6.

(Question 6) Overnight Care

Since our last telephone interview with you on, have you had any other condition that resulted in an overnight...: (Read each procedure, but NOT the responses. Responses are “Yes,” “No,” and “Unsure.”)

...Hospital stay?

...Stay in a nursing home or rehabilitation center?

Emphasize “other” in the initial question, since hospitalizations involving MESA endpoints were already recorded in Question 5 (and Question 5’s *Specific Medical Conditions* form, which records endpoint hospitalization dates).

If YES, complete an *Other Admissions* form for each item with a “Yes” response.

You should complete all *Other Admissions* forms in their entirety before resuming the *General Health* form at Question 7.

NOTE: Again, this is a crucial question because we must identify every overnight care episode. If necessary, remind the participant of the date of his/her last Follow-up phone call with MESA. Only overnight admissions that were NOT recorded in Question 5 and on a *Specific Medical Conditions* form can be recorded here in Question 6 and on the corresponding *Other Admissions* form. A particular hospitalization/overnight stay gets recorded on the *Other Admissions* form OR on the *Specific Medical Conditions* form, but never on both. However, hospitalization dates listed on the *Specific Medical PROCEDURES* form can match dates on either *Other Admissions* forms or *Specific Medical Conditions* forms. Do not record “Yes” for overnight stays that are not admissions.



NOTE: Overnight stays should be recorded here only if the person was actually ‘admitted’ to a hospital, nursing home, or rehabilitation center.

NOTE: Overnight stays that occurred solely because of a participant’s participation in a medical study (e.g., a sleep study) are usually not designated by the hospital as an “admission.” Only an overnight stay designated as an official admission by the hospital should be recorded as an “Other Admission” on the *General Health* form and the *Other Admissions* form.

If a participant had multiple occurrence of an overnight admission of the same type, you must complete a separate *Other Admissions* form for each stay.

The participant is asked in both Question 3 and Question 6 whether he/she has been hospitalized. This information is purposely requested twice. Question 3 is a gateway question that determines whether subsequent questions will be asked at all. Question 6

asks specifically about hospitalizations not related to a condition documented in Question 5 and the *Specific Medical Conditions* form.

If NO or UNSURE to all items, go to Question 7.

(Question 7) Diagnostic Procedures

Since our last telephone interview with you on _____, have you had any of the following diagnostic tests or procedures in or out of the hospital:
(Read each procedure, but NOT the responses. Responses are “Yes,” “No,” and “Unsure.”)



NOTE: This is also a crucial question. Be sure the participant understands each item. Definitions of the following procedures are provided in Appendix F.2: Medical Terminology. If the participant is not sure what a particular condition is, it is acceptable to provide the definition. If necessary, remind the participant of the date of his/her last Follow-up phone call with MESA. Only procedures occurring since this date should be recorded as “Yes.” Record all procedures regardless of whether a corresponding admission has already been noted.

If a particular procedure is obviously a standard element of another procedure, you need only record the existence of the more encompassing procedure. For example, you would need to mark only ETT if the ETT included an Echo as a standard element of the ETT procedure. Likewise, you do not need to mark Electrocardiogram (ECG) when an ECG is included as a standard element of a more substantial procedure (e.g., coronary bypass surgery). Field Center staff will still collect the ECG and Echo information mentioned in cases such as these examples, but the information will be solicited as part of the record of the larger, encompassing procedure. Nevertheless, if you are ever in doubt about whether an Echo, ECG, or other procedure was conducted as a separate procedure or not, it is best to mark it as separate procedure and fill out a separate *Specific Medical Procedures* form.

NOTE: If a procedure was done because of a participant’s participation in a medical study, the procedure should still be recorded here on the *General Health* form and the *Specific Medical Procedures* form (even if the participant had no symptoms or conditions that caused the procedure to be performed).

- **Exercise treadmill or bicycle test** (This includes all types of “stress tests,” such as pharmacological stress tests, also known as chemical stress tests).
- **Coronary angiography or heart catheterization**
- **Echocardiogram** (If echocardiogram was done as a standard element of an exercise treadmill or bicycle stress test, it is not necessary to mark echocardiogram for Question 7, nor is it necessary to complete a separate *Specific Medical Procedures* form for the echocardiogram.) Be aware that the participant/proxy may confuse the words “Electrocardiogram” (ECG, EKG) and “Echocardiogram,” which are not the same.
- **An angioplasty procedure to open up arteries to your heart**
- **Coronary bypass surgery**
- **An angioplasty procedure to open up arteries in either of your legs**
- **Carotid ultrasound or carotid angiogram**
- **Chest x-ray, a chest CT scan, MRI, or other study to assess any findings in your**

chest

- **Other diagnostic procedure or surgery related to your heart or blood vessels.**

NOTE: This category includes ECG tracings. (If ECG tracings were done as a standard element of a larger procedure, such as a coronary bypass surgery, it is not necessary to mark ECG for Question 7, nor is it necessary to complete a separate *Specific Medical Procedures* form for the ECG. But when in doubt, do mark ECG and fill out the form.)

If YES, complete a *Specific Medical Procedures* form for each item with a “Yes” response.

You should complete all *Specific Medical Procedures* forms in their entirety before resuming the *General Health* form.

If NO or UNSURE to all items, go to END.

END: Thank you so much for talking with me today. We greatly appreciate your participation in MESA. Should you have any questions, please feel free to call us at the clinic at (_____).

Some follow-up calls will involve the scheduling of an upcoming Exam, in which case the interviewer will now arrange the date and time with the participant/proxy and record the date and time in the boxes provided here at the end of the *General Health* form. (When summarizing the elements of the exam, the interviewer may change the length of time quoted to fit the length it will take at the specific field center involved, which may vary from exam to exam or field center to field center.)

Enter your Interviewer ID in the boxes provided at the bottom of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry.



NOTE: Before you hang up, inform the participant you would like to verify the tracking information currently listed for him/her. Go to *Participant Tracking* form and verify the tracking information that appears in the left-hand column. See D.1.5: Participant Tracking for full instructions.

D.1.3.3 Other Form Information

In the future, the exact numbering of the questions may vary, and questions that appeared on one version of the *General Health* form may not appear on the next version; or new questions may appear. For example, some General Health forms (e.g., Follow-up 4) will have additional instructions (and a date box) on Page 3 for scheduling an upcoming Exam. Another example: the *General Health* form from Follow-up 1 included questions about MESA test results, but those questions were removed from the *General Health* form for Follow-up 2. Situations like this may occur in the future. This manual provides guidelines on the standard questions and elements of the follow-up forms, but please be alert to possible changes in the forms.

D.1.3.4 Action Required After Form is Complete

Many (not all) conditions, admissions, and procedures require that an Events Investigation be initiated. Please see the Table D.1.3 (page 18) to see how to follow-up with all of the parts to Questions 5, 6 and 7.

During a follow-up call, if a Stroke Interview Form is found to be needed, it is fine – actually optimal – to complete the form during the call in which it's found. Otherwise, it should be done in the course of the investigation as usual.

Note: If an investigation is required, IMMEDIATELY submit an *Initial Notification of Event/Death* to the Coordinating Center. Do not wait until records are gathered that confirm what the participant has reported.

D.1.3.5 General Health - Death

For the *General Health – Death* form, please follow the instructions provided for the regular *General Health* form. In addition, please note the information detailed here.

The *General Health – Death* form should be completed when the Field Center learns of a participant's death during a Follow-up call or through another avenue. This form is required for all deaths, regardless of the means by which MESA staff learn of the participant death. Potential events discovered through means other than Follow-up Calls should not be recorded on Follow-up Call forms, but death is an exception: even if discovered outside a Follow-up Call, it requires the administering of a *General Health-Death* form. If the interviewer learns of a participant's death during a Follow-up call, then the *General Health – Death* form is preferred over the regular *General Health* form. However, if you do not have a *General Health-Death* form on hand, you may continue using the regular *General Health* form if you feel comfortable doing so (remember, though, to note on the *Contact Cover Sheet* that the participant has died). The *General Health – Death* form is still suitable for recording events that occurred prior to death, as well as the death event. For example, if a proxy says that the participant had a diagnosed condition or a procedure in May and died during a separate episode in June, then both of those incidents may be recordable on the *General Health – Death* form. Essentially, the *General Health – Death* form differs from the regular *General Health* form in that the death version of the form (1) is scripted specifically for talking to a proxy about someone who has died, and (2) is a way of alerting MESA that the participant has died.

Questions 1, 2, and 3 on the *General Health –Death* form are exactly like Questions 1, 2, and 3 on the regular *General Health* form. Consequently, the *Specific Medical Conditions, Other Admissions, and Specific Medical Procedures* forms should be filled out as needed. The *General Health – Death* form records any relevant event that occurred between the participant's last contact with MESA and his/her death (including the death if it involves information addressed in Questions 1, 2, or 3).

Before concluding the *General Health – Death* form and hanging up, the interviewer may interview the proxy using the optional *Death Information* form (see full question-by-question instructions below). The *General Health – Death* form includes the following statement:

(Optional) **May I ask you a few questions about (decedent name)'s death?**

(Interviewer may proceed to fill out *Death Information* form before ending the call.)

The optional *Death Information* form may be used whenever the *General Health – Death* form is used. When the *Death Information* form has been completed, the interviewer should return to conclude the *General Health – Death* form by thanking the proxy, checking the proxy's contact information using the *Participant Tracking* form, and providing the proxy with the Field Center phone number to use if s/he has any future questions.

D.1.3.6 Death Information Form

D.1.3.6.1 General Information

NOTE: The *Death Information* form is for field center administrative purposes only and is not scanned into the local MESA database.

The *Death Information* form is an optional, non-scanned form used to collect basic information about a participant's death so that an *Initial Notification* can be filled out by the Events staff, triggering the beginning of an investigation. Although Field Center staff may use the *Death Information* form whenever they find it useful, its most likely use occurs when filling out the *General Health – Death* form during a Follow-up Call.

The *Death Information* form was created to facilitate communication between the interviewers and the Events staff. There may be cases where the death itself is not covered by questions on the *General Health-Death* form. This form collects information that will help the Events staff complete and submit an *Initial Notification*. The *Specific Medical Conditions*, *Other Admissions*, or *Specific Medical Procedures* forms should always be filled out when dictated by the *General Health – Death* form. Completing the *Death Information* form never substitutes for completing other required forms.

Once the interviewer has completed the *Death Information* form, it should be given to the Events staff, who will fill out an *Initial Notification* and begin investigating the death.

Note: An *Initial Notification* will be completed and submitted prior to the Field Center obtaining a Death Certificate. If the Death Certificate indicates a different type of death than the proxy indicated for the *Initial Notification*, the Field Center should investigate the death as the type that the Death Certificate indicates.

D.1.3.6.2 Item-by-Item Instructions

(Introduction)

At the end of the *General Health – Death* form, the interviewer script reads as follows:

(Optional) **May I ask you a few questions about *decedent name's* death?**

(Interviewer may proceed to fill out *Death Information* form before ending the call.)

The interviewer may then switch to the *Death Information* form and begin with the script at the top of that form:

I need to ask you a few short questions about *decedent name's* death. [Previous sentence can be skipped when it repeats the script of the *General Health – Death* form.] **Someone else may also contact you in the future to ask additional questions if necessary. We really appreciate your help.**

As the form notes, “If appropriate, interviewer may use information from other Follow-up forms to fill in parts of this form. Ask only necessary questions.” For example, in some cases, it is possible that the cause of death or the death setting could be found on the *General Health – Death* form. In addition, in some cases, information about hospitalization (admission date, contact information) might be found on the *Specific Medical Conditions, Other Admissions, or Specific Medical Procedures* form when those forms are specifically documenting the death event. This form is most useful for deaths not already covered by other such forms.

The occasions when another MESA staff person might contact the proxy to learn more about the participant’s death include investigations in which MESA desires information in addition to the medical records collected from health care professionals. For example, if necessary, a MESA staff member might contact the proxy again to complete a narrative form that would record symptoms that preceded an out-of-hospital death.

(Question 1) Date of Death

On what date did *decedent name* die?

Record the date of death. If the proxy cannot remember the exact date, record the best estimate and record in the “Notes” section that the date is the proxy’s estimate.

(Question 2) Cause of Death

Do you happen to know whether s/he died because of a heart problem, a stroke, or some other cause?

As the form notes, the interviewer should “mark appropriate category below.” The interviewer does not need to read the choices aloud to the proxy, but should rather listen to the proxy’s answer and then mark the choice that, in the interviewer’s opinion, best fits the proxy’s description. The choices are

Cardiac death

Cerebrovascular death

Non-CVD death. Specify: _____

Unknown

In general, heart-related deaths should be marked “Cardiac death.” Stroke-related deaths should be marked “Cerebrovascular death.” “Non-CVD death” should be marked for all other deaths, and the cause of death should be written in the provided text box (please write clearly in all capital letters, staying within the box). Add more information in the “Notes” section if necessary. If the proxy or interviewer is unsure of the cause of death, “Unknown” should be marked. If the interviewer knows the cause of the death but is unsure whether it should be marked “Cardiac death” or “Cerebrovascular death,” then “Non-CVD death” should be marked and the text box filled in (adding more information in the “Notes” section if necessary).

The cause of death is recorded here, but it will later be confirmed by the Events staff when the investigation is underway. Therefore, the interviewer should not worry that an incorrect cause of death on the *Death Information* form will lead to a permanent error.

(Question 3) Setting of Death

Did s/he die in or out of the hospital? (Interviewer does not need to read choices aloud. Select choice appropriate to response.)

Listen to the proxy's response and mark the appropriate choice:

In-Hospital

Out of the Hospital (put ER deaths here)

"In-Hospital" should be marked only for actual hospital admissions. If the participant arrived at the hospital's emergency room and was subsequently admitted to the hospital (e.g., into the intensive care unit), then "In-Hospital" should be marked. But if the participant died in the emergency room, then "Out of the Hospital" should be marked.

END

Thank you so much for your time. (If appropriate:) Again, please accept our condolences for your loss. We are very grateful for *decedent name's* participation in our study.

After concluding the *Death Information* form, return to the *General Health – Death* form and follow its instructions for finishing the phone call, which involves thanking the proxy, completing the *Participant Tracking* form, and providing the Field Center phone number for the proxy to call if s/he has any questions.

(Notes)

Please record any additional information that might help the Events staff investigate this death.

During or after the interview, use the "Notes" section to record any additional details that do not fit elsewhere on the form. You do not need to prompt the proxy to answer additional questions, but you may record anything useful that the proxy says in the course of answering the existing questions. Provide any information mentioned by the proxy that you think would aid the Events staff in investigating the death. For example, if the proxy mentions that the participant died from a condition recently treated at a local hospital, you could record the name of the hospital. Other examples of useful information might be conditions or procedures (e.g., an autopsy) not recorded on the *Specific Medical Conditions* or *Specific Medical Procedures* forms.

D.1.3.6.3 Action Required After Form Is Completed

The form should not be scanned but should be given immediately to the Events staff.

Table D.1.3

Action required after positive responses to Questions 5, 6, or 7 on the *General Health* form.

Q # ***	Sub-Question	Form Required	Investigation Required[^]
5	MI or heart attack	<i>Specific Medical Conditions</i>	Y
5	Angina pectoris or chest pain due to heart disease.	<i>Specific Medical Conditions</i>	Y
5	Heart Failure or CHF	<i>Specific Medical Conditions</i>	Y
5	PVD, intermittent claudication or pain in legs from blockage of arteries	<i>Specific Medical Conditions</i>	Y
5	Atrial fibrillation	<i>Specific Medical Conditions</i>	Y if hosp N if not hosp
5	Deep vein thrombosis or blood clots in legs	<i>Specific Medical Conditions</i>	Y if hosp N if not hosp
5	TIA or mini-stroke	<i>Specific Medical Conditions</i>	Y
5	Stroke	<i>Specific Medical Conditions</i>	Y
5	Blockage to the carotid artery	<i>Specific Medical Conditions</i>	Y
5	Lung abnormality or nodule	<i>Specific Medical Conditions</i>	Y if hosp N if not hosp
5	Cancer	<i>Specific Medical Conditions</i>	Y if hosp N if not hosp
6	Overnight hospital stay	<i>Other Admissions</i>	Y
6	Overnight NH or rehab center stay	<i>Other Admissions</i>	Y
7	Exercise treadmill or bicycle test (any stress test, including pharmacological stress test, also known as chemical stress test).	<i>Specific Medical Procedures</i>	Y if hosp N if not hosp
7	Coronary angiography or heart catheterization	<i>Specific Medical Procedures</i>	Y
7	Echocardiogram	<i>Specific Medical Procedures</i>	Y if hosp N if not hosp
7	Angioplasty-heart	<i>Specific Medical Procedures</i>	Y
7	Coronary bypass surgery	<i>Specific Medical Procedures</i>	Y
7	Angioplasty-legs	<i>Specific Medical Procedures</i>	Y
7	Chest X-ray, chest CT, MRI, or other study to assess the chest	<i>Specific Medical Procedures</i>	Y if hosp N if not hosp
7	Other diagnostic procedures or surgeries relating to heart or blood vessels (incl. ECG)	<i>Specific Medical Procedures</i>	Y (but N for non-hosp ECG)

***These are the question numbers for the *General Health* form for Follow-up 2 and later. Follow-up 1 has different numbering.

[^]Not all reported diagnoses, admissions, and procedures should be investigated. For those that ARE investigated as 'potential events', please consult the *Eligibility* form to determine if eligible for review.

D.1.4 Participant Tracking

The *Participant Tracking* form is preprinted with the participant's ID and acoustic. Enter the interview date in the upper right-hand corner.

Current tracking information for the participant from the MESA database is preprinted in the left column of this form. Read the printed information to the participant/proxy. Verify that this information is correct, or record any changes reported by the participant in the right column. This information will be used to update the MESA study database for future clinic visits and/or follow-up contacts. In the case of a death, this information does not need to be verified with the proxy.

D.1.4.1 Participant Tracking–Participant

First, I'd like to make sure our records are up to date. Could you please tell me if the following information is correct?

Read participant name, address, phone numbers, e-mail address, and date of birth from "Item A" of the form.

If information is not correct, write any changes on the right side of the page.

You previously provided us with information about friends or relatives who you are likely to keep in touch with, but who do not live with you, and who are not planning to move any time soon. Can you please tell me if the following information is still correct?

Read Contact 1 name, relationship to participant, address, phone numbers, e-mail address from "Item B" of the form.

Read Contact 2 name, relationship to participant, address, phone numbers, e-mail address from "Item C" of the form.

If information is not correct, write any changes on the right side of the page. NOTE: Participant may change contact names and information entirely if necessary.

You previously provided us with information about your personal physician or health care provider. Can you please tell me if the following information is still correct?

Read participant's health care provider name, business address, and telephone numbers from Item D of the form.

If information is not correct, write any changes on the right side of the page.

Thank you.

This completes the follow-up interview. Be sure the participant has no other questions. Enter your Interviewer ID in the boxes provided at the bottom of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form.

D.1.4.2 Other Form Information

Proxy—if the General Health interview (and other “event” interviews, if needed) were completed by a proxy, note this on the *Participant Tracking* form:

- If a previously designated Contact served as the proxy for this contact, indicate this by checking the appropriate “Check if used as proxy for this interview” box section “B. Contacts/Proxies” of the form.
- If a different individual served as the proxy for this contact, indicate this in the “Other Proxy” area (at the end of section) by entering the proxy’s name, address, phone number and relationship to participant in the space provided.

There is no need to verify the participant tracking information if the participant is deceased.

D.1.4.3 Action Required After Form is Complete

If there are any changes to the participant’s information, those changes must be entered into the MESA database. Data Managers will do this. There is no need to update information on deceased participants.

D.1.5 Specific Medical Conditions

Instructions on the *General Health* form instruct the interviewer to complete a *Specific Medical Conditions* form for each condition reported as “yes” in Question 5 (used to be 6) on the *General Health* form. You should complete all *Specific Medical Conditions* forms while recording the participant/proxy’s responses to Question 5 of the *General Health* form interview; do not proceed to Question 6 of the *General Health* form until you have completed all *Specific Medical Conditions* forms in their entirety. If the participant has died and you are interviewing proxy, be sure to change “you” or “your” to the decedent’s name in appropriate places.

D.1.5.1 General Information

The participant’s ID and acoustic **will not** be automatically printed on the *Specific Medical Conditions* form. Interviewers will need to have on hand:

- A supply of *Specific Medical Conditions* forms before beginning a Follow-Up Phone Call.
- A set of ID labels for each participant on your call list for that day.

When a *Specific Medical Conditions* form is warranted, affix a participant ID label on the blank form. So that the form can be read correctly by the scanner, it is essential that the label be placed in the correct spot on the form: in the box in upper right corner.

Enter the date of the interview in the space provided in the upper right corner.

D.1.5.2 Item by Item Instructions

(Question 1) Diagnosis by Health Professional

You said that a doctor or other health professional told you that you had _____. Read and mark the specific condition previously reported (on the *General Health* form).



Note that in the blank above you are reiterating the condition the participant reported on the *General Health* form. You are not re-reading the entire list of possible events. Read the event the participant has indicated on the *General Health* form and mark the corresponding bubble on the form.

- **A myocardial infarction or heart attack**
- **Angina pectoris or chest pain due to heart disease**
- **Heart failure or congestive heart failure**
- **Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries**
- **Atrial fibrillation**
- **Deep Vein thrombosis or blood clots in your legs**
- **A transient ischemic attack (TIA) or mini-stroke**
- **Stroke***
- **Blockage to the carotid artery**
- **Lung abnormality or Nodule**
- **Cancer,** specify type: _____**

**If the participant has indicated a stroke diagnosis since his/her MESA visit, ask:*

Regarding symptoms that you had from your stroke, do you feel that you have made a complete recovery? (Do NOT read the responses. Responses are “Yes,” “No,” and “Unsure.”) “No” should be marked if the participant/proxy responds “Not yet” or “Not yet, but my doctor says I will.”

In the last two weeks, did you require help from another person for everyday activities? (Do NOT read the responses. Responses are “Yes,” “No,” and “Unsure.”).

***If the participant has indicated a cancer diagnosis since his/her MESA visit, ask:*

Can you tell me in what part of the body the cancer was located? (Record type indicated in box provided on form.)

A “health professional” can also be a practitioner of non-Western medicine (e.g., an acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.

(Question 1A) What was the name and address of the doctor you saw?

Record the name and address (as much as the participant can give) in the space provided on the form.

(Question 1B) What was the date of the diagnosis or hospitalization?

Record the month, day and year in the space provided on the form.

For some events, the participant may not be able to recall the exact date. Probe for as specific a date as possible. At a minimum, attempt to get the participant to report (or at least estimate) the month and year. Record unknown day as “15.”



NOTE: If during the investigation process it is discovered that any dates are incorrect, do not go back and change the form. The correct dates will be recorded on the *Final Form*. Edits are allowed for typographic errors (ie: recording 2010 instead of 2012).

If you have any doubt whether two diagnoses, office visits, or hospitalizations belong to two separate events, it is still best to record them as two separate events in order to be sure MESA does not overlook one of them.

(Question 1C) Were you in the hospital at least one night for this condition since our last telephone interview with you on _____?

If YES, continue to Part D on next page.

If NO or UNSURE, ask about the next condition, procedure, or other admission reported on Questions 5, 6, or 7 of the *General Health* form, and record details on an additional *Specific Medical Conditions* form.

Complete as many Specific Medical Condition forms as necessary – one for each potential event reported in Question 5. If there are no additional events, go to Questions 6 and 7 of *General Health* form.

(Question 1D) Would you please tell me the dates of each hospitalization and where you were hospitalized?

- a) Record the month, day and year in the space provided on the form. Probe for as specific a date as possible. At a minimum, attempt to get the participant to report (or at least estimate) the month and year. Record unknown day as “15.”
- b) Ask the participant for the name and address of the hospital. If known, enter the four-digit MESA hospital code* corresponding to that institution. Alternatively, you may write the hospital name and address in the blank space below the “Hospital Code” boxes and fill in the hospital code after the interview is complete. However, it is critical that the actual code be filled in before the form is sent to data-entry for scanning.

To ensure the form scans correctly, it is important you write the hospital name/address in a blank space only, not in the code boxes.



NOTE: Prior to the start-up of events data collection, each MESA Field Center provided the Coordinating Center with a list of area hospitals and other health care institutions where its participants are likely to be having overnight stays. The Coordinating Center assigned each of these institutions a four-digit MESA Hospital Code. This is the value that is entered in the “Hospital Code” field. To see a list of valid hospital codes for your site, you can run the Hospital Code report from the MESA database to see a list of all institutions, sorted by institution name or hospital code. If a participant reports a stay at a hospital that has not been assigned a hospital code, the MESA database allows you to enter a new institution name, which is automatically assigned the next (sequentially) available MESA Hospital Code.

- c) Enter, in days, the length of the hospital stay. If participant is unsure of the exact

length, record his/her best estimate.

Repeat steps a-b-c for all hospitalizations for this condition. Each hospital in a “transfer” should be recorded.

When the form is complete, ask about the next condition reported on Question 5 of the *General Health* form. Complete as many *Specific Medical Condition* forms as necessary (one for each potential event reported in Question 5). If there are no additional events, go to Question 6 and 7 of the *General Health* form.

As each form is completed, enter your Interviewer ID in the boxes provided at the bottom of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry.

D.1.5.3 Other Form Information

All positive responses to conditions should initiate an investigation, **EXCEPT for non-hospitalized** instances of the following conditions:

- Deep vein thrombosis or blood clots in the legs.
- Lung Abnormality or nodule
- Cancer
- Atrial fibrillation

D.1.5.4 Action Required

For conditions that require the initiation of an investigation, complete an *Initial Notification* form and immediately submit to the Coordinating Center. (Please see Section D.2 for instruction on how to complete this form.)

D.1.6 Other Admissions

D.1.6.1 General Information

Instructions on the *General Health* questionnaire instruct the interviewer to complete an Other Admissions form for each condition reported as “yes” in Question 6 on the *General Health* form. You should complete all *Other Admissions* forms while recording the participant/proxy’s responses to Question 6 of the *General Health* form interview; do not proceed to Question 7 of the *General Health* form until you have completed all *Other Admissions* forms in their entirety.



NOTE: Only overnight admissions that were NOT recorded in Question 5 and on a *Specific Medical Conditions* form can be recorded in Question 6 and here on the corresponding *Other Admissions* form. A particular hospitalization/overnight stay gets recorded on the *Other Admissions* form OR on the *Specific Medical Conditions* form, but never on both. However, hospitalization dates listed on the *Specific Medical PROCEDURES* form can match dates on either *Other Admissions* forms or *Specific Medical Conditions* forms. Do not record “Yes” for overnight stays that are not admissions.

The participant’s ID and acrostic will not be automatically printed on the *Other*

Admissions form. Interviewers will need to have on hand:

- A supply of *Other Admissions* forms before beginning a Follow-Up Phone Call.
- A set of ID labels for each participant on your call list for that day.

When an *Other Admissions* form is warranted, you will need to affix a participant ID label on the blank form. So that the form can be read correctly by the scanner, it is essential that label be placed in the correct spot on the form: in the box in upper right corner.

If the participant has died and you are interviewing proxy, be sure to change “you” or “your” to the decedent’s name in appropriate places.

Enter the date of the interview in the space provided in the upper right corner

You said that you stayed overnight as a patient in a _____. Read and mark the admission previously reported in Question 6 on the General Health form.

Note that in the blank above you are reiterating the institution type the participant has indicated in Question 6 of the *General Health* form. You are not re-reading the list of institution types. Read the institution type the participant has indicated on the *General Health* form and mark the corresponding bubble on the *Other Admissions* form.

Hospital

Nursing home or Rehabilitation Center.

D.1.6.2 Item by Item Instructions

Please tell me:

- **Reason for admission** Record in the space provided.
- **Facility** Enter the four-digit MESA hospital code, if known. Alternatively, you can enter the facility name and address in the blank space to the right of the “Facility Code” box and enter this information at a later time. See the Specific Medical Conditions section for information on finding and entering the MESA Hospital Code.
- **Physician name** Record in the space provided.
- **City** (This is not needed if MESA Hospital Code is entered.)
- **Date of admission** Record the month, day, and year in the space provided on the form. Probe for as specific a date as possible. At a minimum, attempt to get the participant to report (or at least estimate) the month and year. Record leading zeros. Record unknown day as “15.”
- **Length of stay** Enter, in days, the length of the hospital stay. If participant is unsure of the exact length, record his/her best estimate.

When the form is complete, ask about any additional “other admissions” reported on Question 6 of the *General Health* form. Complete as many *Other Admission* forms as necessary (one for each admission reported in Question 6). If there are no other admissions, go to Question 7 of the *General Health* form.

As each form is completed, enter your Interviewer ID in the boxes provided at the bottom
This section: 3/4/2013 Version

of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry.

D.1.6.3 Action Required

An investigation must be initiated for all overnight stays. You must complete an *Initial Notification* form and submit to the Coordinating Center. (Please see Section D.2 for more instructions.)

D.1.7 Specific Medical Procedures

D.1.7.1 General Info

Instructions on the *General Health* questionnaire instruct the interviewer to complete a *Specific Medical Procedures* for each condition reported as “yes” in Question 7 on the *General Health* form. You should complete all *Specific Medical Procedures* forms while recording the participant/proxy’s responses to Question 7 of the *General Health* form interview; do not proceed to Question 8 of the *General Health* form until you have completed all *Specific Medical Procedures* forms in their entirety.



NOTE: Hospitalization dates listed on the *Specific Medical PROCEDURES* form can match dates on either *Other Admissions* forms or *Specific Medical Conditions* forms.

The participant’s ID and acrostic will not be automatically printed on the *Specific Medical Procedures* forms. Interviewers will need to have on hand:

- A supply of *Specific Medical Procedures* forms before beginning a Follow-Up Phone Call.
- A set of ID labels for each participant on your call list for that day.

When a *Specific Medical Procedures* form is warranted, you will need to affix a participant ID label on the blank form. In order for the form to be read correctly by the scanner, it is essential that the label be placed in the correct spot on the form: in the box in upper right corner. Enter the date of the interview in the space provided in the upper right corner.

If the participant has died and you are interviewing proxy, be sure to change “you” or “your” to the decedent’s name in appropriate places.

D.1.7.2 Item by Item Instructions

(Question 1) You previously said that a doctor or other health professional told you that you had _____ [Read and mark the specific procedure previously reported in Question 7 (on the *General Health* form)].

A “health professional” can also be a practitioner of non-Western medicine (e.g., an acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.



Note that in the blank above you are reiterating the procedure the participant has indicated in Question 7 of the *General Health* form. You are not re-reading the entire list of possible procedures. Read the procedure the participant has indicated on the *General Health* form and mark the corresponding bubble on the form.

If a particular procedure is obviously a standard element of another procedure, you need only record the existence of the more encompassing procedure. For example, you would need to mark only ETT if the ETT included an Echo as a standard element of the ETT procedure. Likewise, you do not need to mark Electrocardiogram (ECG) when an ECG is included as a standard element of a more substantial procedure (e.g., coronary bypass surgery). Field Center staff will still collect the ECG and Echo information mentioned in cases such as these examples, but the information will be solicited as part of the record of the larger, encompassing procedure. Nevertheless, if you are ever in doubt about whether an Echo, ECG, or other procedure was conducted as a separate procedure or not, it is best to mark it as separate procedure and fill out a separate *Specific Medical Procedures* form.

- **Exercise treadmill or bicycle test** (This includes all types of “stress tests,” such as pharmacological stress tests, also known as chemical stress tests).
- **Coronary angiography or heart catheterization**
- **Echocardiogram** (If echocardiogram was done as a standard element of an exercise treadmill or bicycle stress test, it is not necessary to mark echocardiogram for Question 7, nor is it necessary to complete a separate *Specific Medical Procedures* form for the echocardiogram.) Be aware that the participant/proxy may confuse the words “Electrocardiogram” (ECG, EKG) and “Echocardiogram,” which are not the same.
- **An angioplasty procedure to open up arteries to your heart**
- **Coronary bypass surgery**
- **An angioplasty procedure to open up arteries in either of your legs**
- **Carotid ultrasound or carotid angiogram**
- **Chest x-ray, a chest CT scan, MRI, or other study to assess any findings in your chest.**
- **Other diagnostic procedure or surgery related to your heart or blood vessels.**



NOTE: This category includes ECG tracings. (If ECG tracings were done as a standard element of a larger procedure, such as a coronary bypass surgery, it is not necessary to complete a separate *Specific Medical Procedures* form for the ECG. But when in doubt, do mark ECG and fill out the form. As explained in the manual section concerning the *Initial Notification*, an investigation should not be initiated if the only news reported by the participant is an out-of-hospital ECG.)

➔ If one of these items is answered “Yes,” record the specific procedure in the space

provided.

A. Location

- **Facility Code:** Enter the four-digit MESA hospital code, if known. Alternatively, you can enter the facility name and address in the blank space to the right of the “Facility Code” box and enter this information at a later time. See *Specific Medical Conditions* for information on finding and entering the MESA Hospital Code.
- **Physician Name:** Record in the space provided.
- **City** This is not needed if MESA Hospital Code is entered

B. What was the date of the diagnosis or hospitalization?

Record the month, day, and year in the space provided on the form. Probe for as specific a date as possible. At a minimum, attempt to get the participant to report (or at least estimate) the month and year. Record unknown day as “15.”



NOTE: Hospitalization dates listed on the *Specific Medical PROCEDURES* form can match dates on either *Other Admissions* forms or *Specific Medical Conditions* forms. Do not record “Yes” for overnight stays that are not admissions.

When the form is complete, ask about the next procedure reported on Question 7 of the *General Health* form. Complete as many *Specific Medical Procedures* forms as necessary (one for each procedure or admission reported in Question 7). If there are no other procedures, go to END of *General Health* form.

As each form is completed, enter your Interviewer ID in the boxes provided at the bottom of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry.

D.1.7.3 Other Form Info

All procedures will initiate an investigation, EXCEPT: Out-of-Hospital ETT’s, Echocardiograms, and any procedure that fits into the Chest X-ray category and any routine ECG’s.

D.1.7.4 Action Required

Complete an Initial Notification for all procedures that require an investigation to be initiated. Immediately submit to the Coordinating Center.

D.1.8 Contact Cover Sheet

The *Contact Cover Sheet* is preprinted with the participant’s ID and acrostic. At the top of the form, enter the date the interview was completed or the date a final determination that this interview cannot be obtained was made. Document the final status code for the contact and the final contact status code for the participant at this time.

Note that both a final contact status code and final participant status code are assigned in all cases. The final contact status code documents the ultimate result of the

current contact. The final participant status code documents the participant's current status in the study. While these can influence each other, one cannot necessarily be assumed based on the other.

D.1.8.1 Contact Status Codes

The final contact status code refers only to the current contact. This code indicates whether the contact was successful. That is, was the participant or a proxy interviewed? And, if the interview was not completed, why?

The following codes apply here:

Category	Explanation
Interview completed or partially completed	Participant or proxy was successfully contacted by telephone or in person. The interview, including tracking information, general health, medical conditions, hospitalizations and procedures, if needed, was completed. Indicate whether interview was completed by participant or by proxy. If proxy, indicate reason why participant was unable to complete interview.
Interview not done Field center staff <u>unable</u> to complete interview	Interview was not done for reasons other than refusal. Record the one best reason. These categories should only be used when truly all other options have been attempted. For example, if the participant is reported deceased, every attempt possible should be made to conduct the interview with a proxy.
Participant <u>refused</u> to complete interview	Participant refused to be interviewed. Record the one best reason (see below): <ol style="list-style-type: none"> Refused due to problem with study Participant refused to be interviewed because of a problem with the study. Explain in "Comments" on <i>Contact Log</i>. Study/Events Coordinator should be alerted to follow-up with participant as appropriate. Refused due to life situation Participant refused to be interviewed due to a current life situation. Explain in "Comments" on <i>Contact Log</i>. Study/Events Coordinator should be alerted to follow-up with participant as appropriate. Refused due to lack of time Participant has refused to be interviewed due to lack of time. This may be a temporary situation. Explain in "Comments" on <i>Contact Log</i>. Study/Events Coordinator should be alerted to follow-up with participant as appropriate. Refused for other reason. (Specify: _____) Participant has refused for a reason not listed above. Explain in "Comments" on <i>Contact Log</i>. Study/Events Coordinator should be alerted to follow-up with participant as appropriate.

NOTE: Recording any of the "refusal" categories listed above indicates the participant has refused to be interviewed for this contact at this time. This does not necessarily mean the participant is refusing all further contact with MESA. In each case, surveillance staff should follow-up with the participant, as appropriate, to ascertain if the refusal is temporary, and take steps to ensure the participant will be available for future MESA contacts.

D.1.8.2 Participant Status Code

The final participant status code is used to document both the participant's vital status and his/her current study status. That is, is the participant still alive and, if so, is s/he still an active MESA participant?

The following participant statuses are possible:

Category	Explanation
<i>Alive</i>	Participant or proxy is contacted.
<i>Do Not Contact</i>	<p>Participant or designated proxy has indicated participant no longer wishes any contact with MESA clinic or staff. This is essentially equivalent to a Lost to Follow-Up (LTFU) status, so should be used only when field center staff has exhausted all reasonable means to address the participant's concerns and retain him or her in the study.</p> <p>When you have assigned a participant to Do Not Contact/LTFU, make sure your data manager changes the participant's status to such in the MESA Administration Participant Data screen. This will cause the participant to "fall off" future follow-up call (and other MESA communication) lists.</p> <p>Be sure to distinguish between a wish not to do follow-up calls and a wish not to do exams. A participant may be willing to do one but not the other. We do not want to exclude the participant from the entire study if s/he is still willing to participate in only one component.</p>
<i>Reported Deceased</i>	Reliable information from proxy or contact indicates the participant has died. Field center staff should initiate an <i>Initial Notification of Potential Event/Death</i> form and begin investigation of reported death. Field Center staff should also attempt to obtain a Follow-up Call from a proxy.
<i>Unknown</i>	Field center staff has been unable to contact participant. Designated contacts cannot be reached or cannot provide reliable information regarding the participant's vital status. Use this designation only in rare circumstances, when all leads have been exhausted.

The Events Coordinator is responsible for reviewing all cases of ambiguity or difficulty. These include refusals, difficult contacts, proxy interviews for deaths, and incomplete questionnaires. The coordinator determines when it is no longer practical to continue to attempt to get an interview with a given participant. All possible alternatives must be exhausted for this decision to be made. If a death is reported for which no death certificate can be located, surveillance staff reviews the case and attempts to obtain pertinent documentation. Follow-up Calls are attempted with a proxy. If no death certificate is located after reasonable efforts have been made, including a National Death Index (NDI) search, participant status may be changed to "Unknown."


D.1.8.3 Form Completion

Enter your Interviewer ID in the boxes provided at the bottom of the form. The reviewer should review the form for completeness and accuracy, and discrepancies/questions should be brought to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters his or her Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry.

D.1.9 Initiating an Investigation of a Potential Event

If the participant died, was hospitalized, or had a diagnosis or procedure that requires an investigation, surveillance staff completes an *Initial Notification of Potential Event/Death* form to initiate the event investigation process.

If you learn through the follow-up phone call that the participant has died, complete as much of the interview as possible. Also, ask the respondent if s/he is the best person to provide details about the participant's death and, if so, if it would be acceptable for you (or other staff person) to call back at a later time to conduct an Informant Interview.

<p style="text-align: center;">Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p> <div style="text-align: center;">  </div> <p style="text-align: center;">Contact Log</p>	<p>Participant Id#: Acrostic: Language:</p> <p>Telephone Number:</p> <p>Enrollment Date: Exam 4 Visit Date: Contact Window:</p>
---	--

Use the lines below to record the results of each contact attempt. Pending Contact Status Codes are as follows :

Pending Codes

- 1 Unlisted phone number
- 2 Phone disconnected or out of service
- 3 Busy signal / no answer
- 4 Left message on answering machine
- 5 Person busy, call back

DATE	DAY OF WEEK	TIME	COMMENTS	PENDING CONTACT STATUS CODE
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ ap	_____	<input type="checkbox"/>

<p>Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p>  <p>General Health</p>	<p>Participant Id#:</p> <p>Acrostic:</p> <p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="font-size: small; text-align: center;">Month Day Year</p>
---	---

INTRODUCTION
Hello, my name is *interviewer name*, and I'm calling to follow up with *participant name* about MESA, a medical study in which s/he is currently enrolled. Is s/he available?

If no → When would it be convenient to call back? _____ Thank you. I will call again.

If yes → Hello, *participant name*, this is *interviewer name* with the MESA study. I'm calling to see how you have been since our last telephone interview with you and update our MESA records. Do you have a few minutes to speak on the phone?

If no → When would it be convenient to call back? _____ Thank you. I will call again.

If Yes → We'd like to gather information about your general health and specific medical conditions that you may have had since our last telephone interview with you. I will ask you some questions about your health since the last time we had a telephone interview with you on _____ I want to focus on what happened from _____ (date of last Follow-up Call) until today.

Go to Question 1.

1. Would you say, in general, your health is (read all response categories except Unsure)

- | | | |
|---------------------------------|----------------------------|------------------------------|
| <input type="radio"/> Excellent | <input type="radio"/> Good | <input type="radio"/> Poor |
| <input type="radio"/> Very Good | <input type="radio"/> Fair | <input type="radio"/> Unsure |

2. Since our last telephone interview with you on [DATE], have you had any of the following symptoms (read each symptom)?

	Yes	No	Unsure
Discomfort or pain in your chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Shortness of breath	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain in your legs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Since our last telephone interview with you, have you at any time seen a doctor or other health care professional? [A 'health care professional' is a doctor, nurse, nurse practitioner, or other certified specialist working in a clinic, hospital, or ambulance. This person may also be a practitioner of non-Western medicine (e.g. An acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.]

(Circle answer) Yes No

Since our last telephone interview with you, have you had an overnight stay in a hospital or nursing home?
(Circle answer) Yes No

Did the participant answer 'Yes' to either part of Question 3 (seen a health professional or overnight stay)?

- | | |
|---------------------------|------------------------------|
| <input type="radio"/> Yes | <input type="radio"/> No |
| ↓ | <input type="radio"/> Unsure |

Go to Question 4.

↓
Skip to Question 8

Follow-up Phone Call 8 -- General Health Page 2

4a. Has your doctor or health care professional told you that you had diabetes?

- Unsure (Go to question 4b)
- No (Go to question 4b)
- Yes → If Yes to Diabetes :

Is this a new diagnosis since our last telephone interview with you?

- Unsure
- No
- Yes

Are you currently taking medicine for your diabetes?

- Unsure (Go to question 4b)
- No (Go to question 4b)
- Yes → If Yes to medicine :

What kind of medicine are you taking for your diabetes?

- Pills
- Insulin
- Insulin and Pills

If Yes to Insulin : At what age did you begin taking insulin?

Age Unsure

4b. Has your doctor or health care professional told you that you had one of the following since our last telephone interview with you? (Read each diagnosis.)

	Yes	No	Unsure
High Blood Pressure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If Yes: Was this a new diagnosis since our last contact with you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
High Cholesterol Level	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If Yes: Was this a new diagnosis since our last contact with you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If Yes to any item in Questions 4a or 4b → Go to Question 4c.
 If No or Unsure to all items in Questions 4a or 4b → Go to Question 5.

4c. Did the doctor recommend any new or different treatments?

- Yes → What treatments were recommended?
(Do not prompt for specific responses. Mark all that apply.)
- No
- Unsure

Go to Question 5.

- Start new medicine
- Increase dose of existing medicine
- Advice to lose weight
- Advice to change diet (low fat, low salt, etc.)
- Advice to stop smoking
- Advice to increase exercise
- Other, specify:
- Unsure

Follow-up Phone Call 8 -- General Health Page 3

5. Since our last telephone interview with you, has a doctor or health care professional told you that you had any of the following?

	Yes	No	Unsure
A myocardial infarction or heart attack -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Angina pectoris or chest pain due to heart disease -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heart failure or congestive heart failure -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Atrial fibrillation -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Deep vein thrombosis or blood clots in your legs -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A transient ischemic attack (TIA) or mini-stroke -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A stroke -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Blockage in the carotid artery -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lung abnormality or nodule -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cancer -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓
Complete "Specific Medical Conditions" form for each item with a Yes response.

6. Since our last telephone interview with you, have you had any other condition that resulted in an..

	Yes	No	Unsure
Overnight Hospital stay	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overnight Stay at a nursing home or rehabilitation center	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓
Complete "Other Admissions" form for each item with a Yes response.

7. Since our last telephone interview with you, have you had any of the following tests or procedures in or out of the hospital? (read each procedure):

	Yes	No	Unsure
Stress Test (ETT, bicycle, chemical, etc.) -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coronary angiography or heart catheterization -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Echocardiogram -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
An angioplasty procedure to open up arteries to your heart -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coronary bypass surgery -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
An angioplasty procedure to open up arteries in either of your legs --	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carotid ultrasound or carotid angiogram -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest x-ray, a chest CAT scan, MRI, or other study to assess any findings in your chest -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other diagnostic procedure or surgery related to your heart or blood vessels -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓
Complete "Specific Medical Procedures" form for each item with a Yes response.

Follow-up Phone Call 8 -- General Health Page 4

8 a. Has your employment status or employment location changed since your last MESA clinic exam on [DATE]?

- No → Skip to Question 9
- Yes



b. Choose one of the following which best describes your current situation:

- Started working after retiring or other time off
- Changed job
- Changed job location only
- Retired → Skip to 8d
- Unemployed → Skip to 8d
- Refused/No response → Skip to Question 9

c. What is the street address of your new job or job location?

Street

City

State

ZIP

Country

d. When did your employment status or employment location change?

		/					
Month			Year				

9 Which of the following best describes your current smoking status?

- Never smoked → Skip to question 12
- Former smoker, quit more than 1 year ago
- Former smoker, quit less than 1 year ago
- Current smoker
- Don't know

10 Have you smoked cigarettes during the last 30 days?

- Yes
- No → Skip to question 12

Follow-up Phone Call 8 -- General Health Page 5

11 On average, about how many cigarettes a day do you smoke?

--	--	--

12 Did anyone smoke in your residence in the past 12 months (this includes you)?

- Yes
- No
- Don't know

12a. On average, how often did someone smoke in your residence in the past 12 months?

- Less than once a month
- A few days each month
- More than half of the days of the month, but less than daily
- Every day or almost every day

	Yes	No	Don't Know
13 When walking on level ground, do you get more breathless than people your own age?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14 When walking up hills or stairs, do you get more breathless than people your own age?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15 Do you ever have to stop walking because of breathlessness?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16 Since your last MESA clinic visit have you had swelling of your feet or ankles?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If Yes → Did it tend to come on during the day and go down overnight?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17 Since your last MESA clinic visit have you had to sleep on two or more pillows to help you breathe?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18 Are you taking aspirin on a regular basis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If Yes → How many days a week? <input style="width: 20px; height: 15px;" type="text"/>			
19 Are you taking a medication for cholesterol on a regular basis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Follow-up Phone Call 8 -- General Health Page 6

Reproductive History
WOMEN ONLY -- MEN are finished with this questionnaire.

Check here if participant has previously reported removal of both ovaries and skip to question 24

20 Have you had surgery to remove your ovaries? Yes No Don't Know

If Yes:

a. At what age?

b. How many ovaries were removed? 1 2 → If both ovaries removed, Skip to question 24

Check here if participant has previously reported hysterectomy and skip to question 24

21 Have you had a hysterectomy (surgery to remove your uterus/womb)? Yes No Don't Know

At what age? Skip to question 24

Check here If participant previously reported going through menopause go to question 24

22 Have you had a menstrual period in the past 12 months? Yes No Don't Know

If Yes → How many periods have you had in the last 12 months?

Skip to question 24

23 Have you taken birth control pills since your last MESA clinic visit? Yes No Don't Know

If Yes → Please estimate the total number of months that you took birth control pills since your last MESA clinic visit (keeping in mind you may have started and stopped several times)

Follow-up Phone Call 8 -- General Health Page 7

24 Since your last MESA clinic visit, have you taken hormone replacement therapy?

No → Questionnaire Completed

Yes → a. Are you currently using hormone replacement therapy?

Yes → At what age did you begin?

--	--

No → At what ages did you take hormones?

Age started

--	--

Age stopped

--	--

b. Which type of therapy were you on?

Estrogen alone (like Premarin or Estratab)

Estrogen with progestin (like Provera)

Other types of hormone replacement therapy

Specify:

--

I'd next like to make sure our records are up to date. Could you please tell me if the following information I have is still correct?

Go to "Participant Tracking" form and verify the tracking information that appears in the left-hand column.

This participant is enrolled in MESA Air:

After completing the Participant Tracking Form, administer the "MESA Air Triggers" and then continue to End on General Health.


This participant is not enrolled in MESA Air:

Continue to End

END:

Thank you so much for talking with me today. We greatly appreciate your participation in MESA. Should you have any questions, please feel free to call us at the clinic at telephone number.

Interviewer ID	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					Reviewer ID	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>					Data Entry ID	<table border="1"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>				

<p>Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p>  <p>General Health - Death</p>	<div style="border: 1px dashed gray; width: 100px; height: 40px; margin: 0 auto; text-align: center; font-size: 8px;">Affix ID Label Here</div> <p>Date: <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> Month Day Year </p>
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INTRODUCTION
 Hello, my name is *interviewer name*, and I'm calling to follow up with *proxy name* regarding *decedent's* involvement with the MESA study, a medical study in which *participant name* was enrolled. Is *proxy name* available?

If no → When would it be convenient to call back? Thank you. I will call again.

If yes → Hello, *proxy name*, this is *interviewer name* with the MESA study. We understand that *decedent* had given us your name as someone close to him/her. I want to express our condolences for your loss. [pause] In order to close out *participant name's* file, I need to ask you a few questions about his/her health from the last time our staff talked with him/her to his/her death. Would now be a good time to talk?

If no → When would it be convenient to call back?
Thank you. I will call again.

If Yes → We'd like to gather information about his/her general health and specific medical conditions that may have occurred since our telephone interview with *decedent name* and before his/her death. That call occurred on _____

Go to "Question 1" form.

1. Since our last telephone interview with *decedent* on _____ [*insert date of clinic exam*], had a doctor or health care professional told *decedent* that s/he had any of the following:
 (read each diagnosis):

	Yes	No	Unsure
A myocardial infarction or heart attack -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Angina pectoris or chest pain due to heart disease -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Heart failure or congestive heart failure -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Atrial fibrillation -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Deep vein thrombosis or blood clots in your legs -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A transient ischemic attack (TIA) or mini-stroke -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
A stroke -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Blockage in the carotid artery -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lung abnormality or nodule -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cancer -----	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓
 [Complete "Specific Medical Conditions" form for each item with a Yes response.]

Follow-up Phone Call 8 -- General Health-Death Page 2

2. Since our last telephone interview with decedent, had s/he had any other condition that resulted in an ...

	Yes	No	Unsure
Overnight Hospital stay	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overnight Stay at a nursing home or rehabilitation center	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓

Complete "Other Admissions" form for each item with a Yes response.

3. Since our last telephone interview with decedent, had s/he had any of the following tests or procedures in or out of the hospital

(read each procedure):

	Yes	No	Unsure
Stress test (ETT, bicycle, chemical, etc.).....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coronary angiography or heart catheterization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Echocardiogram.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
An angioplasty procedure to open up arteries to the heart	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coronary bypass surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
An angioplasty procedure to open up arteries in either of the legs --	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carotid ultrasound or carotid angiogram.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest x-ray, a chest CAT scan, MRI, or other study to assess any findings in the chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other diagnostic procedure or surgery related to the heart or blood vessels	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

↓

Complete "Specific Medical Procedures" form for each item with a Yes response.


(Optional:) May I ask you a few additional questions about *decedent name's* death?
 (Interviewer may proceed to fill out Death Information form before ending the phone call.)

END: Thank you so much for answering these questions. Again, I am sorry for your loss. I really appreciate you spending time answering these questions.

We greatly appreciate your cooperation with the MESA study. Should you have any questions, or additional information, please feel free to call us at the clinic at telephone number.

Interviewer ID <input style="width: 30px; height: 20px;" type="text"/> Reviewer ID <input style="width: 30px; height: 20px;" type="text"/> Data Entry ID <input style="width: 30px; height: 20px;" type="text"/>
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Multi-Ethnic Study of Atherosclerosis
Follow-Up Phone Call 8



Death Information

Affix ID Label Here

DO NOT SCAN THIS FORM

INTRODUCTION:

I need to ask you a few short questions about decedent name's death. Someone else may also contact you in the future to ask additional questions if necessary. We really appreciate your help.

(If appropriate, interviewer may use information from other forms to fill in parts of this form. Ask only necessary questions.)

1. On what date did decedent name die?

_____ / _____ / _____
 Month Day Year

2. Do you happen to know whether s/he died because of a heart problem, a stroke, or some other cause? (Interviewer, please mark appropriate category below.)

- Cardiac death
- Cerebrovascular death
- Non-CVD death. Specify: _____

Unknown (Interviewer, please write as many details in notes section as possible.)

3. Did s/he die in or out of the hospital?

- In-Hospital
- Out of Hospital (put ER deaths here)

Notes:

Please record any additional information that might help the Events staff investigate this death.


Abstractor ID: _____

Date of this interview

_____ / _____ / _____
 Month Day Year

END: Thank you so much for your time. (If appropriate:) Again, please accept our condolences for your loss. We are very grateful for decedent name's participation in our study.

Multi-Ethnic Study of Atherosclerosis
Follow-up Phone Call 8



Specific Medical Conditions

Affix ID Label Here

Date: / /

Month Day Year

Complete form for each condition reported as 'Yes' on "General Health" or "General Health-Death" form. If the participant has died, change 'you' or 'your' to decedent's name for all questions below.

You said that a doctor or other health care professional told you that you had _____ [read and mark specific condition name reported previously below]

- A myocardial infarction or heart attack
- Angina pectoris or chest pain due to heart disease
- Heart failure or congestive heart failure
- Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries
- Atrial fibrillation
- Deep vein thrombosis or blood clots in your legs
- A transient ischemic attack (TIA) or mini-stroke
- Stroke _____ →
- Blockage in the carotid artery
- Lung abnormality or nodule
- Cancer, specify type:

Regarding symptoms that you had from your stroke, do you feel that you have made a complete recovery?

Yes No Unsure

In the last two weeks, did you require help from another person for everyday activities?

Yes No Unsure

A. What was the name and address of the doctor you saw?

Name: _____

Address: _____

B. What was the date of the diagnosis or hospitalization?
(Probe for exact date. If exact date cannot be recalled, ask participant to estimate month and year. Record day as 16.)

/ /
 Month Day Year

C. Were you in the hospital at least one night for this condition since our first contact with you on _____?

Yes



(Continue to part D on next page.)

No

Unsure



Ask about next condition reported on "General Health" or "General Health-Death" form, and record details on an additional form. If there are no additional conditions, go to next question on "General Health" form.

Follow-up Phone Call 8 -- Specific Medical Conditions Page 2


D. Would you please tell me the dates of each hospitalization and where you were hospitalized?
 (Probe for exact date. If exact date cannot be recalled, ask participant to estimate month and year. Record day as 15.)

		Date	Hospital Code	Length of Stay (days)																				
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Month	/	Day	/	Year																				

Ask about the next condition reported as 'Yes' on "General Health" or "General Health-Death" form and record details on an additional form. If no additional conditions are reported as 'Yes', go to next question on the form.

For MESA Field Center use only:

		Interviewer ID : <table style="border: 1px solid black; width: 20px; height: 20px; display: inline-table;"></table>	Reviewer ID : <table style="border: 1px solid black; width: 20px; height: 20px; display: inline-table;"></table>	Data Entry ID : <table style="border: 1px solid black; width: 20px; height: 20px; display: inline-table;"></table>
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<p>Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p>  <p>Specific Medical Procedures</p>	<div style="border: 1px dashed gray; width: 150px; height: 50px; margin: 0 auto; text-align: center; font-size: 8px;">Affix ID Label Here</div> <p>Date: <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 40px; height: 20px;" type="text"/></p> <p style="text-align: center; font-size: 8px;">Month Day Year</p>
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Complete form for each procedure reported as Yes in on "General Health" form or "General Health- Death" form. if participant has died, change 'you' to decedent's name for all questions below.

You said that a doctor or other healthcare professional told you that you had _____ [read and mark specific event name reported previously below]

- Stress test (ETT, bicycle, chemical, etc.)
- Coronary angiography or heart catheterization
- Echocardiogram
- An angioplasty procedure to open up arteries to your heart
- Coronary bypass surgery
- An angioplasty procedure to open up arteries in either of your legs
- Carotid ultrasound or carotid angiogram
- Chest x-ray, a chest CAT scan, MRI or other study to assess any finding in your chest

If other study, specify :

Other diagnostic procedure or surgery related to your heart or blood vessels, specify :

A. What was the name and address of the doctor you saw?

Facility Code

Physician Name _____

City _____

B. What was the date of the diagnosis or hospitalization?

(Probe for exact date. If exact date cannot be recalled, ask participant to estimate month and year. Record day as 16.)

/ /

Month Day Year

Ask about the next procedure reported as "Yes" on the "General Health" or "General Health-Death" form and record details on an additional form. If no additional events are reported as Yes, go to END of "General Health" or "General Health-Death" form.

For MESA Field Center use only:

<input style="width: 20px; height: 20px;" type="text"/>	Interviewer ID :	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Reviewer ID :	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Data Entry ID :	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
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<p>Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p>  <p>Other Admissions</p>	<div style="border: 1px dashed gray; width: 100px; height: 40px; margin: 0 auto; text-align: center; font-size: 8px;">Affix ID Label Here</div> <p>Date: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p style="font-size: 8px; text-align: center;">Month Day Year</p>
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Complete this form for each 'Yes' response to the overnight stay question on the "General Health" or "General Health-Death" form. If the participant has died, change 'you' to decedent's name for all questions.

You said that you stayed overnight as a patient in a [read and mark type of facility previously reported by participant below] :

- Hospital Nursing home or Rehabilitation Center

Please tell me [read and record items listed below for each overnight admission] :

(1) Reason for admission _____

Is this the participant's first admission to a Nursing Home for chronic care (not short term rehab)? Facility Code :

Yes No

Physician Name _____

City _____

Date of Admission : / / Length of Stay : days

Month Day Year

(Probe for exact date. If exact date cannot be recalled, ask participant to estimate month and year. Record day as 16.)

(2) Reason for admission _____

Is this the participant's first admission to a Nursing Home for chronic care (not short term rehab)? Facility Code :

Yes No

Physician Name _____

City _____

Date of Admission: / / Length of Stay : days

Month Day Year

(Probe for exact date. If exact date cannot be recalled, ask participant to estimate month and year. Record day as 16.)

Ask about the next admission reported by the participant on the "General Health" or "General Health-Death" form and record details on an additional form. If no additional admissions are reported as "Yes", go to procedures question.

For MESA Field Center use only:

Interviewer ID : Reviewer ID : Data Entry ID :

<p>Multi-Ethnic Study of Atherosclerosis Follow-up Phone Call 8</p>  <p>Contact Cover Sheet</p>	<p>Participant Id#: Acrostic:</p> <p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">Month Day Year</p>
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FINAL STATUS CODES

Enter the following two status codes when the final Follow-up Phone Call 8 contact status has been obtained for the participant (i.e. when contact is determined to be definitely successful or unsuccessful). If participant deceased, make every effort to obtain proxy interview.

1. Mark appropriate final Visit Status Code :

- Interview completed or partially completed
- Interview not done

Reason not done :

- Unable
- Refused MESA only
- Refused MESA Air only
- Refused all studies

Reason refused :

- Problem with the study
- Life situation
- Lack of time
- Other, specify :

Reason unable :

- Could not locate
- Reported deceased
- Hearing problem
- Cognitive problem
- Hospitalized
- Other illness
- Other, specify :

Completed by :

- Participant
- Proxy

Reason, if by proxy:

- Reported deceased
- Hearing problem
- Cognitive problem
- Hospitalized
- Other illness
- Other, specify :

2. Select appropriate Participant Status Code :

- Alive
- Do not contact
- Reported deceased
- Unknown

<input style="width: 20px; height: 20px;" type="text"/>	Interviewer ID	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	Reviewer ID	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	Data Entry ID	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>
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D.2 Initial Notification of Potential Event/Death

D.2.1 General Information

The primary means of identifying cardiovascular (CVD) events in MESA is through scheduled Follow-up Phone Calls and clinic visits. Field Center staff asks participants a standard set of questions and certain responses necessitate the generation and completion of an *Initial Notification of Potential Event/Death* form. Possible events include any hospitalization, any death, and certain cardiovascular procedure or outpatient cardiovascular physician visits.

Other ways in which Field Center staff might learn of a potential MESA event include (a) notification by the participant or his/her proxy, and (b) through the investigation of another reported event, obituaries, and from data from the National Death Index.

Steps for completing the *Initial Notification of Potential Event/Death* form are essentially the same regardless of how the Field Center first becomes aware of the event. The main difference is, when staff learns of the event through a standard MESA Follow-up Call interview, information on the *Initial Notification of Potential Event/Death* form is abstracted from the Follow-up Call form(s) used (*General Health*, *Specific Medical Conditions*, *Other Admissions*, and *Specific Medical Procedures* forms). When staff learns of the event through other means, *Initial Notification of Potential Event/Death* form information is abstracted from available information.

Note: If a field center discovers a potential event through means other than a Follow-up Call (e.g., unscheduled notification by the participant during an Exam), then it is not necessary to fill out Follow-up forms for that potential event (*General Health*, *Specific Medical Conditions*, *Other Admissions*, *Specific Medical Procedures*).

Likewise, do not add the new potential event to a previous Follow-up form (e.g., a *General Health* form completed a week earlier) because doing so will confuse the date-tracking function in the Events software. Instead, you should use the discovered information to submit an *Initial Notification* immediately and then begin gathering the appropriate documentation for a full investigation. Do not wait for the receipt of verifying medical records before submitting the *Initial Notification* (the event type marked on the *Initial* can always be changed later, on the *Final Notice*).

In most cases¹, when a participant reports a potential event on the *General Health* form (with additional details being collected on the *Specific Medical Conditions*, *Other Admissions*, or *Specific Medical Procedures* forms), Field Center staff initiates an *Initial Notification of Potential Event/Death* form to begin the process of investigating the potential event.

As soon as they are aware of a potential event that requires investigation, it is essential that Field Center staff **immediately** generates, completes, and enters an *Initial Notification of Potential Event/Death* form into the EDC. Entering the form is crucial as it triggers the next event collection steps at the Field Center and also helps the Coordinating Center track and resolve self-reported events.

If—before completing an *Initial* but after entering Follow-up Phone Call forms (GH, SMC, OA, SMP)--a Field Center discovers that there is no record of an event (e.g., the hospital reports no such patient admitted), then an *Initial* is not required. (The situations that warrant not beginning an *Initial* are the same as the situations described in Section D.2.5, “Deleting Initial Notification Forms for ‘Non-events.’”) However, even though an *Initial* is not begun, the Field Center must still use the Event Software to mark investigation “not required” for the Follow-up form in question. Note: It is not standard practice to delay the beginning and entering of an *Initial* even if there is doubt about the validity of the potential event reported during the Follow-up call. If necessary, you can delete the *Initial* at a later date.

Records requests should be begin immediately after the scanning of the *Initial*. Federal law requires a signed HIPAA authorization, which does not expire for research purposes, for the release of personal health information (PHI). State laws may impose more stringent rules, however, so it is important to know the local regulations. Some record providers may also require a signed release of information (ROI) in order to release medical records. From time to time, check with the record provider as to what the current ROI requirements are, as rules/procedures may change.

1 There are a handful of exceptions. Do not begin an *Initial Notification of Potential Event/Death* for any of the following conditions and procedures if it is an out-of-hospital occurrence:

Conditions:

- atrial fibrillation (reported on General Health forms dated July 1, 2003, or after)
- deep vein thrombosis
- lung abnormality
- cancer

Procedures:

- ETT – exercise, treadmill, bike, stress, or chemical (reported on General Health forms dated July 1, 2003, or after)
- echocardiogram (reported on General Health forms dated July 1, 2003, or after)
- ECG, EKG
- chest x-ray, chest CT scan or chest MRI
- ablation
- cardioversion

All other diagnoses, admissions, and procedures listed on the Follow-up forms (including others in the ‘other diagnostic,...’ category) should be investigated. Of course, an *Initial Notification* should also be started if any of the conditions/procedures above is accompanied by another condition/procedure that does require an *Initial Notification*.

This Section: 6/6/2017 Version

If an investigation cannot be completed because it lacks written participant/proxy consent to release medical records or a signed, dated HIPAA authorization, then the field center should make a thorough effort to obtain the consent or authorization. Over a six-week period, multiple attempts should be made to contact the ppt/proxy on different days of the week and at varying times of the day. If contact has still not been made, then the Final may be submitted marked “Insufficient Data To Classify” and a comment about the lack of consent or authorization should be included in the “Investigation Notes” section of the Events database (EDC).

The Field Center is expected to have finished its investigation (gathered, scanned and entered all relevant records) within 90 days of the date the *Initial Notification* is entered. The Field Center’s completion of an investigation will be signaled by the entry of the *Final Notice* into the EDC. The *Final Notice* should not be entered until the investigation is complete and the Field Center is ready for it to proceed to review or, if ineligible for review, to be closed. These timeframes will be used by the Coordinating Center to produce monthly reports in order to aid the Field Centers in the timely completion of eligible investigations.

Entering the *Initial Notification* generates a nine digit ID that will be used with all surveillance forms associated with this investigation. The ID consists of the seven-digit participant ID, plus a sequential two-digit “Investigation ID” for event investigations beginning with “01” for event dates up to 3/13/14. After that date, new events will begin with “50.”

NOTE: The two-digit investigation ID is designed to be a unique identifier for the investigation. The Investigation IDs for the same participant may not be in chronologic order.



In some cases, two or more reported conditions, hospitalizations or procedures detailed on the *Specific Medical Conditions*, *Other Admissions* or *Specific Medical Procedures* forms are considered together as a single investigation and result in only one *Initial Notification of Potential Event/Death* form being submitted. Under most circumstances, two or more reported conditions or procedures from the same date or multiple conditions/procedures within the same hospitalization are considered to be linked as such and field center staff needs to initiate only one *Initial Notification of Potential Event/Death* form to begin the review of those events. For conditions or procedures that occur during separate hospitalizations (or on different dates for outpatient events) the Abstractor may decide to include two or more events in the same investigation if there is no more than 30 days separating the events. Remember: The Physician Reviewers can always link investigations later. Please note in the ‘Investigation Notes’ tab in the EDC if you think two investigations may be linked. They will be sent together to Review.

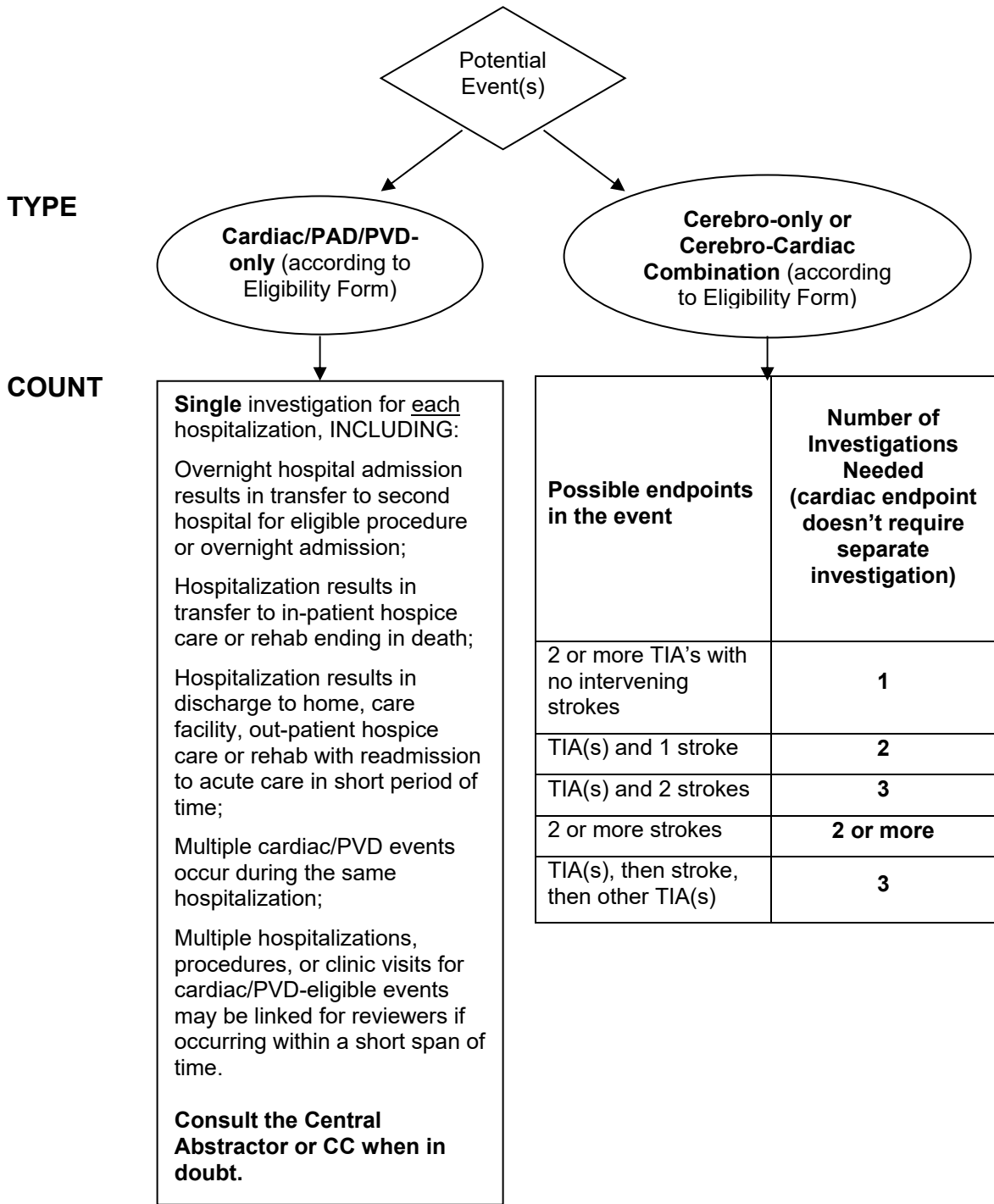
When to divide a potential event into multiple investigations

The following flowchart and instructions below describe when and how to join or divide multiple events into one or several investigations. This is not a matter of distinguishing between ER visits, hospital admissions, and rehab stays; MESA Events protocol regarding those elements remains unchanged. Rather, this is a matter of dividing potential endpoint incidents into multiple investigations.

As you will notice, this issue is more relevant for potential cerebrovascular investigations. For example, if hospital records indicate that a participant was hospitalized for a stroke but had non-hospitalized TIA-like spells in the days or weeks prior to the stroke hospitalization, then we would now like to create an additional out-of-hospital investigations for those potential TIA spells.

After receiving medical records requested from a physician or a hospital, please read them carefully to determine (a) if reports for all significant procedures/consultations mentioned in the records are also included (e.g., CT or MRI reports), and (b) if an additional investigation should be initiated according to the flow chart below (when in doubt, go ahead and initiate an additional investigation, consult your site's local physician reviewer, contact the Coordinating Center or Central Abstractor).

If the Central Stroke or Cardiac/PVD Abstractor, or the MESA Physician Reviewers, identify a need to begin an additional investigation related to an already-completed investigation, the Central Abstractor or Coordinating Center will notify you.



If, in the process of researching or abstracting an investigation, you determine that the event needs to be split into multiple investigations, initiate a new investigation by entering a new Initial Notification into the Events EDC.

D.2.2 Item-by-Item Instructions

Investigation ID

The Investigation ID is automatically assigned and pre-entered on the EDC form when an *Initial Notification of Potential Event/Death* form is generated. The software will not allow the same Investigation ID to print on another event. If the form was initiated in error, contact the Coordinating Center to remove the form from the EDC. Investigation ID's must be unique for each investigation; they do not need to be consecutive. Initial Notification forms may be deleted out of the database under certain circumstances. That Investigation ID will not be used again.

(Question 1) Date

Record the date of the potential event from currently available information:

If abstracting information from the *Follow-Up Phone Call* forms, enter the date of hospitalization, physician/clinic visit, or procedure as it is recorded in Item B or D of the *Specific Medical Conditions* form, Item 1 or 2 of the *Other Admissions form*, or Item A or B of the *Specific Medical Procedures* form. Making sure the date on the *Initial* matches the date on the *Follow-Up Phone Call* form greatly reduces errors in tracking whether all eligible follow-ups have results in the initiation of an investigation.

(Corrections can be made through the Events software, but matching dates right the first time should be your goal.)



NOTE: If during the investigation process it is discovered that any dates are incorrect, do not go back and change the form. The correct dates will be recorded on the *Final Form*. Edits are allowed for typographic errors (ie: recording 2010 instead of 2012).

The order of priority for dates is as follows:

- Date of Death
- Date of Hospital Admission
- Date of Clinic Visit
- Date of Procedure

To use this priority ordering, start at the top of the list and see what is the first type of date that applies to this investigation. Use that date on the *Initial Notification*.

If entering information on a potential event identified through other means, enter as specific a date as possible. At a minimum, obtain (or at least estimate) the month and year. Record unknown day as "15." Record unknown month as "6". Never leave any of the date fields blank. You will have the opportunity to change or make the date more accurate on the *Final Notification*.

(Question 2) Type of Event

On the basis of currently available information, choose the type of event or events. If the participant has indicated that s/he has had more than one event which you have determined should be considered in this investigation, check all that apply (the one exception is that you may not check both “Unknown” and any other type of event).


 Identifying the type of events included in an investigation is a crucial step, because it determines the type of event investigation to be undertaken. If in doubt, contact your Events Coordinator or a MESA Physician Reviewer. In general, if it sounds like a cardiovascular event, it should be placed in one of the first types.

Table D.2 describes the different types of potential events.

Table D.2

Type of Event	When to Use
Hospitalized Cardiac/PVD Non-fatal	This category includes any nonfatal cardiovascular event (other than cerebrovascular disease) for which hospitalization was required. These nonfatal items from the <i>General Health</i> form include myocardial infarction (or heart attack); angina pectoris (or chest pain due to heart disease); heart failure; peripheral vascular disease or intermittent claudication; atrial fibrillation; ETT (exercise treadmill or bicycle stress test, pharmacological or chemical stress test); coronary angiography or heart catheterization; echocardiogram; heart angioplasty; coronary bypass; leg angioplasty; or other heart or blood vessel procedure (excluding neck or brain). NOTE: Being seen in the ER is NOT being hospitalized. If a participant is seen in the ER and then is subsequently admitted, the event is classified as “Hospitalized.”
Hospitalized Cardiac Death	This category is for fatal events for which the participant was hospitalized, and, based on available information, appear to be related to cardiac or peripheral vascular disease. NOTE: This does not include ER deaths (i.e., participant who died in the ER without having been admitted to the hospital). Such deaths should be categorized as out-of-hospital.
Hospitalized Cerebrovascular Non-fatal	This category includes nonfatal cerebrovascular events for which the participant was hospitalized. These include the following items from the <i>General Health</i> form: TIA (or mini-stroke); stroke; blockage to carotid artery; carotid ultrasound or carotid angiogram. NOTE: Being seen in the ER is NOT being hospitalized. If a participant is seen in the ER and then is subsequently hospitalized, then it is “hospitalized.”
Hospitalized Cerebrovascular Death	This category is for fatal events, for which the participant was hospitalized, and, based on available information, appear to be related to cerebrovascular disease. NOTE: This does not include ER deaths (i.e., participant who died in the ER without having been admitted to the hospital). Such deaths should be categorized as out-of-hospital.

Type of Event	When to Use
Out-of-Hospital Cardiac/PVD Non-fatal	This category includes any nonfatal cardiovascular event (other than cerebrovascular disease) for which hospitalization was not required. These nonfatal items from the <i>General Health</i> form include myocardial infarction (or heart attack); angina pectoris (or chest pain due to heart disease); heart failure; peripheral vascular disease or intermittent claudication; coronary angiography or heart catheterization;; heart angioplasty; coronary bypass; leg angioplasty; or other heart or blood vessel procedure (excluding neck or brain). It does not include diseases of veins. Cardiac- or PVD-related visits to the ER should be recorded here (unless the patient was officially admitted to the hospital directly from the ER).
Out-of-Hospital Cardiac Death	This category is for fatal events for which the participant was not hospitalized, and, based on available information, appear to be related to cardiac disease. NOTE: Deaths that occurred in the ER (without hospital admit) and cases in which the participant was dead-on-arrival (DOA) should be included here.
Out-of-Hospital Cerebrovascular Non-fatal	This category includes nonfatal cerebrovascular events for which the participant was not hospitalized. These include the following items from the <i>General Health</i> form: TIA; mini-stroke; stroke; blockage to carotid artery; carotid ultrasound or carotid angiogram. Cerebrovascular-related visits to the ER should be recorded here (unless the patient was officially admitted to the hospital directly from the ER).
Out-of-Hospital Cerebrovascular Death	This category is for fatal events for which the participant was not hospitalized, and, based on available information, appear to be related to cerebrovascular disease. NOTE: Deaths that occurred in the ER (without hospital admit) and cases in which the participant was dead-on-arrival (DOA) should be included here.
Non-CVD Non-fatal Hospitalization	This category includes all hospitalizations not thought to be cardiovascular related. Non-CVD-related visits to the ER should <u>not</u> be recorded here (unless the patient was officially admitted to the hospital directly from the ER).
Non-CVD Death	This category includes all deaths not thought to be cardiovascular related.
Unknown	This category is used if the type of event is unclear at the time the initial notification is completed. More information must be gathered to determine this. NOTE: <u>This category should only be used in rare cases.</u> For example, if the participant undergoes cardiovascular evaluation of any sort, then one of the cardiovascular event types should be marked (rather than “Unknown”) even if the participant says no clear or definitive diagnosis was made by the physician. The event type can always be changed on the <i>Final Notification</i> . Selecting a type on the <i>Initial Notification</i> simply indicates to the CC how you will be investigating the potential event.

(Question 3) How did the FC find out about the event?

Record how the field center became aware of the potential event.

Choose response from the available choices:

- **Participant or spouse contacted the field center**
- **Clinic visit**
- **Follow-up telephone/mail contact**
- **Other clinic-initiated contact (e.g., setting up an appointment, etc.)**
- **Obituary/local news**

Investigation of another event

If none of the listed categories are appropriate, select "Other" and specify details in the box provided.

If the potential event is discovered while setting up an appointment during a Follow-up Call interview, then "Follow-up telephone/mail contact" should be marked, not "Other clinic-initiated contact (e.g., setting up an appointment)."

D.2.3 Additional Form Information

In the "Notes" section, record any additional information that may be relevant to your investigation of this potential event.

If the field center learned of the event through a means other than a Follow-Up Phone Call, make sure Questions 1–3 are complete.

You may change the type of event(s) on the *Initial Notification* if it turns out that you were incorrect about the type. Updating this field will allow the software to properly assist you in compiling the correct documentation.

Enter your ID in the boxes provided at the bottom of the form. Enter the form into the EDC.

Linked Events: If you have a good reason to believe that the investigation you are initiating is part of a single, extended endpoint episode (e.g., CHF) connected to another investigation involving the same participant, then you may recommend that all of the related investigations be "linked." You may consult your Physician Reviewer on such occasions if you like, but your recommendation does not need to be verified. At the review stage, it is the Physician Reviewers who will determine which investigations are to be officially "linked." You should note the possible link in the "Investigation Notes" tab in the EDC event; that note will be seen by the Physician Reviewers. MESA policy is to remind the Reviewers to consider "linking" any similar endpoints that occur within 30 days of each other. All investigations that occur within a 30-day span for the same participant will automatically be sent to review simultaneously, where the Reviewers will make the medical determination whether to link.

Combining Events: Hospitalizations for the *same* condition within thirty days of one another may be combined into a single investigation. The thirty day period refers to the time between the admission dates for the two hospitalizations, not the period from the first discharge to the second admission.

Thirty days is given as a guideline; Events Coordinators and Abstractors should use their best judgment as to whether combining the cases will clarify and simplify the investigation(s). In many situations linking the investigations will be preferable to combining them. Consult the CC or the Central Abstractor when in doubt.

If the investigations are combined, an additional Eligibility Form for the later hospitalization(s) should be entered into the same Event in the EDC.

- Regardless of whether an investigation includes combined events, a separate abstraction form should be completed for each hospital stay.

Cross-Reference: Linked/Combined Events is also discussed in Section 3, Events Eligibility, Appendix D.5, Hospital Abstraction: Cardiac/PVD, and Appendix D.6, Hospital Abstraction: Stroke/TIA.

D.2.4 Action Required After Initial Notification Form is Complete

After the *Initial Notification of Potential Event/Death* form is completed, field center staff begins to obtain documentation appropriate to the type of event reported, as detailed below. This information is then abstracted and entered into an *Events Eligibility* form in the EDC.

NOTE: Federal law requires a signed HIPAA authorization, which does not expire for research purposes, for the release of Personal Health Information, and also requires that the release be for the “minimum necessary” records. State laws may be more stringent, and may require a signed Release of Information as well. Please make sure that all MESA consent/authorization forms meet the requirements of your medical record providers.

For all reported hospitalizations: Using a two-step method of requesting medical records saves time and effort for both hospital medical records and MESA staff, as well as insuring that the “minimum necessary” personal health information is released to the MESA Study. **See Appendix D.3.1 Events Eligibility for more complete directions.**

Step One: The initial request for medical records should stipulate a date range which covers the interval since the last participant contact, e.g. from the last follow-up call to the current follow-up call. If the hospital Encounter Summaries report is available, select the dates of all appropriate overnight admissions for the following record requests:

- ICD-10-CM (or ICD-9-CM) hospital discharge summary diagnosis and procedure codes (sometimes called the physician’s attestation)
- Discharge summary or last physician’s progress note if no discharge summary was written due to a short stay.

Once the initial records are received, the ICD codes as entered into the Events Eligibility form will determine if the Event is eligible for further investigation. If the Event is ineligible, no further records are required. Proceed to complete the Final Notification form as “Ineligible Non-CVD.”

Step Two: If the ICD codes indicate that the Event is eligible, additional records as described in Appendix D.3.4.1 Events Eligibility should be requested.

The advantages of the two-step method of requesting medical records are:

1. Two-thirds of all Events are ineligible for review, therefore, most of the time the codes and discharge summary are the minimum necessary.
2. Health Information Management (HIM) departments will turn the requests around more quickly, saving time for both their staff and the MESA staff.
3. Charges for medical records copy fees, where required, will be greatly reduced.
4. The Privacy Act (HIPAA) guidelines for minimum necessary personal health information to be requested/released will be met.
5. The Central Abstractors and Physician Reviewers will have all the documents they require for a thorough understanding of the event, without unnecessary documents to delete or review.

For reported Out-of-Hospital Events, including clinic visits, out-patient procedures, and deaths, an attempt should be made to receive relevant documents. If those records cannot be obtained, a Physician’s Questionnaire should be sent out, although the return on those questionnaires is infrequent and often lacking detail when received. The following are records that can be requested from ER visits, clinics, nursing homes and other care facilities, and hospice:

- **Clinic Progress Notes and Procedures**
- ***ER Physician Notes, Procedures, EMS Reports**
- ***Residential Care/Hospice Admission History and Physical, Progress Notes and Physician Consults**

*These records are most frequently requested in the case of an out-of-hospital death. In the case of a death in care, it is advisable to ask only for the last consult and the last progress notes before the death. If the participant has not been recently contacted, it may be helpful to also ask for the care facility admission history and physical.

The following **Table** lists the types of events to be investigated, and the records necessary to complete the investigation:

Type of Event	Records Required
Hospitalized cardiac/PAD/PVD event	Discharge summary ICD codes and medical records
Hospitalized cerebrovascular event	Discharge summary ICD codes and medical records
Other hospitalizations	Discharge summary ICD codes and discharge summary or last physician’s progress note only
Any death	Death certificate with cause of death ICD-10 codes and hospital/out-of-hospital records as appropriate
Outpatient cardiac/PAD/PVD nonfatal Event	Records from outpatient facility ¹ . If necessary, obtain <i>Physician Questionnaire for Cardiac/PVD</i>
Outpatient cerebrovascular nonfatal Event	Request records from outpatient facility ¹ . If necessary, obtain <i>Physician Questionnaire for Stroke/TIA</i>

¹Requesting records from an outpatient facility- It is important to specify to the clinic, office, lab, etc...that you are requesting BOTH reports from procedures and tests AND any progress notes from the visits.

See Appendix E, “Sample Letters for MESA Events,” for examples of letters you may need to send to hospitals, physicians, proxies, etc., to obtain additional documentation and information regarding the event.

D.2.5 Deleting Initial Notification Forms

If a participant (or proxy) reports an event of potential interest to MESA, and an *Initial Notification of Potential Event/Death* is completed, but preliminary attempts to document the event fail (e.g., the hospital has no record of the participant's being admitted on or around the stated time, the treating physician does not list the participant as a patient, etc.), re-contact the participant/proxy to clarify the details in question. If the participant/proxy provides a different hospital or physician name, recommence investigation procedures. If the participant/proxy provides only the same unverifiable details, the Initial form is retained, and the Eligibility and Final Notice forms will be completed as Non-Events.

If the participant states the initial report was erroneous and there was no event, or if you begin investigation procedures and realize the event in question has already been reported/investigated (i.e., another Initial Notification already exists for it), you may request the deletion of the Initial Notification of Potential Event/Death from the EDC.

You should think of deleting an *Initial Notification* as equivalent to deleting all traces of an investigation—and thus deleting the whole investigation's existence.

<p>Multi-Ethnic Study of Atherosclerosis</p>  <p>Initial Notification of Potential Event/Death</p>	<p>Participant ID:</p>
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<p>1. Date of potential event/death:</p> <p> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small> </p> <p>2. Type of event <i>(select all that apply):</i></p> <ul style="list-style-type: none"> <input type="radio"/> Hospitalized Cardiac/PVD non-fatal <input type="radio"/> Hospitalized Cardiac death <input type="radio"/> Hospitalized Cerebrovascular non-fatal <input type="radio"/> Hospitalized Cerebrovascular death ----- <input type="radio"/> Out-of-hospital Cardiac/PVD non-fatal <input type="radio"/> Out-of-hospital Cardiac death <input type="radio"/> Out-of-hospital Cerebrovascular non-fatal <input type="radio"/> Out-of-hospital Cerebrovascular death ----- <input type="radio"/> Non-CVD non-fatal hospitalization <input type="radio"/> Non-CVD death ----- <input type="radio"/> Unknown <p>3. How did the field center find out about the event?</p> <ul style="list-style-type: none"> <input type="radio"/> Participant or spouse contacted field center <input type="radio"/> Clinic visit <input type="radio"/> Follow-up telephone/mail contact <input type="radio"/> Through other clinic-initiated contact (e.g., setting up an appointment, etc.) <input type="radio"/> Obituary/Local news <input type="radio"/> During investigation of another event <input type="radio"/> Other: <input style="width: 200px; height: 1.2em;" type="text"/> 	<p>Notes: <i>(If the Field Center learned of this event through a means other than a Follow-up phone call, record hospital or physician name and address here.)</i></p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <p>Abstractor ID: <input type="text"/> <input type="text"/> <input type="text"/> Data Entry ID: <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small></p>
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D.3 Events Eligibility

D.3.1 Introduction

After a possible event of interest to MESA is identified, an *Initial Notification of Potential Event/Death* form is completed and submitted, in order to trigger the next step in events collection at the field center and notify the Coordinating Center of the potential event. Field center staff then commence the process of events data collection, which varies according to the type of event reported (see details in the table below).

To complete the *Events Eligibility* form, the following initial information should be collected for various types of reported events:

Type of Event	Data Collected
Hospitalized cardiac/PVD event	Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician's progress note if discharge summary was not done or is unavailable
Hospitalized cerebrovascular event	Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician's progress note if discharge summary was not done or is unavailable
Other hospitalizations	Discharge ICD-9-CM or ICD-10-CM codes and discharge summary or the last physician's progress note if discharge summary was not done or is unavailable
Cardiac/Cerebrovascular death	Death certificate with cause of death ICD-10 codes and any in-patient records, ER/EMS notes, nursing home and/or hospice progress notes
Outpatient cardiac/PVD nonfatal event	Physician office notes/procedure reports, possibly PQ
Outpatient cerebrovascular nonfatal event	Physician office notes/procedure reports, possibly PQ
Ineligible death	Death certificate with cause of death ICD-10 codes and date of death records (discharge summary, ER/EMS, nursing home, hospice notes.)

After this information is obtained, the Field Center Abstractor abstracts and enters the necessary information from the medical record to complete an *Events Eligibility* form. While the EDC will determine event eligibility depending on the ICD codes entered, it is essential for the abstractor to carefully read the discharge summary, review the diagnostic and procedure information found there, and confirm the eligibility of the event based on the language in addition to the codes.

Whenever possible, the Field Center Abstractor should be the staff member who completes the *Events Eligibility* form.

ICD-10 codes will be requested from the provider of the medical records (ICD-9 codes are acceptable.) In the event the ICD codes cannot be obtained from the hospital, any alternative ICD coding must be performed by a nosologist professionally certified in the specific coding system in use (ICD-9 and ICD-10 require separate certifications). Coding by uncertified but experienced staff members is not acceptable. For a hospitalization to be coded by an outside nosologist both the discharge summary and the history and physical must be sent. The code sheet must be signed and dated by the nosologist.

No ICD codes found in any hospital record other than the discharge summary or the code sheet may be used.

Transfers: If the event under investigation involves a hospital transfer, complete a separate *Events Eligibility* form for each hospitalization using the "[Click here to enter a NEW Eligibility](#)" option in the Event EDC. Only the ICD codes from over-night hospitalizations are entered; ER, clinic, and same-day procedure visits, even if coded, are not entered.

D.3.2 Item-by-Item Instructions

Investigation ID

The Investigation ID is pre-entered in the EDC when an *Events Eligibility* form is opened. It corresponds to the Investigation ID on the *Initial Notification of Potential Event/Death* form for the same investigation.

D.3.2.1 Setting of Event/Death

(Question 1) Record the setting at which the event occurred:

- "In Hospital" is used if the patient was **admitted** to a hospital and stayed overnight, which must always indicate a change of date, even if less than 24 hours. (Emergency Room-only, dead-on-arrival, or other medical settings are recorded under separate categories.) If the participant experiences an event outside the hospital (e.g., suffers a myocardial infarction at home) but is transported to and admitted to the hospital, "Hospital" is the appropriate setting to select.
- "Physician Office/Clinic" is used for an event occurring at any outpatient medical facility. For example, this setting would be chosen for an incidence of angina diagnosed in the physician's office, or a cardiac/PAD/PVD procedure done in a clinic or same-day surgery/specialty center. (If a participant is admitted to a hospital directly from such a procedure, the event is recorded as occurring in Hospital, and abstracted from arrival at the procedure through discharge from the hospital.)
- "Emergency Room" is used if the participant is seen in the emergency room (ER), is alive at discharge, and is **not** admitted to the hospital. If the participant experiences an event outside the ER (e.g., suffers a myocardial infarction at home) but is transported to the ER, not admitted to the hospital, and discharged alive, this is the appropriate setting to select.

NOTE: If a participant is transported to the ER but is dead-on-arrival (DOA), do not choose this category. In this case, the category corresponding to the setting where the death occurred should be selected (example: “Home or Public Place”).

- "Nursing Home/Skilled Nursing Facility" is used if an event occurred at a nursing home, skilled nursing facility (SNF), transitional care facility, long-term care facility, rehab facility, or hospice residence, and the participant is **not** transported to an ER/hospital (e.g., a resident of such a facility dies in his/her sleep there).
- "Home or Public Place" is used if an event occurred at the participant’s home, another private residence, or a public location, and the participant is *not* transported to an ER/hospital.
- "Other" is used if none of the above categories is appropriate. It is expected this will be the case only in rare instances. Record the location in the box specified.

This is the category to choose in the case of a Non-Event. For example, the participant reported a hospital stay but none could be found after investigation. See Appendix D.14, Question 3. The reason for this category selection should be entered in the box specified.

NOTE: If a participant dies at *home* under hospice care, the category to select is “Home or Public Place.” If the participant dies in an *out-patient hospice facility* the correct category is “Nursing Home /Skilled Nursing Facility.” If the participant dies in hospice care while still *in the hospital*, the correct category is “In Hospital.” Always be guided by the location of death on the death certificate.

NOTE: If the event under investigation is a hospitalized event, continue to Question 2. Questions 2–10 are completed only for hospitalized events. For out-of-hospital events (including ER and DOA), skip to Question 11.

D.3.2.2 Hospitalized Events

If the event under investigation involves a hospital transfer, complete a separate *Events Eligibility* form for each hospitalization using the "[Click here to enter a NEW Eligibility](#)" option in the Event EDC. Only the ICD codes from over-night hospitalizations are entered; ER, clinic, and same-day procedure visits, even if coded, are not entered.

(Question 2) Admission Date

Enter the hospital admission date from the face sheet or discharge summary. If the participant was transferred to a second facility, record the admit date from the first hospital. The admit information for the transfer admission should be entered on a second eligibility form.

NOTE: The participant may have arrived at the hospital on one day, but not have been admitted to the hospital until the next day. Record the day of actual admission, but remember that hospital care begins in the ambulance or ER, and abstract the record accordingly. Thus lab results, ECGs, etc. from the ambulance or the ER, prior to admission, will be abstracted as part of the hospitalized event.

(Question 3) Discharge Date/Date of Death

Enter the hospital discharge date or date of death from the face sheet or discharge summary. If the participant was transferred to a second facility, record the discharge date

from the first hospital. The discharge information for the transfer admission should be entered on a second Eligibility form.

If the participant is discharged from acute care and transferred to in-hospital hospice care or in-hospital rehab during the same hospitalization, then survives to discharge, the date of admission to hospice or rehab is the date of discharge for the acute event. The hospice or rehab care is not included in abstraction unless an event of interest occurs in the hospice or rehab setting and the participant is readmitted to acute care. If uncertain, check with the Central Abstractor for determination of event abstraction procedure.

If the participant dies while in in-patient hospice or in-patient rehab care, the date of discharge is the date of death, and the entire hospitalization is abstracted as one event, with the ICD codes from acute care being the ones chosen to enter into the EDC.

(Question 4) Vital Status at Discharge

Enter the participant's vital status at the time of discharge from the face sheet or discharge summary. If the participant was transferred to a second facility, record the vital status at the time of discharge from the first hospital. The discharge information for the transfer admission should be entered on a second eligibility form.

(Question 5) Hospital MESA ID Code

Record the four-digit hospital code for the institution at which the event occurred. If the participant was transferred to a second facility, record the hospital code for the first known hospital. The hospital code for the transfer admission should be entered on a second eligibility form.

NOTE: Prior to the start-up of events data collection, each MESA field center provided the Coordinating Center with a list of area hospitals and other health care institutions where their participants are likely to be having overnight stays. The Coordinating Center assigned each of these institutions with a four-digit MESA Hospital Code. This is the value that is entered in the "Hospital Code" field. If a participant reports a stay at a hospital that has not been assigned hospital code, the MESA database allows you to enter a new institution name, which will be automatically assigned the next (sequentially) available MESA Hospital Code.

(Questions 6 and 7) Hospital Discharge Summary ICD Diagnosis Codes

NOTE: ICD codes may be found in the hospital and other records for ER, rehab, nursing home, clinic visits, and in-patient consults. MESA is only interested in the in-hospital discharge summary codes/billing codes for determining eligibility for cardiac, peripheral arterial disease and cerebrovascular events.

NOTE: Requesting the Discharge Summary Diagnostic and Procedure ICD-10 codes is standard, although some hospitals may send ICD-9 for more remote admissions, which is acceptable.

Record either the ICD-10-CM or ICD-9-CM diagnosis codes documented on the hospital discharge summary code sheet, physician's attestation, or face sheet, **exactly** as they are written and **in the order listed**, including any duplicate codes. Be sure to include the primary diagnosis as well as all secondary diagnoses, but **exclude** the admitting diagnosis.

- If only discharge diagnoses but no ICD codes are available, nosologist coding may be required. See D.3.1 for specific instructions.
- Do not use ICD codes embedded in narrative reports (e.g. HISPHY, CARNOT, etc.)
- It is acceptable to record only the diagnostic codes if the procedure codes were not sent by the hospital, although they should always be requested from both hospital and outside nosologist.
- The EDC can accept any number of ICD codes found in the record. If the participant was transferred to a second facility, record only the ICD codes from the initial hospitalization here. The ICD codes from the transfer facility should be entered on another Events Eligibility form.

Instructions for Data Entry of ICD Diagnostic Codes

1. Click on “ICD Code”.
2. When the dialog box appears, click on the ICD version desired, either 9 or 10.
3. Enter the entire code. The code description will appear in the box – verify that it matches the code description on the hospital code sheet. If it matches, click “Save.”
4. Continue entering all codes provided in the hospital record. When all have been entered, click on “Next Page” to enter the procedure codes.

(Questions 8 and 9) ICD Hospital Procedure Codes

- Record the ICD-9 or -10 procedure codes documented on the hospital discharge summary code sheet, physician’s attestation, or face sheet **exactly** as they are written and **in the order listed**, including any duplicate codes. If no procedures were listed, leave the question blank and proceed to Question 10.
- The EDC can accept any number of procedure codes

Instructions for Data Entry of ICD Procedure Codes

1. Click on “ICDval.”
2. When the dialog box appears, click on the ICD version desired, either 9 or 10.
3. For both ICD-9 and -10, enter the code exactly as written on the code sheet.
4. Verify that the code description in the dialog box matches that found on the hospital code sheet, then click “Save.”
5. When all codes have been entered, click on “Next Page” to continue to Question 10.

(Question 10) Inpatient Event Eligibility Determination

The EDC will determine eligibility based on the ICD codes entered. However, special care must be taken to review the discharge summary/last progress note narrative in case the EDC fails to capture a diagnosis/procedure code of interest (as described in Questions 10.B and 10.D) to the MESA Study. If an eligible diagnosis or procedure is discovered that was not captured by the EDC, notify the Coordinating Center.

NOTE: The hospitalization MUST contain either primary or secondary eligible codes to be eligible for review. All events with eligible cardiac/PAD/cerebrovascular diagnostic codes will be sent for abstraction to the Central Abstractors.

Q10. Are the discharge summary diagnostic and procedure codes ICD-9-CM? Yes No

If Yes, proceed to Q10.A.1. ICD-9-CM Discharge Summary Codes

If No, proceed to Q10.A.2. ICD-10-CM Discharge Summary Codes

Regarding ICD-10 codes: If an ICD-10 code is found that begins as described below but has more numbers or letters appended, consider the longer code eligible also. For example, I21 is an eligible code, so I21.19 would also be eligible.

ICD-9 ELIGIBILITY CODES (Questions 10.A.1 - 10.D.1.)

(Question 10A.1.) The event is eligible for cardiac or peripheral arterial disease (PAD/PVD) investigation if one of the ICD-9-CM diagnosis codes listed below is present in any of the hospitalizations:

402, 410–414, 425, 427.5, 427.9, 428-429, 440, 441, 443.8, 443.9, 518.4

If the three-digit body of any code is one of those listed above, regardless of whether a fourth/fifth digit appears after the decimal (*except* for 427.5, 427.9, 443.8, 443.9, or 518.4, which must appear exactly), record "Yes," the event is eligible for further investigation.

If the case is eligible based on the presence of one or more of these codes, select “yes” and continue at **Question 10C.1.**

If none of the listed codes is present, fill in the circle corresponding to “no” and continue.

(Question 10B.1.) The event is eligible for cardiac or peripheral arterial disease (PAD/PVD) investigation if one of the diagnosis codes listed below is present *AND* at least one of the listed diagnoses or procedures is indicated in the discharge summary/last progress note:

Diagnoses: 35, 250, 390–459, 745-747, 794.3, 798, 799;

Procedures: 00.66, 36–37 (with any post-decimal digits), 38–39 (cardiac/PAD/PVD-related only—not venous) 84.1, 88.5

AND the following words/phrases:

MI, angina, ischemic heart disease, CHD, unstable angina, coronary insufficiency, cardiac arrest, atherosclerotic heart disease, CHF, heart failure, cardiomyopathy, atherosclerosis, PAD/PVD (must be arterial—not venous), claudication, acute pulmonary edema, aortic aneurysm

CABG, coronary stent, elevated CK-MB, cardiac angioplasty, atherectomy, leg amputation, leg angioplasty, other leg revascularization

Procedure codes 38 (Incision, excision, and occlusion of blood vessels) and 39 (Other operations on blood vessels) include many organ systems, and we are interested only if the procedure involves an artery of the heart or leg or the abdominal aorta. Do not include vein procedures. Also, do not include 39.95 (hemodialysis).

As in Question 10A.1., unless the fourth/fifth digit of the ICD-9-CM diagnosis code is specified, presence of the code makes the case “eligible” (assuming a required key word is also present), regardless of code’s fourth/fifth digit.

If the case is eligible based on the presence of one or more of these codes *and* one or more of these words/phrases, fill in the circle corresponding to “yes” and continue with Question 10C.1

OR

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and continue with Question 10C.1

(Question 10C.1.) The event is eligible for cerebrovascular disease investigation if one of the diagnosis codes listed below is present:

430–436

If the three-digit body of any code is as indicated, regardless of whether a fourth/fifth digit appears after the decimal, record "Yes," the event is eligible for further investigation.

If the case is eligible based on the presence of one or more of these codes, fill in the circle corresponding to “yes” and continue at Question 13.

If none of the listed codes is present, fill in the circle corresponding to “no” and

Continue with

(Question 10D.1.) The event is eligible for cerebrovascular disease investigation if one of the diagnosis codes listed below is present **and** at least one of the listed diagnoses or procedures is indicated in the discharge summary.

Make sure any listed diagnosis is specified as being **new** or **acute**, as MESA is interested in ascertaining new diagnoses only.

Diagnoses: 35, 250, 390–459, 745–747, 794.3, 798, 799; Procedures: 38–39 (cerebrovascular-related only)

AND the following words/phrases:

Stroke, TIA, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

During this admission: Carotid endarterectomy, CT/MRI showing new cerebrovascular findings.

NOTE: Procedure codes 38 (Incision, excision, and occlusion of blood vessels) and 39 (Other operations on blood vessels) include many organ systems, and we are interested only if the procedure involves the arteries of the neck, head, or brain.

As in Question 10C.1., unless the fourth/fifth digit of the ICD-9-CM diagnosis code is specified, presence of the code makes the case “eligible” (assuming a required key word is also present), regardless of code’s fourth/fifth digit.

If the case is eligible based on the presence of one or more of these codes **and** one or more of these words/phrases, fill in the circle corresponding to “yes.”

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no.”

ICD-10 CODES (Questions 10.A.2 – 10.D.2.)

(Question 10.A.2.) The EDC will automatically capture eligible ICD-10-CM codes entered for a cardiac or peripheral arterial disease (PAD/PVD) investigation. Watch for the following diagnostic codes and descriptions that may indicate eligibility:

- I11 – Hypertensive heart disease
- I20 – Angina pectoris
- I21 – Acute myocardial infarction
- I24 – Other ischemic heart disease
- I25 – Other chronic ischemic heart disease
- I25.2 – Old myocardial infarction
- I42 – Cardiomyopathy
- I46 – Cardiac arrest
- I49 – Cardiac dysrhythmia
- I50 – Heart failure
- I51-52 – Other heart disease and complications
- I70 – Atherosclerosis
- I71 – Aortic aneurysm/dissection
- I73 – Peripheral vascular disease
- I79 – Other peripheral vascular disease
- J81 – Acute pulmonary edema

If the case is eligible as determined by the EDC, select “yes” and continue at **Question 10C.2.**

If none of the listed codes is present, fill in the circle corresponding to “no” and continue.

(Question 10.B.2)

The event is eligible for a cardiac or peripheral arterial disease (PAD/PVD) investigation if the EDC captures one of the eligible secondary codes *AND* at least one of the listed diagnoses or procedures is indicated in the discharge summary/last progress note.

Watch for the following secondary ICD-10-CM diagnosis or procedure codes that may indicate conditional eligibility:

- E10-13 – Diabetes mellitus
- I00-02 – Acute rheumatic fever
- I05-09 – Chronic rheumatic heart disease
- I10-15 – Hypertensive disease
- I20-25 – Ischemic heart disease

- I26-28 – Disease of pulmonary circulation
- I30-52 – Other forms of heart disease
- I70-79 – Disease of arteries, arterioles, and capillaries
- I80-89 – Diseases of veins, lymphatics, and other diseases of the circulatory system
- Q21.8 – Bulbus cordis anomalies
- Q21.9 – Anomalies of cardiac septal closure
- Q24.8 – Other congenital anomalies of heart
- Q28.9 – Other congenital anomalies of circulatory system
- R94.30 – Abnormal cardiovascular function study, unspecified
- R99 – Sudden death, cause unknown, and other ill-defined and unknown causes of morbidity and mortality

The event is also eligible if certain procedure codes are present.

AND the following words/phrases:

MI, angina, ischemic heart disease, CHD, unstable angina, coronary insufficiency, cardiac arrest, atherosclerotic heart disease, CHF, heart failure, cardiomyopathy, atherosclerosis, PAD/PVD, claudication, acute pulmonary edema, aortic aneurysm CABG, coronary stent, elevated CK-MB, cardiac angioplasty, atherectomy, leg amputation, leg angioplasty, other leg revascularization

NOTE that the eligible ICD-10 procedure codes for cardiac/PVD/PAD events are too complex to enumerate (see Appendix H, “MESA Eligible ICD-10 codes.xlsx” for specific correspondences between eligible ICD-9 and ICD-10 codes.)

If the case is eligible based on the presence of one or more of the EDC-selected codes and one or more of these words/phrases, fill in the circle corresponding to “yes” and continue with Question 10C.2.

OR

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and continue with Question 10C.2.

(Question 10C.2.)

The EDC will automatically capture eligible ICD-10-CM diagnostic codes entered for a cerebrovascular event investigation. Watch for the following codes that may indicate eligibility:

- G45 – Transient cerebral ischemia
- I60 – Subarachnoid hemorrhage (SAH)
- I61 – Intracerebral hemorrhage
- I62 – Other intracranial hemorrhage

- I63 – Cerebral infarction
- I65 – Occlusion/stenosis of pre-cerebral arteries
- I66 – Occlusion of cerebral arteries
- I67 – Acute cerebrovascular disease

If the case is eligible based on the presence of one or more of these codes, fill in the circle corresponding to “yes” and continue at Question 13.

If none of the listed codes is present, fill in the circle corresponding to “no” and

Continue with

(Question 10D.2.)

The EDC will automatically capture eligible secondary ICD-10-CM codes entered for a cerebrovascular investigation.

Watch for the following secondary ICD-10 codes that may indicate conditional eligibility:

- E10-13 – Diabetes mellitus
- I00-99 – Diseases of the circulatory system
- Q20-28 – Congenital anomalies of the circulatory system
- R94.30 – Nonspecific abnormal results of function study of cardiovascular system
- R99 – Sudden death cause unknown, unknown causes of morbidity and mortality

The event is also eligible if certain procedure codes are present.

AND the following words/phrases:

Stroke, TIA, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

During this admission: Carotid endarterectomy, CT/MRI showing new cerebrovascular findings.

Make sure any listed diagnosis is specified as being **new** or **acute**, as MESA is interested in ascertaining new diagnoses only.

NOTE that the eligible ICD-10 procedure codes for cardiac/PVD/PAD events are too complex to enumerate (see Appendix H, “MESA Eligible ICD-10 codes.xlsx” for specific correspondences between eligible ICD-9 and ICD-10 codes.)

If the case is eligible based on the presence of one or more of the EDC-selected codes *and* one or more of these words/phrases, fill in the circle corresponding to “yes” and

If none of the listed codes is present, or one of the listed codes is present, but none of the listed key words is, fill in the circle corresponding to “no” and

Continue at Question 13.

- If Question 10A or 10B is answered “yes,” the case is investigated as a **Hospitalized Cardiac or Peripheral Arterial Event**, and the relevant documents are prepared for the Central CVD Abstractor for abstraction.

- If Question 10C or 10D is answered “yes,” the case is investigated as a **Hospitalized Cerebrovascular Event**, and the relevant documents are prepared for the Central Stroke Abstractor for abstraction.
- A case could be investigated as both a **Hospitalized Cardiac or PVD Event and Hospitalized Cerebrovascular Event**.
- If Questions 10A, 10B, 10C, and 10D are all answered “no,” the case is a non-cardiovascular event. No additional investigation is required. Scan the records collected (e.g., discharge summary/last progress note) and complete a *Final Notification of Events/Death* form to close out the investigation.
- See Section D.3.3, “Action Required After This Form,” for more information on the next steps to take upon completion of this form.

D.3.2.3 Nonfatal Outpatient Events Eligibility Determination

To complete the questions in this section, “Nonfatal Outpatient Events,” you need to review the available supporting documentation for all potential events and determine if, based on this information, an event of interest to MESA did occur. If review of this documentation indicates the event is eligible for further investigation by field center surveillance staff and ultimately for review by MESA physician reviewers (or if there is not enough information contained in the records), the Field Center may attempt to obtain a *Physician Questionnaire*. See Section D.7, “Physician Questionnaire: Cardiac/PVD,” and Section D.8, “Physician Questionnaire: Stroke/TIA,” for information about completing these forms.

(Question 11) Outpatient Events

This includes all potential events that did not involve an admission to a hospital. This includes ER, DOA, Clinic Visits, Same-Day Procedures, Nursing Homes, Hospice, etc.

(Question 11A) Nonfatal outpatient event

If this is **not** a nonfatal, outpatient/out-of-hospital event, record “no” and skip to **Question 13**. If this is an event of interest, record “yes” and continue with **Question 11B**.

(Question 11B) Cardiac/PVD outpatient event

Review all available supporting documentation (records plus any available PQ’s) for references to one or more of the following diagnoses/procedures:

Diagnoses: New myocardial infarction, MI, angina, ischemic heart disease, CHD, angina pectoris, unstable angina, coronary insufficiency, cardiac arrest, CHF, heart failure, cardiomyopathy, PAD/PVD, claudication, acute pulmonary edema, aortic aneurysm

Procedures: Coronary revascularization, peripheral vascular surgery, leg angioplasty or revascularization procedure

NOTE: **These terms are intended as guidelines only.** It is possible that diagnoses/procedures not listed here could be indicative of an outpatient cardiovascular event. If you are uncertain if a case is eligible, check with the Central Abstractor or cardiac physician/reviewer. Also, there may be a cardiac procedure performed as part of a routine work-up. **NOTE:** If there is a routine procedure that is

negative, and there is no mention of a cardiovascular diagnosis, then select ‘no’.

If the event is eligible based on documentation of a listed or other relevant diagnosis/procedure, fill in the circle corresponding to “yes.”

If there is no documentation of a relevant diagnosis/procedure, fill in the circle corresponding to “no.”

Continue at Question 11C.

(Question 11C) Cerebrovascular outpatient event

Review all available supporting documentation for references to one or more of the following diagnoses/procedures:

Diagnoses: Stroke, TIA, mini-stroke, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar syndrome or infarction, cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis

Procedure: Carotid endarterectomy

NOTE: These terms are intended as guidelines only. It is possible that diagnoses/procedures not listed here could be indicative of an outpatient cerebrovascular event. If you are uncertain if a case is eligible, check with the Central Abstractor or cerebrovascular physician/reviewer.

If the event is eligible based on documentation of a listed or other relevant diagnosis/procedure, fill in the circle corresponding to “yes.”

If there is no documentation of a relevant diagnosis/procedure, fill in the circle corresponding to “no.”

Continue at Question 12.

Summary Notes:

- If Question 11B is answered “yes,” the event is investigated as a **Non-Hospitalized Cardiac or PVD Event**.
- If Question 11C is answered “yes,” the event is investigated as a **Non-Hospitalized Cerebrovascular Event**.
- It is possible a single investigation might be investigated as **both cardiac/PVD and cerebrovascular**.
- If both Question 11B and 11C are answered “no,” the event is a non-cardiovascular event. No further investigation is required, but a *Final Notice of Event/Death* form must be entered to close out the event.
- If the out-patient event leads directly to a hospitalization, then the out-patient records are included in the records for the in-hospital abstraction and physician review, and are considered part of the same event. For example, a participant has an out-patient angiogram that reveals serious coronary disease, and is transported immediately to a hospital for additional procedures. Or, a participant has an ecg as an out-patient that reveals him/her to be experiencing a myocardial infarction, and is transported emergently to a hospital.

See Section D.3.4, “Action Required After This Form,” for more information on the next steps to take upon completion of this form.

(Question 12) Date of Event

Record the date of the out-of-hospital/outpatient event from the relevant records or the *Physician Questionnaire*.

If there are multiple events, e.g. clinic visit, followed by procedure, etc., assign the event date according to the following priority: Date of death, date of clinic visit, date of procedure.

Scan the records collected and enter a *Final Notification of Events/Death* form to complete the investigation. Enter this information into the Events Data Management Software.

D.3.2.4 Deaths**(Question 13) Is Event a Death?**

Indicate if the event is a (hospitalized or out-of-hospital) death.

If “yes,” continue to **Question 14**. If “no,” skip to the end of the form.

(Questions 14-19) Death Certificate Information

In order to complete **Questions 14–19**, the death certificate must be obtained. The information documented here (including the date of death, time of death, death certificate number, whether or not an autopsy was performed, whether or not the death was confirmed by a Coroner/Medical Examiner, the cause of death, and the interval between onset and death) is found on all U.S. death certificates and should be abstracted from there and recorded verbatim.

(Question 20) ICD-10 Code for Underlying Cause of Death

ICD-10 codes might be recorded on the death certificate, or they may need to be obtained from your local Health Department. Each field center is responsible for determining how ICD-10 codes are determined within their municipality and working out a system for obtaining those codes. Under rare circumstances, MESA may need to have an ICD-10 - certified nosologist code the cause. Under no circumstances should field center staff members code the deaths themselves.

The underlying cause is an official designation of the cause most central to the death. Obtain and record this ICD-10 code, which may be listed on the death certificate as the “UL” code.

(Question 21) Other ICD-10 Codes

Record the ICD-10 codes corresponding to all the other causes associated with the death. The underlying cause should not be repeated here. Only the ICD-10 codes found on the death certificate should be entered.

(Question 22) Death Events Eligibility Determination

To complete **Question 22**, “Determine if event is eligible,” you need to review the

underlying and supporting ICD-10 codes listed in **Questions 20 and 21**, respectively, and determine if, based on this information, a death event of interest to MESA did occur. In this case, the event is eligible for further investigation by the Central Abstractor and ultimately for review by MESA physician reviewers.

(Question 22A) The event is eligible for cardiac death investigation if one of the ICD-10 codes listed below has been indicated as the underlying cause of death in **Question 20:**

I** (except I60–I69), E10–E13, J81, R07, R96, R98, R99

If the case is eligible based on one of these ICD-10 codes being indicated as the underlying cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as the underlying cause of death, fill in the circle corresponding to “no.”

Continue at **Question 22B.**

(Question 22B) The event is eligible for cardiac death investigation if one of the ICD-10 codes listed below has been indicated as an “other” cause of death in Question 21: I20–I23

If the case is eligible based on one of these ICD-10 codes being indicated as another cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as other cause of death, fill in the circle corresponding to “no.”

Continue at **Question 22C.**

(Question 22C) The event is eligible for cerebrovascular death investigation if one of the ICD-10 codes is listed as the “underlying” or “other” cause of death in Question 20: I60–I67, G45–G46

If the case is eligible based on one of these ICD-10 codes being indicated as the “underlying” or “other” cause of death, fill in the circle corresponding to “yes.”

If none of the listed codes is indicated as the “underlying” or “other” cause of death, fill in the circle corresponding to “no.”

Summary Notes:

If **Question 22A** is answered “yes,” case is investigated as a **Cardiac-Eligible Death.**

NOTE: Cardiac death has an ICD code that relates to heart disease death. The Cardiac eligible codes include a lot of other codes that do not appear to be cardiac, but upon investigation could harbor cardiac deaths.

- If **Question 22B** is answered “yes,” the case is investigated as a **Cardiac Death.**
- If **Question 22C** is answered “yes,” the case is investigated as a **Cerebrovascular Death.**
- A case could be investigated as both a **Cardiac and Cerebrovascular Death.**

- If **Questions 22A, 22B and 22C**, are all answered “no,” the case is a non-cardiovascular death.

NOTE: An in-hospital death may have eligible cardiac, PAD/PVD, or cerebrovascular codes which make the event eligible for review even if the death codes do not. Investigate the event according to the codes which would make it eligible, either hospital or death certificate.

D.3.3 Additional Form Information

Review the form for completeness and accuracy. Enter the date abstraction was completed and your Abstractor ID in the boxes at the bottom of the final page of the form.

D.3.4 Action Required After Form is Complete

D.3.4.1 Ineligible Events

An event under investigation may be ineligible for further investigation (i.e., beyond completion of the *Events Eligibility* form) for any of the following reasons:

- The event is a non-cardiovascular morbid (nonfatal) event or death
- The event is prevalent (i.e. defined as an event that occurred prior to the participant’s MESA enrollment date)
- There is insufficient information
- There was no event (i.e. nothing happened)

In each of these instances, no **additional** documentation (i.e. the information displayed in **Table D.3.2**) need be obtained. However, to close the investigation you must complete a *Final Notification of Events/Death* form. (See Section D.3.14, “Final Notice of Event/Death.”)

The Discharge Summary (or Last Physician’s Progress Note) must be de-identified and scanned into the EDC. See the Privacy Act De-identification guidelines list in Appendix D.5.3.

D.3.4.2 Eligible Events

If it is determined that the event under current investigation is eligible for further investigation, the following specific additional documentation required. *Table D.3.2* shows the documentation that needs to be obtained for each event type. (See also Section 3, page 4 Flow Chart).

Table D.3.2
Documentation Required to Complete Events Investigation

Type of Eligible Event	Additional Documentation Required
Hospitalized Cardiac/PVD non-fatal	<i>Hospital Abstraction: Cardiac/PAD/PVD medical records***</i> <i>Cardiac Interview</i> (if needed)
Hospitalized Cardiac/PVD or Cardiac-Eligible death**	<i>Hospital Abstraction: Cardiac/PAD/PVD medical records***</i> <i>Informant Interview</i> (if needed), <i>Death Certificate</i>

Hospitalized Cerebrovascular non-fatal	<i>Hospital Abstraction: Stroke/TIA medical records*** Stroke/TIA Interview (if needed)</i>
Hospitalized Cerebrovascular death**	<i>Hospital Abstraction: Stroke/TIA medical records*** Stroke/TIA Narrative (if needed), Death Certificate</i>
Out-of-hospital Cardiac/PVD non-fatal	<i>Clinic/Procedure Notes, Physician Questionnaire: Cardiac/PVD* (if needed) Cardiac Interview (if needed)</i>
Out-of-hospital Cardiac or Cardiac-Eligible death**	<i>EMS/ER/NH/Hospice Notes, Physician Questionnaire: Cardiovascular Death (if needed) Informant Interview, Death Certificate</i>
Out-of-hospital Cerebrovascular non-fatal	<i>Clinic/Procedure Notes, Physician Questionnaire: Stroke/TIA* (if needed) Stroke/TIA Interview or Stroke Narrative</i>
Out-of-hospital Cerebrovascular death**	<i>EMS/ER/NH/Hospice Notes, Physician Questionnaire: Stroke/TIA* (if needed) Stroke/TIA Narrative, Death Certificate</i>

*In some cases, the *Physician Questionnaire* will already have been obtained for the purpose of completing the *Events Eligibility* form.

The Field Center will request records first, and will only request a *Physician Questionnaire: Cardiac/PVD* if the information in the records is not sufficient.

In most cases, a *Physician Questionnaire* will not be needed for hospitalized events. However, if the field center determines the hospital record is lacking vital information that a physician knowledgeable about the participant's case/death might be able to provide, a *Physician Questionnaire* may be sent.

**If the case is a death and an autopsy or coroner investigation occurred, obtain the appropriate reports.

*** If a hospital transfer is involved, complete a hospital abstraction form for *each* hospitalization. Despite using separate abstraction forms for each hospital when a transfer is involved, the same investigation ID should be used on the transfer hospital abstraction forms as they are considered part of the same events investigation.

If the event being investigated is a death and a *Follow-Up* form was not just recently completed, surveillance staff should attempt to complete one by proxy as soon as possible or appropriate.

D.3.4.3 Eligible Out-of-Hospital Events: Requested Records

Eligible out-of-hospital events may be found in clinic, nursing home and other care facility, hospice, and same-day procedure records. Out-of-hospital events of interest include *new* diagnoses of:

- MI
- Angina
- CHF
- PAD/PVD
- Stroke
- TIA
- Deaths due to cardiovascular/peripheral arterial diseases.
- Deaths due to cerebrovascular diseases.

Procedures of interest include:

- Revascularization by angioplasty and bypass grafts of coronary and lower extremity arteries.
- Revascularization by endarterectomy/angioplasty of pre-cerebral/cerebral arteries

(See Overview Section 1, Page 1.) Requests for these types of records should include a date range more inclusive than that reported by the participant.

D.3.4.4 Eligible Hospitalized Events: Requested Records

When an eligible hospitalized cardiac/PAD/PVD/cerebrovascular event is identified, the following records *only* should be requested based on the type of event:

CARDIOVASCULAR and PERIPHERAL VASCULAR DOCUMENTS:

- **Discharge Summary ICD Diagnostic and Procedure Codes**
- **Physician's Discharge Summary** (or last Physician's Progress Note if necessary)
- **History and Physical** (including out-patient pre-operative if available)
- **Emergency Physician's Notes, and EMS Report with 12-Lead ECGs** tracings
- **Physician's Consults**
- **Physician's Progress Notes**
- **Laboratory Report** with Patient Values, Normal Ranges, and Collection Times
- **Imaging Reports** including:
 - Chest X-rays
 - CT/MRI/MRA
 - Ultrasounds (including Doppler)
 - Echocardiograms
- **Cardiac and Vascular Procedures** including:
 - 12-Lead ECG Tracing Images
 - CABG (Coronary Artery Bypass Graft) Report with Hemodynamic/Procedure Log
 - Cardiac/Arterial Vascular Surgical Report Summary with Hemodynamic/Procedure Log
 - Angiogram/Angioplasty/PTCA/PCI Reports with Hemodynamic/Procedure Log
 - Cardiac Stress Tests Narrative Summary (such as Myocardial Perfusion, Bruce Protocol, Nuclear, Cardiolite) No stress ECGs or worksheets are required.
 - ABI (Ankle-Brachial-Arm Index) Report
- **Autopsy/Coroner Report**

CEREBROVASCULAR DOCUMENTS:

- **Discharge Summary ICD Diagnostic and Procedure Codes**
- **Physician's Discharge Summary** (or last Physician's Progress Note if necessary)
- **History and Physical** (including out-patient pre-operative if available)
- **Emergency Physician's Notes with EMS Report and 12-Lead ECGs** tracings
- **Physician's Consults**
- **PMR/PT/OT/Rehab/Speech Initial Assessments**
- **Physician's Progress Notes**
- **Imaging Reports** including:
 - CT/MRI/MRA/Angiograms (head and neck)
 - Ultrasounds (including Doppler)
 - Echocardiograms
 - EEG
- **12-Lead ECG Tracing Images**

- **Lumbar Puncture Report**
- **Head and Neck Surgical Reports**
- **Autopsy/Coroner Report**

D.3.4.5 Central Abstraction

Upon the receipt of the requested medical records, eligible events will be prepared for the Central Abstractor as follows:

- Medical records received from the provider will be carefully reviewed for completeness and appropriateness. Inappropriate records (not found on the request guideline list) should be purged.
- Requested records found to be noted in the record, but missing, will be **re-**requested from the record provider. It is helpful to review the Discharge Procedure codes, as well as the Discharge Summary, ER Notes, H and P, etc., to determine which procedures should be found in the record, such as ECGs, CXRs, Echos, etc.
- If the provided record is complete and appropriate, the documents are scanned into the EDC in the order noted on the FINAL form if found as individual reports, **or** in the hospital page order if the reports are run-together, with the exception that the ICD Code sheet should be scanned first following the Coversheet.
- If the event involves a transfer of overnight care, as per item D.3.1, prepare a coversheet for each set of individual hospital records, and scan together in order of hospitalization.
- **DO NOT SCAN THE RECORD UNTIL IT IS COMPLETE.** If there are records that are unobtainable even though mentioned in the record, write a “Note for Abstractor” on the Coversheet.

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--	--

This form determines eligibility of event for cardiac, cerebrovascular, or mortality review. Information from the hospital record (hospitalized event) or death certificate (if fatal event) is needed.

1. Setting of Event/Death:

<input type="radio"/> In-Hospital	<input type="radio"/> Nursing Home/Skilled Nursing Facility
<input type="radio"/> Physician Office/Clinic	<input type="radio"/> Home or Public Place
<input type="radio"/> Emergency Room	<input type="radio"/> Other (specify):
<input style="width: 150px; height: 20px;" type="text"/>	

(If applicable) A. Hospital/Facility Name (or Hospital Code): _____

Address: _____

(If applicable) B. Transfer Hospital (or Hospital Code): _____

Address: _____

(If applicable) C. Physician/Outpatient Facility: _____

Address: _____

(If applicable) D. Informant/Proxy Name: _____ Relationship: _____

Address: _____
 _____ Telephone: _____

In-hospital events, continue.

Out of hospital events (including ER and DOA) skip to Question 11.

Hospitalized Events

NOTE: If participant was transferred from one hospital to another, record first known hospitalization's information here, and information for each additional hospitalization on an Events Eligibility Addendum.

2. Admission date

		/			/				
Month	Day		Year						

3. Discharge date/Date of death

		/			/				
Month	Day		Year						

NOTE: If admission date is earlier than participant's MESA enrollment date, skip to end of questionnaire.

4. Vital Status at Discharge: Alive Dead

5. Hospital Code:

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6. ICD-9-CM Discharge Diagnosis Codes:

Record all ICD-9-CM diagnosis codes in the order they are listed on the hospital record face sheet or discharge summary or index. If there are more than 15 codes listed, record additional codes on an *Events Eligibility Addendum*.

1	<input type="text"/>	-	<input type="text"/>	6	<input type="text"/>	-	<input type="text"/>	11	<input type="text"/>	-	<input type="text"/>
2	<input type="text"/>	-	<input type="text"/>	7	<input type="text"/>	-	<input type="text"/>	12	<input type="text"/>	-	<input type="text"/>
3	<input type="text"/>	-	<input type="text"/>	8	<input type="text"/>	-	<input type="text"/>	13	<input type="text"/>	-	<input type="text"/>
4	<input type="text"/>	-	<input type="text"/>	9	<input type="text"/>	-	<input type="text"/>	14	<input type="text"/>	-	<input type="text"/>
5	<input type="text"/>	-	<input type="text"/>	10	<input type="text"/>	-	<input type="text"/>	15	<input type="text"/>	-	<input type="text"/>

7. Discharge Diagnosis:

Record all discharge diagnoses (TEXT) in the order they are listed on the hospital record face sheet, discharge summary or index, or other source. If there are more than 15 diagnoses listed, record additional diagnoses on an *Events Eligibility Addendum*.

1	<input type="text"/>
2	<input type="text"/>
3	<input type="text"/>
4	<input type="text"/>
5	<input type="text"/>
6	<input type="text"/>
7	<input type="text"/>
8	<input type="text"/>
9	<input type="text"/>
10	<input type="text"/>
11	<input type="text"/>
12	<input type="text"/>
13	<input type="text"/>
14	<input type="text"/>
15	<input type="text"/>

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8. ICD-9-CM Procedure Codes:

Record all ICD-9-CM procedure codes in the order they are listed on the hospital record face sheet or discharge index. If there are more codes than space available, record additional codes on an Events Eligibility Addendum.

1	<input type="text"/>	-	<input type="text"/>	6	<input type="text"/>	-	<input type="text"/>	11	<input type="text"/>	-	<input type="text"/>
2	<input type="text"/>	-	<input type="text"/>	7	<input type="text"/>	-	<input type="text"/>	12	<input type="text"/>	-	<input type="text"/>
3	<input type="text"/>	-	<input type="text"/>	8	<input type="text"/>	-	<input type="text"/>	13	<input type="text"/>	-	<input type="text"/>
4	<input type="text"/>	-	<input type="text"/>	9	<input type="text"/>	-	<input type="text"/>	14	<input type="text"/>	-	<input type="text"/>
5	<input type="text"/>	-	<input type="text"/>	10	<input type="text"/>	-	<input type="text"/>	15	<input type="text"/>	-	<input type="text"/>

9. Procedures:

Record all procedures (TEXT) in the order they are listed on the hospital record face sheet or discharge index. If there are more than 15 procedures listed, record additional procedures on an Events Eligibility Addendum.

1	<input type="text"/>
2	<input type="text"/>
3	<input type="text"/>
4	<input type="text"/>
5	<input type="text"/>
6	<input type="text"/>
7	<input type="text"/>
8	<input type="text"/>
9	<input type="text"/>
10	<input type="text"/>
11	<input type="text"/>
12	<input type="text"/>
13	<input type="text"/>
14	<input type="text"/>
15	<input type="text"/>

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10. Determine if event is eligible:

A. Are any of ICD-9 codes designated as MESA cardiac or PVD endpoints present?

Diagnosis codes: 402, 410-414, 425, 427.5, 427.9, 428-429, 440, 441, 443.8, 443.9, 518.4

Yes No

If "Yes," skip to Question 10C.

B. Are any of the following ICD-9 codes present?

Diagnoses: 35, 250, 390-459, 745-747, 794.3, 798, 799; Procedures: 00.66, 36-37 (with any post-decimal digits, 38-39 (cardiac/PAD/PVD-related only), 84.1, 88.5

and

Are any of the following words/phrases mentioned or suggested in the discharge summary?

Acute:

MI, angina, ischemic heart disease, CHD, unstable angina, coronary insufficiency, cardiac arrest, atherosclerotic heart disease, CHF, heart failure, cardiomyopathy, atherosclerosis, PVD, claudication, acute pulmonary edema, aortic aneurysm.

During this admission:

CCU Care, cardiac catheterization, CABG, coronary stent, elevated CK-MB, coronary angiography, cardiac angioplasty, atherectomy, leg amputation, leg angioplasty or other leg revascularization.

Yes No

C. Are any ICD-9 codes designated as MESA cerebrovascular endpoints present?

Diagnosis codes: 430-436

Yes No

If "Yes," skip to Question 13.

D. Are any of the following ICD-9 codes present?

Diagnoses: 35, 250, 390-459, 745-747, 794.3, 798, 799; Procedure codes: 38-39 (cerebrovascular-related only)

and

Are the following words/phrases mentioned or suggested in the discharge summary?

Acute:

Stroke, TIA, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar (syndrome or infarction), cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

During this admission:

Carotid endarterectomy, CT/MRI scan showing new cerebrovascular findings

Yes No

If "Yes" to A or B: Hospitalized Cardiac/PVD Event

If "Yes" to C or D: Hospitalized Cerebrovascular Event

If "No" to A, B, C and D: Non-Cardiovascular Event

Skip to Question 13.

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8000028 02

Nonfatal Outpatient Events

11A. Is this a nonfatal outpatient event?

- Yes No

If "No," skip to Question 13.

11B. Is this a cardiac/PVD outpatient event?

– i.e., MI, angina, CHF, PVD, or intermittent claudication, but no hospitalization involved:

As indicated by a mention of one or more of the following terms or procedures in the participant's record or on a Physician's Questionnaire.

Diagnoses:

New myocardial infarction, MI, angina, ischemic heart disease, CHD, angina pectoris, unstable angina, coronary insufficiency, cardiac arrest, CHF, heart failure, cardiomyopathy, PVD, claudication, acute pulmonary edema, aortic aneurysm.

Procedures: *(If there was no evidence of an event besides a negative procedure, choose "No" below)*

Exercise treadmill test (ETT), coronary angiography, cardiac catheterization, peripheral vascular surgery, leg angioplasty or revascularization procedure.

- Yes No

If "Yes," Non-hospitalized Cardiac/PVD Event

11C. Is this an outpatient cerebrovascular event?

– i.e., Stroke or TIA, but no hospitalization involved:

As indicated by a mention of one or more of the following terms or procedures in the participant's record or on a Physician's Questionnaire

Acute:

Stroke, TIA, mini-stroke, cerebral infarction, cerebrovascular disease, cerebral embolus, lacunar (syndrome or infarction), cerebral hemorrhage, subarachnoid hemorrhage, cerebral thrombosis.

Procedures:

Carotid endarterectomy

- Yes No

If "Yes," Non-hospitalized Cerebrovascular Event

12. Date of event:

		/			/				
Month			Day			Year			

NOTE: If date is earlier than participant's MESA enrollment date, event is prevalent and not eligible for further investigation or classification.

Skip to end of questionnaire.

Deaths

13. Is this event a death?

- Yes No

If "No," skip to end of questionnaire.

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Death Certificate Information

14A. Date of Death:

Month / Day / Year

14B. Time of Death:

Hour - Minute M

15. Death Certificate Number:

11 digit input field

16. Was an autopsy performed?

- Yes, No, Unknown

17. Was the death confirmed by a Coroner/Medical Examiner?

- Yes, No, Unknown

18. Record all text fields as listed on death certificate for cause of death:

A. Immediate cause:

Text input field

B. Due to or as a consequence of:

Text input field

C. Due to or as a consequence of:

Text input field

D. Due to or as a consequence of:

Text input field

E. Other significant conditions:

Multiple text input fields

19. Interval between onset and death for immediate cause of death:

- 5 minutes or less, 1 week or less, Unknown, 1 hour or less, 1 month or less, 1 day or less, More than 1 month

20. Record ICD-10 code for UNDERLYING cause of death:

ICD-10 code input field

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21. Record ICD-10 code for OTHER causes of death:

1	<input type="text"/>	-	<input type="text"/>	6	<input type="text"/>	-	<input type="text"/>
2	<input type="text"/>	-	<input type="text"/>	7	<input type="text"/>	-	<input type="text"/>
3	<input type="text"/>	-	<input type="text"/>	8	<input type="text"/>	-	<input type="text"/>
4	<input type="text"/>	-	<input type="text"/>	9	<input type="text"/>	-	<input type="text"/>
5	<input type="text"/>	-	<input type="text"/>	10	<input type="text"/>	-	<input type="text"/>

22. Determine if event is eligible:

A. Are any UNDERLYING cause of death codes present which are designated MESA cardiac-eligible death codes? (I** except I60 - I69, E10-E14, J81, R07, R96, R98-99)

Yes No

If "Yes," Cardiac-eligible death

B. Are ANY LISTED codes present which are designated MESA cardiac death codes? (I20-I23)

Yes No

If "Yes," Cardiac death

C. Are ANY LISTED codes present which are designated MESA cerebrovascular death codes? (I60-I67, G45-G46)

Yes No

If "Yes," Cerebrovascular death

If "No" to A, B and C, death is non-cardiovascular and not eligible for investigation.

Abstractor ID:	<input type="text"/>	Date:	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	Data Entry ID:	<input type="text"/>
			Month		Day		Year		

D.5 Hospital Abstraction: Cardiac/Peripheral Arterial Disease

D.5.1 Introduction

The MESA *Hospital Abstraction: Cardiac/Peripheral Arterial Disease* form captures the specific reasons for cardiac or peripheral arterial disease (PAD - also known as peripheral vascular disease or PVD) hospitalizations and the use of various procedures, drugs and treatments.

The purpose of these instructions is to make sure all MESA medical record abstractors are collecting information in the same way. The more specific information you have about each item on the form--and the more you know about where to find the “answers” and how to record them--the more uniform and useful the MESA data will be. Although you may have ample experience in medical record abstraction and medical terminology, these instructions provide many definitions that will help ensure everyone is using the same “tools” to describe an event.

For each item on the form, the instructions will tell you where in the medical record, and in what order, to look for the required information. When consulting several sections of the medical record, you may find that they provide different or even contradictory information. It is, therefore, very important to consult all sections of the medical record listed for a given item on the form. The parts of the medical record you will use to complete the form are listed and defined in section D.5.2, below.

Ideally, the information you need to complete an item on the form will be found in one or more of the medical record sections listed. However, you may have to search other parts of the medical record for an answer. If you are still unable to get the information you need, select “unknown”, where provided. Mark “no” for items in which “unknown” is not an available option.

If you are unable to complete an item on the form because of missing or contradictory information in the medical record, consult your physician reviewer for advice.

ER Visits and Transfers: Separate admissions (e.g., b/c of transfers) are abstracted as separate Cardiac Abstraction form entries, even though both abstractions can be entered as a single MESA event at the judgment of the appropriate Events staff. Since an ER visit alone is not an actual admission, there is no need to do two separate abstractions in a situation where a participant has an ER visit at one hospital, without being admitted, but is then transferred to and admitted at a different hospital. In such a situation, the records of the ER visit should be abstracted as part of the admission at the second hospitalization.

Multiple Care Locations: In general, there are three different options to make sure everything is abstracted when care is received in two locations:

- (a) Two entirely separate investigations, each with its own abstraction form. (Use this method for two events separated by 24 hours, though the Events staff has the option of collapsing events into a single investigation if conditions are directly related and admissions are within 30-day span.)

- (b) One investigation with two or more abstraction forms. (Use for a single event involving two admissions linked by a transfer.)
- (c) One investigation with one abstraction form, even though care was received in two locations. (Use for one event that involves multiple locations but only one actual admission, such as ER visit at one hospital followed by admission to a different hospital.)

D.5.1.1 Sections and Content of the Medical Record Used for Abstraction

You need to consult all of the following sections of the medical record, as appropriate, in order to gather adequate information to complete the form. If the entire chart is available, these sections should be reviewed first. It is a good idea to read through these sections (and others, if possible), before you begin recording information on the form, to familiarize yourself with the course of events that occurred from admission to discharge.

Although the instructions for each individual form item list the **most likely** sources for finding the information sought by that particular question, you can use documentation from anywhere in the chart if these sources do not provide the information you need.

- The **Face Sheet/Admission Sheet** provides participant demographic information and admission and discharge information (dates, treating physician(s), discharge diagnosis(es), and ICD-9-/ ICD-10 CM codes). ICD codes can also be found in Physician's Attestation and Discharge Summary Codes documents.
- The **Emergency Room (ER) Record** and **Emergency Medical Technician (EMT) or Ambulance Report** describe symptoms, dates and times of symptoms, vital signs, initial treatment during transportation to the hospital, ER treatment and response, and disposition. This section is most useful for participants who are dead on arrival (DOA) or who die in the ER before they are admitted to the hospital. This source may also provide the first 12-lead ECG tracing.
- The **Admission History and Physical Exam (H&P)** is a detailed description of symptoms leading to admission, condition of participant on admission, current medication use, and past medical history; it also includes a physical exam, results of tests and procedures done in the ER or upon admission, provisional diagnosis(es), and treatment plan. Records of elective hospitalizations may include a pre-procedure history and physical done at an earlier date outside the hospital.
- The **Discharge Summary** summarizes the entire hospitalization, including admission and discharge dates, treating physician(s), admission H&P, hospital course, treatments and procedures, and discharge disposition. (If the hospitalization is prolonged or if residents or attending physicians rotate while a participant is admitted, there may also be an **interim summary**.) In the event the admission was too short to produce a discharge summary, the last physician's progress note may be used in its place.

- The **Death Summary** may replace or augment the discharge summary, in the event of a participant's death. It may contain, or be attached to, autopsy information or an autopsy report.
- The **Consults** section contains typed or handwritten notes made by specialists (e.g., infectious disease, rehabilitation medicine) consulted while the participant was hospitalized. Consults may also be found in the physician progress notes section.
- **Laboratory Results.** This section will include cardiac enzymes, creatinine, BNP, and pro-BNP, levels.
- **ECG Reports (12-lead tracing images)**
- The **Radiology/Imaging** section contains reports of chest x-rays, MRIs, CTs, and other imaging procedures.
- The **Results/Procedures** section contains reports of Bruce treadmill and pharmacological stress tests, myocardial perfusion tests, echocardiograms, MUGA/SPECT scans, angiograms, angioplasties
- The **Operative/Surgical** section contains operative and pathology reports and may contain autopsy reports.
- **Outpatient Records**, if available, may be used if they can provide more information about the event in question. For instance, they may help to confirm the date of onset of a specific condition, or provide a pre-procedure history and physical report.

If there are conflicting sources of information, take information in this priority: resident/fellow/certified nurse practitioner, cardiologist, attending physician; ER physician, EMT/PA, nurse.

Please avoid using the following secondary sources to gather information, unless primary sources are incomplete or unavailable.

- Physician orders
- Nurse's or multidisciplinary notes
- Vital sign logs
- Physician progress notes, unless there is **no other way** to reconstruct the event.

D.5.1.2 Definitions of Terms

Some questions have response categories of “yes,” “no,” and “unknown.” If nothing is written down that definitely answers the question, generally record “unknown.” The following table lists terms you may encounter in the medical record that, when in doubt, should be recorded on the form as “yes,” “no,” or “unknown.” (Obviously, the entire content of the event should be considered as well.) If a response category does not include “unknown” (i.e., includes “yes” and “no” only), record unknowns as “no.”

Yes	No	Unknown
Present	Not present	Rule out (R/O)
Likely	Low probability	Suggestive
Apparent	Unlikely	Equivocal
Consistent with		Suspicious
Compatible with		Questionable
Definite		Possible
Probable		Uncertain
Highly suspicious		Reportedly
Presumed		Perhaps
Borderline		Could be
Thought to be		Might be
Minimal		May be
Representing		May represent
Seems to be		

In the case of “and/or” take the first condition noted as a “yes.” For example, “pneumonia/CHF”, take pneumonia as the “yes.”

The table below contains time-of-day and length-of-time terms that you may encounter in the medical record and how they should be interpreted and/or recorded on the form. (Use 12-hour clock, not 24-hour clock).

If the medical record says this...	You record this...
[If no time is listed]	1200
Middle of the night	0100
Early morning	0600
Morning	0800
Late morning	1000
Mid-day or noon	1200
Early afternoon	1400
Afternoon or mid-afternoon	1500
Late afternoon	1600
Early evening	1900
Late evening	2300
Midnight	2400
Several days	≥3 days
A few days	≥ 2 but < 4 days
Several hours	≥ 4 but < 6 hours
A few hours	≥ 2 but < 4 hours

Other specific definitions are included in the instructions for each form item.

D.5.1.3 Methods

See specific instructions in Section 3.3.

D.5.1.4 Central Abstraction

Eligible events will be prepared for the Central Abstractor as follows:

- The Eligibility Form will be completed and entered into the MESA EDC.
- Medical records received from the provider will be briefly reviewed for completeness and appropriateness. Inappropriate records (not found on the request guideline list) will be purged.
- Records found to be noted, but missing, will be requested from the record provider. It is helpful to review the Discharge Procedure codes, as well as the Discharge Summary, ER Notes, H and P, etc., to determine which procedures should be found in the record, such as ECGs, CXRs, Echos, etc.
- If the provided record is complete and appropriate, the documents are scanned into the EDC in the order noted on the *Final Notice* form, with the exception that the ICD Code sheet should be scanned first.
- DO NOT SCAN THE RECORD UNTIL IT IS COMPLETE. If there are records that are unobtainable even though mentioned in the record, enter an Investigative Note into the Event record and make a note to the Central Abstractor on the coversheet.
- The Central Abstractor will abstract the event and enter the data into the *Cardiac/PVD Hospital Abstraction* form in the EDC. Documents not needed for Physician Review will be deleted.
- Upon completion of the abstraction the Field Center will be notified and the documents selected for review will be de-identified according to the Privacy Act guidelines using Adobe Acrobat Pro program tools.
- Specific details related to de-identification can be found in Section 3.3.

D.5.2 Item-by-Item Instructions

D.5.2.1 Admission Information

(Question 1) Admission Date

- Sources: Face sheet, discharge or death summary, H&P.
- Be aware the admission date may be different (e.g., the following day) from the ER date. Remember, however, start of care begins with the EMS in the field or in the ambulance.

(Question 2) Discharge date or date of death

- Sources: Face sheet, discharge or death summary; autopsy report.
- If the participant was transferred to a care facility, rehabilitation center, or hospice facility, the discharge date is the date of transfer.

- If the death certificate indicates death-in-hospital for a participant who was transferred from the hospital to in-patient hospice and died, abstract from the date of admission of acute care through the date of death in hospice.

D.5.2.2 Hospital Information

(Question 3) What was the participant's vital status at discharge?

- Sources: Face sheet, ER report (if participant died in ER), discharge or death summary.
- If response is “Alive,” skip to Question 5.

(Question 4) Was there an episode of chest, left arm, or jaw pain during the 72 hours prior to death?

- Sources: EMT/ambulance report, ER report, discharge or death summary, H&P.
- “Chest pain” synonyms are angina; chest tightness, discomfort or heaviness; ischemic pain.
- Timing of death is when respiration and heartbeat cease, not when CPR ends or participant is pronounced dead.
- This may be difficult to determine, if an exact time of pain onset is not recorded in the medical record. If time is not totally clear, follow standard procedures for recording “unknown” or estimated data. (See Appendix D.5.1.2, “Definition of Terms,” for details.)
- If chart says “no symptoms,” or if there was a sudden collapse, record “no,” not “unknown.”
 - ❖ Refer to point 1 in Appendix D.5.4, “Cardiovascular Events: Synonyms and Descriptions,” for more information about these terms.

D.5.2.3 Acute Cardiovascular Events

(Question 5) Was there an acute episode of pain, discomfort, or tightness in the chest, left arm, or jaw within 72 hours of the hospitalization or within 72 hours of the in-hospital event?

- Sources: EMT/ambulance report, ER report, discharge summary or death, H&P, consult; physician or other notes.
- Chest pain may be recorded as "CP" in the medical record. “Chest pain” synonyms are angina, chest tightness, discomfort or heaviness, ischemic pain.
- Tooth pain, back pain, and/or jaw pain qualify as “Yes”, if the physician thought the pain was ischemic. SOB, if identified by a physician as an anginal equivalent, qualifies as a “Yes,” however, SOB, not otherwise specified is recorded as “No.”
- An in-hospital event might include infarction or re-infarction.

- If chart says “no symptoms” or there was a sudden collapse, record “no,” not “unknown.”
- For the purposes of this question, EMS and ER visits leading to hospitalization should be considered as in-hospital (i.e., if the participant experienced pain, etc., within 72 hours of an ER visit, record “yes” here).
- **If you answer “no” or “unknown” to this question, skip to question 8.**

(Question 6) Did the onset of the acute episode occur prior to admission?

- Sources: EMT/ambulance report, ER report, discharge or death summary, H&P, consult; physician or other notes.

(Question 7) Was the discomfort or pain diagnosed as having a non-cardiac origin?

- Sources: Discharge or death summary, consult; physician notes.
- Possible non-cardiac sources include musculoskeletal pain, pleuritic (lung) pain, pericarditis, etc.
- Answer “yes” only if there is a definite, final conclusion that the pain was non-cardiac.
- Arrhythmia (e.g. Afib,) heart failure, and defective heart valves are findings with cardiac origins.

(Question 8) Did a physician indicate any of these as being present *during the hospitalization*?

- Sources: Discharge or death summary, consult, H&P; physician notes.
- Do not use ICD codes as reasons to answer “yes”. Diagnoses must be listed in the record narrative.
- No indication either way is recoded as “no.”
- Mark all that apply to this hospitalization only. Exclude references to old episodes or chronic conditions, except for the last item. Include only if acute, exacerbated, or newly diagnosed, during the hospitalization.
- Angina diagnosis: Ischemia alone does not qualify as “yes”
- Myocardial infarction: ECG description alone does not qualify as “yes”
- Congestive heart failure or pulmonary edema: Both left and right heart failure qualify. CHF is a code description that follows a patient. Make sure symptomatic CHF was “present” according to chest X-ray or MD progress notes. If CHF is listed as an indicator on the chest X-ray, etc., use the results narrative, not the indicator.
- Lower extremity claudication: “Exertional leg pain relieved by rest” qualifies as “yes”

- Atherosclerosis of arteries of the lower extremities: PAD (peripheral arterial disease) and PVD (peripheral vascular disease) diagnoses may be found. Make sure that PVD refers to arterial disease to qualify as “yes”
 - Arterial embolism or thrombosis of the lower extremities: Venous (DVT) does not qualify as a “yes”
 - Abdominal aortic aneurysm (AAA): Aneurysm of upper aorta does not qualify as a “yes”
 - Shock or cardiogenic shock: Septic shock is “no”
 - Ventricular fibrillation, cardiac arrest or asystole: Asystole is “no” for any procedure-induced heart stoppage, i.e. CABG. To be considered asystole, the pause must be 60 seconds or longer. All deaths are “yes.”
 - Deep venous thrombosis or pulmonary embolism: An arterial thrombosis or embolus is recorded elsewhere
 - ST elevation > 1 mm with pain that is not present on ECG without pain: ST elevation and chest pain need not be mentioned in the same sentence to answer “yes”, but these should generally be present together, at the same time. Do not match a chest pain day apart from the ST finding. An ECG interpretation showing ST elevation is sufficient if during chest pain
 - History of chest, left arm or jaw (ischemic) pain at any time in the past: For this item **only**, any reference to a history of physician-diagnosed angina or ischemic pain should be recorded as “yes.” History does not include the present illness and, in general, refers to a period of at least 72 hours prior to this admission. Evidence of outpatient nitroglycerin used for historical pain can be taken as evidence that the pain was ischemic. A past history of documented chest pain with subsequent coronary artery intervention qualifies as “yes”.
- ❖ Refer to the entries of Appendix D.5.4, “Cardiovascular Events: Synonyms and Descriptions,” for the list of findings and their synonyms/descriptions.

D.5.2.4 Electrocardiograms

(Question 9) Were 12-lead electrocardiograms (ECGs or EKGs) recorded and are they codable?

- Sources: ECG report(s). Rhythm strips or single-lead monitor strips are *not* acceptable for coding.
- To be “codable,” the ECG must have +/- 0.5mm calibration or +/- 1.0mm calibration, 12 leads, and date/time.
- If you have an ECG without calibration boxes and are unable to obtain the tracing with boxes, you may scan it and include the date in Question 9. A note should also be made in the Investigation Notes to indicate this.
- The same is also true for narrative reports of ECGs. If you cannot obtain the tracing, include the date in Q 9 and include an Investigative Note.

- If an undated narrative report is found, do not enter it, but you can include it in an Investigative Note
- 12-lead ECGs are the preferred standard and every effort must be made to obtain them.
- If you cannot obtain either a narrative report or the image, then leave the question blank and include an Investigative Note.
- Do not use ECGs taken during stress tests.
- Do not use pre-Naughton GXT-ECG.

If a procedure or test was performed as part of the person's participation in a medical study, the results of that procedure/test should still be abstracted for MESA. For example, if a participant is admitted to the hospital for CHF and while there is asked to join a medical study and undergo a test for that study, then the results should be abstracted, even if the reason for the test was unrelated to the original CHF admission.

- **If you answer “no” or “unknown” to this question, skip to question 10.**
- **If you answer “yes” to this question, follow the instructions below and on the form.**
- If no name or date appears on the ECG, then do not use it.
- If there are ECGs done within 5 minutes of each other, use only the *later* reading. If they are more than 5 minutes apart, take them both.
- Good copies of ECGs will be needed. Highlight the dates and record on each the order in which it was done (e.g., first, #2, #3, last).
- Record dates of ECGs.
 - -- If four or fewer tracings were made, include all tracings.
 - -- If more than four tracings were made, include:
 1. First two codable tracings after admission or from ER if ER visit resulted in admission (ECG#1-First and ECG#2).
 2. Last codable tracing prior to discharge or death (discharge tracing) (ECG-Last)
 3. Last codable tracing on day 3 (or the first tracing thereafter) following an admission or in-hospital event (ECG#3)
- -- If the participant is readmitted (transferred) to the ICU/CCU because of a new episode of chest pain, the first codable tracing may be sent.

- Even though only a maximum of four ECGs can be listed on the abstraction form, additional significant ECGs can be scanned.

The following table shows examples of how to find ECGs to include in the MESA packet:

<u>Example A</u>	<u>Day 1</u>	<u>Day 2</u>	<u>Day 3</u>	<u>Day 4</u>	<u>Day 8 (discharged)</u>
Eight ECGs	1 2	3 4	5 6	7	8
taken	1st 2nd		3rd		last

<u>Example B</u>	<u>Day 1</u>	<u>Day 2</u>	<u>Day 3 (discharged)</u>
Six ECGs	1 2	3 4	5 6
taken	1st 2nd		3rd last

<u>Example C</u>	<u>Day 1</u>	<u>Day 2</u>	<u>Day 3</u>	<u>Day (discharged)</u>
Six ECGs	1 2	3 4		5 6
taken	1st 2nd			3rd last

<u>Example D</u>	<u>Day 1</u>	<u>Day 2</u>	<u>Day 3</u>	<u>Day 4</u>	<u>Day 8 discharge</u>
Two ECGs	1	[No ECG #2 or #3]			2
taken	1st				last

<u>Example E</u>	<u>Day 1</u>	<u>Day 2</u>	<u>Day 5 (discharged)</u>
Six ECGs	1 2	3 4	5 6
taken	1st 2nd	3rd	last

The following examples for finding ECGs include ones for a) no ECG until late in the

hospital course, b) hospitalizations of less than three days, and c) ECGs taken over less than three days, but at least four ECGs are available. General rule: Code up to four ECGs if available and codable, even if definitions do not always fit.

<u>Example F</u>	<u>Day 1</u>	<u>Day 7</u>	<u>Day 9</u>	<u>Day 10 (discharged)</u>
Three ECGs taken		1 1st	2 2nd	3 last

<u>Example G</u>	<u>Day 1</u>	<u>Day 2 (discharged)</u>
Four ECGs taken	1 2 3 1st 2nd 3rd	4 last

D.5.2.5 Serum Enzymes

(Question 10) Were any cardiac enzyme measurements performed during this admission?

- Sources: Lab report.
- Cardiac enzymes are intracellular proteins that are released into the blood stream when there is damage to the cells of the heart muscle. They may include:
 - ✓ creatinine kinase (CK) or creatinine phosphokinase (CPK)
 - ✓ creatine phosphokinase isoenzymes (CK-MB)
 - ✓ troponins (T or cTNT; and I or cTNI, I-Stat Troponin)
 - ✓ myoglobin (put value in Investigation Notes)
 - ✓ lactate dehydrogenase (LD or LDH).
- Use the lab report as your primary source; if this document is not available, request results from the lab. Use results described in consult, discharge or death summary, or H&P only if the actual results cannot be located (unlikely). Add investigation note to explain if enzymes are found in records other than labs.
- Enter results in chronological order, with the earliest first.
 1. Blood draw/specimen/collected time (preferred)
 2. Resulted time
 3. MD order time
- Be sure to extract and record the upper limit of normal ULN for all cardiac-specific tests. The ULNs are used to compute abnormal and borderline results. Telephone the labs for normal ranges used for the specific tests on the specific dates drawn if they are not available in records.

- Do not record enzyme values without the reference range. General biochemistry tests – BNP, pro-BNP, and creatinine, may be recorded without the ULN if the normal range cannot be obtained.
- If a procedure or test was performed as part of the person’s participation in a medical study, the results of that procedure/test should still be abstracted for MESA. For example, if a participant is admitted to the hospital for CHF and while there is asked to join a medical study and undergo a test for that study, then the results should be abstracted, even if the reason for the test was unrelated to the original CHF admission.
- **If you answer “no” or “unknown” to this question, skip to Q 14.**

(Question 11) Did the participant have any active liver disease (cirrhosis, hepatitis, liver cancer, etc.)?

- Sources: ER report, discharge or death summary, consult, H&P, autopsy report.
- "Active liver (hepatic) disease" includes or may be described as:
 - ✓ acute or chronic hepatitis
 - ✓ alcoholic liver disease
 - ✓ cirrhosis
 - ✓ hepatoma
 - ✓ Laennec's cirrhosis
 - ✓ liver cancer or carcinoma
 - ✓ liver metastasis(es)
 - ✓ shock liver
 - ✓ hepatic encephalopathy

(Question 12) Was there any evidence of hemolytic disease during this hospitalization?

- Sources: Discharge or death summary, consult, H&P, autopsy report.
- "Hemolytic disease" refers to the destruction of red blood cells liberating hemoglobin. This includes or may be described as:
 - ✓ hemolytic anemia
 - ✓ disseminated intravascular coagulation (DIC)
 - ✓ myelophthisic anemia
- "Hemolytic disease" does not include:
 - ✓ pernicious anemia
 - ✓ macrocytic anemia
 - ✓ normocytic anemia
 - ✓ microcytic anemia
 - ✓ chronic simple anemia
 - ✓ anemia due to chronic renal failure (CR
 - ✓ iron deficiency anemia

- ✓ thrombocytopenia

(Question 13) Was there any mention of the participant having either trauma, a surgical procedure, or rhabdomyolysis within one week prior to the measurement of the cardiac enzymes?

- Sources: ER report, discharge or death summary, consult, H&P, autopsy report.
- The intent of this question is to determine if there has been damage to muscle.
- “Measurement of the cardiac enzymes” refers to *any* cardiac enzymes.
- Answer “Yes” even if the participant was *already hospitalized*, then experienced a trauma and within one week had his/her cardiac enzymes measured.
- Event need not be, but are recommended to be, listed chronologically.
- All events that qualify should be listed. Events occurring on the same date may be grouped. If more than 4 entry spaces are needed, pick the most relevant to the heart.
- "Trauma and surgical (invasive, cutting) procedures" include:
 - ✓ cardioversion
 - ✓ coronary artery bypass graft (CABG)
 - ✓ CPR (only if compressions are included)
 - ✓ crushing injury
 - ✓ defibrillation
 - ✓ electrical injury
 - ✓ extensive bruising
 - ✓ major fall
 - ✓ major surgery
 - ✓ muscle-penetrating laceration
 - ✓ placement of permanent pacemaker
 - ✓ seizure
 - ✓ cardiac catheterization/PTCA/stent placement (if all of these were done as part of a single procedure, record as a single procedure)
- "Rhabdomyolysis" is the destruction of skeletal muscle cells, often the result of electrical injury, alcoholism, injury (or lying in one position for an extended period of time), drug side effects, or toxins.
- Answer "no" for the following:
 - ✓ barium enema, colonoscopy
 - ✓ biopsies taken during a non-qualifying procedure
 - ✓ carotid endarterectomy
 - ✓ dental surgery
 - ✓ dialysis or CRRT
 - ✓ EGD or other endoscopy (e.g. upper GI)
 - ✓ insertion of a Swan Ganz catheter or pacer
 - ✓ intramuscular (IM) injections
 - ✓ intubation

- ✓ lumbar puncture (LP)
 - ✓ minor trauma such as scrapes, cuts, nicks
 - ✓ PEG/feeding tube placement
 - ✓ placement of temporary pacemaker
 - ✓ psychological trauma
- If yes, specify the type of trauma or procedure in the text box(es) and the date(s) of occurrence.

D.5.2.6 Serum Biochemistry Values

Biochemistry Values – BNP, pro-BNP, and Creatinine

- When laboratory reports are requested the request should include Patient Value, Normal Range, Collection Date, and Collection Time
- Use the lab report as your primary source; if this document is not available, use results described in consult, discharge, death summary, H&P, or progress notes. If all lab results cannot be determined from the record, call the provider hospital lab for the specific tests and reference ranges needed. Add investigation note to explain if reported values are found in records other than labs.
- Collection/specimen time is the preferred time to record, followed by resulted time, then MD order time
- If more than one method of determining the specific test value has been used, record the additional tests and reference range(s) in the investigative notes.
- For BNP, pro-BNP, and creatinine ONLY, the participant lab values may be recorded without a reference range. Leave an investigative note.
- Diagrams may be used to record lab values in some records:

Na (sodium) Cl (chloride) BUN
 K (potassium) CO₂ Creatinine Glucose

(Question 14) Was BNP measured?

- Record the initial BNP measurement if one is present in the chart. Then record the last measurement available (if more than one). If more than two measurements were taken, record the highest measurement of the remaining measurements. Elevated BNP is a marker of CHF.
- In the rare case that values above 99999.9 are found, enter 99999.9 in the form and then add an Investigation Note with the actual value.

(Question 15) Was pro-BNP measured?

- Record the initial pro-BNP measurement if one is present in the chart. Then

record the last measurement available (if more than one). If more than two measurements were taken, record the highest measurement of the remaining measurements. Elevated pro-BNP is a marker for CHF.

- In the rare case that values above 99999.9 are found, enter 99999.9 in the form and then add an Investigation Note with the actual value.

(Question 16) Was serum creatinine measured?

- Record the initial serum creatinine measurement if one is present in the chart. Then record the last measurement available. If more than two measurements were taken, record the **second** measurement taken after the initial measurement. Do not use rapid serum creatinine unless that is the only one available.

(Question 17) Is this patient currently on kidney dialysis (anytime in the last four weeks)?

- This question should be marked YES if the patient was on kidney dialysis at any time during this hospitalization or any time in the four weeks prior to his or her hospitalization.
- Continuous Veno-Venous Hemodiafiltration (CVVHDF), Continuous Renal Replacement Therapy (CRRT,) ultrafiltration, and peritoneal dialysis are kinds of dialysis.

D.5.2.7 MESA Enzyme Chart

Enzymes of interest to MESA are:

Total CK	Synonyms: CK, CPK, Total CPK, creatine kinase, creatine phosphokinase, CKI Total CK has heart (MB), skeletal muscle (MM) and brain (BB) fractions. If MB, MM and BB are given separately, add them to obtain Total CK.
CK-MB	Synonyms: CPK-MB, CK-heart fraction
Total LDH	Synonyms: Lactate dehydrogenase, LD
LDH1 and LDH2	These are fractions of LDH. Synonym for LDH1 is heat stable LDH (There are three other fractions of LDH, 3–5, which are not of interest to MESA.)
Troponin I or T	Synonyms: Tnl, TnT, troponin, or I-Stat troponin
Myoglobin	

Enzyme Units

Enzyme units are variable from hospital-to-hospital. Some hospitals may use different

normal ranges within their own laboratory or may even use normal ranges from another hospital. Possible units are:

CK-MB	Units/ml or I.U. Special units may include: negative/positive, absent/present, normal/abnormal, negative/weak, positive/positive, absent/weak, present or trace/present, normal/high normal/abnormal, absent/small/moderate/large.
	The result may also be reported as a percent or decimal proportion of total CK.
LDH	Units/l or I.U.
LDH1, LDH2	Units/l or I.U.
	The results may also be reported as a percent or decimal proportion of total LDH.
TROPONIN I, TROPONIN T	Results may be reported as ng/L, ng/mL, or ng/dL. Special units may include: negative/positive, absent/present, normal/abnormal, negative/weak, positive/positive, absent/weak, present or trace/present, normal/high normal/abnormal, absent/small/moderate/large.
MYOGLOBIN	Results may be reported as ng/mL, µg/L, or nmol/L. Reference ranges and participant values must be recorded in the Investigative Notes.

Refer to hospital charts, or with the hospital lab, for information concerning unusual formats.

Recording Procedure – Laboratory Standards

You MUST have lab norm values for the date the blood was collected. Ask for a printed lab sheet with reference ranges/normal values when you request the records. If no normal values are received, you must call the hospital lab and ask for DATE- AND TIME-SPECIFIC enzyme normal values.

Range set 1 is the primary set. Only numbers should go in the upper limit field. Examples:

CK-MB (0-10 IU)	<u>0.0</u> (lower) <u>10.0</u> (higher)
LDH1 (0-50% of total LDH)	<u>0.00</u> (lower) <u>50.00</u> (higher)

Range sets 2 and 3 are alternate sets, which may or may not be available. If no range set numbers are available leave them blank.

Occasionally, there may be more than one method used by a hospital to measure a particular enzyme, (e.g., a total LDH, may be done as part of the admission battery and also as part of the cardiac enzyme routine), with differing normal ranges with each test. List

them as indicated and use the second range set. If enzymes are available in both units and percentages, units are preferred.

If a lower limit is not given, (ie. the range is given as "<0.04 ng/ml"), use 0 as the lower limit. In this example the normal range would be recorded as 0.00 to 0.04.

Record enzyme normal ranges exactly as reported. Do not round any values.

Record all enzymes found including STAT, point of care (POC), and point of service (POS).

Recording Procedure – Participant Values

Record all enzymes exactly as reported in chronological order by date and time. (The sequential acquisition number often stamped on the lab reports may be useful in clarifying the testing time order.) If no time is listed, follow standard procedures for recording “unknown” or estimated data. (See Appendix 5.1.2, “Definition of Terms,” for timing details.) Military time will be entered when available.

The EDC can accept an unlimited number of enzyme measures now, so please enter all measures that you find.

If an enzyme is not measured, leave the corresponding blocks blank.

You do not need to zero fill. Leading and trailing zeroes can be omitted.

Record <0.1 as 0.1.

In cases where an enzyme (LDH or CPK) is reported both as a SMAC profile and as part of a specific isoenzyme battery, record the latter value for the total enzyme.

For non-numerical enzyme values: use the directions given on the top of page 5 (Enzyme chart) on the abstraction form: “When a serum enzyme value is recorded using words rather than numerals, use the following codes to record the value:

6666=absent/negative/normal; 7777=trace or weak positive;

8888=present/positive/abnormal.”

D.5.3 Action Required When Abstraction is Complete

Data entries are reviewed for completeness and accuracy and any discrepancies/questions are resolved by consulting the Field Center, a local MESA physician, or other MESA personnel as needed. The Central Abstractor will notify the Field Center when the Cardiac/PVD Hospital Abstraction has been completed and entered into the electronic database.

The Field Center is then responsible for de-identifying all documents chosen for review by the Central Abstractor, according to the Privacy Act guidelines. See Section 3.2 for additional details about de-identification.

After de-identification is completed, the Central Abstractor will enter the *Final Notice* form to close the abstracted event investigation.

D.5.4 Cardiovascular Events: Synonyms and Descriptions

1. **Angina** is a squeezing or crushing pain that usually starts in the center of the chest behind the breastbone and may spread to the arms, neck, jaw, or back. The pain can be mild, moderate, or severe. It is caused by reduced oxygen to the heart, usually from poor blood supply. The pain of angina is usually brief. It often, though not always, appears when participants are physically active or emotionally stressed and is relieved in a few minutes with rest. The pain may radiate to the back, left arm, or jaw. Angina may be accompanied by shortness of breath, sweating, nausea and dizziness.

Synonyms or terms that describe angina include:

- ✓ acute coronary syndrome
- ✓ angina, NOS
- ✓ angina pectoris
- ✓ anginal syndrome
- ✓ arteriosclerotic heart disease
- ✓ chest pain syndrome
- ✓ chronic coronary artery insufficiency
- ✓ chronic ischemic heart disease
- ✓ chronic myocardial ischemia
- ✓ coronary insufficiency
- ✓ crescendo angina
- ✓ impending infarction
- ✓ ischemic heart disease, NOS
- ✓ stable angina
- ✓ nocturnal (also called variant or Prinzmetal) angina, which occurs when a person is at rest, usually at night, and is associated with acute myocardial infarction, severe arrhythmias, and sudden death
- ✓ microvascular angina
- ✓ pre-infarction angina
- ✓ sub-endocardial ischemia
- ✓ unstable angina

Note: Demand ischemia due to any cause is a “NO.”

2. **Myocardial infarction** occurs when an area of the heart is deprived of necessary oxygen-supplying blood, and the lack of oxygen causes injury or death to that part of the heart.

Synonyms or terms that describe myocardial infarction (MI) include:

- ✓ acute myocardial infarction (AMI)
- ✓ heart attack
- ✓ cardiac infarction
- ✓ coronary artery embolism, occlusion, or rupture
- ✓ sub-endocardial infarction
- ✓ coronary occlusion

- ✓ infarction of any wall segment of the heart
- ✓ microinfarct of the heart
- ✓ Non Q Wave MI
- ✓ NSTEMI (non-ST elevation myocardial infarction)
- ✓ ischemic cardiomyopathy

3. **Congestive heart failure** is a condition in which the heart cannot maintain the blood supply required by tissues for oxygenation leading to a back up of blood in vessels and accumulation of fluid in the body tissues, including the lungs. If pulmonary edema is unequivocally due to malignancy, or if it is referred to as “minimal”, answer “no.”

NOTE: Diastolic dysfunction, without other signs, is not an indicator of CHF. Elevated BNP does not equal CHF.

Synonyms or terms that describe congestive heart failure (CHF) include:

- congestive/dilated cardiomyopathy
- congestive heart disease
- right heart failure
- right heart failure, secondary to left heart failure
- left heart failure
- left ventricular failure
- systolic heart failure
- diastolic heart failure
- heart/cardiac/myocardial failure, NOS
- low cardiac output
- pulmonary edema
- cor pulmonale

NOTE: If “mild” is indicated with any of these terms, answer “Yes.” “Minimal” is “No.”

4. **Lower extremity claudication** is an aching, tired, and sometimes burning pain in the legs caused by narrowing of the arteries that carry oxygen-rich blood to the muscles. It is brought on by exercise (e.g., walking) and resolves with rest.

Synonyms or terms that describe lower extremity (LE) claudication include:

- ✓ intermittent claudication

5. **Atherosclerosis of arteries of the lower extremities** is the deposition of plaque in the arteries of the legs.

Synonyms or terms that describe LE atherosclerosis include:

- ✓ peripheral vascular disease (PVD)
- ✓ peripheral vascular disease, NOS
- ✓ peripheral artery disease (PAD)
- ✓ atherosclerosis of legs

- ✓ arteriosclerosis of legs
- ✓ arteriosclerotic vascular disease (ASVD) of legs
- ✓ arterial, arteriovascular, or vascular degeneration
- ✓ peripheral angiopathy, NOS

NOTE: Venous conditions/disease are NOT included in PAD or PVD diagnoses

- If “mild” is indicated with any of these terms, answer “Yes”.

6. **Arterial embolism of the lower extremities** is the sudden blocking of an artery by an embolus, a piece of atherosclerotic plaque or a clot that has been carried by the bloodstream from another artery and forced into a smaller one; **arterial thrombosis of the lower extremities** is the formation or presence of a thrombus—a type of blood clot that stays where it was formed and may or may not obstruct the flow of blood.

Synonyms or terms that describe LE arterial embolism or thrombosis include:

- ✓ blood clot

NOTE: Do not include deep vein thrombosis (DVT)

7. **Abdominal aortic aneurysm (AAA)** is a weakness in the wall of the aorta in the abdomen that allows the aorta to balloon out as the pressure from the passing blood flow presses against it.

Synonyms or terms that describe abdominal aortic aneurysm include:

- ✓ aortic aneurysm
- ✓ abdominal aneurysm
- ✓ aortoiliac aneurysm
- ✓ aortic aneurysmal disease
- ✓ atherosclerotic aneurysm

Answer “no” to this question if the aneurysm is the result of injury, infection, or congenital weakening of the connective tissue component of the artery wall.

8. **Shock or cardiogenic shock** is the failure of the heart to maintain blood supply to the circulatory system and tissues because of inadequate output. If the term “septic shock” is used, answer “no.”

Synonyms or terms that describe shock or cardiogenic shock include:

- ✓ severe pump failure
- ✓ cardiac shock

9. **Ventricular fibrillation** is a condition in which disordered electrical activity causes the ventricles to contract in a rapid, unsynchronized, uncoordinated fashion. When this occurs, little or no blood is pumped from the heart. **Ventricular flutter** and **ventricular tachycardia** are orderly rapid ventricular beating. **Asystole** is the sudden and complete cessation of cardiac function lasting more than 60 seconds. **Cardiac arrest** is the cessation of heart pumping due to arrhythmia, most commonly ventricular fibrillation. If the participant has “sinus asystole,” “sinus pause,” this is not asystole.

Asystole as part of a surgical procedure should be answered "no."

10. **Deep venous thrombosis (DVT)** is the formation of a thrombus (a type of clot) in the deep veins of the thigh or calf. This may be documented on an ultrasound or duplex scan. **Pulmonary embolus (PE)** is the obstruction of the pulmonary artery or one of its branches by an embolus (a clot that formed in another blood vessel, usually the deep veins of the upper leg, and then traveled in the venous system to the lung). PE may be documented in a lung scan or arteriogram and may be found on a VQ scan or lab (D-Dimer)


Synonyms or terms that describe deep venous thrombosis or pulmonary embolus include:

- ✓ deep vein thrombosis
- ✓ clot in the leg
- ✓ lung embolus

11. **ST elevation >1mm with pain that is not present on ECG without pain.** ST elevation on an ECG often means cardiac ischemia, especially if anginal pain is present. However, sometimes ST elevation may be present continuously and not indicative of ischemia. If the MD clearly states the presence of ST elevation >1mm with pain that is not present on ECG without pain, record "yes." If ST elevation is absent, or if ST elevation seems persist even when pain is gone, record "no." If the MD mentions ST segment elevation during pain, but does not describe the ST segments without pain, you may also answer "yes." Obviously, the MD description may be incomplete and you must use your best judgment.

Most likely found in ER or ambulance report.

Multi-Ethnic Study of Atherosclerosis



Hospital Abstraction:
Cardiac/PVD

Participant ID: 8000028 02

Hospital Code:

Admission Information

1. Admission Date:
 / /
 Month Day Year

2. Discharge date or date of death:
 / /
 Month Day Year

Hospital Information

3. What was the participant's vital status at discharge?
 Alive Dead

4. Was there an episode of chest, left arm or jaw pain during the 72 hours prior to death?
 Yes No Unknown

Acute Cardiovascular Events

5. Was there an acute episode of pain, discomfort or tightness in the chest, left arm or jaw within 72 hours of the hospitalization or within 72 hours of the in-hospital event?
 Yes No Unknown
If "No" or "Unknown," skip to Question 8.

6. Did the onset of the acute episode occur prior to admission?
 Yes No Unknown

7. Was the discomfort or pain diagnosed as having a non-cardiac origin?
 Yes No Unknown

8. Did a physician indicate any of these as being present during the hospitalization? *Mark all that apply; exclude old episodes; include only current conditions (except for last item.)*

	Yes	No
Angina diagnosis -----	<input type="radio"/>	<input type="radio"/>
Myocardial infarction -----	<input type="radio"/>	<input type="radio"/>
Congestive heart failure or pulmonary edema -----	<input type="radio"/>	<input type="radio"/>
Lower extremity claudication -----	<input type="radio"/>	<input type="radio"/>
Atherosclerosis of arteries of the lower extremities -----	<input type="radio"/>	<input type="radio"/>
Arterial embolism or thrombosis of the lower extremities -----	<input type="radio"/>	<input type="radio"/>
Abdominal aortic aneurysm -----	<input type="radio"/>	<input type="radio"/>
Shock or cardiogenic shock -----	<input type="radio"/>	<input type="radio"/>
Ventricular fibrillation, cardiac arrest or asystole -----	<input type="radio"/>	<input type="radio"/>
Deep venous thrombosis or pulmonary embolism -----	<input type="radio"/>	<input type="radio"/>
ST elevation > 1mm with pain that is not present on ECG without pain-----	<input type="radio"/>	<input type="radio"/>
History of chest, left arm or jaw (ischemic) pain at any time in the past -----	<input type="radio"/>	<input type="radio"/>

Cardiac Abstract (Page 2)

8000028 02

Electrocardiograms

9. Were electrocardiograms (ECGs or EKGs) recorded?
 Yes No Unknown
If "No" or "Unknown," skip to Question 28.

Record dates of ECGs and make two copies of FOUR ECG tracings as described below. Send one copy to the ECG Reading Center and attach one copy to this form:

- If four or fewer tracings were made, include all tracings.
- If more than four tracings were made, include:

- 1.) First two codable tracings after admission (ECG#1-First and ECG#2)
- 2.) Last codable tracing prior to discharge or death (discharge tracing) (ECG-Last)
- 3.) Last codable tracing on day 3 (or the first tracing thereafter) following an admission or in-hospital event (ECG#3)
- 4.) The next codable tracing after day 3

-- If the participant is readmitted (transferred) to the ICU/CCU because of a new episode of chest pain, the first codable tracing may be sent.

Copy enclosed?

	Date: (m/d/y)			Yes No				
ECG #1: (first)	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>
ECG (last)	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>
ECG #2	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>
ECG #3	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>

Serum Enzymes

10. Were any cardiac enzyme measurements performed during this admission?
 Yes No
If "No," skip to end of form.

11. Did the participant have any active liver disease (cirrhosis, hepatitis, liver cancer, etc.)?
 Yes No

If "Yes," specify:

12. Is there any evidence of hemolytic disease during this hospitalization?
 Yes No

13. Is there any mention of the participant having either trauma, a surgical procedure, or rhabdomyolysis within one week prior to the measurement of the cardiac enzymes?
 Yes No Unknown
If "Yes," please specify type of trauma or procedure below.

Date m/d/y / /

Type of Trauma or procedure:

Date m/d/y / /

Type of Trauma or procedure:

Date m/d/y / /

Type of Trauma or procedure:

Date m/d/y / /

Type of Trauma or procedure:

* Please complete ENZYME CHART. *

Cardiac Abstract (Page 3)

8000028 02

14. Was BNP measured? Yes No *If "No," skip to 35*

Record the value of the first, last, and highest measurements of BNP (pg/ml):

First: [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Last (if more than one): [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Highest of remaining values (if more than two): [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Upper Limit of Normal BNP: [][][][] . []

15. Was pro-BNP measured? Yes No *If "No," skip to 16*

Record the value of the first, last, and highest measurements of pro-BNP (pg/ml):

First: [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Last (if more than one): [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Highest of remaining values (if more than two): [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Upper Limit of Normal for pro-BNP: [][][][] . []

16. Was serum creatinine measured? Yes No *If "No," skip to 17*

Record the value of the first, second, and last measurements of serum creatinine (mg/ml):

First: [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Second: [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Last: [][][][] . [] Date (mm/dd/yyyy): [][] / [][] / [][][][]

Upper Limit of Normal for serum creatinine [][][][] . []

17. Is this patient currently on kidney dialysis (anytime in the last four weeks)? Yes No

If no enzyme measurements were performed (question 10), skip to end of form.

Abstractor ID [][][] Data Entry ID [][][] Date (m/d/y) [][] / [][] / [][][][]

Cardiac Abstract (Page 4)

8000028 02

ENZYME CHART

Laboratory Standards

Record the established laboratory standards (range values) for each of the serum enzymes listed. Record the normal range on the lines for Range Set 1. When more than one normal range is given, record the others on the lines Range Set 2 and Range Set 3. Use 99.99 if value is 100 or more but boxes do not allow triple-digit integer.

Range Sets		Normal Range #	Total CK	CK-MB	LDH	LDH-1	LDH-2	Troponin I	Troponin T
Low	High								
		1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Cardiac Abstract (Page 5)

ENZYME CHART

8000028 02

Participant Values

Record all serum enzyme values from the participant's record. **Exception:** When more than 12 measurements were made, record the highest (peak) values for each enzyme value measured. Use 99.99 if 100 given but boxes lack triple-digit integer.

When a serum enzyme value is recorded using words rather than numerals, use the following codes to record the value: 6666-absent/negative/normal; 7777-trace or weak positive; 8888-present/positive/abnormal.

Date	Time	Range Total CK	Range CK-MB	Range LDH	Range LDH-1	Range LDH-2	Range Troponin I	Range Troponin T
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D.6 Hospital Abstraction Form: Stroke/TIA

D.6.1 Introduction

The MESA *Hospital Abstraction: Stroke/TIA* form captures the specific reasons for hospitalization and the use of various procedures, drugs and treatments.

Please see manual section 5.1 (Introduction to Hospital Abstraction: Cardiac/PVD) for instructions clarifying when one or two abstraction forms should be filled out for events involving multiple locations (ER visits and transfers). The same policy applies to abstraction for Stroke/TIA hospitalizations.

D.6.1.1 Instructions to Field Centers

Field Center (FC) staff does not complete the *Hospital Abstraction: Stroke/TIA* form.

Central MESA Abstraction staff will complete this form in the EDC. See specific instructions in Section 7.1 on how to prepare records for scanning.

D.6.2 Central Abstraction

Eligible events will be prepared for the Central Abstractor as follows:

- The Eligibility Form will be completed and entered into the MESA EDC.
- Medical records received from the provider will be briefly reviewed for completeness and appropriateness. Inappropriate records (not found on the request guideline list) will be purged.
- Records found to be noted, but missing, will be requested from the record provider. It is helpful to review the Discharge Procedure codes, as well as the Discharge Summary, ER Notes, H and P, etc., to determine which procedures should be found in the record, such as ECGs, CXRs, Echos, etc.
- If the provided record is complete and appropriate, the documents are scanned into the EDC in the order noted on the *Final Notice* form, with the exception that the ICD Code sheet should be scanned first.
- DO NOT SCAN THE RECORD UNTIL IT IS COMPLETE. If there are records that are unobtainable even though mentioned in the record, enter an Investigative Note into the Event record and make a note to the Central Abstractor on the coversheet.
- The Central Abstractor will abstract the event and enter the data into the *Cardiac/PVD Hospital Abstraction* form in the EDC. Documents not needed for Physician Review will be deleted.
- Upon completion of the abstraction the Field Center will be notified and the documents selected for review will be de-identified according to the Privacy Act guidelines using Adobe Acrobat Pro program tools.
- Specific details related to de-identification can be found in Section 3.3.

The instructions below describe for the Central Abstractor how the *Stroke/TIA Hospital Abstraction* form is to be completed using the records sent by the Field Center. The purpose of these instructions is to ensure records are consistently abstracted in the same way. The more specific information you have about each item on the form, and the more you know about where to find the “answers” and how to record them, the more uniform and useful the MESA data will be. Although you may have ample experience in medical record abstraction and medical terminology, the instructions provide many definitions that will help ensure that everyone is using the same “tools” to describe an event.

For each item on the form, the instructions will tell you where in the medical record to look for the required information. When consulting several sections of the medical record, you may find they provide different or even contradictory information. It is, therefore, imperative to consult all sections of the medical record listed for an item on the form. If you are still confronted with conflicting information, use your good judgment and knowledge of priority sources to determine the most reliable source of information.

Each question on the *Abstraction* form will point you towards suggested parts of the record. Ideally, the information you need to complete an item on the form will be found in one of the medical record sections listed. However, you may have to search other parts of the medical record for an answer. If you are still unable to get the information you need, mark the “unknown” bubble on the form.

The several sections of this document define and describe symptoms of events that we are attempting to capture on the abstraction form. However, you are not expected, nor should you try, to formulate a diagnosis based on descriptions or lists of symptoms. For example, question 9 asks, “Was the patient diagnosed with a typical ‘lacunar syndrome’?” Answer “yes” only if the treating or consulting physician or radiologist states in a report or notes that the patient was diagnosed with “lacunar syndrome.” Search the patient’s record only for the specific terms (or known synonyms) that the abstraction form asks about.

If you are unable to complete an item on the form because of missing or contradictory information in the medical record, consult your local physician reviewer for advice.

Two or more events in one investigation packet: If a single investigation packet (with single Investigation ID number) contains evidence of two separate events, the physician reviewers will follow the guidelines in the table below. If the stroke abstractor identifies a single investigation with multiple events, the stroke reviewer can contact the Coordinating Center to discuss whether to have the field center split the single investigation into multiple investigations. If the abstracted event is a series or flurry of TIA's being abstracted as a single event, this should be noted by the abstractor on the coversheet, with a prompt for the field center to enter that information into the "Investigation Notes" in the EDC.

Event types in single investigation	Reviewer Action
2 or more TIA's	Code review form for one TIA (the worst one)
TIA(s) and 1 stroke	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>two</u> investigations.
TIA(s) and 2 strokes	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>three</u> investigations.
2 or more strokes	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>two or more</u> investigations.

D.6.2.1 Sections and Content of the Medical Record Used for Abstraction

You will need to consult the medical record, as appropriate, in order to gather adequate information to complete the form. If the entire chart is available, the sections listed above should be reviewed first. In order to familiarize yourself with the course of events that occurred from admission to discharge, it is a good idea to read through these sections (and others, if possible), before you begin recording information on the form.

D.6.2.2 Definitions of Terms

Terms you may encounter in the medical record that should be recorded on the form as “yes,” “no,” or “unknown”:

Yes	No	Unknown
Present	Not present	Rule out (R/O)
Likely	Low probability	Suggestive
Apparent	Unlikely	Equivocal
Consistent with		Suspicious
Compatible with		Questionable
Definite		Possible
Probable		Uncertain
Highly suspicious		Reportedly
Presumed		Perhaps
Borderline		Could be
Thought to be		Might be
Minimal		May be
Representing		May represent
Seems to be		
Subtle		
Trace		
Slight		
Somewhat		

The table below shows time-of-day and length-of-time terms you may encounter in the medical record and how they should be interpreted and/or recorded on the form:

If the medical record says this...	You record this...
Early morning	6:00 a.m.
Morning	8:00 a.m.
Late morning	10:00 a.m.
Mid-day or noon	12:00 p.m.
Early afternoon	2:00 p.m.
Afternoon or mid-afternoon	3:00 p.m.
Late afternoon	4:00 p.m.
Early evening	7:00 p.m.
Evening	9:00 p.m.
Last night or bedtime	10:00 p.m.
Late evening	11:00 p.m.
Midnight	12:00 a.m.
During the night or middle of the night	1:00 a.m.
Several days	≥3 days
A few days	≥ 2 but < 3 days
Several hours	≥ 4 but < 6 hours
A few hours	≥ 2 but < 4 hours
Several minutes	= 3
A couple minutes	= 2

Other specific definitions are included in the instructions for each form item.

D.6.2.3 Methods

The Central Abstractor will need to complete a separate *Hospital Abstraction: Stroke/TIA* form for each stroke- or TIA-related hospitalization. This includes hospitalizations for stroke or in which a stroke occurred, according to the discharge summary or diagnoses list. For some situations, however, abstraction is *not* necessary (inquire if in doubt):

- A silent infarction or bleed picked up by imaging alone, with no clinical symptoms or signs;
- Syncope or near syncope;
- A subdural hematoma (SDH) with or without trauma;
- An elective admission for carotid endarterectomy coded 433;
- Asymptomatic positive carotid bruit without TIA or other symptoms.
- An old stroke with no other cerebrovascular indications.

For each of those situations, the Central Abstractor does not need to begin an abstraction form (this is a decision for the Central Abstractor to make, not the staff at the originating Field Center). Instead, send the records back to the Field Center with a note written on the coversheet notifying the Field Center of the reason for the returned packet, at which point the Field Center

may mark the *Final Notification* to indicate the absence of a stroke/TIA event. If, however, a past stroke is picked up by signs or symptoms and confirmed by imaging, you should complete the form as fully as possible. If a participant with a possible stroke or TIA is transferred to another hospital without first being discharged home, complete a separate form for each subsequent hospitalization. If a patient is discharged from the hospital but dies soon after, complete a separate event investigation. Do not assume that the events are linked.

If participant is hospitalized for a cerebrovascular event and, while hospitalized, is asked to join a medical study and undergo a test for that study, then the results should be abstracted for MESA, even if the reason for the test was unrelated to the original cerebrovascular admission.

The Field Center staff will send all relevant medical records and the abstraction form to Minnesota, as explained earlier. The abstractors will complete the abstraction form and return the original form to the Field Center. They will also send a coversheet back to the Field Center indicating what documents they believe should be included with the Final Notice Form.

Please follow these general guidelines when completing the form:

- Record dates as MM/DD/YYYY (e.g., 01/27/2001). If you are reasonably confident of the entire date please fill in all the boxes. If you are unsure of the day of the month, record “15.” If you are sure of the year but not month or day, mark “6” for month and “15” for day. If you are unsure of year, mark “unknown.” You may not enter partial dates into the boxes.
- Record times as HH:MM (e.g., 04:55) and specify a.m. or p.m.

D.6.3 Item-by-Item Instructions

The Central Abstractor will begin filling out the form at Question #1.

D.6.3.1 History, Hospital Record

- 1. Was the participant hospitalized as an immediate consequence of this event?**
 - Sources: Face sheet, discharge or death summary, H&P.
 - Answer “yes” if a stroke or TIA was a concern at admission. If this was an asymptomatic condition, there is no “event.”
 - If abstracting a series/flurry of potential TIA’s that resulted in hospitalization, answer “yes” even if only one of the spells resulted in hospitalization.
- 2. Did the stroke/TIA occur during hospitalization for a different reason?**
 - Sources: Face sheet, discharge or death summary, physician notes, autopsy report.
 - Answer “yes” if the stroke/TIA occurred after admission, if the stroke/TIA was an incidental finding, or if the timing of the stroke/TIA is unclear.

3. Please answer the following (date of admission and date of discharge or death) for the hospital admission (If a transfer, answer for the first admission and fill out separate abstraction form for each transfer):

- Sources: Face sheet, discharge or death summary, H&P.
- A separate, additional Stroke/TIA Hospital Abstraction Form should be filled out for each individual hospitalization within an investigation—*if the hospitalization included significant or new symptoms*. If, after an initial stroke/TIA hospitalization, the participant was transferred to a rehabilitation center where that patient experienced no new symptoms and where no new information was gathered concerning the initial incident, then the abstractor does not need to fill out an abstraction form for that second stay. Similarly, if a participant was hospitalized for a cardiac problem and then transferred to a second facility for cardiac recovery and ended up having a stroke at the second facility, then the abstractor would need to assess whether the first hospitalization (cardiac) had relevance for the second hospitalization (stroke). The cardiac hospitalization may well have relevance for the stroke situation, in which case two separate Stroke/TIA Hospital Abstraction Forms should be filled out. If the cardiac hospitalization has no relevance for the stroke situation, however, only one abstraction would be necessary (for the stay at the second facility, where the stroke occurred). The general rule is to do a separate abstraction if not doing one would omit any additional information that the MESA physician reviewers might need while reviewing the case.
- Record only the actual admission date, not the ER date (if any), which may be different (e.g., the preceding day).
- If the participant was transferred within the same institution for in-patient rehab, the discharge date is the date of transfer.
- If the participant was transferred to a second hospital, rehabilitation center, or chronic care facility, the discharge date is the date of transfer.
- Give best estimate of the date. If the date is not known, mark ‘unknown’. No partial dates.

4. Was the participant transferred to this hospital from another hospital, or from this hospital to another?

- If there was a transfer, then both abstraction forms should say “yes.”
- Sources: Face sheet, discharge or death summary, physician notes.
- “Hospital” means an acute-care facility to which the participant has been **admitted**.
- If the participant was transferred **from** a nursing home, skilled care facility, rehabilitation center, or another hospital’s ER or outpatient clinic, **answer “no” to this question**. Transfers to facilities other than acute care (e.g.,

rehabilitation, extended care, etc.) should be answered “yes” only if the participant experienced a stroke or TIA while there, or if the records from that stay include significant information about the onset or diagnosis of stroke.

- *If “yes,” continue with question 5 and complete this form. Additionally, obtain the hospital records for the other admission and complete the relevant abstraction form.*
- *If ‘no,’ continue with question 5.*

5. Is the time of the onset of symptoms known?

- Sources: EMT/ambulance report, ER record, discharge or death summary, H&P, physician notes.
- Mark ‘yes’ only if participant or informant noticed symptom onset as it occurred. Mark one of the ‘no’ responses for question 5 if the participant or informant noticed symptoms later and is unable to name hour of onset.
- If times are unknown, leave the question blank.

6. Has the participant ever had a TIA before this [i.e., the current] event?

- Sources: H&P, discharge or death summary, physician notes, ER report.
- TIA (transient ischemic attack) is a “threatened” stroke that lasts only a few minutes. It occurs when the blood supply to part of the brain is briefly interrupted. TIA symptoms, which usually occur suddenly, are the same as those of ischemic stroke but do not last as long. Most symptoms of a TIA disappear within an hour, although they may persist for up to 24 hours. Symptoms can include: numbness or weakness in the face, arm, or leg, especially on one side of the body; confusion or difficulty in talking or understanding speech; visual disturbances in one or both eyes; and difficulty with walking, dizziness, or loss of balance and coordination.
- Synonyms or terms that describe TIA include:
 - ✓ acute cerebrovascular insufficiency
 - ✓ amaurosis fugax
 - ✓ spasm of cerebral arteries
 - ✓ insufficiency of basilar, carotid or vertebral arteries
 - ✓ neurological deficit lasting less than 24 hours
- Patient must have a documented diagnosis by a physician, not just recorded symptoms.
- Question refers to past events only. Do *not* include the current event.
- If abstracting a series/flurry of possible TIA’s, Question 6 should not be marked “yes” unless the participant had a documented TIA prior to all spells in the series/flurry currently being abstracted.
- If a patient has a history of more than one TIA, the historical event closest in

time to the event for which records are being abstracted should be coded when answering the subquestion “How long before the current event?”

- If “no” or “unknown,” skip to question 7. Answer “no” if absence of past TIA is specifically mentioned. Answer “unknown” if there is no reference to a history, or lack of history, of TIA. If there is no specific reference to the lack of a TIA history, but there are clearly made statements about patient health such as “healthy,” “negative,” or “no medical problems,” you should still answer “no.” If the history is missing or ambiguous, answer “unknown.”
- If “yes,” continue with question 6 to provide information about temporal relationship to current event (i.e., previous TIA occurred within the last 30 days inclusive or more than 30 days ago).
- If “yes,” also indicate if the sign and symptoms of the previous TIA were in the same territory as those of the current event. Physician does not need to specifically state that symptoms are in same territory. Use your best judgment if the symptomology is similar; if unsure, put “unknown.” For example, if the current event is a stroke that has caused paralysis on the left side, and the previous TIA had caused weakness on the left side, both could be said to have occurred in the same territory or arterial distribution. Be aware that, if there is vision loss associated with a neurologic event, it will be in the eye that is *opposite* the side of the body affected by weakness or paralysis.

7. Has the participant ever had a stroke before this [i.e., the current] event?

- Sources: H&P, discharge or death summary, physician notes, ER report.
- A stroke (cerebrovascular accident, or CVA; cerebrovascular disease) occurs when the blood supply to a part of the brain is suddenly interrupted by a thrombus or embolus (ischemic stroke) or when a blood vessel in or on the surface of the brain bursts (hemorrhagic stroke). Hemorrhagic stroke is further divided into intracerebral hemorrhage, which is bleeding within the brain, and subarachnoid hemorrhage, which is bleeding between the brain and the skull. Once the brain’s blood oxygen supply is interrupted by blockage or hemorrhage, the cells in the affected area cease to function and die.
- Synonyms or terms that describe stroke include:
 - ✓ cortical infarction
 - ✓ intracranial hemorrhage (*not* subdural or epidural hematoma)
 - ✓ cerebral thrombosis
 - ✓ cerebral artery occlusion
 - ✓ cerebral infarction/apoplexy
- Patient must have a documented diagnosis by a physician, not just recorded symptoms.
- The symptoms of ischemic stroke are extremely variable and can include sudden onset of headache and seizures; loss of feeling on one side of the face

or in an arm or leg, or blindness in one eye; difficulty swallowing; difficulty with speech, including inability to express thoughts verbally or to understand spoken words; dizziness, vomiting, loss of muscle tone. Stroke symptoms must last at least 24 hours.

- The symptoms of intracerebral hemorrhage typically begin very suddenly and evolve over several hours. They include headache, nausea and vomiting, and altered mental state. Stroke symptoms must last at least 24 hours.
- The symptoms of subarachnoid hemorrhage include abrupt headache, nausea and vomiting, sensitivity to light, and various other neurological abnormalities and may occur a few days to a month before the vessel ruptures. Signs of rupture include severe headache, neck stiffness, vomiting, confusion, altered states of consciousness; loss of vision, stupor, and coma. Stroke symptoms must last at least 24 hours.
- Only include if the patient has an actual diagnosis, not just symptomology.
- Question refers to past events only. Do *not* include the current event.
- If a patient has a history of more than one stroke, the historical event closest in time to the event for which records are being abstracted should be coded.
- If “no” or “unknown.” skip to Question 8. Answer “no” if absence of previous stroke is specifically mentioned, if symptoms lasted less than 24 hours, if stroke was “possible” or “questionable,” or if patient had TIA only, with no residual findings. Answer “no” if the only evidence of previous stroke was found incidentally on exam or on neuroimaging. Answer “unknown” if there is no reference to a history, or lack of history, of stroke. If there is no specific reference to the lack of a CVA history, but there are clearly made statements about patient health such as “healthy,” “negative,” or “no medical problems,” you should still answer “no.” If the history is missing or ambiguous, answer “unknown.”
- If “yes,” continue with question 7 to provide information about the temporal relationship to the current event (≤ 30 days or > 30 days) and give approximate date of previous stroke; record the type(s) of stroke that occurred; and indicate if the signs and symptoms were in the same location as the current event. If type of stroke is ‘hemorrhagic’ only, skip to question 8. For approximate date of old stroke, if you are unsure of the day of the month, record “15.” If you are sure of the year but not month or day, mark “6” for month and “15” for day. If you are unsure of year, mark “unknown.” Any source may be used to answer this question if you judge it to be reliable.
- If “yes,” also indicate if the signs and symptoms of the previous stroke were in the same territory as those of the current event. Physician does not need to specifically state that the stroke is in same territory. Use your best judgment if the symptomology is similar; if unsure, put “unknown.” For example, if the current event is a stroke that has caused paralysis on the left side, and the previous stroke had caused paralysis on the left side, both could be said to

have occurred in the same territory or arterial distribution. Be aware that, if there is vision loss associated with a neurologic event, it will be in the eye that is *opposite* the side of the body affected by weakness or paralysis.

- If past history of stroke is reported, but there is no additional info, select “unknown” for timing, date, and stroke type.
- For “unknown” stroke type, do not select “Yes” for the subsequent question regarding stroke territory.

D.6.3.2 Stroke/TIA symptoms related to this event

(Symptoms according to patient self-report or family witnessed, though patient takes priority.)

8. Is the duration of event known to be:

- Sources: EMT/ambulance report, ER report, H&P, discharge or death summary.
- If *any* symptom or sign elicited by an examiner lasted longer than 24 hours, choose “More than 24 hours.”
- If symptom(s) or sign elicited by an examiner lasted longer than 24 hours (regardless of whether the patient died or not), choose “More than 24 hours.”
- If symptoms or sign elicited by an examiner lasted less than 24 hours, choose either “Until death within 24 hours” or “Resolved within 24 hours (specify below).”
- For the option “Until death within 24 hours”, a distinction should not be made between ‘brain death’ and time of expiration. Since hospitals may define death differently, the time of death (brain or otherwise) should be defined as whatever is specified by the physician.
- If *all* symptoms or sign elicited by an examiner resolved within 24 hours and the participant died *more* than 24 hours after the disappearance of the last symptom, then choose “Resolved within 24 hours (specify below).”
- Choose “Resolved within 24 hours (please specify)” for physician comments such as “symptoms were gone by the next day” or “symptoms gone by next morning.”
- If “Resolved within 24 hours” is chosen, specify the hours and minutes in the boxes provided for hours and minutes. If “Resolved within 24 hours” is chosen, never leave the hours and minutes boxes blank. If either hours or minutes are unknown, mark 99 in the appropriate box. If records show time only in minutes (e.g., 90 minutes), translate to hours and minutes (e.g., 1 hr, 30 min). If less than one hour, use 00 in the hours box. Zero-fill hours and minutes. Use the “D.6.1.3 Definitions of Terms” time table in this manual to estimate lengths of time if necessary. Examples:

“Unknown time” < 24 hrs	9	9	hours	9	9	min
“Next day/morning”	9	9	hours	9	9	min
“Less than an hour”	0	0	hours	9	9	min
“1-2 hours”	0	1	hours	9	9	min
“1 hour and 12 min.”	0	1	hours	1	2	min
“90 minutes”	0	1	hours	3	0	min
“24 hours”	2	4	hours	0	0	min
“One day”	2	4	hours	0	0	min
“Afternoon till Bedtime” (see D.6.1.3 time table)	0	7	hours	0	0	min

9. Was the patient diagnosed with a typical "lacunar syndrome"?

- Sources: EMT/ambulance report, ER report, H&P, discharge or death summary.
- Only mark “yes” for a *new* diagnosis. A previous diagnosis (existing prior to the current event) is not of interest.
- Lacunar syndrome (or lacunar stroke) is a type of ischemic stroke that is caused by blockage in small blood vessels within the brain. Typical lacunar syndromes, depending on the location of the blockage, include pure motor hemiparesis, pure sensory stroke, sensorimotor stroke, and ataxic hemiparesis.
 - ✓ Pure motor hemiparesis is weakness on one side of the body (face, arm, and/or leg), without any other sensory, mental, or speech symptoms.
 - ✓ Pure sensory stroke results in numbness and/or tingling on one side of the body (face, arm, and/or leg), without any other motor, mental, or speech symptoms.
 - ✓ Sensorimotor stroke is a combination of the above types of lacunar strokes.
 - ✓ Ataxic hemiparesis is weakness or paralysis on one side of the body (face, arm, and or leg), with ataxia (impairment of coordination) on the same side.
- Mention of “ataxic hemiparesis” qualifies as indication of Lacunar syndrome.
- Clumsy hand-dysarthria is weakness in the hand accompanied by speech impairment. The dysarthria is often severe, but the hand weakness may be subtle. Patient must have documented diagnosis of a lacunar syndrome, not just symptomology.
- This syndrome must be diagnosed by a physician. Do not try to formulate a diagnosis based on descriptions or lists of symptoms. Answer “yes” only if the treating or consulting physician or radiologist states in a report or notes that the patient was diagnosed with “lacunar syndrome.”

D.6.3.3 Neurological Examination

10. What was the patient's degree of alertness during the exam?

- Sources: ER report, H&P, consult, discharge or death summary.

D.6.3.4 Diagnostic Procedures

11. Were any of the following diagnostic procedures done during this hospitalization?

- Sources: Radiology reports, ER report, H&P, consult, physicians' notes, discharge or death summary, operative reports. Radiology reports or neurologists' interpretations of the reports take priority over other sources of information. If there is a disagreement between a radiology report and a neurologist interpretation, record the neurologist interpretation. The following examples can be used as general guidelines when assessing whether additional records are needed in order to determine diagnosis:
 - ✓ Example: CT indicates stroke and MRI report exists, but MRI report was not sent to Field Center or to Central Abstractor. Action: If CT indicates stroke and its location, then no need to request MRI. But if CT does not indicate stroke or location, then the MRI should be requested. Please note: the stroke reviewers find the MRI more informative than the CT report.
 - ✓ Example: MRI done but no report included; CT was unremarkable; patient discharged while MRI report was pending. Action: The MRI should be requested (to help localize the stroke).
 - ✓ Example: Discharge summary summarizes results (e.g., "MRA positive for infarct"), but the report itself is missing. This might also be the case for CT, MRI, MRA, Carotid Doppler, Cardiac Echo. Action: The report(s) should be requested. If none are supplied after six weeks, then the abstractor should proceed, using available records. A revised abstraction form may be submitted at a later date if new records are later supplied.

11A. Did the patient undergo CT (of the head)?

- Sources: CT reports, discharge or death summary. All parts of Question 11A deal only with CT scans (MRI scans are addressed in Question 11B).
- It is permissible to mark "yes" for both "within 48 hours" and "after 48 hours" when CT scans were done both before and after the 48-hour mark.
- If more than one CT scan was done, choose the single CT scan that is most representative of the event to answer all information requested in Question

11A. (Choose only one CT scan regardless of whether you did or did not mark “yes” for both “before 48 hours” and “after 48 hours” above.)

- *If “yes,” record temporal relationship to the current event and record findings.*
- *If ‘no’ or ‘unknown’ skip to question 11B.*
- *If ‘yes’ to infarct, continue to categorize the type of infarct. If ‘no’ or ‘unknown’ skip to 11B.*
- “No” or “unknown” should never be marked in combination with any “yes” answer of the same type.
- Subarachnoid hemorrhage is bleeding between the brain and the skull, seen in Fissure of Sylvius, between the frontal lobes, in basal cistern or within a ventricle, with no associated intraparenchymal hematoma.
- Intra-parenchymal hemorrhage (cerebral hemorrhage) is bleeding within the brain.
- Accepted terms for dating: “chronic” = “old”; “acute”=“new”; “subacute”=“new”; “recent”=“new.”
- If scans indicate that an ischemic infarct converted to a hemorrhagic, mark “yes” for both types (even though you have chosen a specific single scan as the source of your responses to all subquestions for 11A and 11B).
- Infarct (infarction) is an area of dead tissue within the brain caused by decreased or absent bloody supply. If infarct is present, further define using the terms below.
 - ✓ If records indicate unknown (uncertainty) for infarct or infarct age but a location is specified for the uncertainty, then mark “Infarct” as “unknown” and also mark relevant infarct location subtype as “unknown” (mark irrelevant ones as “no”).
 - ✓ Hemorrhagic infarction (or hemorrhagic conversion) is bleeding caused by ruptured blood vessels that were damaged or destroyed by inadequate or absent blood supply.
 - ✓ Cerebral cortical infarct is the formation of an infarct within the cerebral cortex, the convoluted layer of gray matter covering each cerebral hemisphere. If the location is described as “lobe,” mark location as “cerebral cortical infarct.”
 - ✓ Small deep infarct (lacunar infarct or lacune) is usually <2 cm at its greatest diameter and affects only deeper structures of the brain (i.e., subcortical white matter; centrum semiovale [the white matter above the ventricles]; corona radiata [white matter tracts beside the ventricles]; internal, external, and extreme capsules; basal ganglion, including caudate, putamen, globus pallidus, thalamus, subthalamus, and hypothalamus).

- ✓ Brain stem infarct is an ischemic stroke in the brain stem—the area of the brain that controls certain involuntary functions (e.g., respiration, blood pressure, heartbeat) and voluntary functions (eye movement, hearing, speech, swallowing). The brain stem (also called encephalic trunk) connects the cerebral hemispheres with the spinal cord and comprises the pons, medulla oblongata, and mesencephalon.
- ✓ Cerebellar infarct is an ischemic stroke that occurs in the cerebellum—the part of the brain that controls balance, coordination, and reflexes of the head and torso.

11B. Did the patient undergo MRI (of the head)?

- Sources: MRI reports, discharge or death summary. All parts of Question 11B deal only with MRI scans (CT scans are addressed in Question 11A).
- Note: For MRI scans, it is not necessary for the abstraction form to record whether the MRI scan was done within 48 hours and after 48 hours.
- If more than one MRI scan was done, choose the single MRI scan that is most representative of the event to answer all information requested in Question 11B.
- *If ‘no’ or ‘unknown’ skip to question 11C.*
- *If ‘yes’ to infarct, continue to categorize the type of infarct. If ‘no’ or ‘unknown’ skip to 11C.*
- “No” or “unknown” should never be marked in combination with any “yes” answer of the same type.
- Subarachnoid hemorrhage is bleeding between the brain and the skull, seen in Fissure of Sylvius, between the frontal lobes, in basal cistern or within a ventricle, with no associated intraparenchymal hematoma.
- Intra-parenchymal hemorrhage (cerebral hemorrhage) is bleeding within the brain.
- Accepted terms for dating: “chronic” = “old”; “acute” = “new”; “subacute” = “new”; “recent” = “new.”
- If scans indicate that an ischemic infarct converted to a hemorrhagic, mark “yes” for both types (even though you have chosen a specific single scan as the source of your responses to all subquestions for 11A and 11B).
- Infarct (infarction) is an area of dead tissue within the brain caused by decreased or absent bloody supply. If infarct is present, further define using the terms below.
 - ✓ If records indicate unknown (uncertainty) for infarct or infarct age but a location is specified for the uncertainty, then mark “Infarct” as “unknown”

and also mark relevant infarct location subtype as “unknown” (mark irrelevant ones as “no”).

- ✓ Hemorrhagic infarction (or hemorrhagic conversion) is bleeding caused by ruptured blood vessels that were damaged or destroyed by inadequate or absent blood supply.
- ✓ Cerebral cortical infarct is the formation of an infarct within the cerebral cortex, the convoluted layer of gray matter covering each cerebral hemisphere. If the location is described as “lobe,” mark location as “cerebral cortical infarct.”
- ✓ Small deep infarct (lacunar infarct or lacune) is usually <2 cm at its greatest diameter and affects only deeper structures of the brain (i.e., subcortical white matter; centrum semiovale [the white matter above the ventricles]; corona radiata [white matter tracts beside the ventricles]; internal, external, and extreme capsules; basal ganglion, including caudate, putamen, globus pallidus, thalamus, subthalamus, and hypothalamus.
- ✓ Brain stem infarct is an ischemic stroke in the brain stem—the area of the brain that controls certain involuntary functions (e.g., respiration, blood pressure, heartbeat) and voluntary functions (eye movement, hearing, speech, swallowing). The brain stem (also called encephalic trunk) connects the cerebral hemispheres with the spinal cord and comprises the pons, medulla oblongata, and mesencephalon
- ✓ Cerebellar infarct is an ischemic stroke that occurs in the cerebellum—the part of the brain that controls balance, coordination, and reflexes of the head and torso.

11C. Did the patient have a lumbar puncture (LP)?

- Sources: Lab report or, if not available, discharge summary, death summary, physician notes.
- Lumbar puncture (“spinal tap”) is the introduction of a hollow needle into the subarachnoid space of the spinal canal, usually between the fourth and fifth lumbar vertebrae. A lumbar puncture is done for diagnostic purposes to determine the pressure within the cerebrospinal cavities, to determine the presence of an obstruction to the flow of cerebrospinal fluid (CSF), to remove a specimen of CSF for laboratory examination.
- *If “yes,” indicate if there was evidence of hemorrhage (i.e., the presence of red blood cells [RBCs] that is not the result of trauma caused by the LP procedure. To answer “yes evidence of hemorrhage,” xanthochromia of the spun CSF must be present, or the LP must have been done less than 4 to 6 hours after the onset of symptoms (the ictus). If the blood is caused by trauma during the LP, no matter how much blood, xanthochromia in the spun CSF*

will be absent and “no evidence of hemorrhage should be marked” (six or more hours are needed for the blood to break down, release pigment, and result in the yellow discoloration of the spun CSF--xanthochromia). Mark “no evidence of hemorrhage” if hemorrhage was *caused* by the LP (i.e., traumatic tap) or if fluid was clear of RBCs. If there are a few RBC’s, answer “yes” only if xanthochromia is present. If no mention is made of xanthochromia, the Central Abtractor may rely on the clinician's impression of whether or not the LP was traumatic. If traumatic, mark no evidence for hemorrhage.

- *If ‘no’ or ‘unknown’, skip to 11D.*

11D. Did patient undergo non-invasive vascular imaging (carotid or transcranial Doppler)?

- Sources: Imaging report, discharge or death summary.
- Carotid Doppler (carotid duplex) is an ultrasound procedure used to assess blood flow in the carotid artery.
- Transcranial Doppler (TCD, brain ultrasound or sonogram) is an ultrasound procedure used to assess blood flow in the six intracranial arteries (see list of the six intracranial arteries below in instructions for 11E).
- *If “Yes” for “Carotid Doppler Done” or “Transcranial Doppler Done”, provide information about findings. If ‘no’ or ‘unknown,’ for both, skip to 11E*
- Carotid Doppler must indicate *both sides* as normal or less than 50% stenosis to mark “yes” for “Carotid Doppler indicating normal or less than 50% stenosis.” If “yes,” skip to next portion of question (vertebral artery abnormality).
- The two questions referring to stenosis pertain only to internal carotid stenosis. Exclude external common carotids in neck
- For stenosis/occlusion percentages, use highest percentage provided. For example, a range of 30-69% would be understood as 69% and the correct response marked accordingly. An indication of “mild” or “mild to moderate” stenosis/occlusion should be marked as less than 50%, but “moderate,” “significant,” or “moderate-severe” would be marked as greater than 50%.
- If report indicates “normal” or “unremarkable” for intracranial arteries without specifying particular arteries, mark “no” to all listed intracranial problems.
- If report indicates “normal” or “unremarkable” for extracranial arteries without specifying particular arteries, mark “no” to all listed extracranial problems.
- Vertebral artery abnormality pertains only to carotid or transcranial doppler.

- Stenosis is narrowing of an artery due to the buildup of plaque on the inside wall of the artery; occlusion is the blockage of an artery.
- If there is no mention of vertebral or intracranial arteries, or if one vertebral or intracranial artery is “normal” and other is “not seen,” then record “unknown” (rather than “no”). Besides stenosis and occlusion, indications of “high resistance” or “reversed flow” should be considered abnormalities. (Vessel tortuosity is not relevant.)

11E. Did the patient have an angiogram (MR, CT, or conventional)?

- Sources: Imaging report, operative report, discharge or death summary.
- Angiogram (angiography, arteriography; cerebral, vertebral, or carotid angiogram; angiogram of the head or brain) is a series of specialized x- rays of the head and neck arteries following the injection of a contrast medium through a catheter. AVM (arteriovenous malformation) is congenital disorder of the blood vessels in the brain resulting in a tangle of arteries and veins.
- If multiple tests were done, choose the most informative one and use it for all information requested. A conventional cerebral angiogram is preferred, followed by either a CT or MR. If both a CT and MR are present, choose the one that the diagnosing clinician used.
- For stenosis/occlusion percentages, use highest percentage provided. For example, a range of 30-69% would be understood as 69% and the correct response marked accordingly. An indication of “mild” stenosis/occlusion should be marked as less than 50%, but “moderate,” “significant,” or “moderate-severe” would be marked as greater than 50%.
- If report indicates “normal” or “unremarkable” for intracranial arteries without specifying particular arteries, mark “no” to all listed intracranial problems.
- If report indicates “normal” or “unremarkable” for extracranial arteries without specifying particular arteries, mark “no” to all listed extracranial problems.
- AVM must be present to mark “yes.” Otherwise mark “no.”
- *If ‘no’ or ‘unknown’ skip to question 11F. If ‘yes’ describe.*
- Extracranial arteries include:
 - ✓ Right internal carotid artery
 - ✓ left internal carotid artery
 - ✓ (Exclude extracranial external carotid)
 - ✓ Vertebral artery

- Intracranial arteries include:
 - ✓ major cerebral stem arteries (MCA, ICA [internal carotid artery], ACA, PCA)
 - ✓ vertebral artery
 - ✓ basilar artery
- Dissection is a condition in which there is bleeding into and along the wall of an artery from the heart; may also be associated with an aneurysm (dissecting aneurysm).
- Arteritis is inflammation of an artery that can cause the vessel to weaken, stretch, increase in size, or narrow; vasculitis is a general term that refers to inflammation of blood vessels.
- MRA of the neck or head can be coded here. If an MRA of the neck is completed, the questions regarding the extracranial carotids and vertebrals can be answered. If an MRA of the head, then the MCA, Basilar and other intracranial arteries can be answered. If only an MRA of the neck is done, select “unknown” for questions about intracranial arteries. If “unknown” is not available, leave it blank and make an Investigation Note.

11F. Did the patient have echocardiography (transthoracic or transesophageal)?

- Sources: Imaging report, discharge or death summary.
- Echocardiography (cardiac ultrasound, echocardiography) is a method of studying the heart's structure and function by analyzing sound waves bounced off the heart and recorded by an electronic sensor placed on the chest. A computer processes the information to produce a one-, two-, or three-dimensional picture that shows how the heart and heart valves are functioning. Types of echocardiography include M-mode, two-dimensional (2-D), spectral Doppler, color Doppler, contrast, and stress. Transesophageal echocardiography (TEE) may be done to obtain views of the heart that cannot be obtained with conventional echocardiography.
- If both transthoracic and transesophageal echos were done, combine results from both to answer questions here.
- Mark “yes” for Aortic arch atheroma only if specifically mentioned.
- *If “yes,” provide information about the findings.*
- *If ‘no’ or ‘unknown’, skip to 11G.*
- Embolism of cardiac source is the sudden blocking of an artery by a clot of foreign material (embolus) that has been brought to its site of lodgment by the blood current from the heart. The obstructing material is most often a blood clot, but may be a fat globule, air bubble, piece of tissue, or clump of bacteria.
- Intracardiac thrombus or clot (intraventricular thrombus or clot, ventricular aneurysm *with clot*, atrial myxoma) is a type of blood clot that has formed within the heart.

- Valve vegetations should not be included under Valvular heart disease.
- Spontaneous echo contrast is sometimes referred to as “smoke” or “Rouleaux formation.”
- Mitral annular calcification and valve sclerosis are not of interest.
- Valvular heart disease, which does not include mitral valve prolapse, is the improper functioning of the heart valves. Valvular stenosis is the narrowing of a valve opening that limits the forward flow of blood. Valvular insufficiency (regurgitation, incompetence or “leaky valve”) occurs when a valve does not close tightly, allowing blood to leak backwards across the valve. Only indications more severe than “mild” or more than 1+ should be marked “yes.”
- Dilated ventricle or poor ventricular function (dilated cardiomyopathy) is the enlargement and weakening of the ventricle(s) of the heart. Answer “yes” if his condition is specifically mentioned in a physician report or note or if the left ventricular ejection fraction (LVEF or EF) is <30%. “Left ventricular hypertrophy” (LVH) alone does not meet the criteria for dilated cardiomyopathy.
- Aortic arch atheroma is a mass of plaque composed of lipids, cholesterol, and the degenerated, thickened inner layer of the aorta at its arch. Moderate atherosclerosis of arch is “yes”.
- Atrioseptal aneurysm (ASA) is a localized saccular deformity of the atrial septum that bulges into the right or left atrium. Diagnosis can be established using transthoracic (TTE) and transesophageal echocardiography.
- Patent foramen ovale (PFO) is a hole between the left and right atria of the heart that fails to close naturally soon after a baby is born. If the PFO is not easily seen on an echo, a cardiologist may perform a “bubble test.”
- If “yes” is marked for “Artificial valve,” use the “Specify” box to note condition or relevant information regarding the artificial valve.

11G. Was an ECG (electrocardiogram, “EKG”) done?

- Sources: ECG (EKG) report (signed by MD), discharge or death summary.
- Answer “yes” only if atrial fibrillation/myocardial infarction were believed to be present *at event onset*.
- If “yes,” describe the finding of the initial post-event ECG.
- If ‘no’ or ‘unknown’, skip to 11H.
- Atrial fibrillation or flutter (AF or A-fib) is a condition of rapid, uncoordinated contractions (350–600/minute) of the muscles in the atria. This information may be taken directly from ECG—physician notation elsewhere is not necessary.
- Acute myocardial infarction occurs when an area of the heart is deprived of

necessary oxygen-supplying blood, which causes injury or death to that part of the heart.

Synonyms or terms that describe myocardial infarction (MI) include:

- ✓ acute myocardial infarction
- ✓ cardiac infarction
- ✓ coronary artery embolism, occlusion, or rupture
- ✓ sub-endocardial infarction
- ✓ coronary occlusion
- ✓ infarction of any wall segment of the heart
- ✓ microinfarct of the heart

11H. Was there surgical or autopsy (post mortem) evidence of stroke?

- Sources: Operative report, discharge or death summary
- More than one item may be marked for each subquestion (e.g., an ischemic stroke that converted to a hemorrhagic).
- *If yes, record type; if ischemic, record subtype.*
- If ‘no’ or ‘unknown’, skip to 12.
- Embolic stroke is caused by an embolus (clot) that has traveled from an artery in another part of the body, lodged in a smaller artery in the brain, and decreased or stopped blood flow in that artery.
- Atherosclerotic stroke is caused by the occlusion (by plaque) of an artery that supplies blood to the brain.
- A ventriculostomy procedure should not be considered as surgical or autopsy evidence of a stroke.

D.6.3.5 Outcome

12. Did the participant receive thrombolytic treatment for stroke?

- Sources: H&P, physician notes, discharge or death summary.
- Thrombolytic treatment is the use of a thrombolytic agent (tissue plasminogen activator, TPA, t-PA) to break up or “dissolve” a clot in an artery, thereby restoring blood flow. This type of therapy is typically administered emergently (within three hours of the stroke) to a patient who has a confirmed ischemic stroke.
- Answer “no” if treatment was given for myocardial infarction (MI).

13. Are any of the following conditions documented as having been present within four weeks prior to or during this hospitalization?

- MESA Central Stroke Abstractor may determine validity of diagnosis according to her/his judgment of available records but may consult MESA physician as needed.
- Sources: ER report, H&P, consult, physician notes, discharge or death summary.
- Myocardial infarction (see *Question 11G*).
- Atrial fibrillation (see *Question 11G*); atrial flutter (AF) is a condition of organized, rapid contractions (200–400/minutes) of the atria.
- Rheumatic heart disease (RHD) is damage to the heart valves caused by rheumatic fever; valvular heart disease (see *Question 11F*). Answer “yes” to any history of valve disease, unless it is described as mild.
- A known history of an artificial valve should be marked as “Rheumatic heart disease or any valvular heart disease.”
- Intracardiac thrombus (see *Question 11F*).
- Systemic or pulmonary embolus is an embolus in any part of the body other than the brain.
- Hematologic abnormality: hypercoagulable state is a condition of being prone to developing blood clots. Look for any of the following: promyelocytic leukemia (PML), protein S deficiency, protein C deficiency, antithrombin III deficiency, Factor V Leiden, resistance to activated protein C, prothrombin gene mutation, polycythemia vera, dysproteinemias, or other blood condition specifically termed hypercoagulable or described as causing hyperviscosity by a physician; include disseminated intravascular coagulability (DIC), if it resulted in hypercoagulable state.
- Other evidence of cause of stroke: [write on form in capital letters]
 - ✓ Tumor includes brain neoplasm, glioma, meningioma, astrocytoma, oligodendroglioma, pituitary adenoma, brain metastasis, neuroma or subarachnoid cyst; conditions that are “probable” or “consistent with brain tumor.”
 - ✓ Trauma (blunt trauma to the head, with loss of consciousness [LOC]) includes basilar skull fracture (with or without CSF leak or rhinorrhea), subdural hematoma (subdural hemorrhage, or SDH), epidural hematoma. If trauma due to a fall at onset of neuro symptoms, then record “no.” SDH with or without known trauma and no other evidence of stroke/TIA (e.g., SDH coded 432. _) should be marked by the Central Abstractor as “no event” if it indeed has no cerebrovascular relevance. The Central Abstractor should then inform the Field Center to indicate “no event” on the Final Notification form as well.

- ✓ Infection may include subacute bacterial endocarditis (infective endocarditis), which can predispose to emboli.
 - ✓ Hemorrhagic states may include blood diseases that lead to defects in clotting, such as thrombocytopenia (TCP), leukemia, aplastic anemia, liver disease, vitamin K deficiency; anticoagulation therapy such as Coumadin, warfarin, or heparin; side effects from anti-cancer drugs.
 - ✓ If the records indicate a history of Patent Foramen Ovale (PFO) but no echocardiography was performed, PFO should be written as an ‘other’ cause of stroke.
 - ✓ If ‘other’ cause, write in name in capital letters.
 - ✓ If any of the above (tumor, trauma, infection, or hemorrhagic state) were present *but did not cause the stroke*, they should instead be recorded in the next category (“Other non-stroke disease process that likely caused a focal neurological deficit”). Look at information from attending physician (e.g., discharge summary) to determine whether the above did or did not cause the stroke.
 - Other non-stroke disease process that likely caused a focal neurological deficit.
 - ✓ Use the clinical opinion of the attending physician to determine “likely caused”? [write on form in capital letters] include: multiple sclerosis (MS), hyper- or hypoglycemia, vasculitis, systemic lupus erythematosus (SLE), giant cell Arteritis, tertiary syphilis, CNS abscess, radiation to the head, peripheral neuropathy, diabetic neuropathy, myopathy/muscular dystrophies, Guillain-Barre syndrome, polyneuropathy, entrapment neuropathy (i.e., carpal tunnel syndrome), radicular problems (i.e., cervical or lumbar radiculopathy), subclavian steal, shock, severe hypotension, or other likely cause identified by physician.
- 14. Did the participant die during this hospitalization?**
- Sources: ER report, H&P, consult, physician notes, discharge or death summary.
 - *If ‘yes’, skip last two questions.*
- 15. At the time of discharge, had the participant made a complete recovery from this neurologic event?**
- Sources: Consult, physician notes, discharge summary.
 - The presence of any residual deficits or any weakness is an indication of an incomplete recovery.

16. At the time of discharge, did the participant require more help from another person for everyday activities (e.g., dressing, bathing, eating) compared to state prior to event?

- This question concerns change from pre-event status.
- “Unknown” may be marked if records do not provide adequate information to know whether help was needed.
- Sources: Consult, physician notes, discharge summary. (PT, OT, or Nsg notes may be used if available)

D.6.4 Action Required When Abstraction Form is Complete

After the *Hospital Abstraction* form is complete, the Central Abstractor will tell the site to blind the remaining pages in the PDF on the secure server and complete the *Final Notice*. See more instruction on the managing of medical records in Section 7.1.

Multi-Ethnic Study of Atherosclerosis Hospital Abstraction / Stroke Form

Participant ID: _____

Hospital Code: _____

History and Hospital Record

1. Was the participant hospitalized as an immediate consequence of this event?
 - Yes
 - No
 - Unknown
2. Did the stroke/TIA occur during a hospitalization for a different reason?
 - Yes
 - No
 - Unknown
3. Please answer the following for the hospital admission abstracted on this form:
 - Date of admission:
 - Unknown
 - Month / Day / Year: __/__/____
 - Date of discharge or death:
 - Unknown
 - Month / Day / Year __/__/____
4. Was the participant transferred to this hospital from another hospital, or from this hospital to another?
 - Yes **Obtain hospital records from other hospital and complete relevant abstraction form(s). Continue to Question 5**
 - No (If "No" or "Unknown," continue to Question 5.)
 - Unknown
5. Is the time of onset of symptoms known?
 - Yes
 - No, patient awoke from sleep with deficits
 - No, patient found with deficits
6. Has the participant ever had a TIA before this event?
 - Yes
 - No (If "No" or "Unknown," skip to Question 7.)
 - Unknown
 - How long before the current event?
 - Within the last 30 days (inclusive)
 - More than 30 days prior
 - Unknown
 - Prior TIA in same territory as present neurologic signs and symptoms?
 - Yes
 - No
 - Unknown
7. Has the participant ever had a stroke before this event?
 - Yes
 - No (If "No" or "Unknown," skip to Question 8.)
 - Unknown
 - How long before the current event?
 - Within the last 30 days (inclusive)
 - More than 30 days prior

- Unknown
 - Approximate date of old stroke, if known:
 - Unknown
 - Month / Day / Year ___/___/___
 - Types of stroke (check any that apply):
 - Ischemic
 - Yes
 - No
 - Unknown
 - Intracerebral hemorrhage
 - Yes
 - No
 - Unknown
 - Subarachnoid hemorrhage
 - Yes
 - No
 - Unknown
 - Unknown type
 - Yes
 - No
 - Unknown
 - Prior stroke(s) in same territory as the present neurologic signs and symptoms?
 - Yes
 - No
 - Unknown
- 8. Is duration of this event known to be:
 - Unknown
 - More than 24 hours
 - Until death within 24 hours
 - Resolved within 24 hours (specify below):
 - ___ Hours ___ Minutes
- 9. Was the patient diagnosed with a typical "lacunar syndrome" (i.e., pure motor, pure sensory, ataxic hemiparesis, clumsy hand dysarthria, sensori motor)?
 - Yes
 - No
 - Unknown

Answers to questions 10 should be based on the neurologic exam done at or around the time of admission or, for strokes occurring during the hospitalization, after the stroke.

Neurologic Examination

- 10. Degree of alertness during exam
 - Alert
 - Lethargic, drowsy or stupor
 - Coma
 - Unknown

Diagnostic Procedures

11. Were any of the following diagnostic procedures done during this hospitalization? If Yes, please indicate specific result.

11A. CT scan of head

- Yes
- No
- Unknown
- Done within 48 hours of event onset
 - Yes
 - No
 - Unknown
- Done after 48 hours of event onset
 - Yes
 - No
 - Unknown

If yes: (otherwise go to 11B)

- Subarachnoid hemorrhage
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Intraparenchymal hemorrhage
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown

If yes: (otherwise go to 11B)

- Hemorrhagic infarction
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Cerebral cortical infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No

- Unknown
 - Small deep infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
 - Brain stem infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
 - Cerebellar infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- 11B. MRI scan of head
- Yes
 - No
 - Unknown

If yes: (otherwise go to 11C)

- Subarachnoid hemorrhage
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Intraparenchymal hemorrhage
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown

If yes: (otherwise go to 11C)

- Hemorrhagic infarction
 - Yes, new
 - Yes, old
 - Yes, both old and new

- No
- Unknown
- Cerebral cortical infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Small deep infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Brain stem infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown
- Cerebellar infarct
 - Yes, new
 - Yes, old
 - Yes, both old and new
 - No
 - Unknown

11C. Lumbar Puncture

- Yes
- No
- Unknown

If yes: (otherwise go to 11D)

- Evidence of hemorrhage
 - Yes
 - No
 - Unknown

11D. Carotid Doppler done

- Yes
- No
- Unknown

If yes: (otherwise go to : transcranial Doppler question below)

- Carotid Doppler indicating normal or less than 50% stenosis
 - Yes
 - No
 - Unknown
- Carotid Doppler indicating normal or less than 50% stenosis Carotid Doppler indicating greater than or equal to 50% stenosis or occlusion on the

- Right side:
 - Yes
 - No
 - Unknown
- Left side:
 - Yes
 - No
 - Unknown
- Carotid Doppler indicating normal or less than 50% stenosis Carotid Doppler indicating vertebral artery abnormality
 - Yes
 - No
 - Unknown
- Transcranial Doppler done
 - Yes
 - No
 - Unknown

If yes: (otherwise go to 11E)

- Transcranial Doppler done Transcranial Doppler indicating intracranial artery abnormality
 - Yes
 - No
 - Unknown
- Transcranial Doppler indicating extracranial artery abnormality
 - Yes
 - No
 - Unknown

11E. Angiogram done (magnetic resonance angiogram, CT angram, or conventional angiogram)

- Yes
- No
- Unknown

If yes: (otherwise go to 11F)

Greater than or equal to 50% stenosis or occlusion of:

- Extracranial arteries
 - Right carotid artery
 - Yes
 - No
 - Unknown
 - Left carotid artery
 - Yes
 - No
 - Unknown
 - Vertebral artery
 - Yes
 - No

- Unknown

- Intracranial arteries

- Major cerebral stem artery (MCA, ICA, ACA, PCA)
 - Yes
 - No
 - Unknown
- Vertebral artery
 - Yes
 - No
 - Unknown
- Basilar artery
 - Yes
 - No
 - Unknown
- AVM
 - Yes
 - No
- Intracranial aneurysm
 - Yes
 - No
- Dissection
 - Yes
 - No
- Arteritis or vasculitis
 - Yes
 - No

11F. Echocardiography (transthoracic or transesophageal)

- Yes
- No
- Unknown

If yes: (otherwise go to 11G)

- Intracardiac thrombus
 - Yes
 - No
- Valvular heart disease
 - Yes
 - No
- Dilated ventricle or poor ventricular function
 - Yes
 - No
- Aortic arch atheroma
 - Yes
 - No
- Atrioseptal aneurysm
 - Yes
 - No

- Patent foramen ovale (PFO)
 - Yes
 - No
- Valve vegetations
 - Yes
 - No
- Spontaneous echo contrast
 - Yes
 - No
- Artificial valve (if yes, specify)
 - Yes. Specify _____
 - No

11G. Initial EKG

- Yes
- No
- Unknown

If yes: (otherwise go to 11B)

- Atrial fibrillation or flutter
 - Yes
 - No
- Acute myocardial infarction
 - Yes
 - No

11H. Surgical or autopsy evidence of stroke

- Yes
- No
- Unknown

If yes: (otherwise go to 12)

- Subarachnoid hemorrhage
 - Yes
 - No
 - Unknown
- Intraparenchymal hemorrhage
 - Yes
 - No
 - Unknown
- Ischemic stroke
 - Yes
 - No
 - Unknown

If yes:

- Lacunae
 - Yes
 - No
 - Unknown

- Embolic
 - Yes
 - No
 - Unknown
- Atherosclerotic
 - Yes
 - No
 - Unknown

12. Did the patient receive thrombolytic treatment for stroke?

- Yes
- No
- Unknown

13. Are any of the following conditions documented as having been present within four weeks prior to or during this hospitalization?

- Myocardial infarction
 - Yes
 - No
 - Unknown
- Atrial fibrillation or flutter
 - Yes
 - No
 - Unknown
- Rheumatic heart disease or any valvular heart disease
 - Yes
 - No
 - Unknown
- Intracardiac thrombus
 - Yes
 - No
 - Unknown
- Systemic or pulmonary embolus
 - Yes
 - No
 - Unknown
- Hematologic abnormality: hypercoagulable state
 - Yes
 - No
 - Unknown
- Other evidence of cause of stroke (e.g., tumor, trauma, infection, or hemorrhagic state)
 - Yes Specify: _____
 - No
 - Unknown
- Another non-stroke disease process which likely caused a focal neurological deficit
 - Yes Specify: _____
 - No
 - Unknown

14. Did the patient die during this hospitalization?

- Yes
- No
- Unknown

15. At the time of discharge, had the patient made a complete recovery from this event?

- Yes
- No
- Unknown

16. At the time of discharge, did the patient require more help from another person for everyday activities compared to state prior to event?

- Yes
- No
- Unknown

Abstractor ID: ____

Data Entry ID: ____

Date: __/__/____

D.7 Physician Questionnaire: Cardiac/PVD

D.7.1 Introduction

The purpose of the *Physician Questionnaire: Cardiac/PVD* form (which will be referred to as “the physician questionnaire” in the rest of these instructions) is to confirm a diagnosis of myocardial infarction (MI), angina, congestive heart failure (CHF), or peripheral vascular disease (PVD). The physician questionnaire is intended to be used primarily with non-hospitalized events (i.e., cases of outpatient diagnosis and treatment only). However, field center events staff, in consultation with a MESA physician investigator, may decide to send a physician questionnaire in cases of a hospitalized event if they feel the hospital records are incomplete or inconsistent and the investigation/classification process would benefit from the additional information a physician questionnaire might provide.

NOTE: It is preferred that when investigating an out of hospital event, that the Field Center request records (progress notes and test/procedure results) first. If the Abstractor determines that there is not enough information, then the physician questionnaire should be sent to obtain more information. Since this PQ is no longer required, you will not need to override it. It is requested that you comment in the ‘Investigation Notes’ tab in the software if you try to obtain it and cannot. This information will go to the Reviewers.

In order to simplify the instructions, the pronoun “she” will be used to refer to the physician, “he” to the participant.

The physician questionnaire is a self-administered form. It is mailed to the participant’s primary care physician or cardiologist or other specialist who treated the participant for his cardiac condition. In most cases, sending one physician questionnaire will be sufficient. However, there may be more than one physician who can supply vital information about the event under investigation. In that case, send a physician questionnaire to more than one physician. Also include a copy of a release of information that the participant has signed.

The physician questionnaire should be sent with a cover letter, signed by the principal investigator that explains what MESA is and why you are seeking the physician’s input (see Appendix E for sample letters). Enter the participant’s name and date of birth in the spaces provided so he can be easily identified by the physician. Include a stamped, self-addressed envelope in which the physician can return the questionnaire.

Review returned forms carefully to make sure they are “scannable.” Ensure, for example, there are no stray marks that cover items essential for the form to be scanned (such as the ID number in the lower left corner). Also, a form that has been mailed out and back may have extraneous folds, creases, tears, etc., that would make it difficult or impossible to be scanned properly. In these cases, it is acceptable to transcribe the physician responses to a clean form for scanning. Be sure to (a) document that the scanned form is a copy of the original and (b) retain a copy of the original form.

In most cases, the questionnaire will be completed by the physician and returned by mail. If surveillance staff members feel that a PQ is needed, they should attempt several times to obtain it (e.g., two to three attempts over a two month period). This may require some judgment based on the receptiveness of the physician's office. Sometimes it may help to have the Field Center physician call to help get the PQ completed. However, the physician does have the option of completing the form over the phone (or in person), with a MESA abstractor or physician reviewer. When the questionnaire is administered by phone, use the following guidelines to complete the questions.

D.7.2 Item-by-Item Instructions

(Question One) Physician familiarity with patient history

If the physician indicates she is not familiar with the participant's medical history or the circumstances surrounding this potential event, ask her if she knows of another physician who might be able to supply this information. If she says no, thank her for her time and conclude the interview. If she knows of another physician who might be better able to supply pertinent information about the event, ask for and document that second physician's name and contact information. Thank the physician for her time and conclude the interview.

(Question Two) Physician familiarity with specific medical history

If the physician indicated in Question One that she is aware of the participant's medical history, specifically ask if the participant has had any of the following conditions: MI, angina, CHF, or PVD/PAD. Mark all that apply. If the physician indicates no knowledge of the participant's having been diagnosed with any of these conditions, thank the her for her time and conclude the interview.

Sections A-D

Complete the section(s) appropriate to the physician's responses above. That is:

- If the physician indicates the participant has a history of MI, complete Section A.
- If the physician indicates the participant has a history of angina, complete Section B.
- If the physician indicates the participant has a history of CHF, complete Section C.
- If the physician indicates the participant has a history of PVD/PAD (peripheral vascular disease/ peripheral arterial disease) or AA (aortic aneurysm), complete Section D.

Complete all applicable sections.

Keep in mind these questions ask about the participant's most recent event of each given type. If the participant was hospitalized for any of these conditions, the name and city of the hospital is needed in order to collect the respective records. In addition, the certainty of the diagnosis is recorded as "definite" or "probable" here.

(Question Three) Diagnosis

Complete **sections a–d of Question Three** as appropriate.

- If the physician has indicated a participant diagnosis of MI, angina or CHF, ask her all items in all sections.
- If the physician has indicated a participant diagnosis of PVD (PAD) **only**, complete only relevant sections of **section a** (i.e., other diagnostic test) and **section b** (i.e., leg angioplasty).

section a

If the physician has indicated a participant diagnosis of MI, angina or CHF, ask her if the participant had any of the diagnostic tests listed in **section a**. Specifically ask about each listed test, and then ask if the participant had any cardiac diagnostic test not listed in **section a**. If so, indicate which test. Record a brief summary of pertinent findings from the diagnostic work-up. Ask the physician to send copies of all reports for tests for which she gave a “yes” response.

section b

If the physician has indicated a participant diagnosis of MI, angina or CHF, ask her if the participant had any of the procedures listed in **section b**. Specifically ask about each listed procedure. For each “yes” response, record the date of the procedure and ask the physician to send copies of all applicable reports.

section c

If the physician has indicated a participant diagnosis of MI, angina or CHF, ask her if the participant has/had been prescribed any of the medications listed in **section c**. Specifically ask about each listed medication. Ask if the participant has/had been prescribed any cardiac medication not listed in **section c**. If yes, specify which medication(s).

section d

If the physician has indicated a participant diagnosis of MI, angina or CHF, ask her if the participant had any of the symptoms listed in **section d**. Specifically ask about each listed symptom and mark “yes,” “no,” or “unknown,” as appropriate, for each.

D.7.3 Other Form Information

In the “Sequence ID” field on the upper right corner of page 1, enter the sequence number appropriate to this form. The “Sequence ID” is determined by number of a particular form completed for a given event. If this is the first physician questionnaire sent **for this investigation**, the Sequence ID is “01”; the second (if any) physician questionnaire sent **for this investigation** is Sequence ID “02,” etc. The Sequence ID is necessary to distinguish each physician questionnaire sent as a unique form within the MESA database.

In the “Notes” section, write down any additional notes or comments the physician may provide.

Review the form carefully and enter your Reviewer ID in the space at the bottom of pg. 3.

Record the physician's name in the "Form Completed By" field and enter the date the interview was completed. Submit the form for data entry.

D.7.4 Action Required After Form is Complete

Determine if any additional follow-up is needed. For example, if the physician identified a previously unknown physician who treated the participant, it may be appropriate to send her a physician questionnaire. If the physician indicated the participant was hospitalized and these records have not yet been obtained, you will need to commence the records collection procedure.

Send additional forms or collect additional data as needed.

Multi-Ethnic Study of Atherosclerosis

**Physician Questionnaire:
Cardiac/PVD**

OMB #0925-0493 Exp: 10/31/07

Participant ID: 8000028 02

Sequence Num: *(For MESA Field Center use only)*

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD, 20892-7974, ATTN: PRA 0925-0493. Do not return the completed form to this address.

Participant Name: _____ **Date-of-Birth:** ____/____/____

Please complete only this page if participant has not had any condition listed in Question 2 below, OR if you are not familiar with participant's medical history.

Please fill in the appropriate bubbles and write responses in the blanks provided.

1. Are you familiar with the participant's medical history?

Yes No →

Please complete Question 2 below.

Are you aware of another physician who could provide information regarding this participant?

Yes No ↓

Please sign and date the form at the bottom of page 4 and return form.

Please fill in the physician's name and address, sign and date the form at the bottom of page 4 and return form.

2. In your opinion, has the participant had any of the conditions below? (Please check any that apply.)

- MI *Please complete section A on page 2.*
- Angina *Please complete section B on page 2.*
- CHF *Please complete section C on page 2.*
- PAD/AA* *Please complete section D on page 2.*

None ***Please sign and date at the bottom of page 4 and return form.***

* Peripheral Arterial Disease/Aortic Aneurysm.

If participant has had any of the conditions listed, we would appreciate copies of pertinent office notes, including physical exams, reports of stress tests, caths and EKGs.

Physician Questionnaire: Cardiac/PVD (Page 2)

8000028 02

A. Myocardial Infarction

Has the participant ever been diagnosed with a myocardial infarction?

- Yes
- No
- Unknown

If "Yes," when was the most recent event of this type?

/ /
 Month Day Year

Was the participant hospitalized?

- Yes
- No
- Unknown

If "Yes," where was the participant hospitalized?

Name of Hospital: _____

City, State: _____

The certainty of the diagnosis is:

- Definite
- Probable

Go to next relevant section or, if none, skip to Question 3.

B. Angina

Has the participant ever been diagnosed with angina pectoris or coronary insufficiency?

- Yes
- No
- Unknown

If "Yes," did s/he have chest pain or equivalent, or was the diagnosis only the result of diagnostic tests?

- Pain or pain equivalent
- No pain; diagnostic testing only

If pain (or pain equivalent), when was the most recent episode of this type?

/ /
 Month Day Year

Was the participant hospitalized for angina/coronary insufficiency?

- Yes
- No
- Unknown

If "Yes," where was the participant hospitalized?

Name of Hospital: _____

City, State: _____

The certainty of the diagnosis is:

- Definite
- Probable

Go to next relevant section or, if none, skip to Question 3.

C. CHF

Has the participant ever been diagnosed with congestive heart failure or congestive cardiomyopathy?

- Yes
- No
- Unknown

If "Yes," when was the most recent episode of this type?

/ /
 Month Day Year

Was the participant hospitalized?

- Yes
- No
- Unknown

If "Yes," where was the participant hospitalized?

Name of Hospital: _____

City, State: _____

The certainty of the diagnosis is:

- Definite
- Probable

Go to next relevant section or, if none, skip to Question 3.

D. PAD

Has the participant ever been diagnosed with claudication, peripheral artery disease, or abdominal aortic aneurysm?

- Yes
- No
- Unknown

If "Yes," when was the most recent episode of this type?

/ /
 Month Day Year

Was the participant hospitalized?

- Yes
- No
- Unknown

If "Yes," where was the participant hospitalized?

Name of Hospital: _____

City, State: _____

The certainty of the diagnosis is:

- Definite
- Probable

Go to next relevant section or, if none, skip to Question 3.

Physician Questionnaire: Cardiac/PVD (Page 3)

8000028 02

3. Please complete the following sections for the most recent event.

If participant has been diagnosed with MI, Angina or CHF, please complete all sections on pages 3 and 4.

If participant has been diagnosed with PAD only, complete only relevant items in sections a and b.

Section a.

Which (if any) of the following diagnostic tests did the participant have? (Please attach copy of report.)

	Yes	No	Unknown
Electrocardiogram	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial of Nitroglycerin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Exercise Tolerance Test	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
---With Thallium?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cardiac Enzymes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Echocardiogram	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Angiography	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest X-Ray	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If Other, please specify:

Pertinent Results: _____

Section b.

Which (if any) of the following procedures were done?
When were they performed?

Cardiac Catheterization Yes No Unknown

Date: / /
 Month Day Year

Angioplasty or Stent Placement Yes No Unknown

Date: / /
 Month Day Year

CABG (Coronary Artery Bypass Graft) Yes No Unknown

Date: / /
 Month Day Year

Intravenous or Intracoronary Thrombolytic Therapy (TPA, Streptokinase) Yes No Unknown

Date: / /
 Month Day Year

Leg angioplasty or other leg revascularization Yes No Unknown

Date: / /
 Month Day Year

Physician Questionnaire: Cardiac/PVD (Page 4)

8000028 02

Section c.

Which (if any) of the following medications were prescribed as a therapy?

	Yes	No	Unknown
Nitroglycerin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beta-Blockers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Calcium Channel Blockers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Aspirin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diuretics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ace Inhibitors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Digitalis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oxygen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Vasodilators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If other, please specify:

Section d.

Were any of the following present?

	Yes	No	Unknown
Chest pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jugular Venous Distention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carotid Bruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basilar Rales or Crackles Only	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rales or Crackles Above Bases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wheezing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
S-3 Gallop	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cardiac Murmur	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hepatojugular Reflex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hepatomegaly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peripheral/Ankle Edema	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Thank you very much for your contribution to MESA. Please sign and date this questionnaire and return it to us in the self-addressed, stamped envelope with copies of pertinent office notes or tests. If you do not have the envelope, the address is:

Notes: _____

Form completed by: _____ Date: _____

For MESA Field Center Use Only:		Reviewer ID:	Data Entry ID:

D.8 Physician Questionnaire: Stroke/TIA

D.8.1 Introduction

The purpose of the *Physician Questionnaire: Stroke/TIA* form (which will be called “the physician questionnaire” for the remainder of these instructions) is to confirm a diagnosis of stroke or TIA. The physician questionnaire is an “if needed” form intended to be used primarily with non-hospitalized events (i.e., cases of outpatient diagnosis and treatment only) when the requested physician records and progress notes are insufficient. Field center events staff, in consultation with a MESA physician reviewer, may also decide to send a physician questionnaire in cases of a hospitalized event if they feel the hospital records are incomplete or inconsistent and the investigation/classification process would benefit from the additional information a physician questionnaire might provide.

NOTE: It is preferred that, when investigating an out-of-hospital event, the Field Center request records (progress notes and test/procedure results) first. If the Abstractor determines that there is not enough information, then the Physician Questionnaire should be sent to obtain more information. If you collect records rather than a PQ, you do not need to submit an override for the PQ. It is requested that you comment in the ‘Investigation Notes’ tab in the software if you try to obtain it and cannot. This information will go to the Reviewers.

In order to simplify the instructions, the pronoun “she” will be used to refer to the physician, “he” to the participant.

The physician questionnaire is a self-administered form. It is mailed to the participant’s primary care physician or neurologist or other specialist who treated the participant for his cerebrovascular condition. In most cases, sending one physician questionnaire will be sufficient. However, there may be more than one physician who can supply vital information about the event under investigation. In that case, you may send a physician questionnaire to more than one physician.

The physician questionnaire should be sent with a cover letter that explains what MESA is and why you are seeking the physician’s input. (See *Appendix E* for sample letters.) Enter the participant’s name and date of birth in the spaces provided so he can be easily identified by the physician. Include a stamped, self-addressed envelope in which the physician can return the questionnaire. Also include a copy of a release of information that the participant has signed.

Review returned forms carefully to make sure they are “scannable.” Ensure, for example, there are no stray marks that cover items essential for the form to be scanned (such as the ID number in the lower left corner). Also, a form that has been mailed out and back may have extraneous folds, creases, tears, etc., that would make it difficult or impossible to be scanned properly. In these cases, it is acceptable to transcribe the physician responses to a clean form for scanning. Be sure to (a) document that the scanned form is a copy of the original and (b) retain a copy of the original form.

In most cases, the questionnaire will be completed by the physician and returned by mail.

However, the physician may complete the form over the phone (or in person), with an MESA abstractor or physician reviewer. When the questionnaire is administered by phone, use the following guidelines to complete the questions.

D.8.2 Item-by-Item Instructions

Question One

If the physician indicates she is not familiar with the participant's medical history or the circumstances surrounding this potential event, ask her if she knows of another physician who might be able to supply this information. If she says "no," thank her for her time and conclude the interview. If the physician knows of another physician who might be better able to supply pertinent information about the event under discussion, ask for and document that second physician's name and contact information. Thank the physician for her time and conclude the interview. If the physician is familiar the participant, proceed to *Question Two*.

Question Two

Ask the physician the date she last saw the participant. Document response.

Question Three

If the physician indicated in *Question One* that she is aware of the participant's medical history, ask if the participant has ever "had, or been suspected of having, a cerebrovascular event such as a stroke, TIA, or amaurosis fugax." If the physician indicates no knowledge of the participant's having been diagnosed with, or suspected of having, any of these conditions, thank the physician for her time and conclude the interview.

Question Four

Ask the physician the date of the *most recent* event of this type (i.e., any major neurologic event). Document response.

- Read all listed diagnosis responses. Mark the diagnosis the physician feels most closely defines the participant's most recent neurologic event. If the physician indicates the participant's most recent neurologic event was not a stroke or TIA, indicate the type of event in the space provided. Please write response in all capital letters.
- Ask the physician if the certainty of this diagnosis was "definite," "probable," or "possible." Record response.
- Ask if the participant was hospitalized for this event. If yes, the name and city of the hospital is needed in order to collect the respective records. If no, skip to *Question Five*.

Question Five

Ask the physician, "The symptoms were in the distribution of which vessel?" and read

choices. Record response.

Question Six

Ask the physician if the participant had any of the diagnostic tests listed in *Question Six*. Specifically ask about each listed test, and then ask if the participant had any cerebrovascular diagnostic test not listed in *Question Six*. If so, indicate which test (please write in all capital letters). For all reports that you do not already have at the FC, ask the physician to send copies of all reports for tests for which she gave a “yes” response.

Question Seven

Ask the physician if the participant had any of the symptoms listed in *Question Seven*. Specifically ask about each listed symptom and mark “yes,” “no,” or “unknown,” as appropriate, for each. Ask if there were any other symptoms, and, if so, specify what type. Please write in all capital letters.

Question Eight

Ask the physician if the neurological findings lasted longer than 24 hours from onset. If so, specify the length of time the symptoms lasted (please write in all capital letters—“FIFTY HOURS,” for example).

Question Nine

Ask the physician if the participant has/had been prescribed any of the medications listed in *Question Nine*. Specifically ask about each listed medication. Ask if the participant has/had been prescribed any medication not listed in *Question Nine*. If yes, specify which generic or brand name medication(s)—please write in all capital letters.

Ask the physician if the participant has had more than one event of the type described in the preceding questions. If there was, then continue to *Question Ten*; if there was not, then thank the physician for her time and conclude the interview.

Question Ten

If there was a previous event, ask for the date of the first event. Record the answer.

- Read all listed diagnosis responses. Select the diagnosis the physician feels most closely defines the participant’s neurologic event. If the physician indicates the event was not a stroke or TIA, indicate the typed of event in the space provided (write response in all capital letters).
- Ask the physician if the certainty of this diagnosis was “definite,” “probable,” or “possible.” Record response.
- Ask if the participant was hospitalized for this event. If yes, the name and city

of the hospital is needed in order to collect the records of this hospitalization.

D.8.3 Other Form Information

In the “Sequence ID” field on the upper right corner of page 1, enter the sequence number appropriate to this form. The “Sequence ID” is determined by number of a particular form completed for a given event. If this is the first physician questionnaire sent *for this investigation*, the Sequence ID is “01”; the second (if any) physician questionnaire sent *for this investigation* is Sequence ID “02,” etc. The Sequence ID is necessary to distinguish each physician questionnaire sent as a unique form within the MESA database.

Review the form carefully and enter your Reviewer ID in the space at the bottom of pg. 3.


If a telephone interview, record the physician’s name in the “Form Completed By” field and enter the date the interview was completed. Submit the form for data entry.

D.8.4 Action Required After Form is Complete

Determine if any additional follow-up is needed. For example, if the physician identified a previously unknown physician who treated the participant, it may be appropriate to send her a physician questionnaire. If the physician indicated the participant was hospitalized and these records have not yet been obtained, you will need to commence the records collection procedure.

Send additional forms or collect additional data as needed.

Multi-Ethnic Study of Atherosclerosis



Physician Questionnaire:
Stroke/TIA

OMB #0925-0493 Exp: 10/31/07

Participant ID: 8000028 12

Sequence Num: *(For MESA Field Center use only)*

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD, 20892-7974, ATTN: PRA 0925-0493. Do not return the completed form to this address.

Participant Name: _____ Date-of-Birth: ____/____/____

Please complete only this page if you are not familiar with this participant's medical history.

Please fill in the appropriate bubbles and write responses in the blanks provided.

1. Are you familiar with the participant's medical history?

Yes No →

↓
Please continue to Question 2 on page 2

Are you aware of another physician who could provide information regarding this participant?

Yes No

↓
Please sign and date the form at the bottom of page 3 and return form.

Please fill in the physician's name and address, sign and date the form at the bottom of page 3 and return form.

2. When did you last see the patient?

		/			/				
Month			Day			Year			

3. In your opinion, has the patient ever had a cerebrovascular event such as a stroke, TIA or amaurosis fugax?

Yes
 No
 Unsure

↓

If "No," skip to the end of the form, sign and date at the bottom of page 3 and return form..

4. When was the **most recent** event of this type?

		/			/				
Month			Day			Year			

4a. This most recent event was a(n):

- Subarachnoid hemorrhage
- Intraparenchymal hemorrhage
- Brain infarction
- TIA
- Stroke, uncertain type
- Not a stroke or TIA

If not a stroke or TIA, what was the diagnosis?

4b. The certainty of the diagnosis is:

- Definite
- Probable
- Possible

4c. Was the patient hospitalized?

Yes
 No → *If "No," skip to Question 5.*

Name of Hospital: _____

City/State: _____

5. The symptoms were in the distribution of which vessel?

- Right carotid
- Left carotid
- Vertebral/Basilar
- Unknown

6. Which (if any) of the following diagnostic tests did the patient have?

	Yes	No	Unknown
CT of the head	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
MRI of the brain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carotid ultrasound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Electrocardiogram	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Echocardiogram	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypercoagulation work-up	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If other, Please specify:

7. Which (if any) of the following symptoms or physical findings were present in the most recent event?

	Yes	No	Unknown
Severe headache	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diminished level of consciousness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of consciousness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Language deficit/aphasia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hemineglect	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dysarthria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Visual field deficit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Weakness or drift	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hemiplegia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ataxia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sensory deficit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Asymmetry of reflexes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Babinski	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Abnormal gait	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If other, please specify:

Physician Questionnaire: Stroke/TIA (Page 3)

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8. Did any neurological findings persist longer than 24 hours from onset?

Yes No

Please specify:

9. Which (if any) of the following medications were prescribed as therapy?

	Yes	No	Unknown
Aspirin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dipyridamole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anti-coagulants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ticlopidine or Clopidogrel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Extended Release Dipyridamole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If other, please specify:

If there has been more than one event of this type, please continue to Question 10.

If not, please skip to the end of the form, sign and date, and return the form to the MESA clinic.

10. When was the first event of this type?

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month		Day		Year			

10a. This first event was a(n):

- Subarachnoid hemorrhage
- Intraparenchymal hemorrhage
- Brain infarction
- TIA
- Stroke, uncertain type
- Not a stroke or TIA

If not a stroke or TIA, what was the diagnosis?

10b. The certainty of the diagnosis

- Definite
- Probable
- Possible

10c. Was the patient hospitalized?

Yes No

If "No," skip to Question 5.

Name of hospital: _____

City/State: _____

Thank you very much for your contribution to MESA. Please sign and date this questionnaire and return it to us in the self-addressed, stamped envelope. If you do not have the envelope, the address is:

Form completed by: _____ Date: _____

For MESA Field Center Use Only:

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Reviewer ID:

Data Entry ID:

D.9 Physician Questionnaire: Cardiac Death

D.9.1 Introduction

The purpose of the *Physician Questionnaire: Cardiovascular Death* form (which will be referred to as “the physician questionnaire” for the remainder of these instructions) is to obtain a detailed account of the circumstances surrounding a participant’s death, in cases in which the death is known or is suspected to be cardiovascular in nature. The physician questionnaire is intended to acquire primarily additional information in cases of non-hospitalized deaths. However, field center events staff, in consultation with a MESA Physician Reviewer, may decide to send a physician questionnaire in cases of a hospitalized death if they feel the hospital records are incomplete or inconsistent and the investigation/classification process would benefit from the additional information a physician questionnaire might provide. **This form is required for out of hospital deaths.**

In order to simplify the instructions, the pronoun “she” will be used to refer to the physician, “he” to the participant.

The physician questionnaire is a self-administered form. It is mailed to the participant’s primary care physician or a specialist or ER physician who treated the participant just prior to his death. In most cases, sending one physician questionnaire will be sufficient. However, there may be more than one physician who can supply vital information about the event under investigation. In that case, you should send a physician questionnaire to more than one physician. Also include a copy of a release of information that the participant has signed.

The physician questionnaire should be sent with a cover letter, signed by the principal investigator, which explains what MESA is and why you are seeking the physician’s input. (See Appendix E for sample letters.) Enter the participant’s name and date of birth in the spaces provided so he can be easily identified by the physician. Include a stamped, self-addressed envelope in which the physician can return the questionnaire.

Review returned forms carefully to make sure they are “scannable.” Ensure, for example, there are no stray marks that cover items essential for the form to be scanned (such as the ID number in the lower left corner). Also, a form that has been mailed out and back may have extraneous folds, creases, tears, etc., that would make it difficult or impossible to be scanned properly. In these cases, it is acceptable to transcribe the physician responses to a clean form for scanning. Be sure to (a) document that the scanned form is a copy of the original and (b) retain a copy of the original form.

A completed questionnaire is preferred, but physician office notes are acceptable in lieu of the completed questionnaire. In most cases, the questionnaire will be completed by the physician and returned by mail. If surveillance staff members feel that a PQ is needed, they should attempt several times to obtain it (e.g., two to three attempts over a two month period). This may require some judgment based on the receptiveness of the physician’s office. Sometimes it may help to have the Field Center physician call to help get the PQ completed. However, the physician also may complete the form over the phone (or in person) with a MESA Abstractor or Physician Reviewer. When the PQ is administered by phone, use the following guidelines to complete the questions:

D.9.2 Item-by-Item Instructions

(Question One) Physician familiarity with patient history

Ask the physician if she is familiar with the events surrounding the participant's death. In order to answer "yes," the physician need not have been present at the time of death, but may have received information from others who did attend the death.

(Question Two) Physician familiarity with specific medical history

Ask the physician if she witnessed the participant's death. In order to answer "yes," the physician must have been present at the time the participant expired.

If the physician answers "yes" to both or either Questions One and Two, skip to Question Four.

(Question Three) Other familiar physicians

If the physician answered "no" to both Questions One and Two, ask her if she is aware of another physician who may be able to provide information about the death. If she says "no," thank her for her time and conclude the interview. If the physician knows of another physician who might be better able to supply pertinent information about the death under discussion, ask for and document that second physician's name and contact information. Thank the physician for her time and conclude the interview.

(Question Four) Underlying cause of death

Ask the physician what she believes is the underlying cause of death. Read each option listed.

(Question Five) Time between acute symptoms and death

Ask the physician to specify the time between the onset of the acute episode of symptoms and death. "Death" is "the point at which spontaneous breathing stopped and the participant never recovered."

Read each of the listed options. Check the one the physician states to be the most accurate.

(Question Six) Pain 72 hours prior

Ask the physician if the participant experienced an acute episode of pain in the chest, left arm, or jaw during the last 72 hours prior to death. "Pain" includes discomfort or feelings of tightness in the chest, left arm or shoulder, or jaw. Check "yes," "no," or "unknown," as indicated by the physician.

(Question Seven) SOB 72 hours prior

Ask the physician if there was an acute episode of shortness of breath during the last 72 hours prior to death. Check "yes," "no," or "unknown," as indicated by the physician.

(Question Eight) Nitrates or nitroglycerin

Ask the physician if the participant took or was given nitrates or nitroglycerin at the time of the acute episode. Check “yes,” “no,” or “unknown,” as indicated by the physician.

(Question Nine) Physician familiarity with medical history

Ask the physician if s/he is familiar with the participant’s medical history. If she responds “no,” thank her for her time and conclude the interview. If she is familiar, continue with Question 10.

(Question Ten) History of listed conditions

Ask the physician if the decedent had a history of any of the listed conditions. Read each condition and, for any condition for which the physician responds “yes,” ask her for the date of the **earliest** diagnosis.

(Question Eleven) Contact within one month of death

Ask the physician if /he saw the participant within a month of his death, and, if so, please supply the following information:

- Date of visit
- The participant’s chief complaint
- The physician’s primary diagnosis
- Any changes in medical management stemming from that visit

D.9.3 Other Form Information

In the “Sequence ID” field on the upper right corner of page 1, enter the sequence number appropriate to this form. The “Sequence ID” is determined by number of a particular form completed for a given event. If this is the first physician questionnaire sent **for this investigation**, the Sequence ID is “01”; the second (if any) physician questionnaire sent **for this investigation** is Sequence ID “02,” etc. The Sequence ID is necessary to distinguish each physician questionnaire sent as a unique form within the MESA database.

Review the form carefully and enter your Reviewer ID in the space at the bottom of page 3.

Record the physician’s name in the “Form Completed By” field and enter the date the interview was completed. Submit the form for data entry.


D.9.4 Action Required After Form is Complete

Determine if any additional follow-up is needed. For example, if the physician identified a previously unknown physician who treated the participant, it may be appropriate to send this second physician a physician questionnaire.

Send additional forms or do any other additional follow-up as needed.

OMB #0925-0493 Exp: 10/31/07

Multi-Ethnic Study of Atherosclerosis



**Physician Questionnaire:
Cardiovascular Death**

Participant ID: 8000028 02

Hospital Code:

Sequence Num:

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD, 20892-7974, ATTN: PRA 0925- . Do not return the completed form to this address.

Please complete the following questions to the best of your ability by filling in the appropriate bubbles or writing the answer in the blank provided. Please return completed forms in the self addressed stamped envelope provided. Thank you for your contribution to MESA.

Details of Death

1. Are you familiar with the events surrounding the decedent's death?
 Yes No

2. Did you witness the death?
 Yes No

If you answered "Yes" to both or either of Questions 1 and 2, please skip to Question 4.

3. If you answered "No" to both Questions, are you aware of another physician who could provide information regarding the death?
 Yes No

If "No," please sign and date the form at the bottom of page 2.

If "Yes," please provide the physician's name and address, then sign and date the form at the bottom of page 2.

Name of physician: _____

Address: _____

Circumstances Surrounding Death

4. What do you believe to be the underlying cause of death?

Acute Myocardial Infarction

Other Ischemic Heart Disease

Cerebrovascular Disease

Other Cardiovascular Disease

Non-Cardio/Cerebrovascular
(Please specify)

5. Please specify the time between the onset of the acute episode of symptoms and death. (We are defining death as the point where spontaneous breathing ceased and the patient never recovered.) Please check the appropriate time period.

Less than 5 minutes

5 minutes to 1 hour

1 hour to 24 hours

More than 24 hours

Unknown

6. Was there an acute episode of pain in the chest, left arm or jaw during the last 72 hours prior to death?
 Yes No Unknown

7. Was there an acute episode of shortness of breath during the 72 hours prior to death?
 Yes No Unknown

8. Did the decedent take or was s/he given nitrates or nitroglycerin at the time of the acute episode?
 Yes No Unknown

Phys. Quest.: Cardiovascular Death (Page 2)

8000028 02

Medical History

9. Are you familiar with the decedent's medical history?

- Yes No

If you answered "No," please skip to the bottom of the page

10. Did the decedent have a medical history of any of the following conditions or medications prior to the acute event which led to death?

Myocardial Infarction (MI)

- Yes No Unknown

If "Yes," date of most recent MI:

/ /
 Month Day Year

Angina Pectoris, Coronary Insufficiency or Other Chronic Ischemic Heart Disease

- Yes No Unknown

If "Yes," date of first diagnosis:

/ /
 Month Day Year

Congestive Heart Failure (CHF) or Congestive Cardiomyopathy

- Yes No Unknown

Stroke (CVA)

- Yes No Unknown

If "Yes," date of most recent CVA:

/ /
 Month Day Year

Continued next column

Transient Ischemic Attack (TIA)

- Yes No Unknown

If "Yes," date of first diagnosis:

/ /
 Month Day Year

Intermittent Claudication or Other Peripheral Vascular Disease (PVD)

- Yes No Unknown

Lower Extremity Bypass, Angioplasty or Amputation Secondary to PVD

- Yes No Unknown

Coronary Bypass Surgery

- Yes No Unknown

Coronary Angioplasty

- Yes No Unknown

11. If you saw the participant within one month of death, please fill out the following for the most recent visit:

Date of Visit:

/ /
 Month Day Year

Chief Complaint: _____

Primary Diagnosis: _____

Changes in Medical Management: _____

Form completed by: _____ Date: _____

For MESA Field Center Use Only:

/ /
 Month Day Year

Reviewer ID:

Data Entry ID:

D.10 Cardiac/PVD Interview

D.10.1 Introduction

The purpose of the *Cardiac/PVD Interview* is to obtain additional details about a potential cardiac or PVD event in cases where other available documentation (e.g., hospital records, physician questionnaires, etc.) does not provide sufficient data to decisively classify the event. The information provided in the narrative is meant to supplement data already collected and, ideally, contribute sufficient facts to make a final classification of the event.

The *Cardiac/PVD Interview* will be used rarely and will generally be most useful for non-hospitalized events. However, it can be used for hospitalized events as well, if events staff feels the hospital records are incomplete or inconsistent and the investigation/classification process would benefit from the additional information an interview might provide. The decision to use this form is left to local events staff, with consultation with a MESA physician investigator, though a Physician Reviewer may also request an interview (e.g., when review materials contain only a procedure report without clinical information). This form is to be utilized on an “If Needed” basis.

Ideally, the *Cardiac/PVD Interview* will be conducted with the MESA participant. (The *Informant Interview* is used for deceased participants.) However, if a living participant is unable to complete the interview for any reason, it may be completed with the participant’s spouse, son/daughter, caregiver, or other proxy knowledgeable of the circumstances and details surrounding the event.

D.10.2 The Narrative

To begin the interview and obtain the narrative, read the following script, “filling in the blanks” with the appropriate field enter location, event type and date.

We are calling today from the MESA Clinical Center at (your Field Center). We understand that you had a diagnosis of (MI/Angina/CHF/PVD) on (date of diagnosis). To help us complete our records, could you please tell us more about this? For example: What were you doing when symptoms started? What were your symptoms? How long did they last? What happened? Did you see a physician? What was done? Please describe what happened in your own words.

If the interview is with a proxy, modify the questions as appropriate (e.g., “What was **your husband** doing when the symptoms started?”).

Record the details of the event as related by the participant or proxy. The dialogue does not need to be recorded verbatim. It is recommended to record the conversation on a blank piece of paper, and then transcribe a coherent summary of the conversation onto the form after the phone call is complete. Make sure to note with whom the interview was conducted. If the interview is too long for one page, you may write on a second form or a

blank piece of paper.

Allow the participant/proxy to speak freely, but if s/he starts to stray from providing details about the event under discussion, attempt to re-focus the interview on the points asked about in the opening script. (See Appendix C.1, General Interviewing Instructions, for more information on general interview techniques.)

Probe for details about symptoms and their duration if the interviewee does not provide these. **If, during the course of the narrative, the participant/proxy does not offer information about chest, arm, or jaw pain, specifically ask for this.**

When the participant/proxy has completed the narrative, ask if s/he has any questions or additional details to offer. Close the interview by thanking the participant/proxy for his/her time and reiterating how the success of MESA depends on the cooperation of people like him/her.

D.10.3 Other Form Information

Record the date the interview was completed and your Interviewer ID. If needed, the interview text may be put onto another form. In this case, make sure to mark the page number in the text of the narrative, as well as on the label for the document. If there are multiple interviews conducted, complete a form for each interview.

NOTE: Although this form looks like a Teleform, it is scanned in as a NON-Teleform. The interview will be transmitted to the Coordinating Center as an image. It is important that the handwriting (or typing) be legible, because there will be no chance to verify the text on this form. The narrative does not need to be transcribed onto the actual form. It may also be written on a blank piece of paper. As long as the label is affixed in the correct location and is properly completed, the narrative will scan.

D.10.4 Action Required After Form is Complete

If not already done, transcribe (with neat handwriting or type) the interview onto the interview form. The Cardiac/PVD interview is saved in the MESA database as an “image file” in the same manner as all other non-TELEForm documents (e.g., discharge summaries, ECG tracings, etc.) Affix an appropriate document label (showing the Investigation ID, document type, page number and Sequence ID) to the upper left corner of the typed narrative and submit the form for data entry as part of the final events package for this investigation. (See the MESA Events Database Manual for information on scanning image files.)

Determine if any additional follow-up is needed. For example, if the participant/proxy identified a previously unknown physician who treated the participant, it may be appropriate to request records from that physician. Or the interviewee may identify a proxy (or additional proxy) who can provide additional details about the event, and you may decide to conduct an additional *Cardiac/PVD Interview* with this person.

Send additional forms or make additional calls as needed.

8000028 02

Page Num

CARI NT

Multi-Ethnic Study of Atherosclerosis

Cardiac/PVD Interview

This form should be used if there is insufficient information from hospital, physician or other records/forms to classify the cardiac event. The purpose is to obtain a narrative of events surrounding the event to supplement data already collected.

We are calling today from the MESA Clinical Center at (). We understand that you had a diagnosis of (MI/angina/CHF/PVD) on (date). To help us complete our records, could you please tell us more about this? For example: What were you doing when symptoms started? What were your symptoms? How long did they last? What happened? Did you see a physician? What was done? Please describe what happened in your own words.

Probe for details regarding symptoms and their duration; ask about chest, arm, and jaw pain specifically if not volunteered.

Narrative: _____

_____/_____/_____
Month Day Year

Interviewer ID:

D.11 Informant Interview

D.11.1 Introduction

The purpose of the *Informant Interview* is to better define the factors associated with the onset of a fatal event, including the participant's location and activity at onset, circumstances related to the onset, symptoms, history of medical treatment, and use of various medical services. This form is required for out-of-hospital deaths for which the cause is suspected to be a cardiovascular endpoint of interest to MESA. This form is to be utilized on an "If Needed" basis for hospitalized cardiovascular events.

The interview with the informant is potentially very emotional because, in most cases, it will be with a close relative or friend of the decedent. Care should be taken to be aware of the sensitive nature of the interview and the informant's response to the questions. No interview should take place less than 30 days following the participant's death. On the other hand, very distant events may be difficult to recall. The need to provide time for grieving should be balanced with the idea that the sooner the interview takes place, the more details the informant is likely to accurately relate.

The person to whom the *Informant Interview* is administered will generally be identified through one of three ways:

1. The person is listed as the "next of kin" on the participant's death certificate.
2. The person had been designated by the participant as a "contact" or "proxy."
3. The person is indicated by a previous informant as someone who has additional information regarding the participant's death.

The questionnaire is divided into six sections.

- The **Informant Information** section is concerned with the relationship of the informant to the decedent.
- **Circumstances Surrounding Death** addresses the details immediately surrounding the fatal event.
- The **History** section is concerned with the decedent's medical history.
- The **Symptoms** section is concerned with any acute symptoms the deceased may have experienced at the time of death.
- **Emergency Medical Care** addresses any emergency medical services the decedent may have received just prior to death.
- **Reliability** asks the interviewer to assess the dependability of the information obtained during the interview.

D.11.2 Item-by-Item Instructions

Most questions have multiple-choice responses; however, if necessary, in all instances, please feel free to write in the margins any additional information or comments that may be important to understanding the reply. In these instances, write word-for-word (in short phrases and/or abbreviations) the response of the informant, being careful to ensure that additional comments do not affect the proper scanning of the form by infringing upon "bubbles" or text boxes. These details may be helpful if there are any questions later about how to "code" a response. For questions asking the informant to provide names or

other specific information, if more than one answer is given, write all responses.

When reading questions to the informant, fill in the blanks with the name of the decedent. For example, the question, “I would like to ask you about the circumstances surrounding [the participant’s] death,” should be read, “I would like to ask you about the circumstances surrounding **your father’s**, or **your wife’s**, or **John’s** death,” etc., as appropriate.

The interviewer should be familiar with skip patterns and the nature of each question. Several questions are similar, with only slight differences. Such questions may sound repetitive and to ensue that the informant understands the distinctions and provides the most accurate response possible, the interviewer must make the distinction clear to the informant when necessary.

If the informant contradicts a previous answer, probe to clarify and correct the previous response if necessary.

If the informant says at the start of the interview that s/he does not know anything about the death, try to persuade the informant to start the interview and complete as much as possible. The interviewee may know more than s/he realizes. If the informant is obviously not helpful, gracefully end the interview.

Ask the informant for access to medical records during the interview, if appropriate, but request written permission only if needed.

Finally, the **interviewer** is responsible for thoroughly reviewing the *Informant Interview* form following the interview and editing as needed. Review every question and the skip patterns carefully. Every question must be answered unless skip patterns indicate otherwise.

NOTE: In order to accurately complete the informant interview, the interviewer needs to thoroughly understand the MESA definition of death. “Death” is defined as the point at which the decedent stopped breathing on his or her own and never recovered. Thus, the onset of death for someone who is resuscitated or ventilated is the point at which s/he last breathed spontaneously. [S/he may recover several times after resuscitations, but the last cessation of breathing is considered death.] Death is not the time “pronounced dead.” If the participant is “found dead,” the time of death may be estimable if the time since last seen alive was short. However, if long, the exact time of death may remain unknown.

Record the participant’s date of death in the designated field in the upper right corner of the form. Confirm the date entered matches the actual date-of-death as indicated on the participant’s death certificate.

D.11.2.1 Informant Information

(Question 1)

(Question 1a) Record the relationship of the informant to the decedent. Take care not to reverse this. For example, “She was my mother” should be answered “daughter/son.” “Other relative” includes aunt, uncle, cousin, in-law, grandchild,

etc. “Other” includes any relationship not listed. This can be completed in advance of the interview, if known.

(Question 1b) Record the name of the informant in the manner in you will address him or her throughout the interview.

D.11.2.2 Circumstances Surrounding Death

(Question 2) Ask the informant to provide details regarding the circumstances surrounding the participant’s death. Allow the informant to recount what happened in his/her own words. Transcribe this narrative as close to word-for-word as possible, using short phrases, abbreviations, etc., where appropriate. If the informant does not offer this information on his/her own, probe neutrally for **symptoms, order, and timing** of relevant occurrences, medical care, etc. Record the narrative on the separate *Informant Interview Narrative* sheet. The description of the incidents preceding the death is extremely important for diagnostic and Event review purposes. Therefore, pay particular attention in recording the following information:

Circumstance

- General/usual health of decedent prior to final events, major chronic illnesses, including whether or not there was a history of MI or coronary disease.
- Nursing home or other care? What changed, if anything, before death?
- Was the death witnessed? Or could have decedent been heard if s/he had cried out?
- Any emergency actions taken.

Symptoms

- Symptoms, particularly whether or not there was pain, and signs.
- Specifically ascertain whether or not there was pain and, if so, where.
- When describing the occurrences surrounding the death itself, be sure to differentiate between the onset of the last symptoms, the death (recalling MESA definition of death), and the participant’s being “pronounced dead.”
- Don't ask about risk factors (smoking, diabetes, hypertension).

Timing

- Timing around death. Timing should be clear, in terms of minutes/hours between steps. Key is the timing from onset of symptoms or last seen alive until cessation of breathing.
- If decedent was found dead, note as clear as possible the timing since last known alive and death.
- Make sure the description includes the timing of relevant occurrences and the symptoms experienced.
- Timing between incidents should be clear in minutes or hours.

Record the narrative on the separate *Informant Interview Narrative* sheet; if the interview produces no narrative information at all, you should still write that fact on the *Informant Interview Narrative* sheet. **Be sure to scan the Narrative sheet, regardless of whether it contains a narrative or not.**

(Question 3) Indicate whether or not someone was present at the time of the participant's death. This question should be answered "yes" whether the person present was the informant or someone else. "Present" is defined as being within **sight** of the deceased at the time of death. For example, someone was lying next to the decedent in bed, sitting in a chair in the room, etc. "Not Present" would be the correct response if no one was in the decedent's room at the time of his/her death, or someone left the decedent alive and returned to find him or her deceased, etc.

If the informant indicates someone was present at the time of death, skip to **Question 6**. If not, continue with **Question 4**.

(Question 4) Indicate whether, though no one was physically present (i.e., in the same room) when the participant died, someone was close enough to have heard the participant if s/he had called out just before his/her death.

(Question 5) Ask the informant how long it was between when the participant was last known to be alive and when s/he was found dead. Do not initially read the choices aloud to the informant. If the informant answers, mark the bubble appropriate to the informant's response. If the informant hesitates, read the intervals in order, starting with the shortest. Record "Unknown" if the participant does not know or refuses to answer.

Skip to **Question 7**.

(Question 6) If the informant indicated in **Question 3** that someone was present when participant died, ask the informant who was present, wait for response, and mark appropriate answer. If the informant hesitates, read the list and mark correct answer

If the informant indicates an "other lay person" (an individual without medical training) was present at the time of the participant's death, obtain more information about this person at **Question 21** (i.e., name, relation to participant). Consider whether an additional **Informant Interview** is needed with this person.

If the informant indicates s/he was present at the time of death, skip to **Question 8**. If not, continue with **Question 7**.

(Question 7) Ask the informant how much time passed between when s/he last saw the participant alive and the time of the participant's death. Do not initially read the choices aloud. If the informant answers, mark the bubble appropriate to the informant's response. If the informant hesitates, read the intervals in order, starting with the shortest. Record "Unknown" if the informant does not know or refuses to answer.

D.11.2.3 History

(Question 8) Ask the question as written: "Was s/he restricted to home, able to leave home only with assistance or great effort, or was his/her activity unrestricted?" Mark the bubble appropriate to the informant's response.

This question refers to any **history** of restriction from the decedent's usual day-to-day activities and excludes the circumstances immediately surrounding the participant's death.

(Question 9) Ask the informant if the decedent was hospitalized for **any** reason within

the four weeks prior to his/her death.

If the informant indicates the participant was not hospitalized for any reason within four weeks of his/her death, skip to **Question 12a**. Otherwise, continue with **Question 10**.

(Question 10) Ask the informant the reason for the hospitalization. **Do not** read the list. You may need to probe to obtain pertinent details. Mark the most appropriate answer based on the informant's response. If "Other" is indicated, specify in informant's own words.

(Question 11)

Question 11a) Enter the date of the hospital admission. If decedent was hospitalized more than once in the four weeks preceding his/her death or stayed in more than one hospital, record the most recent on the form and then list all dates, names, cities, and states of other hospitalizations on a separate piece of paper. If exact days are unknown, fill in month and year and enter 15 for the day.

Complete an *Initial Notification of Potential Event/Death* form for each new hospitalization indicated. Commence events investigation procedures to see if an event eligible for classification occurred prior to the participant's death. See Section D.2, "Initial Notification of Potential Event/Death," for more information about completing this form.

(Question 11b) Record the name, city, and state of the hospitalization recorded in **Question 11a**, or enter the MESA Hospital Code*.

* Prior to the start-up of events data collection, each MESA field center provided the Coordinating Center with a list of area hospitals and other health care institutions where their participants are likely to be having overnight stays. The Coordinating Center assigned each of these institutions a four-digit MESA Hospital Code. This is the value you may enter here if available/desired. To see a list of valid hospital codes for your site, you can run the Hospital Code report from the MESA database to see all institutions, sorted by institution name or hospital code. If a participant reports a stay at a hospital that has not been assigned a hospital code, the MESA database allows you to enter a new institution name, which will be automatically assigned the next (sequentially) available MESA Hospital Code.

(Question 12)

(Question 12a) Ask the informant if the participant was seen by a physician for any reason in the four weeks prior to his/her death.

If yes, continue with **Question 12b**. If not, skip to **Question 13**.

(Question 12b) Ask the informant the name and address of the physician the participant saw within the four weeks prior to his/her death. If more than one, record the additional names/addresses on a separate sheet of paper or in the "Notes" section on page 3 of the form.

Determine if it is appropriate to send the physician(s) indicated in Question 12b a *Physician Questionnaire: Cardiovascular Death* form.

D.11.2.4 Symptoms

(Question 13) Ask the informant if the participant experienced pain, discomfort or tightness in the chest, left arm, or jaw. This includes symptoms that were part of or followed the final episode of acute symptoms. Record response.

If yes, continue with **Question 14**. If not, skip to **Question 20**.

(Question 14) Ask the informant if the pain, discomfort or tightness specifically involved the chest. Record response.

(Question 15) Ask the informant if this episode of pain, discomfort or tightness was new or if the participant had previously experienced similar symptoms.

If the informant indicates the participant previously had similar symptoms, continue with **Question 16**. If not, skip to **Question 20**.

(Question 16) Ask the informant if the episodes of pain, discomfort, or tightness had been getting longer or more frequent. Record response.

(Question 17) Ask the informant if the episodes of pain, discomfort, or tightness had been getting more severe. Record response.

If the informant answers “no” or “unknown” to **both Question 16 and Question 17**, continue with **Question 18**. Otherwise, skip to **Question 20**.

(Question 18) Ask the informant over what period of time these episodes became longer, more frequent, or more severe. Do not initially read the responses aloud to the informant. If the informant answers, mark the bubble appropriate to the informant’s response. If the informant hesitates, read the intervals in order starting with the shortest. Record “Unknown” if the informant does not know or refuses to answer.

(Question 19) Ask the informant to indicate the interval of time between the participant’s last episode of pain, discomfort, or tightness and his/her death. Mark the shortest interval known to be reliable. Do not initially read the choices aloud to the informant. If the informant hesitates, read the intervals in order starting with the shortest. Record “Unknown” if the informant does not know or refuses to answer.

D.11.2.5 Emergency Medical Care

(Question 20) Ask the informant if the decedent was taken to the hospital, to the emergency room, or to another emergency care facility because of his/her condition.

- This includes visits to a hospital emergency room whether or not it resulted in an inpatient visit.
- This excludes instances when the participant went to a clinic or physician’s office or was already hospitalized when the event occurred.

(Question 21) This question asks if there is any person who may be able to provide additional information about the events leading up to the death or the death itself. For example, a spouse may know most about the three days prior to death, while a co-worker may have actually witnessed the death.

If the informant indicated in **Question 6** that someone other than him/herself or medical

personnel was present at the time of the participant's death, probe here for more information about that person, if it was not offered.

If the informant does indicate that another person may be able to provide additional details about the participant's death, determine if an additional *Informant Interview* with that individual is warranted.

(Question 22) This question asks for the relationship of the person indicated in **Question 21** to the decedent. "Other relative" includes aunt, uncle, cousin, in-law, grandchild, etc. "Other" includes any relationship not listed.

(Question 23) Ask the informant for the name and address of the person identified in **Question 21**.

Close the interview by thanking the informant for his/her time and reiterating how much the quality of our research depends on the cooperation of people like him/her. Ask the informant if s/he has additional questions. If s/he does, answer as best possible or refer the informant to additional resources if appropriate. Thank the informant again for his/her time.

D.11.2.6 Reliability

(Question 24) Immediately after completing the interview, record your assessment of the informant's reliability:

- Select **Good** when it is your opinion that the interview provided accurate and complete information to be used in evaluating the death, history, and symptoms.
- Select **Fair** when it is your opinion that the interview provided reasonably accurate and reasonably complete information to be used in evaluating the death, history, and symptoms.
- Select **Poor** when it is your opinion that the interview did not provide accurate or complete information to be used in evaluating the death, history, and symptoms.

Write any comments about the interview in the "Notes" section. This will help the Physician Reviewers understand how the interview went.

D.11.3 Action Required When Form is Complete

Review the form for completeness and accuracy. Enter your Interviewer ID and the date of the interview in the boxes provided at the bottom of the final page of the form.


In the "Sequence ID" field on the upper right corner of page 1, enter the sequence number appropriate to this form. The "Sequence ID" is determined by the number of a particular form completed for a given event. If this is the first *Informant Interview* sent, the Sequence ID is "01"; The second (if any) *Informant Interview* sent is Sequence ID "02," etc. The Sequence ID is necessary to distinguish each *Informant Interview* sent as a unique form within the MESA database.

Transcribe (type) the narrative from Question 2 on the separate *Informant Interview*

Narrative sheet; if the interview produces no narrative information at all, you should still type that fact on the *Informant Interview Narrative* sheet. Be sure to scan the sheet, regardless of whether it contains a narrative or not. The *Informant Interview* narrative is saved in the MESA database as an “image file” in the same manner as all other non-TELEForm documents (e.g., discharge summaries, ECG tracings, etc.). Affix an appropriate document label (showing the Investigation ID, document type, page number, and Sequence ID) to the upper left corner of the typed narrative and submit the form for data entry as part of the final events package for this investigation. (See the MESA Events Database Manual for information on scanning image files.)

Make sure your data manager changes the participant’s status to deceased in the “MESA Administration Participant Data” screen. This will cause the participant to “fall off” all MESA communication lists, such as the “Follow-Up Calls Due” report.

OMB #0925-0493 Exp: 10/31/07

<p>Multi-Ethnic Study of Atherosclerosis</p>  <p>Informant Interview</p>	<p>Participant ID: 8000028 02</p> <p>Sequence Num: <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/></p> <p><small>Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD, 20892-7974, ATTN: PRA 0925-0493. Do not return the completed form to this address.</small></p>
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Where there is a blank () in the text of a question, insert the name of the participant.

Date of Death: / /

Month Day Year

Informant Information

1a. Relationship of informant to deceased:

- Spouse
- Daughter/Son
- Parent
- Friend
- Workmate
- Other Relative:
- Other:

1b. Name of informant (for interviewer use):

Circumstances Surrounding Death

I would like to ask you about the circumstances surrounding ()'s death. If you have any questions as we go along, please ask me.

2. Please tell me about his/her general health, health on the day s/he died, and about the death itself.

Record a brief synopsis of the events surrounding the death as related by the informant. Append a typed copy of this account to this questionnaire.

Some of the remaining questions may repeat information already provided, but it helps us to ask these items specifically.

3. Was anyone present when s/he died?

Yes No Unknown

If "Yes," skip to Question 6.

4. Was anyone close enough to hear () if s/he had called out?

Yes No Unknown

5. How long was it between the time () was last known to be alive and the time s/he was found dead?

- Less than 5 minutes
- 5 minutes to 1 hour
- 1 to 24 hours
- Longer than 24 hours
- Unknown

Skip to Question 7.

6. Please tell me who was present:

- Self
- Nursing staff, physician or paramedic
- Other lay person

If "Self," skip to Question 8.

7. When was the last time you saw () prior to his/her death?

- Less than 5 minutes
- 5 minutes to 1 hour
- 1 to 24 hours
- Longer than 24 hours
- Unknown

Informant Interview (Page 2)

8000028 02

History

The next few questions concern ()'s medical history.

8. Was s/he restricted to home, able to leave home only with assistance or great effort, or was his/her activity unrestricted?

- Restricted to home
Able to leave home only with assistance or great effort
Unrestricted

9. Was s/he hospitalized within the four weeks prior to death?

- Yes No Unknown

If "No" or "Unknown," skip to Question 12a.

10. What was the reason for the hospitalization?

- Coronary heart disease, heart attack, angina, or cardiac arrest
Cerebrovascular disease or stroke
Other cardiovascular disease
Other non-cardiovascular disease
Heart surgery
Other surgical procedure(s)
Diagnostic procedure(s)
Other:
Unknown

11a. What was the date of the hospital admission?

Month / Day / Year grid

11b. What was the name and location of the hospital?

Blank lines for hospital name and location

12a. Was () seen by a physician at any other time in the last four weeks prior to death?

- Yes No Unknown

If "No" or "Unknown," skip to Question 13.

12b. What is the name and address of this physician?

Blank lines for physician name and address

Symptoms

The next set of questions deals specifically with acute symptoms such as pain, discomfort or tightness that () may have experienced at the time of his/her death (i.e., starting at the time s/he noticed the symptoms that caused him/her to stop or change what s/he was doing).

13. Did s/he experience pain, discomfort or tightness in the chest, left arm or jaw?

- Yes No Unknown

If "No" or "Unknown," skip to Question 20.

14. Did the pain, discomfort or tightness specifically involve the chest?

- Yes No Unknown

15. Were these episodes new, or had they occurred previously?

- New symptoms
Previous symptoms
Unknown

If "New symptoms," skip to Question 20.

16. Were the episodes getting longer or more frequent?

- Yes No Unknown

17. Were the episodes getting more severe?

- Yes No Unknown

If "No" or "Unknown," to Questions 16 and 17, skip to Question 19.

18. Over what period of time did these episodes become longer, more frequent, or more severe?

- Days
Weeks
Months
Unknown

19. You may not be able to answer this: How long was it from ()'s last episode of symptoms to the time that s/he stopped breathing on his/her own?

- Less than 5 minutes
Less than 1 hour
Less than 24 hours
Greater than 24 hours
Unknown

Informant Interview (Page 3)

8000028 02

Emergency Medical Care

20. Was () taken to the hospital, emergency room, or any other emergency care facility?

- Yes No Unknown

21. Is there anyone else we could contact who might be able to provide additional information about the circumstances surrounding ()'s death or his/her usual state of health?

- Yes No Unknown

If "No" or "Unknown," skip to "Closing Script."

22. How is s/he related to the deceased?

- Spouse
- Daughter/Son
- Parent
- Friend
- Workmate
- Other Relative:

- Other:

23. What is the name and address of this person?

Closing Script: Thank you very much for your assistance in this important study. Do you have any questions? (Pause, and continue if there are no questions.) Thanks again for your help.

Reliability

24. What is your rating of reliability of the interview?

- Good
- Fair
- Poor

Notes

/ /

Month Day Year

Interviewer ID:

Data Entry ID:

D.12 Interview for Stroke/TIA Symptoms

D.12.1 Introduction

The purpose of the *Interview for Stroke/TIA Symptoms* is to characterize certain cerebrovascular (stroke/TIA) events. A stroke generally includes one or more of the following symptoms that begin *suddenly*:

- loss or change of speech
- loss of vision
- double vision
- numbness or tingling on one side of the body
- paralysis or weakness on one side of the body
- spells of dizziness or loss of balance

Therefore, in this interview, a series of questions is asked for each symptom to determine whether an event took place, its duration, and its location.

TIA, or transient ischemic attack, is defined as a “warning stroke,” during which the same patterns of symptoms occur as in a stroke, the major difference being the duration of the symptoms (i.e., less than 24 hours).

The form should be used in the following instances:

- all reported non-fatal out-of-hospital strokes or TIAs (if the participant is incapacitated, however, the form should not be administered; instead, the *Stroke/TIA Narrative* form should be administered to a proxy).
- hospitalized stroke or TIAs for which the hospital record is lost or inadequate (if the participant is incapacitated, however, the form should not be administered; instead, the *Stroke/TIA Narrative* form should be administered to a proxy)

If the last two digits of the Investigation ID number are not pre-printed on the form, it is critically important that you place a label on the form with the full Investigation ID number, so that the interview is associated with the correct investigation.

This questionnaire at first appears somewhat lengthy. However, large subsets of questions are administered only to participants who indicate having experienced specific symptoms. So, significant portions of the questionnaire will be skipped during each interview.

Throughout this questionnaire, participants are asked about specific stroke or TIA symptoms they may have had when they experienced their stroke, TIA, or similar symptoms. If a participant has had one or more episodes, ask him/her to respond for the episode in which a doctor first diagnosed a stroke or TIA, or otherwise the “worst” episode. If the participant asks, “worst” can be defined in terms of severity, intensity, or association with other symptoms.

This form was adapted from similar forms used in ARIC and CHS.

D.12.2 Item-by-Item Instructions

Read the *introductory script* at the top of the form:

Introduction: You reported to us that you had a stroke, a small stroke, or a transient ischemic attack, also called a TIA, on about [specify date]. We are interested in possible stroke or TIA symptoms you may have had related to that experience. You may have had one or more episodes during that experience, but I would like you to respond for the episode in which a doctor diagnosed a stroke or TIA, or otherwise the worst episode. [NOTE: If participant asks, "worst" can be defined in terms of severity, intensity, or association with other symptoms.]

The interviewer should be aware that this form is keyed to Investigation Date. It is the symptoms related to that date that are of interest for this particular form. Try to be sure that the participant's responses for this form are not describing a separate event from a different month or year. If the participant has had multiple, separate stroke/TIA events, you may need to verify that MESA has begun an investigation for each.

"Small stroke" ("light" or "minor" stroke) is the same as a TIA.

Sudden Loss or Change in Speech

(Question 1) When you had your episode, did you have any sudden loss or changes in speech?

"Your episode" refers to the stroke/mini-stroke/TIA experience associated with this investigation. Emphasize *sudden* loss/change in speech. This should help to differentiate a neurologic cause from that of laryngitis, sore throat, cold, or being drunk. Record response. Record "Don't Know" as "No."

If response is "No," skip to Question 12. If response is "Yes," informally ask whether this happened more than once and, if so, ask him/her to focus on the one a physician diagnosed, or the worst one.

(Question 2) Did the change or loss last 24 hours or more?

Record response. Record "Don't Know" as "No."

(Question 3) Did the change or loss come on suddenly?

Record response. Record "Don't Know" as "No."

(Question 4) Do any of the following describe your change or loss in speech?

Read responses. Mark "Yes" for each symptom that applies to the participant's episode. Mark "No" for each symptom that does not apply. Record "Don't Know" as "No."

(Questions 5-11b) While you were experiencing this change in speech, did any of the following occur?

While asking the participant/proxy Questions 5-11b, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing difficulty with speech.

Mark “Yes” for each symptom that applies.

(Question 5a) Numbness or tingling?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

If response is “No,” skip to Question 6a.

(Question 5b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to *Question 5a* (i.e., numbness/tingling).

Record one response.

(Question 6a) Paralysis or weakness?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

If response is “No,” skip to Question 7.

(Question 6b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to *Question 6a* (i.e., paralysis/weakness).

Record one response.

(Question 7) Lightheadedness, dizziness, or loss of balance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

(Question 8) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

(Question 9) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

(Question 10) Headache?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

(Question 11a) Vision loss or blurring of vision?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

If response is “No,” skip to Question 12.

(Question 11b) During this vision loss or blurring of vision, did you have:

- ⊗ Double vision? (If “yes,” probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble.)
- ⊗ Vision loss in right eye only?
- ⊗ Vision loss in left eye only?
- ⊗ Total vision loss in both eyes?
- ⊗ Trouble in both eyes seeing to the right?
- ⊗ Trouble in both eyes seeing to the left?
- ⊗ Trouble in both eyes seeing to both sides or straight ahead?
- ⊗ None of the above

Read responses until a positive response is given. Record only the first symptom reported by the participant (i.e., one response). Do not read additional choices. If no choice is applicable, record as “none of the above.”

Sudden Loss of Vision

(Question 12) When you had your episode, did you have any sudden loss or blurring of vision, complete or partial?

“Your episode” refers to the stroke/mini-stroke/TIA experience associated with this investigation.

Emphasize *sudden* loss/blurring of vision. Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 24. If response is “Yes,” informally ask whether this happened more than once and, if so, ask him/her to focus on the instance a physician diagnosed or else the worst instance.

(Question 13) Did the visual symptoms last 24 hours or longer?

Be sure the participant realizes that “symptoms” refers only to the sudden loss/blurring of vision. Other symptoms the participant may have experienced are discussed in other sections of the form.

Record response. Record “Don’t Know” as “No.”

(Question 14) Did the visual symptoms come on suddenly?

Record response. Record “Don’t Know” as “No.”

(Question 15a) During this episode, which of the following parts of your vision were affected?

Read responses. Record one response.

If response is “only the right eye” or “only the left eye” (i.e., not “both eyes”), skip to Question 16.

(Question 15b) Did you have:

- ⊗ Trouble seeing to the right side but not the left
- ⊗ Trouble seeing to the left side but not the right
- ⊗ Trouble seeing to both sides or straight ahead
- ⊗ Other (Record other condition in text box provided.)

Read responses until a positive response is given. Record only the first symptom reported by the participant (i.e., one response). Do not read additional choices. If no choice is applicable, record as “none of the above.”

(Questions 16-23) While you were experiencing this loss of vision, did any of the following occur: (Mark “Yes” for each symptom that applies.

While asking the participant/proxy Questions 16-23, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing loss of vision.

(Questions 16) Speech disturbance?

Mark “Yes” if participant reports having this symptom Mark “No” if not. Record “Don’t know” as “No.”

(Question 17a) Numbness or tingling?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

If response is “No,” skip to Question 18a.

(Question 17b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 17a (i.e., numbness/tingling). Record one response.

(Question 18a) Paralysis or weakness?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

If response is “No,” skip to Question 19.

(Question 18b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 18a (i.e., paralysis/weakness). Record one response.

(Question 19) Lightheadedness, dizziness, or loss of balance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

(Question 20) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

(Question 21) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

(Question 22) Headache?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

(Question 23) Flashing lights?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

Sudden Double Vision

(Question 24) When you had your episode, did you have a sudden spell of double vision; that is, did you see two objects side by side, or one on top of the other?

“Your episode” refers to the stroke/mini-stroke/TIA experience associated with this investigation.

Emphasize *sudden* onset of double vision. Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 24. If response is “Yes,” informally ask

whether this happened more than once and, if so, ask him/her to focus on the one a physician diagnosed or else the worst.

If response is “No,” skip to Question 35.

(Question 25) Did the double vision last longer than 24 hours?

Record response. Record “Don’t Know” as “No.”

(Question 26) If you closed one eye, did the double vision go away?

Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 35.

(Question 27) Did the double vision come on suddenly?

Record response. Record “Don’t Know” as “No.”

(Questions 28-34) While you were experiencing double vision, did any of the following occur? (Mark “Yes” for each symptom that applies.)

While asking the participant/proxy Questions 28-34, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing the episode of double vision.

(Question 28) Speech disturbance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

(Question 29a) Numbness or tingling?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t know” as “No.”

If response is “No,” skip to Question 30a.

(Question 29b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 29a (i.e., numbness/tingling). Record one response.

(Question 30a) Paralysis or weakness?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 31.

(Question 30b) Did you have this difficulty on (right side only, left side only, both

sides)?

Read responses to participant. “Difficulty” refers to Question 30a (i.e., paralysis/weakness). Record one response.

(Question 31) Lightheadedness, dizziness, or loss of balance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 32) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 33) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 34) Headache?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

Sudden Numbness or Tingling

(Question 35) When you had your episode, did you have sudden numbness, tingling, or loss of feeling in one side of your body, including your face, arm or leg?

“Your episode” refers to the stroke/mini-stroke/TIA experience associated with this investigation.

Emphasize *sudden* onset of numbness or tingling. Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 49. If response is “Yes,” informally ask whether this happened more than once and, if so, ask him/her to focus on the one a physician diagnosed or else the worst.

(Question 36) Did the numbness or loss of feeling symptoms last 24 hours or longer?

Record response. Record “Don’t Know” as “No.”

(Question 37) Did the feeling of numbness or tingling occur only when you kept your arms or legs in a certain position?

Record response. Record “Don’t Know” as “No.”

If response is “Yes,” skip to Question 49.

(Question 38) Did the feeling come on suddenly?

Record response. Record “Don’t Know” as “No.”

(Question 39) During the numbness or tingling, which part or parts of your body were affected?

Read responses. Record “yes” or “no” for each. Record “Don’t Know” as “No.”

(Question 40) When you experienced this numbness or tingling, did the abnormal sensation start in one part of your body and spread to another, or did it stay in the same place?

Record one response.

(Questions 41-48) While you were experiencing numbness, tingling, or loss of sensation, did any of the following occur?

(Mark “Yes” for each symptom that applies.)

While asking the participant/proxy Questions 41-48, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing numbness, tingling, or loss of sensation.

(Question 41) Speech disturbance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 42a) Paralysis or weakness?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 43.

(Question 42b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 42a (i.e., paralysis/weakness). Record one response.

(Question 43) Lightheadedness, dizziness, or loss of balance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 44) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 45) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 46) Headache?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 47) Pain in the numb or tingling arm, leg, or face?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

Emphasize “pain” so that the participant/proxy understands it can mean something in addition to the numbness or loss of feeling that the participant/proxy has already acknowledged was present.

(Question 48a) Vision loss or blurring of vision?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 49.

(Question 48b) During this vision loss or blurring of vision, did you have:

- ⊗ Double vision? (If “yes,” probe to ensure that the participant saw two objects side by side or one on top of the other. If not, go on.)
- ⊗ Vision loss in right eye only?
- ⊗ Vision loss in left eye only?
- ⊗ Total vision loss in both eyes?
- ⊗ Trouble in both eyes seeing to the right?
- ⊗ Trouble in both eyes seeing to the left?
- ⊗ Trouble in both eyes seeing to both sides or straight ahead?
- ⊗ None of the above

Read responses until a positive response is given. Record only the first symptom reported by the participant (i.e., one response). Do not read additional choices. If no choice is applicable, record as “none of the above.”

Sudden Paralysis or Weakness

(Question 49) When you had your episode, did you have any sudden paralysis or weakness on one side of your body, including your face, arm or leg?

“Your episode” refers to the stroke/mini-stroke/TIA experience associated with this investigation.

Emphasize *sudden* paralysis or weakness. Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to Question 62. If response is “Yes,” informally ask whether this happened more than once and, if so, ask him/her to focus on the one a physician diagnosed or else the worst..

(Question 50) Did the paralysis or weakness symptoms last longer than 24 hours?

Be sure the participant realizes that “symptoms” refers only to the sudden paralysis or weakness. Other symptoms the participant may have experienced are discussed in other sections of the form.

Record response. Record “Don’t Know” as “No.”

(Question 51) Did the paralysis or weakness come on suddenly?

Record response. Record “Don’t Know” as “No.”

(Question 52) During the paralysis or weakness, which part or parts of your body were affected?

Read responses. Record “yes” or “no” for each.

(Question 53) During this experience of paralysis or weakness, did the paralysis or weakness start in one part of your body and spread to another, or did it stay in the same place?

Record one response.

(Questions 54-61) While you were experiencing this paralysis or weakness, did any of the following occur?

(Mark “Yes” for each symptom that applies.)

While asking the participant/proxy Questions 54-61, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing paralysis or weakness.

(Question 54) Speech disturbance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 55a) Numbness or tingling?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “no,” skip to Question 56.

(Question 55b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 55a (i.e., numbness/tingling). Record one response.

(Question 56) Lightheadedness, dizziness, or loss of balance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 57) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 58) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 59) Headache?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 60) Pain in the weak arm, leg or face?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

(Question 61a) Vision loss or blurring of vision?

Mark “Yes” if participant reports having this symptom. Mark “No” if not.

If response is “No,” skip to Question 62.

(Question 61b) During this vision loss or blurring of vision, did you have:

- ⊗ Double vision? (If “yes,” probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble.)
- ⊗ Vision loss in right eye only?
- ⊗ Vision loss in left eye only?
- ⊗ Total vision loss in both eyes?
- ⊗ Trouble in both eyes seeing to the right?
- ⊗ Trouble in both eyes seeing to the left?
- ⊗ Trouble in both eyes seeing to both sides or straight ahead?
- ⊗ None of the above

Read responses until a positive response is given. Record only the first symptom reported by the participant (i.e. one response). Do not read additional choices. If no choice is applicable, record as “none of the above.”

Dizziness or Loss of Balance

(Question 62) When you had your episode, did you have any sudden spells of dizziness, loss of balance or sensation of spinning?

“Your episode” refers to the stroke/mini-stroke/TIA experience associated with this investigation.

Emphasize *sudden* dizziness or loss of balance. Record response. Record “Don’t Know” as “No.”

If response is “No,” skip to end of questionnaire. If response is “Yes,” informally ask whether this happened more than once and, if so, ask him/her to focus on the one a physician diagnosed or else the worst.

(Question 63) Did the dizziness or loss of balance last longer than 24 hours?

Be sure the participant realizes at this point “symptoms” refers only to the sudden dizziness or loss of balance. Other symptoms the participant may have experienced are discussed in other sections of the form.

Record response. Record “Don’t Know” as “No.”

(Question 64) Did the dizziness, loss of balance, or spinning sensation occur only when changing the position of your head?

Record response. Record “Don’t Know” as “No.”

If response is “yes,” skip to end of questionnaire.

(Question 65) Did the dizziness, loss of balance, or spinning sensation come on suddenly?

Record response. Record “Don’t Know” as “No.”

(Questions 66-72) While you were experiencing this dizziness, loss of balance, or spinning sensation, did any of the following occur:

(Mark “Yes” for each symptom that applies.

While asking the participant/proxy Questions 66-72, you may need to remind him/her that the responses concern *only* the period when the participant was experiencing dizziness, loss of balance, or spinning sensation.

(Question 66) Speech disturbance?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 67a) Paralysis or weakness?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” go to Question 68a.

(Question 67b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 67a (i.e., paralysis/weakness).

Record one response.

(Question 68a) Numbness or tingling?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” go to Question 69.

(Question 68b) Did you have this difficulty on (right side only, left side only, both sides)?

Read responses to participant. “Difficulty” refers to Question 68a (i.e., numbness/tingling).

Record one response.

(Question 69) Blackouts or fainting?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 70) Seizures or convulsions?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 71) Headaches?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

(Question 72a) Vision loss or blurring of vision?

Mark “Yes” if participant reports having this symptom. Mark “No” if not. Record “Don’t Know” as “No.”

If response is “No,” skip to end of questionnaire.

(Question 72b) During this vision loss or blurring of vision, did you have:

- ⊗ Double vision? (If “yes,” probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble.)
- ⊗ Vision loss in right eye only?

- ⊗ Vision loss in left eye only?
- ⊗ Total vision loss in both eyes?
- ⊗ Trouble in both eyes seeing to the right?
- ⊗ Trouble in both eyes seeing to the left?
- ⊗ Trouble in both eyes seeing to both sides or straight ahead?
- ⊗ None of the above

Read responses until a positive response is given. Record only the first symptom reported by the participant (i.e. one response). Do not read additional choices. If no choice is applicable, record as “none of the above.”

(Question 73) What is your reliability rating of the interview?)

Immediately after completing the interview, record your assessment of the informant’s reliability:

- Select **Good** when it is your opinion that the interview provided accurate and complete information to be used in evaluating the participant’s
- Select **Fair** when it is your opinion that the interview provided reasonably accurate and reasonably complete information to be used in evaluating the participant’s symptoms.
- Select **Poor** when it is your opinion that the interview did not provide accurate or complete information to be used in evaluating the participant’s.

Write any comments about the interview in the “Notes” section. Notes recorded in the small box will be saved in the MESA database. However, any notes written on the lines provided are not recorded in the database and thus are for Field Center paper copy use only. If you would like to write an extra message to be seen by the Coordinating Center and/or the Physician Reviewers, you may put it in the “Investigation Notes” section in the Events software for this investigation.

D.12.3 Action Required When Form is Complete

Review the form for completeness and accuracy. Record in the administrative box on the last page of the form whether the *Interview for Stroke/TIA Symptoms* form was administered to the MESA participant who reported the stroke or to the proxy. Fill in the appropriate response bubble.

Enter your Interviewer ID and the date of the interview in the boxes at the bottom of the final page of the form.

In the “Sequence ID” field on the upper right corner of page 1, enter the sequence

number appropriate to this form. The “Sequence ID” (not to be confused with the last two digits of the Investigation ID) is determined by number of a particular form completed for a given event. If this is the first *Interview for Stroke/TIA Symptoms* sent for this investigation, the Sequence ID is “01”; the second (if any) *Interview for Stroke/TIA Symptoms* sent for this investigation is Sequence ID “02,” etc. The Sequence ID is necessary to distinguish each *Interview for Stroke/TIA Symptoms* sent as a unique form within the MESA database.

Submit the form for data entry.

Multi-Ethnic Study of Atherosclerosis



Interview for Stroke/TIA Symptoms

Participant ID: 8000028 02

Introduction: You reported to us that you had either a stroke, a small stroke, or a transient ischemic attack, also called a TIA, on about [specify date]. We are interested in possible stroke or TIA symptoms you may have had related to that experience. You may have had one or more episodes during that experience, but I would like you to respond for the episode in which a doctor diagnosed a stroke or TIA, or otherwise the worst episode. [NOTE: If participant asks, "worst" can be defined in terms of severity, intensity, or association with other symptoms.]

Sudden Loss or Change of Speech

1. When you had your episode, did you have any sudden loss or changes in speech?

- Yes No

If "No," skip to question 12.

2. Did the change or loss last at least 24 hours?

- Yes No

3. Did the change or loss come on suddenly?

- Yes No

4. Do any of the following describe your change or loss in speech? (Read responses.)

- | | Yes | No |
|--|-----------------------|-----------------------|
| Slurred speech like you were drunk | <input type="radio"/> | <input type="radio"/> |
| Could talk but the wrong words came out | <input type="radio"/> | <input type="radio"/> |
| Knew what you wanted to say but the words would not come out | <input type="radio"/> | <input type="radio"/> |
| Could not think of the right words | <input type="radio"/> | <input type="radio"/> |

Symptoms During Speech Disturbance

While you were experiencing this change in speech, did any of the following occur? (Mark "Yes" for each symptom that applies.)

5a. Numbness or tingling?

- Yes No

If "No," go to Question 6a.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

6a. Paralysis or weakness?

- Yes No

If "No," go to Question 7.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

7. Lightheadedness, dizziness, or loss of balance?

- Yes No

8. Blackouts or fainting?

- Yes No

9. Seizures or convulsions?

- Yes No

10. Headache?

- Yes No

11a. Vision loss or blurring of vision?

- Yes No

If "No," go to Question 12.

b. During this vision loss or blurring of vision, did you have: (Read responses until a positive response is given.)

- Double vision (If yes, probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble)
 Vision loss in right eye only
 Vision loss in left eye only
 Total loss of vision in both eyes
 Trouble in both eyes seeing to the right
 Trouble in both eyes seeing to the left
 Trouble in both eyes seeing to both sides or straight ahead
 None of the above

Stroke/TIA Interview (Page 2)

8000028 02

Sudden Loss of Vision

12. When you had your episode, did you have any sudden loss or blurring of vision, complete or partial?

- Yes
- No

If "No" skip to Question 24.

13. Did the visual symptoms last at least 24 hours?

- Yes
- No

14. Did the visual symptoms come on suddenly?

- Yes
- No

15a. During this episode, which of the following parts of your vision were affected? (Read responses.)

- Only the right eye
- Only the left eye
- Both eyes

If only right or left eye, go to Question 16.

b. Did you have: (Read choices until a positive response is given.)

- Trouble seeing to the right side but not the left
- Trouble seeing to the left side but not the right
- Trouble seeing to both sides or straight ahead
- Other:
- None of the above

Symptoms During Sudden Vision Loss

While you were experiencing this loss of vision, did any of the following occur: (Mark "Yes" for each symptom that applies.)

16. Speech disturbance?

- Yes
- No

17a. Numbness or tingling?

- Yes
- No

If "No," go to Question 18a

b. Did you have this difficulty on: (Read responses.)

- The right side only
- The left side only
- Both sides

18a. Paralysis or weakness?

- Yes
- No

If "No," go to Question 19.

b. Did you have this difficulty on: (Read responses.)

- The right side only
- The left side only
- Both sides

19. Lightheadedness, dizziness, or loss of balance?

- Yes
- No

20. Blackouts or fainting?

- Yes
- No

21. Seizures or convulsions?

- Yes
- No

22. Headache?

- Yes
- No

23. Flashing lights?

- Yes
- No

Sudden Double Vision

24. When you had your episode, did you have a sudden spell of double vision; that is, did you see two objects side by side, or one on top of the other?

- Yes
- No

If "No", go to Question 35.

25. Did the double vision symptoms last at least 24 hours?

- Yes
- No

26. If you closed one eye, did the double vision go away?

- Yes
- No

If "No," go to Question 35.

27. Did the double vision come on suddenly?

- Yes
- No

Symptoms During Sudden Double Vision

While you were experiencing double vision, did any of the following occur? (Mark "Yes" for each symptom that applies.)

28. Speech disturbance?

- Yes
- No

Stroke/TIA Interview (Page 3)

8000028 02

29a. Numbness or tingling?

- Yes No

If "No," go to Question 30a.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

30a. Paralysis or weakness?

- Yes No

If "No," go to Question 31.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

31. Lightheadedness, dizziness, or loss of balance?

- Yes No

32. Blackouts or fainting?

- Yes No

33. Seizures or convulsions?

- Yes No

34. Headache?

- Yes No

Sudden Numbness or Tingling

35. When you had your episode, did you have sudden numbness, tingling, or loss of feeling in one side of your body, including your face, arm or leg?

- Yes No

If "No," go to Question 49.

36. Did the numbness or loss of feeling last at least 24 hours?

- Yes No

37. Did the feeling of numbness or tingling occur only when you kept your arms or legs in a certain position?

- Yes No

If "Yes," go to Question 49.

38. Did the feeling come on suddenly?

- Yes No

Symptoms During Sudden Numbness or Tingling

39. During the numbness or tingling, which part or parts of your body were affected? (Read responses.)

	Yes	No
Left arm or hand	<input type="radio"/>	<input type="radio"/>
Left leg or foot	<input type="radio"/>	<input type="radio"/>
Left side of face	<input type="radio"/>	<input type="radio"/>
Right arm or hand	<input type="radio"/>	<input type="radio"/>
Right leg or foot	<input type="radio"/>	<input type="radio"/>
Right side of face	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>

40. When you experienced this numbness or tingling, did the abnormal sensation start in one part of your body and spread to another, or did it stay in the same place?

- In one part and spread to another
 Stayed in one part

While you were experiencing numbness, tingling, or loss of sensation, did any of the following occur?

41. Speech disturbance?

- Yes No

42a. Paralysis or weakness?

- Yes No

If "No," go to Question 43.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

43. Lightheadedness, dizziness, or loss of balance?

- Yes No

44. Blackouts or fainting?

- Yes No

45. Seizures or convulsions?

- Yes No

46. Headache?

- Yes No

47. Pain in the numb or tingling arm, leg or face?

- Yes No

Stroke/TIA Interview (Page 4)

8000028 02

48a. Vision loss or blurring of vision?

- Yes No

If "No," go to Question 49.

b. During this vision loss or blurring of vision, did you have: (Read responses until a positive response is given.)

- Double vision (If yes, probe to ensure that the participant saw two objects side by side or one on top of the other. If not, go on.)
- Vision loss in right eye only
- Vision loss in left eye only
- Total loss of vision in both eyes
- Trouble in both eyes seeing to the right
- Trouble in both eyes seeing to the left
- Trouble in both eyes seeing to both sides or straight ahead
- None of the above

Sudden Paralysis or Weakness

49. When you had your episode, did you have any sudden paralysis or weakness on one side of your body, including your face, arm or leg?

- Yes No

If "No," go to Question 62.

50. Did the paralysis or weakness last at least 24 hours?

- Yes No

51. Did the paralysis or weakness come on suddenly?

- Yes No

52. During the paralysis or weakness, which part or parts of your body were affected? (Read responses.)

	Yes	No
Left arm or hand	<input type="radio"/>	<input type="radio"/>
Left leg or foot	<input type="radio"/>	<input type="radio"/>
Left side of face	<input type="radio"/>	<input type="radio"/>
Right arm or hand	<input type="radio"/>	<input type="radio"/>
Right leg or foot	<input type="radio"/>	<input type="radio"/>
Right side of face	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>

53. During this experience of paralysis or weakness, did the paralysis or weakness start in one part of your body and spread to another, or did it stay in the same place?

- In one part and spread to another
- Stayed in one part

While you were experiencing this paralysis or weakness, did any of the following occur: (Mark "Yes" for each symptom that applies.)

54. Speech disturbance?

- Yes No

55a. Numbness or tingling?

- Yes No

If "No," go to Question 56.

b. Did you have this difficulty on: (Read responses.)

- The right side only
- The left side only
- Both sides

56. Lightheadedness, dizziness, or loss of balance?

- Yes No

57. Blackouts or fainting?

- Yes No

58. Seizures or convulsions?

- Yes No

59. Headache?

- Yes No

60. Pain in the weak arm, leg or face?

- Yes No

61a. Vision loss or blurring of vision?

- Yes No

If "No," go to Question 62.

b. During this vision loss or blurring of vision, did you have: (Read responses until a positive response is given.)

- Double vision (If yes, probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble.)
- Vision loss in right eye only
- Vision loss in left eye only
- Total loss of vision in both eyes
- Trouble in both eyes seeing to the right
- Trouble in both eyes seeing to the left
- Trouble in both eyes seeing to both sides or straight ahead
- None of the above

Stroke/TIA Interview (Page 5)

8000028 02

Dizziness or Loss of Balance

62. When you had your episode, did you have any sudden spells of dizziness, loss of balance or sensation of spinning?

- Yes No

If "No," go to End.

63. Did the dizziness or loss of balance last at least 24 hours?

- Yes No

64. Did the dizziness, loss of balance, or spinning sensation occur only when changing the position of your head?

- Yes No

If "Yes," go to End.

65. Did the dizziness, loss of balance, or spinning sensation come on suddenly?

- Yes No

Symptoms During Dizziness or Loss of Balance

While you were experiencing this dizziness, loss of balance, or spinning sensation, did any of the following occur: (Mark "Yes" for each symptom that applies.)

66. Speech disturbance?

- Yes No

67a. Paralysis or weakness?

- Yes No

If "No," go to Question 68a.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

68a. Numbness or tingling?

- Yes No

If "No," go to Question 69.

b. Did you have this difficulty on: (Read responses.)

- The right side only
 The left side only
 Both sides

69. Blackouts or fainting?

- Yes No

70. Seizures or convulsions?

- Yes No

71. Headache?

- Yes No

72a. Vision loss or blurring of vision?

- Yes No

If "No," go to End.

b. During this vision loss or blurring of vision, did you have: (Read responses until a positive response is given.)

- Double vision (If yes, probe to ensure that the participant saw two objects side by side or one on top of the other. If not, do not mark this bubble.)
 Vision loss in right eye only
 Vision loss in left eye only
 Total loss of vision in both eyes
 Trouble in both eyes seeing to the right
 Trouble in both eyes seeing to the left
 Trouble in both eyes seeing to both sides or straight ahead
 None of the above

End:

Thank you very much for taking the time to talk with us. Please remember to contact us should there be any change in your health in the future.

(Interviewer: continue to page 6 to complete reliability question, record any relevant notes, and insert date and ID.)

Stroke/TIA Interview (Page 6)

8000028 02

Reliability

73. What is your rating of the interview's reliability?

- Good
- Fair
- Poor

Notes

Notes in box are saved in MESA database. Notes on lines below are for Field Center paper copy use only.

For Administrative Use Only:

Interview Administered to:

- Participant
- Proxy (if participant is unable)

Interviewer ID:

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Data Entry ID:

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Date:

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 /

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Month Day Year

D.13 Narrative for Stroke/TIA

D.13.1 Introduction

The purpose of the *Stroke/TIA Narrative* is to obtain additional details about a potential stroke or TIA event in cases where other available documentation (e.g., hospital records, physician questionnaires, etc.) does not provide sufficient data to decisively classify the event. The information provided in the narrative is meant to supplement data already collected and, ideally, contribute sufficient facts to make a final classification of the event. More than one narrative may be submitted.

The *Stroke/TIA Narrative* is a required form for out-of-hospital stroke/TIA deaths and an optional (“if needed”) form for hospitalized stroke/TIA deaths. In addition, for out-of-hospital non-fatal stroke/TIA events, the *Stroke/TIA Narrative* form may be administered to a proxy if the participant him/herself is incapacitated and unable to respond to the *Interview for Stroke/TIA Symptoms* form. The *Stroke/TIA Narrative* may also be completed as an addition to the *Interview for Stroke/TIA Symptoms* if the events staff believes narrative information is necessary to complete the picture begun by the *Interview for Stroke/TIA Symptoms*. When the *Stroke/TIA Narrative* is optional, it can be used if events staff feels the collected medical records are incomplete or inconsistent and the investigation/ classification process would benefit from the additional information an interview might provide.

D.13.2 The Narrative

To begin the interview and obtain the narrative, read the following script, “filling in the blanks” with the appropriate field center location, event type and date.

We are calling today from the MESA Clinical Center at (your Field Center). We understand that the participant/you had a diagnosis of (stroke/TIA) on (date). To help us complete our records, could you please tell us more about this? For example: What was the participant/were you doing when symptoms started? What were the participant’s/your symptoms? How long did they last? What happened? Did you see a physician? What was done? Please describe what happened in your own words.

Be sure narrative describes symptoms associated with the date tied to this particular investigation (not a different investigation). Probe for details regarding symptoms and their duration.

If the interview is with a proxy, modify the questions as appropriate (e.g., “What was **your husband** doing when the symptoms started?”).

Record the details of the event as related by the participant or proxy. The dialogue does not need to be recorded verbatim. It is recommended to record the conversation on a blank piece of paper, and then transcribe a coherent summary of the conversation onto the form after the phone call is complete. Make sure to note with whom the interview was conducted and his/her relation to the participant. If the interview is too long for one

page, you may write on a second form or a blank piece of paper.

Allow the participant/proxy to speak freely, but if s/he starts to stray from providing details about the event under discussion, attempt to re-focus the interview on the points asked about in the opening script. (See Appendix C.1, General Interviewing Instructions, for more information on general interview techniques.)

Probe for details about symptoms and their duration if the interviewee does not provide these. **If, during the course of the narrative, the participant/proxy does not offer information about _____, specifically ask for this.**

When the participant/proxy has completed the narrative, ask if s/he has any questions or additional details to offer. Close the interview by thanking the participant/proxy for his/her time and reiterating how the success of MESA depends on the cooperation of people like him/her.

D.13.3 Other Form Information

Record the date the interview was completed and your Interviewer ID. If needed, the interview text may be put onto another form. In this case, make sure to mark the page number in the text of the narrative, as well as on the label for the document. If more than one *Stroke/TIA Narrative* is administered (i.e., to multiple people), remember that each page number must be unique on the label.

NOTE: Although this form looks like a Teleform, it is scanned in as a NON-Teleform. The interview will be transmitted to the Coordinating Center as an image. It is important that the handwriting (or typing) be legible, because there will be no chance to verify the text on this form. The narrative does not need to be transcribed onto the provided form. It may also be written/typed on a blank piece of paper. As long as the label is affixed in the correct location and is properly completed with the STKNAR document code, the narrative will scan.

D.13.4 Action Required After Form is Complete

Determine if any additional follow-up is needed. For example, if the participant/proxy identified a previously unknown physician who treated the participant, it may be appropriate to request records from that physician. Or the interviewee may identify a proxy (or additional proxy) who can provide additional details about the event, and you may decide to conduct an additional *Stroke/TIA Narrative* with this person. If the participant was unclear, consider interviewing the spouse or a proxy. Send additional forms or make additional calls as needed.

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Page Num

STKNAR

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Stroke/TIA Narrative

This form should be (1) administered to a proxy if a participant has an out-of-hospital fatal stroke or an out-of-hospital non-fatal stroke that leaves the participant incapacitated and unable to complete the Stroke Interview -OR- (2) administered to the participant when there is insufficient information from hospital, physician or other records/forms to classify the cerebrovascular event. The purpose is to obtain a narrative of events surrounding the event to supplement data already collected.

We are calling today from the MESA Clinical Center at (). We understand that the participant/you had a diagnosis of stroke/TIA on (date). To help us complete our records, could you please tell us more about this? For example: What was the participant/were you doing when symptoms started? What were the participant's/your symptoms? How long did they last? What happened? Did the participant/you see a physician? What was done? Please describe what happened in your own words.

Be sure narrative describes symptoms associated with the date tied to this particular investigation (not a different investigation). Probe for details regarding symptoms and their duration.

Narrative: _____

_____/_____/_____
Month Day Year

Interviewer ID:

D.14 Final Notice of Event/Death Form

D.14.1 General Information

The *Final Notice of Event/Death* summarizes the data collection activities in the (full or partial) investigation of all nonfatal events and deaths. A *Final Notice of Event/Death* should be completed for ALL (i.e., eligible and ineligible) MESA investigations that have been initiated (note the one exception stated below). The *Final Notice of Event/Death* serves to “close out” the event by notifying the Coordinating Center that no further data is expected for this case and that the event is ready to be reviewed for classification by a MESA Physician Reviewer. **This form should NOT be entered until all documentation for this investigation has been de-identified and scanned into the EDC. If an investigation contains both cardiac and stroke elements, all abstraction, data entry, redaction, and scanning associated with both areas must be done before the *Final* is entered.**

NOTE: The only exception to the above instructions is if the investigation is deleted. **Investigations should only be deleted when it is determined that the reported event is a duplicate to an earlier reported event, or the event was initiated in error.**

The Field Center is expected to have finished its investigation (obtained, de-identified, abstracted, entered, and scanned all relevant records) within 90 days of the date the *Initial Notification* is entered. The Field Center’s completion of an investigation will be signaled by the entry of the *Final Notice* into the EDC. The *Final Notice* should not be entered until the investigation is complete and the Field Center is ready for the Event to proceed to review or if ineligible for review, to be closed. These timeframes will be used by the Coordinating Center to produce monthly reports in order to aid the Field Centers in the timely completion of eligible investigations.

D.14.2 Item-by-Item Instructions

(Question 1) Date of Event

Record the date of the nonfatal event or death. Do not enter an estimated date. By this point in the investigation, an exact date should always be available – through a hospital discharge summary, physician questionnaire, death certificate, etc. Enter the correct date even if it is different than the date as it appeared on the *Initial Notification of Potential Event/Death* form.

The order of priority for dating the event is as follows:

1. Death
2. Admission Date
3. Date of outpatient event:
 - a. office/clinic visit
 - b. procedure date

NOTE: If there are multiple events contained in the same investigation, then the highest priority date will be the “event date” for that investigation. For example, if a participant was hospitalized for an MI and died several days later, the “event date” for that investigation would be the death date.

(Question 2) Type of Event

Select the type of event(s) contained in this investigation. Select all applicable, non-contradictory, categories. For example, if the participant experienced both a myocardial infarction (MI) and a stroke, was hospitalized, and did not die, you would select both “Hospitalized Cardiac/PVD Nonfatal” and “Hospitalized Cerebrovascular Nonfatal.” The type(s) of event indicated here determines what documentation is ultimately required for this investigation. If you need assistance determining what type of events are a part of this investigation, please consult either your Lead Abstractor or the Physician Reviewer for your Field Center.

Select “Other/Ineligible” only if none of the above eight eligible event categories is applicable. Selecting “Other/Ineligible” indicates that the investigation contains no events that are eligible for Review. [See below for more detailed instructions.] You still need to complete the “Form Status” section of this form for ineligible events.

NOTE: Events cannot be both non-fatal and fatal. If a death occurred, the event is fatal, either cardiac, stroke, or combination. If the death is recorded on the death certificate as occurring in-hospital, it is a hospitalized fatal event.

NOTE: Events cannot be both eligible and ineligible. If the hospital-provided ICD codes indicate an eligible event, even if the death certificate codes do not, or vice versa, select the appropriate type of event as indicated by the hospital/death certificate codes.

Other / Ineligible Event

If you have entered “Other/Ineligible” for Question 2 (type of event), select the appropriate option corresponding to the type of ineligible event as determined by your investigation. You may only select one of these options.

The possible types of ineligible events are:

Event Type	Reason for Ineligibility
Non-CVD nonfatal event	The participant has experienced a hospitalization or other event that does not involve any endpoints of interest to MESA. This category includes non-CVD/PAD/stroke elective surgery, and other non-CVD/PAD/stroke illnesses. For hospitalized events this category is determined by the answers to Questions 10.a through 10.d. of the Eligibility form.
Non-CVD death	The participant has died through a clearly non-CVD/PAD/stroke cause (e.g., cancer, auto accident) and there are no eligible codes found in the hospitalization record or death certificate.

Insufficient Data To Classify*	This category is reserved for cases where the Field Center truly could not obtain enough information to assess the event. The most likely reason for this would be if the medical records are unobtainable. Reasonable efforts should be made to obtain information on events.
Not an Event	<p>This category is reserved for when nothing actually happened. For example, the Field Center can find no documentation that an event of interest occurred. This is most likely to be the correct selection if the care facility is contacted, but cannot find any record of the participant being there around that time period.</p> <p>This category should also be used for instances where there was a negative cardiac procedure with no cardiac diagnosis (ex/ETT, Echo)</p> <p>An ER visit without admission or eligible (OOH) findings is a non-event.</p>

NOTE: If an investigation cannot be completed because it lacks written participant/proxy consent to release medical records or a signed, dated HIPAA authorization, then the field center should make a thorough effort to obtain the consent/authorization. Over a six-week period, multiple attempts should be made to contact the ppt/proxy on different days of the week and at varying times of the day. If contact has still not been made, then the *Final* may be submitted marked “Insufficient Data To Classify” and a comment about the lack of consent/authorization should be included in the “Investigation Notes” section of the EDC.

Forms Status

The purpose of this section is to record which forms/documents and the numbers of reports and pages were scanned into the EDC database. In the case of eligible events, the Final Notice also serves to act as an index of available documents for review, as recorded from the Event Coversheet.

Procedures for Ineligible Events

Field centers will process ineligible events. All Ineligible Event types will include an “Event Eligibility Form” abstraction and a “Final Notice” form.

Even though these events will not be reviewed, please obtain discharge summaries, or the last physician’s progress note when no discharge summary was written, for all hospitalized events. These documents should be labeled, de-identified and scanned. No coversheet is necessary for these events. If the field center Events staff has not scanned all discharge summaries, it should retroactively scan them as soon as possible, notifying the CC of the addition to the EDC record.

Procedures for Eligible Events

Events that are eligible for review by the MESA Physician Reviewers should be fully documented. The physicians need to be able to re-create what happened through records and notes that you submit. It is important to submit enough information so that the reviewing physician can follow what occurred. The Central Abstractor is responsible for abstracting the medical records and selecting which records will be retained for review, so she should receive all the documents pertinent to the particular eligible event – cardiac, PAD/PVD, or stroke/TIA.

Following abstraction, the Central Abstractor will delete from the Event PDF file any documents deemed unnecessary for physician review. She will then complete the Event Coversheet section titled “Notes for Field Center” as a guide for the data entry of the Final Notice, and will notify the Field Center that the Event is ready for de-identification, if necessary, and Final Notice completion.

Final Notice Data Entry

The documents submitted for review are listed by category on the coversheet and will be transferred directly to the same form categories on the Final Notice form. You may mark any document submitted, regardless of what type of event it falls under, but mark the particular type only once. For example, if the event is both cardiac and stroke eligible, mark “ECHO” only once, either for the cardiac portion or the stroke portion, not both.

Form Status Categories

Hospitalizations:

- **Discharge Summary (acronym: DISSUM):** The final summary of the events of the hospital stay. Included here could also be the Last Physician’s Progress Note if used as a discharge summary, and the Death Summary.

For long admissions, there may be one or more Interim Discharge Summaries. Treat these as PHYNOT’s, CARNOT’s, or CVNOT’s as appropriate.

- **History and Physical (HISPHY):** This is the admitting physician’s assessment of the patient’s past medical history, description of presenting/admitting complaint/illness, current status, physical assessment, and treatment plan. Included here is the pre-procedure/pre-operative history and physical done as an out-patient prior to an elective admission.

Cardiac Documents:

- **ECG Tracing (ECG):** 12-lead electrocardiogram tracing images. Do not include rhythm strips from cardiac monitors, pacemakers, Holter monitors, loop recorders, or stress test ecgs.

(If no tracing images were obtained, but narrative reports are available, treat the documents as if they were tracings and leave a note in the investigative notes noting that tracings were not available/received.)

- **Cardiac Cath Report (CATH):** The report from a left or right heart catheterization that includes angiography, arteriography, digital subtraction angiography, digital cardiac angiography, or contrast ventriculography, but not an intervention/revascularization such as angioplasty, stent, or atherectomy
- **ETT/Stress Test Report (ETT):** These tests may be exercise (treadmill or Bruce protocol) or pharmacological (drugs), with or without imaging, and with or without nuclear dye injection. See Appendix D.5.5.3 for examples and definitions.
- **MUGA/Other Heart Scan (MUGA):** Radionuclide ventriculogram (RVG or RNV), also called radionuclide ventriculography cardiac blood pooling imaging, nuclear heart scan, multi-gated acquisition (MUGA), heart scan, thallium scan,

infarct scan, PET scan, Ejection Fraction imaging (EF), or SPECT.

- **Chest X-Ray Report (CXR)**
- **MRI of Heart Report (MRICAR):** Cardiac magnetic resonance imaging
- **Echocardiography (ECHO):** Also known as cardiac ultrasound, cardiac sonogram, stress echo, TTE (transthoracic echocardiogram), TEE (transesophageal echocardiogram.)
- **PTCA/Angioplasty Report (PTCA):** Includes interventions to revascularize stenosed and occluded coronary arteries: Percutaneous transluminal coronary angioplasty (PTCA), balloon angioplasty, balloon dilation, and coronary stent placement. Also includes atherectomy, coronary endarterectomy, and Rotablator.

This procedure is always preceded by a catheterization and angiography, which are recorded under “Cath.”
- **CABG/Other Ops Reports (CABG):** Coronary bypass grafting, as well as cardiac valve replacement, AAA repair, aortic dissection repair, septoplasty, intra-aortic balloon pumps (IABP), counter-pulsation pumps, left, right, or bi-ventricular assist devices (LVAD, RVAD, BiVAD), pacemaker/AICD (automatic implantable cardioverter defibrillator) implantation, radio-frequency ablation, MAZE procedures, and others.
- **Cardiac Consult Notes (CARNOT):** Include all notes/reports written by cardiologists. All other physician notes/consults, except neurology (CVNOT) should be considered Physician Notes.
- **Doppler of Leg Arteries (DOPLEG):** Also called Doppler ultrasound, PVR waveform – for lower extremity arteries *only*. Include ABI (Ankle-Brachial-Arm) summaries.
- **Angiogram/Angioplasty of Leg (ANGIO):** Also arteriography.
- **Leg Operation Notes (LEGOP):** Includes amputation, arterial bypass, arterial thrombectomy
- **Ultrasound/CT/MRI of Abdomen (ABDFLM):** Includes procedures done for the investigation of the presence/severity of abdominal aorta aneurysms *only*.
- **Ultrasound/CT/MRI of Chest (CFLM)**
- **Enzyme Report (ENZ):** Laboratory or other reports of cardiac enzymes only: **Troponin** (I or T), **CK** (creatinine kinase, CPK, creatine phosphokinase), **CKMB** (creatine kinase myocardial band, CPK-MB, CK-heart fraction), **LDH** (lactate dehydrogenase, LD, LDH 1, and LDH2 fractions), **MYOGLOBIN**

No other blood tests, cultures, or pathology reports are scanned for cardiac review.

Death Documents:

- **Autopsy Report (AUTOPS):** May be found as part of the hospital record, but may need to be ordered from the County Coroner’s (Medical Examiner’s) office

if indicated in the hospital record or death certificate.

- **Coroner/ME (Medical Examiner) Report (CORME):** May be requested from the County Coroner's (Medical Examiner's) office.
- **Death Certificate (DCERT):** Request from the appropriate State Department records, including the ICD-10-CM death codes.

Cerebrovascular Documents:

- **CT of Head Report (CT):** Computed Tomography
- **MRI of Head Report (MRICV):** Magnetic resonance imaging
- **Lumbar Puncture Report (LUMBAR):** Also called spinal tap or LP. Results may be found in laboratory reports
- **TCD (Transcranial Doppler) Report (TCD):** Also called brain ultrasound or sonogram.
- **Carotid Ultrasound Report (CARUT):** Also called carotid duplex.
- **Cerebral Angiogram (CVANG):** Also angiography, arteriography; cerebral, vertebral, or carotid angiogram; angiogram of the head or brain, by CT, MR or conventional means
- **Echocardiography Report (ECHO):** Also known as cardiac ultrasound, cardiac sonogram, TTE (transthoracic echocardiogram), TEE (transesophageal echocardiogram.)
- **Neurology Consultation Notes (CVNOT):** Include all notes/reports written by neurologists. All other physician notes/consults, except cardiology (CARNOT) should be considered Physician Notes.
- **Endarterectomy (ENDART)**
- **Craniotomy (CRANIO)**
- **Skull X-Ray (SKLXR)**
- **Cerebrovascular Operation Report (CVOP)**

Out-of-Hospital Documents:

NOTE: Emergency room, EMS, and Physician progress note documents will be collected for in-patient stays as well.

- **Emergency Room/Ambulance (ER):** Include ER (ED) Physician Notes, Procedures, and Laboratory Reports, EMS/EMT Notes including 12-Lead ECGs.
- **Physician/Office Notes (PHYNOT):** Include clinic, same-day procedure notes/summaries, care facility progress notes, and hospice notes.

Record Cardiology consults/progress notes as (CARNOT) and Neurology consults/notes as (CVNOT).

- **PQ for Cardiac/Peripheral Arterial/Vascular Disease**

- PQ for Stroke/TIA
- PQ for Cardiac Death

Interview Documents:

- Informant Interview (Death) (INFINT)
- Interview – Stroke/TIA (STKINT)
- Interview – Cardiac/Peripheral Arterial/Vascular Disease (CARINT)
- Narrative – Stroke/TIA (STKNAR)

Other Documents (OTH): Include documents which don't fit the above categories, but will be informative and helpful for Physician review. These might include PMR/OT/PT/Rehab/Speech Assessments, EEG reports, etc.

Total Documents: This is how many reports or sets of reports, you are submitting as documentation. For example, if a participant had two cardiac catheterizations you will mark '02' in the first column. (Remember to write in the leading zero.)

Total Pages: Record the total number of pages of the indicated documents. (Remember to write in the leading zero.)

Scanned: This column is to be marked if that document has been scanned

NOTE: In order to properly record documentation on the *Final Notice* you must complete the first two columns on the form.

Investigation Notes

If anything needs further explanation, write your comments in the 'Investigation Notes' box in the EDC. This field should be used to fill in any holes in the rest of the documentation. For example, if the record indicates ECGs were done, but there are only ECG narratives without the corresponding 12-lead tracing images found in the record, record the lack of images in the Investigative Notes (and scan the narratives). Or, if the only ECHO to be found is a narrative report in the discharge summary, record where that narrative can be found.

If the event might be linked to another event, this is the place to record that information, as well as any clarifying information about a transfer.

D.14.3 Other Form Information

The *Final Notice* is one of the most important forms that you will submit for any investigation. This form indicates to the Coordinating Center and the Physician Reviewers what type of potential events are contained within the investigation, as well as what supporting information is available. If any information pertaining to the investigation changes, the *Final Notice* must be updated as well. **Do NOT submit this form to the Coordinating Center until all abstraction, de-identification, and scanning has been completed.**

D.14.4 Action Required After Form is Complete

After the Final Notice has been submitted, the investigation is completed and is ready to be submitted for closure or review. Be sure that all requests/instructions from the Central Abstractors have been addressed before submitting the Final Notice.

The Review Process will be coordinated through the Coordinating Center. You will only be involved if the Coordinating Center or your Local Reviewer has any questions regarding the investigation documentation.

Multi-Ethnic Study of Atherosclerosis



Final Notice of Event/Death

Participant ID: 8000028 02

1. Date of event:

		/			/			
Month			Day			Year		

2. Type of event: (check all that apply)
- Hospitalized Cardiac/PVD non-fatal
 - Hospitalized Cardiac death
 - Hospitalized Cerebrovascular non-fatal
 - Hospitalized Cerebrovascular death
 - Out-of-hospital Cardiac/PVD non-fatal
 - Out-of-hospital Cardiac death
 - Out-of-hospital Cerebrovascular non-fatal
 - Out-of-hospital Cerebrovascular death

Other/Ineligible

↓

If "Other," specify:

- Prevalent (pre-Baseline) event only
- Non-CVD non-fatal event
- Non-CVD death
- Insufficient data to classify
- Not an event

Forms Status	Total Documents	Total Pages	Scanned
All Potential Events:			
Event Eligibility Form			<input type="radio"/>
Hospitalizations:			
Discharge Summary (Req'd for all hosp. events)	[][]	[][]	<input type="radio"/>
History and Physical (Req'd for hosp. cardiac & neuro events only)	[][]	[][]	<input type="radio"/>

Forms Status	Total Documents	Total Pages	Scanned
Cardiac Documents:			
Hospital Abstraction- Cardiac/PVD	[][]	[][]	<input type="radio"/>
ECG Tracing	[][]	[][]	<input type="radio"/>
Cardiac Cath Report	[][]	[][]	<input type="radio"/>
ETT/Stress Test Report	[][]	[][]	<input type="radio"/>
MUGA/Other Heart Scan	[][]	[][]	<input type="radio"/>
Chest X-Ray Report	[][]	[][]	<input type="radio"/>
MRI of Heart Report	[][]	[][]	<input type="radio"/>
Echocardiography Report	[][]	[][]	<input type="radio"/>
PTCA/Angioplasty Report	[][]	[][]	<input type="radio"/>
CABG/Other Ops Reports	[][]	[][]	<input type="radio"/>
Cardiac Consultation Notes	[][]	[][]	<input type="radio"/>
Doppler of Leg Arteries	[][]	[][]	<input type="radio"/>
Angiogram/Angioplasty of Leg	[][]	[][]	<input type="radio"/>
Leg Operations Notes	[][]	[][]	<input type="radio"/>
Ultrasound/CT/MRI of Abdomen	[][]	[][]	<input type="radio"/>
Ultrasound/CT/MRI of Chest	[][]	[][]	<input type="radio"/>
Enzyme Report	[][]	[][]	<input type="radio"/>

Death Documents	Total Documents	Total Pages	Scanned
Autopsy Report	[][]	[][]	<input type="radio"/>
Coroner/ME Report	[][]	[][]	<input type="radio"/>
Death Certificate	[][]	[][]	<input type="radio"/>

Final Notice of Event/Death (Page 2)

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Cerebrovascular Documents

	<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>		<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>
Stroke Hospital Abstraction	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Echocardiography Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>
CT of Head Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Neuro. Consultation Notes	<input type="text"/>	<input type="text"/>	<input type="radio"/>
MRI of Head Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Endarterectomy	<input type="text"/>	<input type="text"/>	<input type="radio"/>
Lumbar Puncture Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Craniotomy	<input type="text"/>	<input type="text"/>	<input type="radio"/>
TCD Doppler	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Skull X-Ray	<input type="text"/>	<input type="text"/>	<input type="radio"/>
Carotid Ultrasound Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Cerebro. Operation Report	<input type="text"/>	<input type="text"/>	<input type="radio"/>
Cerebral Angiogram	<input type="text"/>	<input type="text"/>	<input type="radio"/>				

Out-of-Hospital Documents

	<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>		<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>
Emergency Room/Ambulance	<input type="text"/>	<input type="text"/>	<input type="radio"/>	PQ for Stroke/TIA	<input type="text"/>	<input type="text"/>	<input type="radio"/>
Physician/Office Notes	<input type="text"/>	<input type="text"/>	<input type="radio"/>	PQ for Cardiac Death	<input type="text"/>	<input type="text"/>	<input type="radio"/>
PQ for Cardiac Disease/PVD	<input type="text"/>	<input type="text"/>	<input type="radio"/>				

Interview Documents

	<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>		<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>
Informant Interview (Death)	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Interview - Cardiac	<input type="text"/>	<input type="text"/>	<input type="radio"/>
Interview - Stroke/TIA	<input type="text"/>	<input type="text"/>	<input type="radio"/>	Narrative-Stroke/TIA	<input type="text"/>	<input type="text"/>	<input type="radio"/>

Other Documents

	<u>Total Documents</u>	<u>Total Pages</u>	<u>Scanned</u>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/>

Abstractor ID
 Date: / /
 Data Entry ID

Month Day Year

D.15 Cardiac/PVD Review

D. 15.1 Introduction

Both the local physician reviewer and/or the central physician reviewer(s) should complete this form for any potential cardiac/pvd event, nonfatal or fatal. In special cases this form may be completed in an M&M committee setting or by a third reviewer.

The Coordinating Center will provide an investigation ‘review packet’ to each reviewer for each investigation that the reviewer is responsible for. Each packet will contain the following items:

- **Coversheet**–This one page sheet will detail the type(s) of events covered in this packet, as well as which review forms need to be completed. If this investigation is being sent to the reviewer because two previous reviewers disagreed about a diagnosis, the coversheet would direct the physician to what portions of the review form need be completed.
- **Summary Report**–This six page report highlights important data pieces that pertain to the investigation at hand.
- **Form Info Sheets**–In addition to the Summary Report, the raw form data are printed out. The reviewer may see the marked response to all questions asked on a teleform.
- **Medical Records**–Copies of hospital/office/clinic notes and procedure reports will be included in the packet. Any other useful documentation provided by the Field Center will be included, as well.
- **Hardcopy of Review Forms**–The review forms that you will be required to fill out online will be provided in hardcopy. It is recommended that the hardcopy be filled out and retained by the reviewer for a month after he/she has submitted the online review forms. Alternately, the reviewer may print out the completed online review form.

It is recommended that the reviewer start by looking at what information is available for the investigation, and then identify what types of events are being examined in the investigation. The types of events are clearly listed at the top of all the Summary Report pages. What information is available is located on the Form Info Sheet for the *Final Notification Form*.

Completing the hardcopy form

NOTE: The Coordinating Center recommends that you complete a hard copy version of the form before you login to the online version. This will avoid any problems with the server timing out, as well as provide you with a hardcopy of what you decided. You may choose, also, to fill out the online form as you review the investigation. You may then print out the completed form to retain in your records.

Whether you are filling out a hardcopy or an online version, you will need the following

items to complete this form:

- The review packet that was sent to you by the Coordinating Center
- Your data entry ID
- Access to the web (only for online entry portion)

Both the hardcopy and the online version of the review form will ask for your data entry ID (which the Coordinating Center will provide) at the end of the form. It is important that you use your own ID, as this will identify which physician reviewed which case. The Coordinating Center will track how many investigations each physician has reviewed and spread the cases out as evenly as possible.

Both the hardcopy version and the online version will already have the participant ID, investigation ID, and type of review marked in advance.

D.15.2 Type of Review

The first thing that you do is confirm the type of review that you are performing. The choices are as follows:

- Local (Field Center Review) – Mark this choice if you are reviewing an investigation from your own Field Center. (If you are not affiliated with a Field Center you will never check this option.)
- Central (other committee member review) – Mark this choice if you are reviewing an investigation as a ‘central’ reviewer. Most investigations that are not from your Field Center will be marked with this choice. For exceptions, see below.
- Final (consensus) – This option may be checked in these circumstances:
 - “Third Reviewer”: You are entering the final decision for a diagnosis that was in dispute. The “Third Reviewer” might be someone other than the two original reviewers, or (more often) it might be the original local or central reviewer who is now entering results after the two reviewers have discussed and resolved their initially conflicting diagnoses. ALL REVIEW FORMS MARKED ‘FINAL’ ARE CONSIDERED PERMANENT. THEY WILL NOT BE CHANGED.
 - The M&M committee decides as a group how to complete the form.

D.15.3 Linked Investigations

The second thing that the reviewer must address on the form is whether to link the current investigation with any other(s) as part of a single, continuous incident. As of February 2004, reviewers will submit a separate review form for each individual investigation even when a participant’s multiple investigations are identified as “linked”-part of a single, continuous incident (e.g., a single CHF or angina experience that spans different investigations). Even though individual reviews are submitted, the reviewer should still use the linking boxes on each review form to list the two-digit Investigation ID of the other linked investigation(s); this information will be stored in the database for reference at the time of analysis and will not substitute for submitting a separate, individual review form for each investigation. Reviewers may add notes in the

“Comments” box to clarify any issue (e.g., that the current CHF endpoint is linked to a preceding event but the current angina endpoint is not).

The Coordinating Center will send to reviewers all investigations within 30 days of another investigation involving the same participant. For example, investigations dated 3/4/03, 3/25/03, and 4/25/03 will all be sent to review together (and only once all records have been gathered for all three). If the reviewer believes the investigations should be linked (see below), then two or more may be linked.

Field Center staff may indicate to the Coordinating Center when they feel that two or more different investigations are representative of the same occurrence of one or more endpoints. If the reviewing physician agrees, then s/he may “link” the investigations together. It is helpful to discern whether linked investigations exist because it is an issue that will affect how endpoint episodes are counted (e.g., whether a participant is said to have had one or two CHF events).

Reviewer disagreements about linking will not be sent to Third Review for resolution. Instead, reviews will be designated as final in the database according to the protocols already in place for reviews without disagreements (local review accepted, unless two central reviews are done, in which case the later review is accepted since it was presumably done with the knowledge of any late developments).

If, during review, you would like to consider linking an investigation to an investigation for which you do not currently have review materials, you may notify the Coordinating Center of your wish and defer your review of the potentially related investigations until you have all necessary materials at hand.

When multiple investigations are sent to you that may be linked, please look over all packets before filling out any review forms.

Example: If you are going to link the first three investigations for participant 9999999, the upper right-hand corner of the page should have ‘01’ marked (b/c you are using the lowest investigation number’s form) and the boxes underneath the header will be filled in with ‘02’ and ‘03’. This will link investigations ‘01’, ‘02’, and ‘03’ together. You will need to complete separate review forms for the ‘02’ and ‘03’ investigations, whose forms should also list the linked events.

D.15.4 Non-endpoint CVD

The next part of the form (directly under the linking area) has two questions about whether the investigation suggests cardiovascular diseases that are not end points for MESA. The first question is intended to allow reviewers to record types of nonacute or nonsymptomatic CVD that do not meet MESA criteria but could cause confusion in the endpoint-specific questions. It should be answered whether or not MESA endpoint events are present in the medical record. Unlike with endpoint questions, any non-endpoint CVD found should be recorded in this question regardless of whether it is prevalent or long-standing. Disagreements between reviewers on non-endpoint CVD will not be adjudicated.

Examples of CVD recorded in the first question include prior PCI (recorded as “Coronary Disease”) and prior heart failure with an EF of 40% (recorded as “ventricular dysfunction”). Other examples include Aortic aneurysm (known); AV block, pacemaker

inserted; Other CVD: minimal, nonobstructive CAD found on cath; bilateral popliteal aneurysms; previous stroke; aortic regurgitation, atrial fibrillation.

D.15.5 “Is a MESA Event or Revascularization Present?”

The second question, “Is a MESA Event or Revascularization Present?” allows you to skip to the end of the form. You should only choose “No” if you are positive that the investigation contains no MESA endpoints (including no revascularization). If you choose “No”, you must skip to Question 7. If you choose “Yes” (MESA events or revascularization are present), then you are required to provide at least one answer in all six sections of the form (i.e., MI, angina, etc...).

If the investigation in question has already been reviewed by the Stroke Committee, the results of that review will appear on the Summary Report included in the review packet. If the indicated cerebrovascular event was unaccompanied by any cardiac event, then the Cardiac/PVD review form should be marked “No Event or Revascularization.” If a cardiac event did accompany the cerebrovascular event, then the Cardiac/PVD form should be submitted with the appropriate cardiac endpoints and information recorded.

For mortality reviews, only the committee associated with the cause of death should complete the mortality form for combination cardiac/cerebro cases. If a reviewer arrives at a mortality review form and believes the cause of death to be associated with the other committee (stroke committee for stroke-related deaths, cardiac committee for all other deaths), then the reviewer should not complete the mortality review form; instead, the reviewer should use the mortality review form’s “send comment” box to inform the Coordinating Center that the mortality review should be completed by the other committee.

D.15.6 Cardiac Endpoint Classification and Criteria

Pre-baseline endpoints should not be entered on the review form. If a reviewer has information about a pre-baseline event, it can be conveyed to the Coordinating Center through a note in the “Comment” field, clearly distinguishing between pre-baseline and post-baseline dates.

(Question 1) Myocardial Infarction

Classify MI as definite, probable, and no MI based on the algorithm in Table 4.2 of the Events Manual, based on chest pain, enzyme and ECG findings. The ECG criteria on the form are the Minnesota code version of the criteria, while Table 4.2 uses the Novacode version. Some clinical judgment is allowed. If you decide that there is no MI in the investigation, then you fill in ‘No MI’ and skip to section 2. If you think that there is a ‘probable’ or ‘definite’ MI, then you must complete the remainder of section 1.

A. Criteria

1. Chest Pain

Pain is classified based on the criteria in section 4.1.1 of the events manual. The interpretation of chest pain in the overall MI algorithm might be influenced by an inability of the participant to voice chest pain, for example in the setting of surgery or coma. Chest pain may be detailed in the discharge summary, but is also

abstracted and located on the Summary Report (page 3) and on the Form Info Sheet for the Hospital Abstraction or Physician Questionnaire.

2. Enzymes

Classify enzymes according to the algorithm in Table 4.1 of the Events Manual. Enzymes, and any procedure or trauma that might interfere, are listed on the Summary Report (page 5). The algorithm has been programmed into the summary reports. The result will show up on the enzyme page of the summary.

Note that there are special considerations for enzymes in the face of procedures. The reviewer must decide whether this is a likely source of enzyme distortion when applying the criteria. A particularly confusing situation is enzyme elevation after cardiac arrest and CPR. MESA will tend to classify this under either Resuscitated Cardiac Arrest, if the participant survived, or as a death, rather than try to interpret enzyme values for MI after CPR.

3. ECG

ECGs will be included in the packet and are to be read clinically into the categories listed on the Review Form.

B. Procedure Related

For this question, and all similar questions on the form, decide if this event resulted from a procedure and whether that procedure was a cardiovascular or non-cardiovascular procedure. The most common example may be MI during CABG. Procedure ICD codes and names are listed on page 2 of the Summary Report. The discharge summary may clarify the time sequence.

(Question 2) Resuscitated Cardiac Arrest

Classify as definite, probable (anticipated to be rare), or not present. The summary form indicates whether there was an arrest and resuscitation (Page 2). The Form Info Sheet for the Hospital Abstraction and any discharge summary may also have this info. If there was a resuscitated arrest but the patient ultimately died, **do not record it here**, but rather on the mortality review. Follow the procedure-related instruction from the previous section (MI).

(Question 3) Angina Pectoris

Classify angina as definite, probable, or absent based on the criteria in section 4.1.3 the Events Manual. Note that definite or probable angina requires ischemic pain. Chest pain is indicated in the Summary Report (page 3).

A. Criteria

Record the criteria met, or the supporting evidence for the classification of angina. This information can be found in a variety of places. The discharge summary and diagnoses will be helpful for hospitalized angina, and any MD documents could be helpful for

outpatient angina. Additionally, the Summary Report and Form Info Sheet for the Final Notification Form state what procedures and tests were done (selected results).

In cases where revascularization was performed without clinical symptoms, the Reviewers will record the revascularization, but not record angina. Angina requires clinical symptoms to be considered a MESA Event. If there is only a physician diagnosis/treatment then the diagnosis cannot be ‘definite’. If there is more than just a physician diagnosis, then the reviewer can assign ‘definite’ instead of ‘probable’.

B. Procedure-related

Follow instructions for 1.B.

(Question 4) Congestive Heart Failure

Classify CHF as definite, probable, or absent based on the criteria in section 4.1.4 of the Events Manual. Relevant information is listed on the Summary Report (page2) or the Form Info Sheet for Hospital Abstraction. The discharge summary and diagnoses will be helpful for hospitalized CHF, and any MD documents could be helpful for outpatient CHF. (A ruling of “definite” requires more than a physician diagnosis.)

A. Criteria

Record the criteria met, or the supporting evidence for the classification of CHF.

B. Procedure-related

Follow instructions for 1.B.

C. Comorbid conditions

Indicate all conditions that may have been present or led to the CHF. If none can be identified, check unknown. The discharge summary and diagnoses or consultant notes will be the most likely source of this information.

D. Ejection Fraction

When there are multiple types of measures of EF, the priority from highest to lowest is: EF from heart cath or other contrast ventriculography, transthoracic or transesophageal echo, and nuclear study. If medical report specifies EF value as a range, specify the midpoint value. If the midpoint is a fraction, round down to the nearest whole value. A resting value of EF is preferred over a post-stress or exercise value. Do not average resting and post-stress EF.

E. Source of Ejection Fraction

Specify the medical test that provided the Ejection Fraction data. If ‘Other’, specify the data source in the provided text box.

(Question 5) Revascularization

Record whether any of these procedures were done regardless of whether the procedure was successful or not at restoring flow. “Other arterial revascularization” includes aortic aneurysm repair, leg revascularization, etc., which should be specified. These procedures are recorded in the Form Info Sheet for the Hospital Abstraction Form. The Form Info Sheet for the Final Notification will indicate if records from either procedure are available. In cases where revascularization was performed without clinical symptoms, the Reviewers will record the revascularization, but not record angina. Angina will require

clinical symptoms to be considered a MESA Event.

(Question 6) PAD (PVD)

PAD in MESA refers only to the lower body and should be classified as definite, probable, or absent based on the criteria in Section 4.1.5 of the Events Manual. (A ruling of “definite” requires more than a physician diagnosis.) Relevant information on PAD can found in the Summary Report (page 2), or on the Form Info Sheet for the Hospital Abstraction.. The discharge summary and diagnoses, and any accompanying documents may be helpful.

A. Diagnosis

Record the type of PAD. Note that more than one type may be recorded.

B. Criteria

Record the criteria met, or the supporting evidence for the classification of PAD. Check all that apply.

(Question 7) Dead or Alive

Vital status is located on Summary Report (page 2). If the patient died during this event, also complete a Mortality Review Form after completing the Cardiac/PVD Review Form. This question must be completed even if there is no event.

Physician ID/Date

You have been assigned a unique ID number by the Coordinating Center. If you forget your number, please contact the Events Director at the CC. This three digit number should be entered at the bottom of the second page of the form, next to the words ‘Reviewing Physician’s ID’. Please, also, write in the date that you completed your review. Leave the Data Entry ID box blank.

Participant, Investigation ID:



Type of Review:

- Local (Field Center review)
- Central (other committee member review)
- Third Reviewer
- Committee

If other investigations are evaluated in this review, please list their two-digit IDs:

ID: ID: ID: ID: ID:

I. Regardless of MESA Event status, is there Other CVD present that does not qualify as a MESA Event or Revascularization?

- No (proceed to question II)
- Yes

Non-Event (eg. Asymptomatic) CVD

Select all that apply

- Coronary Disease
- Ventricular Dysfunction
- Aortic aneurysm
- Leg PAD
- Other CVD (specify)

Specify:

II. Is a MESA Event or Revascularization Present?

- No (Proceed to Section 7)
- Yes (Proceed to Section 1)

Cardiac Endpoint Classification and Criteria

Please complete entire form. Skip sections only when indicated.

1. Myocardial infarction

- Definite
- Probable
- No MI (skip to section 2)

If 'Definite' or 'Probable' enter date of MI (MM/DD/YYYY):

A. Criteria

1. Chest Pain

- Present
- Absent

2. Cardiac Enzymes

- Abnormal Incomplete
- Equivocal Normal

3. ECG Serial Reading (pick one)

- Evolution of Major Q-Wave
- Evolution of ST-T Elevation with or without Q-Wave
- New LBBB
- Evolution of ST-Depression/inversion alone
- Evolution of Minor Q-Wave alone
- Single ECG with Major Q-Wave
- Single ECG with LBBB, described as new
- Absent, Uncodable or Other ECG

B. Procedure-related:

- Yes, cardiovascular
- Yes, non-cardiovascular
- No

2. Resuscitated Cardiac Arrest

- Definite
- Probable
- No (skip to section 3)

If "Definite" or "Probable" enter date of Resuscitated Cardiac Arrest (MM/DD/YYYY):

Procedure-related:

- Yes, cardiovascular
- Yes, non-cardiovascular
- No

3. Angina Pectoris (including unstable angina):

Chest pain, tightness, or shortness of breath produced by myocardial ischemia that does not result in infarction (usually caused by coronary insufficiency).

- Definite
- Probable
- Absent (skip to section 4)

If "Definite" or "Probable" enter date of Angina (MM/DD/YYYY):

A. Criteria (check all that apply):

- Physician diagnosis of angina and receiving medical treatment for angina (e.g. nitrate, beta-blocker, or calcium channel blocker)
- CABG surgery or other revascularization procedure
- 70% or greater obstruction of any coronary artery on angiography
- Horizontal or down-sloping ST-segment depression OR abnormal ST depression OR abnormal ST elevation ≥ 1 mm on exercise OR pharmacological stress testing with pain
- Scintigraphic or echocardiographic stress test positive for ischemia
- Resting ECG shows horizontal or down-sloping ST depression or abnormal ST elevations ≥ 1 mm with pain that is not present on ECG without pain

B. Procedure-related:

- Yes, cardiovascular
- Yes, non-cardiovascular
- No

4. Congestive Heart Failure

- Definite
- Probable
- No CHF (skip to section 5)

If "Definite" or "Probable" enter date of new onset or worsened Congestive Heart Failure (MM/DD/YYYY):

A. Criteria (Check all that apply):

- Congestive Heart Failure diagnosed by physician and receiving medical treatment for CHF (e.g., diuretics, digitalis, vasodilator and/or ACE-inhibitor)
- Pulmonary edema/congestion by chest x-ray
Dilated ventricle or poor left ventricular function (e.g., low ejection fraction or wall motion abnormalities) by echocardiography, radionuclide ventriculogram (RVG)/multigated acquisition (MUGA), or other contrast ventriculography, OR evidence of left ventricular diastolic dysfunction

B. Procedure-related:

- Yes, cardiovascular
- Yes, non-cardiovascular
- No

C. Comorbid conditions (Check all that apply):

- Coronary Disease
- Valvular Disease
- Arrhythmia
- Hypertension
- Pulmonary Disease
- Pulmonary Infection
- Medications Withdrawal
- Volume Overload
- Toxins
- Unknown
- Other

Specify: **D. Ejection fraction measurement (choose one):**

- Known value: percent (specify; if EF given as range, enter midpoint value)
- Less than: percent (specify)
- More than: percent (specify)
- Normal
- Low
- Unknown

E. Source of ejection fraction information (choose one):

- Trans-esophageal Echocardiography
- Trans-thoracic Echocardiography
- Cardiac Catheterization
- Nuclear Imaging (e.g. SPECT)
- Other (please specify):

5. Revascularization (on this admission)**A. Coronary Artery Bypass Graft (CABG):**

Yes No

If "Yes" enter date of CABG (MM/DD/YYYY):

B. Percutaneous Transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy:

Yes No

If "Yes" enter date of procedure (MM/DD/YYYY):

C. Other arterial Revascularization (please specify):

If "Yes", enter date of other revascularization (MM/DD/YYYY):

6. Peripheral Arterial Disease (aorta, iliac arteries, or below):

Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and have a diagnostic procedure or require therapeutic intervention (e.g. vascular or surgical procedure for arterial insufficiency in the lowest extremities or abdominal aortic aneurism).

- Definite
 Probable
 No PAD (skip to section 7)

If "Definite" or "Probable" enter date of Peripheral Arterial Disease (MM/DD/YYYY):

A. Diagnosis (check all that apply):

- Lower extremity claudication
 Atherosclerosis of arteries of the lower extremities
 Arterial embolism and/or thrombosis of the lower extremities
 Abdominal aortic aneurysm (AAA)

B. Criteria defined by symptoms plus one or more of the following (check all that apply):

- Ultrasonographically- or angiographically demonstrated obstruction, OR ulcerated plaque ($\geq 50\%$ of the diameter or $\geq 75\%$ of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below
 Absence of pulse by doppler in any major vessel of lower extremities

- Exercise test that is positive for lower extremity claudication
- Surgery, angioplasty, or thrombolysis for peripheral artery disease
- Amputation of one or more toes or part of the lower extremity due to ischemia or gangrene.
Exertional leg pain relieved by rest and at least one of the following: 1) claudication
- diagnosed by a physician; or 2) ankle-arm systolic blood pressure ratio less than or equal to 0.8.
- Abdominal aortic aneurysm demonstrated by ultrasound, angiogram, CT or MRI.
- Surgical or vascular procedure for abdominal aortic aneurysm.

Clear PAD section

Complete question 7 for all investigations.

7. Did the patient die?

Yes No

If yes, then on submission you will be taken to the *Mortality Review* form

Reviewing Physician's ID: Date: Data Entry ID:

Reviewer Comments:

Clear entire form

Click on here to unselect all answers and restart.

Submit

Click Submit to enter this review.

Investigations

Click here to return to list of Investigations Needing Review without submitting review.

Send Comment

Click here to send comments.

If this review cannot be completed due to missing information, pre-baseline conditions, or other issues, please enter your comments in the Reviewer Comments field and press the 'Send Comments' button. Your comments will be forwarded to the CC Events Data Director.

D.16 Stroke/TIA Review

D.16.1 Introduction

The physician reviewer(s) will complete this form for all eligible potential stroke/TIA events, nonfatal or fatal. In special cases this form may be completed in an M&M committee setting. For investigations with both cardiac and stroke components, the stroke reviewers will review first. This form will be completed and results forwarded to the cardiac reviewers for their classification. This form must be entered online. Please see Section C.3 for instructions on using the web-based form.

The Coordinating Center will provide an investigation ‘review packet’ to each reviewer for each investigation that the reviewer is responsible for. Each packet will contain the following items:

- **Coversheet**—This one page sheet will detail the type(s) of events covered in this packet, as well as which review forms need to be completed. If this investigation is being sent to the reviewer because two previous reviewers disagreed about a diagnosis, the coversheet would direct the physician to what portions of the review form need be completed.
- **Summary Report**—This several page report highlights important data pieces that pertain to the investigation at hand.
- **Form Info Sheets**—In addition to the Summary Report, the raw form data are printed out. The reviewer may see the marked response to all questions asked on a teleform.
- **Medical Records**—Copies of hospital/office/clinic notes and procedure reports will be included in the packet. Any other useful documentation provided by the Field Center will be included, as well.
- **Hardcopy of Review Forms**—The review forms that you will be required to fill out online will be provided in hardcopy. It is recommended that the hardcopy be filled out and retained by the reviewer for a month after he/she has submitted the online review forms. Alternately, the reviewer may print out the completed online review form or save the file.

It is recommended that the reviewer start by looking at what information is available for the investigation, and then identify what types of events are being examined in the investigation. The types of events are clearly listed at the top of all the Summary Report pages. What information is available is located on the Form Info Sheet for the *Final Notification Form*.

Completing the hardcopy form

NOTE: The Coordinating Center recommends that you complete a hard copy version of the form before you login to the online version. This will avoid any problems with the server timing out, as well as provide you with a hardcopy of what you decided. You may choose, also, to fill out the online form as you review the investigation. You may then print out the completed form to retain in your records.

Whether you are filling out a hardcopy or an online version, you will need the following items to complete this form:

- The review packet that was sent to you by the Coordinating Center
- Your data entry ID
- Access to the web (only for online entry portion)

Both the hardcopy and the online version of the review form will ask for your data entry ID (which the Coordinating Center will provide) at the end of the form. It is important that you use your own ID, as this will identify which physician reviewed which case. The Coordinating Center will track how many investigations each physician has reviewed and spread the cases out as evenly as possible. You may elect to have other staff enter your classifications in online. Any other staff using the online forms will need their own ID.

Both the hardcopy version and the online version will already have the participant ID, investigation ID, and type of review marked in advance.

Two events in one investigation packet

If a single investigation packet (with single Investigation ID number) contains evidence of two separate events, the reviewer should follow these guidelines:

Event types in single investigation	Action
2 or more TIA's	Code review form for one TIA (the worst one)
TIA(s) and 1 stroke	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>two</u> investigations.
TIA(s) and 2 strokes	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>three</u> investigations.
2 or more strokes	Do not do any reviews. Contact Coordinating Center using "Comment" box and request that the single investigation be reassigned as <u>two or more</u> investigations.

Recurrent Events

Reviews are to be done for both recurrent TIA's and recurrent strokes. On the review form, the recurrent event should be classified with all characteristics specific to its occurrence. If occurring within two weeks of each other and uninterrupted by intervening stroke events, multiple recurrent TIA's may be grouped together into a single review that codes the investigation according to the most severe TIA within the group. But multiple recurrent strokes (or a TIA and stroke occurring in close proximity) should be split into two separate reviews by the Coordinating Center, with each potential endpoint occurrence having its own review form.

D.16.2 Type of Review

The first thing that you do is confirm the type of review that you are performing. The choices are as follows:

- First Review – First time the review is done (not by committee).
- Disagreement Review – Reviewers given opportunity to resolve differences before having to turn to the next option.
- Final (consensus) – This option may be checked in these circumstances:
 - The M&M committee decides as a group how to complete the form.
 - You are entering the final decision for a diagnosis that was in dispute. (This could mean that you are a third reviewer, or that you are one of the two original reviewers and you both came to consensus.) ALL REVIEW FORMS MARKED ‘FINAL’ ARE CONSIDERED PERMANENT. THEY WILL NOT BE CHANGED.

D.16.3 Linked Investigations

Stroke/TIA reviews will not be linked

D.16.4 Stroke/TIA Endpoint Classification and Criteria

“No Event” Investigations

If an investigation is deemed an incident containing no endpoints relevant to the study, the review can be classified as a ‘No Event’. To code an investigation as a ‘No Event’ on the review form, specific morbidity review questions need completion:

Question 1a. Criteria: Symptoms and Signs

Question 1b. Criteria: Clinically relevant lesion on brain imaging

Question 1c. Primary Diagnosis

- Should be coded as ‘Not a TIA or Stroke’

Question 7. Did the patient die?

(Question 1) Criteria

A. Symptoms and Signs

Choose the set of symptoms and signs that best describes the event. Only one choice allowed. Question

- Non-focal symptoms, such as headache
- Focal neurological deficit lasting < 24 hours
- Focal symptoms lasting \geq 24 hours
- Unknown

Symptoms from a brainstem lesion such as dizziness or coma can be considered ‘focal’ for the purposes of this question.

B. Clinically relevant lesion on brain imaging

Use imaging reports included in the events review packet to identify any relevant brain lesion. Mark one choice only. If you identify a hemorrhage, continue on to part C. Otherwise skip to Question 2.

- Subarachnoid Hemorrhage (SAH) (go to 1c)
- Intraparenchymal Hemorrhage (IPH) (go to 1c)
- Both SAH and IPH (go to 1c)
- Brain infarction (bland or bloody) (skip to 2)
- No clinically relevant lesion (skip to 2)
- Results unknown or no brain imaging done (skip to 2)

An intraparenchymal hemorrhage with intraventricular extension would be coded as intraparenchymal hemorrhage, while an intraparenchymal hemorrhage with subarachnoid extension seen on imaging would be coded as both SAH and IPH.

C. If hemorrhage, please specify origin

Please identify the origin of hemorrhage found in part B. If hypertensive hemorrhage suspected, mark "Unknown." Mark only one choice.

- AVM
- Aneurysm
- Specify:
- Unknown

(Question 2) Primary Diagnosis

- Not a TIA or Stroke (skip to 7)
- TIA (skip to 7)
- Stroke

Please consult the MESA Criteria in Section 4 of the manual for diagnosis requirements. A diagnosis of TIA would require focal neurologic deficits, but could be interpreted broadly if the region of the brain affected were the brainstem. Retinal infarcts should be coded as a stroke.

(Question 3) Stroke Type**A. Type**

Choose the type of brain lesion identified in the participant. See section 4 for definition of stroke types. Retinal infarction should be classified as a ‘brain infarction’ but requires documentation by an ophthalmologist.

- Subarachnoid Hemorrhage
- Intraparenchymal Hemorrhage
- Other Hemorrhage
- Brain infarction
- Other Stroke Type
- Unknown Stroke Type

B. Procedure-related

Record whether stroke can be related to a procedure undergone by the participant.

Mark “Yes” for procedures such as cardiac surgery, carotid surgery, vascular surgery, post angiogram, and post thrombolysis for MI.

If “Yes,” specify procedure in space provided.

(Question 4) Location

Record the location of event using 2-digit codes.

A. Primary Location

Select the number from the list of brain locations that best describes the ‘primary’ location of the event.

B. Other Location

If more than one site, enter the number for the second through fifth sites as needed.

Codes:

<u>Left</u>		<u>Right</u>
01	Cerebral Hemisphere	02
03	Frontal Lobe	04
05	Parietal	06
07	Insular-operculum	08
09	Occipital lobe	10
11	Temporal lobe	12
13	Basal Ganglion	14

15	Thalamus	16
17	Internal capsule	18
19	Cerebellum	20
21	Fronto-parietal lobe	22
23	Parietal-occipital lobe	24
25	Temporo-parietal lobe	26
27	Temporo-occipital lobe	28
29	Fronto-temporo-parietal lobe	30
31	Basal ganglia and capsule	32
41	Retina	42

33	Midline (third ventricular callosum)
34	Intracranial (not further specified)
35	Brain stem
36	Midbrain
37	Pons
38	Medulla
39	Subarachnoid space
40	Intraventricular space
99	Unknown

C. More than 5 cerebral sites?

Record whether there were more than 5 cerebral sites containing infarcts.

(Question 5) Vascular Territory

Record location of event using 2-digit codes.

A. Primary Vascular Territory

Select the number from the list of brain locations that best describes the ‘primary’ location of the event.

B. Other Vascular Territories

If more than one site, enter the number for the second through fifth sites as needed.

Codes:

<u>Left</u>		<u>Right</u>
20	Common Carotid	50
21	External Carotid	51
22	Internal Carotid	52
23	...At bifurcation	53
24	...Distal extracranial	54
25	...Intracranial	55
26	...Junction of posterior communicating	56
27	...Other	57
28	Anterior cerebral	58
29	...Junction of anterior communicating	59
30	...Other	60
31	Middle cerebral	61
32	...Penetrating or lenticulostriate	62
33	...Stem	63
34	...Upper branch	64
35	...Lower branch	65
36	Posterior communicating	66
37	Posterior cerebral	67

Codes (continued)

<u>Left</u>		<u>Right</u>
38	...Penetrating	68
39	...Stem	69
40	...Calcarine branch	70
41	Superior cerebellar	71
42	Posterior inferior cerebellar	72
43	Vertebral	73
44	Subclavian	74
45	Anterior choroidal	75
46	Ophthalmic	76

80	Anterior communicating
81	Basilar
82	...Penetrating
83	...Full
84	...Upper branch
85	...Lower branch
86	Innominate
99	Unknown

C. Are there more than 5 vascular territories indicated?

Record whether there were more than 5 cerebral sites containing infarcts.

(Question 6) If Brain infarct subtypes:

Complete this question if the participant had a brain infarct. Otherwise skip to 7. Record the top three choices for subtypes. Refer to Appendix B for detailed descriptions of subtypes. All three boxes need not be filled.

- First choice of Subtype: reflection of strict adherence to the subtype algorithm in manual Appendix B. If the first choice selected is 1, 2, 3, 4 or 5, responses to the second and third choice are not allowed. To ensure this rule is enforced, the second and third subtype fields are conditionally deactivated.
- Second choice of Subtype: allows for some loosening of the criteria and is an attempt to reduce the number of cases classified as “Unknown.” If the first choice subtype is 6, 7, or 8, a response to the second choice is required, even though it might still be 6 or 8.
- Third choice of Subtype: allows for a choice if the first choice is “more than one.” The third choice would only be used if the first choice equals 7 (unknown, multiple).

(Question 7) Dead or Alive

Vital status is located on the Summary Report of the review packet. If the patient died during this event, also complete a Mortality Review Form, which will be provided automatically when the morbid review form is submitted. This question must be completed even if there is no stroke or TIA.

The criteria for a stroke death consist of:

- Stroke occurrence and type determined by stroke event adjudication: subarachnoid hemorrhage, intraparenchymal hemorrhage, other hemorrhage, brain infarction, other stroke type, or unknown stroke type
- Mechanism of death is recorded as due to critical brain injury or as secondary to complications such as infections (lungs, urine, skin), pulmonary embolism, or arrhythmia. Critical brain injury can be lethal either because of the size of the infarct or bleed with herniation, or because of the location in the brain stem.

Reviewer Comments

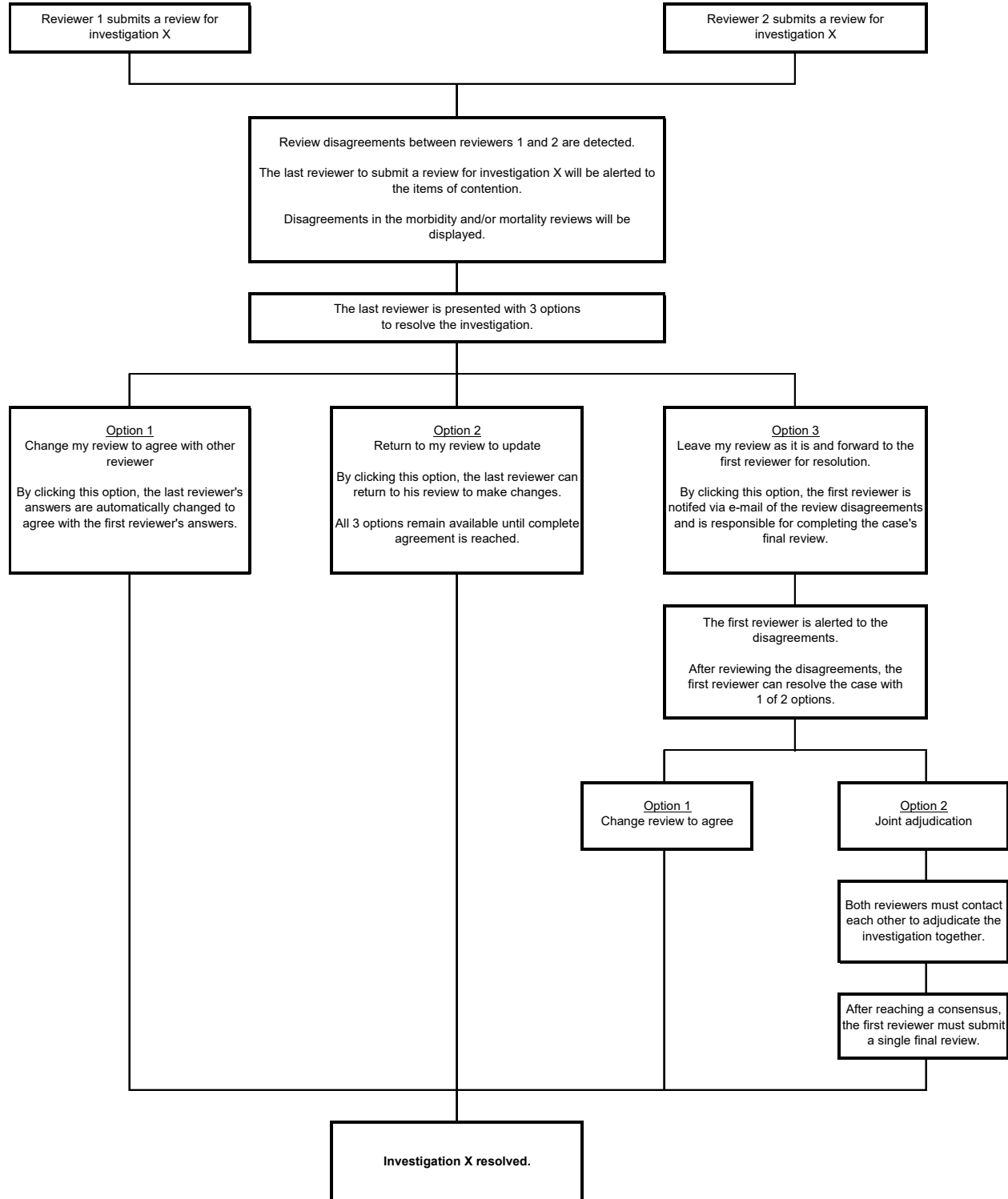
This is a place where you may write any comments that you have. Any comments are automatically emailed to the Coordinating Center Events Staff, whether you chose to “submit” the review form or “send comment only.” Please see Section C.3 (“Instructions for Online Review Forms”) for complete details about the use of the “send comment” function

Physician ID/Date

You have been assigned a unique ID number by the Coordinating Center. If you forget your number, please contact the Events Director at the CC. This three digit number should be entered at the bottom of the second page of the form, next to the words ‘Reviewing Physician’s ID’. Please, also, write in the date that you completed your review. The Data Entry ID box should be filled in with the ID of the person who does the actual entering of the data into the online form.

D.16.5 Process for Resolving Review Disagreements

If disagreements exist in the morbidity and/or mortality reviews, both reviewers will have the opportunity to independently address the review conflicts.



The last reviewer to submit his review is the first to be alerted of the items of contention. To resolve the differences, the last reviewer is given three options:

Option 1: Change my review to agree with other reviewer. This option will alter the last reviewer's responses to match that of the first reviewer. After the option is selected, a message will appear on the screen confirming the change was completed. No additional action is required after selecting this option.

Option 2: Return to my review to update. This option allows the last reviewer to revisit his review and make revisions. To compare the disagreeing responses, a pop-up window displaying both reviewers' responses will appear. If the updated modifications result in agreement, the case is resolved. If disagreements still exist after the revision of the morbid and/or mortality reviews, the last reviewer will be presented with the same 3 options again. This option may be used to resolve some disagreements prior to sending the investigation to the first reviewer.

Option 3: Leave my review as it is and forward to other reviewer for third review. If disagreements exist and the last reviewer does not wish to amend their review to agree with the first reviewer, the last reviewer may opt to alert the first reviewer of the disagreements.

In addition to an e-mail notification, the first reviewer will have the investigation appear as a new final review assignment in his online queue.

1. Upon opening the final review, the first reviewer can compare the differing responses:
 - The first reviewer's answers will be in a bold **RED** font
 - The last reviewer's answers will be in a bold **BLUE** font
 - If both reviewers agreed on an item, it will appear in a bold **BLACK** font. Since the question is not in disagreement, it does not require revision and will be locked out from editing.
2. The first reviewer can resolve the disagreements with two options:

Option 1: Change my review to agree with other reviewer. This option will alter the first reviewer's responses to match that of the last reviewer. The 'Change my review to agree' button is located at the bottom of the form. After the option is selected, a message will appear on the screen confirming the change was completed. To return to the assignments queue, the reviewer can click on the 'Return to Investigations Needing Review' button.

Option 2: Adjudicate the case with the other reviewer and submit a single final review.

If the first reviewer does not agree with the last reviewer's assessment, the investigation requires both reviewers to collaborate on a single and final review (i.e. a third review).

1. **NOTE:** Third reviews are required only for stroke disagreements on morbidity questions 1A, 1B, 1C, 2, 3A, 3B or 7.
2. For the remaining morbidity questions (4, 5, and 6), the first reviewer may re-enter his initial responses to finalize the investigation's review.
3. After all disagreeing items are resolved; the morbidity review can be submitted by clicking the 'Submit' button.

Submitting the Final Mortality Review

1. If the investigation included the completion of a mortality review, the mortality review will appear. Like the morbidity form, both reviewer responses are shown:
 - The first reviewer's answers will be in a bold **RED** font
 - The last reviewer's answers will be in a bold **BLUE** font
 - If both reviewers agreed on an item, it will appear in a bold **BLACK** font. Since the question is not in disagreement, it does not require revision and will be locked out from editing.
2. **NOTE:** Mortality third reviews are required only for disagreements on questions 3, 8 and 9.
3. If no disagreements exist for the mortality review, the 'Submit' button can be clicked. This instance may exist if a third review was assigned due to disagreements only in the morbidity reviews. Clicking the mortality form's 'Submit' button will complete the third review process.
4. If disagreements only exist for the mortality review, the morbidity form will be automatically bypassed. In these instances, the reviewer will have access only to the investigation's final mortality form.



Participant + Investigation ID:

Type of Review:

- First review
- Final (consensus)

Check here if no event or revascularization and skip to section 7.

1. Criteria

A. Symptoms and Signs

- Non-focal symptoms, such as headache
- Focal neurologic deficit lasting < 24 hours
- Focal neurological deficits lasting until death or \geq 24 hours
- Unknown

B. Clinically relevant lesion on brain imaging

- Subarachnoid Hemorrhage (SAH) (go to 1c)
- Intraparenchymal Hemorrhage (IPH) (go to 1c)
- Both SAH and IPH (go to 1c)
- Brain Infarction (bland or bloody) (skip to 2)
- No clinically relevant lesion (skip to 2)
- Results unknown or no brain imaging done (skip to 2)

C. If hemorrhage, please specify origin:

(If hypertensive hemorrhage suspected, mark "Unknown.")

- AVM
- Aneurysm
- Specify:
- Unknown

2. Primary Diagnosis

- Not a TIA or stroke (skip to 7)
- TIA (skip to 7)
- Stroke

3. Stroke Type

A. Type:

- Subarachnoid Hemorrhage
- Intraparenchymal Hemorrhage
- Other Hemorrhage
- Brain Infarction
- Other Stroke Type
- Unknown Stroke Type

B. Procedure-related?

- Yes
- No

If yes, please specify:

4. Location - record using 2 digit codes below:

A. Primary Location:

B. Other Locations:

C. Are more than five sites indicated?

- Yes
- No

Codes:

<u>Left</u>	<u>Right</u>
01 Cerebral Hemisphere	02
03 Frontal Lobe	04
05 Parietal	06
07 Insular-operculum	08
09 Occipital lobe	10
11 Temporal lobe	12
13 Basal ganglion	14
15 Thalamus	16
17 Internal capsule / corona radiata / centrum semiovale	18
19 Cerebellum	20
21 Fronto-parietal lobe	22
23 Parietal-occipital lobe	24
25 Temporo-parietal lobe	26
27 Temporo-occipital lobe	28
29 Fronto-temporo-parietal lobe	30
31 Basal ganglia and capsule	32
41 Retina	42
33 Midline (third ventricular callosum)	
34 Intracranial (not further specified)	
35 Brain stem	
36 Midbrain	
37 Pons	
38 Medulla	
39 Subarachnoid space	
40 Intraventricular space	
99 Unknown	

5. Vascular Territory - record using 2 digit codes below:

A. Primary Vascular Territory:

B. Other Vascular Territories:

C. Are more than five vascular territories indicated?

Yes No

Codes:

<u>Left</u>	<u>Right</u>
20 Common Carotid	50
21 External Carotid	51
22 Internal Carotid	52
23 ...At bifurcation	53
24 ...Distal extracranial	54
25 ...Intracranial	55
26 ...Junction of posterior communicating	56
27 ...Other	57
28 Anterior cerebral	58
29 ...Junction of anterior communicating	59
30 ...Other	60
31 Middle cerebral	61
32 ...Penetrating or lenticulostriate	62
33 ...Stem	63
34 ...Upper branch	64
35 ...Lower branch	65
36 Posterior communicating	66
37 Posterior cerebral	67
38 ...Penetrating	68
39 ...Stem	69
40 ...Calcarine branch	70
41 Superior cerebellar	71
42 Posterior inferior cerebellar	72
43 Vertebral	73
44 Subclavian	74
45 Anterior choroidal	75
46 Ophthalmic	76
80 Anterior communicating	
81 Basilar	
82 ...Penetrating	
83 ...Full	
84 ...Upper branch	
85 ...Lower branch	
86 Innominate	
99 Unknown	

If Stroke Type is not Brain Infarction, skip to 7.

6. Brain infarct subtypes:

All three boxes need not be filled.

- First choice of Subtype (reflection of strict adherence to the algorithm)
- Second choice of Subtype (allows for some loosening of the criteria and is an attempt to reduce the number of cases classified as "Unknown")
- Third choice of Subtype (to be completed only if 'First choice of subtype' is '7: more than one etiology' – This box should contain the second of the two selected etiologies)

Choices:

- 1 - Large vessel extracranial atheroembolic
- 2 - Large vessel intracranial atheroembolic
- 3 - Cardioembolic
- 4 - Small vessel (lacunae)
- 5 - Acute ischemic stroke of other known etiology
- 6 - Ischemic stroke of unknown cause (no probable etiology despite complete workup)
- 7 - Ischemic stroke of unknown cause (more than one etiology)
- 8 - Ischemic stroke of unknown cause (workup is incomplete)

Complete question 7 for all diagnoses.

7. Did the patient die?

Yes No

If the cause of death is stroke, the stroke reviewer(s) will fill out the Mortality Review Form. For all other causes of death, the cardiac reviewer(s) will fill out the Mortality Review Form. Is stroke the cause of death?

Yes No Cancel

Reviewing Physician's ID:

Date:

Data Entry ID:

Reviewer Comments:

D.17 Mortality Review

D.17.1 Introduction

Both the local physician reviewer and/or the central physician reviewer(s) for any fatal event should complete this form. In special cases this form may be completed in the M&M committee setting or by a third reviewer. This form will be completed for all types of deaths.

The *Mortality Review Form* is filled out only after completion of the morbid review form (*Cardiac/PVD Review* or *Stroke/TIA Review*) for the same investigation. The online *Mortality Review Form* is generated automatically upon completion of the morbid review form and is accessible only via completion of that morbid review form.

For mortality reviews, only the committee associated with the cause of death should complete the mortality form. If, on the morbid form, the reviewer answers “yes” to “Did the patient die,” then he/she will be prompt with a pop-up question that asks which committee (Cardiac or Stroke) should do the Mortality Review. The Stroke committee member should do the Mortality review for all stroke deaths; the Cardiac committee should do the Mortality review for all other causes of death. If reviewers have questions about which committee should do the Mortality review, those questions can be communicated to the Coordinating Center via the “Send Comments” box in the morbid form.

The Coordinating Center strongly recommends that you complete a hard copy version of the form before you login to the online version. This will avoid any problems with the server timing out, as well as provide you with a hardcopy of what you decided. This hardcopy will be useful in the event that adjudication is needed.

Whether you are filling out a hardcopy or an online version, you will need the following items to complete this form:

- The review packet that was sent to you by the Coordinating Center
- Your data entry ID
- Access to the web (only for online entry portion)

Both the hardcopy and the online version of the review form will ask for your data entry ID (which the Coordinating Center will provide) at the end of the form. It is important that you use your own ID, as this will identify which physician reviewed which case. The Coordinating Center will track how many investigations each physician has reviewed and spread the cases out as evenly as possible.

After you are familiar with the case, fill out the hardcopy form. Then enter the information into the online form. Both the hardcopy version and the online version will already have the participant ID, investigation ID, and type of review marked in advance.

The Reviewer ID number belongs to the Reviewer. The Data Entry ID should be the ID of person actually filling in the online form (same as the Reviewer ID if reviewer is do data entry him/herself, or a different ID if another staff member is entering the data on behalf of the reviewer).

All subsequent instructions are for the hardcopy forms. **Detailed instructions on how to**

use the online forms can be found in Appendix C.3. The content of the hardcopy and online forms are identical.

D.17.2 Type of Review

The first thing that you do when completing the *Mortality Review Form* is to confirm the type of review that you are performing. The choices are as follows:

- **Local (Field Center Review)**—Mark this choice if you are reviewing an investigation from your own Field Center. (If you are not affiliated with a Field Center or are a Stroke Reviewer, you will never check this option. This will never be selected for stroke-only deaths)
- **Central (other committee member review)**—Mark this choice if you are reviewing an investigation as a ‘central’ reviewer. All investigations (Cardiac and Stroke) require at least one central reviewer.
- **Final (consensus)**—This option may be checked in three circumstances:
 - The M&M committee decides as a group how to complete the form.
 - You are entering the final decision for a diagnosis that was in dispute. (This could mean that you are a third reviewer, or that you are one of the two original reviewers and you both came to consensus.) ALL REVIEW FORMS MARKED ‘FINAL’ ARE CONSIDERED PERMANENT. THEY WILL NOT BE CHANGED.

D.17.3 Linked Investigations

This is the standard area on MESA review forms for linking investigations. However, all linking will be indicated on the *Cardiac/PVD Review* or *Stroke/TIA Review* forms, not on the Mortality Review forms. Please return to the appropriate review form if you would like to link investigations.

D.17.4 All Deaths

Complete this section for all deaths, regardless of the nature of the death.

(Question 1) Location of Death

The location of death is recorded in the Summary Report (in the investigation packet) but might be addressed also in a next of kin interview. That info is available on the Form Info Sheet for the *Informant Interview*. The “Out of hospital” option includes ‘dead on arrival’, but not ER or NH. Those are separate choices. You may only choose one location.

(Question 2) Was the death witnessed?

Information about being witnessed is in the Summary Report (last page) but may be on the Form Info Sheet for the *Informant Interview*, as well.

Note: Whether the death was “witnessed” is often obvious, but can be confusing if the witness was only nearby. In general, MESA considers sudden deaths where someone was in the same room (e.g., in bed) or nearby so that s/he could have heard a cry for help as “witnessed.”

(Question 3) MESA classification of underlying cause

The classification for underlying cause of death should follow the established MESA criteria (Section 4 of the Events Manual). In addition, the Reviewer must be familiar with the ICD 10 codes assigned on the death certificate as transcribed onto the Summary Report. Review all available materials in order to decide the classification.

CHF cannot be designated as the underlying cause of death.

Some rules found useful in other studies are:

- The relative credibility of conflicting witnesses is established from all available evidence, i.e., there is no fixed hierarchy of credibility (such as a physician overriding a lay informant). However, as a general rule (1) a knowledgeable physician takes priority for medical history and (2) a witness takes priority for events around death and timing of death.
- If the decedent was debilitated from a potentially lethal non-CVD process and had a related downhill course, with a cardiac arrest with no clear evidence of another CVD event, the death is classified as non-CVD.
- In the case of conflicting information, the broader classification (e.g., Other Atherosclerotic Disease Death rather than Atherosclerotic CHD Death) is generally preferred.
- Record ischemic cardiomyopathy as "atherosclerotic CHD" death; record hypertensive cardiomyopathy or nonspecific cardiomyopathy as "other cardiovascular" death; record critical limb ischemia as "other atherosclerotic disease" death.

Follow the skip pattern to complete the necessary other sections of the form. You may choose only one answer for Question 3 of the form.

D.17.5 Coronary Heart Disease (CHD) Deaths

Only complete this section if you thought the death was of a cardiac nature (i.e., choose the first option for Question 3) and you are a cardiac reviewer. If you are a stroke reviewer (and think that the case is cardiac, not stroke-related), skip to the end of the form. When the data is entered online, you will have the chance to refer the review to the other committee by writing in the comments box.

(Question 4) Type of Fatal CHD

If the death is CHD in nature (and you are a cardiac reviewer), look over all available materials in order to decide whether it is definite fatal MI (usually requires a definite hospitalized MI or autopsy), definite fatal CHD, or possible fatal CHD. An unwitnessed death may be classified as "definite" in cases where there is a history of CHD or chest pain. An unwitnessed death may be classified as "Non-cardiovascular disease" if there is a history of another likely cause of death.

Some rules that have proved useful for heart related events in other studies:

- When the death certificate is the only available document, and the underlying cause ICD code is compatible with CHD (I20-25, I46, I51.6, R96, or R98-R99), then the final classification of cause of death is usually Possible Fatal CHD.
- Autopsy evidence of an acute MI or MI within 4 weeks, including coronary thrombosis or myocardial necrosis, may be used to classify Definite Fatal MI. Autopsy evidence of old MI or other chronic CHD counts as evidence of a history of CHD for classification purposes.
- Definite Fatal CHD is usually assigned when someone dies during an elective CABG as a complication of the surgery.
- Death during thrombolysis or other direct vascular intervention also would be assigned according to the event process being treated. For example, tPA for an MI with a hemorrhagic stroke resulting in death would be coded as a death due to MI (in its absence no stroke would have occurred). The stroke, however, would also be coded on the morbid review form and be coded as procedure related.

Continue to Question 5.

(Question 5) Time between Acute Cardiac Symptoms and Death

Timing is best determined by reviewing medical records and the Form Info Sheet for the *Informant Interview*.

Timing is often confusing. Some general rules used in other studies are

- Death is assumed to have occurred at the time the patient stops breathing on his or her own and does not recover.
- Symptoms are assumed to begin when the patient changes his/her activity. If symptoms come and go, the onset of symptoms is the time when they crescendo, leading to death.
- Symptoms of CHD leading to a hospital admission for CHD are usually considered to be related to a subsequent death from CHD, which occurs either before discharge or within 28 days of admission. Deaths of unclear chronology admitted for the investigation or treatment of CHD are classified as occurring >24 hours if admitted for at least 24 hours.
- In cases where the timing of symptoms or death is unknown, the best estimate of the chronology is to be made.
- Unknown chronology of death in an institutionalized patient is usually considered to be <24 hours.

Proceed to Question 6.

D.17.6 Cardiovascular Death (including CHD)

Do not complete this section if you believe the death to be due to stroke or a non-cardiovascular reason.

(Question 6) Mechanisms of Cardiac Death

Use your best clinical judgment based on all of the forms and scanned materials. Choose as many answers as apply.

(Question 7) Treatment or procedure-related

Indicate whether you think this event resulted from either a cardiovascular or non-cardiovascular treatment or procedure, or not.

Skip to End and submit review.

D.17.7 Stroke Death

Complete this section for all stroke deaths, if you are a stroke reviewer. If you believe that the death was stroke-related, but you are not a stroke reviewer, skip to the end of the form. When the data is entered online, you will have the chance to refer the review to the stroke committee by writing in the comments field. If you are a stroke reviewer, and believe there is a stroke component to the death, please complete the remaining sections of the form.

(Question 8) Time between stroke symptoms and death

See instructions under Question 5 for time-of-death information.

(Question 9) Mechanism of stroke death

Use your best clinical judgment based on all of the forms and scanned materials. Check all that apply. **Note: Ensure form image includes ‘withdrawal of support’ after ‘pulmonary embolus’ and before ‘other’ –OR—instructions to not withdrawal of support in the ‘Other’ text field.**

D.17.8 End of form**Physician ID/Date**

You have been assigned a unique ID number by the Coordinating Center. If you forget your number, please contact the Events Coordinator at the CC. This three digit number should be entered at the bottom of the second page of the form, next to the words ‘Reviewing Physician’s ID’. Please, also, write in the date that you completed your review. If you are making your entries online and enter the Reviewer ID and Data Entry ID on the login screen, both (as well as the date) will be auto-completed by the online form.

Data Entry ID

You may elect to have a staff person enter your data into the online form. If this is the case, then that person must obtain an ID from the CC and enter it in this box. If you enter your own results then place your ID in this box. If you are making your entries online and

enter the Reviewer ID and Data Entry ID on the login screen, both (as well as the date) will be auto-completed by the online form.

Reviewer Comments

This is a place where you may write any comments that you have. Any comments are automatically emailed to the Coordinating Center Events Staff, whether you chose to “submit” the review form or “send comment only.” Please see Section C.3 (“Instructions for Online Review Forms”) for complete details about the use of the “send comment” function.



Participant + Investigation ID:

Type of Review:

- Local (Field Center review)
- Central (other committee member review)
- Final (consensus)
- Committee

All Deaths

1. Location of death:

- Out-of-Hospital
- Emergency Room (not DOA)
- In Hospital
- Nursing Home, SNF, or ECF
- Other, specify:

2. Was the death witnessed?

- Yes
- No
- Unknown

3. MESA classification of underlying cause of death (choose one)

- Atherosclerotic coronary heart disease (complete questions 4-7 only)
- Stroke (complete questions 8-9 only)
- Atherosclerotic disease other than coronary disease or stroke (specify):
 (complete questions 6 & 7 only)
- Other cardiovascular disease, not defined above (specify):
 (complete questions 6 & 7 only)
- Non-cardiovascular disease (specify):
 (skip to end of form)
- Unknown because death certificate unavailable (skip to end of form)

Coronary Heart Disease (CHD) Deaths

4. Type of fatal coronary heart disease:

- Definite fatal MI (no known non-atherosclerotic cause and definite MI within 4 weeks of death)
- Definite fatal CHD (no known non-atherosclerotic cause, and one or both of the following: chest pain within 72 hours of death or a history of chronic ischemic heart disease)
- Possible fatal CHD (no known non-atherosclerotic cause, and and death certificate underlying cause: I20-25, I46, I51.6, R96 or R98-99)

5. Estimated time between onset of acute cardiac symptoms and death:

- Less than 5 minutes
- 5 minutes to 1 hour
- 1 hour to 24 hours
- More than 24 hours
- Unknown

(Continue to question 6.)

Cardiovascular Death (including CHD)

6. Mechanism of death in patients dying of cardiovascular causes (check all that apply):

- Primary arrhythmic death
- Secondary arrhythmic/mechanical death
- Congestive heart failure (CHF)
- Cardiac procedure such as CABG or angioplasty
- Hemorrhage from thrombolytic therapy
- Other (specify):
- Unknown or Uncertain

7. Treatment or procedure-related:

- Yes, cardiovascular (specify):
- Yes, non-cardiovascular (specify):
- No

(Skip to End and submit.)

Stroke Death

8. Estimated time between onset of acute stroke symptoms and death:

- Less than 5 minutes
- 5 minutes to 1 hour
- 1 hour to 24 hours
- 1 day to 1 week
- 1 week to 1 month
- Longer than one month

9. Mechanism of stroke death (check all that apply):

- Critical Brain injury
- Infection
- Pulmonary Embolus
- Other:

- Unknown

Reviewer ID: Date: Data Entry ID:

Reviewer Comments: _____

Form Date: 6/22/2010

Reset Click on Reset if you would like to cancel and restart.

Submit Click Submit to enter this review.

Investigations Click here to return to list of Investigations Needing Review without submitting review

Send Comment Click here to send comments.

If this review cannot be completed due to missing information, pre-baseline conditions, or other issues, please enter your comments in the Reviewer Comments field and press the 'Send Comments' button. Your comments will be forwarded to the CC Events Coordinator.

D.18 Events Contact Log

D.18.1 Introduction

The purpose of the *Events Contact Log* form (which is not the same form as the *Contact Log* used for Follow-up Calls) is to document calling history and assign a “pending” call status code for each contact attempt. Preprinted on the form are the participant’s ID, acrostic, language preference, telephone number, and enrollment (or Visit 1) date. The Events Contact Log may be used to track phone calls aimed to complete the following Events forms:

- Cardiac Interview*
- Stroke/TIA Interview*
- Informant Interview*
- The Events Contact Log may also be used by the Events staff to track other phone inquiries. For example, the Events Contact Log may be used when a member of the Events staff needs to phone a physician to verify or inquire about something the physician documented in a medical record or on a physician questionnaire.*

NOTE: This form is for field center administrative purposes only and is not scanned into the local MESA database.

At each contact attempt, record your Interviewer ID or initials and call attempt date, circle the day of the week, and record the time of the contact. Several calls should be attempted at different times of the day before a participant is declared unreachable. MESA would prefer to have no unreachable participants. At the end of each contact attempt, record the applicable pending code from the available list of codes on the top half of the page. Assigning a pending code is very important, as the code may be necessary for determining the final contact status code in the event the participant is ultimately not successfully contacted.

Pending codes are:


Code	Category	Explanation
1	Unlisted phone number	Number for this participant is unlisted. Interviewer should call the participant’s designated Contact 1 (and Contact 2, if necessary) to obtain a phone number for the participant.
2	Phone disconnected or out of service	Telephone number for this participant is incorrect or the number has been disconnected. Interviewer should call the participant’s designated Contact 1 (and Contact 2, if necessary) to determine if this is a temporary disconnection, and, if possible, obtain another phone number at which the participant can be reached.
3	Busy signal/no answer	Telephone is busy or no answer and there is no answering machine at the number. Another contact attempt should be made within the hour. If five attempts result in no answer, determine if the number is correct or if an alternate phone number is available for the participant.

Code	Category	Explanation
4	Left message on answering machine or with person	Telephone number for this participant is presumed to be correct, but an answering machine, or someone else, is reached. Record details in the "Comments" section for this contact.
5	Person busy, call back	Telephone number for this participant is correct, but the participant is temporarily unavailable. Person answering phone has information about participant's availability and when the participant may be re-contacted. Record date to call again in the "Comments" section for this contact.

On the "Comments" line, you may write any useful information. For example, if the person answering the phone says that the participant will be back at home in a week, then that information may be noted so that the Events staff know when to try phoning again.

Somewhere near the top or middle of the Events Contact Log, you may make a note about why it is necessary to phone the participant (e.g., "Need to conduct Cardiac Interview").

Multi-Ethnic Study of Atherosclerosis



Events Contact Log

Investigation ID:

Acrostic:

Language:

Telephone Number:

Enrollment Date:

Note: Form is for Field Center tracking purposes only and is not scanned into the MESA database

This generic Events Contact Log may be used to track phone calls with the following Events Interviews:

- Cardiac Interview*
- Stroke/TIA Interview*
- Informant Interview*

Use the lines below to record the results of each contact attempt. Pending Contact Status Codes are as follows :

Pending Codes

- 1 Unlisted phone number
- 2 Phone disconnected or out of service
- 3 Busy signal / no answer
- 4 Left message on answering machine
- 5 Person busy, call back

DATE	DAY OF WEEK	TIME	COMMENTS	PENDING CONTACT STATUS CODE
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>
___/___/___	S M T W T F S	___:___ a p	_____	<input type="checkbox"/>

APPENDIX E: Sample Letters for MESA Events

E.1 Introduction

The following letters are samples/templates for letters/requests you may need to send to outside resources (i.e., proxies, physicians, coroners, etc.) to obtain participant medical records and other documentation pertinent to MESA events ascertainment. Please note you are not required to use these formats, but, rather these letters may be used as guidelines to help ensure pertinent information is requested from each source.

The following sample letters are included in this appendix:

E.2.1.	HOSPREL	Hospital medical record release form
E.2.2.	HOSPCOV	Cover letter to hospital to obtain medical records
E.2.3	PHYSREL	Physician/clinic record release form
E.2.4	PHYSCOV	Cover letter to physician/clinic to obtain medical records
E.2.5	MELET	Cover letter to next of kin to obtain medical examiner/coroner reports
E.2.6	MEREL	Medical examiner record release form
E.2.7	MECOV	Cover letter to medical examiner to obtain ME/coroner reports
E.2.8	PQCERT	PQ cover letter to physician signing death certificate
E.2.9	PQATND	PQ cover letter to attending physician of decedent
E.2.10	PQCLIN	PQ cover letter to medical clinic of decedent
E.2.11	INFLET	Letter to informant/next of kin, known telephone number
E.2.12	INFNONUM	Letter to informant/next of kin, unknown telephone number
E.2.13	RETNUM	Reply postcard from informant/next of kin with telephone number
E.2.14	INFNEIGH	Letter to neighbor of decedent
E.2.15	RETNEIGH	Reply postcard from neighbor of decedent

E.2 Sample MESA Events Letters

E.2.1 HOSPREL (Hospital medical record release form)

MESA STUDY HOSPITAL MEDICAL RECORD RELEASE FORM

Patient: [participant name]
[participant street address]
[participant city, state zip]

Hospital: [hospital name]
[hospital street address]
[hospital city, state zip]

Please release to the Multi-Ethnic Study of Atherosclerosis (MESA):

All records of hospitalizations which occurred during the period **[time between clinic visit and follow-up phone call 1]**.

I authorize the above agency to release copies of my medical records to the **[institution]**, MESA. This information will be used to statistical purposes only, and will remain strictly confidential.

Signature of Patient

Date

E.2.2 HOSPCOV (Cover letter to hospital to obtain medical records)

[date]

[hospital name]

[hospital street address]

[hospital city, state zip]

Dear Correspondence Clerk:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the [institution], along with five other centers in the United States.

[participant] (date of birth [date of birth]), a participant in our study, was a patient at [hospital name] during [year]. Enclosed you will find a release of medical information signed by [next of kin name]. We are needing medical records involving that hospitalization including ER report, History and Physical, Discharge ICD-9 or ICD-10 codes, Discharge Summary, Progress Notes, ECGs and Enzyme reports, and all other test and procedure results.

If you have any questions, please feel free to call NAME, our local Surveillance Supervisor, at PHONE NUMBER.

This information will be used for statistical purposes only, and will remain strictly confidential. Thank you very much in advance for your help in this important study.

Sincerely,

NAME

Principal Investigator

Enclosure: Release Form

E.2.3 PHYSREL (Physician/clinic record release form)

MESA STUDY PHYSICIAN/CLINIC RECORD RELEASE FORM

Patient: **[participant name]**
 [participant street address]
 [participant city, state zip]

Hospital: **[doctor's office or clinic name]**
 [doctor's office or clinic street address]
 [doctor's office or clinic city, state zip]

Please release to the Multi-Ethnic Study of Atherosclerosis (MESA):

All records of diagnoses and procedures that occurred during the period **[time between clinic visit and follow-up phone call 1]**.

I authorize the above agency to release copies of my medical records to the **[institution]**, MESA. This information will be used to statistical purposes only and will remain strictly confidential.

Signature of Patient

Date

E.2.4 PHYSCOV (Cover letter to physician/clinic to obtain medical records)

[date]

[doctor's office or clinic name]

[doctor's office or clinic street address]

[doctor's office or clinic city, state zip]

Dear Correspondence Clerk:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the **[institution]**, along with five other centers in the United States.

[participant] (date of birth **[date of birth]**), a participant in our study and your patient, reported being under your care during **[year]**. Enclosed you will find a release of medical information signed by **[next of kin name]**. We are needing medical records involving diagnoses and procedures including History and Physical, Discharge ICD-9 or ICD-10 codes, Discharge Summary, Progress Notes, ECGs and Enzyme reports, and all other test and procedure results.

If you have any questions, please feel free to call **NAME**, our local Surveillance Supervisor, at **PHONE NUMBER**.

This information will be used for statistical purposes only, and will remain strictly confidential. Thank you very much in advance for your help in this important study.

Sincerely,

NAME

Principal Investigator

Enclosure: Release Form

E.2.5 MELET (Cover letter to next of kin to obtain medical examiner/coroner reports)

[date]

[contact/next of kin name]
[street address]
[city, state zip]

Dear [contact/next of kin name]:

I am writing with regard to our telephone interview on [date] regarding [participant]. Your information has been extremely valuable to the Multi-Ethnic Study of Atherosclerosis (MESA). Thank you.

[participant]'s death was investigated by the County Medical Examiner's Office. With your permission, the MESA would like to review those records to confirm the medical details. The Medical Examiner requires a written consent for release of medical information. Would you please sign the enclosed consent form for the Medical Examiner and return it to us in the enclosed stamped envelope?

Please note your consenting to the release of this information is completely voluntary and, if you choose to not offer us your consent, it will in no way affect any relationship you may have with this institution. If you have any questions, please feel free to call **NAME** at **PHONE NUMBER**.

Thank you again for your help in this matter.

Sincerely,

NAME
MESA Study Coordinator

NAME
Principal Investigator

Enclosures: Release Form and Return Envelope

E.2.6 MEREL (Medical examiner record release form, if needed)

MESA STUDY MEDICAL EXAMINER RECORD RELEASE FORM

Patient: **[participant name]**
 [participant street address]
 [participant city, state zip]

County: [county name]

I, **[contact/next of kin name]**, the closest relative of **[participant]**, who is deceased, give permission for the County Medical Examiner to release medical information to the **[institution]**, Multi-Ethnic Study of Atherosclerosis (MESA). This information will be used to statistical purposes only, and will remain strictly confidential.

Signature of Next of Kin

Date

E.2.7 MECOV (Cover letter to medical examiner (ME) to obtain ME/coroner reports)

[date]

[medical examiner name]
[street address]
[city, state zip]

Dear [medical examiner name]:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the [institution] along with five other centers in the United States.

We are needing information on [participant], who died on [date of death], and whose death was listed as a Medical Examiner case. MESA requests a copy of the Medical Examiner's report. A consent form signed by his/her next of kin is enclosed.

This information will be used for statistical purposes only, and will remain strictly confidential. If you have any questions, please feel free to call NAME, our local Surveillance Supervisor, at PHONE NUMBER. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

NAME
Principal Investigator

Enclosure: Release Form

E.2.8 PQCERT (PQ cover letter to physician signing death certificate)

[date]

**[physician name]
[street address]
[city, state zip]**

Dear **[physician name]**:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the **[institution]** along with five other centers in the United States.

We are needing information on **[participant]**, who died on **[date of death]**, and whose death certificate you signed on **[date]**. The information is needed to supplement the death certificate in assigning a cause of death. Could you or your nurse take a few moments to provide from your records the answers to the questions on the enclosed form?

This information will be used for statistical purposes only, and will remain strictly confidential. Of course, your participation is entirely voluntary, and, if you choose to not complete and return this form, it will in no way affect any relationship you may have with this institution. If you have any questions, please feel free to call me collect, at **PHONE NUMBER**, or our local Surveillance Supervisor, **NAME**, at **PHONE NUMBER**. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

NAME
Principal Investigator

Enclosure: Physician Questionnaire

E.2.9 PQATND (PQ cover letter to attending physician of decedent)

[date]

[physician name]
[street address]
[city, state zip]

Dear [physician name]:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the [institution] along with five other centers in the United States.

We are needing information on [participant], who died on [date of death], and who, according to the family, was your patient. The information is needed to supplement the death certificate in assigning a cause of death. Could you or your nurse take a few moments to provide from your records the answers to the questions on the enclosed?

This information will be used for statistical purposes only, and will remain strictly confidential. Of course, your participation is entirely voluntary, and, if you choose to not complete and return this form, it will in no way affect any relationship you may have with this institution. If you have any questions, please feel free to call me collect, at **PHONE NUMBER**, or our local Surveillance Supervisor, **NAME**, at **PHONE NUMBER**. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

NAME
Principal Investigator

Enclosure: Physician Questionnaire

E.2.10 PQCLIN (PQ cover letter to medical clinic of decedent)

[date]

[doctor's office or clinic name]
[doctor's office or clinic street address]
[doctor's office or clinic city, state zip]

Dear **[physician name]**:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the **[institution]** along with five other centers in the United States.

We are needing information on **[participant]**, who died on **[date of death]**, and who, according to the family, was a patient at **[doctor's office or clinic name]**. The information is needed to supplement the death certificate in assigning a cause of death. Could you or your nurse take a few moments to provide from your records the answers to the questions on the enclosed form?

This information will be used for statistical purposes only, and will remain strictly confidential. Of course, your participation is entirely voluntary, and, if you choose to not complete and return this form, it will in no way affect any relationship you may have with this institution. If you have any questions, please feel free to call me collect, at **PHONE NUMBER**, or our local Surveillance Supervisor, **NAME**, at **PHONE NUMBER**. Thank you very much in advance for your kind assistance and consideration of this request.

Sincerely,

NAME
Principal Investigator

Enclosure: Physician Questionnaire

E.2.11 INFLET (Letter to informant/next of kin, known telephone number)

[date]

[contact/next of kin name]

[street address]

[city, state zip]

Dear [contact/next of kin name]:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the [institution] along with five other centers in the United States, to ask for your help.

Your name is listed on the death certificate of [participant name] who passed away on [date of death]. In a few days a member of my staff will be calling to explain further about the project and seek your permission to ask a few medical questions.

The information you provide will be used for statistical purposes only, and will remain strictly confidential. Of course, your participation is entirely voluntary, and, if you choose to not speak with us on this matter, it will in no way affect any relationship you may have with this institution.

Thank you very much in advance for your help in this important study.

Sincerely,

NAME

Principal Investigator

E.2.12 INFNONUM (Letter to informant/next of kin, unknown telephone number)

[date]

[contact/next of kin name]

[street address]

[city, state zip]

Dear **[contact/next of kin name]**:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the **[institution]** along with five other centers in the United States, to ask for your help.

Your name is listed on the death certificate of **[participant name]** who passed away on **[date of death]**. We would like to call you to explain more about the project and to ask a few medical questions, but have been unable to find your telephone number.

Could you take a few moments to fill out and mail the enclosed postcard?

The information we will be calling about will be used for statistical purposes only, and will remain strictly confidential. Of course, your assistance in our research is entirely voluntary, and, if you choose to not provide your phone number and speak with us on this matter, it will in no way affect any relationship you may have with this institution

Thank you very much in advance for your help in the important study.

Sincerely,

NAME

Principal Investigator

Enclosure: Return Postcard

E.2.13 RETNUM (Reply postcard from informant/next of kin with telephone number)

POSTCARDS SHOULD BE RETURN-ADDRESSED TO LOCAL SURVEILLANCE CENTER AND STAMPED.

Dear **[name of Surveillance Supervisor]**:

I will be able to help with you with the Multi-Ethnic Study of Atherosclerosis (MESA).

_____ I **do** have a telephone number which is _____ - _____ - _____ .

The best times to reach me are _____ or _____ .

An alternative telephone number is _____ - _____ - _____ .

The best times to reach me at this number are _____ or _____ .

_____ I **do not** have a telephone number, but I agree to be interviewed in person.

I will be calling your staff to set up a time and a place for the interview.

Sincerely,

[name of informant]

E.2.14 INFNEIGH (Letter to neighbor of decedent)

[date]

[neighbor name]

[street address]

[city, state zip]

Dear **[neighbor]**:

I am writing on behalf of the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic project of the **[institution]** along with five other centers in the United States, to ask for your help.

As you may know, **[participant name]** passed away on **[date of death]**. As part of the study, we are systematically attempting to contact a next-of-kin or another person who lived with the decedent in order to obtain some medical information that would help us to find out about the circumstances surrounding **[participant name]**'s death. We have not been able to locate such a person and since you were **[participant name]**'s neighbor, we believe that you may be able to help us do so.

Could you take a few moments to fill out and mail the enclosed postcard?

The information we wish to obtain from the next-of-kin or other person who lived with **[participant name]** will be used for research purposes only, and will remain strictly confidential. Of course, your assistance in this matter is entirely voluntary, and, if you choose to not speak with us on this matter, it will in no way affect any relationship you may have with this institution

Thank you very much in advance for your help in this important study.

Sincerely,

NAME

Principal Investigator

Enclosure: Return Postcard

E.2.15 RETNEIGH (Reply postcard from neighbor of decedent)

POSTCARDS SHOULD BE RETURN-ADDRESSED TO LOCAL SURVEILLANCE CENTER AND STAMPED.

Dear **[name of Surveillance Supervisor]**:

The following individual(s) was (were) living with **[participant name]** at the time of his/her death:

Name	Relationship to deceased	Present address	Present telephone number

I do not have any information on persons who were living with **[participant name]** at the time of his/her death.

Sincerely,

[name of neighbor]

APPENDIX F: Glossary of Key Surveillance/Events Data Collection Terms

F.1 General Events Terms


Admission, Admitted	A specific status determined by the hospital involved. Not every visit to a hospital constitutes an official hospital admission. For example, an emergency room visit or hospital outpatient procedure is not a hospital “admission” unless the hospital takes the further step of “admitting” the patient, which would be signaled by an indication of “Admitted” date on hospital documents (e.g., on a discharge summary). If a participant is “admitted,” then his/her MESA investigation will be designated “Hospitalized,” but it will be designated “Out-of-Hospital” if the participant was not officially “admitted.”
Baseline	The date of the specific participant’s enrollment in MESA.
Contact	An interaction, or attempted interaction, between the field center and a MESA participant or proxy. For the purpose of collecting surveillance/events information, this will usually be by phone.
Contact 1 or 2	A person designated by the participant as someone who is likely to know his or her whereabouts/phone number should the field center be unable to reach the participant with its current contact information. This person may or may not be qualified/willing to serve as a proxy.
Documentation	Evidence of the medical treatment or diagnosis given to a participant, as well as evidence of symptoms. The most significant documentation is generated by physicians and hospitals (discharge summaries, physicians’ notes, or x-ray reports, for example), but documentation may also include interview information from participants/relatives/proxies or from medical staff.
Eligible	<p>“Eligible <u>for investigation</u>” means that a medical incident meets the criteria to trigger the <i>Initial Notification of Potential Event/Death</i> form. Investigation continues until the Final notice is completed or the investigation is determined to be ineligible for review.</p> <p>“Eligible <u>for review</u>” is a subsequent determination, which means that an investigation meets the criteria triggering Physician Review as determined by the <i>Events Eligibility</i> form (as explained by the manual).</p> <p>Note that some events are ineligible for investigation and thus ineligible for review, while other events are eligible for investigation but ineligible for review. For full details about eligibility matters, please see the manual sections for Follow-up Forms (D.1), Initial Notification (D.2), and Events Eligibility (D.3).</p>

Endpoint	One of the specified diagnoses or conditions that MESA studies: Myocardial Infarction (MI), Angina, Congestive Heart Failure (CHF), Peripheral Vascular Disease (PVD), Stroke, Transient Ischemic Attack (TIA), and Deaths due to Cardiovascular Disease (CVD). MESA Field Centers investigate events that may potentially have involved these incidents. In the end, for the purposes of MESA, only the physician reviewers can determine whether a participant experienced one of the designated endpoints.
Enrollment Date	The date the participant was enrolled in MESA. This is synonymous with the Exam 1 date or baseline visit date.
Event	An event is a medical incident that is an actual or potential MESA endpoint. If the incident is determined to be ineligible for investigation, it may be called a non-CVD event or may be determined to be “not an event.” (Please see Appendix D.14 for more information on what constitutes “not an event.”) A patient can have multiple events within a single investigation. For example, a patient may have CHF and an MI within the same hospitalization, which would amount to two events rather than one. Death also constitutes an event.
Events Document Code	The short abbreviation in all capital letters that is placed on the label used to scan image documents (also called Non-TELEforms—see glossary entry for that term). Every page of every Non-TELEform that is scanned must be labeled with the appropriate code. When scanned, the code is automatically read by the Events software, the document is assigned a filename using that code. These codes are available as a report in the software.
Exam 1	The participant’s baseline clinic visit, at which s/he is enrolled in MESA.
Exam 2	The participant’s second clinic visit, which takes place 18 months to two years after Exam 1 (depending on when the participant was enrolled in the study) and nine months to one year after administration of the Follow-Up Phone Call 1.
Final Contact Status Code	The final status of the Follow-Up Phone Call 1. The possible statuses are that the interview was successfully completed (with the participant or a proxy), the field center was unable to reach the participant to complete the call, or the participant refused to be interviewed by the field center. If the interview was not completed, or the interview was completed by proxy, the reason why is also coded.

Final Participant Status Code	The final status of the participant's status in MESA. The choices are: Alive, indicating the field center either reached the participant or, if not, received sufficient information to document the participant is still alive and willing to be contacted by MESA staff in the future; Do Not Contact, signifying the participant has indicated s/he does not wish to have any further contact with MESA staff; Reported Deceased, indicating the field center had received information that the participant has died. An event should be generated and death investigation begun. Unknown, indicating field center has insufficient information to document the participant's vital status.
Follow-Up Phone Call 1	A surveillance contact between field center staff and a MESA participant that takes place 9–12 months after Exam 1, depending on the participant's MESA enrollment date. It is used to confirm/update the participant's vital status and tracking information and vital status and to obtain information about the participant's general health and any specific medical conditions, hospital admissions, or medical procedures the participant may have experienced since his/her Exam 1.
Form Info Sheets	Sheets produced at the Coordinating Center from information drawn from Events TELEforms. When a TELEform (such as the <i>Eligibility</i> form or the <i>Final Notification of Event/Death</i> form) is scanned into the MESA database. It is the information (and not an image of the form itself) that is saved in the database and transmitted to the Coordinating Center. Additional software at the Coordinating Center later arranges the form's information into what are called Form Information Sheets (Form Info Sheets), which have only abbreviated captions (rather than the full questions or instructions of the original form) next to the information or data. At the time of review, a form info sheet is produced for each of the following forms present for the investigation in question: Final Notice of Event/Death, Eligibility Form, Hospital Abstraction—Cardiac/PVD, Hospital Abstraction—Stroke/TIA, Physician Questionnaire—Cardiac/PVC, Physician Questionnaire—Stroke/TIA, Interview (Cardiac/PVD, Stroke/TIA, or Informant).
Health professional	A “health professional” is a doctor, nurse, nurse practitioner, or other certified specialist working in a clinic or hospital (or ambulance). A “health professional” can also be a practitioner of non-Western medicine (e.g., an acupuncturist or Asian herbalist) but should not include chiropractors, exercise instructors, or diet coaches.
Image documents	Also called Non-TELEforms. “Image” does not refer to picture or photograph but rather to any document that is saved as an image file by the scanner (the image may only contain words). See glossary entry for Non-TELEforms.

Informant	A person (usually a spouse, other family member, or caregiver) who is knowledgeable of circumstances surrounding a participant's death and provides this information to the field center.
Investigation	<p>A unit containing one or more chronologically linked potential or actual MESA endpoint events. All actual or potential events within this unit will be reviewed together.</p> <p>Investigation is also used to refer to the act of inquiry or research; for example, Reviewers may ask Field Center staff to "conduct further investigation" into a specific event.</p>
Lost to Follow-Up (LTFU)	A participant status that indicates the participant either a) cannot be found through available tracking information or b) has refused all contact with the MESA field center.
Morbid	Non-fatal. Although the word "morbid" means death-like or gloomy in common usage, in medical settings the word "morbid" refers to non-fatal incidents that do not result in death. At the time of review, MESA investigations are designated either morbid (participant survived event) or fatal (participant did not survive event).
Mortality	In medical settings, "mortality" usually refers to death. A mortality review is a review of a fatal event (death event).
Non-TELEforms	Also sometimes referred to as "image documents." These are medical documents that are scanned to be included as part of an investigation (examples: discharge summary, physician notes, ETT reports, ECG tracings). Each Non-TELEform document must have a label attached in its upper left corner so that the Events scanner saves the document to the appropriate investigation location. The scanner saves the entire document as an image file, which means that the software (unlike for TELEforms) cannot understand any information or text within the image except for the information on the label. When scanned, the margins of the Non-TELEform documents are not saved and some parts of the document may not be legible, which is why measures must be taken during the verification process to ensure that all relevant information is visible and legible on the saved image. Within the Events software, Non-TELEforms are found by clicking on the button titled "Open Summary Screen for Other Events Documents," which is located in each investigation's "Investigation Summary" window.
"Other Events Documents"	This is the phrase (found in the "Investigation Summary" window of the Events software) that is used to refer to Non-TELEforms (image documents). See above glossary entry for Non-TELEforms for more information.
Pre-baseline	Before the date of the specific participant's enrollment in MESA.

Prevalent	Existing. A participant is prevalent for a particular condition (such as MI or CHF) if MESA Physician Reviewers have ruled her/him to have experienced a MESA endpoint event. From that event forward, the participant is said to be prevalent for that condition, regardless of the fact that the condition may have occurred only once or occurred far in the past. A participant can also be prevalent for a condition if that condition occurred Pre-baseline (before his/her MESA enrollment) and was later verified by a MESA local Physician Reviewer.
Proxy	A person (usually a spouse, other family member, or caregiver) who is knowledgeable of circumstances surrounding a participant's event and provides this information to the field center should the participant be unable to do so.
Recurrent	Repeat/repeated. A recurrent event is one in which a participant presents with the same potential endpoint as one that was ruled positive by MESA physician reviewers in a previous review. All potentially recurrent events are reviewed as if they were occurring for the first time, and if the event is not ruled positive, then the participant cannot be said to be recurrent for the endpoint condition in question.
Summary Report	A report of several pages that is generated at the Coordinating Center from the data and information available on the multiple TELEforms completed by the Field Centers for an investigation. The Summary Report is the first document in the investigation packet given to the physician reviewer for a ruling. The Summary Report summarizes a participant's prior conditions, prior reviewed investigations, symptoms, medications, diagnostic procedures, tests, laboratory results, and (when necessary) death information.
Surveillance	The tracking, in MESA, of a participant to make sure information and exam data is gathered. Surveillance staff are those staff members who have contact with participants and/or their records in order to investigate potential events.
Surveillance Staff	Field center staff who are responsible for contacting MESA participants between clinic visits to make sure the participant's tracking information is up-to-date and to obtain information on any medical diagnoses, hospitalizations, or procedures of interest to the study the participant may have experienced since his/her most recent clinic visit.
Target Follow-Up Contact Date	The target date for the participant's Follow-Up Phone Call 1. Depending on when the participant was enrolled in the study, this is 9–12 months after Exam 1.
Target Window	The period of time between one month before and one month after the target follow-up contact date. A participant's Follow-Up Phone Call 1 should be made within this "window."

TELEforms	The scannable forms on which exam and interview data are collected (examples: <i>Eligibility Form, Final Notice of Event /Death, Hospital Abstraction</i>). TELEforms have bubbles, text boxes, and other fields that are read automatically by the TELEform scanner. TELEforms are distinguished by the small corner registration marks like this  and by unique (random) form ID numbers in the lower right corner of each page. Each TELEform is created to capture only the information in the designated field areas; information written outside of those designated areas will not be collected by the TELEform software when scanned. It is the information (and not an image of the form itself) that is saved in the database and transmitted to the Coordinating Center. Additional software at the Coordinating Center later arranges the form information into what are called Form Information Sheets, which have only abbreviated captions (rather than the full questions or instructions of the original form) next to the information or data.
Vital Status	Participant's status "alive" or "dead."

F.2 Medical Terminology

Syndrome or Diagnosis	Definition	Synonyms
A myocardial infarction or heart attack	Damage to the heart muscle caused by inadequate blood supply. Usually accompanied by chest pain.	MI
Angina pectoris or chest pain due to heart disease	Severe pain and constriction about the heart, usually radiating to the left shoulder and down the left arm, or, rarely, from the heart to the abdomen. Pain may also radiate to the back or to the jaw. Caused by an insufficient supply of blood to the heart.	Angina
Balloon	Balloons are used in angioplasty procedures.	angioplasty
Stent	Stents are used in angioplasty procedures.	angioplasty
Heart failure or congestive heart failure	Heart does not pump adequately to provide blood to the organs. Usually accompanied by shortness of breath and swelling of feet.	
Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries	Diseases of the arteries of the extremities, due to inadequate flow of blood to the extremities, such as atherosclerosis with narrowing of the artery.	
Atrial fibrillation	One type of heartbeat irregularity.	A-fib
Deep vein thrombosis or blood clots in your legs	A blood clot forms in a <i>vein</i> of the leg.	
A stroke	Bleeding or lack of blood supply to brain, leading to neurologic damage.	Cerebral or brain hemorrhage, cerebral infarction
A transient ischemic attack (TIA) or mini-stroke	A reversible short-lived stroke, with recovery.	
Blockage to the carotid artery	Atherosclerosis (hardening) of a carotid artery of the neck.	
Lung abnormality or nodule	Any lung problem.	
Cancer	Malignant growth.	
Exercise treadmill or bicycle test	An exercise test on a treadmill, bicycle or similar device in which people increase their heart rate in order to have the function of the heart measured, usually by an ECG.	
Coronary angiography or heart catheterization	A procedure used to examine the heart or a heart artery by introducing a thin tube (catheter) and injecting dye.	Cardiac cath

Echocardiogram	A test in which sound is transmitted into the body and electronically plotted to produce a picture of the heart's size, shape and movements.	Echo
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Syndrome or Diagnosis	Definition	Synonyms
An angioplasty procedure to open up arteries to your heart	A procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon on its tip is passed into the narrowed artery segment, the balloon inflated, and the narrow segment widened. Angioplasties can now also be done by laser. To keep arteries from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty. This can be done to the coronary arteries of the heart. Be sure to include angioplasty of non-heart arteries elsewhere.	Percutaneous angioplasty, balloon dilation, balloon test or procedure, PTCA, stent(s),
Coronary bypass surgery	Surgery to improve blood supply to the heart muscle. This surgery is performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Veins are used to connect good portions of the coronary arteries.	CABG, "cabbage" operation, bypass graft or operation
An angioplasty procedure to open up arteries in either of your legs	See Angioplasty above	
Carotid ultrasound or carotid angiogram	A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.	Echo
Other diagnostic procedure or surgery related to your heart or blood vessels	Examples of surgery include valve replacement, ventricular aneurysm resection, aortic stenosis, ventricular stenosis, defect repair, patent ductus closure, pacemaker, implantation of automatic defibrillator, coronary atherectomy. Examples of diagnostic procedures include electrocardiogram, imaging or stress tests involving injection of dye, etc.	
Chest x-ray, a chest CAT scan, MRI, or other study to assess any findings in your chest	MRI: A diagnostic procedure using powerful magnets to look inside the body. Computer-generated pictures image the body and can identify abnormalities, such as damage from an injury. CAT Scan: A non-invasive diagnostic technique that produces an image of the body and can identify abnormalities.	

Other diagnostic procedure or surgery related to your heart or blood vessels	Examples of surgery include valve replacement, ventricular aneurysm resection, aortic stenosis, ventricular stenosis, defect repair, patent ductus closure, pacemaker, implantation of automatic defibrillator, coronary atherectomy. Examples of diagnostic procedures include electrocardiogram, imaging or stress tests involving injection of dye, etc.	
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Terminología Médico

Síntoma o Diagnóstico	Definición	Sinónimos
Infarto miocárdico o ataque al corazón	Daño al músculo del corazón causado por una insuficiencia en el abastecimiento de sangre. Generalmente acompañado de dolor en el pecho.	Infarto de miocardio, ataque cardíaco
Angina de pecho o dolor de pecho debido a la enfermedad de corazón	Dolor intenso y sensación de opresión alrededor del corazón, generalmente irradiado hacia el hombro izquierdo y hacia abajo por el brazo izquierdo, o en casos excepcionales, del corazón al abdomen. El dolor también puede irradiarse hacia la espalda o la mandíbula. Causado por un aporte insuficiente de sangre al corazón.	Angina, cardiopatía isquémica
Globo	Globos que se utilizan en los procedimientos de angioplastia	
Dispositivo intravascular (soporte de acero inoxidable) o <i>stent</i> por su nombre en inglés	Dispositivos intravasculares, también llamados <i>stents</i> , que se utilizan en los procedimientos de angioplastia	
Insuficiencia cardíaca o insuficiencia cardíaca congestiva	El corazón no bombea adecuadamente para proveer de sangre a los órganos. Generalmente esta acompañado por dificultad respiratoria e hinchazón de los pies.	“Fracaso” o “fallo” cardíaco
Fibrilación auricular	Un tipo de irregularidad del ritmo cardíaco.	
Trombosis de vena profunda o trombos (coágulos) en las piernas	Formación de trombos (coágulos) de sangre en una vena de la pierna	
Accidente cerebrovascular	Sangrado intracraneal o falta de abastecimiento de sangre al cerebro que produce lesiones	Ictus, hemorragia o derrame

	neurológicas	cerebral, ACVI
Accidente isquémico transitorio	Accidente cerebrovascular reversible de pequeña duración, con buena recuperación.	AIT
Bloqueo de la arteria carótida	Aterosclerosis (endurecimiento) de la arteria carótida del cuello	
Nódulo o anomalía pulmonar	Cualquier problema pulmonar	
Cáncer	Neoplasia maligna	
Prueba de ejercicio	Prueba de ejercicio en una cinta sin fin, bicicleta o aparato similar para aumentar el ritmo cardiaco de las personas y tomar medidas de la función del corazón, generalmente con un electrocardiograma	Prueba de esfuerzo, ergometría
Angiografía coronaria o cateterización del corazón	Procedimiento que se utiliza para examinar el corazón o una arteria del corazón a través de la inserción de una sonda o tubo (llamado catéter) e inyectando contraste.	Cateterización cardiaca
Ecocardiografía	Prueba en que los ecos de ultrasonido transmitidos al cuerpo se registran electrónicamente produciendo una imagen que da información sobre el tamaño, forma y movimientos del corazón	Ultrasonografía

医学术语		
症状或诊断	解释	代名词
心肌梗塞或心脏病发作	由于心脏供血不足造成的心肌损害；通常伴有胸部疼痛。	心肌梗塞
由心脏疾病引起的心绞痛或胸部疼痛	由于心脏供血不足引起的心前区剧烈疼痛和压迫感；通常放射到左肩，传至左前臂；极少见传导至腹部，有些疼痛可以传导到背部或下颌。	心绞痛
球囊	球囊扩张用于血管成形术	血管成形术
支架	支架用于血管成形术	血管成形术
心力衰竭或充血性心力衰竭	心脏不能供应器官充足的血液。通常伴有呼吸短促和下肢浮肿的症状。	
外周血管疾病，由于下肢动脉堵塞；引起下肢疼痛或间歇性跛行。	由于下肢供血不足，引起的腿部动脉疾病。例如：下肢动脉硬化合并动脉狭窄。	
心房纤颤	心脏跳动不规则的一种。	房颤
深静脉血栓症或下肢血管栓塞	下肢静脉内血栓形成。	
中风	脑出血或供血不足，造成神经系统的损害。	脑出血或脑梗塞
瞬间缺血或轻微中风	可以恢复的短暂中风	
颈动脉阻塞	颈部动脉硬化	
肺部不正常或小结	任何肺部疾病	
癌症	恶性新生物	
运动式传动踏板或单车测试	通过使用传动踏板，单车或类似的运动装置，增加受试者的心跳次数，同时用心电图来监测心脏功能。	
冠状动脉造影或心脏导管插入	一种检测心脏或心脏功能的方法。通过插入受试者血管内一根较细的导管注射造影剂，获得心脏或心脏血管的图像。	心脏导管插入
超声波心脏动态图	一种检测手段，通过发射超声波进入人体内，用计算机处理产生有关心脏的大小，形状及运动状态的图像。	心脏超音图
心血管成形术是用来通畅通向您心脏的动脉	血管成形术是用于扩张您狭窄的血管，使用一个顶端带有球囊的导管插入血管狭窄的部分，扩张球囊使狭窄的管腔扩张；也可以用激光法扩张管腔。为了防止血管塌陷，使用支架（一种不口钢支口物）插入血管，以保证术后血管的通畅。	血管成形术，球囊扩张术，球囊实验，冠状动脉成形术，支架，

冠状动脉搭桥手术	一种提高心脏肌肉血流供应的手术方式，当狭窄的冠状动脉不能提供心脏足够的含氧血液时，我们需要做这个手术来改善血流状态。通常用静脉做搭桥血管。	冠状动脉搭桥手术，血管嫁接或搭桥手术。
血管成形术用来通畅您腿部的动脉	参考以上，血管成形术。	
颈动脉超声波或颈动脉图	一种诊断方法。发射脉冲波到颈部动脉，通过收集动脉壁的反射波，产生有关动脉硬化程度的图像。	颈动脉超声波
其它任何与您心脏或血管有关的诊断或手术方法	相关的手术方法有：瓣膜替换术，室壁瘤切除术，主动脉狭窄，心室狭窄，缺损修补术，动脉导管闭合术，起搏器，除颤器植入，冠状动脉斑块切除术。相关的诊断方法有：心电图，负荷试验。	
胸部透视，胸部断层扫描，核磁共振图像或其它任何评估您胸部发现问题的研究	核磁共振：一种诊断方法，通过使用强磁场观察您的身体内部脏器，并用计算机处理产生图像，可以识别任何不正常，例如：外伤后的损伤。 断层扫描：一种无创性诊断手段，通过观察身体内部脏器图像，识别任何异常。	

APPENDIX G: Drug Therapies: Synonyms and Equivalents *

1. **Nitroglycerin** is a vasodilator used for the prevention and treatment of angina pectoris. It is also used to treat hypertensive emergencies and congestive heart failure associated with myocardial infarction. It is available in tablets that are either swallowed or placed under the tongue, a patch, and a paste that is applied to the skin.

Generic names	Trade names			
glyceril trinitrate	Bidil	Mi-trates	Nitroglyn-SA	PB/PETN
nitroglycerin	Cardilate	Monoket	Nitrol	Pentylan
trinitroglycerine	Deponit	Nitrek	Nitrolin	Peritrate
	Dilatrate-SR	Nitro	Nitrolingual	Peritrate-SA
	Duotrate	Nitrobid	Nitrol-tsar	PETN
	I.S.D.	Nitro-Bid	Nitronal	PETNTD
	Imdur	Nitrobidpl	Nitrong	Sorbitrate
	Ismo	Nitrocap	Nitro-par	Sorbitrate SA
	Iso-Bid	Nitrocine	Nitroquick	Thscisodin
	Isochron	Nitrocot	Nitrorex	Transderm
	Isordil	Nitrodisc	Nitrospan	Transderm NTG
	Isordiltemb	Nitrodur	Nitrostat	Transdermni
	Isosorb딘	Nitro-dur	Nitrotab	Transderm-Ni
	Isosorbide	Nitro-dur II	Nitro-time	Transderm-Nitro
	Isosorbidedi	Nitrogard	Nitro-transd	Transd-Ntg
	Isosorbidedemo	Nitroglyc	Nitrotransde	Tridil
	Isosorbmono	Nitroglycer	NTG	
	Isotrate	Nitroglyceri	NTG-Spray	
	Minitran	Nitroglyn	NTS	

2. **Beta blockers** (beta agonists) are antihypertensive drugs that block primarily adrenaline's effects on the body's beta receptors. Beta blockers slow the heart rate, decrease the force of heart contractions, reduce blood pressure, and reduce anxiety. Beta-blockers are used in the treatment of angina, arrhythmias, hypertension, and mitral valve prolapse. They also have many non-cardiovascular applications.

Generic names	Trade name			
acebutolol	ACB	Bisoprolol	Inderalla	Nadolol/bend*
atenolol	Atel*	Bisoprolol	Inderide*	Normodyne □
betaxolol	Atenoblock*	Bisoprolol	Inderidela*	Normozide*
bisoprolol	Atenol/Chlor *	Blocadren	Innopran XL	Ocupress
carteolol	Atenolol w/chlorthalidone*	Brevibloc	Kerlone	Optipres
carvedilol □	Atensin	Bystolic	Labetal/HCTZ*	Penbutololsu
esmolol	Bartrol	Cartrol	Labetalol	Pronol
labetalol □	Beloc	Coreg □	Levatol	Propran/HCTZ *
metoprolol	Betachron	Corgard	Lopress HCTZ*	Propranol/HCTZ*
nadolol	Betapace	Corzide*	Lopresshct *	Propranolol
nebivolol	Betaxololhcl	Diasectral	Lopressor	Propranololh
penbutolol	Betoptic	Espesil	Lopressor HCT*	Propranololx
pindolol	Bisoprol/HCTZ *	Hctz/Propran*	Lupar	Rhotral
propranolol	Bisoprol/hctz*	Inderal	Metoprolol XL	Sectral
sotalol	Bisopro/HCTZ *	Inderal LA	Metoprololta	Tenolin

* Beta blocker/diuretic combination

□ Alpha & beta blocker

* See Appendix D, section D.5, for related material.

2. Beta blockers (continued)

Generic names	Trade names			
timolol	Tenoretic*	Thscmetoprl	Timololmalea	Trandate HCTZ*
	Tenorin	Thscpropran	Timoptic	Visken
	Tenormin	Timolide*	Toprol	Wesfalín
	Tensig	Timolol/HCTZ*	Toprol XL	Zebeta
	Thscatenolo	Timololmal	Trandate α	Ziac*

* Beta blocker/diuretic combination

α Alpha & beta blocker

3. **Calcium channel blockers** (calcium antagonists) are a group of medications that inhibit the influx of extracellular calcium across the myocardial (heart) and vascular (blood vessel) smooth muscle cell membranes. Calcium channel blockers relax blood vessels and increase the supply of blood and oxygen to the heart, while reducing its workload. They are used to treat CHF, angina, arrhythmias, and hypertension.

Generic names	Trade names		
amlodipine	Adalat	Diltiazem LA	Nimotop
bepidil	Adalat CC	Diltiazem SR	Nisoldipine
diltiazem	Afeditab	Diltiazem XR	Norvasc
felodipine	Amlod/Benaze	Diltiazemhcl	Plendil
isradipine	Amlodipine	Dynacirc	Posicar
nicardipine	Azor	Dynacirc CR	Procardia
nifedipine	Bepidil	Enal/Diltiaz	Procardia XL
nimodipine	Caduet	Enalap/Felod	Sular
nisoldipine	Calan	Enalapril/Diltiazem	Tarka^
verapamil	Calan SR	Exforge	Taztiaxt
	Cardene	Felod/Enalap	Teczem CR
	Cardene I.V.	Felodipine	Teczem^
	Cardene SR	Flodipine/Enalap	Teczemcr
	Cardizem	Isoptin	Thscnifedip
	Cardizem CD	Isoptin SR	Thscnifedip
	Cardizem LA	Ispotin	Thscverapam
	Cardizem SR	Isradipine	Tiamate
	Cartia XT	Lexxel^	Tiazac
	Clevidipine	Lotrel^	Trando/Verap
	Cleviprex	Mibefradil	Trando/Verapamil
	Covera	Mibefradil	Vascor
	Covera-HS	Nicardipine	Veralan
	Dilacor	Nicardipineh	Verapamil
	Dilacor XR	Nicardipines	Verapamilhcl
	Diltia XT	Nifedical XL	Verapamil-HS
	Diltiazem	Nifedipine	Verapamilsr
	Diltiazem CD	Nifedipine CR	Verelan
	Diltiazem ER	Nifedipine XL	Verelanpm
	Diltiazem HC	Nimodipine	

^ Calcium channel blocker/ACE inhibitor combination

4. **Antiarrhythmic agents** are a group of medications that either suppress the abnormal firing of pacemaker tissue or depress the transmission of impulses in tissues that either conduct too rapidly or participate in reentry

Generic names	Trade names		
adenosine	Adenocard	Lidocaine I.V.	Quinadure
amiodarone	Amiodaronehc	Mesantoin	Quinaglute
azimilide	Betapace	Mexiletinehc	Quinalan
bretylium	Betapaceaf	Mexitil	Quinalan lan
disopyramide	Bretylium	Multaq	Quinatime
dofetilide	Bretylium I.V.	Norpace	Quin-G
dronedarone	Bretylol I.V.	Norpace CR	Quinidex
flecainide	Cardioquin	Pacerone	Quinidex EXT
ibutilide	Cinquin	Pacerone 10	Quinidine GL
lidocaine	Cordarone	Peganone	Quinidine SU
mexilitine	Corvert	Phenurone	Quinora
morizizine	Dilantin	Phenysod	Quin-tab
procainamide	Dilantin EX	Phenytek	Rhythmol
propafenone	Dilantin-125	Phenytoin	Rythmol
quinidine	Dilantin-30	Phenytoin EX	Sorine
sotalol	Dilantinex	Phenytoin NA	Sotalol
tocaininde	Dilantin-PB	Phenytoin SA	Sotalolaf
	Di-phen	Phenytoinsod	Sotalolhcl
	Diphenylan	Procamide SR	Tambocor
	DPH	Procan	Thscdilantn
	Duraquin	Procan SR	Thscquinidn
	Encainide	Procanbid	Tikosyn
	Encainidehcl	Pronestyl	Tonocard
	Enkaid	Pronestyl SR	Xylocaine
	Ethmozine	Propafenoneh	Xylocaine I.V.

5. **Diuretics** (commonly called “water pills”) constitute a class of many different drug families that have the same action—they remove water from the body. Diuretics are used to lower blood pressure in people with hypertension and to improve heart function in people with congestive heart failure. Diuretics are also used to reduce water accumulation caused by other diseases. Diuretics are divided into two general groups: potassium-sparing diuretics and potassium-depleting diuretics. Potassium-depleting diuretics are further divided into thiazide diuretics and loop diuretics.

Generic names	Trade names		
acetazolamide	3HW/R φ	BT-HCTZ	Diurigen/res
amilorid	Accuretic ∞	Bumex	Diuril
benzthiazide	Acetadiazol	Cam-ap-es £	Diutensen
bendroflumethiazide	Alamethyl	Candasartan HCTZΩ	Diutensen-r Δ
bumetanide	Aldactazide	Capozide ∞	Dyazide
chlorothiazide	Aldactone	Captopril/HCTZ ∞	Dyrenium
chlorthalidone	Aldoclor ж	Carozide	Edecrin
ethacrynic acid	Aldoril ж	Chloro-Res	Enalapril/HCTZ ∞
furosemide	Amilocomp Beta	Chloroserpine Δ	Enduron
hydrochlorothiazide	Amiloride	Chlorothiaz	Enduronyl Δ
hydroflumethiazide	Amiloride/HCTZ	Chlorothiaz	Eplerenone
indapamide	Amuretic	Chlorthalid	Eprosartan HCTZΩ
methyclothiazide	Anhydron	Chlorthalido	Eserdine Δ
metolazone	Apresazide φ	Clonidine/chlor	Esidrix
polythiazide	Apres-esidrx	Clorpres ж	Esimil Δ
quinethazone	Apresodex	Combipres ж	Ethacrynicac
spironolactone	Apresoline-Esidirx φ	Combipres-1 φ	Eutron φ
torsemide	Aquacot	Combipres-2 φ	Exna
triamterene	Aquapresr φ	Combipres-3 φ	Ezide
trichlormethiazide	Aquatag	Corzide ψ	Flumezide Δ
	Aquatensen	Demadex	Furocot
	Aquazide	Demi-Regrot	Furomide
	Aquex	Demi-Regroton Δ	Genutensin Δ
	Atacand HCT Ω	Diamox	HCTZ
	Atacand HCTZ Ω	Diaqua	Hctz/Amilori
	Atel ψ	Diaserp Δ	HCTZ/Deserpine φ
	Atenblok ψ	Diovan HCT Ω	Hctz/Spiro
	Atenolol w/chlorthalidone ψ	Diovan HCTZ Ω	Hctz/Triamt
	Avalide Ω	Diucardin	HHR £
	Benazep/HCTZ ∞	Diulo	H-H-R φ
	Bendroflumet	Diupres Δ	Hychlor
	Benicar HCTZ Ω	Diurese	Hydone
	Biogroton	Diuretic	Hydral/HCTZ φ
	Bi-press φ	Diuretic-ap-es £	Hydral/res/ φ
	Bisoprolol/HCTZ Ψ	Diurigen Δ	Hydralplus φ
φ diuretic/vasodilator combination		φ diuretic/vasodilator combination	
ж diuretic/alpha adrenergic agonist combination		ж diuretic/alpha adrenergic agonist combination	
Φ diuretic/alpha blocker combination		Φ diuretic/alpha blocker combination	
Ψ diuretic/beta blocker combination		Ψ diuretic/beta blocker combination	

List of Diuretics continued on next page

5. Diuretics (continued)

Generic names	Trade names		
	Hydrap-ES £	Hytroton	Mictrin
	Hydra-zide ϕ	Hyzaar Ω	Midamor
	Hydrex	Hy-zide ϕ	Midomor
	Hydro par	Inderide ψ	Minizide ϕ
	Hydroap-es £	Inderidela Ψ	Moduretic
	Hydroapes ϕ	Inspra	Moexipr/HCTZ ∞
	Hydrochlorothiazide	Labetal/HCTZ Ψ	Mono-Press
	Hydrochlorul	Lasix	Monopril HCTZ ∞
	Hydrocot	L-Dopre/HCTZ ϕ	Mykrox
	Hydrodiuril	Lisinopril/HCTZ ∞	M-Zide
	Hydroflu/res ϕ	Lo-Aqua	Nadolol/bend Ψ
	Hydroflumeth	Lopress HCTZ Ψ	Naqua
	Hydro-fluser ϕ	Lopressor HCT ψ	Naquival Δ
	Hydrofluserpine Δ	Loqua	Naturetin
	Hydromal	Loretic	Normozide Ψ
	Hydromox	Losartan/HCTZ Ω	Novamilor
	Hydromox-R	Lotensin HCT ∞	Olmesartan HCTZ Ω
	Hydro-Par	Lotensin HCTZ ∞	Oretic
	Hydropine Δ	Lozol	Oreticyl ϕ
	Hydroplus-50 Δ	Mallopress Δ	Oreticylfort ϕ
	Hydropres Δ	Maquavil	Presaril
	Hydro-reserp Δ	Marazide II	Prinzide ∞
	Hydrorex Δ	Marpres £	Proaqua
	Hydro-Ride	Maxzide	Propranolol/HCTZ Ψ
	Hydroserp Δ	Maxzide-25	Rautrax ϕ
	Hydroserpala ϕ	Maxzide-25Mg	Rautrax-N ϕ
	Hydroserpalan Δ	Meserpidine Δ	Rauwolf/bend ϕ
	Hydroserpazi ϕ	Metahydrin	Rauzide Δ
	Hydroserpazine £	Metatensin Δ	Regroton ϕ
	Hydroserpine Δ	Methyclothia	Renese
	Hydroserpine Plus £	Methyclothia	Renese-R Δ
	Hydro-T	Methylcl/des ϕ	Repres Δ
	Hydrotone	Methyld/chlo ϕ	Res/hydral/ ϕ
	Hy-Es ϕ	Methyld/HCTZ ϕ	Reserpine/chlor ϕ
	Hygroton	Micardis HCTZ Ω	Reserpine/HCTZ ϕ
	Hyserp £	Microzide	Reserpine/hdrfl ϕ
ϕ diuretic/vasodilator combination	ϕ diuretic/vasodilator combination		
⋈ diuretic/alpha adrenergic agonist combination	⋈ diuretic/alpha adrenergic agonist combination		
Φ diuretic/alpha blocker combination	Φ diuretic/alpha blocker combination		
Ψ diuretic/beta blocker combination	Ψ diuretic/beta blocker combination		

List of Diuretics continued on next page

5. Diuretics (continued)

Generic names	Trade names		
	Reserpine/polyt ϕ	Spirochlor	Triamt/HCTZ
	Retrogon Δ	Spironazide	Triamterene/HCTZ
	Rose-40	Spironazide/HCTZ	Trichlor/res ϕ
	Sae £	Spirono/HCTZ	Trichlorex
	Salazide Δ	Spironolact	Trichlorix
	Saluron	Spironolactone	Trichlormas
	Salutensin Δ	Spironoplus	Trichlormeth
	Salutensin-D ϕ	Spirozide	Trichlortens ϕ
	Sanazide	Spirozone	Tri-hydroser ϕ
	Ser-a-gen £	Telmisartan HCTZ Ω	Trihydroserpine £
	Seralazide £	Tenoretic ψ	Unipres £
	Ser-ap-es £	Teveten HCTZ Ω	Uniretic ∞
	Serapes ϕ	Thalitone	Uni-serp £
	Serathide £	Thiaserp250 ϕ	Valsartan/HCTZ Ω
	Serflugen Δ	Thscfurosem	Vaseretic ∞
	Serp-apres ϕ	Thschctz	Zaroxolyn
	Serp-esidrix	Timolide ψ	Zestoretic ∞
	Serpasil-esidrix Δ	Timolol/HCTZ Ψ	Ziac ψ
	Serpazide £	Torse mide	Zide
	Serpex £	Trandate HCTZ Ψ	Zide-50
	Spenzide	Triam/HCTZ	
∞ diuretic/ace inhibitor combination Ω diuretic/angiotensin II receptor blocker combination Δ diuretic/adrenergic neuron antagonist combination £ diuretic/adrenergic neuron antagonist/vasodilator combination		ϕ diuretic/vasodilator combination ж diuretic/alpha adrenergic agonist combination Φ diuretic/alpha blocker combination Ψ diuretic/beta blocker combination	

6. **Digitalis** is a general term often used to refer to a group of compounds derived from *digitalis purpurea* (foxglove) or that have actions similar to that of digitalis. These compounds are used to increase cardiac contractile force, increase cardiac output, reduce edema associated with congestive heart failure, and control certain arrhythmias.

Generic names	Trade names		
digitoxin	Cardoxin	Digoxinped	Lanoxin
digoxin	Crystodigin	Digoxin-tab	Lanoxinped
	Digitek	Lanoxicaps	Thscdigoxin

7. **ACE Inhibitors** are drugs that lower blood pressure by preventing angiotensin-converting enzyme (ACE) from activating the hormone angiotensin II, a powerful vasopressor (an agent that stimulates contraction of the muscles of the capillaries and arteries). They are used to treat hypertension and heart failure and to prolong the survival of participants who have had myocardial infarction.

Generic names	Trade names		
benazepril	Accupril	Enalapril/HCTZ @	Monopril
captopril	Accuretic @	Enalaprilma	Monopril HCTZ @
enalapril	Aceon	Enalaprilmal	Perindpril
enalaprilat	Altace	Fampress	Prinivil
eprosartan	Amlod/benaze	Felod/Enalap	Prinzide @
fosinopril	Atacand	HCTZ/Captopr @	Sapril
irbesartan	Avalide @	HCTZ/Lisinop @	Tarka #
lisinopril	Avapro	Hyzaar @	Teczem #
losartan	Benazep/hctz @	Lexxel #	Teczem CR
moexipril	Capoten	Lisinop/HCTZ	Teveten
perindopril	Capozide @	Lisinop-Hctz	Thscaptopr
quinapril	Captopr/HCTZ	Lisinopril/HCTZ @	Thscclisopr
ramipril	Captopril/HCTZ @	Lisinoprilhc	Trando/Verap
telmisartan	Cozaar	Lotensin	Uniretic @
trandolapril	Diovan	Lotensin HCT @	Univasc
valsartan	Diovan HCT @	Lotensin HCTZ @	Vasoretic @
	Enal/diltiaz #	Lotrel #	Vasotec
	Enalap/Felod	Mavik	Zestoretic
	Enalapr/HCTZ	Moexipr/HCTZ @	Zestril

ACE inhibitor/calcium channel blocker combination

@ ACE inhibitor/diuretic combination

8. **Other vasodilators** are antihypertensive medications that relax the muscle in the walls of the blood vessels, allowing the vessels to dilate (widen).

Generic names	Trade names		
alprostadil	3HW/R	Clonidinehcl	Hctz/Reserp Φ
amrinone	Aldoclor Φ	Clorpres Φ	Hctz/Reserpi Φ
cyclandelate	Aldomet	Combipres Φ	HHR Φ
diazoxide	Aldoril Φ	Combipres-1 Φ	H-H-R Φ
dipyridamole	Aldoril-15 Φ	Combipres-2 Φ	Hydral/hctz Φ
doxazosin	Aldoril-25 Φ	Combipres-3 Φ	Hydral/res/ Φ
epoprostenol	Aldoril-D30 Φ	Corlopam	Hydralazine
fenoldopam	Aldoril-D50 Φ	Cyclospasmol	Hydralazineh
hydralazine	Alostil	Demi-regrot Φ	Hydralplus Φ
isosorbide dinitrate	Alphamethyl	Dilatrate	Hydrap-es Φ
isosorbide mononitrate	Anagrelide	Dipridicot	Hydrazide Φ
minoxidil	Apresazide Φ	Diupres-250 Φ	Hydroapes Φ
neseritide	Apres-esidrx Φ	Diupres-500 Φ	Hydrochloride
nitroprusside	Apresodex Φ	Diuretic Φ	Hydroflu/res Φ
phentolamine	Apresoline	Diuretic-ap-es Φ	Hydro-fluser Φ
prazosin	Apresrex	Diurigen/res Φ	Hydromox-r Φ
terazosin	Aquapresr Φ	Diutensen Φ	Hydropine Φ
tolazoline	Bi-press Φ	Diutensen-r Φ	Hydropinehp Φ
	Cam-ap-es Φ	Doxazosin	Hydroplus-50 Φ
	Cardura	Doxazosinmes	Hydropres Φ
	Catapres	Dralzine	Hydro-reserp Φ
	Catapres-TTS	Edex	Hydroserp Φ
	Cataprestts1	Enduronyl Φ	Hydroserp#1 Φ
	Cataprestts2	Esimil Φ	Hydroserp#2 Φ
	Cataprestts3	Eutonyl	Hydroserpala Φ
	Caverject	Eutron Φ	Hydroserpazi Φ
	Chlo/Methyl Φ	Flolan	Hydroserpine Φ
	Chloro/Reser Φ	Flumezide Φ	Hy-es Φ
	Chloro-Res Φ	Guanabenz	Hyloriel
	Chloroserp Φ	Guanethidine	Hyper Stat IV
	Chloroserpin Φ	Guanfacine	Hyperstat
	Cilostazol	H.H.R. Φ	Hyserp Φ
	Clonid/Chlor Φ	Harmony	Hytrin
	Clonidine	Hctz/Deserpi Φ	
	Clonidine/chlor Φ	HCTZ/deserpine Φ	

Φ diuretic/vasodilator combination

List of other Vasodilators continued on next page

8. Other vasodilators (continued)

Generic names	Trade names		
	Hy-zide Φ	Oreticyl Φ	Salutensin Φ
	Inocor	Oreticylfort Φ	Salutensin-d Φ
	Inversine	Pletal	Ser-a-gen Φ
	Ismelin	Prazocinhcl	Seralazide Φ
	Isonate	Prazosin	Serapes Φ
	Isopar	Prazosinhcl	Ser-ap-es Φ
	Isopen-20	Priscoline	Serathide Φ
	Isordil	Proglycem	Serpalan
	Isorem	Prostin VR	Serp-apres Φ
	Isotrate	Raudixin	Serpasil
	L-dopre/hctz Φ	Rautrax Φ	Serpatabs
	L-Dopres	Rautrax-n Φ	Serpazide Φ
	Loniten	Rauwiloid	Serp-esidrix Φ
	Mallopress Φ	Rauwolf/bend Φ	Serpex Φ
	Maquavil Φ	Rauwolfia	Tenex
	Marpres Φ	Rauwolfiaser	Terazosin
	Metatensin Φ	Rauzide Φ	Thiaserp250 Φ
	Methylcl/des Φ	Regetine	Treprostinil Sodium
	Methyld/chlo Φ	Regroton Φ	Trichlor/res Φ
	Methyld/hctz Φ	Renese-r Φ	Trichlortens Φ
	Methyldopa	Res/hydral/ Φ	Tri-hydroser Φ
	Minipress	Res/Hydroflu Φ	Trihydroserpine
	Minizide Φ	Reser/Chloro Φ	Unipres Φ
	Minoxidil	Reserp/Chlor Φ	Uni-serp Φ
	Moderil	Reserp/HCTZ Φ	Viridal
	Muse	Reserp/Hdrfl Φ	Wytensin
	Nanitroprus	Reserp/Polyt Φ	
	Naquavil Φ	Reserpalkal	
	Natrecor	Reserpine	
	Nipride	Reserpine/chlor Φ	
	Nitropress	Reserpine/hctz Φ	
	Nitropress IV	Reserpine/hdrfl Φ	
	Nitroprussid	Reserpine/polyt Φ	
	Nitroprusside IV	Sae	

Φ diuretic/vasodilator combination

9. **Aspirin** is an anti-platelet drug that can help to prevent the formation of blood clots, thereby reducing the incidence of cardiovascular and cerebrovascular events.

Aspirin given for prevention of these events may be plain or buffered, and may come in tablet, chewable, effervescent, or enteric-coated form.

Answer “yes” to this question only if the participant is taking aspirin *on a daily basis* to lessen his/her risk of above events. Aspirin does *not* include other over-the-counter analgesics such as acetaminophen (Tylenol) only or ibuprofen (Motrin or Advil).

The following list is only partial but includes several types of aspirin or aspirin compounds that may be prescribed to prevent cardiovascular and cerebrovascular events. There are also numerous over-the-counter generic and brand-name aspirins, some of which are listed below.

Generic names	Trade names		
aspirin	1/2halfprin	Arthritis BC	Aspirin EC
asa	AA&C	Arthritis PA	Aspirin LS
baby aspirin	A.S.A.Ens	Arthritis pain formula	Aspirin M/S
buffered aspirin	A/strpain	Arthritis PF	Aspirin ped
	Acetard	Arthritpain	Aspirin/apap
	Acetylsalicy	Arthropan	Aspirin/calc
	Acetylsalicylic Acid	ASA Enseals	Aspirinad
	Acuprin	ASA/Antacid	Aspirinadlt
	Addstrpain	ASA/caff	Aspirinchld
	Adltasalow	ASA/caff/but	Aspirinlow
	Adltstrasa	ASA+Antaci	Aspirinnon-
	Adprinb	Asabuffered	Aspirisucre
	Adultpain	Asalo-dose	Aspir-low
	Adultstreng	Asalowdose	Aspir-Lox
	Aggrenox »	Asalowstr	Aspir-loxad
	Alka-selzter	Asaphen	Aspir-Mox
	Amigesic	As-caff	Aspir-moxib
	Aminodyne	Ascriptin	Aspirtab
	Amiprin	Ascriptina/d	Aspirtabm/s
	Amiprine	Ascriptine	Aspir-trin
	Anacin	Ascriptine	Aspralum
	Analgesic	Ascriptin-ES	Aspralum EB
	Anaprin	Aspercinext	Aspidrox
	Anodynos	Aspergum	Asprimox
	Anodynosfor	Aspicin	Asprimoxe/p
	Antalgesic	Aspir-81	B.C.Cold
	Apacomp	Aspirbar	B.C.Headach
	Apapfortifi	Aspircaf	Backacherel
	Argesic-SA	Aspirin buff	Bayer
	Arthpain FO	Aspirin E/S	Bayer child

» Aspirin/anti-platelet combination

List of Aspirin continued on next page

9. Aspirin (continued)

Generic names	Trade names		
	Bayer low	Doansexstr	Genasan
	Bayer max	Doanspills	Gennin-fc
	Bayer plus	Dolobid	Genprin
	Bayer pm	Duradyne	Gensan
	Bayerasa	Easprin	Glaspirin
	Bcheadache	Ecaspirin	Halfprin
	Biocin	Ecotrin	Hcaaspirin
	Biodrin	Ecotrin m/s	Hmanalgesic
	Buffaprin	Ecpirin	Hmasachild
	Buffasal	Efferpain&	Hmaspirin
	Buffaspirin	Effervescent	Hmaspridrox
	Bufferedasa	Emagrin	Hmpnreliev
	Bufferin	Empirin	Hmtri-buff
	Buffetsii	Entaprin	Idenal
	Buffex	Entercote	Ini-asplus
	Buffinol	Entrophen	Isobutyl
	Bufpirin	Excedrin	Lanorinal
	But/asa/caff	Exstrbayer	Litecoatasa
	Butalbitol	Exstrpain	Lo-Doseasa
	Butalbitcpd	Extra-gesic	Low-Doseasa
	Butalgen	Extraprin	Magan
	Cafiaspirina	Extrastreng	Magnaprin
	Cama	Farbital	Magnesiumsal
	Childasa	Fembutal	Major-Cin
	Childasals	Fiorgen	Maprin
	Childaspir	Fiormor	Maprina/D
	Chomagtris	Fiortal	Marthritic
	CMT	Fortabs	Mdladdstr
	Coatedasa	Fvasachild	Mdlanalges
	Cope	Fvasatri-B	Mdlasatri-
	Cortal	Fvaspirin	Mdlaspirin
	CP-2	Fvaspridrox	Measurin
	CTD Aspirin	Gelpirin	Medaspirin
	Dasin	Gelprin	Medi-Seltzer
	Dasprin	Genaced	Megaprin
	Diflunisal	Genacote	Meprogesic
	Disalcid	Genacotemax	Minitabs

» Aspirin/anti-platelet combination

List of Aspirin continued on next page

9. Aspirin (continued)

Generic names	Trade names		
	Mobidin	Salagen	Synalgos
	Mono-Gesic	Salagesic	Therapbayer
	MS-650	Saleto	Thscaspirin
	Neutralin	Saleto-200	Thscbut/Asa
	Non-Irrasa	Saleto-400	Tri-Bufferasa
	Non-Irriasa	Saleto-600	Tri-Buffered
	Norgesic	Saleto-800	Tricosal
	Norwich	Salflex	Trigesic
	Norwichasa	Salgesic	Trilisate
	Novasen	Salgesic-500	Trinprin
	Orph/asa/caf	Salgesic-750	Tri-Pain
	Orphencpd	Salgesoc	Ultra-Gesic
	Or-Prin	Salicylic Acid	Uni-Ann
	Orprin-LA	Salicylsalic	Uni-Asplus
	Oascoasalow	Salocol	Uni-Buffer
	Oascoaspirin	Salsalate	Uni-Case
	Pabalate	Salsitab	Uni-Tren
	Pabalate-SF	Sav-On ASA	Valomag
	P-A-C	Sbasalow	Vanquish
	Paccompound	Sbaspirin	Verin
	Pain-Drin	Sbbuffasa	Vibutal
	Painrelief	Sgasalow	V-Raddstr
	Painrelieve	Sgaspirin	V-Ranalges
	Presalin	Sgchildasa	V-Rasachld
	Prolexdm	Sgtri-Buffer	V-Raspirin
	Protranplus	Sloprin	V-rtri-buff
	Q-Acin	Slo-Prin	Wesprin
	Qualaflex	Sodsalicyl	X-Strasa
	Qualityasa	St. Joseph	X-Strpain
	Quietworld	Stanbackana	X-Strpain
	Raaspirin	Supac	Yspaspirin
	Rachildrens	Superstrpa	Zorprin
	Ridiprin	Sureprin81	

» Aspirin/anti-platelet combination

10. **Heparin and enoxaparin** are anticoagulants used for the treatment of deep venous thrombosis, pulmonary embolism, and acute arterial occlusion. They are also given immediately after an acute myocardial infarction for anticoagulation.

Generic names	Trade names	
enoxaparin	Angiomax	Heparinsod
heparin	Anisindione	Lepirudin
	Argaroban	Lovenox
	Arixtra	Liquaemin
	Bivalirudin	Miradon
	Clexane	Normiflo
	Fondaparinux	Orgaran
	Fragmin	Refludan
	Heparin	

11. **Warfarin, dicumarol, rivaroxaban, dabigatran, and apixaban** are anticoagulants used to prevent and treat venous thrombosis, pulmonary embolism, and thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement; and to reduce the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.

Generic names	Trade names	
apixaban	Coumadin	Sofarin
dabigatran	Eliquis	Warfarina
dicumarol	Jantoven	Warfarinsod
rivaroxaban	Miradon	Warfarinsodi
warfarin	Panwarfin	Xarelto
	Pradaxa	

12. Anti-platelet agents inhibit platelet clumping and are used prevent myocardial infarction, stroke, and vascular death in participants with atherosclerosis.

Generic names	Trade names	
abciximab	Acova	Permole
anisindione	Aggrastat	Persantine
argatroban	Anagrelide	Plavix
cilostazol	Centorx	Pletal
clopidogrel	Dipridicot	Reopro
dalteparin	Dipyridamole Aspirin	Ticlid
dipyridamole	Effient	Ticlopidine HCL
epoprostenol	Flolan	Tirofiban HCL
eptifibatide	Innohep	Treprostinil Sodium
prasugrel	Integrelin	
ticlopidine	Integrilin	
tirofiban	Miradon	

13. Other drugs include those not listed above but given for any of the above-listed events or indications.