## 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 cases[[1]](#footnote-1), 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.

##### 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.

Potential Event(s)

**TYPE**

|  |  |
| --- | --- |
| **Possible endpoints in the event** | **Number of Investigations Needed  (cardiac endpoint doesn’t require separate investigation)** |
| 2 or more TIA’s with no intervening strokes | **1** |
| TIA(s) and 1 stroke | **2** |
| TIA(s) and 2 strokes | **3** |
| 2 or more strokes | **2 or more** |
| TIA(s), then stroke, then other TIA(s) | **3** |

**COUNT**

**Single** investigation for each hospitalization, INCLUDING:

Overnight hospital admission results in transfer to second hospital for eligible procedure or overnight admission;

Hospitalization results in transfer to in-patient hospice care or rehab ending in death;

Hospitalization results in discharge to home, care facility, out-patient hospice care or rehab with readmission to acute care in short period of time;

Multiple cardiac/PVD events occur during the same hospitalization;

Multiple hospitalizations, procedures, or clinic visits for cardiac/PVD-eligible events may be linked for reviewers if occurring within a short span of time.

**Consult the Central Abstractor or CC when in doubt.**

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 place 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 *General Health* 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 *General Health* 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. |
| 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 *General Health* 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 *General Health* 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 not 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: This category should only be used in rare cases. 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 *Final Notification*. Selecting a type on the *Initial Notification* 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 facility1. If necessary,  obtain *Physician Questionnaire for Cardiac/PVD* |
| Outpatient cerebrovascular nonfatal  Event | Request records from outpatient facility1. If  necessary, obtain *Physician Questionnaire for*  *Stroke/TIA* |

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.



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*. [↑](#footnote-ref-1)