

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 arterial disease (PAD), 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 Summary contains preprinted information about the participant's language preference in the upper right-hand corner of the screen.

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, 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, contact information and proxy 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)
- For Follow-up 11, to introduce Exam 5 and schedule an appointment.

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
- Medications Inventory
- Participant Tracking
- General Health – Death (as needed)
- Death Information (as needed)
- 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.

The forms should be completed via computer aided entry. If a computer is not available at the time of the interview, paper forms may be used, but answers will need to be entered into the computer when it becomes available.

On paper forms, all questions and responses that should be read aloud are in normal font. Directions and responses that should not be read aloud are indicated in bold. Phrases that should be modified and read by the interviewer are indicated in italics and brackets.

On the computerized data entry system, all questions and responses that should be read aloud are in normal font. Directions and instructions use blue font. Any questions that should be skipped, due to a skip pattern, are grey-out and should not be read to the participant.

Timing of Questionnaire Administration

Each Follow-up call is scheduled at a regular interval after the previous Follow-up call. The Coordinating Center provides web reports to identify participants who are due for their follow-up call. Specifically, given a user-specified window of time, the report will list all participants who require a follow-up phone call interview within that time window. These reports provide the necessary paperwork for Follow-up 15, 16, and 17. The specific follow-up desired is selected from a drop down list.

At minimum, these reports should be run once each month to identify participants who

should be contacted in the upcoming month. The Coordinating Center recommends running the reports mid-month for all participants whose follow-up phone call is due in the following calendar month (e.g., running the report 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.

The contact information (contact window, phone numbers, etc.) is downloaded automatically every time the Follow-up program starts up and there is an internet connection.

Starting with Follow-up 17, participants that are identified as living in the same residence will have the same contact window assigned.

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.

2015			2016			2017			2018			2019			2020		
			FY01			FY02			FY03			FY04			FY05		
						Exam 6											
FU15			FU17			FU18			FU19			FU20					
FU16																	

Each field center should run its follow-up reports 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 report was run and the designated “start date” for the current run.

The information collected on these forms applies to the time period since the last contact. 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 unscheduled call to 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 or five 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 contact
- Space to record if participant has had specific procedures, hospital/nursing home admissions, or diagnoses of interest to MESA since his/her last MESA contact.

Medications Inventory Form

- Space to record participant's current medications, dosage, and instructions for use.

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

NOTE: The information received from the participant should be entered directly into the computer. Write this information described above on the paper form only if the computer system is not available.

The target follow-up contact date for each participant is nine to 12 months after his/her last contact. 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

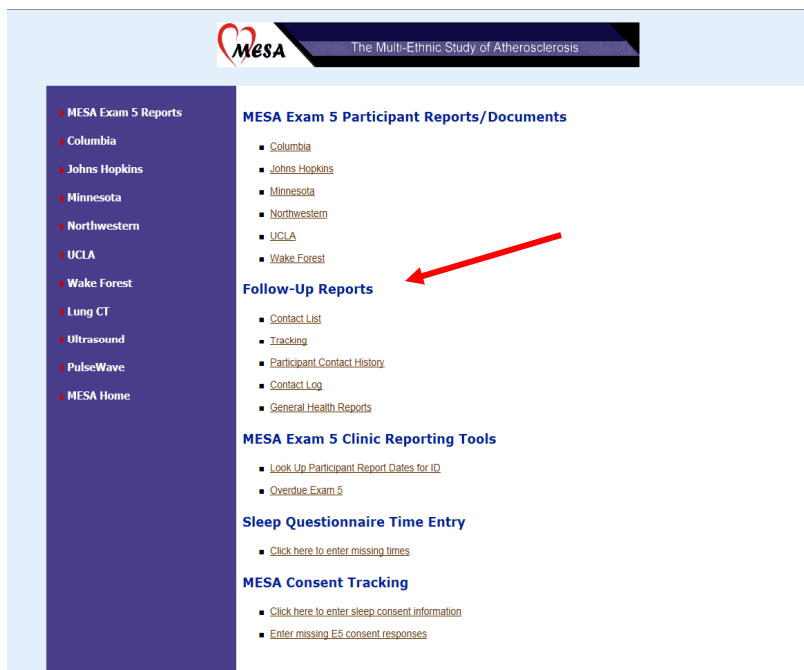
The following chart briefly outlines the order in which the forms for the MESA Follow-up Phone Call are generally administered. Key points to remember are:

- *Contact Log* and *Contact Cover Sheet* are completed for ALL participants for whom contact is attempted.
- *General Health* (or *General Health—Death*), *Participant Status*, and *Participant Tracking* forms 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

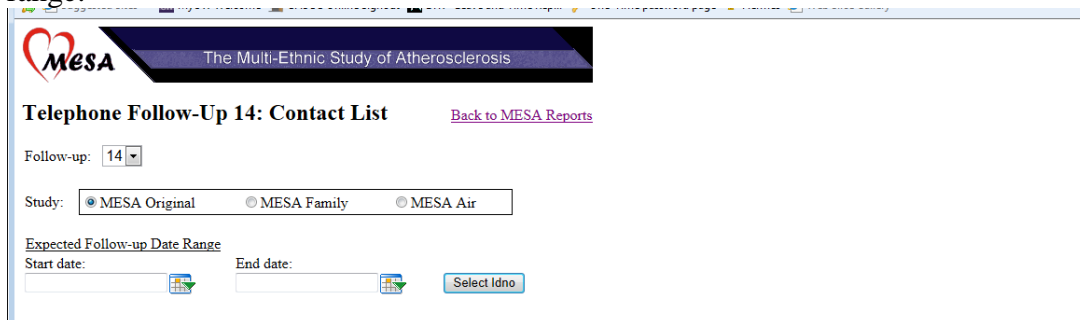
potential event on the *General Health* form.

The Contact Log, Contact Cover Sheet, and other relevant documents are created as reports on the MESA web site. To create these documents, open a browser and navigate to

<https://www.uwchsc.org/MESAE5Reports/login.aspx?ReturnUrl=%2fMESAE5Reports%2fDefault.aspx>. To ensure that participant information can only be viewed by the appropriate site, a site-specific user name and password will be required to navigate to the site page. (Contact your study coordinator or the CC for this information.) Once the password for your site has been entered, you will see the following screen. The reports for follow-up are listed under “Follow-up Reports”.



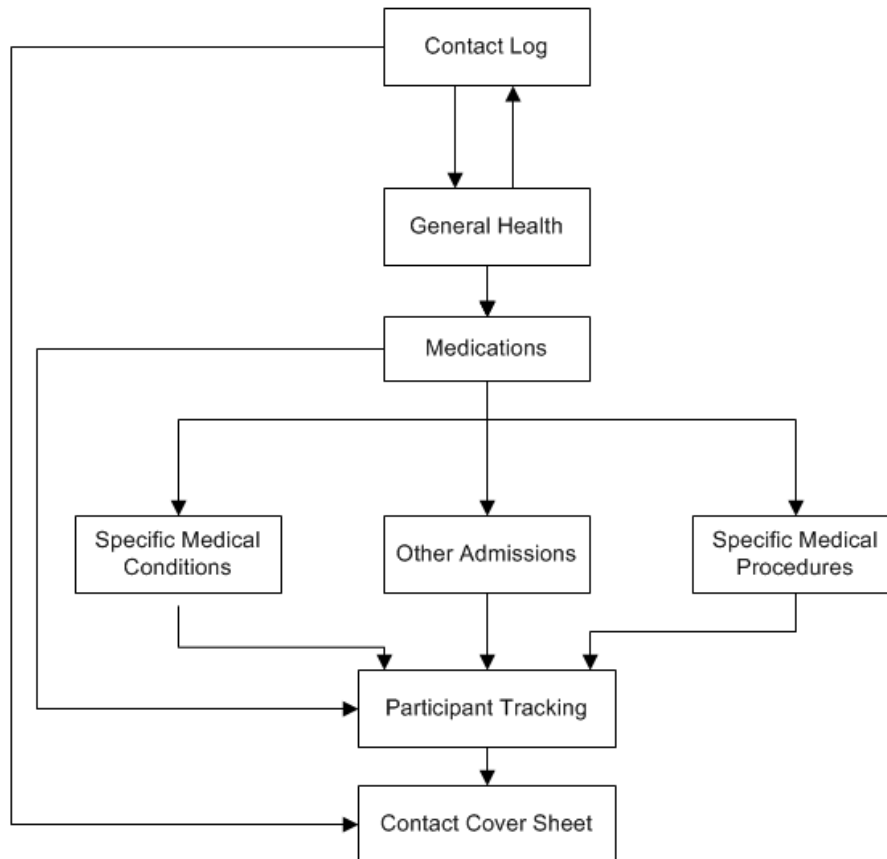
After selecting any of “Contact List”, “Tracking”, “Participant Contact History”, or “Contact Log” reports, a screen will open that will allow selection of individual ID numbers or all ID numbers with follow-up due in the specified date range.



Perform the following steps:

This section: 11/4/2014 Version

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

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*.

Contact Cover Sheet for ALL participants, even if no contact was made.

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.

Starting an interview with the Electronic Data Entry System

From the first screen of the Telephone Follow-up Data Entry System, enter your Tech ID and password and select “OK”, then select a participant by clicking on a name in the contact list:

ID	Participant Name	Expected Follow-up	Forms Uploaded (To CC)
9900001	MARY SMITH	08/15/2015	GenH Track Cover
9900002	KEN ARROYO	08/15/2015	GenH Track Cover
9900003	ALICE JONES	08/15/2015	GenH
9900004	GEORGE BROWN	08/15/2015	
9900005	YUAN LI	08/15/2015	
9900006	MAT RAMIREZ	08/15/2015	
9900007	ANN WU	08/15/2015	
9900008	RYAN HAWK	08/15/2015	
9900009	MARIA WELLBY	08/15/2015	
9900010	ROBERT CRANSTON	08/15/2015	
9900011	ESTELA HARPER	08/15/2015	
9900012	OSCAR REYES	08/15/2015	
9900013	Linda THOMAS	08/15/2015	
9900014	RICK ANDREWS	08/15/2015	
9900015	PEGGY KING	08/15/2015	Med

Select a participant above or type the ID number here:

This will generate the participant’s Contact Summary that displays information about the participant as well as the forms required for the Follow-up Call.

Participant: 9900001

Language: English Expected Contact Date: 08/15/2015 Contact Status: Air Participant

Home Phone: (555) 123 1234
 Cell Phone: (555) 123 1234
 Work Phone: (555) 123 1234
 Email: user@isp.net
 Preferred Contact: Phone

Uploaded: GenH Track Cover

Prev. Notes

Notes:

Follow-up Form	Date	Status	Data Entry	Uploaded To CHSCC
Participant Tracking	08/10/2015	Complete	999	08/11/2015
General Health	08/10/2015	Complete	999	08/11/2015
Medications		Not Done		
Contact Cover	08/10/2015	Complete	999	08/10/2015
MC--Myocardial Infarction	08/10/2015	Complete	999	08/10/2015
OA--Overnight Nursing Home/RC	08/10/2015	Complete	999	08/10/2015
MP--Angioplasty of Heart	08/10/2015	Complete	999	08/10/2015

Back

If this is a new Follow-up call, you will start at the beginning of the Participant Tracking Form. If the interview was partially completed for this participant during a previous phone call, you will be taken to the last completed page of the last questionnaire completed in the previous call. At the end of each screen click ‘Next’ to advance to the next screen. If any questions are left blank, a warning box will alert you of the skipped questions. If you want to continue without filling out all the questions, you may close the alert box and click ‘save and continue.’ Note that as you work through the program, questions that do not need to be asked due to skip patters are not displayed.

If you start an interview and wish to close the program before completing all questionnaires, click ‘Quit Data Entry’ to end the interview session.

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, acoustic, language preference, telephone number, enrollment (or Visit) 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 Participant Tracking

Current tracking information for the participant from the MESA database is displayed in the left column of the screen. 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.1.3.1 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?

MESA Followup Data Entry -- Tracking Page One

Participant ID#: 9900001 Acrostic: ABCDEFF [Changes](#) [Quit](#)

Participant Information

MARY SMITH

Home Phone: (555) 123 1234
Cell Phone: (555) 123 1234
Work Phone: (555) 123 1234
Email: user@isp.net

4002 Lakeview Road
Townsville ST 12345

Mailing only

If the above address is a MAILING Address only, enter the STREET address.

Street Address:
4002 Realview Street
Townsville ST 12345

Tracking Date: 8/10/2015

Home Phone: 444 4446666 Cell Phone: 444 4444333 Work Phone: 444 4444444

Email: _____

Address: _____

City: _____ St: _____ Zip: _____

If the above is a NEW Address, enter the Month and Year of change: Month: _____ Year: _____

Street Mailing

Street Address: _____

City: _____ St: _____ Zip: _____

If the above is a NEW Address, enter the Month and Year of change: Month: _____ Year: _____

[Next](#)

Read participant name, address, phone numbers, and e-mail address from top left box on the screen.

If information is not correct, type any changes on the right side of the page. Record the month and year of the address change and record whether the new address is a mailing address or a street address. The Street address should where the participant lives for most of the year. If a mailing address is given in box A, record a mailing address where indicated.



NOTE: Only enter information for addresses, phone numbers, or other information that has changed. For example, if the address has changed but the phone number has not changed, only enter a new address in the Participant Tracking screen.

Select "Next."

Now, could you tell me if you have a secondary residence?

Record the address of any secondary residence where a participant spends more than 4 weeks per year in Item B. The 4 weeks do not need to be consecutive. Then record the month and year that the participant began use of their secondary residence.

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 names, relationship to participant, address, phone numbers, e-mail address from “Item C” of the form.

After verifying the information for each contact, ask: **May we send [Contact Name] a brochure or newsletter to tell him/her about MESA and his/her role as your contact person for MESA?** Enter YES or NO.

If information is not correct, type any changes on the right side of the screen. NOTE: Participant may change contact names and information entirely if necessary. If there are no changes, click ‘Save and Continue.’

After verifying information for all contacts, ask: **Which of your contacts is the best person to provide information about your health status or any hospitalizations that you may have had if we cannot reach you?** Select the appropriate contact.

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.

MESA Followup Data Entry -- Physician

Participant ID#: 9900001 Acrostic: ABCDEFF

D. Health Care Providers Changes

Enter a new health care provider below

First Name Last Name

Title (MD, PA, etc.)

Place of Business (name of clinic or hospital)

Address

City St Zip

Phone

Send participant's results to this person: Yes No

If information is not correct, type any changes on the right side of the page. If there are no changes, click 'Save and Continue' and you will return to end of the General Health Form.

Thank you.

Be sure the participant has no other questions.

D.1.3.2 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 General Health

D.1.4.1 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. NOTE: Choose the appropriate cohort to refer to in the introduction: MESA or MESA Air.

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.1.6 for more information about the *General Health- Death* form.

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

Hello, my name is [interviewer name] and I’m calling to speak with [participant name]. Is [participant name] 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 [interviewer name] with the [MESA] study.**

I'm calling to see how you have been since our last telephone interview with you and to update our [MESA] records. Do you have a few minutes to speak on the phone?

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 since our last telephone interview with you on ____ . I realize that we have asked you some of these questions several times, but learning about changes in your health is very important in helping us understand more about the causes of heart disease and stroke and how these diseases may be related to other things in your life.**

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

MESA Followup Data Entry - General Health page 1

Participant ID#: 9900001 Acrostic: ABCDEFF

General Health Date: 8/10/2015

Data Collection Method: Computer Paper

Death Version: Yes No

Language: English Spanish Chinese

Quit

Show Script

INTRODUCTION

Hello, my name is [interviewer name], and I'm calling to speak with MARY SMITH. Is MARY SMITH available?

Yes No

Hello, MARY SMITH, 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?

Yes No

We'd like to ask you some questions about your general health and specific medical conditions since our last telephone interview with you on 08/10/2015. I realize that we have asked you some of these questions several times, but learning about changes in your health is very important in helping us understand more about the causes of heart disease and stroke and how these diseases may be related to other things in your life.

Next

D.1.4.2 Item by Item Instructions

The interview data will pre-populate on the form if both introduction questions are answered ‘yes.’

(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?**

Click 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) Contact with health system

Since our last telephone interview with you, have you at any time seen a doctor or other health care professional? (Click YES or NO)

Since our last telephone interview with you, have you had an overnight stay in a hospital or nursing home? (Click YES or NO)

Did the participant answer YES to either part of Question 2 above (seen a health professional or overnight stay)? (Do NOT read the responses. Click YES, NO, or UNSURE)

Optional to read: A “health 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.

If YES to either part of Question 2, go to Question 3.

If NO, or UNSURE, skip to Question 7.

The participant is asked in both Question 2 and Question 5 whether he/she has been hospitalized. This information is purposely requested twice. Question 2 is a gateway question that determines whether subsequent questions will be asked at all. Question 5 asks specifically about hospitalizations not related to a condition documented in Question 5 and the *Specific Medical Conditions* form.

(Question 3) Symptom Diagnosis (Note these questions will be skipped if diabetes, high blood pressure, or high cholesterol were previously reported)

(Question 3a) Has your doctor or health care professional told you that you had diabetes? (Wait for response)

If NO or UNSURE go to Question 3b

If YES to Diabetes ask **Is this a new diagnosis since our last telephone interview/contact with you?** (Do NOT read the responses. Responses are YES, NO, and UNSURE.

(Question 3b) 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**
- **High cholesterol level**

Participant ID#: 9900011	Acrostic: ABCDEFF	Quit
3b. 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.)		
High Blood Pressure		
<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure		
Was this a new diagnosis since our last contact with you?		
<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure		
High Cholesterol Level		
<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure		
Was this a new diagnosis since our last contact with you?		
<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure		
Back	Next	

As each diagnosis is read, if response is YES, ask: **Was this a new diagnosis since our last contact with you?** (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.

(Question 4) 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 arterial 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**
- **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 5.

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

Participant ID#: 9900011 Acrostic: ABCDEFF Quit

4. Since our last telephone interview with you, has a doctor or health care professional told you that you had any of the following? (read each diagnosis):

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

Back Next

(Question 5) Overnight Care

Since our last telephone interview with you on, have you had any other condition that resulted in an ...: (Read each procedure, but NOT the responses. Responses are YES, NO, and UNSURE.)

...Overnight hospital stay?

...Overnight stay in a nursing home or rehabilitation center?

Emphasize “other” in the initial question, since hospitalizations involving MESA endpoints were already recorded in Question 4 (and Question 4’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 6.



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 4 and on a *Specific Medical Conditions* form can be recorded here in Question 5 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 2 and Question 5 whether he/she has been hospitalized. This information is purposely requested twice. Question 2 is a gateway question that determines whether subsequent questions will be asked at all. Question 5 asks specifically about hospitalizations not related to a condition documented in Question 4 and the *Specific Medical Conditions* form.

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

(Question 6) Diagnostic Procedures

6a. 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, but NOT the responses. Responses are YES, NO, and UNSURE.)

6b. Have you ever had any of the following 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).

- **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**
- **A cardioversion where electricity is applied to your chest to convert your heart rhythm from atrial fibrillation or atrial flutter to a normal rhythm?"**
- **An ablation procedure, where a long flexible tube, or catheter, is inserted into the heart, and energy is applied to destroy tiny areas of tissue to block atrial fibrillation or atrial flutter?**

If YES, complete a *Specific Medical Procedures* form for each item with a “Yes” response by clicking on ‘Enter SMP.’ See section D.1.5 Specific Medical Procedures for instructions on completing the SMP form.

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Participant ID#: 9900001 Acrostic: ABCDEFF Quit

5. Since our last telephone interview with you, have you had any other condition that resulted in an ... Yes No Unsure

Overnight Hospital stay	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Overnight Stay at a nursing home or rehabilitation center	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Details

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

6a. 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):

An angioplasty procedure or stent to open up arteries to your heart	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Details
Coronary bypass surgery	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	
An angioplasty procedure or stent to open up arteries in either of your legs	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	

6b. Have you ever had any of the following tests or procedures in or out of the hospital? (read each procedure):

A cardioversion where electricity is applied to your chest to convert your heart rhythm from atrial fibrillation or atrial flutter to a normal rhythm?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Details
An ablation procedure, where a long flexible tube, or catheter, is inserted into the heart, and energy is applied to destroy tiny areas of tissue to block atrial fibrillation or atrial flutter?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Details

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

Back Next

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 Question 7.

(Question 7) Which of the following best describes your current smoking status? Read all responses except 'Don't Know and choose the appropriate response. **If never smoked or former smoker, quit more than one year ago, skip to question 10** and continue with the questionnaire.

(Question 8) Have you smoked cigarettes during the last 30 days: Do NOT read the responses. Fill in bubble for YES, or "No."

If NO, go to Question 10.

(Question 9) On average, about how many cigarettes a day do you smoke? Provide the number of cigarettes smoked per day.

The participant should record 00 if the average number of cigarettes per day is less than one. Make sure participants record the number of *cigarettes* per day. If a participant answers in number of packs per day, recalculate into number of cigarettes per day (1 pack = 20 cigarettes).

(Question 10) During the past year about how many hours per week were you in close contact with people when they were smoking (e.g. in your home, in a car, at work, or other close quarters)? Enter the number of hours.

(Question 11) Did anyone smoke in your residence in the past 12 months (this includes you)? Do NOT read the responses. Select YES, NO or DON'T KNOW.

If NO, go to Question 12.

Participant ID#: 9900001 Acrostic: ABCDEFF Quit

12. Have you ever used an electronic cigarette or e-cigarette?

Yes
 No
 Don't Know

12a When did you start using e-cigarettes? 3 2004
Month Year

12b Do you still use e-cigarettes? Yes No Don't Know

12c When did you stop using e-cigarettes? 7 2006
Month Year

12d How often do/did you use e-cigarettes?

Every day
 Most days (4 or more days per week)
 Some days (1-3 days per week)
 Less than once a week
 Less than once a month

12e How many times a day do/did you use an e-cigarette? 7

12f In one week, how many e-cigarettes cartridges do/did you use? 3

12g What brand of e-cigarettes do/did you use?

blu NJOY
 Henley V2
 Joye Other, please specify:

Back Next

If YES, ask Question 11a **On average, how often did someone smoke in your residence in the past 12 months?** Read all responses and choose the appropriate response.

(Question 12) Have you ever used an electronic cigarette or e-cigarette? Do NOT read the responses. Select YES, NO or DON'T KNOW.

If the participant asks for a definition of an “e-cigarette,” read the following: An electronic cigarette (or e-cig, e-cigarette, or personal vaporizer (PV)) is a small, battery-powered vaporizer that produces a mist of nicotine and other substances instead of cigarette smoke, which contains nicotine and other substances. Most (but not all) of them are made to look and feel like cigarettes but they use capsules of liquid (which are vaporized) instead of matches (to do the lighting). [The nicotine in e-cigarettes and regular cigarettes is the addictive part. Forty years of research shows that the other substances in regular cigarettes cause heart disease, lung disease and cancer. The other substances in e-cigarettes are mostly unknown and, because e-cigarettes are new, little is known about whether the other substances they contain are harmful, although some early research suggests that that may be the case.]

If YES, ask Question 12a **When did you start using e-cigarettes?** Enter month and year.

(Question 12b) Do you still use e-cigarettes? Do NOT read the responses. Select YES, NO or DON'T KNOW.

If YES, go to Question 12d.

(Question 12c) When did you stop using e-cigarettes? Enter month and year.

If still using e-cigarettes, enter 99/9999.

(Question 12d) How often do/did you use e-cigarettes? Read all responses and choose the appropriate response.

(Question 12e) How many times a day do/did you use e-cigarettes? Enter number (0-99).

(Question 12f) In one week, how many times a day do/did you use? Enter number (0-99)

(Question 12g) What brand of e-cigarettes do/did you use? Read all responses and choose the appropriate response. If other, specify the brand.

(Question 13) When walking on level ground, do you get more breathless than people your own age? Do NOT read the responses. Select YES, NO or DON'T KNOW.

(Question 14) When walking up hills or stairs, do you get more breathless than people your own age? Do NOT read the responses. Select YES, NO or DON'T KNOW.

(Question 15) Do you ever have to stop walking because of breathlessness? Select Do NOT read the responses. Select YES, NO or DON'T KNOW.

(Question 16) Are you taking aspirin on a regular basis? Do NOT read the responses. Select YES, NO or DON'T KNOW.

If YES **How many days a week?** If participant takes aspirin less than one day a week, enter zero.

(Question 17) Since [date of last medications form] have you taken any non-aspirin blood thinners or anticoagulants? Do NOT read the responses. Select YES, NO, DON'T KNOW, or REFUSED.

Participant ID#: 9900001 Acrostic: ABCDEFF Quit

17. Since 10/20/2014 have you taken any non-aspirin blood thinners or anticoagulants?

Yes
 No
 Don't Know
 Refused

**17a Which blood thinner or anticoagulant have you taken since 10/20/2014?
(Check all that apply)**

Drug Name		Start	Stop
Coumadin (warfarin)	[X]	07/2010	02/2014
Plavix (clopidogrel)	[X]	09/2011	99/9999
Pradaxa (dabigatran)	[]		
Xarelto (rivaroxaban)	[]		
Equilis (Apixiban)	[]		
Brilinta (ticagrelor)	[]		
Effient (prasugrel)	[]		
Persantine (dipyridamole)	[]		
Savaysa (edoxaban)	[X]	03/2013	02/2014
Other: Blood Thinner	[X]	01/2010	03/2010
Other, please specify	[]		
Don't Know	[X]	00/0000	00/0000

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Next

If YES, ask Question 17a **Which blood thinner or anticoagulant have you taken since [Date of last Medications Form]?** Read all choices and check all that apply. If other, specify the medication.

(Question 17b) What month and year did you start taking [insert drug name]? Enter month and year or DON'T KNOW.

GeneralHealth_EnterAntiCoagulant

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Blood thinner or anticoagulant drug: Savaysa (edoxaban)

17b What month and year did you start taking Savaysa (edoxaban)? 3 2013 Don't know
Month Year

17c What month and year did you stop taking Savaysa (edoxaban)? 2 2014 Don't know
Month Year
 If still taking drug, enter 99/9999

17d Did you start and stop Savaysa (edoxaban) more than once since your last Medications Questionnaire? Yes No Don't Know

17e What is next month and year that you started taking Savaysa (edoxaban)? 4 2014 Don't know
Month Year

17f What is next month and year that you stopped taking Savaysa (edoxaban)? 99 9999 Don't know
Month Year
 If still taking drug, enter 99/9999

Delete this blood thinner or anticoagulant drug: Delete Save/Close

(Question 17c) What month and year did you stop taking [insert drug name]? Enter month and year or DON'T KNOW. If still using drug, enter 99/9999.

(Question 17d) Did you start and stop [insert drug name] more than once since your last Medications Form? If answer Questions 17e and 17f for each separate instance of starting and stopping the drug. If NO, Questions 17b-f will be repeated for each additional drug reported in Question 17a. If no other drugs were reported in Question 17a, go on to Question 18.

(Question 17e) What is the next month and year that you started taking [insert drug name]? Enter month and year or DON'T KNOW.

(Question 17f) What is the next month and year that you stopped taking [insert drug name]? Enter month and year or DON'T KNOW. If still using drug, enter 99/9999.

If more than one drug was reported in Question 17a, Questions 17b-f will be repeated for each additional drug. If no other drugs were reported in Question 17a, go on to Question 18.

(Question 18) Has a doctor or healthcare professional ever told you that you

have weak or failing kidneys? Select YES, NO, DON'T KNOW. If YES, answer Question 19a and 19b.

(Question 19) Have you ever seen a nephrologist or a kidney doctor? Select YES, NO, DON'T KNOW. If YES, answer Question 19a and 19b.

(Question 19a) Have you even been evaluated to receive a kidney transplant? Select YES, NO, or DON'T KNOW.

(Question 19b) Have you ever undergone surgery to create a dialysis shunt (also called a fistula or a graft) or had a peritoneal dialysis catheter placed? Select YES, NO, or DON'T KNOW.

MESA Followup Data Entry - General Health - Kidneys

Participant ID#: 9900001 Acrostic: ABCDEFF Quit

	Yes	No	Don't Know
18 Has a doctor or healthcare professional ever told you that you have weak or failing kidneys?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
19 Have you ever seen a nephrologist or a kidney doctor?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
19a Have you ever been evaluated to receive a kidney transplant?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
19b Have you ever undergone surgery to create a dialysis shunt (also called a fistula or a graft) or had a peritoneal dialysis catheter placed?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

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Note: Questions 20-23 will be skipped if there were answered during the MESA Follow-up 16 call.

The next two questions ask about food security, which will help MESA researchers understand how access to healthy food is related to cardiovascular health. Please tell me whether the following statements are often true, sometimes true, or never true.

(Question 20) Within the past 12 months, you worried whether food would run out before you got money to buy more. Read all responses and choose the appropriate response.

(Question 21) Within the past 12 months, the food you bought just didn't last and you didn't have money to get more. Read all responses and choose the appropriate response.

The next questions ask about your living situation.

(Question 22) Do you currently live in: Read all responses and choose the appropriate

response. If “Your own home or apartment” go to Question 20a.

Definitions:

Your own home or apartment: Includes living alone or with family or roommates in a home or apartment owned by the participant or rented.

Assisted Living Center: An assisted living center is a housing facility for individuals who receive help with activities of daily living. It includes independent living sections of retirement centers if the participant receives help with activities of daily living such as household chores, meals, or monitoring daily activities.

Nursing Home: a nursing home, convalescent home, or skilled nursing facility is a place of residence for people who require continual nursing care and have significant difficulty coping with the required activities of daily living.

Other:

(Question 22a) Do you get help with your daily activities from a caregiver, friend or relative that allows you to live in your own home or apartment?

Select YES or NO.

(Question 23) Has a doctor or other health professional ever told you that you had gout? Select YES, NO, DON'T KNOW, or REFUSED. If YES, answer Question 21a.

(Question 23a) How old were you when you were first told that you had gout? Enter age in years, DON'T KNOW or REFUSED.

(Question 24) At what age did you go through menopause? Enter the age in years. This questions will be skipped for men, and for women who have previously reported their age of menopause.

(Question 25) When we have an exam in 2016, we want to do our best to help you to participate. What things could we do to make it easier for you to attend? Enter free text to summarize participant's response.

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Participant ID#: 9900001 Acrostic: ABCDEFF Quit

24. At what age did you go through menopause? Age

25. When we have an exam in 2016, we want to do our best to help you to participate. What things could we do to make it easier for you to attend?

Back ** END ** Next

Go to the Medications Inventory

D.1.4.2 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.

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

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 [clinic phone number].


At some sites, 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.)

The computer data entry system will automatically save the tech ID who is logged into

This section: 11/4/2014 Version

the system to the forms that are administered. At the end of the Participant Status Form, when you click 'Save and Continue,' the program will take you to the Participant Tracking Form.

If you are using paper forms, enter your Interviewer ID in the boxes provided and indicate the method of data collection 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.1.5.1 Action Required After Form is Completed

Many (not all) conditions, admissions, and procedures require that an Events Investigation be initiated. Please see the Table D.1.4 below to see how to follow-up with all of the parts to Questions 5, 6 and 7.

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	PAD, 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	Carotid Ultrasound or angiogram	<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.

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.1.5 Medications Inventory

As part of MESA Follow-Up software package, the medication data collection program has been developed to do the following:

- Review most recent MESA medications records
- Keep or edit the existing medication data in the CHSCC database to reflect current status
- Enter any new Follow-Up 16 medication data to the CHSCC database
- Delete any previous medications no longer being taken

The Medications Form will only be completed during Follow-up 17 if it was not completed during the Follow-up 16 phone call.

MESA Followup Data Entry -- Contact Summary

Participant:
990006

14

Language
Expected Contact Date
Contact Status

Home Phone: (555) 123 1234
 Cell Phone: (555) 123 1234
 Work Phone: (555) 123 1234
 Email: user@isp.net

Uploaded:
 GenH ResH Cover

Preferred Contact: Phone

Notes:

Follow-up Form	Date	Status	Data Entry	Uploaded To CHSCC
Participant Tracking		Not Done		
General Health	04/19/2013	Complete	999	04/19/2013
Medications		Not Done		
Residential History	04/19/2013	Complete	999	04/19/2013
Contact Cover	04/19/2013	Complete	999	04/19/2013

- Select 'Medications' from the list box

EnterMedicationNote

Participant ID#: 9900006 Acrostic: ABCDEFM

Language: English Spanish Chinese

Now we would like to ask you about prescription medications you are currently taking. We just want to know about any prescription medications that you have taken in the past two weeks. Do you have this information available now?

First I will list the medications you told us you took previously and you can let me know if you are still taking them and if the does is the same. Then you can tell me about any other medications you are taking now.

Continue

- Select 'Language' then continue

This page appears **only** if previous MESA medication data is available and at least one prescription medication was reported:

Participant ID#: 9900001 Acrostic: ABCDEFF Followup Date: 10/20/2014 Quit

Enter Medications:

Enter all meds? Yes Took None Refused

Unable to enter: 4

Comment: Follow-up 16 medication data.

Blood thinners or anticoagulants specified on General Health form:

- Coumadin (warfarin)
- Plavix (clopidogrel)
- Savaysa (edoxaban)

	Med Name	Med Dose	RX	DWM	PRN	TKN	DWM	Unmatched
▶	COUMADIN	2	3	Day	<input checked="" type="checkbox"/>	3	Day	<input type="checkbox"/>

Add New Edit Delete Save

- The medications listed above are **only** the **prescribed** medication records of the most recent Medications Inventory
- The ‘keep?’ box should be checked (True) if the medication is still being taken for the MESA Follow-Up 16. (If there is a change in the medication, it can be made in a later screen.)
- Go to ‘Next page’

If previous Mesa medication data is **not** available, **or** “keep?” has not been selected **or** participant previously reported taking no medications, you will see the page below:

Participant ID#: 9900015 Acrostic: ABCDEFF FU 14 Date: 6/14/2013

Enter Medications: Previous Exam Date:

Enter all meds? Yes Took None Refused

Unable to enter:

Comment:

Med Name	Med Dose	RX	DWM	PRN	TKN	DWM	Unmatched
----------	----------	----	-----	-----	-----	-----	-----------

If previous Mesa medication data is available, and “keep?” has been selected (True), you will see the page below. The medications listed are the ones that were kept:

Participant ID#: 9900006 **Acrostic:** ABCDEFM **FU 14 Date:** 6/18/2013 Quit

Enter Medications: Previous Exam Date: 10/14/2011 12:00:00

Enter all meds? Yes Took None Refused

Unable to enter:

Comment:

Med Name	Med Dose	RX	DWM	PRN	TKN	DWM	Unmatched
MIRTAZAPINE	15	0.5	Day	<input type="checkbox"/>	0.5	Day	<input type="checkbox"/>
VYVANSE	50	1	Day	<input type="checkbox"/>	1	Day	<input checked="" type="checkbox"/>
LANTUS	100/ML	100	Day	<input type="checkbox"/>	100	Day	<input type="checkbox"/>
NOVOLOG	100/ML	20	Day	<input type="checkbox"/>	20	Day	<input type="checkbox"/>

Add New Edit Delete Save

- The Medications appearing on this page are from a previous MESA Medications Form. Each one should be checked and modified, kept, or deleted for MESA Follow-Up 16.
- If a medication is no longer being taken, select it in the medication list and click on the ‘Delete’ button to remove it from the list
- If the participant is still taking one of the medications in the list, but some information has changed, click on “Edit”
- For each new medication that does not appear on the list, click on “Add New” button, the Enter medication page will appear with no data

“Add New” button clicked:

EnterMedicationDEI

Participant ID#: 9900006 Acrostic: ABCDEFM

Enter Medications:

Type: Prescription Only

Name

Strength

Number Prescribed Value / DWM

PRN

Number Taken /

Unmatched

- Enter any new MESA Follow-Up 16 Prescribed Medication in this screen

“Edit” button clicked:

The screenshot shows a window titled "EnterMedicationDEI" with the following content:

Participant ID#: 9900006 Acrostic: ABCDEFM

Enter Medications:

Type: Prescription Only

Name: MIRTAZAPINE

Strength: 15

Number Prescribed: Value 0.5 / DWM Day

PRN

Number Taken: 0.5 / Day

Unmatched

Buttons: Cancel, Save

- Modify any previous prescribed Medication in this screen
- Edit existing record by changing the contents of any field

After all additions, changes, and deletions have been completed, you will see the page below:

Participant ID#: 9900006 Acrostic: ABCDEFM FU 14 Date: 6/18/2013
Quit

Enter Medications: Previous Exam Date: 10/14/2011 12:00:00

Enter all meds? Yes Took None Refused

Unable to enter:

Comment:

Med Name	Med Dose	RX	DWM	PRN	TKN	DWM	Unmatched
LANTUS	100/ML	100	Day	<input type="checkbox"/>	100	Day	<input type="checkbox"/>
NOVOLOG	100/ML	20	Day	<input type="checkbox"/>	20	Day	<input type="checkbox"/>
MIRTAZAPINE	15	1	Day	<input type="checkbox"/>	1	Day	<input type="checkbox"/>
VYVANSE	50	2	Day	<input type="checkbox"/>	2	Day	<input checked="" type="checkbox"/>
1/2HALFPRIN	165	2	Day	<input type="checkbox"/>	2	Day	<input type="checkbox"/>

Add New
Edit
Delete
Save

- Click “Quit” button to go back to Follow-Up Form page without saving data
- Click “Save” button to save data and go back to Follow-Up Form page

Medication entry for this participant is completed:

Participant:
9900006

14

Language: English
Expected Contact Date: 01/02/2012
Contact Status: Air Participant
Uploaded: GenH ResH Cover

Home Phone: (555) 123 1234
Cell Phone: (555) 123 1234
Work Phone: (555) 123 1234
Email: user@isp.net
Preferred Contact: Phone

Notes:

Follow-up Form	Date	Status	Data Entry	Uploaded To CHSCC
Participant Tracking		Not Done		
General Health	04/19/2013	Complete	999	04/19/2013
Medications	06/18/2013	Complete	999	06/18/2013
Residential History	04/19/2013	Complete	999	04/19/2013
Contact Cover	04/19/2013	Complete	999	04/19/2013

Back

- Click “Back” button to select another participant

D.1.6 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.1.7 Death Information Form

D.1.7.1 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.1.7.2 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

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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.1.7.3 Action Required After Form Is Completed

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

D.1.8 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 4 on the *General Health* form. You should complete all *Specific Medical Conditions* forms while recording the participant/proxy's responses to Question 4 of the *General Health* form interview; do not proceed to Question 5 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.1.8.1 General Information

After completing a Specific Medical Conditions Form, when returning to Q4 on the General Health Form, reread Q4 before listing the next health condition.

The Specific Medical Conditions Form is accessed by clicking on ‘Enter SMC’ next to the condition reported in Q4 of the General Health Form.

Participant ID#: 9900011 Acrostic: ABCDEFF Quit

4. Since our last telephone interview with you, has a doctor or health care professional told you that you had any of the following? (read each diagnosis):

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

Back Next

D.1.8.2 Item by Item Instructions

(Question 1) Diagnosis by Health Professional

You said that a doctor or other health professional told you that you had _____. The specific condition previously reported (on the *General Health* form) will appear on the Specific Medical Conditions form.

**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).

Participant ID#: 9900011 Acrostic: ABCDEFF Date: 7/24/2013

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

Cancer #1

Cancer type

A. What was the name and address of the doctor you saw?
 [OPTIONAL. Only record name and address if they are of use to Events staff.]

Name

Address

(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."

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 [date of last Follow-up call]?

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.

Participant ID#: 9900011 Acrostic: ABCDEFF Quit

Cancer #1

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 15.) 01/04/2013 Clear Date

C. Were you in the hospital at least one night for this condition since our last contact with you on [date of last follow up]?

Yes
 No
 Unsure

D. Would you please tell me the dates of each hospitalization and where you were
(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)
1.	01/04/2013 Clear Date	9999	1
2.	Clear Date		
3.	Clear Date		
4.	Clear Date		
5.	Clear Date		

Back Next

(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.

* 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.

Participant ID#: 9900011	Acrostic: ABCDEFF
Do you wish to enter/edit another Cancer?	
<input type="button" value="Yes"/>	<input type="button" value="No"/>

When the form is complete, click ‘save and continue’ and indicate whether you want to report the next medical condition reported on the General Health Form, Enter another of the same medical condition that you just entered, or Return to the General Health Form. When you return to Q5 on the General Health form. If there are no additional events, go to Question 6 and 7 of the *General Health* form.

D.1.8.3 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.1.8.4 Action Required

This section: 11/4/2014 Version

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.)

The screenshot shows the 'MESA Follow-Up 3' application window. The title bar reads 'MESA Follow-Up 3'. The main window has a header with 'General Health' on the left, '9900006 MARTMF' in the center, and 'Interview Date 06/05/2008' on the right. Below the header is a question: '6. Since our last telephone interview with you, have you had any other condition that resulted in an...'. There are two rows of data: 'Overnight Hospital stay' and 'Overnight Stay at a nursing home or rehabilitation center'. Each row has three radio buttons labeled 'Yes', 'No', and 'Unsure', and a 'Complete?' column with 'Enter NA' and 'NA' options. A dialog box titled 'MESA' is open in the center, asking 'Are you sure you want to quit data entry?' with 'Yes' and 'No' buttons. At the bottom of the window, there are three buttons: '<- Back', 'Quit Data Entry' (circled in red), and 'Save And Continue ->'. A note at the bottom of the form reads: 'Complete "Other Admissions" form for each item with a Yes response.'

You will be prompted to confirm that you want to quit data entry, and then asked to confirm whether you want to save the responses that you have made on the screen. If you confirm that you want to quit the program, you will return to the Contact Summary Page.

This screenshot is identical to the one above, showing the 'MESA Follow-Up 3' application window with the 'Quit Data Entry' dialog box. However, the dialog box now asks: 'You have made some changes on this page. Do you wish to save these changes?' with 'Yes' and 'No' buttons. The 'Quit Data Entry' button at the bottom of the window is no longer circled.

If you restart this interview at a later time, the program will start on the last screen where
 This section: 11/4/2014 Version

you clicked ‘save and continue.’

D.1.9 Other Admissions

D.1.9.1 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.

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.

You said that you stayed overnight as a patient in a _____.
[The admission previously reported in Question 6 on the General Health form will appear on the Other Admissions form.]

D.1.9.2 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.

D.1.9.3 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.1.10 Specific Medical Procedures

D.1.10.1 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.

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.1.10.2 Item by Item Instructions

(Question 1) You previously said that a doctor or other health professional told you that you had _____ [The specific procedure previously reported in Question 7 (on the *General Health* form) will appear on the *Specific Medical Procedures* form].

A “health 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.

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.

- **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**
- **Cardioversion**
- **Ablation**

➔ If one of these items is answered YES, record the specific procedure in the space provided.

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

- **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 6 of the *General Health* form. Complete as many *Specific Medical Procedures* forms as necessary (one for each procedure or admission reported in Question 6). If there are no other procedures, go to Q7 of *General Health* form.

D.1.10.3 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.1.10.4 Action Required

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

D.1.11 Contact Cover Sheet

The *Contact Cover Sheet* should be completed after all questionnaires have been administered.. It is used to 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.1.11.1 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	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, were completed. Indicate whether interview was completed by participant or by proxy. If proxy, indicate reason why participant was unable to complete interview.
Interview 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, were partially completed. Indicate whether interview was started by participant or by proxy. If proxy, indicate reason why participant was unable to complete interview. Also complete section 1b to indicate the reason the interview was partially completed.
Interview not completed 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 refused to complete interview	<p>Participant refused to be interviewed. Record the one best reason (see below):</p> <ol style="list-style-type: none"> 1. 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. 2. 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. 3. 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. 4. 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.
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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.1.11.2 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.

<p><i>Do Not Contact</i></p>	<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>
<p><i>Reported Deceased</i></p>	<p>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.</p>
<p><i>Unknown</i></p>	<p>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.</p>

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.1.11.3 Form Completion

Click 'Continue' to finish the questionnaire and return to the Contact Summary page. Verify that all required questionnaires show 'Complete' in the status column.

D.1.12 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.