

MESA Follow-up 26 Call Manual of Operations

Version 1 August 1, 2024

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1. General Information

1.1.Introduction

Clinic staff contact participants by telephone at regular intervals (Follow-up Calls) to ask questions regarding health since the previous telephone interview, specifically those 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).

1.1. Use of Secondary contact

If a participant is not able to complete the interview (e.g., due to a medical problem), a secondary contact may be used. A secondary contact is a relative or other knowledgeable contact who can update contact information or answer health-related questions on behalf of the participant. If the participant has died, the secondary contact may complete the questionnaire for the period between the last exam and the date of death.

The secondary contact may or may not be someone previously designated as a contact by the participant. For example, the participant may have designated their spouse as a secondary 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.

Record dates, times, and explanatory notes for each call attempt on the *Call Log*. Eight contact attempts should be made over a two-week period during different times of the day. If no contact is made, repeat in four weeks.

1.2. Motivation

The Follow-up phone interview in MESA serves several purposes:

- To ascertain whether participants have experienced any potential events
- To update tracking data including address, phone number, email address, contact information and secondary 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 or 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 or clinic visit
- To obtain detailed information about any procedures or hospitalizations participants have had since their last MESA Follow-up call (not since clinic visit)
- To introduce upcoming exams and schedule an appointment

1.3. Mode of Administration

Follow-up call materials are interviewer-administered 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.

Be sure to match non-English speaking participants with like-speaking interviewers. The *Participant Information* form in the MESA Follow-up 26 REDCap Program includes the participant's language preference.



Data should be directly entered in the MESA Follow-up 26 REDCap Program and not on paper forms. If an internet connection is not available at the time of the interview, paper forms may be used, but answers will need to be entered into the MESA Follow-up 26 REDCap program when available. Recording answers on paper forms misses the quality control measures that are programmed in the software (skip patterns, range checks, etc.).

Data entry cannot proceed in the REDCap program without an internet connection. Ensure there is a strong internet connection prior to contacting a participant.

Formatted paper follow-up forms are available on the <u>internal MESA website Follow-Up Call</u> <u>Forms</u> page.

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.

In the REDCap program questions that should be skipped will be hidden from view.

1.4. 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. The report lists all participants who require a follow-up phone call interview within a specified time window. See Section 1.5 for additional details.

The following table shows the schedule for all MESA Follow-up Calls for the MESA IV contract.

Table 1: Timeline of Scheduled Follow-up Calls

	2021			2022 2023		3	2024			2025									
F	FU22		I	U23		FU24		FU25		FU26									
	Exam Prep				Exam	7		Close											

The information collected at each Follow-up call applies to the time period since the last follow-up contact. Remind participants to report information about conditions, admissions, and procedures that occurred since the previous Follow-up Call (not since other MESA contact, such as the exam 7 visit, the amyloidosis visit, a COVID-19 questionnaire, a MESA-MIND phone visit, or an unscheduled call to gather information about a specific, already-discovered event). Tell the participant the date of the previous Follow-up Call and remind them of that date as often as necessary during the call.

The target follow-up contact date for each participant is 9 to 12 months after their 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. It is acceptable to collect information outside of the target window if it cannot not be obtained within the target window. However, all reasonable efforts should be made to contact the participant and obtain the information within the target window.

1.5. Details on Administration of Forms

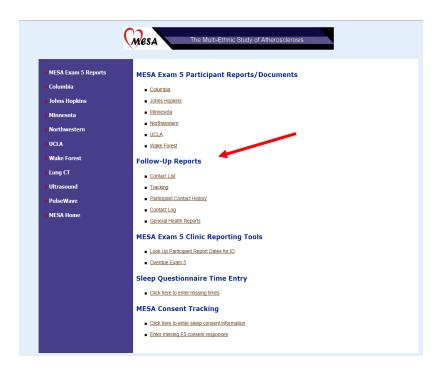
The following list briefly outlines the order in which the forms for the MESA Follow-up 26 Phone Call are generally administered. Key points to remember are:

FU26 Call Log and FU26 Contact Cover are completed for ALL participants for whom contact is attempted.

FU26 General Health (or General Heath—Death), FU26 General Health Supplement, and FU26 Participant Tracking Survey forms are completed for all participants with whom contact is made and who agree to an interview.

Specific Medical Conditions, Other Admissions, or Specific Medical Procedures sections of the General Health Form are completed only for those participants who indicate a corresponding potential event on the FU26 General Health form. If using paper forms, these three sections are available as separate forms.

For those who wish to use the old forms, the Contact Log, Contact Cover Sheet, and other relevant documents are created as reports on the MESA web site at https://www.uwchscc.org/MESAE5Reports/login.aspx?ReturnUrl=%2fMESAE5Reports%2fDefault.aspx. Site-specific usernames and passwords are available from the Coordinating Center at jerryw@uw.edu. Follow-up 26 documents are available under the "Follow-up Reports" section.



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.



The **Contact List** report displays name, IDNO, contact window, FU26 contact date, phone number, email, and language.

The **Tracking Report** displays everything from the Contact List, plus acrostic, address, secondary contact, and health care providers.

The **Participant Contact History** displays contact information plus the dates and status of all follow-up calls and exams, and brief participant notes.

The **Contact Log** displays everything from the Contact List and includes space to record the result of multiple contact attempts. See Section 2.1 for more information.

Follow-up reports should be run frequently to ensure that calls are made within their target window and 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.

Participants that are identified as living in the same residence will have the same contact window assigned.

1.6. Overview of Follow-up Call Forms

The following steps demonstrate the flow of forms during the Follow-up call.

- 1. When contact is made, begin following *FU26 Introduction Script* form in the MESA Follow-up 26 REDCap Data Collection Program.
- 2. If a participant (or secondary contact) indicates they would prefer you to call at another time, end the call and record the appointment on the *FU26 Call Log*.
- 3. Repeat steps 1 and 2 until the interview is completed.
- 4. If contact is made, complete the *FU26 Participant Tracking Survey* and update as necessary.
- 5. Complete the FU26 General Health form.
- 6. Complete the FU26 General Health Supplement form.
- 7. Update final contact and participant status in the *FU26 Call Log* form and the *FU26 Contact Cover* form for ALL participants, even if no contact was made.

2. REDCap Data Entry

2.1. Using REDCap

Log into REDCap at the site https://redcap.iths.org/, entering "University of Washington" as the institution. Contact Jerry Watson (jerryw@uw.edu) for a username and password.

On the top navigation menu choose My Projects.



From the My Projects screen choose MESA Follow-up 26

There are two ways to select participants from the Project Home page.

On the left navigation panel, find the **Data Collection** box and select the **Record Status Dashboard** link.



This dashboard displays the forms and form completion status for all participants. You can select an individual form to complete or select the ID number to go to the Record Home Page.

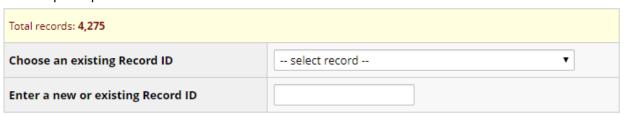
Displaying: Instrument status only | Lock status only | All status types

MESA ID	Participant Information	Contact proxy reference	Health Care Provider reference	up 26	Call	F26 Introduction script	Tracking	General	F26 General Health Supplement	Contact	
1											

The other option for selecting participant records is from the **Add / Edit Records** in the **Data Collection** box.



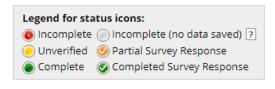
To select a participant, either select the MESA Participant ID (Record ID) from the dropdown menu or enter their MESA Participant ID in the box and press the Enter key. This option takes you to the Record Home page that displays all forms (and their completion status) for the selected participant.



The forms available to complete will show on the next screen. There are colored indicators for the completion status of each form. Select one of the circle buttons next to the form to open the desired form.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

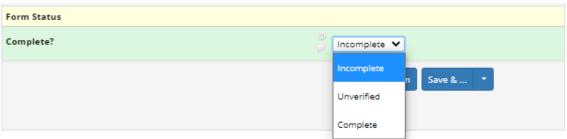




MESA ID 1

Data Collection Instrument	Status
Participant Information	
Contact proxy reference	
Health Care Provider reference	
Follow-up 26 Notes	
F26 Call Log	
F26 Introduction script	
F26 Participant Tracking Survey (survey)	
F26 General Health (survey)	
F26 General Health Supplement	
F26 Contact Cover	

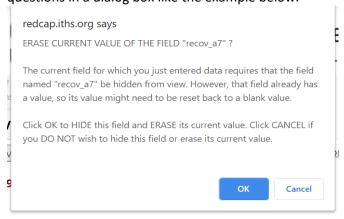
The completion status color code for each form is generated from the "Complete?" data entry field at the end of each form. Forms with status "Incomplete" are shown in red. Those with "Unverified" display a yellow dot, and those marked as "Complete" display a green dot. If a form is started and you need to return to it later to add additional information, mark it as "Unverified," which will display a yellow box, providing a visual cue in the Record Status Dashboard to return to the form later.



At the end of each form, there are several options to Cancel or Save the changes made. There are additional Save options available in the dropdown list (see image below). Selecting "Cancel" will return you to the home page for the record (ID) without saving any changes.



Skip patterns are programmed to appear automatically based on the answers to the root questions. If you change a previous response which affects downstream questions that have also already been answered, you may be asked to review the responses to affected downstream questions in a dialog box like the example below.



After exiting a form, a status bar will appear above the table of available forms indicating the action taken on the form. For example:

Record ID 3010104 data entry cancelled - not saved

2.2. Data Entry Practice

The FU26 REDCap Data Collection Program includes test IDs that can be used to practice data entry. To access these "test IDs" use the "Dashboard displayed" filter to "Test Participant IDs"

Ⅲ Record Status Dashboard (all records) Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in Legend for status icons: the table to open a new tab/window in your browser to view that record on that particular data 💿 Incomplete 🔘 Incomplete (no data saved) 💽 collection instrument. Please note that if your form-level user privileges are restricted for certain data Onverified OPartial Survey Response collection instruments, you will only be able to view those instruments, and if you belong to a Data Complete Occupied Survey Response Access Group, you will only be able to view records that belong to your group. Dashboard displayed: [Default dashboard] 🕶 Create custom dashboard Displaying Data Access Group 5 Johns Hopkins V Displaying record | Page 1 of 2: "5900001" through "5900100" v | of 128 records records per page Displaying: Instrument status only | Lock status only | All status types F24 Contact Follow-F24 **Participant** F24 F24 Participant Provider proxy up 24 Call Introduction Tracking General Contact MESA ID Log script 5900001 (ARROKEM) 5900002 (ANDRRIM) 5900003 (MOORALF) 5900004 (JONEALF) 5900005 (ARROJOF) 5900006 (ARROJOM) 5900007 (RAMIMAM)

3. Specific Form Instructions

3.1. Participant Information

The information in this form is prefilled from data entered in the CC MESA database. It is for reference only. If edits are needed, they are entered in the *FU26 Participant Tracking Survey*.

The participant's name and contact window will be pre-filled, and the data used to inform skip patterns in the FU26 forms are displayed in the *Participant Information* form. Notes from previous follow-up calls are printed here. Information cannot be edited within this form.

3.2. Contact Proxy Reference

The information in this form is prefilled from data entered in the CC MESA database. It is for reference only. If edits are needed, they are entered in the FU26 Participant Tracking Survey.

3.3. Health Care Provider Reference

The information in this form is prefilled from data entered in the CC MESA database. It is for reference only. If edits are needed, they are entered in the *FU26 Participant Tracking Survey*.

3.4. Follow-up 26 Notes

Enter notes from the FU26 phone call in this form. This text will be available in the *Participant Information* for the next follow-up phone call (FU26).

3.5. FU26 Call Log

The FU26 Call Log is used to document calling history and assign a call status code for each contact attempt. The form includes contact date(s) and status of the calls.

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 call status. Assigning a call status is important, as the status may be necessary for determining the final contact status in the event the participant is ultimately not successfully contacted.

Call Statuses are:

Call Status
Refused Follow-up
Completed Follow-up
Arranged a call back time
Left a message
No answer
Deceased
Unable
Participant returned call
Cancelled Follow-up

If Call Status is "Unable", complete the next field in REDCap for the "Unable or Refused Reason". Options include:

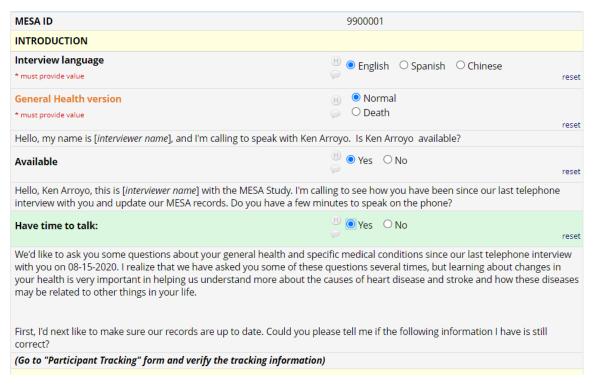
Could not locate
No valid contact information
Hearing problem
Cognitive problem
Hospitalized
Other illness
Other specify

If "Other specify" is selected, enter the reason in the text box.

If participant refuses to complete the FU call, enter the reason in the "Unable or Refused Reason" text box.

3.6. FU26 Introduction Script

The FU26 Introduction Script is used when attempting to reach the participant. Before initiating the phone call, select the interview language. If during a phone call attempt you learn that the participant is deceased, update the FU26 General Health form version from "Normal" to "Death."



Begin by reading the script in the *FU26 Introduction Script*. Be flexible and modify the script as necessary. (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? If a time is provided, follow with: Thank you, I will call again. Record time to call back in the FU26 Introduction Script form.

If you learn 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 secondary contact and if this is a convenient time to talk. If yes, continue with the interview by secondary contact, using the *FU26 General Health* form by selecting "Death" as the General Health Version type. Indicate the death in the *FU26 Introduction Script* form. At the end of the interview, inform the respondent that someone from the MESA staff may contact a family member at a later date for more information, and ask when the best time would be to call. Record this information in the "Notes" line of the *FU26 Call Log*.

In addition to the "Notes" line and participant status (alive/deceased) on the of the FU26 Call Log, you may use the optional <u>Death Information</u> form to record the date, cause, and location of death. The <u>Death Information</u> form is a paper form designed to facilitate communication between the interviewers and the Events staff so that a death investigation can begin. Provide the completed <u>Death Information</u> form to the Events staff. The <u>Death Information</u> form was created because the <u>FU26 General Health</u> form doesn't have a specific way to record a death. Interviewers must communicate well with Event staff to ensure that no deaths are overlooked.

Complete an <u>Initial Notification of Potential Event/Death form</u> to begin the death investigation process. See Section 4 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, as the informant is comfortable proceeding.

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

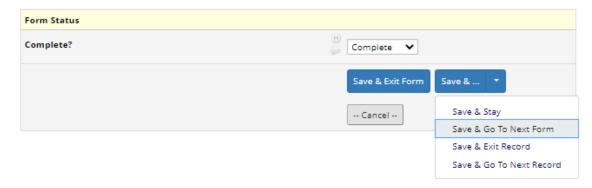
I'm calling to see how you have been since our last telephone interview with you and to update our [MESA] records. Do you have a few minutes to speak on the phone?

If no, say: When would it be convenient to call back? Record this information in the *Introduction Script Form* 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.

Remind the participant to report information for events that occurred since their last *MESA Follow-Up phone call* (not "since last contact with MESA," which may have been an exam 7 visit, MESA-MIND visit, or an unscheduled interim phone call). Refer to the participant's *Participant Information Form* to verify the date of the previous Follow-up call.

When finished, update the Form Status to "Complete." Click "Save & Go to Next Form" or return to the Record Home Page by selecting "Save & Exit Form."



The next step is to review the information in the FU26 Participant Tracking Survey form.

3.7. FU26 Participant Tracking Survey

Current tracking information for the participant from the MESA database is displayed in the form. Read the current phone number and address information to the participant/secondary contact. Verify that this information is correct or update the record with any changes reported by the participant. 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 secondary contact.

If contact or participant status information is obtained outside of a follow-up phone call, the new information should be updated in the MESA-Data-Management program instead of the Follow-up software. See Appendix B for details.

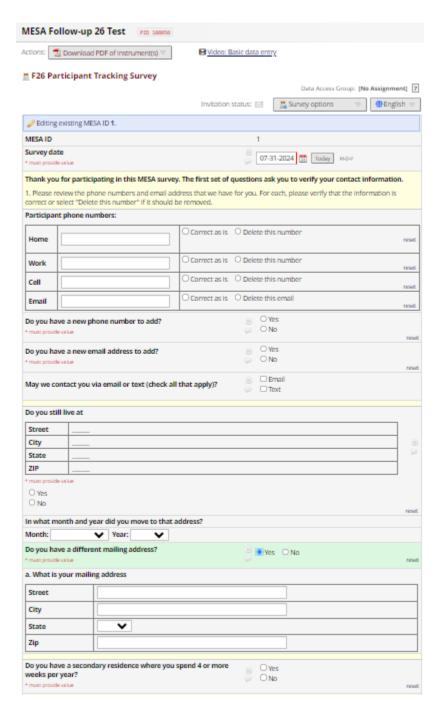
3.7.1. Item by Item Instructions

Start by entering the date.

Thank you for participating in this MESA survey. The first set of questions ask you to verify your contact information. For your phone numbers, I have XXX-XXXX as your home/cell/work numbers. Are these numbers still correct? (update as necessary).

For your email address, I have xxx@xxxxxx.xxx. Is that still correct? (update as necessary). Or,

I don't have an email address in our records. Would you like to provide an email address? (update as necessary).



May we contact you by email or text? Inquire if the participant would like to receive text or email messages from MESA coordinators for visit or phone call reminders. Check all that apply.

Do you still live at XXX...

Read the provided home address and update as necessary. If a new address is given, record the month and year of the move.

If the MESA CC has sent mail to this address previously and it was returned as invalid, "MESA mail returned Verify address" will be marked as "Verify." Make a special attempt to update these addresses.

In what month and year did you move to that address?

Record month and year. If unknown, ask participant to estimate.

Do you have a different mailing address?

Some participants use a PO box or get their mail at a different address than from their street address. Record information if applicable.

Do you have a secondary residence where you spend 4 or more weeks per year?

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

The next set of questions will ask you to verify the contact information for the friends or relatives that you have listed as your contacts, in case we cannot reach you.

If contacts are provided: Next, we'll review the contacts that you have named in case we can't reach you in the future. Let's review their information.

If contacts are not provided: **Do you have contact person that we can add to your MESA record** in case we can't reach you in the future?

Would you like to keep the contact person listed below?

Read Contact names, relationship to participant, address, phone numbers, e-mail address from the form.

If less than 3 secondary contacts are provided, ask for a minimum of 3.

After verifying the information for each contact, ask: May we send [Contact Name] a brochure or newsletter to tell them about MESA and their role as your contact person for MESA? If you say yes, we will send a newsletter to them at the address you provided. Enter Yes or No.

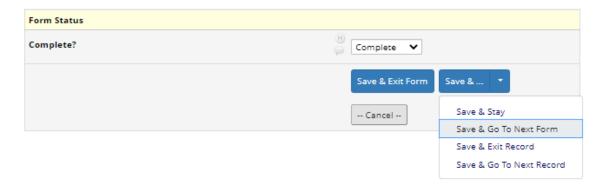
Next, let's review the contact information for your health care providers.

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

Would you like to send MESA Exam results to this healthcare provider? Select Yes or No.

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

When finished, update the Form Status to "Complete." Click "Save & Go to Next Form" or return to the Record Home Page by selecting "Save & Exit Form."



The next step is to complete the FU26 General Health form.

3.7.2. Other Form Information

Secondary contact—if the *FU26 General Health* interview was completed by a secondary contact, note this on the *FU26 Participant Tracking Survey* form:

If a previously designated Contact served as the secondary contact for this contact, indicate this by checking the appropriate "Check if used as secondary contact for this interview" box section "B. Contacts/Proxies" of the form.

If a different individual served as the secondary contact for this contact, indicate this in the "Other Secondary contact" area (at the end of section) by entering the secondary contact'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.

3.8. FU26 General Health

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

3.8.1. Item by Item Instructions

The interview data will pre-populate on the form if both introduction questions are answered 'yes.' Before starting the form, record the General Health version, the data collection method, interviewer ID and the date.

General Health Data Access Group: 9 test ? Ø Editing existing MESA ID 9900001 (ARROKEM) MESA ID 9900001 **General Health version** Normal O Death * must provide value reset → Computer Data collection method O Paper reset Interviewer ID **General Health date** 08-16-2021 Today M-D-Y * must provide value

1. Would you say, in general, your health is Excellent, Very Good, Good, Fair, or Poor?

Read all the response categories EXCEPT "Unsure." Click the participant's response and go on to the next question. If participant is unsure of their response, fill in circle next to UNSURE. Go to Question 2.

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

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.

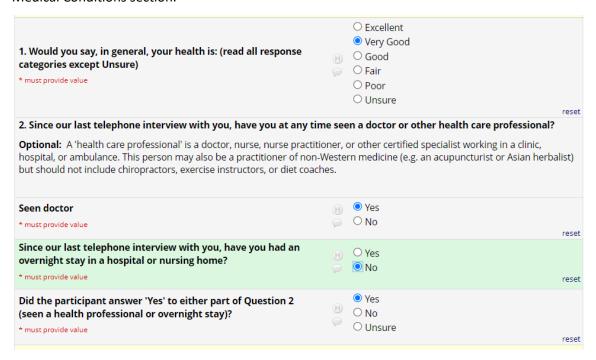
3. Since our last telephone interview with you, have you had an overnight stay in a hospital or nursing home? (Click Yes or No)

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 or No)

If Yes to either part of Question 2, go to Question 3a.

If No, 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 section.



Questions 3a and 3b will be skipped if diabetes, high blood pressure, or high cholesterol were previously reported)

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.

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



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 their 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.

4. 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.)

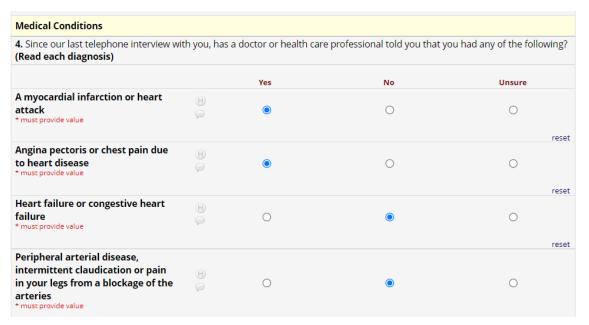
This is a crucial question for finding events. Read slowly and be certain the participant understands. Definitions of the following events are provided in Appendix A: Medical Terminology. If the participant is not sure what a particular condition is, it is acceptable to

provide the definition. If necessary, remind the participant of the date of their 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
- COVID-19 infection

If Yes to any part of question 4, the Specific Medical Conditions section is completed for <u>each</u> item with a "Yes" response. Determine if a participant was told that they had one of the conditions on more than one occasion—complete the Specific Medical Conditions information for each occasion.

If No or Unsure to <u>all</u> items, go to Question 5.



Select the medical condition reported in question 4 from the drop down box and read **You said** that a doctor or other health professional told you that you had ______.

1) You said that a doctor or other health care professional told you that you had:	A myocardial infarction or heart attack
1) A. What was the name and address of the doctor you saw?	
[OPTIONAL. Only record name and address if they are of use	e to Events staff.]
Physician name:	
Physician address:	
1) B. What was the date of the diagnosis or hospitalization?	
(Probe for exact date. If exact date cannot be recalled, ask p	participant to estimate month and year.
Record day as 15.)	
Diagnosis/hospitalization date:	D-Y
1) C. Were you in the hospital at least one night for this condition	since our last contact with you on 08-15-2020?
○Yes	
○ No	
○ Unsure	reset

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.

1b. What was the date of the diagnosis or hospitalization?

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

If the participant cannot 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.

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.

If the participant has indicated a COVID-19 infection AND responded yes to 1c, ask:

- 1e. While in the hospital, did you have any of the following? Read the following responses except for Unsure and Decline to answer. Check all that apply.
 - Oxygen (by mask or nose)
 - A breathing tube or ventilator
 - "Intensive care unit" or ICU monitoring
 - Dialysis
 - Unsure
 - Decline to answer

1d. Would you please tell me the dates of each hospitalization and where you were hospitalized?

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."

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.

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.

Enter, in days, the length of the hospital stay. If participant is unsure of the exact length, record their best estimate.

Collect date, hospital code and length of stay for all hospitalizations for this condition. Each hospital in a "transfer" should be recorded.

If the participant has indicated a stroke diagnosis since their 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/secondary contact 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.) No should be marked if the participant/secondary contact responds NOT YET or NOT YET, BUT MY DOCTOR SAYS I WILL.

Repeat questions 1a-d for each potential event reported in Question 4. If there are no additional events, go to Questions 5 of the *FU26 General Health* form.

All positive responses to conditions in questions 4 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

For conditions that require the initiation of an investigation, complete an *Initial Notification* form and immediately submit to the Coordinating Center. See Section 4 for additional details.

- 5. Since our last telephone interview with you on, have you had any <u>other</u> 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 section, which records endpoint hospitalization dates).

If Yes, complete an *Other Admissions* section for <u>each</u> item with a Yes response.

Again, this is a crucial question for identifying every overnight care episode. If necessary, remind the participant of the date of their last Follow-up phone call with MESA. Only overnight admissions that were NOT recorded in Question 4 and in the Specific Medical Conditions section can be recorded here in Question 5 and in the corresponding Other Admissions section. A particular hospitalization/overnight stay gets recorded in the Other Admissions section OR in the Specific Medical Conditions section, but not in both places. However, hospitalization dates listed on the Specific Medical PROCEDURES section can match dates on either Other Admissions section or Specific Medical Conditions section. Do not record Yes for overnight stays that are not admissions.

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

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 FU26 General Health form.

If a participant had multiple occurrences of an overnight admission of the same type, complete Other Admissions information for each stay.

The participant is asked in both Question 2 and Question 5 whether they have been hospitalized. This information is purposely requested twice. Question 2 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 in the Specific Medical Conditions section.

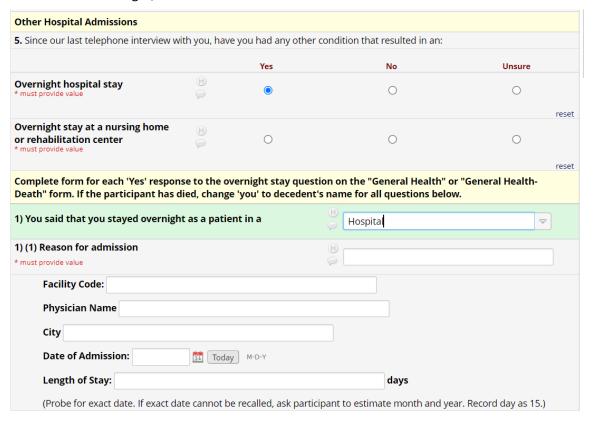
If No or Unsure to all items, go to Question 6.

If the participant has died and you are interviewing secondary contact, be sure to change "you" or "your" to the decedent's name in appropriate places.

Select the type of c	overnight stay f	rom the dropo	down box and	d read You said	that you stayed
overnight as a pati	ent in a		_•		

PΙ	ease	tell	me
----	------	------	----

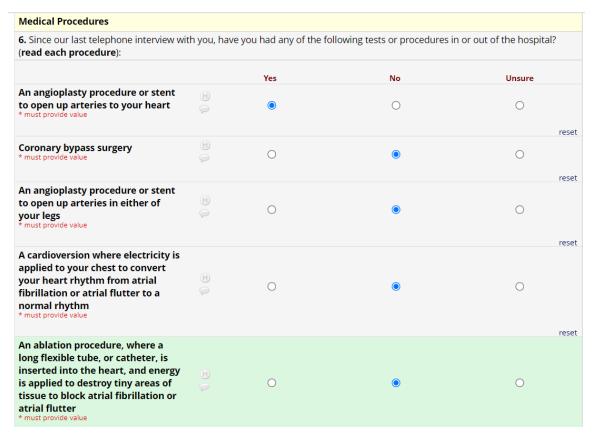
- Reason for admission: Record in the space provided.
- **Facility**: Enter the four-digit MESA hospital code, if known. Alternatively, you can enter the facility name and address in the blank space to the right of the "Facility Code" box and enter this information at a later time. See the Specific Medical 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 their best estimate.



When the form is complete, ask about any additional "other admissions" reported on Question 5 of the *FU26 General Health* form. Complete as many *Other Admission* forms as necessary (one for each admission reported in Question 5). If there are no other admissions, go to Question 6 of the *FU26 General Health* form.

An investigation must be initiated for all overnight stays. You must complete an *Initial Notification* form and submit to the Coordinating Center. See Section 4 for additional details.

- 6. 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.)
 - An angioplasty procedure or stent to open up arteries to your heart
 - Coronary bypass surgery
 - An angioplasty procedure or stent 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 flutier 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 any areas of pressure to block atrial fibrillation or atrial flutter



This is also a crucial question. Be sure the participant understands each item. Definitions of the following procedures are provided in Appendix A: 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 their 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.

If a procedure was done because of a participant's participation in a medical study, the procedure should still be recorded here on the *FU26 General Health form* (even if the participant had no symptoms or conditions that caused the procedure to be performed).

If Yes to any part of question 6, complete the Specific Medical Procedures section for <u>each</u> item with a "Yes" response.

1) You said that you had a	An angioplasty procedure to open up arterie 🗸
1) A. What was the name and address of the doctor you saw?	
[Physician name and City are OPTIONAL. Only record name Facility Code (if hospitalized)	and city if they are of use to Events staff.]
Physician Name:	
City:	
1) B. What was the date of the test or procedure?	Today M-D-Y
(Probe for Exact date. If exact date cannot be recalled, ask parti	cipant to estimate month and year)

Hospitalization dates listed on the Specific Medical Procedures section can match dates in either Other Admissions or Specific Medical Conditions sections.

If the participant has died and you are interviewing secondary contact, be sure to change "you" or "your" to the decedent's name in appropriate places.

Select the Other Medical Procedure rep	ported in question 6	from the drop d	lown box and re	ead
You said that you had a	•			

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 required details.

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."

Hospitalization dates listed on the Specific Medical Procedures section can match dates in either Other Admissions or Specific Medical Conditions sections. Do not record "Yes" for overnight stays that are not admissions.

Record the details for procedure or admission reported on Question 6 of the *General Health* form.

All five procedures will initiate an investigation.

Complete an Initial Notification for all procedures that require an investigation to be initiated. Immediately submit to the Coordinating Center. See Section 4 for additional details.

If No or Unsure to <u>all</u> items, go to Question 7.

7. Are you taking aspirin on a regular basis? Do NOT read the responses. Select Yes, No or Unsure.

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

For participants with a history of pacemaker or implanted cardioverter defibrillator:

8a. Based on your prior MESA interviews, I see that you had a [pacemaker or other device type from investigation] implanted on Month/Day/Year [CC inserts date of insertion based on event investigation]. Is that right? Do you still have an implanted device? Select Yes, No, Don't Know

For participants with a history of pacemaker or implanted cardioverter defibrillator:

8b. Do you have an implanted cardiac pacemaker or an implanted cardioverter-defibrillator (ICD)?

If YES, to 8a or 8b, go to 8c. Otherwise, end questionnaire

8c. Is it a cardiac pacemaker or a cardioverter-defibrillator? Select one.

9. List all the languages and dialects you can speak and understand, including English, in order of fluency:

Enter the first language or dialect participant indicates as most fluent in the first row.

Where did you learn it? Select Home, School, Community, or Other. If "Other" is selected, please specify in the text box.

At what age did you learn it? (If learned from birth, write age "0").

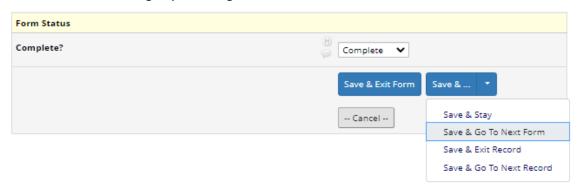
On a scale of 0-10, rate your proficiency in the language in terms of your ability to speak, write, and read the language. Read each response and enter a value between 0 and 10 for each.

Repeat the above steps for question 9 for each additional language or dialect reported by participant, starting with the language or dialect most fluent and continuing to the least fluent. Up to five languages or dialects can be entered.

9. List all the languages and diale	ects you can speak and understar	nd, including English, in orde	r of fluency:			
Language	Where did you learn it?	At what age did you learn it? (If learned from birth write age "0")	On a scale of 0-10, rate your proficiency in the language in terms of your ability to speak, write, and read the language			
	○ Home ○ School ○ Community ○ Other		Speak: Read: Write:			

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].

When finished, update the Form Status to "Complete." Click "Save & Go to Next Form" or return to the Record Home Page by selecting "Save & Exit Form."



The next step is to complete the FU26 General Health Supplement Form.

3.8.2. Other Form Information

If this is a secondary contact interview for a living participant, complete the entire form, substituting the participant's name for "you." If this is a secondary contact interview for a deceased participant, use the alternate version (*General Health- Death*) to conduct the interview. Please see Section 3.10 for more information about the *General Health- Death* form.

If using paper forms, enter the Interviewer ID in the boxes provided and indicate the method of data collection at the bottom of the form. A second staff member should review paper forms

for completeness and accuracy and bring discrepancies/questions to the attention of the interviewer. Once any uncertainties are resolved, the reviewer enters their Reviewer ID in the boxes provide at the bottom of the form. Submit the form for data entry

3.8.3. Action Required After Form is Completed

Many (not all) conditions, admissions, and procedures require that an Events Investigation be initiated. Please see Table 2 below to see how to follow-up with all of the parts to Questions 4, 5, and 6.

Table 2: Action required after positive responses to Questions 4, 5, and 6, on the *FU26 General Health* form.

Q#			Investigation
***	Sub-Question	Form Required	Required^
4	MI or heart attack	Specific Medical Conditions	Υ
4	Angina pectoris or chest pain due to heart	Specific Medical Conditions	Y
	disease.	Constitution Constitution	
4	Heart Failure or CHF	Specific Medical Conditions	Y
4	PAD, intermittent claudication or pain in legs from blockage of arteries	Specific Medical Conditions	Y
4	Atrial fibrillation	Specific Medical Conditions	Y if hosp
			N if not hosp
4	Deep vein thrombosis or blood clots in legs	Specific Medical Conditions	Y if hosp N if not hosp
4	TIA or mini-stroke	Specific Medical Conditions	Υ
4	Stroke	Specific Medical Conditions	Y
4	Blockage to the carotid artery	Specific Medical Conditions	Y
4	Cancer	Specific Medical Conditions	Y if hosp
_	Currect	Specific Wedicar Conditions	N if not hosp
4	COVID-19 Infection	Specific Medical Conditions	Y if hosp
			N if not hosp
5	Overnight hospital stay	Other Admissions	Y
5	Overnight NH or rehab center stay	Other Admissions	Υ
6	An angioplasty procedure or stent to open up	Specific Medical Procedures	
	arteries to your heart		
6	Coronary bypass surgery	Specific Medical Procedures	Υ
6	An angioplasty procedure or stent to open up	Specific Medical Procedures	Υ
	arteries in either of your legs		
6	A cardioversion where electricity is applied to	Specific Medical Procedures	Υ
	your chest to convert your heart rhythm		
	from atrial fibrillation or atrial flutter to a		
	normal rhythm		
6	An ablation procedure, where a long flexible	Specific Medical Procedures	Y
	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		

'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.

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.

3.9. FU26 General Health Supplement

This questionnaire will be administered at all field centers except for Johns Hopkins University (JHU). Staff from JHU should disregard information and language related to the *FU26 General Health Supplement*.

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

Some of the information asked in this questionnaire may address sensitive topics. If a participant chooses not to finish the questionnaire, they are free to do so at any time. For instructions on how to document such refusals, please refer to Section 3.9.1.

3.9.1. Item by Item Instructions

If a participant begins this questionnaire but then chooses not to respond to all the questions, please select the "Refused" checkbox at the top of the form. After documenting participant refusal to finish questionnaire, mark the form status as "Complete" and exit the form. On the *FU26 Contact Cover*, if all other FU26 procedures have been completed, select the final Visit Status Code as "Interview completed".

Instructions for respondents: How we see ourselves depends on many different things. As you are completing the questionnaire, think about who you are at your core—the part of you that is most important to who you are regardless of the different roles you occupy from day to day. There are no right or wrong answers; the most important thing is to respond honestly.

Please read/<u>listen to</u> each of the following statements carefully and rate your agreement as:

Not at all (1), Somewhat disagree (2), Somewhat agree (3), and Strongly agree (4).

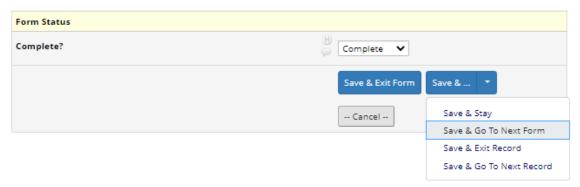
- 1. I don't have to be what other people expect. Read the responses.
- 2. What people think of me doesn't much impact who I am. Read the responses.
- **3.** For the most part, I decide who I am. Read the responses.
- 4. I tend to adhere to society's expectations of me. Read the responses.
- 5. What others think of me has very little to do with who I try to be. Read the responses.
- 6. When someone says something about me I know is not true, I generally don't get bothered. Read the responses.

- 7. I recognize right away when I am even a little uncomfortable with something that happens. Read the responses.
- 8. I can usually tell the difference between what I care about on my own and thoughts that come from the influence of others. Read the responses.
- 9. Even when it's easier to do something else, I always try to do what I believe is right. Read the responses.
- 10. Being myself no matter what is an important part of who I am. Read the responses.
- **11.** I would rather be myself than worry about what others think of me. Read the responses.
- **12.** I act like a different person in certain situations. Read the responses.
- **13.** Some situations require me to act like someone other than who I really am. Read the responses.
- **14.** The physical parts people see when they look at me are not what make me who I am. Read the responses.
- 15. Though we may look different on the outside, at the core I am the same as everyone else. Read the responses.
- **16.** My physical body is a big part of who I am. Read the responses.
- **17.** The main way I think of myself is as a soul existing in a physical body. Read the responses.
- 18. The characteristics of my body (for example, my race, gender, height, or physical ability, etc.) are only temporary parts of who I am. Read the responses.
- 19. When someone insults me, even if they are right about what they're saying, it doesn't usually bother me. Read the responses.
- **20.** Negative stereotypes about people like me make me feel bad about being who I am. Read the responses.
- 21. I wish I was someone people thought more highly of. Read the responses.
- **22.** What others think of me influences what I think about myself. Read the responses.
- 23. Although it should not matter, knowing people like me are not highly thought of makes me feel bad about being who I am. Read the responses.
- **24.** My opinion of what I am worth doesn't depend on how others view me. Read the responses.
- **25.** Regardless of what anyone else thinks of me, I am happy being who I am. Read the responses.
- **26.** My opinion of what I am worth depends on my status in society. Read the responses.
- 27. I don't really care much if people think highly of me. Read the responses.

- 28. Even when I fail at something or make a mistake, I don't question if I am a valuable person. Read the responses.
- **29.** I am valuable because all living beings are valuable. Read the responses.
- **30.** Caring for others is an important part of who I am. Read the responses.
- **31.** I do my best to minimize the suffering of all living beings. Read the responses.
- **32.** I don't worry much about the well-being of people who are not like me. Read the responses.
- **33.** I do not need to identify with someone in order to care about what happens to them. Read the responses.
- **34. Even people I don't know deserve my concern.** Read the responses.
- 35. I'm not willing to make sacrifices for people who don't deserve it. Read the responses.

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].

When finished, update the Form Status to "Complete." Click "Save & Go to Next Form" or return to the Record Home Page by selecting "Save & Exit Form."



The next step is to complete the *FU26 Contact Cover* form (see section 3.12).

3.10. 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 secondary contact 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 secondary contact 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. The Specific Medical Conditions, Other Admissions, and Specific Medical Procedures information is filled out as needed. The *General Health – Death* form records any relevant event that occurred between the participant's last contact with MESA and their 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 secondary contact 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?

The 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 secondary contact, checking the secondary contact's contact information using the *Participant Tracking form*, and providing the secondary contact with the Field Center phone number to use if they have any future questions.

3.11. Death Information Form

3.11.1. General Information

The *Death Information* form is for field center administrative purposes only and is not entered in the FU26 REDCap Data Collection Program.

The *Death Information* form is an optional, paper 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* sections are 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.

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 secondary contact indicated for the *Initial Notification*, the Field Center should investigate the death as the type that the Death Certificate indicates.

3.11.2. 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* sections 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 secondary contact 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 secondary contact 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 secondary contact cannot remember the exact date, record the best estimate and record in the "Notes" section that the date is the secondary contact'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 secondary contact but should rather listen to the secondary contact's answer and then mark the choice that, in the interviewer's opinion, best fits the secondary contact'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 secondary contact or interviewer is unsure of the cause of death, "Unknown" should be marked. If the interviewer knows the cause of the death but is unsure whether it should be marked "Cardiac death" or "Cerebrovascular death," then "Non-CVD death" should be marked and the text box filled in (adding more information in the "Notes" section if necessary).

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

(Question 3) Setting of Death

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

Listen to the secondary contact'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 secondary contact, completing the *Participant Tracking* form, and providing the Field Center phone number for the secondary contact to call if they have any questions.

(Notes)

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 secondary contact to answer

additional questions, but you may record anything useful that the secondary contact says in the course of answering the existing questions. Provide any information mentioned by the secondary contact that you think would aid the Events staff in investigating the death. For example, if the secondary contact 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* sections of the *General Health Form*.

3.11.3. Action Required After Form Is Completed

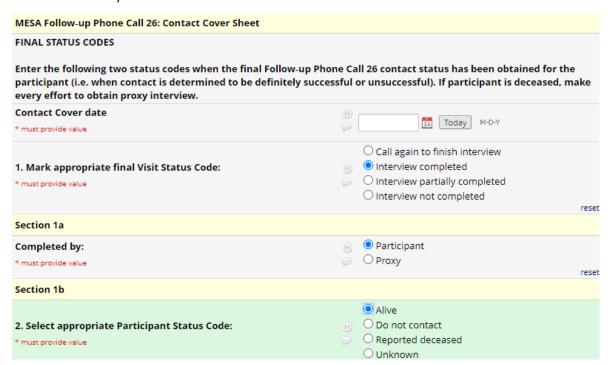
The form is not entered in REDCap. It should be given immediately to the Events staff.

3.12. FU26 Contact Cover

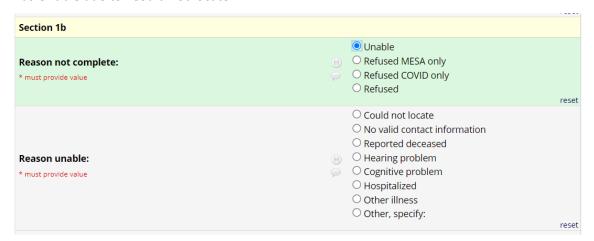
The *FU26 Contact Cover* form reports the final visit and participant status code for each active participant. It should be completed after the phone call is complete or after all attempts to contact a participant are done.

Visit status code documents the result of the current contact as 1) call again to finish interview, 2) interview completed, 3) interview partially completed or 4) Interview not completed. "Call again to finish interview" is an interim status code that should be updated to Interview completed, Interview partially completed, or Interview not completed before the end of the follow-up period.

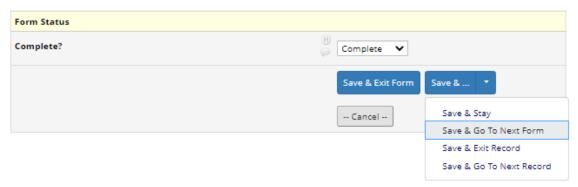
The final participant status documents the current status in the study as Alive, Do not contact, Reported deceased or Unknown. While these two status codes can influence each other, one cannot necessarily be assumed based on the other.



If an interview is partially complete, select Unable, Refused MESA only, or Refused from the list of reasons. If Unable, or Interview not completed, select the reason why. If all attempts to contact a participant have failed (left messages, sent letters, etc) indicate that the participant was Unable due to "Could not locate."



When finished, update the Form Status to "Complete." Click "Save & Go to Next Form" or return to the Record Home Page by selecting "Save & Exit Form."



3.12.1. Visit Status Codes

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

The following codes apply here:

Category	Explanation
Interview	Participant or secondary contact was successfully contacted by telephone or in
completed	person. The interview, including tracking information, general health, general health supplement, medical conditions, hospitalizations, and procedures, if needed, were completed. Indicate whether interview was completed by participant or by secondary contact. If secondary contact, indicate reason why participant was unable to complete interview. If the participant refuses to complete the General Health Supplement and the
	form is marked as "Refused", the interview should still be marked as "Interview completed".
Interview partially completed	Participant or secondary contact was successfully contacted by telephone or in person. The interview, including tracking information, general health, general health supplement, medical conditions, hospitalizations and procedures, if needed, were partially completed, or a portion of the interview was refused. Indicate whether interview was started by participant or by secondary contact. If secondary contact, indicate reason why participant was unable to complete interview. Also complete section 1b to indicate the reason the interview was partially completed.
Interview	Interview was not done for reasons other than refusal. Record the one best
not	reason. These categories should only be used when truly all other options have
completed	been attempted. For example, if the participant is reported deceased, every
Field center	attempt possible should be made to conduct the interview with a secondary
staff <u>unable</u>	contact.
to	
complete	
interview	
Interview	Participant refused to be interviewed. Record the one best reason (see below):
not	Refused due to problem with study Refused due to life situation
completed Participant	3. Refused due to life situation 3. Refused due to lack of time
refused to	4. Refused for other reason. (Specify:)
complete	In all cases, provide notes and comments in the Contact Cover Sheet as
interview	appropriate and notify the Study/Events Coordinator to follow-up with participant as appropriate.

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.

Section 1b	
Reason not complete: * must provide value	 ○ Unable ○ Refused MESA only ○ Refused COVID only ○ Refused
Reason refused: * must provide value	Problem with the study Life situation Lack of time Other, specify:

3.12.2. Participant Status Code

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

The following participant statuses are possible:

Category	Explanation
Alive	Participant or secondary contact is contacted.
Do Not Contact	Participant or designated secondary contact 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.
	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.
	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 they are still
	willing to participant in only one component.
Reported Deceased	Reliable information from secondary contact indicates the participant has died. Field center staff should initiate an
	Initial Notification of Potential Event/Death form and begin
	investigation of reported death. FC staff should obtain an
	Informant Interview or Physician Questionnaire if records are
	unavailable or do not provide enough information about the
	death.
Unknown	Field center staff has been unable to contact participant.
	Designated contacts cannot be reached or cannot provide
	reliable information regarding the participant's vital status.
	Use this designation only in rare circumstances, when all
	leads have been exhausted.

The Events Coordinator is responsible for reviewing all cases of ambiguity or difficulty. These include refusals, difficult contacts, secondary contact 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 secondary contact. 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."

4. 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 a death is identified during the Follow-up Call process, complete as much of the interview as possible. Also, ask the respondent if they are the best person to provide details about the participant's death and, if so, if it would be acceptable to call back at a later time to conduct an Informant Interview.

If a potential event is identified through means other than a Follow-up Call (e.g., unscheduled notification by the participant during an Exam), then it is <u>not</u> 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, use the discovered information to submit an *Initial Notification* immediately and then begin gathering the appropriate documentation for a full investigation.

5. Training and Certification

New MESA follow-up interviewers should review the information in this MOP and practice entering data in the MESA Follow-up 26 REDCap program using test participant ID numbers.

7-digit Test IDs start with the Field Center ID number and have a "9" in the second digit.



Practice administering the forms and interviewing participants to become familiar with the questions, responses, and flow of the follow-up call interviews.

Certification requires submitting 3 recorded interviews and entering the corresponding data using test IDs in the REDCap Follow-up Test project. Submitting a certification review packet to the MESA Coordinating Center requires two steps:

- 1. Enter the certification details in the Smartsheet form at MESA Certification Submission form.
- 2. Upload the recorded interviews to NextCloud.

Certification interviews can be completed using a MESA staff member or any volunteer as a mock MESA participant. If the interview is conducted over the phone, have the mock participant on speaker in order to hear them in the recording. The MESA CC has provided Sony digital recording devices to the Field Centers for certification activities. The recorded files can be transferred from the device to a computer and then transferred to the CC. Interviews can also be recorded using a cell phone or as a recorded Zoom session.

Recorded interviews must include the FU26 Introduction Script, FU26 Participant Tracking Survey, FU26 General Health, and FU26 General Health Supplement (except for Johns Hopkins) forms. The submitted REDCap Forms must also include the FU26 Contact Cover Form. The FU26 General Health interview must include data entry for a yes response to questions 4, 5, or 6 (Medical Conditions, Other Admissions, or Medical Procedures).

Interviewers who were certified on the previous Follow-Up interview do not need to redo certification.

6. Appendix A: Medical Terminology

6.1. English

Syndrome or Diagnosis	Definition	Synonyms
A myocardial infarction or heart attack	Damage to the heart muscle caused by inadequate blood supply. Usually accompanied by chest pain.	МІ
Angina pectoris or chest pain due to heart disease	Severe pain and constriction about the heart, usually radiating to the left shoulder and down the left arm, or, rarely, from the heart to the abdomen. Pain may also radiate to the back or to the jaw. Caused by an insufficient supply or blood to the heart.	Angina
Balloon	Balloons are used in angioplasty procedures.	angioplasty
Stent	Stents are used in angioplasty procedures.	angioplasty
Heart failure or congestive heart failure	Heart does not pump adequately to provide blood to the organs. Usually accompanied by shortness of breath and swelling of feet.	

Syndrome or Diagnosis	Definition	Synonyms
Peripheral vascular disease, intermittent claudication or pain in your legs from a blockage of the arteries	Diseases of the arteries of the extremities, due to inadequate flow of blood to the extremities, such as atherosclerosis with narrowing of the artery.	
Atrial fibrillation	One type of heartbeat irregularity.	A-fib
Deep vein thrombosis or blood clots in your legs	A blood clot forms in a <i>vein</i> of the leg.	
A stroke	Bleeding or lack of blood supply to brain, leading to neurologic damage.	Cerebral or brain hemorrhage, cerebral infarction
A transient ischemic attack (TIA) or mini- stroke	A reversible short-lived stroke, with recovery.	
Blockage to the carotid artery	Atherosclerosis (hardening) of a carotid artery of the neck.	
Lung abnormality or nodule	Any lung problem.	
Cancer	Malignant growth.	
Exercise treadmill or bicycle test	An exercise test on a treadmill, bicycle or similar device in which people increase their heart rate in order to have the function of the heart measured, usually by an ECG.	
Coronary angiography or heart catheterization	A procedure used to examine the heart or a heart artery by introducing a thin tube (catheter) and injecting dye.	Cardiac cath
Echocardiogram	A test in which sound is transmitted into the body and electronically plotted to produce a picture of the heart's size, shape and movements.	Echo

Syndrome or Diagnosis	Definition	Synonyms
An angioplasty procedure to open up arteries to your heart	A procedure used to dilate (widen) narrowed arteries. A catheter with a deflated balloon on its tip is passed into the narrowed artery segment, the balloon inflated, and the narrow segment widened. Angioplasties can now also be done by laser. To keep arteries from collapsing, stents (stainless steel supports) can be inserted into the artery during angioplasty. This can be done to the coronary arteries of the heart. Be sure to include angioplasty of non-heart arteries elsewhere.	Percutaneous angioplasty, balloon dilation, balloon test or procedure, PTCA, stent(s),
Coronary bypass surgery	Surgery to improve blood supply to the heart muscle. This surgery is performed when narrow coronary arteries reduce the flow of oxygen-containing blood to the heart. Veins are used to connect good portions of the coronary arteries.	CABG, "cabbage" operation, bypass graft or operation
An angioplasty procedure to open up arteries in either of your legs	See Angioplasty above	
Carotid ultrasound or carotid angiogram	A diagnostic method in which pulses of sound are transmitted into the neck arteries and the echoes returning from the surfaces of the artery walls are electronically plotted to produce a picture of a small portion of the carotid artery showing the amount of atherosclerosis (hardening of the arteries) that can be seen in the arterial wall.	Echo
Other diagnostic procedure or surgery related to your heart or blood vessels	Examples of surgery include valve replacement, ventricular aneurysm resection, aortic stenosis, ventricular stenosis, defect repair, patent ductus closure, pacemaker, implantation of automatic defibrillator, coronary atherectomy. Examples of diagnostic procedures include electrocardiogram, imaging or stress tests involving injection of dye, etc.	
Chest x-ray, a chest CAT scan, MRI, or other study to assess any findings in your chest	MRI: A diagnostic procedure using powerful magnets to look inside the body. Computergenerated pictures image the body and can identify abnormalities, such as damage from an injury. CAT Scan: A non-invasive diagnostic technique that produces an image of the body and can identify abnormalities.	

Syndrome or Diagnosis	Definition	Synonyms
Other diagnostic procedure or surgery related to your heart or blood vessels	Examples of surgery include valve replacement, ventricular aneurysm resection, aortic stenosis, ventricular stenosis, defect repair, patent ductus closure, pacemaker, implantation of automatic defibrillator, coronary atherectomy. Examples of diagnostic procedures include electrocardiogram, imaging or stress tests involving injection of dye, etc.	

6.2. Spanish Translations for Medical Terminology

Terminología Médico

Síntoma o Diagnóstico	Definición	Sinónimos
Infarto miocárdico o ataque al corazón	Daño al músculo del corazón causado por una insuficiencia en el abastecimiento de sangre. Generalmente acompañado de dolor en el pecho.	Infarto de miocardio, ataque cardíaco
Angina de pecho o dolor de pecho debido a la enfermedad de corazón	Dolor intenso y sensación de opresión alrededor del corazón, generalmente irradiado hacia el hombro izquierdo y hacia abajo por el brazo izquierdo, o en casos excepcionales, del corazón al abdomen. El dolor también puede irradiarse hacia la espalda o la mandíbula. Causado por un aporte insuficiente de sangre al corazón.	Angina, cardiopatía isquémica
Globo	Globos que se utilizan en los procedimientos de angioplastia	
Dispositivo intravascular (soporte de acero inoxidable) o <i>stent</i> por su nombre en inglés	Dispositivos intravasculares, también llamados stents, que se utilizan en los procedimientos de angioplastia	
Insuficiencia cardíaca o insuficiencia cardíaca congestiva	El corazón no bombea adecuadamente para proveer de sangre a los órganos. Generalmente esta acompañado por dificultad respiratoria e hinchazón de los pies.	"Fracaso" o "fallo" cardíaco
Fibrilación auricular	Un tipo de irregularidad del ritmo cardíaco.	

Síntoma o Diagnóstico	Definición	Sinónimos
Trombosis de vena profunda o trombos (coágulos) en las piernas	Formación de trombos (coágulos) de sangre en una vena de la pierna	
Accidente cerebrovascular	Sangrado intracraneal o falta de abastecimiento de sangre al cerebro que produce lesiones neurológicas	Ictus, hemorragia o derrame cerebral, ACVI
Accidente isquémico transitorio	Accidente cerebrovascular reversible de pequeña duración, con buena recuperación.	AIT
Bloqueo de la arteria carótida	Ateroesclerosis (endurecimiento) de la arteria carótida del cuello	
Nódulo o anomalía pulmonar	Cualquier problema pulmonar	
Cáncer	Neoplasia maligna	
Prueba de ejercicio	Prueba de ejercicio en una cinta sin fin, bicicleta o aparato similar para aumentar el ritmo cardiaco de las personas y tomar medidas de la función del corazón, generalmente con un electrocardiograma	Prueba de esfuerzo, ergometría
Angiografía coronaria o cateterización del corazón	Procedimiento que se utiliza para examinar el corazón o una arteria del corazón a través de la inserción de una sonda o tubo (llamado catéter) e inyectando contraste.	Cateterización cardiaca
Ecocardiografía	Prueba en que los ecos de ultrasonido transmitidos al cuerpo se registran electrónicamente produciendo una imagen que da información sobre el tamaño, forma y movimientos del corazón	Ultrasonografía

6.3. Chinese Translations for Medical Terminology

	医学术语	
症状或诊断	解释	代名词
心肌梗塞或心脏 病发作	由于心脏供血不足造成的心肌损害,通 常伴有胸部疼痛。	心肌梗塞
由心脏疾病引起的心绞痛或胸部疼痛	由于心脏供血不足引起的心前区剧烈疼 痛和压迫感;通常放射到左肩,传至左 前臂; 极少见传导至腹部,有些疼痛可以传导 到背部或下颌。	心绞痛
球業	<u>球業扩张用于血管成形术</u>	血管成形术
支架	支架用于血管成形术 心脏不能供应器官充足的血液。通常件	血管成形术
心力衰竭或充血 性心力衰竭	有呼吸短促和下肢浮肿 的症状。	
外周血管疾病, 由于下肢动脉堵 塞;引起下肢疼 痛或间歇性跛行。	由于下肢供血不足,引起的腿部动脉疾病。 例如,下肢动脉硬化合并动脉狭窄。	
心房纤颤	心脏跳动不规律的一种。	房颤
深静脉血栓症或 下肢血管栓塞	下肢静脉内血栓形成。	
中风	脑出血或供血不足,造成神经系统的损害。	脑出血或脑 梗塞
瞬间缺血或轻微 中风	可以恢复的短暂中风	
颈动脉阻塞	颈部动脉硬化	
肺部不正常或小 结	任何肺部疾病	
癌症	恶性新生物	
运动式传动踏板 或单车测试 	通过使用传动踏板,单车或类似的运动 装置,增加受试者的心跳次数,同时用 心电图来监测心脏功能。	
冠状动脉造影或 心脏导管插入	一种检测心脏或心脏功能的方法。通过 插入受试者血管内一根较细的导管注射 造影剂,获得心脏或心脏血管的图像。	心脏导管 插入
超声波心脏动态 图	一种检测手段,通过发射超声波进入人体内,用计算机处理产生有关心脏的大	心脏超音图
心血管成形术是 用来通畅通向您 心脏的动脉	小,不仅及自己。 血管成形术是用于扩张您狭窄的血管, 使用一个顶端带有球囊的导管插入血管, 狭窄的部分,扩张球囊使狭窄的管腔扩 张,也可以用激光法扩张管腔。为了防 止血管塌陷,使用支架(一种不□钢支 □物)插入血管,以保证术后血管的通 畅。	血球業状术, 球業状术, 球業状术, 成 形之架,

冠状动脉搭桥手 术	一种提高心脏肌肉血流供应的手术方式, 当狭窄的冠状动脉不能提供心脏足够的含 氧血液时,我们需要做这个手术来改善血 流状态。通常用静脉做搭桥血管。	冠状动脉 搭桥管嫁养 血或搭 或 水。
血管成形术用来 通畅您腿部的动 脉	参考以上,血管成形术。	
颈动脉超声波或 颈动脉图	一种诊断方法。发射脉冲波到颈部动脉, 通过收集动脉壁的反射波,产生有关动脉 硬化程度的图像。	颈动脉超 声波
其它任何与您心 脏或血管有关的 诊断或手术方法	相关的手术方法有,办膜替换术,室壁瘤切除术,主动脉狭窄,心室狭窄,缺损修补术,动脉导管闭合术,起博器,除颤器植入,冠状动脉斑块切除术。相关的诊断	
胸部透视,胸部 断层扫描,核磁 共振图像作为其 长何问题的研究 发现	有效 核磁共振:一种诊断方法,通过使用强磁 场观察您的身体内部脏器,并用计算机处 理产生图像,可以识别任何不正常,例 如:外伤后的损伤。 断层扫描:一种无创性诊断手段,通过观 察身体内部脏器图像,识别任何异常。	

7. Appendix B: Data Management

7.1. Updating participant contact or status information

If the participant or designated secondary reports that the participant no longer wants to receive any contact with MESA clinic or staff, update their status in the MESA Data

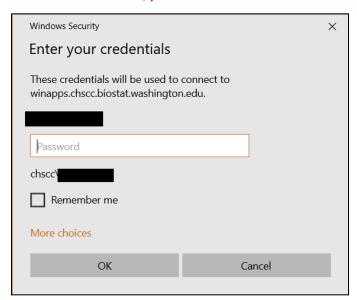
Management Program. This "Lost to Follow-Up" (LTFU) status should be used only when field center staff has exhausted all reasonable means to address the participant's concerns and retain them in the study.

Participants with a status code of Lost to Follow-up will not be included in future follow-up call lists or other MESA communication.

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 they are still willing to participant in only one component.



Access the MESA Data-Management program using a Remote Desktop link, Mesa_DataManagement. Click the Remote Desktop link to login. When entering your MESA domain account name, preface our domain name like so: CHSCC\





Enter your three or four digit MESA Tech-ID number and password.

Participant List



Set the Participant List to display participants from any of the three MESA cohorts by selecting the cohort from the dropdown list next to "Study Name".

Note: by default, only active participants are list. To view participants who have dropped out of the study, check the "Include Study Dropouts" box at bottom.

Select or enter a participant ID number from the Participant List to view or edit that participant's study status.

7.2. Contact Information update outside of a follow-up call.

Updates to name, address, phone numbers, email address provided outside of a MESA Follow-up call should be entered in the MESA Data Management Program (not the Follow-up data entry program).

7.3. Follow-up data report

Review progress on completing MESA Follow-up call on the MESA website at https://internal.mesa-nhlbi.org/internal/data/reports.

7.4. Creating Participant Mailing Labels.

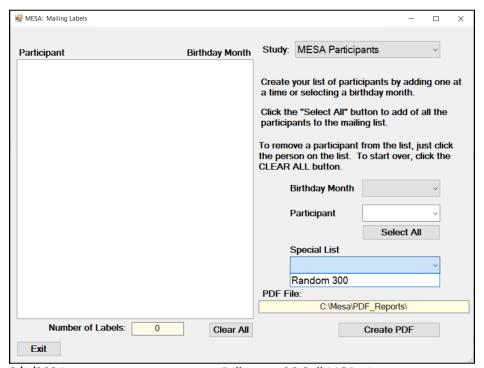
The following provides instructions for creating mailing labels for active participants.

Build a mailing list by adding participants to the mailing list. You can add participants in the following ways:

- 1. Enter or select a participant ID from the participant dropdown box to add one or more participants to the list.
- 2. Click the Select All button to add all participants from the select MESA cohort to the list
- 3. Select a month from the "Birthday Month" dropdown box to add all participants who have a birthday in that month.
- 4. Selecting "Random 300" from the "Special List" dropdown option randomly selects 300 participants to add to the mailing list.

Click a participant from the mailing list to remove that participant from the list. Click the "Clear All" to remove all participants from the mailing list.

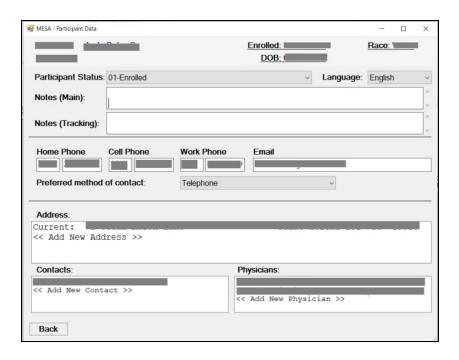
Click the "Create PDF" button to create a mailing label PDF file that you can edit and print. This file will be located in the folder specified just above the button.



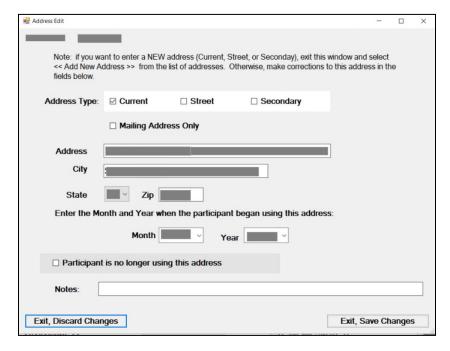
8/1/2024

Follow-up 26 Call MOP v1

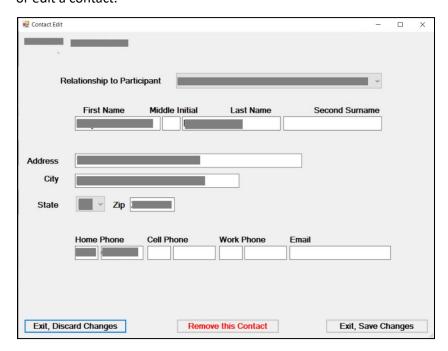
Participant Data Forms



Click an address or click "Add New Address" to open the Participant Address form to view or edit an address.



Click a contact person or click "Add New Contact" to open the Participant Contact form to view or edit a contact.



Click a physician or click "Add New Physician" to open the Participant Physician form to view or edit a physician.

