



MESA COVID-19

Baseline Telephone Interview Manual of Operations

Version 1.1

2020-05-22

Contents

1	Overview	1
1.1	Sample.....	1
1.2	Interview Contents.....	1
2	Call Scheduling	1
2.1	Calls Performed Solely for the Collection of COVID-19 Information	2
2.2	Integration with MESA Follow-up 21	Error! Bookmark not defined.
2.3	Integration with MESA-MIND	Error! Bookmark not defined.
2.4	Call Frequency.....	2
3	Entering Data in REDCap.....	2
3.1	Using REDCap.....	2
3.2	Contact Information Form	5
3.3	Verbal Consent Form	5
3.4	Call Log Form.....	6
3.5	COVID-19.....	6
4	Conducting the Interview	6
4.1	Before the Call.....	6
4.2	Phone Scripts	6
4.3	Interview Questions.....	7

1 Overview

The MESA COVID-19 questionnaire is a telephone-administered interview estimated to take 5 minutes (if the participant has not been diagnosed with COVID-19 and has no symptoms) to 30 minutes to administer. It is designed to collect data on the diagnosis, symptoms, and medical interventions associated with the newly identified disease called COVID-19 caused by infection with the SARS-CoV-2 virus.

Self-report of diagnoses, symptoms, and medical interventions will be collected during the interview. Any associated medical records will be collected, if required, after the interview.

1.1 Sample

All active MESA participants will be contacted for this interview.

1.2 Interview Contents

The interview consists of a telephone script preamble and the COVID-19-related interview questions. This interview may be completed as a standalone call or combined with the MESA-Follow-up 21 or MESA-MIND interview on the same call, at the discretion of the Field Center.

The following sites require additional informed consent before conducting the interview: Northwestern.

2 Call Scheduling

Whenever possible, the COVID-19 questionnaire should be completed as part of the Follow-up 21 (FU21) and/or MESA-MIND phone call to reduce the number of calls to the participant or proxy. The Coordinating Center has provided a tracking report in REDCap (Contact Information Form) that lists: the dates, if applicable, that Follow-up 21, MESA-MIND, or a previous COVID-19 questionnaire was completed; the interviewer associated with each type of call; and the FU21 window (for calls not already performed). This will enable Field Centers to prioritize call schedules according to local requirements.

2.1 Integration with MESA Follow-up 21 or Follow-up 22

Follow-up 21 calls (FU21) will continue into August 2020. If the FU21 call is scheduled within the next three months (through July 10, 2020) the baseline COVID-19 questionnaire may be administered at the same time as the follow-up call. The questionnaire should be completed at the beginning of the phone call prior to the General Health Questionnaire. Follow-up 22 will begin in mid-August 2020. The follow-up COVID-19 questionnaire may be administered at the same time as the FU22 call.

2.2 Integration with MESA-MIND

If the FU21 call has already occurred, or the participant's MESA-MIND call is scheduled for an earlier date than FU21, the MESA COVID-19 questionnaire may be administered at the beginning of the MESA-MIND call.

2.3 Calls Performed Solely for the Collection of COVID-19 Information

If FU21 and/or MESA-MIND has already been completed, or there is a need to capture the baseline COVID-19 questionnaire outside of the window for either FU21 or MESA-MIND, interviewers may call the participant to ask the COVID-19 questionnaire.

2.4 Call Frequency

The MESA COVID-19 interview will be repeated at least once for each participant to allow tracking of symptoms and testing over time. The frequency is site-specific. At a minimum, the baseline questionnaire will be administered at least once between 4/10/2020 and 8/10/2020. The questionnaire will be repeated at least once between 5/11/2020 and 5/29/2021. The schedule for repeated questionnaires may vary by Field Center, depending on local public health requirements or concerns.

Site 3: Baseline and repeat schedule is to be determined.

Site 4: Baseline questionnaires will be completed between 4/10/2020 and 8/10/2020. Repeat questionnaires will be completed every 3-4 months.

Site 5: Baseline questionnaires will be completed between 4/10/2020 and 8/10/2020. Repeat questionnaire schedule is to be determined.

Site 6: Baseline and repeat schedule is to be determined

Site 7: Baseline questionnaires will be completed between 4/10/2020 and 5/9/2020 and repeated every 2-4 weeks during peak infection period.

Site 8: Baseline and repeat schedule is to be determined.

3 Entering Data in REDCap

3.1 Using REDCap

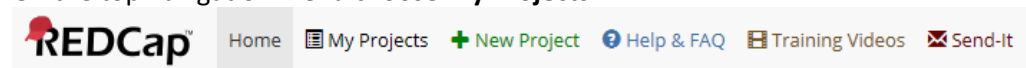
Key Terms

Instance – One copy of a form that will be administered to the same participant on more than one occasion

Record – Equivalent to MESA ID, participant

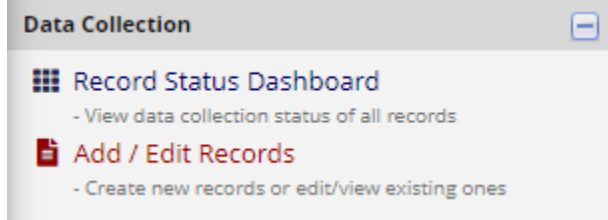
Log into REDCap at the site <https://redcap.iths.org/>, entering “University of Washington” as the institution. Use the username and password assigned to you by the Coordinating Center.

On the top navigation menu choose **My Projects**.



From the My Projects screen choose **MESA COVID-19 Questionnaire**

On the Project Home page for the project, you can add a new participant record or edit an existing record. On the left navigation panel, find the **Data Collection** box and select the **Add / Edit Records** link.



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:

Total records: 4,275	
Choose an existing Record ID	<input type="text" value="-- select record --"/>
Enter a new or existing Record ID	<input type="text"/>

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. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

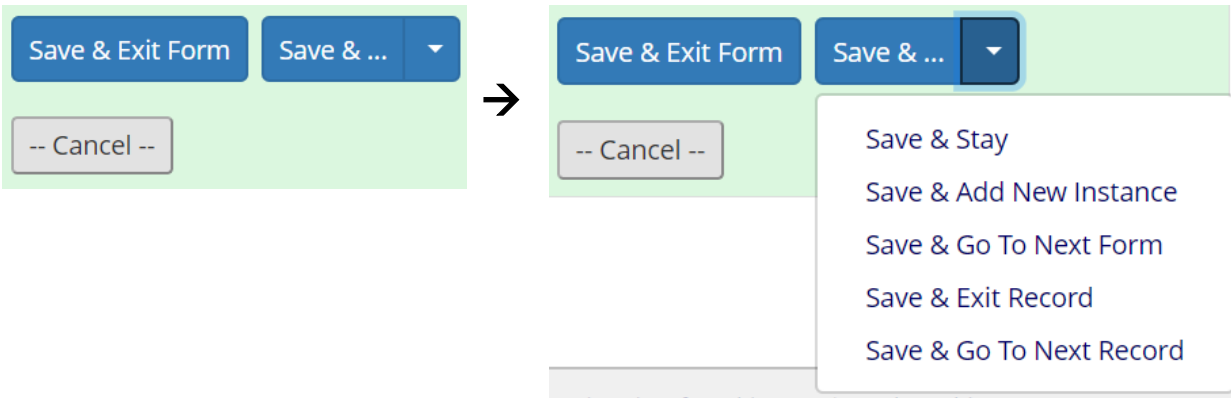
Legend for status icons:

- Incomplete ? Incomplete (no data saved)
- Unverified ●●●● Many statuses (all same)
- Complete ●●●● Many statuses (mixed)

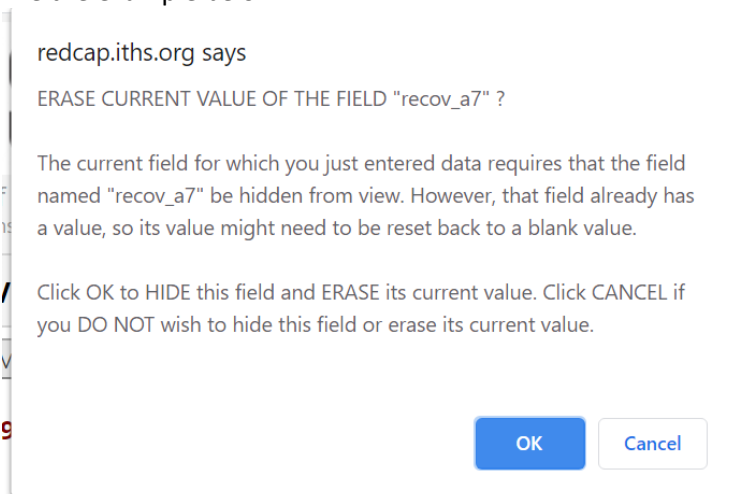
NEW Record ID 9099905

Data Collection Instrument	Baseline	FU
Contact Information	●	
Verbal Consent	●	
Call Log	●	
COVID-19	●	

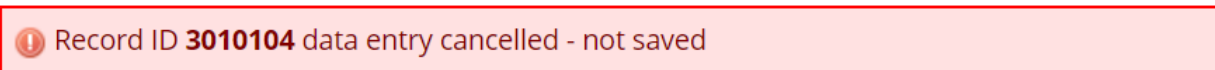
At the end of each form, there are several options to Cancel or Save the changes made. There are additional Save options available in the dropdown list (see image below). Selecting Cancel will return you to the home page for the record (ID) without saving any changes.



Skip patterns are programmed to appear automatically based on the answers to the root questions. If you change a previous response which effects 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:






Forms that can be administered repeatedly are displayed underneath the Data Collection Instrument table. This section is triggered to appear after opening the repeating forms. You can access an existing form or add a new instance of a form from both sections.




For quick reference, the participant's response to the call is visible in the "Repeated Instruments" section after the date of the form.

Record ID **9099903**

 Data Collection Instrument	Baseline	FU
Contact Information		
Verbal Consent		
Call Log	 +	
COVID-19	 +	

Repeating Instruments

Call Log 	
Baseline (2)	
1	 04-09-2020 14:00, , Completed questionnaire
2	 04-09-2020 15:24, , Completed questionnaire
<input type="button" value="+ Add new"/>	

COVID-19 	
Baseline (2)	
1	 04-09-2020, , "Yes - okay to ask", "Yes - okay to call again"
2	 04-09-2020, , ,
<input type="button" value="+ Add new"/>	

3.2 Contact Information Form

The participant's contact information, proxy information, and their FU21 completion status will be pre-filled.

Changes cannot be made to the data on this form.

If the participant or proxy has new contact information, enter the new information in the 'Notes' text box of the Call Log form to save the information. After the call, update the MESA FU21 electronic data capture system contact information (see FU21 Manual of Operations) or notify your MESA Field Center Data Manager responsible for FU21 to update the contact information.

3.3 Verbal Consent Form

Items will appear on this form if your site requires verbal consent to administer the MESA COVID-19 interview.

If your site does not require verbal consent, this form will not appear.

3.4 Call Log Form

This form collects the details of one contact attempt. A new Call Log form can be filled out each time an attempt is made to contact a participant.

3.5 COVID-19

Create a new instance of this form each time the COVID-19 questionnaire is administered to the same participant. The schedule of administration is site-specific and is discussed in Section 2.4.

Detailed instructions on administering each question are found in Section 4.3.

4 Conducting the Interview

4.1 Before the Call

Before the call...

- Determine which MESA-COVID phone script should be used:
 - Script A: Not being conducted on the same call as MESA Follow-up 21, MESA Follow-up 22, or MESA-MIND AND informed consent *is* required (rare)
 - Script B: Not being conducted on the same call as MESA Follow-up 21, MESA Follow-up 22, or MESA-MIND AND informed consent *is not* required
 - Script C: Being conducted on the same call as MESA Follow-up 21, MESA Follow-up 22, or MESA-MIND
- Have participant's prior MESA consent available to confirm prior consent to release medical records and to reference if they request it.

4.2 Phone Scripts

There are 3 versions of the phone script differing by the need for verbal consent and whether or not other questionnaires are being administered on the same call:

- A. For calls completed separately from regular MESA follow-up Call that require informed consent verification (Northwestern and Columbia. Other sites TBD).
- B. For calls completed separately from regular MESA follow-up Call that DO NOT require informed consent verification.
- C. For calls completed at the same time as the regular MESA Follow-up Call

Scripts are provided in a separate document.

4.3 Interview Questions

Additional details for the interview questions are provided below. Clarifications and additional instructions are *italicized*.

For any numeric fields, such as “number of days” please have the participant or proxy provide their best estimate. If the participant or proxy cannot answer the question, please mark “-99”. This will clarify that the question was asked, but the participant could not respond to the question.

For any date fields, please choose the most likely date. For dates of testing and hospitalization, the date will assist medical records collection.

1. Baseline: Have you had COVID-19, or the illness caused by the novel coronavirus?

- Yes, definitely → *have a positive test result or confirmation by Healthcare Professional (HCP)*

- Yes, I think so → *believe they have/had it but have not been tested or have not yet received test results, or HCP was unsure*

- Maybe → *aren't sure, any circumstance*

- No → *have a negative test result or have no reason to believe they have had it*

All responses continue to question #2.

2. Baseline: Has a healthcare provider ever told you that you had COVID-19?

- Yes, definitely *Participant is certain they have been told they have/had COVID-19*
→ Proceed to box below

- Yes, probably or suspected *Participant is not completely sure they have been told they have/had COVID-19, but think they have been told they have/had it. This also applies if their healthcare provider told them they “might have it” but they have no formal diagnosis/positive test.*
→ Proceed to box below

- No → Proceed to question 3

If answered “Yes, definitely” or “Yes, I think so” to #2:

Item	Explanation
<i>Ask all questions in this box</i>	
Did you have:	
a) Symptoms of COVID-19	<i>a) One or more of: cough, sore throat, fever, difficulty breathing, etc. (see list of symptoms in questions 7 and 8)</i>
<input type="radio"/> Yes	
<input type="radio"/> No	

d. Can you provide details regarding your first COVID-19 test?

- i. Date
- ii. Reason for testing:

iii. Type of test

iv. Result

e. Can you provide details regarding your most recent COVID-19 test?

f. Baseline: If you did not experience a positive result on your first or most recent test, have you ever had a positive COVID-19 test?

Follow-up: Since our last call, if you did not experience a positive result on your first or most recent test, have you ever had a positive COVID-19 test?

- Yes

- No
- Unsure

g. Are you willing and able to **send** a copy of your COVID-19 results to the study?

- Yes
- No

For follow-up calls, only include tests since the last call. Date test performed.

ii. Response required for each item 1-4. If participant was in close contact with someone who tested positive, please add that under 'other' – close contact with COVID-19 patient/neighbor/family member. See 2b, above, for definition of close contact.

iii. Response required for each item 1-3.

iv. "Unsure/Pending" includes if test result is still pending.

e. If participant has only had one test, skip item e and proceed to item f (this happens automatically in REDCap).

f. Complete item if:

- participant's first and only result was negative*
- OR*
- participant has had more than one test and most recent test was negative*

Else, proceed to item g.

Proceed to sub-item f.i.

See explanation for item d.i. to d.iv.

Proceed to g.

"Unsure" includes if test result is pending or inconclusive.

Proceed to g.

Please note, this question is to be re-worded. We will request the test results from the clinic/facility in 2c above during medical records collection.

4. Baseline: Have you had any x-ray or computed tomography (“cat”) scans for suspected or diagnosed COVID-19?

- Yes → Proceed to box below.
- No → Proceed to question 5.

If answered “Yes” to #4:

<u>Item</u>	<u>Explanation</u>
a. Did you have a chest X-ray?	<i>a. Record response.</i>
b. Did you have a CT scan of your lungs?	<i>b. Record response.</i>
c. Are you willing to have your lung images shared with the study?	<i>c. If yes, we will collect this information via the events medical records collection process.</i>

5. Baseline: Have you ever had an overnight stay in a hospital for suspected or diagnosed COVID-19?

- Yes → Proceed to box below
- No → Proceed to question 7.

If answered “Yes” to #5:

<u>Item</u>	<u>Explanation</u>
a. How many nights were you in the hospital?	<i>Record number of days</i>
i. Date arrived at hospital:	<i>a.i. If date of arrival and formal admit date are different, record the earlier date.</i>
ii. Date discharged from hospital:	
b. Did you require any of the following treatments?	<i>b.i. to b.v. “# Days needed” calculated as the difference between calendar days treatment started and treatment stopped.</i>
For ascertainment of medical records: Name of doctor/clinic/hospital where test or diagnosis was obtained:	<i>Ask for contact information of doctor/clinic/hospital <u>where COVID-19 test was obtained</u></i>

Address of doctor/clinic/hospital:	

Contact number:	

6. Baseline: If you were hospitalized for suspected or diagnosed COVID-19, how were you discharged?

Where did the participant live after being discharged?

- | | |
|--------------------|--|
| ○ Home | <i>Record response.</i> |
| ○ Nursing facility | <i>Any facility in which nursing care is available or necessary.
Record response.</i> |
| ○ Other | <i>If answer to a and b was “no”, record response to c.
If answer to a or b was “yes”, do not record a response.</i> |

7. Baseline: If you know, or believe, that you had COVID-19: have you recovered to your usual state of health?

To be answered if participant answered question #1 as “Yes, definitely” or “Yes, I think so” or “Maybe”. If not, proceed to question #8 on page 8.

- | | |
|-------|--|
| ○ Yes | <i>Record response to the follow-up item:
a. How long did it take for you to recover?
○ Days calculated as the difference in calendar days between day first felt symptoms and first day returned to usual health.</i> |
|-------|--|

Proceed to the boxed items on page 6, prefaced with If yes to Q7: For participants who have recovered from symptoms related to COVID-19 illness:”

- | | |
|------|---|
| ○ No | <i>Proceed to the boxed items on page 7, prefaced with “If no to Q7: For participants who continue to have symptoms related to COVID-19 illness:”</i> |
|------|---|

If yes to Q7:

For participants who have recovered from symptoms related to COVID-19 illness:

- For each symptom (row), record response to A. If A is “yes”, record response to items B and C. If A is “No”, proceed directly to next symptom (row).
- B: response options 1 to 5 correspond to: 1 (“Not at all”), 2 (“A little bit”), 3 (“Somewhat”), 4 (“Quite a bit”), and 5 (“Very much”).
- C: Calculated in days as the difference between calendar days symptom started and symptom stopped.
- Item: Overall, when these symptoms were at their worst, when you had these symptoms, how bad or bothersome were they?
 - Record response as “Mild”, “Moderate”, “Severe”, or “Very Severe”
- Item: Overall, when these symptoms were at their worst, did they interfere with your daily activities?
 - Record response as “Not at all”, “A little bit”, “Somewhat”, “Quite a bit” or “Very much”
- After completing page 6, proceed directly to question #9.

If no to Q7:

For participants who continue to have symptoms related to COVID-19 illness:

- For each symptom (row), record response to A. If A is “yes”, record response to items B and C. If A is “No”, proceed directly to next symptom (row).
- B: response options 1 to 5 correspond to: 1 (“Not at all”), 2 (“A little bit”), 3 (“Somewhat”), 4 (“Quite a bit”), and 5 (“Very much”).
- C: Calculated in days as the difference between calendar days symptom started and symptom stopped.
- Item: Overall, when these symptoms were at their worst, when you had these symptoms, how bad or bothersome were they?
 - Record response as “Mild”, “Moderate”, “Severe”, or “Very Severe”
- Item: Overall, when these symptoms were at their worst, did they interfere with your daily activities?
 - Record response as “Not at all”, “A little bit”, “Somewhat”, “Quite a bit” or “Very much”
- After completing page 7, proceed directly to question #9.

For question 8 below:

Baseline: Participants who have not had diagnosed or suspected COVID-19 illness, record symptoms the participant has experienced since February 1, 2020.

8. If you have not had diagnosed or suspected COVID-19 illness, have you had any of the following symptoms since our last call?

Note: For baseline, last call = February 1, 2020.

For participants who do not report diagnosed or suspected COVID-19:

To be answered only if participant answered question #1 as “No”.

- For each symptom (row), record response to A. If A is “yes”, record response to items B and C. If A is “No”, proceed directly to next symptom (row).
- B: response options 1 to 5 correspond to: 1 (“Not at all”), 2 (“A little bit”), 3 (“Somewhat”), 4 (“Quite a bit”), and 5 (“Very much”).
- C: Calculated in days as the difference between calendar days symptom started and symptom stopped.
- Item: Overall, when these symptoms were at their worst, when you had these symptoms, how bad or bothersome were they?
 - Record response as “Mild”, “Moderate”, “Severe”, or “Very Severe”
- Item: Overall, when these symptoms were at their worst, did they interfere with your daily activities?
 - Record response as “Not at all”, “A little bit”, “Somewhat”, “Quite a bit” or “Very much”
- After completing page 8, proceed to question #9.

The purpose of Question 9 is to determine whether certain medications have an effect on the duration or severity of COVID-19 symptoms and outcomes.

For Question 9, if the participant had more than one medication in a given class, answer the sub-questions for the most frequently used medication in the class. In the “name of the medications” field, enter the most frequently used medication first and then list any others taken.

9. Baseline: If you had any of the symptoms we talked about, did you take any medicines?

- Yes *Proceed to the table of medicines.*
For each group of medicines (each row), record response to:
 - Did you take it?
 - Was it prescribed by health care professional?
 - What was the date when you started to take it?
 - What was the total number of days that you took it?
 - *Difference in calendar days between date started and date stopped.*
 - What was the specific name of the medication(s)?
 - *This would be the name on the bottle, trade name, etc.*

- No *Proceed to question #10.*

For Question 9 “Other Medications”, include major prescription medications such as blood pressure medication that the participant took while having symptoms.

10. Baseline: Has anyone in your household (or the place you are residing) been tested for COVID-19?

- Yes *Proceed to the boxed items.*
 - a. When was the first test conducted? _____
 - b. What was the result of the first test?
 - Positive
 - Did you change your behavior at home? (*As a result of the test performed on the household member/s*)
 - Yes → *Record whether or not the participant implemented each of the 3 behaviors listed. Then continue to question #11.*
 - No → *Proceed to question #11.*
 - Negative → *Proceed to question #11.*
 - Unsure → *Proceed to question #11.*
 - c. Was there a second test?
Repeat questions a and b for up to four COVID-19 tests

- No *Proceed to question #11.*

- Unsure *Proceed to question #11.*

The purpose of Question 11 is to determine if the participant lowered their risk of exposure to the COVID-19 virus. Answer “yes” only if the participant actively made a change in their risk exposure. For example, if a participant previously went to restaurants/bars, but stopped going to

restaurants/bars (whether or not this change was due to local requirements/laws), the answer would be “Yes” because the participant changed their behavior/risk. If, however, the participant never went to restaurants/bars and still does not, then the answer is “No” because they did not change their behavior.

11. Baseline: What actions have you taken to reduce your risk of exposure to COVID-19?

Record a response for each of the following items a. to l.

- a. Washing hands and/or using sanitizer frequently
- b. Staying at least 6 feet away from others
- c. Avoiding large gatherings
- d. Not going out to restaurants or bars
- e. Cancelled planned travel
- f. Wearing a face mask
- g. Not shaking hands or touching people
- h. Staying home when I am sick
- i. Not going to work
- j. Wiping down surfaces with disinfectant
- k. Following government guidelines or rules to stay at home and limiting contacts with other people
- l. Placed under full quarantine by local authorities

Continue to question #12.

12. Do you currently use any tobacco products?

Record response for each item a. to e. Note that item a has a follow-up question if answered “yes”.

Cigarettes

Yes → Cigarettes per day: _____

No

.....
 Pipes

Yes

No

.....
 Cigars

Yes

No

.....
 E-
cigarettes

Yes

No

.....
 Other

Yes → Specify Other: _____

No

13. Baseline: Did you receive vaccination for influenza (“the flu shot”) between September 2019 and March 2020?

Yes

.....
 No

14. Baseline: Have you had a test for influenza since January 2020?

- Yes *Proceed to boxed items a. and b.*
 - a. What was the result of the flu test?
 - b. Was this test performed at the same time as a COVID-19 test?*MESA-COVID interview completed.*

- No *MESA-COVID interview completed.*

Closing Statement:

Thank you for your time and your contribution to the MESA study. We look forward to speaking to you again in the future.