Phase VII

Morbidity & Mortality Surveillance

DRAFT Data Management Manual

REDCap

**THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
OF THE NATIONAL INSTITUTES OF HEALTH**

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1. Introduction

This manual is to assist SHS morbidity and mortality (M&M) event abstractors in three Field Centers (FC, the MedStar Health Research Institute, Phoenix, Arizona, the Missouri Breaks Industry Research Inc, Eagle Butte, South Dakota, and the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma) in understanding and using the REDCap data entry forms developed for M&M surveillance events. Please refer to the SHS Phase VII Morbidity and Mortality Surveillance Manual of Operations document for procedures on abstracting and reporting morbidity and mortality events.

In addition, this manual is to help staff at the SHS Coordinating Center (CC) or M&M reviewers enter M&M decisions forms and supplemental event forms in REDCap.

2. The University of Oklahoma Health Sciences Center REDCap Application

The University of Oklahoma Health Sciences Center (OUHSC) REDCap (**R**esearch **E**lectronic **D**ata **C**apture) application can be accessed by pointing a web browser to the following address:

<p style="text-align:center">https://redcap.ouhsc.edu/</p>

In order to access the application, OUHSC staff may use their OUHSC user name and password. For users that do not have an OUHSC account, a user account must be created by the SHS REDCap admin, Pravina Kota, at pravina-kota@ouhsc.edu. To request accounts, the Site PI should send the names and email addresses of the requested users to the Data Coordinating Center (DCC) data manager Kimberly Malloy, at kimberly-malloy@ouhsc.edu.

User accounts on the OUHSC REDCap application should be used for the following tasks:
1. Entry or edits of abstractor forms and checklists used by the M&M FC event abstractors.
2. Entry or edits of M&M decision forms and supplemental event forms used by the DCC or M&M reviewers.
3. Tracking M&M event progress.

To connect to the OUHSC REDCap application, point your web browser to the server address provided above, then enter your OUHSC user name and password into the login screen:

You will then see the main REDCap screen, where you should click on the "My Projects" tab:
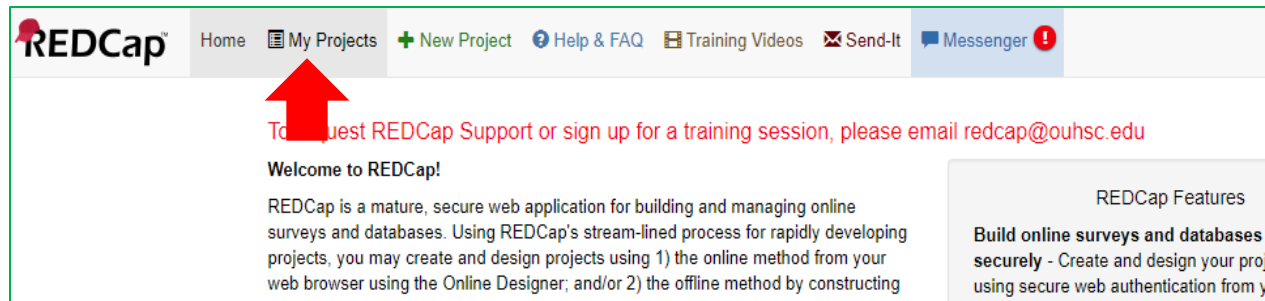
2.1. Summary of REDCap Project

Select SHS Morbidity & Mortality Surveillance 2022 – 2026 project. This REDCap project can be separated into 4 categories for data entry:
1. Morbidity event abstractions, checklist, and reviewer assignment
2. Mortality event abstractions, checklist, and reviewer assignments
3. Morbidity decision form including stroke decisions and supplemental forms
4. Mortality decisions forms including stroke decisions and adjudications.

2.1.1. Morbidity event abstraction, checklist, and reviewer assignment

Data collected on the following forms should be entered by the FC event abstractor for any identified morbidity event(s):
1. Abstractor Form & Checklist Morbidity
2. Reviewer Information and Assignment

2.1.2. Mortality event abstraction, checklists, and reviewer assignment

Data collected on the following forms should be entered by the FC event abstractor for any identified mortality event:
1. Abstractor Form/Checklist Mortality
2. Reviewer Information and Assignment

The following forms should be entered if they apply:
1. Mortality Survey Packet Checklist
2. Mortality informant interview

2.1.3. Morbidity decision form including stroke decisions and supplement forms

Data collected on the following forms should be entered by staff at the CC or Morbidity reviewer for identified morbidity event(s):
1. Morbidity decision form

The following form should be entered if a stroke is identified:
1. Stroke Review Form

The following supplemental forms should be entered if they apply:
1. Cardiovascular Test Procedures Supplement
2. Heart Failure Procedures Supplement
3. PVD Procedures Supplement

2.1.4. Mortality decision form including stroke decisions and adjudications

Data collected on the following forms should be entered by staff at the CC or Mortality reviewer for identified mortality event:
1. Mortality decision form

The following form should be entered if a stroke is identified:
1. Stroke Review Form

The following forms should be entered by staff at the CC if the mortality decisions were adjudicated:
1. Mortality decision form
2. Adjudications – Special cases – CC only

3. Data Entry Instruction for Event Abstractors

3.1. Before Starting

Before entering data, the event abstractor needs to identify the eligible population, identify sources for events, collect medical records, compile and scan packets with the event information, and prepare the packets to be uploaded on REDCap. The Phase VII Morbidity and Mortality Surveillance Manual of Operations provides all the details for these processes.

3.2. Getting Started

To enter data for a participant, select SHS Morbidity & Mortality Surveillance 2022-2026 on the REDCap front page:
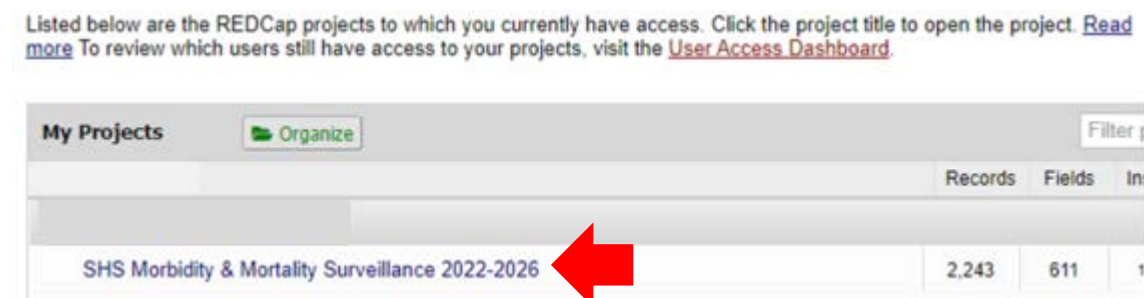
3.3. Confirm Participant Information

Eligible participant SHS IDs and names have already been populated in this REDCap database. To find a participant, select Add / Edit Records link under the Data Collection menu on the left side of the screen.
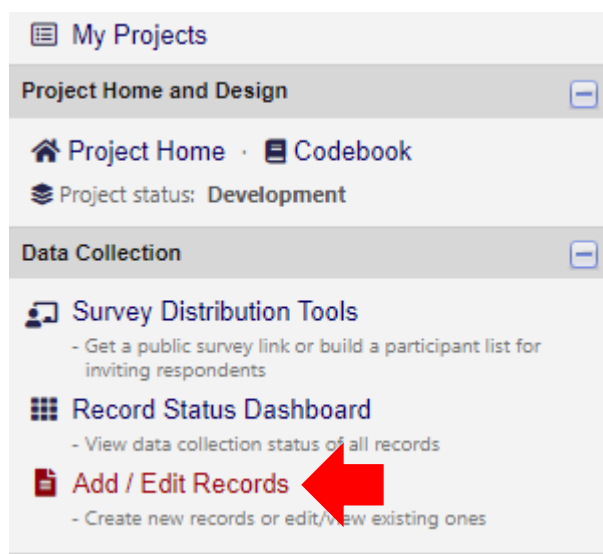
In the Search query field, the SHS ID number or name can be entered. A drop down menu will appear, and the correct record should be selected. Note: ID numbers have been redacted from this manual.
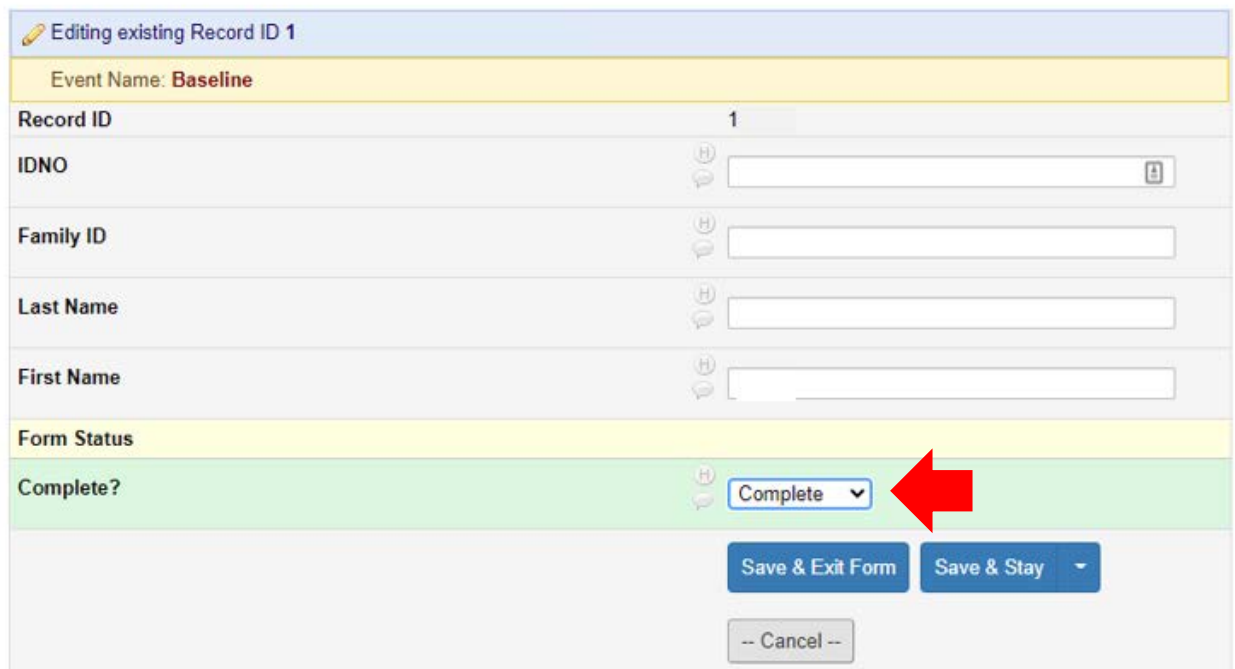

The Participant Information page will appear. The abstractor will need to confirm the SHS ID Number, Last Name, and First Name. If the name has changed or spelling of either name needs to be fixed, the abstractor can make changes here. If the participant has a SHS family ID number, this ID number will also appear on this page. Once all fields have been confirmed, the abstractor will need to change the form status to Complete. The abstractor can then click Save & Exit Form.
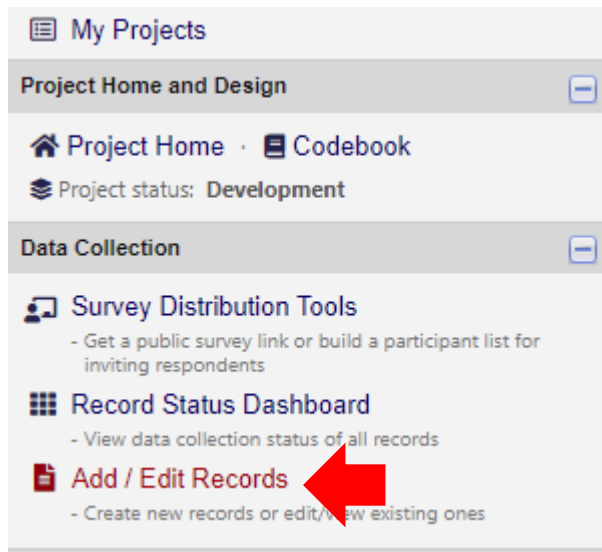
REDcap will be directed to the Record Home Page for the selected participant. If the Participant information form has been completed, the circle next to Participant information will be green.   The Participant Information form will only need to be entered once. If there are any changes in the name, the form can be updated at any time.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5	Round6(Nov23-Oct24) Round6	Round7(Nov24-Oct25) Round7	Round8(Nov25-Oct26) Round8
1.Participant Information	●				

3.3.1. Adding Participant

If there is a participant who has an event and cannot be found in the current list of participants, the abstractor or CC staff can add a participant. Select Add / Edit Records link under the Data Collection menu on the left site of the screen.

My Projects

Project Home and Design ⊟

⌂ Project Home · ▤ Codebook
≋ Project status: Development

Data Collection ⊟

🗐 Survey Distribution Tools
    - Get a public survey link or build a participant list for inviting respondents
⊞ Record Status Dashboard
    - View data collection status of all records
📄 Add / Edit Records
    - Create new records or edit/view existing ones

Select the green + Add new record button.

Choose an existing Record ID	-- select record -- ⌄
	+ Add new record

This will create a new record in the database. The participant information form will be blank and need to be filled out first. Click the radio button next to Participant Information.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23)
1.Participant Information	⊙	
2.Abstractor Form & Checklist Morbidity		⊙
3.Abstractor Form/Checklist Mortality		⊙
4.Reviewer Assignments & CC Tracking		⊙

The participant's SHS ID number and name will need to be filled out. Include the SHS Family ID if applicable. Select Complete in the form status when the information has been entered. The abstractor can then click Save & Exit Form.

⊕ Adding new Record ID		
Event Name: **Baseline**		
Record ID		
IDNO	Ⓗ 💬	[ ]
Family ID	Ⓗ 💬	[ ]
Last Name	Ⓗ 💬	[ ]
First Name	Ⓗ 💬	[ ]
Form Status		
Complete?	Ⓗ 💬	Complete ▾
		Save & Exit Form Save & Stay ▾
		-- Cancel --

REDcap will be directed to the Record Home Page for the selected participant. If the Participant information form has been completed, the circle next to Participant information will be green.   The Participant Information form will only need to be entered once. If there are any changes in the name, the form can be updated at any time.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5	Round6(Nov23-Oct24) Round6	Round7(Nov24-Oct25) Round7	Round8(Nov25-Oct26) Round8
1.Participant Information	🟢				

3.4. Morbidity event abstraction, checklist, and reviewer assignment

3.4.1.   Medical Records Abstract Checklist for Non-Fatal CVD Events or Procedures
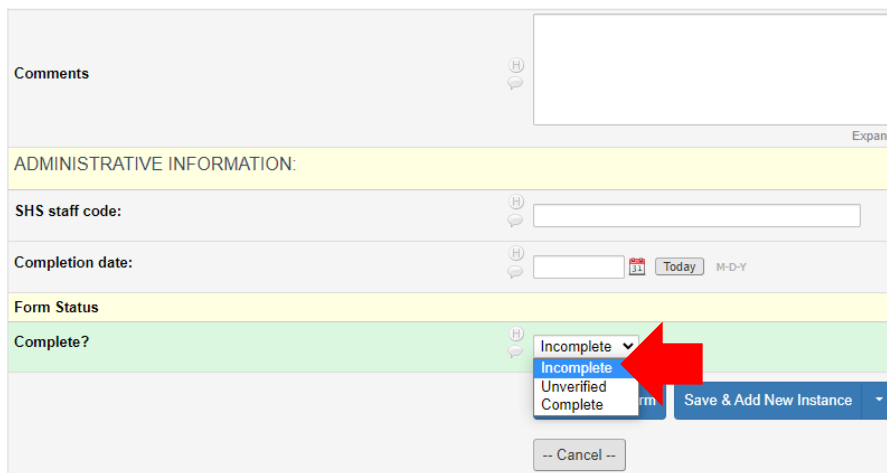
For an identified morbidity event, select 2. Abstractor Form & Checklist Morbidity form for the appropriate surveillance round. For example, if a morbidity event was identified in Round 5, select the circle under Round 5 (Oct22 – Oct23).

Fill in the appropriate information for the medical records abstract checklist for each morbidity event. Please refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for more details on how to complete this form. One form should be complete for each event. Note: The SHS ID Number field will be populated for the abstractor. It was redacted for this manual.

After the form has been completed, there is an additional comment field if the astractors ahs any additional notes that need to conveyed to the reviewer that wasn't captured on the form. The abstractor should enter their SHS Staff code and the date they completed the form. If the abstractor is still waiting on information to complete the form, they can either leave the form status as Incomplete or Unverified. Once all of the information is complete, the abstractor needs to change the form status to Complete.

If there are additional morbidity events, an abstractor form should be completed for each event. Again, refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for details on how to index multiple morbity events. In REDCap, after completing the first abstractor form, select the Save & Add New Instance button to add an additional form for the second event. This will save the current form and create an additional form for the next morbidity event.

If this is the last event for participant, click the Save & Exit From button.

Below is an example of the top of the page of the REDCap database would look like for a second morbidity abstractor checklist form. A current instance is added to the top to indicate this is the second form added under the morbidity abstractor checklist.

Once you save and exit out of the morbidity abstractor checklist and return to the participant's Record Home Page, the circle next to 2. Abstractor Form & Checklist Morbidity will be Green if the form has been completed. If there are multiple abstractor forms, you will see multiple circles. Clicking on the circle will provide a pop up window that will allow you to see the number of forms that were completed. By clicking on any of the green circles in this pop-up menu, REDCap will redirect to that specific form.

By clicking on the plus sign next to the Green circle, an additional form can be created, if needed.

The abstractor and can also see all of the repeated instruments for a participant at the bottom participant's Record Home Page.

Repeating Instruments

2.Abstractor Form & Checklist Morbidity Round5(Oct22-Oct23) (2)	▽
1	🟢
2	🟢
+ Add new	

The abstractor morbidity form(s) need to be converted to a PDF in order to include the information in the morbidity packet created for the morbidity reviewer. To create the PDF(s), open the form. At the very top, there is a drop down menu next to Actions. Click the Drop down menu and select This data entry form with saved data. Save the form and include the PDF in the compilation of the morbidity packet (more details are provided in the Phase VII Morbidity and Mortality Surveillance Manual of Operations). Note: This will need to be done for each instance of this abstractor form.

SHS Morbidity & Mortality Surveillance 2022-2026

Actions: 📄 Download PDF of instrument(s) ▽   ⊞ VIDEO: Basic

📄 This data entry form (blank)

📄 This data entry form with saved data

📄 This data entry form with saved data (compact)

📄 All forms/surveys (blank)

📄 All forms/surveys with saved data

📄 All forms/surveys with saved data (compact)

3.4.2. Morbidity Reviewer Assignment

To assign the morbidity reviewer, the Reviewer Information & Assignment form needs to be completed. To access the form, navigate to the participant's Record Home Page and select the circle next to Reviewer Information & Assignment.

Select Morbidity as the Type of Review. Upload the morbidity packet that was created by clicking the Upload file link.

Click the Choose File button and navigate to the morbidity packet that was saved on your computer

Once the correct file is select from your computer, click the Upload file button.

The morbidity packet will now be uploaded on REDCap. NOTE: the morbidity packet should be name according to the naming conventions described in the Phase VII Morbidity & Mortality Surveillance Manual of Operations. SHS ID numbers are not used in this document and were replaced by the word SHSID in the example below.

If you need to upload a new version, please select the green Upload new version link under the uploaded file. If for some reason, this file needs to be removed, select the Remove file link under the uploaded file. **DO NOT** select the Send-It button. This triggers a different process in sending the file through email that SHS will NOT be using. For more information about sending the Reviewer an email and for Reviewers accessing the PDF, please see instructions below.

For tracking purposes at the Coordinating Center, the FC abstractor also needs to complete the remaining fields on the Reviewer Assignment page.

Under file number, type the file name that is used for the packet. Details on the file naming convention are provided in the Phase VII Morbidity & Mortality Surveillance Manual of Operations. SHS ID numbers are not used in this document and were replaced by the word SHSID in the example below.

If the morbidity packet does not include a stroke, select No under Stroke Review. A list of morbidity reviewers will be populated. Select a Morbidity Reviewer that was chosen to review this event. Select the abstractor who assigned the review.
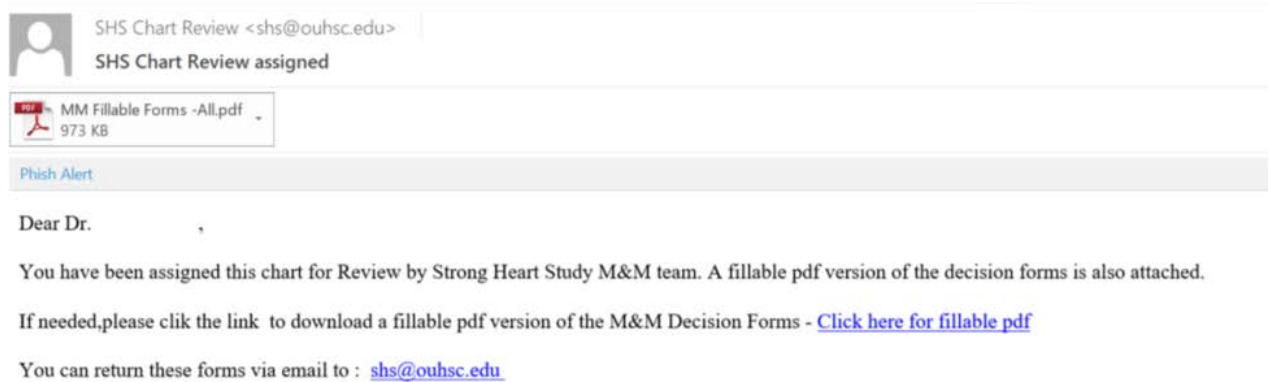
If the morbidity event includes a stroke, use the correct naming convention for the file number by adding STK to the name (see Phase VII Morbidity & Mortality Surveillance Manual of Operations for more information). Select Yes for Stroke Review and select a stroke reviewer.

There is a comment box if additional information needs to be provided. Select Unverified in the form status. The CC will need to come back and add dates when the decision forms are received and the CC will complete this form.

When the abstractor clicks Save & Exit button, an email to the selected Reviewer will automatically be generated to alert the reviewer that a new Morbidity chart has been assigned to them.

SHS Chart Review <shs@ouhsc.edu>
SHS Chart Review assigned

MM Fillable Forms -All.pdf
973 KB

Phish Alert

Dear Dr.   ,

You have been assigned this chart for Review by Strong Heart Study M&M team. A fillable pdf version of the decision forms is also attached.

If needed,please clik the link to download a fillable pdf version of the M&M Decision Forms - Click here for fillable pdf

You can return these forms via email to : shs@ouhsc.edu

Further information for the reviewers is provided below.

To see how many charts are assigned to each morbidity reviewer, select the Morbidity Reviewer Assignment Report for the specific reviewer under the Reports menu on the left site of the browser window.

The following information will appear for the selected reviewer.

Fields in this report include Record ID with SHS ID, Event (SHS reviewer round), Repeat instrument information, date reviewer was assigned, the type of review (Morbidity), assigned reviewer, the name of the file (following M&M naming conventions), the abstractor who assigned the review, and the reviewer form status.

If you would like to re-order this report, you can select the up or down arrow next to any of the provided fields.

If the date CC received the decision form and the Reviewer Assignment form status has been changed to Complete, the chart will no longer appear in the Morbidity Reviewer Assignment report.

3.5. Mortality event abstraction, checklist, and reviewer assignment

3.5.1. Checklist for Medical Records Review Mortality Surveillance – CVD and Non-CVD

For an identified mortality event, select 3. Abstractor Form/Checklist Mortality form for the appropriate surveillance round. For example, if a mortality event was identified in Round 5, select the circle under Round 5 (Oct 22 – Oct 23).

Fill in the appropriate information for the medical records abstract checklist for the mortality event. Please refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for more details on how to complete this form. Note: The SHS ID Number field will be populated for the abstractor. It was redacted for this manual.
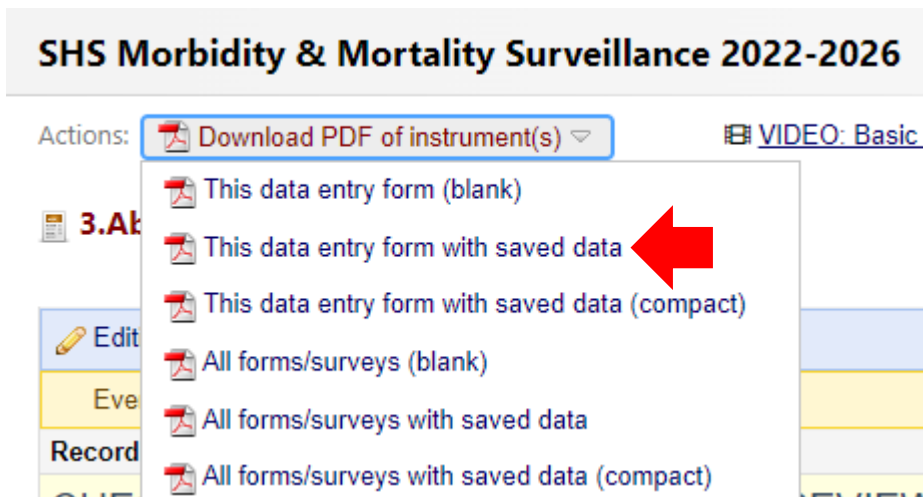
After the form has been completed, the abstractor should enter their SHS staff code and the date they completed the form. There is an additional comment field if the abstractor has additional notes that need to be conveyed to the reviewers that wasn't on the form. If the abstractor is still waiting on information to complete the form, they can either leave the form status as Incomplete of Unverified. Once all of the information is complete, the abstractor needs to change the form status to Complete. Save the form.

The abstractor mortality checklist form needs to be converted to a PDF in order to include the information in the mortality packet created for the mortality reviewers. To create the PDF, open the form. At the very top, there is a drop down menu next to Actions. Click the Drop down menu and select This data entry form with saved data. Save the form and include the PDF in the compilation of the morbidity packet (more details are provided in the Phase VII Morbidity and Mortality Surveillance Manual of Operations).

3.5.2. Mortality Survey Packet Checklist

If the mortality event occurred in the hospital, select 7. Mortality survey packet checklist for the appropriate surveillance round.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	●	
2.Abstractor Form & Checklist Morbidity		○
3.Abstractor Form/Checklist Mortality		● +
4.Reviewer Assignments & CC Tracking		○
7.Mortality Survey Packet Checklist		○ ←
8.Mortality Informant Interview		○

Fill in the appropriate information for the mortality checklist for a death in the hospital. Please refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for more details on how to complete this form.

🖉 Editing existing Record ID 10	
Event Name: **Round5(Oct22-Oct23)**	
Record ID	10

MORTALITY SURVEY PACKET CHECKLIST

SHS ID Number :

1. Death Certificate	⊕ ○ Yes ○ No	reset
2. Autopsy performed	⊕ ○ Yes ○ No	reset
3. Autopsy report	⊕ ○ Yes ○ No	reset
4. Medical Records Checklist	⊕ ○ Yes ○ No	reset

After the form has been completed, the abstractor should enter their SHS staff code and the date they completed the form. There is an additional comment field if the abstractor has additional notes that need to be conveyed to the reviewers that wasn't on the form. If the abstractor is still waiting on information to complete the form, they can either leave the form status as Incomplete of Unverified. Once all of the information is complete, the abstractor needs to change the form status to Complete. Save the form.

The mortality checklist form needs to be converted to a PDF in order to include the information in the mortality packet created for the mortality reviewers. To create the PDF, open the form. At the very top, there is a drop down menu next to Actions. Click the Drop down menu and select This data entry form with saved data. Save the form and include the PDF in the compilation of the morbidity packet (more details are provided in the Phase VII Morbidity and Mortality Surveillance Manual of Operations and screen shots above).

3.5.3. Mortality Informant Interview

If the mortality event did not occur in the hospital (i.e. death occurred at home), select 8. Mortality Informant Interview for the appropriate surveillance round.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	●	
2.Abstractor Form & Checklist Morbidity		○
3.Abstractor Form/Checklist Mortality		● +
4.Reviewer Assignments & CC Tracking		○
7.Mortality Survey Packet Checklist		○
8.Mortality Informant Interview		○

Fill in the appropriate information for the mortality survey informant interview. Please refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for more details on how to complete this form.

After the form has been completed, the abstractor should enter their SHS staff code and the date they completed the form. There is an additional comment field if the abstractor has additional notes that need to be conveyed to the reviewers that wasn't on the form. If the abstractor is still waiting on information to complete the form, they can either leave the form status as Incomplete of Unverified. Once all of the information is complete, the abstractor needs to change the form status to Complete. Save the form.

The mortality informant interview form needs to be converted to a PDF in order to include the information in the mortality packet created for the mortality reviewers. To create the PDF, open the form. At the very top, there is a drop down menu next to Actions. Click the Drop down menu and select This data entry form with saved data. Save the form and include the PDF in the compilation of the morbidity packet (more details are provided in the Phase VII Morbidity and Mortality Surveillance Manual of Operations and screen shots above).

3.5.4. Mortality Reviewer Assignment

To assign the mortality reviewer, the Reviewer Information & Assignment form needs to be completed. To access the form, navigate to the participant's Record Home Page and select the circle next to Reviewer Information & Assignment.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	🟢	
2.Abstractor Form & Checklist Morbidity		⚪
3.Abstractor Form/Checklist Mortality		🟢 +
4.Reviewer Assignments & CC Tracking		⚪

Select Mortality as the Type of Review. Upload the mortality packet that was created by clicking the Upload file link.

Editing existing Record ID **10**	
Event Name: **Round5(Oct22-Oct23)**	
Record ID	10
Reviewer Assignment	
SHS ID Number :	
Type of Review:	⚪ Morbidity 🔘 Mortality ...dication reset
Attach review PDF packet	🔼 Upload file
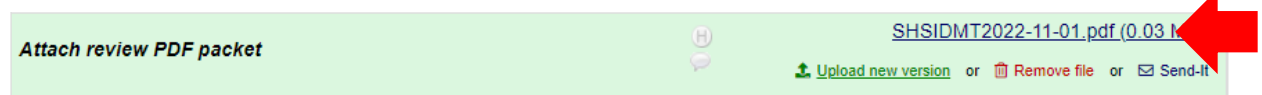
Click the Choose File button and navigate to the morbidity packet that was saved on your computer

Once the correct file is select from your computer, click the Upload file button.

The mortality packet will now be uploaded on REDCap.

If you need to upload a new version, please select the green Upload new version link under the uploaded file. If for some reason, this file needs to be removed, select the Remove file link under the uploaded file. **DO NOT** select the Send-It button. This triggers a different process in sending the file through email that SHS will NOT be using. For more information about sending the Reviewer an email and for Reviewers accessing the PDF, please see instructions below.

For tracking purposes at the Coordinating Center, the FC abstractor also needs to complete the remaining fields on the Reviewer Assignment page.

Under file number, type the file name that is used for the packet. Details on the file naming convention are provided in the Phase VII Morbidity & Mortality Surveillance Manual of Operations. SHS ID numbers are not used in this document and were replaced by the word SHSID in the example below

For all mortality cases, select No for stroke review. More information about stoke deaths are provided below. Select one mortality review from each list. Select the abstractor who assigned the review.

Type of Review:	○ Morbidity ● Mortality ○ Adjudication reset
Attach review PDF packet	SHSIDMT2022-11-01.pdf (0.03 MB) ⬆ Upload new version or 🗑 Remove file or ✉ Send-It
File Number	SHSIDMT2022-11-01
Date reviewer assigned:	08-09-2022 📅 Today M-D-Y
Stroke review:	● No ○ Yes reset
Assign mortality reviewer #1	○ Dr. Adrian Ruiz ● Dr. Lyle Best ○ Dr. Richard Devereux ○ Dr. Stacy Jolley ○ Dr. Sunny Jhamnani ○ Dr. Gernot Pichler ○ Dr. Dorothy Rhoades reset
Assign mortality reviewer #2	○ Dr. Adrian Ruiz ○ Dr. Lyle Best ● Dr. Richard Devereux ○ Dr. Stacy Jolley ○ Dr. Sunny Jhamnani ○ Dr. Gernot Pichler ○ Dr. Dorothy Rhoades reset
Abstractor who assigned reviewer	● Cheryl Tarlton ○ Wendy Lawerence ○ Sharon Taho reset

If one or both mortality reviewers determine that the cause of death is stroke related, the reviewers will notify the CC. The CC will then assign the review to one of the stroke reviewers.

There is a comment box if additional information needs to be provided. Select Unverified in the form status. The CC will need to come back and add dates when the decision forms are received and they will complete this form.

When the abstractor clicks Save & Exit button, an email to each of the selected Mortality Reviewers will automatically be generated to alert the reviewer that a new chart has been assigned to them.

Further information for the reviewers is provided below.

To see how many charts are assigned to each mortality reviewer, select the Mortality Reviewer Assignment Report for the specify reviewer under the Reports menu on the left site of the browser window.

The following information will appear for the selected reviewer.

Fields in this report include Record ID with SHS ID, Event (SHS reviewer round), repeat instrument information, date reviewer was assigned, the type of review (Mortality), first mortality reviewer assigned, second mortality reviewer assigned, the name of the file (following M&M naming conventions), the abstractor who assigned the review, and the reviewer form status.

The specific reviewer can appear in either the first assigned mortality reviewer or the second assigned mortality reviewer column.

If you would like to re-order this report, you can select the up or down arrow next to any of the provided fields.

If the date CC received the decision form and the Reviewer Assignment form status has been changed to Complete, the chart will no longer appear in the Mortality Reviewer Assignment reports.

4. Accessing for Morbidity and Mortality Charts on REDCap

4.1. Getting Started

A FC abstractor will assign a chart for reviewer in REDCap. When this assignment is completed, an automatic email will be generated and sent to the respective reviewer.

Below is an example of what the email will look like:
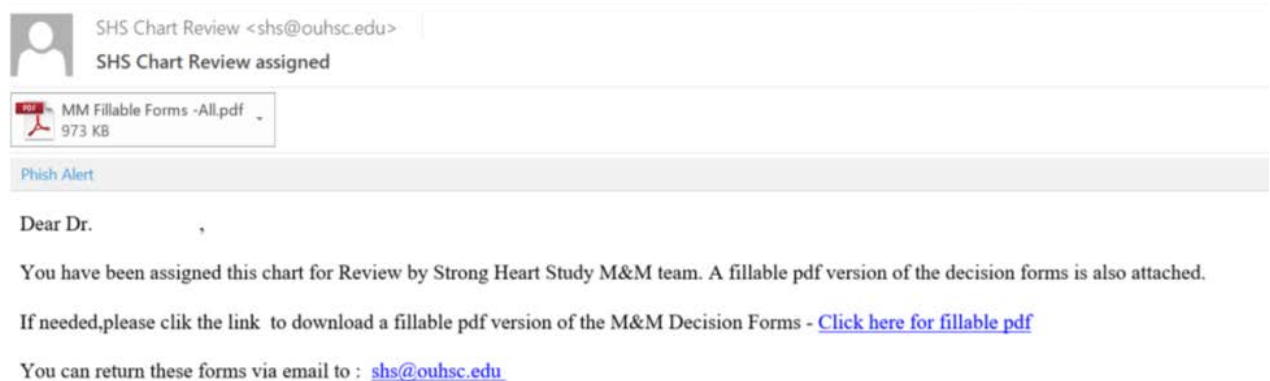
To access the charts for review, the reviewer will need to login in the REDCap (https://redcap.ouhsc.edu) using their provided user name and user created password.

Once the reviewer is logged into REDCap, the reviewer will need to select the SHS Morbidity & Mortality Surveillance 2022-2026 project on the REDCap front page.

4.2. Accessing M&M Chart

The reviewer will then select their respective reviewer report under Reports on the left side of the screen.
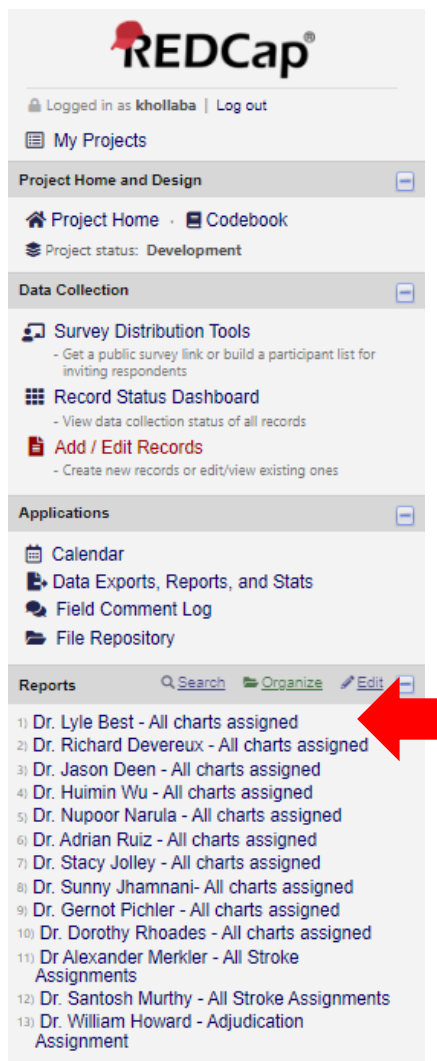
The reviewer will select their own report.

Once a report is selected, REDCap will navigate to the respective report. To keep this section short, the instructions and screenshots below are shown for a mortality reviewer. The process is the same for each report and for each reviewer.

Fields in this report include Record ID with SHS ID, Event (SHS reviewer round), repeat instrument information, date reviewer was assigned, the type of review (Mortality), first mortality reviewer assigned, second mortality reviewer assigned, the name of the file (following M&M naming conventions), the abstractor who assigned the review, and the reviewer form status. If the review is morbidity reviewer, then the name of the morbidity reviewer will appear.

Record ID record_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Date reviewer assigned: ra_date	Type of Review: ra_1	Assign mortality reviewer #1 mt_review1	Assign mortality reviewer #2 mt_review2	File Number fno	Abstractor who assigned reviewer mb_abstractor	Complete? reviewer_assignments_cc_tracking_complete
2	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	1		Mortality (2)	Dr. Adrian Ruiz (1)	Dr. Lyle Best (2)			Incomplete (0)
1	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	1	08-02-2022	Mortality (2)	Dr. Adrian Ruiz (1)	Dr. Lyle Best (2)			Unverified (1)
30	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	1	08-11-2022	Mortality (2)	Dr. Sunny Jhamnani (5)	Dr. Adrian Ruiz (1)			Unverified (1)

The report will only show charts that remain to be reviewed.

If you would like to re-order this report, you can select the up or down arrow next to any of the provided fields.

To navigate to the assigned chart for an individual participant, click the record ID number that is blue and underlined.

Record ID record_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Date reviewer assigned: ra_date
5	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	4	
1906	d5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	1	08-09-2022
74	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	1	08-11-2022
5	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	3	09-05-2022
5	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	6	09-05-2022
2	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	2	09-06-2022
2	Round5(Oct22-Oct23)	4.Reviewer Assignments & CC Tracking	3	09-09-2022

By selecting this link, you will be directed to the participants Reviewer Assignment & CC Tracking page. The reviewer will be able to select the PDF packet and download the PDF packet onto the reviewer's computer by selecting the link in Attach review PDF packet field. By selecting this link, a Save As window will appear on the computer and the reviewer can save the downloaded PDF. A TEST file is shown below, but the reviewer will see the a PDF with the correct naming conventions.

If the reviewer also needs to download the M&M decision forms and supplemental forms, they can select the MM Fillable Forms-all.pdf link provided.

4.Reviewer Assignments & CC Tracking

Current instance: ● 1 – M&M TEST ▽

🖉 Editing existing Record ID 1906

Event Name: Round5(Oct22-Oct23)

Record ID	1906

Reviewer Assignment

SHS ID Number :

Type of Review: ⊙ Morbidity   ○ Mortality   ○ Adjudication   reset

Attach review PDF packet   M&M TEST FILE.pdf (0.03 M
    ⬆ Upload new version   or   🗑 Remove file   or   ✉ Send-It

Download fillable pdf forms

Attachment: 📄 MM Fillable Forms -All.pdf (0.95 MB)

Once the PDF is downloaded, the reviewer can proceed with filling out the decision form(s).

5. Data Entry Instruction for Morbidity and Mortality Decision Forms

5.1. Who can enter decision data

The M&M reviewer can enter their decisions forms and any supplemental forms directly into REDCap or they can continue filling out the Morbidity and Mortality decisions forms and any supplemental forms using a provided fillable PDF.

The fillable forms will be available as an attachment in the reviewer assignment email each reviewer will receive. The packet of forms attached to the reviewer email will include ALL decisions forms, both the morbidity and mortality decision forms and all of the supplemental forms.

The forms are also available for download on the Strong Heart Study website (https://strongheartstudy.org/Research/Research-Overview/M-M-Surveillance). The packet of forms available on the SHS website also include ALL decisions forms, both the morbidity and mortality decision forms and all of the supplemental forms.

If the M&M reviewer chooses to fill out the fillable decisions forms and have the CC enter the information into REDCap, the decisions forms will need to be emailed to shs@ouhsc.edu.

Below are instructions on how to directly enter decision forms into the REDCap system if the reviewer choses to do enter the information themselves.

5.2. Getting Started

To enter data for a participant, select SHS Morbidity & Mortality Surveillance 2022-2026 on the REDCap front page:

The reviewer has to options to navigate to the participant's record page to enter the decision form. (1) They can follow the process outlined above, using the Morbidity and Mortality Reports and looking at their individual report to find the participant ID. Or (2) To find a participant, select Add / Edit Records link under the Data Collection menu on the left side of the screen.
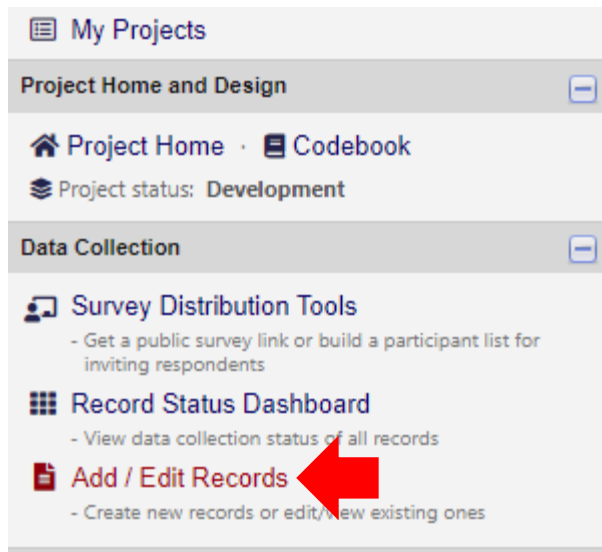
In the Search query field, the SHS ID number can be entered. A drop down menu will appear, and the correct record should be selected. Note: ID numbers have been redacted from this manual.
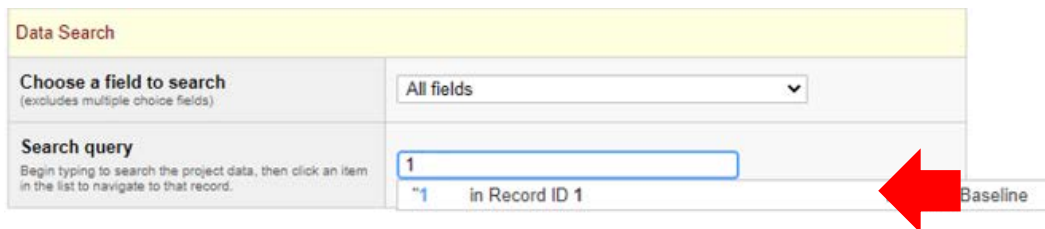
The Reviewer Assignment & CC Tracking page will appear. Select the Record ID link under Data Collection on the left side of the screen. You will be directed to the Record Home Page for the participant.
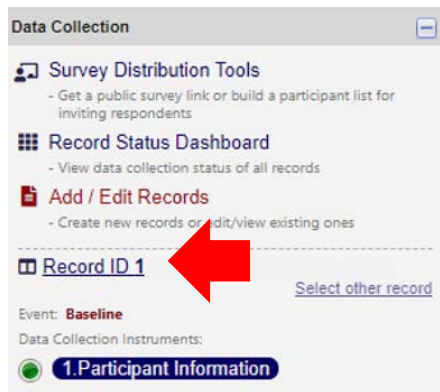
5.3. Morbidity decision form including stroke decisions and supplemental forms

To enter data in the morbidity decision form, select the button next to 5. Morbidity Decision Form.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	●	
2.Abstractor Form & Checklist Morbidity		●)) +
3.Abstractor Form/Checklist Mortality		○
4.Reviewer Assignments & CC Tracking		● +
5.Morbidity Decision Form		○ ⬅
5a.Cardiovascular Test Procedures Supplement		○
5b.Heart Failure Procedures Supplement		○
5c.PVD Procedures Supplement		○

Fill in the appropriate information for the Morbidity Decision Form.

🖉 Editing existing Record ID 9	
Event Name: **Round5(Oct22-Oct23)**	
Record ID	9
SHS ID Number :	
Date of this event:	Ⓗ [____] 📅 [Today] M-D-Y
A. DIAGNOSIS (enter appropriate code number):	
01. Definite non-fatal myocardial infarction	Ⓗ [_____]
1b. Probable non-fatal myocardial infarction	Ⓗ [_____]
02. Possible non-fatal myocardial infarction	Ⓗ [_____]
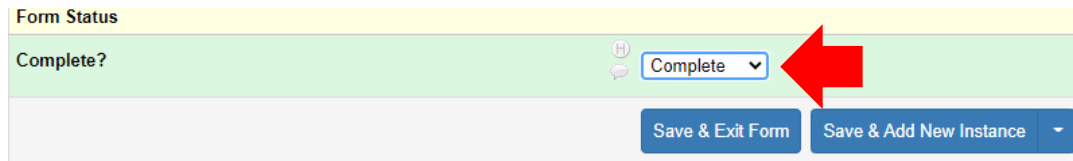
When all data is entered, select Compete under Form Status. Save & Exit form.
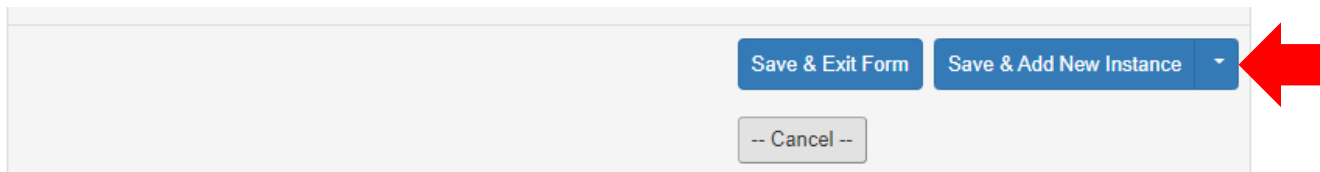
When you Save & Exit the morbidity decision form, you will be redirected to the Record Home Page.
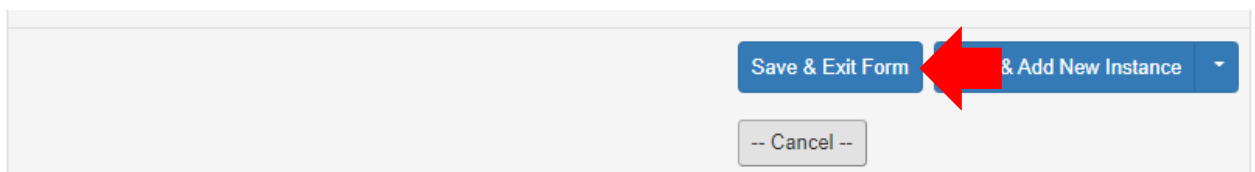
If there are additional morbidity events, an morbidity decision form should be completed for each event. Refer to the Phase VII Morbidity and Mortality Surveillance Manual of Operations for details on how to index multiple morbity events. In REDCap, after completing the first morbidity decision form, select the down arrow next to Save & Add New Instance for the second event. This will save the current form and create an additional form for the next morbidity event.

If this is the last event for participant, click the Save & Exit Form button.

Below is an example of the top of the page of the REDCap database would look like for a second morbidity decision form. A current instance is added to the top to indicate this is the second form added under the morbidity abstractor checklist.

Once you save and exit out of the morbidity decision form and return to the participant's Record Home Page, the circle next to 5. Morbidity Decision Form will be Green if the form has been completed. If there are multiple Morbidity Decision forms, you will see multiple circles. Clicking on the circle will provide a pop up window that will allow you to see the number of forms that were completed. By clicking on any of the green circles in this pop-up menu, REDCap will redirect to that specific form.

You can also see how all the repeated Morbidity Decision Forms at the bottom of the participant's record home page, under the Repeated Instruments.

If any supplemental forms were included in the decision packet, they need to be entered. Select the appropriate supplement form from the list by clicking the circle next to the form name.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	●	
2.Abstractor Form & Checklist Morbidity		●)) [+]
3.Abstractor Form/Checklist Mortality		○
4.Reviewer Assignments & CC Tracking		● [+]
5.Morbidity Decision Form		○
5a.Cardiovascular Test Procedures Supplement		○
5b.Heart Failure Procedures Supplement		○
5c.PVD Procedures Supplement		○

If the morbidity event included a stroke, the stroke reviewer will also include the Stroke Review form with their Morbidity Decision Form. Enter the data from the stroke form in 9. Stroke Review Form.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	●	
2.Abstractor Form & Checklist Morbidity		●)) [+]
3.Abstractor Form/Checklist Mortality		○
4.Reviewer Assignments & CC Tracking		● [+]
5.Morbidity Decision Form		○
5a.Cardiovascular Test Procedures Supplement		○
5b.Heart Failure Procedures Supplement		○
5c.PVD Procedures Supplement		○
6.Mortality Decision Form		○
7.Mortality Survey Packet Checklist		○
8.Mortality Informant Interview		○
9.Stroke Review Form		○

5.4. Mortality decision form including stroke decisions and adjudications

5.4.1. Mortality Decision Form from Reviewer #1

To enter data from the received mortality decision forms, select the button next to 6. Mortality Decision Form.

Data Collection Instrument	Baseline	Round5(Oct22-Oct23) Round5
1.Participant Information	🟢	
2.Abstractor Form & Checklist Morbidity		⚪
3.Abstractor Form/Checklist Mortality		🟢 +
4.Reviewer Assignments & CC Tracking		🟢 +
5.Morbidity Decision Form		⚪
5a.Cardiovascular Test Procedures Supplement		⚪
5b.Heart Failure Procedures Supplement		⚪
5c.PVD Procedures Supplement		⚪
6.Mortality Decision Form		⚪ ⬅

Fill in the appropriate information for each Mortality Decision Form.

📄 6.Mortality Decision Form

🖉 Editing existing Record ID **10**	
Event Name: **Round5(Oct22-Oct23)**	
Record ID	10

MORTALITY SURVEY - FINAL DECISION
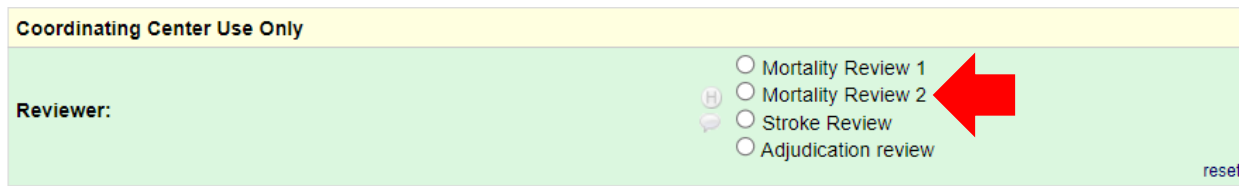
SHS ID Number :

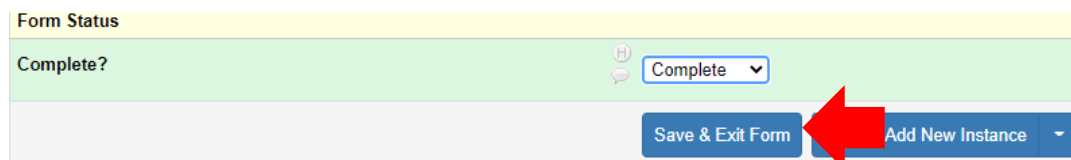| Date of death:		📅 Today M-D-Y
Age at death:		
Cause of death:		⌄

If this is the first mortality review, select Mortality Review 1 under Coordinating Center Use Only.

When all data is entered, select Complete under Form Status. Save & Exit the form.

5.4.2. Mortality Decision Form from Reviewer #2

If this is the second mortality review, the button on the participants record page for the Mortality Decision form will already be Green since the first mortality decision was entered into the database. To enter the second mortality decision form, select the plus sign next to the green button on 6. Mortality Decision Form to create a second instance of the form.

Fill in the appropriate information for each Mortality Decision Form. The form will also include (Instance # 2) at the top of the form.

This is second mortality review, so select Mortality Review 2 under Coordinating Center Use Only.

When all data is entered, select Complete under Form Status. Save & Exit the form.

5.4.3. Mortality Decision Form from Stroke Death

If the morality event is a Stroke, the CC will assign a stroke reviewer and enter the Mortality Decision form from the stroke review. A third instance can be added for the mortality decision form for the stroke review and stroke review selected at the bottom of the Mortality Decision form. A Stroke Review form will also be entered by the CC from the stroke reviewer.

5.4.4. Mortality Decision Form from Adjudication

If the two reviewers disagree about the cause of death, the two decisions forms will be sent for adjudication. Please refer to the SHS Phase VII Morbidity and Mortality Surveillance Manual of Operations document for procedures adjudication.

When the Mortality Decision Form is received from the adjudicator, the CC will enter this form into REDCap. A fourth instance (if a stroke was included) or a third instance (if no stroke was included) can be added for the mortality decision form for the adjudicated death review. Adjudication review should also be selected at the bottom of the Mortality Decision form.

There is a form called Adjudication – Special cases – CC only that can be used by the CC to help track information from the adjudicated deaths that will be easier to use for creating the ALLDEAD dataset at the CC.

7. Complete Reviewer Information & Assignment form – CC Use Only

The dates reviews are completed need to be entered on this form. The CC will be responsible for ensuring these dates are entered. The Reviewer Information will be moved from Unverified to Complete when all of the dates have been entered.

For CC Use only - Dr JL Yeh			
Date CC Received Decision Form 1 - Mortality		Today	M-D-Y
Date CC Received Decision Form 2 - Mortality		Today	M-D-Y
Date CC Received Decision Form - Morbidity		Today	M-D-Y
Date Stroke Review Assigned		Today	M-D-Y
Date CC received stroke review form		Today	M-D-Y
Date Adjudication Review Assigned		Today	M-D-Y
Date CC received adjudication review form		Today	M-D-Y

8. If You Have Questions

REDCap: Pravina Kota MBA, MS
            Pravina-Kota@ouhsc.edu
            phone 405-271-2229 Ext48914

SHS M&M forms, processes and other general SHS M&M questions: shs@ouhsc.edu