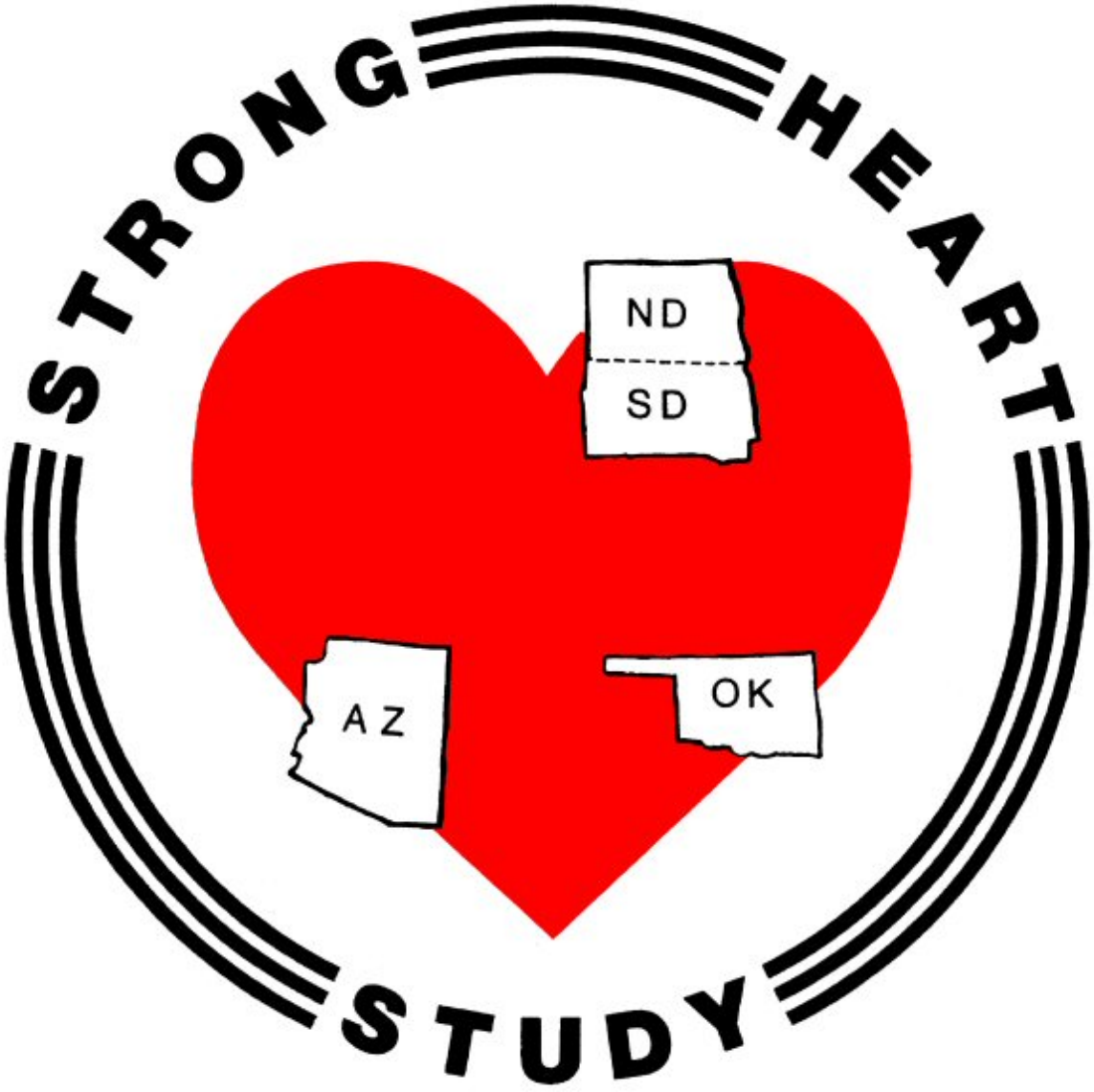


Phase VI

Manual of Operations

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

Table of Contents

DATA ENTRY

Introduction

This Section is to assist the Field Center (FC) data entry personnel in understanding and using the programs developed for Phase VI of The Strong Heart Study. The following topics will be discussed: first and second data entry, editing data, correcting data entry errors, data entry codes and data clean up. We are using the "Medical History" data entry program as an example to demonstrate the related issues.

Before Starting

Before entering data, the data entry operator should screen each participant's folder. This includes putting the forms in numerical order and skimming each form to make sure it has been filled out properly. If errors are found, contact the interviewer and correct them before entering the data. Performing these preliminary steps will make the data entry process more efficient and less tedious. If complications should arise when using the data entry program, contact the Coordinating Center (CC).

Getting Started

The data entry program is hosted on the Strong Heart Study Phase VI Data Entry Server (SHS6-DES). To access the SHS6-DES, follow these instructions below:

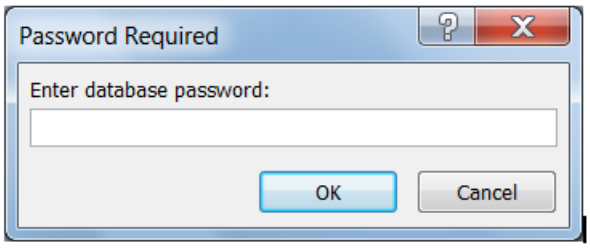
1. Log into https://connect.ouhsc.edu/dana-na/auth/url_default/welcome.cgi using the OUHSC username and password provided to you.
2. Click on the "Start" button next to "Junos Pulse" under "Client Application Sessions." This will download the required software to your computer and allow the Junos Pulse Setup to install and complete.
3. Once the software is installed, it may make you restart your machine. (Please note, once connected to "Junos Pulse" a flower icon should appear in the lower right hand side corner task bar of your screen.)
4. After you have established the Junos Pulse, map the network drive using instructions below:

To map network drive

1. Click on "Computer," and then click on "Map Network Drive." This will open the "Map Network Drive" box. Next, in the box for "Folder" copy and paste the following link: \\10.26.128.39\SHSVI Data Entry.
2. Then click on "Finish." This will add the \\10.26.128.39\SHSVI Data Entry link under "Computer" in Windows Explorer. Next, double click on this link. In the login box enter your user name as follows: ouhsc\your username. Finally, enter your password to connect to the data entry server.

Data Entry Session

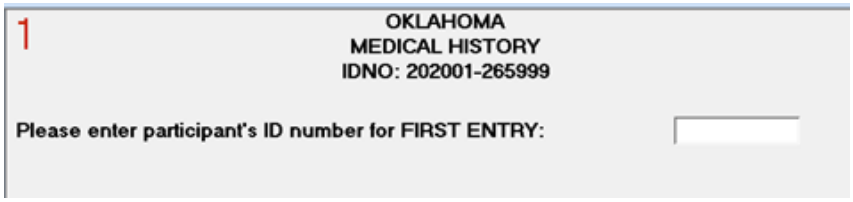
When the data entry session begins, the field staff needs to enter thir site-specific password, as requested in the following screen.



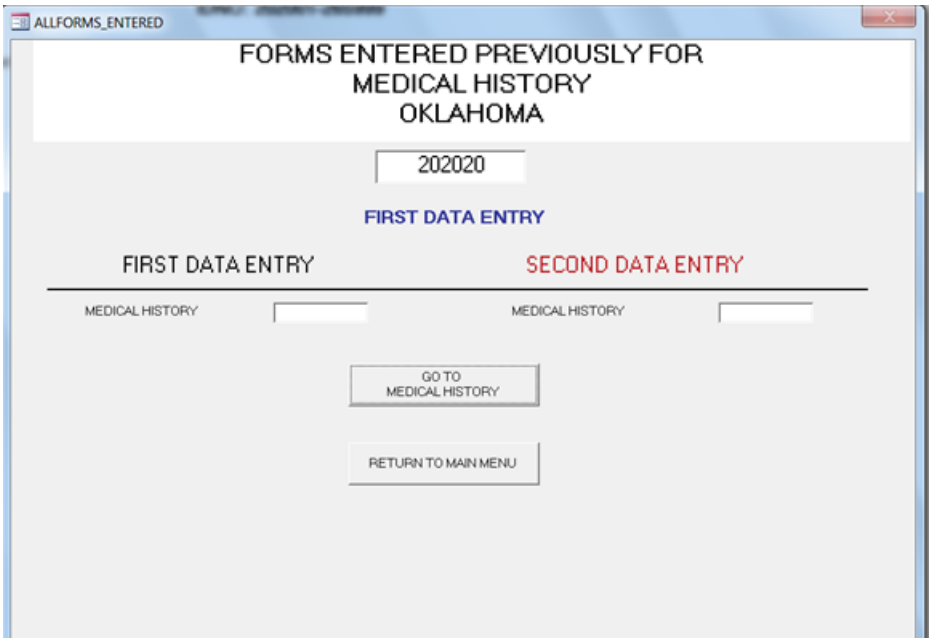
First Data Entry

After the password is entered, the following input box appears. We'll use Oklahoma as an example:

If 'FIRST ENTRY' is selected, the following input box appears.



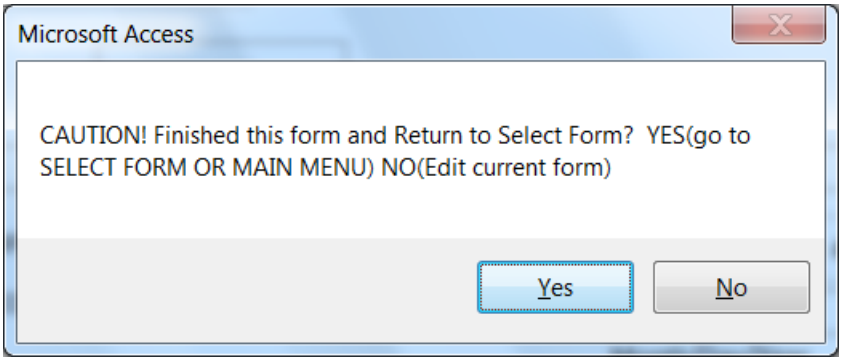
After the SHS ID is entered and the 'Enter' key is pressed, the following screen is displayed.



If a date is displayed in the 'FIRST DATA ENTRY' slot, the form has been entered previously on the date shown for the participant whose SHS ID appears at the top of the form.

If the date is not displayed, click the button labeled 'GO TO MEDICAL HISTORY.' The Medical History form will then be displayed.

After the form is completed and the last question on the form is answered, the following message box will appear, allowing return to the 'Main Menu/Select form,' or editing the current form.



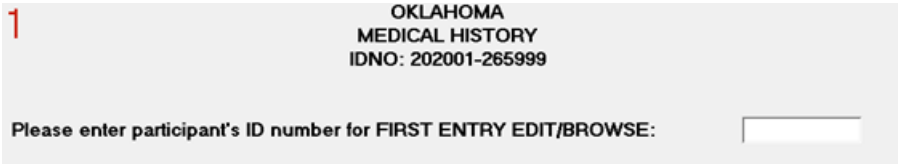
After changes are made, the field staff can exit the system by clicking on the 'Yes' button, as shown in the message box above.

Second Data Entry

The process of entering data for 'SECOND ENTRY' is identical to that for 'FIRST ENTRY' starting with the instructions on page 3. Because the second data entry screens are identical to the first data entry screens, a red '2' appears in the top left-hand corner of the second data entry forms to differentiate the two.

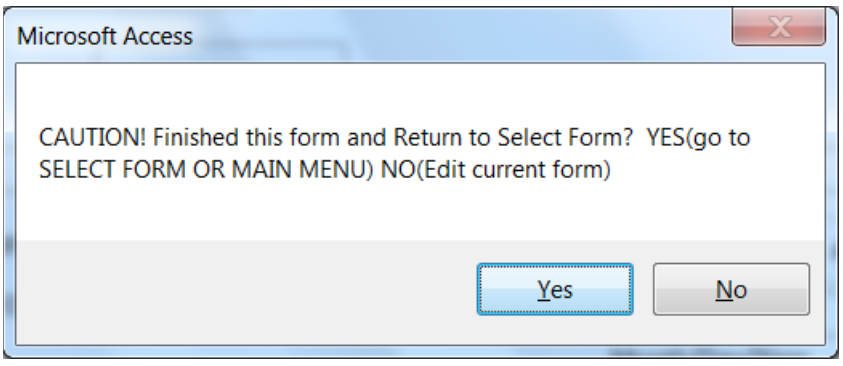
Edit/Browse

When 'EDIT/BROWSE FIRST OR SECOND' is selected from the 'MAIN MENU' (screen as shown below), the input box below will request for the ID number.



After a SHS ID is entered and the 'Enter' key is pressed, the form opens, displaying the data entered for the specific participant.

After corrections have been made, the form can be closed by exiting the last question on the form.



Making Corrections

In order to produce a data entry program that is user-friendly and selective about the data entered, skip patterns and message boxes have been added. Unfortunately, the same features that are intended to help the data entry operator can be a source of frustration when one is trying to correct errors, unless you follow these suggestions.

We will discuss two different situations--a data entry error noticed **BEFORE** exiting the field and an error noticed **AFTER** exiting the field in question.

1) **BEFORE** exiting the field, if in data entry mode or edit/browse mode:

   Solution: Use the backspace key to remove the error and enter the correct value.

2) **AFTER** exiting the field in data entry mode:

   Solution: Continue entering the remainder of the form, exiting the last field on the form. At this time 'Edit Current Form' can be selected, leaving the form open for editing. If the field to be changed is visible, place the cursor in the field and click to make the correction. **In this mode, the vertical scroll bar, the cursor or the 'Enter' key can be used to select another field.** When editing is completed, the form can be exited by hitting the 'Enter' button on the last field of the form. If the error is noticed after the form is closed, make a note of it and correct it through using edit/browse mode for that participant.

3) **AFTER** exiting the field in edit/browse mode:

   Solution: Place the cursor in the field and click to make the correction. **In this mode, the vertical scroll bar, the cursor or the 'Enter' key can be used to select another field.** When editing is completed, the form can be exited htting the 'Enter' button on the last field of the form.

Data Entry Codes

In some cases, the participant responding to a question may not know the answer or refuse to answer the question. Some questions have these options listed while others do not. For those that do not, the **interviewer** should indicate these responses by putting a question mark for unknown or drawing two lines through the box for refusal. Since the data entry program will not allow the operator to use these symbols, codes which can be used instead have been developed. It was not possible to use the same code for every type of field (e.g. text, numeric, etc.), but the codes were made as consistent as possible. Finally, if a question is not answered and there is no indication that the participant did not know or refused, this should be classified as missing. The following is a list of data entry codes by variable type.

Text variables (questions that have options listed or are not quantitative)

OR

Numeric variables (questions requiring quantitative information, such as measurement

data):

7, 77 or 777 = Missing
8, 88 or 888 = Refused
9, 99 or 999 = Unknown

Time variables (questions requesting the time of an event):

00:07 = Missing
00:08 = Refused
00:09 = Unknown

Date variables (questions requesting the date of an event):

01/01/1007 = Missing
01/01/1008 = Refused
01/01/1009 = Unknown

Note: If only the year is known, use 06/30/year.
If only the month and year are known, use month/15/year.

Guidelines for First Data Entry and Second Data Entry

To reduce the likelihood that a data entry error will be repeated during second data entry, first data entry and second data entry should not be done by the same person. It is understood that this is not possible at all field centers. If the same person is performing both first and second data entry, the following are two suggestions:

For the same participant, do first data entry and second data entry at least a day apart.

OR

1) If both first data entry and second data entry must be entered on the same day and there are data for more than one participant:

i) Do first data entry for all of the participants, then
ii) Do second data entry for all of the participants in the same order that data entry was performed.

Data Clean Up

Data will be stored at the CC as entered (form-by-form), so there will be no need for separate backup or transmission procedures at the FC computers. Opportunities to edit previously entered data through the online Data Entry program are allowed; CC staff will copy all raw data on a monthly basis.

The CC will be responsible for identifying: missing forms, orphan records (records which do not belong to any participant according to the SHS ID listed on the form), incomplete forms, discrepancies between 'First Data Entry' and 'Second Data Entry' and values which appear to be unreasonable. The FCs will be responsible for providing information to the CC so that the aforementioned problems can be rectified.

Data clean up will occur in two stages.

Stage One: Raw data are examined at the CC. Incomplete items and discrepancies between 'First Data Entry' and 'Second Data Entry' are listed and sent to the FCs via email. The Field Coordinators will make corrections through online Edit/Browse mode.

Stage Two: Statistical checks will be performed to identify unreasonable values. These items will be listed and sent to the FC. FC personnel will perform verification of the suspect data. A response (fax, as detailed under stage one) is expected within 2 weeks.

Upon completion of both stages, cleaned records will be appended to the Main Database. Please note that the Main Database will be used to perform analyses for reports and publications. Therefore, if a FC were to identify any data entry errors after data clean up has been completed, they must notify the CC promptly.

In cases where there are many data entry errors found in stage one of data clean up, the CC may request that changes to a specific record be made at the FC. Said records be re-entered through the online Data Entry program.

If You Have Questions

So that your questions can be answered efficiently, please address your queries to the following CC personnel:

Forms and Data Entry Programs	- Fawn Yeh, MPH, PhD
Data Clean Up	- TBN
Data Entry On-line Server	
Log-ins or Terminal Services	
(FC computer) client program	- Pravina Kota, MS

Morbidity and Mortality Surveillance Procedures

Guidelines for Outpatient Tests

1. **Echocardiogram:** In the PDF files for the reviewers:
   a) Do not include reports showing only mild valvular abnormalities; include reports with moderate and severe valvular abnormalities
   b) Do not include reports only showing left atrial enlargement.
   c) Do not include reports only showing small pericardial effusion.
   d) Do not include reports only showing left ventricular hypertrophy.
   e) If multiple outpatient echocardiograms were done during the time frame of 2009 to present, include only the latest report – unless earlier reports show important findings that are not present in the latest report.
2. **Carotid Ultrasound:** In the PDF files for the reviewers:
   a) Do not include reports showing less than 70% obstruction. However, in the presence of stroke or TIA, carotid ultrasound reports showing any degree of obstruction or no obstruction should be included.
3. **Stress Test:** In the PDF files for the reviewers:
   a) Do not include normal reports.
4. **Holter Monitor:** In the PDF files for the reviewers:
   a) Upload only the cover page that contains summary of findings.
5. **Computed Tomographic Calcium Scoring:** In the event when this test is done as a stand-alone test, reviewers will only complete Cardiovascular Test and Procedures Abstract form.

Guidelines for Abstracting Recurrent CHF and AFIB Events

For recurrent CHF and AFIB events, abstract no more than three hospitalizations or outpatient visits for these events.

Guidelines for Abstracting Cancer, Liver Diseases, and Inflammatory Conditions

Only abstract records that establish diagnoses for these conditions. Do not abstract further records of treatment for these conditions. If pathology report is available indicating the type of cancer, include this report in the PDF file for the reviewers; and check the “Pathology” checkbox in the Mortality Surveillance Checklist (for mortality event) or put a check mark in the “Yes” column in the “Other, specify:” item in the Morbidity Surveillance checklist for morbidity event.

Pre-Scanning Procedures:

1. **Stamp SHS ID number** on each page of participants’ medical records.
2. **Scanning Order for Multiple Events:**

a) For participants with multiple events, organize events in reverse chronological date order, i.e., put latest event at the beginning and earliest event at the end.
b) All events should be separated by Morbidity and/or Mortality Checklists.
c) Using Morbidity Checklist for outpatient tests, procedures, and consultations will be left up to the discretion of the field sites.

3. **Scanning Documentation Order for Each Event:** Organize medical records for each event in the Scanning Documentation Order provided in Table 1.
4. **For Mortality Files** organize medical records in the following order:
   a) Put the Mortality Survey Packet Checklist and include death certificate, autopsy report (if done) and informant interview (if done).
   b) Then the Mortality Checklist and include the most recent discharge summary or other clinical information immediately preceding the death.
   c) Then previous CVD related discharges for past year in reverse chronological date order. Non CVD discharges not needed in most cases.
5. **For Morbidity Files:** A single PDF File should be created even if a participant had multiple events.

Post-Scanning Procedures:

1. **Naming of PDF File:** Name the PDF file using the format shown in the examples below:
   a) Name Morbidity file as follows: 203557MB2011-05-17 (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2011 denotes the year of event, 05 denotes the month of event, and 17 denotes the date of event).
   b) Name Mortality file as follows: 203231MT2013-10-02 (wherein 203231 denotes the SHS ID number; MT denotes Mortality; 2013 denotes the year of death, 10 denotes the month of death, and 02 denotes the date of death).
   c) Make sure to add a "0" in front of a single digit day and month in the PDF file name.
   d) For hospitalization/outpatient visit involving stroke, the PDF file for the stroke reviewer should be named according to the following example: 203557MB2011-05-17-STK (wherein 203557 denotes the SHS ID number; MB denotes Morbidity; 2011 denotes the year of event, 05 denotes the month of event, and 17 denotes the date of event; STK denotes stroke event).
2. **Create Bookmarks in PDF File:** Create separate book marks for each event and for sections under each event.
3. **Activate Text Recognition Feature in PDF File**
4. **Upload PDF Files into the M&M Reviewers' Folders on the SHS SharePoint Website:**
   a) Morbidity PDF file should be uploaded into the folder of one morbidity reviewer.
   b) Mortality PDF files should be uploaded into the folders of two mortality reviewers.
   c) Stroke morbidity PDF file should be uploaded into Dr. Kamel's folder.
   d) Stroke mortality PDF file should be uploaded into the folders of two regular mortality reviewers. If one or both mortality reviewers determine that the cause of death is stroke related, they will notify the Coordinating Center (CC); CC will then upload that PDF file into Dr. Kamel's mortality folder.

Morbidity and Mortality Reviewers:

Following is a list of SHS M&M reviewers along with their email addresses:

Morbidity Reviewers:

Dr. Lyle Best: lbest@restel.com
Dr. Ingrid Hriljac: hriljac@med.cornell.edu
Dr. Jason Deen: jason.deen@seattlechildrens.org
Dr. Jocelyn Dorscher: joycelyn.dorscher@med.und.edu
Dr. Mary Owen: mjowen@d.umn.edu
Dr. Richard Devereux: rbdevere@med.cornell.edu
Dr. Tracy Hagerty: hagertyt@gmail.com

Mortality Reviewers:

Dr. Dorothy Rhoades: Dorothy-Rhoades@ouhsc.edu
Dr. Everett Rhoades: everettrhoades@msn.com
Dr. Jeffrey Henderson: jhenderson@bhcaih.org
Dr. Stacey Jolly: jollys@ccf.org
Dr. Sunny Jhamnani: sunny.jhamnani@yale.edu
Dr. Thomas Welty: thomaswelty@gmail.com

Stroke Reviewer:

Dr. Hooman Kamel: hok9010@med.cornell.edu

Mortality Adjudicator

Dr. William Howard: wm.james.howard@medstar.net

Continued on next page

Table 1

Scanning Documentation Order for Each Event

1 – Hospital Admin Documents
- – Hospital Face Sheet – ICD9-CM Codes
- – Physician Attestation; Coding Abstract

2- Discharge Summary
- – Discharge Summary
- – Outpatient/Short Stay Record

3 – Physician Documents
- – History and Physical/Physical Exam
- – Emergency Room/Emergency Department report

4 – Consultations
- – Consult

5 – ECGs
- – 12-Lead ECG tracings, all days

6 – Labs
- – Cardiac Enzyme Reports (e.g., Troponin I, Troponin T, CKMG, CK or CPK), all days
- – Lab: Brain B-type natriuretic peptide (BNP), pro-BNP
- – Lab: Blood urea nitrogen (BUN), creatinine
- – Complete blood count (CBC)
- – Lab: Electrolyte Reports

7 – Imaging
- – Chest X-ray Report all days
- – Stress Test by treadmill ECG echo or nuclear perfusion scintigraphy report
- – Carotid Artery Angiography, Doppler flow study
- – Doppler flow study report
- – Echocardiogram and Doppler (all reports of 2-D, transesophageal-TEE, or transthoracic-TTE)
- – Ventilation/Perfusion Lung Scan Report
- – Pulmonary Angiogram
- – CT Scan Report
- – MRI Report
- – Radiology and/or bone scan reports/isotope or nuclear med bone scan
- – Nuclear Scans, e.g., thallium, Myoview®, sestamibi, RVG/MUGA
- – Reports of cardiac MRI/MR angiography
- – Reports of Cardiac CT scan /CT angiography
- – Reports of angiograms of head, neck or brain (MRA, CT, or catheter based)
- – Reports of angiograms of the lower extremities (MRA, CT, or catheter-based angiography)

7 – Imaging (continued)
- – Reports of Segmental Doppler assessment of the lower extremities
- – Reports of Abdominal Ultrasound of aorta or other arteries
- – Reports of Head/Brain CT scans
- – Reports of head/brain MRIs

8 – Op and Procedures
- – Coronary Artery Bypass Graft (CABG)
- – Percutaneous Coronary Intervention (PCI): PTCA; Coronary Stent/Artherectomy
- – Operative or Procedure Report
- – Cardiac catheterization including coronary angiograms and arteriograms and contract ventriculogram
- – Venogram report
- – Operative/Procedure reports (including Aortic Stent Graft)
- – Operative/Procedure reports (including angioplasty and /or stent of lower extremities)

9 – Pathology
- – All pathology reports
- – Cytology reports, all

10 – Fatal Events
- – Death certificate
- – Autopsy or Medical Examiner/Coroner's report
- – Emergency Medical Services (EMS) or ambulance report

11 – Miscellaneous

99 – Miscellaneous document, specify

Instructions to Access SHS M&M SharePoint Website

Go the following website:

https://strongheartstudy.ouhsc.edu/_layouts/StrongHeartLogin/Login.aspx?ReturnUrl=%2f_layouts%2fAuthenticate.aspx%3fSource%3d%252Fdatalib%252FForms%252FAllItems%252Easpx&Source=%2Fdatalib%2FForms%2FAllItems%2Easpx

Enter your username and password:

Username:

Password:

Click on Submit

Procedures for Reviewers to Access PDF Files

Click on “Strong Heart Data Library” on the Strong Heart Study Phase VI SharePoint website homepage

Click on the “Morbidity Surveillance” or “Mortality Surveillance” on the “Strong Heart Data Library” page

Click on your name

Click on the file name that you want to open => Select “Read Only” in the “Open Document” box => Click on OK => Click on either “Save” or “Save as” in the “Do you want to save …… from strongheartstudy.ouhsc.edu” box => if you clicked on “Save” in the previous step, => Click on “Open” to view the document

Files can be sorted by clicking on the desired column header, e.g., files can be sorted by ID number by clicking on the “Name” or they can be sorted by when they were uploaded by clicking on “Created”.

Procedures for the Reviewers to identify a chart as reviewed:

a) Place cursor anywhere on the line of the chart that needs to be identified as reviewed and then click in the box that appears to the left side of the “Type” column in the line for the chart in question
b) Click at the top in the middle on “Edit Properties”.
c) In the “Edit Properties” box in the “Reviewed by” section, a reviewer could either: **1)** select her/his name from the drop down choices by first clicking in the top in the circle in the “Reviewed by” and then clicking on the black down-pointing small triangle; or **2)** type her/his name after clicking in the circle in front of the “Specify your own value” and then type her/his name in the box below it.

d) In the “Edit Properties” box in the “Reviewed date” section, click on the calendar icon and select the date of review.
e) Click on save.

Procedures for Uploading a PDF Files into Reviewers’ Folder

Click on “Strong Heart Data Library” on the Strong Heart Study Phase VI SharePoint website homepage

Click on the “Morbidity Surveillance” or “Mortality Surveillance” on the “Strong Heart Data Library” page

Click on the name of the reviewer you will be uploading the file to

Upload the PDF file from your computer by clicking on the “Documents” tab => “Upload Document” => click on “Browse” => select the PDF in your computer that you want to upload => uncheck “Overwrite existing files” => click on “OK”

Notify M&M Reviewer and CC:

a) When a PDF file is uploaded into the folder of the M&M reviewer, make sure to send a notification email to that reviewer and cc Drs. Jeunliang Yeh and Wenyu Wang.
b) Include the name of the file in the subject line of the email.
c) Include URL for the SharePoint site in the email.
d) Notify the reviewer in the email if the chart belongs to a participant who is also a participant of the Strong Heart Stroke Study.

Responsibility of M&M Reviewer after Completing Chart Reviews

a) Reviewers after completing reviews on a batch of charts will send the decision forms for those charts by **FedEx Ground** to Dr. Jeunliang Yeh at 801 NE 13th Street, Room 112P, Oklahoma City, OK 73104. Reviewers will notify Dr. Jeunliang Yeh by email (jeuliang.yeh@ouhsc.edu) when sending him shipment of decision forms and cc Dr. Fawn Yeh (fawn.yeh@ouhsc.edu).

SharePoint "No Decision at CC" View

After receiving final decision forms at CC, a staff at CC will enter date final decision forms received at CC in the “CC Rec’d” column on SharePoint. This will remove the corresponding PDF file from the reviewer’s folder in the "No Decision at CC" view. Anyone who is interested in looking at all the charts that have been uploaded in a folder will need to change the view by clicking on the down arrow that is on the right side of "No Decision at CC" and select "Default View" from the drop down menu.

Tracking Log for Uploaded Events

a) Create logs to track PDF files upload activity

b) Use the following column titles for Morbidity log:

REVIEWER	CC COPY UPLOADED	SHS ID #	PDF FILE NAME	UPLOAD DATE	TYPE OF MORBID EVENT	EMAIL SENT DATE

c) Use the following column titles for Mortality log:

REVIEWER 1	REVIEWER 2	CC COPY UPLOADED	SHS ID	PDF FILE NAME	UPLOAD DATE	TYPE OF MORTAL EVENT	EMAIL SENT DATE

d) Send use Morbidity and Mortality tracking logs to the CC on the third Friday of each month.

Data Collection Forms

THE STRONG HEART STUDY – VI

CONTACT AND MEDICAL HISTORY

SHS I.D.: |___|___|___|___|___|___|___| SHS Family I.D.: |___|___|___|___|___|___|___|

1. Your name: _____
   Last First Middle
2. Date of Birth: |___|___|/|___|___|/|___|___|___|___|
   Month Day Year
3. What is your nickname/other name: _____
4. If ever married, what was your maiden name? _____
5. If married, what is your spouse's name?

   _____
   Last First Middle
6. What is your current mailing address?

a. _____
   Street/P.O. Box

b. _____
   City/town

c. _____
   State and zip code

7. Is your residential (physical) address the same as above?

   Yes |___| No |___| ***If no, what is your current residential (physical) address?***

a. _____
   Street/P.O. Box

b. _____
   City/town

c. _____
   State and zip code

8. What is your home telephone number |___|___|___|—|___|___|___|—|___|___|___|___|
9. What is your cell telephone number |___|___|___|—|___|___|___|—|___|___|___|___|
10. Does your phone allow text messages Check one box Yes |___| No |___|
11. What is your work or other telephone # |___|___|___|—|___|___|___|—|___|___|___|___|
12. What is your email address _____

13. Please list two of your relatives or friends not living with you who would be able to help us find you in the future:

Contact #1: _____
Name

_____
PO Address Residential (Physical) Address

_____
City/Town State, ZIP code

_____
Phone with area code Cell e-mail address

Contact #2: _____
Name

_____
PO Address Residential (Physical) Address

_____
City/Town State, ZIP code

_____
Phone with area code Cell e-mail address

MEDICAL CONDITIONS:

14. Gender**:** Female |___| Male |___| *(information to be filled in by field staff)*

15. To which IHS and non-IHS Hospital/Clinic do you usually go? *List the one you go to most often first.*

	Hospital/Clinic		IHS, check if YES
a.	_____	City: _____	|___|
b.	_____	City: _____	|___|

16. What is your current weight: |___|___|___| Pounds Current height |___| / Feet |___|___| Inches

17. Do you have arthritis? **Y=Yes, N=No, U=Unknown** Y|___|N|___|U|___|
If yes, have you been told if it is rheumatoid arthritis? Y|___|N|___|U|___|

18. Has a doctor or other health care provider ever told you that you have/had any of the following conditions **Please check the appropriate boxes below.**

a. Asthma	Y|___|N|___|U|___|	f. Liver disease	Y|___|N|___|U|___|
b. Lung disease	Y|___|N|___|U|___|	g. Gout	Y|___|N|___|U|___|
c. Retinopathy/diabetes eye problem	Y|___|N|___|U|___|	h. Kidney stones	Y|___|N|___|U|___|
d. Are you currently on dialysis	Y|___|N|___|U|___|	i. Lupus/scleroderma	Y|___|N|___|U|___|
e. Have you had a kidney transplant	Y|___|N|___|U|___|	j. Diabetes/prediabetes	Y|___|N|___|U|___|

If YES to Diabetes/prediabetes, what type of treatment are you taking?

j1. Insulin Y|___|N|___|U|___| j3. Oral hypoglycemic pills Y|___|N|___|U|___|

j2. Dietary and/or exercise Y|___|N|___|U|___| j4. No Treatment Y|___|N|___|U|___|

Have you ever been told you have high blood pressure? Y|___|N|___|U|___|

19. Have you ever been prescribed medications for high blood pressure? Y|___|N|___|U|___|

20. E-cigs are battery powered devices that provide inhaled doses of nicotine. Have you ever used e-cigs (electronic cigarettes)? Y|___|N|___|U|___|

21. Since your last SHS exam, have you had a heart attack, heart failure or any problems with your heart? Y|___|N|___|U|___|

If so, which hospital or clinic took care of you?

Hospital/Clinic:_____City:_____

22. Since your last SHS exam did you have a stroke, a mini-stroke or TIA? Y|___|N|___|U|___|

If so, which hospital or clinic took care of you?

Hospital/Clinic:_____City:_____

Did you receive rehab at a clinic, inpatient or other facility? Y|___|N|___|U|___|

Hospital/Clinic/other facility:_____City:_____

23. Has a health care provider ever told you that you have/had cancer? Y|___|N|___|U|___| (If No or Unknown: Female skip to question 25; Male skip to question 31)

If "YES," what type is/was it? Check all that apply from the following list:

a.	|___|	Breast	f.	|___|	Kidney/Bladder
b.	|___|	Ovary/uterus	g.	|___|	Liver
c.	|___|	Prostate	h.	|___|	Mouth / Throat
d.	|___|	Lung	i.	|___|	Melanoma and/or Skin cancer
e.	|___|	Colon/Rectum	j.	|___|	Blood or immune system
k.	|___|	Other, not on this list:_____			

If yes, please provide name of health care provider or hospital where you receive/received cancer care:

_____City:_____

If yes, did you have an operation or biopsy for the cancer? Y|___|N|___|U|___|

If yes, where?
Hospital/Clinic:_____City:_____

If yes, did you receive any chemotherapy and/or radiation therapy? Y|___|N|___|U|___|

If yes, where?
Hospital/Clinic:_____City:_____

Female Participant only:

24. How many pregnancies have you had? |___|___|

25. How many live births have you had? |___|___|

26. Did you have a still birth (last 3 months of pregnancy)?

Y|___|N|___|U|___|

If yes, when? |___|___| / |___|___|___|___|
Month Year

27. During your **first pregnancy**, were you told that you had any of the following conditions and check all the complications that occurred:

a. pre-eclampsia (toxemia) Y|___|N|___|U|___| d. diabetes (gestational diabetes) Y|___|N|___|U|___|

b. high blood pressure Y|___|N|___|U|___|

c. high blood pressure along with protein in your urine Y|___|N|___|U|___|

Please provide date of delivery for first pregnancy: |___|___| / |___|___| / |___|___|___|___|
Month Day Year

Hospital of delivery:_____City:_____

28. Was there **any other pregnancy** complicated by pre-eclampsia (toxemia) or high blood pressure?

Y|___|N|___|U|___|

If yes, please list one pregnancy that was complicated by these conditions

Date of delivery: |___|___| / |___|___| / |___|___|___|___|
Month Day Year

Hospital of delivery:_____City:_____

Check all complications that occurred:

a. pre-eclampsia (toxemia) Y|___|N|___|U|___| d. diabetes (gestational diabetes) Y|___|N|___|U|___|

b. high blood pressure Y|___|N|___|U|___|

c. high blood pressure along with protein in your urine Y|___|N|___|U|___|

---

29. Interviewer code (administrative use only): |___|___|___|

30. Interview date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY – VI

Diabetes Ascertainment

SHS I.D.: |___|___|___|___|___|___|

14. |___| Diagnosis of diabetes established by prior SHS or SHSS exam, 1=Yes (skip to Q9), 2=No
15. |___| No medical records available, 1=Yes (skip to Q9), 2=No
16. Diagnosis made by the abstractor (check all that apply)

    |___| Diabetes

    |___| Gestational diabetes only (skip to Q9)

    |___| Diabetes not mentioned in medical records (skip to Q9)

    |___| Diabetes mentioned but no supporting evidence in medical records

17. Date of first mention of diabetes (not gestational diabetes) |___|___|/|___|___|/|___|___|___|___|
    Month Day Year
18. FASTING PLASMA GLUCOSE ≥ 126 mg/dL
    First FPG ≥ 126 mg/dL _____ mg/dL _____ Date (mm/yyyy) ____ N/A
19. HEMOGLOBIN A1c ≥ 6.5%
    First A1c ≥ 6.5% _____ % _____ Date (mm/yyyy) ____ N/A
20. 2-HOUR PLASMA GLUCOSE DURING OGTT ≥ 200 mg/dL
    First 2-H PG ≥ 200 mg/dL _____ mg/dL _____ Date (mm/yyyy) ____ N/A
21. Treatment for diabetes. Check all that apply

    |___| Insulin |___| Oral agents |___| Dietary and/or exercise |___| None |___| Unknown

22. SHS staff code: |___|___|___|
23. Abstraction date: |___|___|/|___|___|/|___|___|___|___|
    Month day year

Procedures to ascertain diabetes status since last SHS exam:

a. SH Family Study: Ascertain diabetes status in the SH Family Study up until the last exam.
b. SH cohort that were in the SH Stroke Study: Go back to the last SH Stroke exam and use the available fasting glucose measurements to aid in the ascertainment of diabetes status.
c. SH cohort NOT in the SH Stroke Study: Perform chart review until the last exam.

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY

Medical Records Abstract Checklist for Non-Fatal CVD Events or Procedures

ID number:

|___|___|___|___|___|___|

1. a. Hospital name:_____

   b. Hospital location _____

2. Date of ADMISSION to this hospital or date of this OUTPATIENT visit:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Date of discharge:

   |___|___|/|___|___|/|___|___|___|___|
   month day year

4. Was the patient transferred to or from another acute care hospital?

   Yes |___|1 ***(be sure information is listed on M&M master list form)*** No |___|2

5. Enter the ICD-9 or ICD-10 code numbers for the hospital discharge diagnoses and procedure codes recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. Be sure they are ICD-9 codes. Record diagnoses if no codes are available.

   Indicate which code numbers entered: ICD-9 |___|1 or ICD-10 |___|2

   1. |___|___|___| • |___|___|
   2. |___|___|___| • |___|___|
   3. |___|___|___| • |___|___|
   4. |___|___|___| • |___|___|
   5. |___|___|___| • |___|___|
   6. |___|___|___| • |___|___|
   7. |___|___|___| • |___|___|
   8. |___|___|___| • |___|___|
   9. |___|___|___| • |___|___|
   10. |___|___|___| • |___|___|
   11. |___|___|___| • |___|___|
   12. |___|___|___| • |___|___|
   13. |___|___|___| • |___|___|
   14. |___|___|___| • |___|___|
   15. |___|___|___| • |___|___|
   16. |___|___|___| • |___|___|

RENAL DIALYSIS AND KIDNEY TRANSPLANT

6. Has the participant received a kidney transplant? Yes |___| 1 No|___|2

   If yes, was the transplant done this admission? Yes |___| 1 No|___|2

   If no, date of first transplant: |___|___|/|___|___|/|___|___|___|___|
   month day year

7. Was the participant receiving kidney dialysis during this hospital or outpatient visit?

   Yes |___| 1 No|___|2

   If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and assemble them for each admission). Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets), including Diagnoses	_____	_____	_____
Admitting History and Physical Exam	_____	_____	_____
Discharge Summary	_____	_____	_____
ECGs (see instruction)	_____	_____	_____
Cardiac enzyme report (days 1 to 4)	_____	_____	_____
Neurology Consult Report	_____	_____	_____
Reports of Procedures:			
1. Echocardiogram	_____	_____	_____
2. Coronary angiogram	_____	_____	_____
3. Exercise tolerance test (Treadmill)	_____	_____	_____
4. Cardiac catheterization	_____	_____	_____
5. Coronary bypass	_____	_____	_____
6. Coronary angioplasty	_____	_____	_____
7. Swan-Ganz catheterization	_____	_____	_____
8. Intracoronary or I.V. streptokinase, or TPA reperfusion	_____	_____	_____
9. Aortic balloon pump	_____	_____	_____
10. Radionuclide scan	_____	_____	_____
11. CAT or CT of the head	_____	_____	_____
12. Magnetic Resonance Image (MRI) of the head	_____	_____	_____
13. Carotid ultrasound/Doppler	_____	_____	_____
14. Lumbar puncture	_____	_____	_____

15. Angiography (including vessels in the lower extremities) _____ _____ _____
16. Peripheral Angioplasty (lower extremity vessel(s)) _____ _____ _____
17. Surgical revascularization of peripheral vessel(s)) _____ _____ _____
18. Amputation _____ _____ _____
19. Chest X-ray _____ _____ _____
20. Carotid endarterectomy _____ _____ _____
21. CAT or CT of abdomen or other part of the body _____ _____ _____
22. MRI of abdomen or other part of the body _____ _____ _____
23. Other, specify: _____ _____ _____ _____

Be sure to include Tracking Sheet in the packet

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY – DECISION

ID number: |___|___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. DIAGNOSIS (enter appropriate code number):

01. Definite non-fatal myocardial infarction |___|___|

1b. Probable non-fatal myocardial infarction |___|___|

02. Possible non-fatal myocardial infarction |___|___|

03. Definite non-fatal stroke |___|___|

04. Possible non-fatal stroke |___|___|

06. Definite CHD |___|___|

07. Possible CHD (those with some, but not all, criteria or with equivocal criteria for definite CHD) |___|___|

08. TIA |___|___|

09. Other CVD, specify: _____ |___|___|

10. Non–CVD, specify: _____ |___|___|

11. ESRD (dialysis or transplant): _____ |___|___|

12. Heart Failure (**Please fill out the HF PROCEDURE FORM**) |___|___|

B. Criteria used:

1. MYOCARDIAL INFARCTION (Please check all applicable criteria)

A. Definite MI |___|
1. Evolving diagnostic ECG*, or |___|
2. Diagnostic biomarkers (2 x ULN)* |___|

B. Probable MI |___|
1. Positive ECG findings plus cardiac symptoms or signs without available biomarkers, or |___|
2. Positive ECG findings plus equivocal biomarkers |___|

C. Possible MI |___|

1. Equivocal biomarkers plus nonspecific ECG findings, or |___|
2. Equivocal biomarkers plus cardiac symptoms or signs, or |___|
3. Missing biomarkers plus positive ECG |___|

**** For ECG and cardiac biomarker definition, please refer to: SHS VI Manual, Section 2.3.***

COMMENTS: _____

_____

_____

2. STROKE

A. Definite non-fatal stroke |___|

1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage. |___|
2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI, (or lumbar puncture if done). A nonvascular etiology must be absent. |___|
3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke. |___|
4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI - not caused by trauma. |___|
5. Non-fatal stroke after cardiovascular invasive interventions: Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions. |___|
6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery. |___|

B. Possible non-fatal stroke |___|

a. History or rapid onset (approximately 48 hours from onset to time of admission or maximum acute neurologic deficit) of localizing neurologic deficit and/or change in state of consciousness, and |___|

1b. Documentation of localizing neurologic deficit by unequivocal physician or laboratory finding within 6 weeks of onset with 24 hours duration of objective physician findings, or |___|

2a. Discharge diagnosis with consistent primary or secondary codes (ICD-9-CM codes 431, 432, 434, 436, 437), and |___|

2b. No evidence by unequivocal physician or laboratory findings of any other disease process or event causing focal brain deficit or coma other than cerebral infarction or hemorrhage according to hospital records. |___|

C. Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data, and results of diagnostic studies are consistent with one subtype and other etiologies have been excluded. A **possible** diagnosis is made when the

clinical findings and neuroimaging data suggest a specific subtype but other studies are not done.

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

COMMENTS: _____

_____

_____

3. DEFINITE CORONARY HEART DISEASE (CHD)

a. Cardiac cath proven coronary artery disease (1 or more vessels ≥ 50% stenosis), ***or*** |___|

b. PTCA, ***or*** |___|

c. Coronary artery bypass grafting, ***or*** |___|

d1. Abnormal stress ECG, **and** |___|

d.2. Abnormal imaging, ***or*** |___|

e. Positive functional test of ischemia (such as treadmill) |___|

COMMENTS: _____

_____

_____

4. HEART FAILURE *(if yes, fill out Heart Failure form)*

Two major criteria or one major and two minor criteria:

a. Major criteria
- [ ] i. Paroxysmal nocturnal dyspnea or Orthopnea
- [ ] ii. Neck vein distention
- [ ] iii. Rales
- [ ] iv. Cardiomegaly
- [ ] v. Acute pulmonary edema
- [ ] vi. S3 gallop
- [ ] vii. Increased venous pressure >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

b. Minor criteria
- [ ] i. Ankle edema
- [ ] ii. Night cough
- [ ] iii. Dyspnea on exertion
- [ ] iv. Hepatomegaly
- [ ] v. Pleural effusion
- [ ] vi. Vital capacity reduced by one-third from maximum
- [ ] vii. Tachycardia (rate of ≥ 120/min.)

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure

COMMENTS: _____

_____

_____

5. OTHER NON-FATAL CARDIOVASCULAR DISEASE

a. Purposely left blank – CHF moved to #4 above

- [ ] b. CHF secondary to ESRD (diagnosis = 10)
- [ ] c. Cardiomyopathy
- [ ] d. Valvular Heart Disease
- [ ] e. Left Ventricular Hypertrophy
- [ ] f. Atrial Fibrillation
- [ ] g. Non-coronary heart surgery or carotid or other vascular surgery (does not include procedures for PVD)
- [ ] h. Pacemaker implantation
- [ ] i. Positive non-coronary angiography (does not include procedures for PVD)
- [ ] j. Arrhythmia
- [ ] k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; diagnosis = 07)
- [ ] l. PVD (either peripheral arterial surgical procedures, angiogram or amputation)
- [ ] m. Aortic aneurysm

If there was coronary or peripheral vascular procedure done, fill out CVD Test Procedures form or Peripheral Vascular Procedure form.

COMMENTS: _____

_____

_____

_____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
Cardiovascular Test Procedures Abstract

ID number: |___|___|___|___|___|___|

1. **WAS CATHETERIZATION/ANGIOGRAM DONE?**
   Yes |___|1 No **(*Go to Q18*)** |___|2 Yes, but no report |___|3

2. If YES, When? |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Where: _____
   Hospital/Clinic City/State

Was Any Vessel ≥ 50% Stenotic in ...

		Yes	No	Uncertain	Unknown
4.	Left Main:	|___|1	|___|2	|___|8	|___|9
5.	Left anterior descending:	|___|1	|___|2	|___|8	|___|9
6.	Right coronary:	|___|1	|___|2	|___|8	|___|9
7.	Circumflex artery:	|___|1	|___|2	|___|8	|___|9

8. Ejection Fraction (%): |___|___|___|

777= normal, % not specified 888=abnormal, % not specified
999=unknown/no response

9. Left Ventricular Function: Normal |___|1 Assessed, results not specified |___|3
Depressed |___|2 Not assessed **(*Go to Q17*)** |___|9

10. Was Akinetic Wall Observed?

Yes |___|1 No (***Go to Q15***) |___|2 Uncertain |___|8 Unknown|___|9

		Yes	No	Uncertain	Unknown
11.	Anterior:	|___|1	|___|2	|___|8	|___|9
12.	Inferior:	|___|1	|___|2	|___|8	|___|9
13.	Apex:	|___|1	|___|2	|___|8	|___|9
14.	Diffuse:	|___|1	|___|2	|___|8	|___|9

Finding of Valvular Function:

		Yes	No	Uncertain	Unknown
15.	Mitral regurgitation:	|___|1	|___|2	|___|8	|___|9
16.	Aortic regurgitation:	|___|1	|___|2	|___|8	|___|9
17.	***Was Angioplasty performed?***	|___|1	|___|2	|___|8	|___|9

18. WAS COMPUTED TOMOGRAPHIC CALCIUM SCORING DONE?

Yes |___|1 No **(*Go to Q22*)** |___|2 Yes, but no report |___|3

19. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

20. Where: _____
Hospital/Clinic City/State

21. **Agotston score:** |___|___|___|___|

22. WAS TREADMILL EXERCISE TEST DONE?

Yes |___|1 No **(*Go to Q29*)** |___|2 Yes, but no report |___|3

23. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

24. Where: _____
Hospital/Clinic City/State

25. Treadmill ECG:

Normal |___|1 Borderline |___|2 Abnormal |___|3 Inconclusive |___|8 No report |___|9

26. Maximum heart rate (beats/minute): 999=no report |___|___|___|

27. Maximum systolic blood pressure (mmHg): 999=no report |___|___|___|

28. Treadmill time (round to nearest whole number minute): 99=no report |___|___|

29. WAS THALLIUM TEST, OR OTHER NUCLEAR IMAGE TEST DONE?

Yes |___|1 No **(*Go to Q34*)** |___|2 Yes, but no report |___|3

30. If YES, When? |___|___|/|___|___|/|___|___|___|___|
month day year

31. Where: _____
Hospital/Clinic City/State

32. What Stress: Exercise |___|1 Adenosine |___|2 Dobutamine |___|3 Other Drug |___|4

33. Test results: Positive |___|1 Negative |___|2 Equivocal |___|3 No report |___|9

ADMINISTRATIVE INFORMATION:

34. Reviewer code |___|___|___|

35. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY
PERIPHERAL VASCULAR PROCEDURES/REVASCULARIZATION ABSTRACT

ID number: |___|___|___|___|___|___|

1. **Was peripheral angiogram (ICD-9 procedure code 88.48) done?**

Yes |___|1 No |___|2 **(Go to Q2)** Yes, but no report |___|9

a. If yes: Contrast angiogram |___| MR angiogram |___| CT angiogram |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

d. Was any vessel ≥ 50% stenotic?

i. Aorta: Yes |___|1 No |___|2 Uncertain|___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

ii. Iliac: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iii. Femoral: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

iv. Popliteal or lower: Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

v. Carotid stenosis Yes |___|1 No |___|2 Uncertain |___|8 Unknown |___|9
If yes, which side? Right |___| Left |___| Both |___|

e. Was there evidence of previous revascularization? Yes |___|1 No |___|2

2. **Was peripheral angioplasty or surgical revascularization done?**

Yes, angioplasty |___|1
(ICD-9 procedure code 39.50)

Yes, revascularization |___|3
ICD-9 procedure code 39.25 and 39.29)

No |___|2 **(Go to Q3)** Yes, but no report |___|9

a. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

b. Where: _____

3. **Was amputation (ICD-9 procedure codes 84.10 – 84.19) performed?**

Yes |___|1 No |___|2 **(Go to Q4.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. Which part?

Upper body, Arm=1, Hand=2, Finger=3, |___|

Lower body, Above knee=1, Below knee=2 |___|
Foot=3, Toe(s)=4

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

4. **Was carotid angioplasty/stenting done?**

Yes |___|1 No |___|2 **(Go to Q5.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. If yes, when? |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

5. **Was carotid endarterectomy done?**

Yes |___|1 No |___|2 **(Go to end.)** Yes, but no report |___|9

a. If yes, which side? Right |___| Left |___| Both |___|

b. When: |___|___|/|___|___|/|___|___|___|___|
month day year

c. Where: _____

ADMINISTRATIVE INFORMATION:

5. Reviewer code: |___|___|___|

6. Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Instructions: The same procedures used for the ongoing surveillance in each center should be used, including evaluation of clinic charts and/or use of the IHS computerized records as well as direct contact with participants when necessary.

The purpose of this study is to derive an estimate of the proportion of participants who have undergone diagnostic or therapeutic procedures documenting definite lower extremity peripheral arterial disease since the Phase III SHS examination, and the proportion thereof for whom the necessary records are still available. Therefore, medical records for hospitalizations or outpatient encounters dealing with the diagnostic or procedural codes listed below and occurring since 1 January 1998 should be requested and reports of the procedures of interest should be obtained. Earlier events that correspond to the same procedures should be noted but charts need not be abstracted.

The following diagnostic codes should be identified:

For Peripheral Angiograms: ICD-9 procedure code **88.48**
For Peripheral Angioplasty: ICD-9 procedure code **39.50**
For Peripheral Surgical Revascularization: ICD-9 procedure codes **39.25 and 39.29**
For Amputation: ICD-9 procedure codes **84.10-84.19**
For Carotid Endarterectomy: ICD-9 procedure code **38.12**
For Angioplasty: ICD-9 procedure code **00.61**
For Stenting: ICD-9 procedure code **00.45**

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

HEART FAILURE PROCEDURES

SHS ID: |___|___|___|___|___|___|___| Date of Event: |___|___|/|___|___|/|___|___|___|___|
month day year

A. ATRIAL FIBRILLATION AT TIME OF HF? Yes |___| 1 No |___| 2 Unknown |___| 9

B. WHICH IMAGING STUDY WAS PERFORMED DURING THIS ADMISSION? Please check ALL that were done. If more than one imaging study was done in the same admission, please use one of these forms for EACH IMAGING STUDY to record the results of that study.

|___|1 Echocardiogram

|___|2 Nuclear Imaging

|___|3 Invasive Angiogram

|___|4 CT Angiogram

|___|5 MRI Angiogram

|___|6 Other, Specify: _____

|___|7 Not sure, no results found in chart

|___|8 None

If not sure or none, skip to Q8.

1. Name of test: _____

2. Date of test: |___|___|/|___|___|/|___|___|___|___|
month day year

3. Facility name: _____

   City/State: _____

4. Ejection fraction: Measured: | _____|% Estimated: | _____|%

   If % not stated, 777 = normal, or range ≥ 50% 888 = abnormal, or range < 50% 999 = unknown/no response

5. Ejection fraction interpretation: Normal |___| 1 Depressed |___| 2 NR |___| 9

6. Segmental wall motion abnormalities? Yes |___| 1 No |___| 2 NR |___| 9

   If yes, degree of abnormality: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

7. Transmitral time: E Velocity: ____cm/sec A Velocity: _____ cm/sec Peak E/A Ratio: _____

   Decel. Time: _____msec IVRT: ____ Septal E':_____ Peak S':_____ Septal A':____

SHS ID: |___|___|___|___|___|___|

8. **Valvular disease?** Yes |___| 1 No |___| 2 Unknown |___| 9

If No or Unknown, go to Q9.

If Yes,

a. Mitral regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

b. Mitral stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

c. Aortic regurgitation/insufficiency:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

d. Aortic stenosis: Mild |___| 1 Moderate |___| 2 Severe |___| 3 Unknown |___| 9

e. Tricuspid regurgitation:

1+ |___| 1 2+ |___| 2 3+ |___| 3 4+ |___| 4 Unknown |___| 9

9. **Right ventricular systolic pressure/PA systolic pressure (mmHg): |___|___|___|**

If not stated, 777 = normal 888 = abnormal 999 = unknown/no response

C. B-TYPE NATRIURETIC PEPTIDE (BT-BNP):_____pg/ml. Upper Limit of Normal:_____pg/ml

N-TYPE NATRIURETIC PEPTIDE (NT-BNP): _____ pg/ml. Upper Limit of Normal:_____pg/ml

D. CARDIOMYOPATHY DIAGNOSIS: Ischemic: ____ Non-Ischemic: _____ Hypertrophic: _____

Valvular disease: ____ Acute MI:_____ NR |___| 9

No cardiomyopathy _____

Reviewer Code: |___|___|___| Review Date:|___|___|/|___|___|/|___|___|___|___|
month day year

STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

CHECKLIST FOR MEDICAL RECORDS REVIEW
MORTALITY SURVEILLANCE -- CVD and NON-CVD

Admission date: |___|___|/|___|___|/|___|___|___|___| ID Number: |___|___|___|___|___|___|
mo day year

For each hospital admission WITHIN the YEAR prior to death, obtain electronic records or photocopies of each of the following sections of the medical history (when available) and assemble them for each admission. Be sure that photocopies are legible.

1. a. Hospital name: _____

   b. Hospital location _____

2. Date of discharge: |___|___|/|___|___|/|___|___|___|___|
   month day year

3. Enter the ICD-9 or ICD-10 code numbers for the hospital discharge diagnoses and procedure codes recorded in the medical record exactly as they appear on the front sheet of the medical record and/or on the discharge summary. Record diagnoses if no codes are available.

   Indicate which code numbers entered: ICD-9 |___|1 or ICD-10 |___|2

   1. |___|___|___| • |___|___|
   2. |___|___|___| • |___|___|
   3. |___|___|___| • |___|___|
   4. |___|___|___| • |___|___|
   5. |___|___|___| • |___|___|
   6. |___|___|___| • |___|___|
   7. |___|___|___| • |___|___|
   8. |___|___|___| • |___|___|
   9. |___|___|___| • |___|___|
   10. |___|___|___| • |___|___|
   11. |___|___|___| • |___|___|
   12. |___|___|___| • |___|___|
   13. |___|___|___| • |___|___|
   14. |___|___|___| • |___|___|

RENAL DIALYSIS AND TRANSPLANT

Provide answers to Question 4 only for the last admission within 12 months prior to death.

4. Was the participant receiving kidney dialysis during this hospital visit? Yes |___| 1 No|___|2

   If yes, was dialysis started during this admission? Yes |___| 1 No|___|2

   Did participant request stopping dialysis during this hospitalization? Yes |___| 1 No|___|2

5. Has this participant ever had a kidney transplant? Yes |___|1 No |___|2

6. **<u>FOR MORTALITY REVIEW:</u> Obtain the following medical records (when available) for this final admission. In addition, obtain these medical records for each hospitalization WITHIN the YEAR prior to death (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>).**
<u>FOR MORBIDITY REVIEW:</u> Obtain the following medical records (when available) for each hospitalization or outpatient visit since this participant's last morbidity chart review (and <u>assemble</u> <u>them</u> <u>for</u> <u>each</u> <u>admission</u>). Be sure that photocopies are legible.

	YES	NO	DONE, No Report
Admission Sheets (Face Sheets)	|___|1	|___|2	|___|9
Admitting History and Physical Exam	|___|1	|___|2	|___|9
Discharge Summary	|___|1	|___|2	|___|9
ECGs	|___|1	|___|2	|___|9
Cardiac Enzyme (including Troponin)	|___|1	|___|2	|___|9
Reports of results of:			
Chest X-ray	|___|1	|___|2	|___|9
Echocardiogram	|___|1	|___|2	|___|9
Angiogram	|___|1	|___|2	|___|9
Exercise tolerance test (Treadmill)	|___|1	|___|2	|___|9
Cardiac catheterization	|___|1	|___|2	|___|9
CT (CAT) scan	|___|1	|___|2	|___|9
MRI	|___|1	|___|2	|___|9
Carotid ultrasound	|___|1	|___|2	|___|9
Lumbar puncture	|___|1	|___|2	|___|9
Creatinine	|___|1	|___|2	|___|9
Liver Function test	|___|1	|___|2	|___|9
Pathology	|___|1	|___|2	|___|9
Cultures	|___|1	|___|2	|___|9

Other Laboratory results, SPECIFY:

_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9
_____	|___|1	|___|2	|___|9

Operative reports:

Coronary bypass	|___|1	|___|2	|___|9
Angioplasty	|___|1	|___|2	|___|9
Swan-Ganz catheterization	|___|1	|___|2	|___|9
Non-CVD operation	|___|1	|___|2	|___|9

For terminal Event Only:

Ambulance report	|___|1	|___|2	|___|9
ER Admission and Discharge Summary	|___|1	|___|2	|___|9
Any clinical notes regarding DOA	|___|1	|___|2	|___|9
Autopsy Report/ Coroner's Report	|___|1	|___|2	|___|9
From IHS clinic chart (if available), photocopy notes and test results from the most recent visit prior to death	|___|1	|___|2	|___|9

Abstractor Number |___|___|___|

Date abstract completed: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORTALITY SURVEY PACKET CHECKLIST

ID number: |___|___|___|___|___|___|

1.	Death Certificate	Yes |___|1	No |___|2
2.	Autopsy performed	Yes |___|1	No |___|2
3.	Autopsy report	Yes |___|1	No |___|2
4.	Medical Records Checklist	Yes |___|1	No |___|2
5.	Copy reports as specified	Yes |___|1	No |___|2
6.	Check if the decedent is eligible for the morbidity survey and proceed as required by the morbidity survey protocol.	Yes |___|1	No |___|2
7.	Check if tracking form was sent	Yes |___|1	No |___|2
8.	Informant Interview Form	Yes |___|1	No |___|2

9. Was he/she in a nursing home at the time of death?

Yes |___|1 No |___|2 Unknown |___|9

10. Was he/she receiving care from a home hospice care program at the time of death?

Yes |___|1 No |___|2 Unknown |___|9

ADMINISTRATIVE INFORMATION:

SHS staff code: |___|___|___|

Completion date: |___|___|/|___|___|/|___|___|___|___|
month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORTALITY SURVEY – FINAL DECISION

ID number: |___|___|___|___|___|___|___|

Date of death: |___|___|/|___|___|/|___|___|___|___| Age at death: |___|___|
month day year

A. Cause of death, choose from the list below:

Cause of death: |___|___|

Contributory cause of death 1: |___|___|

Contributory cause of death 2: |___|___|

01 = Definite myocardial infarction
1a = Probable myocardial infarction
02 = Definite sudden death due to coronary heart disease
03 = Definite coronary heart disease
04 = Possible coronary heart disease
05 = Definite stroke
06 = Possible stroke
07 = Definite congestive heart failure
08 = Possible congestive heart failure
09 = Other cardiovascular diseases, specify: _____

If is Non-CVD death, choose one from the following list and complete the evidence code:

Evidence Code: |___|___|
(up to 3 Codes) |___|___|
|___|___|

21 = Malignant neoplasm;
primary site: _____
22 = Unintentional injury and adverse effects/MVA
23 = Unintentional injury and adverse effects/all other
24 = Chronic obstructive pulmonary disease and allied conditions
25 = Pneumonia and influenza
26 = Diabetes mellitus
27 = Chronic liver disease and cirrhosis
28 = Suicide
29 = Homicide and legal intervention
30 = Nephritis, nephrotic syndrome and nephrosis
31 = ESRD
32 = Septicemia
33 = HIV/AIDS
88 = Other, specify: _____
99 = Can not be determined.

01 = Pathology Report
02 = Clinical Diagnosis only
03 = Pulmonary function test
04 = Blood glucose test
05 = Abnormal liver function tests
06 = Abnormal kidney function test
07 = Positive culture (blood or sputum)
08 = Positive antibody test
09 = Positive blood test (any type)
10 = Autopsy
11 = Police/Coroner's investigation
12 = Other medical records evidence
Specify: _____

Was the death alcohol related? Yes |___|1 No |___|2 Unknown |___|9

B. Criteria used for the cause of death: (Please check the appropriate boxes.)

01. Definite fatal myocardial infarction

[ ] 1(a) Definite MI within 4 weeks of death by criteria: Yes No

1.	Evolving diagnostic ECG*, or	|___|1	|___|2
2.	Diagnostic biomarkers (2 x ULN)*	|___|1	|___|2

OR

[ ] 1(b) Acute MI diagnosed by autopsy

AND

[ ] 2. No known non-atherosclerotic or noncardiac-atherosclerotic condition that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

1a. Probable fatal MI

[ ] 1. Death within 28 days of hospital admission, cases defined as:

		Yes	No
1a.	Positive ECG findings plus cardiac symptoms or signs Without biomarkers, or	|___|1	|___|2
1b.	Positive ECG findings plus equivocal biomarkers	|___|1	|___|2

OR

[ ] 2. Death within 6 hours of hospital admission with cardiac symptoms and/or signs. Other confirmatory data (biomarkers, ECG) are absent or non-diagnostic. \|___\|1 \|___\|2

**** For ECG and cardiac biomarker definitions, please refer to: SHS VI Manual, Section 2.3.***

02. Definite sudden death due to CHD

[ ] 1. Death witnessed as occurring within 1 hour after the onset of cardiac symptoms (prolonged cardiac pain, shortness of breath, fainting) or within 1 hour after the subject was last seen without symptoms.

AND

[ ] 2. No documentation of acute MI within 4 weeks prior to death.

AND

[ ] 3. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records or physician report.

03. Definite fatal CHD

[ ] 1. Death certificate with consistent underlying or immediate causes, **AND**
[ ] 2. No documentation of definite acute MI within 4 weeks prior to death, **AND**
[ ] 3. Criteria for sudden death not met (above), **AND**
[ ] 4. No known non-atherosclerotic or noncardiac-atherosclerotic process or event that was probably lethal according to death certificate, autopsy report, hospital records, or physician records,

AND

[ ] 5(a) Previous history of MI according to relative, physician, or hospital records,
OR
[ ] 5(b) Autopsy reporting severe atherosclerotic-coronary artery disease or old MI without acute MI (50% proximal narrowing of two major vessels or 75% proximal narrowing of one more vessel, if anatomic details given.),
OR
[ ] 5(c) Death occurring greater than 1 and less than or equal to 24 hours after the onset of severe cardiac symptoms or after subject was last seen without symptoms (without meeting criteria for Probable MI),
OR
[ ] 5(d) Angiogram reporting severe (≥ 50% narrowing) atherosclerotic coronary artery disease,
OR
[ ] 5(e) Other positive physical signs or lab findings.

04. Possible fatal CHD

[ ] 1. No documentation by criteria of definite acute MI within 4 weeks prior to death,
AND
[ ] 2. No documentation by criteria of definite sudden death,
AND
[ ] 3. No documentation by criteria of definite fatal CHD,
AND
[ ] 4. Death certificate with consistent underlying or immediate cause,
AND
[ ] 5. No known non-atherosclerotic or noncardiac-atherosclerotic process that was probably lethal according to death certificate, autopsy report, hospital records, or physician records.

05. Definite fatal stroke (**also complete 6.1, 6.2 and Supplemental Form**)

[ ] 1a. Cerebral infarction or hemorrhage diagnosed at autopsy,
AND
[ ] 1b. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,
OR

[ ] 2a. History of rapid onset (approximately 48 hours from onset to time to admission or maximum acute neurologic deficit) of focal neurologic deficit with or without change in state of consciousness,

AND

[ ] 2b. Focal neurologic deficit within 6 weeks of death documented by unequivocal physician or laboratory findings with 24 hours duration of objective physician findings,

AND

[ ] 2c. No other known disease process or event such as brain tumor, subdural hematoma, metabolic disorder, or peripheral lesion that could cause focal neurologic deficit, with or without coma, according to death certificate, autopsy, hospital records, or physician records,

06. Possible (Undocumented) fatal stroke

[ ] 1. Death certificate consistent with underlying or immediate cause (ICD-9, code 431 – 437), but neither autopsy evidence nor adequate pre-terminal documentation of the event,

AND

[ ] 2. No evidence at autopsy examination of the brain, if performed, of any disease process that could cause focal neurologic signs that would not be connected with cerebral infarction or hemorrhage.

OR

[ ] 3. Focal neurological deficit and death within 24 hours, without MRI or other diagnostic image.

<u>Stroke subtype classification (complete for cases of definite fatal stroke).</u>

[ ] 1. Stroke of unknown type etiology: Definite stroke of unknown etiology when CT or MRI not done. Information is inadequate to diagnose ischemic (infarction), intracerebral hemorrhage, or subarachnoid hemorrhage.

[ ] 2. Definite ischemic stroke: CT or MRI scan within 14 days of onset of a focal neurological deficit lasting more than 24 hours with evidence of brain infarction (mottled cerebral pattern or decreased density in a defined vascular territory), no intraparenchymal or subarachnoid hemorrhage by CT/MRI. A nonvascular etiology must be absent.

[ ] 3. Definite primary intracerebral hemorrhage: Focal neurological deficit lasting more than 24 hours. Confirmation of intraparenchymal hemorrhage in a compatible location, not caused by trauma, with CT/MRI scan within 14 days of stroke.

[ ] 4. Subarachnoid hemorrhage: Sudden onset of a headache, neck stiffness, loss of consciousness. There may be a focal neurological deficit, but neck stiffness is more prominent. Blood in the subarachnoid or intraventricular space by CT/MRI, not caused by trauma.

[ ] 5. Non-fatal stroke after cardiovascular invasive interventions:
Stroke associated with the intervention within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization, arrhythmia ablation, angioplasty, atherectomy, stent deployment or other invasive coronary or peripheral vascular interventions.

[ ] 6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery.

Ischemic stroke subtype classification (complete for cases of definite ischemic stroke).

[ ] 1. Large-artery atherosclerosis: Clinical and brain imaging findings of either significant (>50%) stenosis or occlusion of a major brain artery or branch cortical artery, presumably due to atherosclerosis, and clinical findings of cerebral cortical impairment (aphasia, neglect, restricted motor involvement, etc.) or brain stem or cerebellar dysfunction. A history of intermittent claudication, transient ischemic attacks (TIAs) in the same vascular territory, a carotid bruit, or diminished pulses helps support the clinical diagnosis. Cortical or cerebellar lesions and brain stem or subcortical hemispheric infarcts greater than 1.5 cm in diameter on CT or MRI are considered to be of potential large-artery atherosclerotic origin. Supportive evidence by duplex imaging or arteriography of a stenosis of greater than 50% of an appropriate intracranial or extracranial artery is needed. Diagnostic studies should exclude potential sources of cardiogenic embolism. The diagnosis of stroke secondary to large- artery atherosclerosis cannot be made if duplex or arteriographic studies are normal or show only minimal changes.

*Probable |___| *Possible |___|

[ ] 2. Cardioembolism: Patients with arterial occlusions presumably due to an embolus arising in the heart. Cardiac sources are divided into high-risk and medium-risk groups based on the evidence of their relative propensities for embolism. At least one cardiac source for an embolus must be identified for a possible or probable diagnosis of cardioembolic stroke. Clinical and brain imaging findings are similar to those described for large-artery atherosclerosis. Evidence of a previous TIA or stroke in more than one vascular territory or systemic embolism supports a clinical diagnosis of cardiogenic stroke. Potential large-artery atherosclerotic sources of thrombosis or embolism should be eliminated. A stroke in a patient with a medium-risk cardiac source of embolism and no other cause of stroke is classified as a possible cardioembolic stroke.

*Probable |___| *Possible |___|

[ ] 3. Small-artery occlusion (lacune): Patients whose strokes are often labeled as lacunar infarcts in other classifications. The patient should have one of the traditional clinical lacunar syndromes and should not have evidence of cerebral cortical dysfunction (aphasia, neglect, restricted motor involvement, etc.). A history of diabetes mellitus or hypertension supports the clinical diagnosis. The patient should also have a normal CT/MRI examination or a relevant brain stem or subcortical hemispheric lesion with a diameter of less than 1.5 cm demonstrated. Potential cardiac sources for embolism should be absent, and evaluation of the large extracranial arteries should not demonstrate a stenosis of greater than 50% in an ipsilateral artery.

*Probable |___| *Possible |___|

* A **probable** diagnosis is made if the clinical findings, neuroimaging data, and results of diagnostic studies are consistent with one subtype and other etiologies have been excluded. A **possible** diagnosis is made when the clinical findings and neuroimaging data suggest a specific subtype but other studies are not done.

[ ] 4. Acute stroke of other determined etiology: Patients with rare causes of stroke, such as non atherosclerotic vasculopathies, hypercoagulable states, or hematologic disorders. Patients in this group should have clinical and CT or MRI findings of an acute ischemic stroke, regardless of the size or location. Diagnostic studies such as blood tests or arteriography should reveal one of these unusual causes of stroke. Cardiac sources of embolism and large-artery atherosclerosis should be excluded by other studies.

[ ] 5. Stroke of undetermined etiology: In several instances, the cause of a stroke cannot be determined with any degree of confidence. Some patients will have no likely etiology determined despite an extensive evaluation. In others, no cause is found but the evaluation was cursory. This category also includes patients with two or more potential causes of stroke so that the physician is unable to make a final diagnosis. For example, a patient with a medium-risk cardiac source of embolism who also has another possible cause of stroke identified would be classified as having a stroke of undetermined etiology. Other examples would be a patient who has atrial fibrillation and an ipsilateral stenosis of 50%, or the patient with a traditional lacunar syndrome and an ipsilateral carotid stenosis of 50%.

07. Definite fatal congestive heart failure (**Please fill out the HF PROCEDURE FORM**)

Two major criteria or one major and two minor criteria:

a. Major criteria
- [ ] i. Paroxysmal nocturnal dyspnea or Orthopnea
- [ ] ii. Neck vein distention
- [ ] iii. Rales
- [ ] iv. Cardiomegaly
- [ ] v. Acute pulmonary edema
- [ ] vi. S3 gallop
- [ ] vii. Increased venous pressure >16cm water
- [ ] viii. Circulation time ≥ 25 seconds
- [ ] ix. Hepatojugular reflux

b. Minor criteria
- [ ] i. Ankle edema
- [ ] ii. Night cough
- [ ] iii. Dyspnea on exertion
- [ ] iv. Hepatomegaly
- [ ] v. Pleural effusion
- [ ] vi. Vital capacity reduced by one-third from maximum
- [ ] vii. Tachycardia (rate of ≥ 120/min.)

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure

08. Possible fatal congestive heart failure

[ ] Death certificate or medical records with consistent underlying or immediate cause, but neither autopsy evidence nor adequate pre-terminal documentation of the event.

09. Other fatal cardiovascular diseases

[ ] i. Death certificate or medical records with consistent underlying or immediate Cause. Check that applies.

[ ] ii When death certificates are the only source of information: ICD9: 390 to 398, 402, 404 to 429; ICD 10: I00 to I09, I11, I13, I20 to I25, I27, I30 to I52. Check that applies.

ICD – 9	**ICD – 10**	**Disease**	
390-392	I00-I02	Acute rheumatic fever	[ ]
393-398	I05-I09	Chronic rheumatic heart disease	[ ]
402	I11	Hypertensive heart disease	[ ]
404-405		Hypertensive disease	[ ]
410-414	I20-I25	Ischemic heart disease	[ ]
415-417		Diseases of pulmonary circulation	[ ]
420-429		Other forms of heart disease	[ ]
429.2		Cardiovascular disease, unspecified	[ ]
431-437		Cerebrovascular disease	[ ]
799		Ill-defined or unknown	[ ]
	I13	Hypertensive heart and renal disease	[ ]
	I27	Other pulmonary heart disease	[ ]
	I30-I52	Other forms of heart disease	[ ]
443.9	I73.9	Peripheral vascular disease	[ ]

Comment: _____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
month day year

Coordinating Center Use Only

Reviewer:
First review |___|1 Second review |___|2 Stroke review |___|3 Adjudication |___|9

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

SUPPLEMENTAL STROKE FORM - Mortality and Morbidity Surveys
(Complete for mortality codes 5 or 6 and morbidity codes 3, 4 or 8)

ID number: |___|___|___|___|___|___|___|___|

Date of this event: |___|___|/|___|___|/|___|___|___|___|
Month day year

A. ISCHEMIC STROKE LOCATION

		YES	NO
1.	Right hemisphere	|___|1	|___|2
2.	Left hemisphere	|___|1	|___|2
3.	Basilar	|___|1	|___|2
4.	Hemispheric and Basilar	|___|1	|___|2
5.	Unknown	|___|1	|___|2

B. BRAIN IMAGING

6. *HEAD CT*

	Yes	|___|1
	No (go to Q 7)	|___|2
	Yes, but no report	|___|3
6.1 If yes, timing of Head CT	<48 h since symptom onset	|___|1
	≥48 h since symptom onset	|___|2
	Unknown	|___|9

7. *BRAIN MRI*

Yes	|___|9
No (go to Q 8)	|___|9
Yes, but no report	|___|9

C. NEUROVASCULAR IMAGING

8. *CAROTID DUPLEX* |___|9

No (go to Q 9)	|___|2
Yes, but no report	|___|3

9.	*TRANSCRANIAL DOPPLER (TCD)*	Yes	|___|1
		No, (go to Q 10)	|___|2
		Yes, but no report	|___|3
10.	*MAGNETIC RESONANCE ANGIOGRAPHY* (*MRA)*	Yes	|___|1
		No (go to Q 11)	|___|1
		Yes, but no report	|___|1
11.	*CT ANGIOGRAPHY*	Yes	|___|1
		No (go to Q 12)	|___|1
		Yes, but no report	|___|1
12.	*ANGIOGRAPHY*	Yes	|___|1
		No, (go to Q 13)	|___|1
		Yes, but no report	|___|1

D. STROKE DEFICIT

13. MODIFIED RANKIN SCALE (0-5) |___|
(Code Maximal Severity Within 7 Days of Stroke)

0 = no symptoms at all
1 = no significant disability despite symptoms: able to carry out all usual duties and activities
2 = slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
3 = moderate disability: requiring some help, but able to walk without assistance
4 = moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance
5 = severe disability: bedridden, incontinent, and requiring constant nursing care and attention
9 = information insufficient for coding

E. STROKE TREATMENT

14.	Intravenous thrombolysis	Yes	|___|1
		No	|___|1
15.	Presentation within 3 hours from symptom onset	Yes	|___|1
		No	|___|1
F.	**BRAIN EXAMINATION AT AUTOPSY**	Yes	|___|1
		No	|___|1
		Yes, but no report	|___|1

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

Review date: |___|___|/|___|___|/|___|___|___|___|
Month day year

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORTALITY SURVEY
INFORMANT INTERVIEW

ID number: |___|___|___|___|___|___|___|

A. DECEDENT (*Completed by study center staff prior to interview.)*

1. Name: _____
   Last First Middle

2. Date of death: |___|___|/|___|___|/|___|___|___|___|
   month day year

B. RECORD OF CALLS or HOME VISIT TO COMPLETE INTERVIEW

DATE (mo/day/yr)	TIME (24 hr clock)	Method of contact 1=Phone 2=Home Visit 3=Other	Contact successful 1=Yes 2=No	Interview Completed 1=Yes 2=No 9=Refused
1) _____	_____	_____	_____	_____
2) _____	_____	_____	_____	_____

C. Person Providing Information (*Completed by study center staff prior to interview.)*

3. a. Name: _____
   Last First Middle

   b. Address: _____

   c. Telephone: ( ) _____

4. Before we get started, could you please tell me what was your relationship to the deceased?

   You are the _____ of the deceased.

5. What did the patient die from?

   _____

6. Were you present when he/she died?

   Yes |___|1 (Go to Q8) No |___|2 Unknown |___|9

7. If no, how long before he/she died did you last see him/her?

1 hour or less	|___|1	More than 24 hours	|___|3
24 hours or less	|___|2	Unknown	|___|9

8. Do you know of anyone else who may have been present at about the time of his/her death?

Yes |___|1 No |___|2 Unknown |___|9

If yes can you give me that person's name and contact information:
Contact information_____
_____
_____

9. Please describe the events that occurred at the time of death, specifically, did he/she manifest any of the following conditions: chest pain, shortness of breath, agitation, sudden collapse or loss of consciousness, sudden weakness, slurred speech, etc. Please tell me what you know of his/her general health, health on the day he/she died, and of the death itself. This information will be reviewed by a physician and will help to better understand the cause of your loved one's death. ***(Record summary verbatim and ask pertinent questions when appropriate attach additional sheet if needed)*** Probing Questions: Are you aware of any illnesses the individual had prior to death? If yes – how long did the person have the illness? Was the individual involved in any accidents or trauma prior to death? If yes – what type and how long prior to death.

The next set of questions deal specifically with the last episode of pain or discomfort that occurred before his/her death. This is defined as starting at the time you noticed discomfort that caused him/her to stop or change what he/she was doing. ***NOTE TO INTERVIEWERS: If the informant has already answered these questions in the description of circumstances, just fill out the correct answer(s) as noted below.*** **Respect the informant's wishes about continuing the interview and record answers to as many of the following questions as possible.**

10. Did his/her last episode of pain or discomfort specifically involve the chest?
Yes |___|1 No |___|2 Unknown |___|9

11. Did he/she experience pain or discomfort in his/her chest, left arm or shoulder or jaw either just before death or within 3 days (72 hours) of death?
Yes |___|1 No |___|2 Unknown |___|9
(If NO or Unknown go to Q15)

12. Did he/she take nitroglycerine because of this last episode of pain or discomfort?
Yes |___|1 No |___|2 Unknown |___|9

13. Did he/she take any other medicine for chest discomfort prior to death? Yes_____ No____
If yes what?_____

14. How long was it from the beginning of his/her last episode of pain or discomfort to the time he/she stopped breathing on his/her own? ***(use the shortest interval known to be true)***

5 minutes or less	|___|1	24 hours or less	|___|4
10 minutes or less	|___|2	More than 24 hours	|___|5
1 hour or less	|___|3	Unknown	|___|9

15. Did he/she ever have dialysis for kidney failure? Yes |___|1 No |___|2 Unknown |___|9

a. If yes, what year did he/she start dialysis? |___||___||___||___|

b. How many times per week did he/she receive dialysis? |___||___|

c. Did he/she stop dialysis before death? Yes |___|1 No |___|2 Unknown |___|9

If yes, how long before death? |___||___|/ |___||___|/ |___||___|
days months years

16. Within 3 days of death, or just before he/she died, did any of the following symptoms begin for the first time or did the patient complain of any of these symptoms:

		Yes	No	Unknown
a.	Shortness of breath?	|___|1	|___|2	|___|9
b.	Dizziness?	|___|1	|___|2	|___|9
c.	Palpitations (pounding in the chest)?	|___|1	|___|2	|___|9
d.	Marked or increased fatigue, tiredness, or weakness?	|___|1	|___|2	|___|9
e.	Headache?	|___|1	|___|2	|___|9
f.	Sweating?	|___|1	|___|2	|___|9
g.	Paralysis?	|___|1	|___|2	|___|9

h.	Loss of speech?	|___|1	|___|2	|___|9
i.	Attack of heartburn or indigestion or abdominal discomfort?	|___|1	|___|2	|___|9
j.	nausea or vomiting?	|___|1	|___|2	|___|9
k.	Other? specify: _____	|___|1	|___|2	|___|9

<u>These next questions are about his/her medical history</u>
<u>Please provide as much information as possible</u>

17. Before his/her final illness, had he/she ever had pains in the chest from heart disease, for example, angina pectoris?
Yes |___|1 No |___|2***(If no, go to Q20?)*** Unknown |___|9

18. Did he/she ever take nitroglycerin for this pain?
Yes |___|1 No |___|2 Unknown |___|9

19. Any other medications such as aspirin, tums or other antacids?
Yes |___|1 No |___|2 Unknown |___|9

20. Did he/she ever have any of the following medical condition or procedures before his/her final illness?

		Yes	No	Unknown
a.	heart attack?	|___|1	|___|2	|___|9
b.	stroke?	|___|1	|___|2	|___|9
c.	heart failure?	|___|1	|___|2	|___|9
d.	any other heart disease or heart condition If yes, specify:_____	|___|1	|___|2	|___|9
e.	coronary bypass surgery (CABBAGE)	|___|1	|___|2	|___|9
f.	coronary angioplasty (balloon angioplasty)	|___|1	|___|2	|___|9
g.	insertion of pace maker (defibrillator)	|___|1	|___|2	|___|9
h.	any other heart surgery?	|___|1	|___|2	|___|9

The next few questions are about his/her health in the <u>year</u> prior to death

21. Was he/she hospitalized or taken to a clinic

	Yes	No	Unknown
In the year prior to death?	|___|1	|___|2	|___|9
In the month prior to death?	|___|1	|___|2	|___|9
In the 7 days prior to death?	|___|1	|___|2	|___|9

22. Were any hospitalizations for heart attack or chest pain?
Yes |___|1 No |___|2 Unknown |___|9

23. Was a hospitalization for heart surgery? Yes |___|1 No |___|2 Unknown |___|9

24. What was the date of the ***<u>last</u>*** hospital admission? |___|___|/|___|___|/|___|___|___|___|
(If unknown, draw two lines across the boxes) month day year

If the information in questions 25- 28 is already known to you, skip to Q29.

25. Can you tell me the name and location of the hospital? ***(If unknown, check the box.)*** |___|
a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

26. Was he/she seen by a physician anytime in the year prior to death?
Yes |___|1 No |___|2 Unknown|___|9

27. Can you tell me the name and address of this physician or healthcare facility? |___|
IHS only

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

28. Can you tell me the name and address of his/her usual physician?
If same as Q27, check here. |___|

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

29. Now, think back to about <u>one month</u> before he/she died. At that time, was he/she sick or ill; were his/her activities limited, or was he/she normally active for the most part?

Sick/ill/limited activities |___|1 Normally active |___|2 Unknown |___|9

30. Was he/she being cared for at a nursing home or at another place at the time of death?
Yes, nursing home, specify |___|1_____
Yes, at home |___|2
Yes, other, specify |___|3 _____
No |___|4
Unknown |___|9

The next few questions are concerned specifically with emergency medical care he/she may have received just prior to or at the time of death.

31. Was he/she taken to a hospital/clinic in the week before his/her death? Yes |___|1 No |___|2

32. If Yes, could you tell me the name and location of this facility:

a. Name: _____

b. Address: _____

City/town: _____

State-Zip: _____

33. Is there someone else whom we could contact, who might know more about the circumstances surrounding his/her death or his/her usual state of health?

Yes |___|1 No |___|2 Unknown |___|9

(If Yes, complete the front of the second Informant Interview)

34. Did informant provide consent to gather further information?

Yes |___|1 No |___|2 Not applicable |___|3

(If Yes, ask the informant to sign the consent form for us to review the decedent's medical records)

35. How reliable was the participant in completing the questionnaire?

Very reliable |___|1 Reliable |___|2 Unreliable |___|3 Very unreliable |___|4 Uncertain |___|5

ADMINISTRATIVE INFORMATION:

36. Interviewer code: |___|___|___|

37. Interview date: |___|___|/|___|___|/|___|___|___|___|

month day year
