Data Collection Forms

THE STRONG HEART STUDY – VI

CONTACT AND MEDICAL HISTORY

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

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)* MEDHX6_14

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.	MEDHX6_15	City: MEDHX6_16	|___| MEDHX6_17
b.	MEDHX6_18	City: MEDHX6_19	|___| MEDHX6_20

16. What is your current weight: MEDHX6_21 |___|___|___| Pounds Current height MEDHX6_22 |___| / MEDHX6_23 |___|___| Feet Inches

17. Do you have arthritis? **Y=Yes, N=No, U=Unknown** MEDHX6_24 Y|___|N|___|U|___|
If yes, have you been told if it is rheumatoid arthritis? MEDHX6_25 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.**

MEDHX6_26 a. Asthma	Y|___|N|___|U|___|	f. Liver disease	MEDHX6_31 Y|___|N|___|U|___|
MEDHX6_27 b. Lung disease	Y|___|N|___|U|___|	g. Gout	MEDHX6_32 Y|___|N|___|U|___|
MEDHX6_28 c. Retinopathy/diabetes eye problem	Y|___|N|___|U|___|	h. Kidney stones	Y|___|N|___|U|___| MEDHX6_33
MEDHX6_29 d. Are you currently on dialysis	Y|___|N|___|U|___|	i. Lupus/scleroderma	Y|___|N|___|U|___| MEDHX6_34
MEDHX6_30 e. Have you had a kidney transplant	Y|___|N|___|U|___|	j. Diabetes/prediabetes	Y|___|N|___|U|___| MEDHX6_35

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

MEDHX6_36

j1. Insulin Y|___|N|___|U|___|

j2. Dietary and/or exercise Y|___|N|___|U|___|

MEDHX6_37

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

MEDHX6_38

j4. No Treatment Y|___|N|___|U|___|

MEDHX6_39

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

MEDHX6_40

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

MEDHX6_41

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

MEDHX6_42

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

MEDHX6_43

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

Hospital/Clinic:_____ City:_____

MEDHX6_44

MEDHX6_45

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

MEDHX6_46

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

Hospital/Clinic:_____ City:_____

MEDHX6_47

MEDHX6_48

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

MEDHX6_49

Hospital/Clinic/other facility:_____ City:_____

MEDHX6_450

MEDHX6_51

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)

MEDHX6_52

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

MEDHX6_53 a. |___| Breast
MEDHX6_54 b. |___| Ovary/uterus
MEDHX6_56 c. |___| Prostate
MEDHX6_63 d. |___| Lung
MEDHX6_55 e. |___| Colon/Rectum
MEDHX6_57 k. |___| Other, not on this list:_____

f. |___| Kidney/Bladder
g. |___| Liver
h. |___| Mouth / Throat
i. |___| Melanoma and/or Skin cancer
j. |___| Blood or immune system

MEDHX6_58
MEDHX6_59
MEDHX6_60
MEDHX6_62
MEDHX6_64
MEDHX6_61

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

_____ City:_____

MEDHX6_65

MEDHX6_66

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

MEDHX6_67

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

MEDHX6_68

MEDHX6_69

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

MEDHX6_70

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

MEDHX6_71

MEDHX6_72

Female Participant only:

24. How many pregnancies have you had? |___|___| MEDHX6_73

25. How many live births have you had? |___|___| MEDHX6_74

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

Y|___|N|___|U|___| MEDHX6_75

If yes, when? MEDHX6_76a |___|___| / |___|___|___|___| MEDHX6_76b
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:

MEDHX6_78 a. pre-eclampsia (toxemia) Y|___|N|___|U|___| d. diabetes (gestational diabetes) Y|___|N|___|U|___| MEDHX6_81

MEDHX6_79 b. high blood pressure Y|___|N|___|U|___|

MEDHX6_80 c. high blood pressure along with protein in your urine Y|___|N|___|U|___|

Please provide date of delivery for first pregnancy: |___|___| / |___|___| / |___|___|___|___| MEDHX6_82
Month Day Year

Hospital of delivery: MEDHX6_83 _____ City: MEDHX6_84 _____

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

Y|___|N|___|U|___| MEDHX6_85

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

Date of delivery: |___|___| / |___|___| / |___|___|___|___| MEDHX6_86
Month Day Year

Hospital of delivery: MEDHX6_87 _____ City: MEDHX6_88 _____

Check all complications that occurred:

MEDHX6_89 a. pre-eclampsia (toxemia) Y|___|N|___|U|___| d. diabetes (gestational diabetes) Y|___|N|___|U|___| MEDHX6_92

MEDHX6_90 b. high blood pressure Y|___|N|___|U|___|

MEDHX6_91 c. high blood pressure along with protein in your urine Y|___|N|___|U|___|

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

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

THE STRONG HEART STUDY – VI

Diabetes Ascertainment

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

14. |___| Diagnosis of diabetes established by prior SHS or SHSS exam, 1=Yes (skip to Q9), 2=No DIAB6_1
15. |___| No medical records available, 1=Yes (skip to Q9), 2=No DIAB6_2
16. Diagnosis made by the abstractor (check all that apply)

    |___| Diabetes DIAB6_3a

    |___| Gestational diabetes only (skip to Q9) DIAB6_3b

    |___| Diabetes not mentioned in medical records (skip to Q9) DIAB6_3c

    |___| Diabetes mentioned but no supporting evidence in medical records DIAB6_3d

17. Date of first mention of diabetes (not gestational diabetes) |___|___|/|___|___|/|___|___|___|___| DIAB6_4
    Month Day Year
18. FASTING PLASMA GLUCOSE ≥ 126 mg/dL
    First FPG ≥ 126 mg/dL DIAB6_5a _____ mg/dL DIAB6_5b _____ Date (mm/yyyy) DIAB6_5c ____ N/A
19. HEMOGLOBIN A1c ≥ 6.5%
    First A1c ≥ 6.5% DIAB6_6a _____ % DIAB6_6b _____ Date (mm/yyyy) DIAB6_6c ____ N/A
20. 2-HOUR PLASMA GLUCOSE DURING OGTT ≥ 200 mg/dL
    First 2-H PG ≥ 200 mg/dL DIAB6_7a _____ mg/dL DIAB6_7b _____ Date (mm/yyyy) DIAB6_7c ____ N/A
21. Treatment for diabetes. Check all that apply
    DIAB6_8a DIAB6_8b DIAB6_8c DIAB6_8d DIAB6_8e
    |___| Insulin |___| Oral agents |___| Dietary and/or exercise |___| None |___| Unknown

22. SHS staff code: REV_CODE |___|___|___|
23. Abstraction date: REV_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	_____	_____	_____

THE STRONG HEART STUDY VI
CARDIOVASCULAR DISEASE IN AMERICAN INDIANS

MORBIDITY SURVEY – DECISION

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

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

A. DIAGNOSIS (enter appropriate code number):

01. Definite non-fatal myocardial infarction |___|___| DF6_1

1b. Probable non-fatal myocardial infarction |___|___| DF6_2

02. Possible non-fatal myocardial infarction |___|___| DF6_3

03. Definite non-fatal stroke |___|___| DF6_4

04. Possible non-fatal stroke |___|___| DF6_5

06. Definite CHD |___|___| DF6_6

07. Possible CHD (those with some, but not all, criteria or with equivocal criteria for definite CHD) |___|___| DF6_7

08. TIA |___|___| DF6_8

09. Other CVD, specify: _____ |___|___| DF6_9

10. Non–CVD, specify: _____ |___|___| DF6_10

11. ESRD (dialysis or transplant): _____ |___|___| DF6_11

12. Heart Failure (**Please fill out the HF PROCEDURE FORM**) |___|___| DF6_12

B. Criteria used:

1. MYOCARDIAL INFARCTION (Please check all applicable criteria)

A. Definite MI |___| DF6_13

1. Evolving diagnostic ECG*, or |___| DF6_14
2. Diagnostic biomarkers (2 x ULN)* |___| DF6_15

B. Probable MI |___| DF6_16

1. Positive ECG findings plus cardiac symptoms or signs without available biomarkers, or |___| DF6_17
2. Positive ECG findings plus equivocal biomarkers |___| DF6_18

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

C. Possible MI |___| DF6_19

1. Equivocal biomarkers plus nonspecific ECG findings, or |___| DF6_20
2. Equivocal biomarkers plus cardiac symptoms or signs, or |___| DF6_21
3. Missing biomarkers plus positive ECG |___| DF6_22

**** For ECG and cardiac biomarker definition, please refer to: SHS VI Manual, Section 2.3.*** DF6_23

COMMENTS: _____

_____

_____

2. STROKE

A. Definite non-fatal stroke |___| DF6_24

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. |___| DF6_25
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. |___| DF6_26
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. |___| DF6_27
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. |___| DF6_28
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. |___| DF6_29
6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery. |___| DF6_30

B. Possible non-fatal stroke |___| DF6_31

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 |___| DF6_32

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 |___| DF6_33

2a. Discharge diagnosis with consistent primary or secondary codes (ICD-9-CM codes 431, 432, 434, 436, 437), and |___| DF6_34

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. |___| DF6_35

C. Ischemic stroke subtype classification (complete for cases of definite ischemic stroke). DF6_36

[ ] 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 |___| DF6_36a *Possible |___| DF6_36b

[ ] 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. DF6_37

*Probable |___| DF6_37a *Possible |___| DF6_37b

[ ] 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. DF6_38

*Probable |___| DF6_38a *Possible |___| DF6_38b

* 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. DF6_39

[ ] 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%. DF6_39a

COMMENTS: DF6_40 _____

_____

_____

3. DEFINITE CORONARY HEART DISEASE (CHD)

a. Cardiac cath proven coronary artery disease (1 or more vessels ≥ 50% stenosis), ***or*** |___| DF6_40

b. PTCA, ***or*** |___| DF6_42

c. Coronary artery bypass grafting, ***or*** |___| DF6_43

d1. Abnormal stress ECG, **and** |___| DF6_44

d.2. Abnormal imaging, ***or*** |___| DF6_45

e. Positive functional test of ischemia (such as treadmill) |___| DF6_46

COMMENTS: DF6_47 _____

_____

_____

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 DF6_48
- [ ] ii. Neck vein distention DF6_49
- [ ] iii. Rales DF6_50
- [ ] iv. Cardiomegaly DF6_51
- [ ] v. Acute pulmonary edema DF6_52
- [ ] vi. S3 gallop DF6_53
- [ ] vii. Increased venous pressure >16cm water DF6_54
- [ ] viii. Circulation time ≥ 25 seconds DF6_55
- [ ] ix. Hepatojugular reflux DF6_56

b. Minor criteria
- [ ] i. Ankle edema DF6_57
- [ ] ii. Night cough DF6_58
- [ ] iii. Dyspnea on exertion DF6_59
- [ ] iv. Hepatomegaly DF6_60
- [ ] v. Pleural effusion DF6_61
- [ ] vi. Vital capacity reduced by one-third from maximum DF6_62
- [ ] vii. Tachycardia (rate of ≥ 120/min.) DF6_63

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment DF6_64

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure DF6_65

COMMENTS: DF6_66 _____

_____

_____

5. OTHER NON-FATAL CARDIOVASCULAR DISEASE

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

- [ ] b. CHF secondary to ESRD (diagnosis = 10) DF6_67
- [ ] c. Cardiomyopathy DF6_68
- [ ] d. Valvular Heart Disease DF6_69
- [ ] e. Left Ventricular Hypertrophy DF6_70
- [ ] f. Atrial Fibrillation DF6_71
- [ ] g. Non-coronary heart surgery or carotid or other vascular surgery (does not include procedures for PVD) DF6_72
- [ ] h. Pacemaker implantation DF6_73
- [ ] i. Positive non-coronary angiography (does not include procedures for PVD) DF6_74
- [ ] j. Arrhythmia DF6_75
- [ ] k. Angina pectoris (Class 2 chest pain, or relieved by nitroglycerides; diagnosis = 07) DF6_76
- [ ] l. PVD (either peripheral arterial surgical procedures, angiogram or amputation) DF6_77
- [ ] m. Aortic aneurysm DF6_78

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

COMMENTS: DF6_79

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___| REV_CODE

Review date: |___|___|/|___|___|/|___|___|___|___| REV_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

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

ADMINISTRATIVE INFORMATION:

34. Reviewer code |___|___|___|

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

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 – FINAL DECISION

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

Date of death: |___|___|/|___|___|/|___|___|___|___| DOD (month / day / year) Age at death: |___|___| AOD

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

Cause of death: |___|___| FD6_1

Contributory cause of death 1: |___|___| FD6_2

Contributory cause of death 2: |___|___| FD6_3

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: FD6_4

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

Evidence Code: (up to 3 Codes) |___|___| FD6_5 |___|___| FD6_6 |___|___| FD6_7

21 = Malignant neoplasm; primary site: FD6_8
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: FD6_10
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: FD6_9

Was the death alcohol related? Yes |___|1 No |___|2 Unknown |___|9 FD6_11

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

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 FD6_12

1.	Evolving diagnostic ECG*, or	|___|1	|___|2	FD6_13
2.	Diagnostic biomarkers (2 x ULN)*	|___|1	|___|2	FD6_14

OR

[ ] 1(b) Acute MI diagnosed by autopsy FD6_15

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. FD6_16

1a. Probable fatal MI

[ ] 1. Death within 28 days of hospital admission, cases defined as: FD6_26

		Yes	No	
1a.	Positive ECG findings plus cardiac symptoms or signs Without biomarkers, or	|___|1	|___|2	FD6_27
1b.	Positive ECG findings plus equivocal biomarkers	|___|1	|___|2	FD6_28

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 FD6_29

**** 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. FD6_30

AND

[ ] 2. No documentation of acute MI within 4 weeks prior to death. FD6_31

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. FD6_32

03. Definite fatal CHD

[ ] 1. Death certificate with consistent underlying or immediate causes, **AND** FD6_33
[ ] 2. No documentation of definite acute MI within 4 weeks prior to death, **AND** FD6_34
[ ] 3. Criteria for sudden death not met (above), **AND** FD6_35
[ ] 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, FD6_36

AND

[ ] 5(a) Previous history of MI according to relative, physician, or hospital records, FD6_37
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.), FD6_38
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), FD6_39
OR
[ ] 5(d) Angiogram reporting severe (≥ 50% narrowing) atherosclerotic coronary artery disease, FD6_40
OR
[ ] 5(e) Other positive physical signs or lab findings. FD6_41

04. Possible fatal CHD

[ ] 1. No documentation by criteria of definite acute MI within 4 weeks prior to death, FD6_42
AND
[ ] 2. No documentation by criteria of definite sudden death, FD6_43
AND
[ ] 3. No documentation by criteria of definite fatal CHD, FD6_44
AND
[ ] 4. Death certificate with consistent underlying or immediate cause, FD6_45
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. FD6_46

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

[ ] 1a. Cerebral infarction or hemorrhage diagnosed at autopsy, FD6_47
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, FD6_48
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, FD6_49

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, FD6_50

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, FD6_51

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, FD6_52

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. FD6_53

OR

[ ] 3. Focal neurological deficit and death within 24 hours, without MRI or other diagnostic image. FD6_54

<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. FD6_55

[ ] 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. FD6_56

[ ] 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. FD6_57

[ ] 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. FD6_58

[ ] 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. FD6_59

[ ] 6. Non-fatal stroke post non-cardiovascular surgery: Stroke occurring within 30 days of non-cardiovascular surgery. FD6_60

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. FD6_61

*Probable |___| FD6_61a *Possible |___| FD6_61b

[ ] 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. FD6_62

*Probable |___| FD6_62a *Possible |___| FD6_62b

[ ] 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. FD6_63

*Probable |___| FD6_63a *Possible |___| FD6_63b

* 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. FD6_64

[ ] 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%. FD6_65

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 FD6_66
- [ ] ii. Neck vein distention FD6_67
- [ ] iii. Rales FD6_68
- [ ] iv. Cardiomegaly FD6_69
- [ ] v. Acute pulmonary edema FD6_70
- [ ] vi. S3 gallop FD6_71
- [ ] vii. Increased venous pressure >16cm water FD6_72
- [ ] viii. Circulation time ≥ 25 seconds FD6_73
- [ ] ix. Hepatojugular reflux FD6_74

b. Minor criteria
- [ ] i. Ankle edema FD6_75
- [ ] ii. Night cough FD6_76
- [ ] iii. Dyspnea on exertion FD6_77
- [ ] iv. Hepatomegaly FD6_78
- [ ] v. Pleural effusion FD6_79
- [ ] vi. Vital capacity reduced by one-third from maximum FD6_80
- [ ] vii. Tachycardia (rate of ≥ 120/min.) FD6_81

c. Major or minor criteria
- [ ] i. Weight loss > 4.5kg in 5 days in response to treatment FD6_82

AND

d. [ ] No known non-cardiac process leading to fluid overload such as renal failure FD6_83

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. FD6_84

09. Other fatal cardiovascular diseases

[ ] i. Death certificate or medical records with consistent underlying or immediate Cause. Check that applies. FD6_85

[ ] 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. FD6_86

ICD – 9	ICD – 10	Disease	
390-392	I00-I02	Acute rheumatic fever	[ ] FD6_87
393-398	I05-I09	Chronic rheumatic heart disease	[ ] FD6_88
402	I11	Hypertensive heart disease	[ ] FD6_89
404-405		Hypertensive disease	[ ] FD6_90
410-414	I20-I25	Ischemic heart disease	[ ] FD6_91
415-417		Diseases of pulmonary circulation	[ ] FD6_92
420-429		Other forms of heart disease	[ ] FD6_93
429.2		Cardiovascular disease, unspecified	[ ] FD6_94
431-437		Cerebrovascular disease	[ ] FD6_95
799		Ill-defined or unknown	[ ] FD6_96
	I13	Hypertensive heart and renal disease	[ ] FD6_97
	I27	Other pulmonary heart disease	[ ] FD6_98
	I30-I52	Other forms of heart disease	[ ] FD6_99
443.9	I73.9	Peripheral vascular disease	[ ] FD6_100

Comment: FD6_101 _____

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___| REV_CODE

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

Coordinating Center Use Only

Reviewer: REV_NO
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
