THE STRONG HEART STUDY VII
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

If you have any comments on this case, please use the space below:

THE STRONG HEART STUDY VII
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 VII
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 VII
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

THE STRONG HEART STUDY VII

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 ☐ 4

If you have any comment on this case, please use the space below:

THE STRONG HEART STUDY VII
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.

_____

_____

_____

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_____

_____

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

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

16. <u>Within 3 days of death</u>, 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 ***last*** 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 |___|2 No

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

THE STRONG HEART STUDY VII
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	|___|3

7. *BRAIN MRI*

Yes	|___|1
No (go to Q 8)	|___|2
Yes, but no report	|___|3

C. NEUROVASCULAR IMAGING

8. *CAROTID DUPLEX*

Yes	|___|1
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)	|___|2
		Yes, but no report	|___|3
11.	*CT ANGIOGRAPHY*	Yes	|___|1
		No (go to Q 12)	|___|2
		Yes, but no report	|___|3
12.	*ANGIOGRAPHY*	Yes	|___|1
		No, (go to Q 13)	|___|2
		Yes, but no report	|___|3

D. STROKE DEFICIT

13. MODIFIED RANKIN SCALE (0-6) |___|
(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
6 = death
9 = information insufficient for coding

E. STROKE TREATMENT

14.	Intravenous thrombolysis	Yes	|___|1
		No	|___|2
15.	Presentation within 3 hours from symptom onset	Yes	|___|1
		No	|___|2
F.	**BRAIN EXAMINATION AT AUTOPSY**	Yes	|___|1
		No	|___|2

Yes, but no report |___|3

ADMINISTRATIVE INFORMATION:

Reviewer code: |___|___|___|

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

If you have any comments on this case, please use the space below: