THE STRONG HEART STUDY
Cardiovascular Disease in American Indians
(Phase II)

Operational Manual
Volume Two
Personal Interview and General Examination

July 1, 1993

For copies, please contact
Strong Heart Study Coordinating Center
Center for Epidemiologic Research
University of Oklahoma Health Sciences Center
P.O. Box 26901
Oklahoma City, OK 73190
# VOLUME II
PERSONAL INTERVIEW AND GENERAL EXAMINATION

Table of Contents

1. Clinical Examination
   1.1 Introduction .......................................................... 1
   1.2 Components of the Clinical Examination, Endpoints
       and Risk Factors .................................................. 2
       1.2.1 Components of Clinical Examination .................. 2
       1.2.2 Endpoints and Risk Factors .......................... 4
   1.3 Recruiting ........................................................... 17
   1.4 Personal Interview ................................................ 18
       1.4.1 Components of Personal Interview .................. 18
       1.4.2 Guidelines for Interviewers ......................... 18
       1.4.3 Training & Quality Control of Interviewers .... 25
   1.5 Rationale for Measurements .................................... 26
       1.5.1 Blood Pressure .............................................. 26
       1.5.2 Measurement of Body Fat ............................... 26
       1.5.3 Anthropometric Measurements ....................... 27
       1.5.4 Measurements of Peripheral Vascular Disease .... 27
       1.5.5 Examination of the Heart, Lungs, Carotids
           and Neck Veins .............................................. 28
       1.5.6 Electrocardiograms ....................................... 29
       1.5.7 Overview of Laboratory Measurements ............... 29
   1.6 Procedure for Glucose Tolerance Test (GTT) .................. 36
   1.7 General Physical Examination .................................. 37
       1.7.1 Anthropometry .............................................. 37
       1.7.2 Training and Certification for Anthropometry .... 40
       1.7.3 Sitting Blood Pressure .................................... 41
       1.7.4 Ankle Systolic Blood Pressure ......................... 49
       1.7.5 Electrocardiogram ......................................... 51
1. Clinical Examination - General

1.1 INTRODUCTION

Tribal members who have resided in one of the study communities for at least 6 months and who are between 45 and 74 years of age during the examination phase were invited to participate in the Phase I physical examination. Persons who are institutionalized were excluded. All those who participated in the Phase I exam are eligible for the Phase II exam. This component of the study consists of a personal interview, a limited physical examination and laboratory tests. The objectives are to estimate the prevalence of CVD and its risk factors and to assess the degree of association between the risk factors and CVD.

The examination will be conducted at local IHS hospitals and clinics. In the Dakotas, it will be performed at the Aberdeen Area IHS hospitals and clinics on three reservations. In Phoenix, the IHS hospital at Sacoton (GRIC), the IHS outpatient clinic at Salt River (SRIC) and the outpatient clinical AkChin will be the examination sites. In Oklahoma, the IHS hospital in Lawton and the IHS clinic in Anadarko will provide space and facilities for the examination.

The objective of the Strong Heart Study and the examination procedures will be explained to the participants. A consent form will be signed by each participant. Appendix 1 gives an example of the consent form.

All examinations are performed by trained personnel, nurse practitioners, registered nurses, medical students, physician assistants or physicians. All examination items are within the scope of training that these providers have received and are usual, if not daily, parts of physical examinations. Detailed descriptions and training are aimed at achieving consistency from examination to examination, and among centers. This is the main goal of this component of the protocol.

The training of the registered nurses, nurse practitioners, medical students, physician assistants and physicians on the Phase II protocol occurred on April 22, 1989 at the Black Hills Training Center, Rapid City, S.D. and is based on the written protocol. Each Study Center has designated a primary examiner and at least one other person who is available to perform examinations in the absence of this primary person.

Certification requires adequate performance of the components of the examination as validated during training. In case of loss of a center's staff member, a replacement may be trained locally by someone certified in the procedure(s). The same certification requirements as used in the initial training must be met. Quality control focuses on the potential for false positive examinations. Because most participants are healthy, the frequency of abnormal findings is relatively small. The presence of real abnormalities
among those with normal examinations is also small (a low false negative rate), and this makes it inefficient to re-examine the many individuals with normal findings. The review of positive findings is part of the medical data review. After the initial training, continuing education includes regular review of the protocol.

1.2 COMPONENTS OF THE CLINICAL EXAMINATION, ENDPOINTS AND RISK FACTORS

1.2.1 Components of the Clinical Examination

The clinical examination has two parts: a personal interview and a physical examination.

1. **Personal Interview**

The following questionnaires will be administered.

(1) Demographic information, personal habits including smoking, alcohol and beverage consumption, stress and acculturation.

(2) Medical history, including Rose questionnaire for angina pectoris and intermittent claudication.

(3) Dietary survey

2. **Physical Examination**

The physical examination includes the following procedures:

(1) Anthropometric measurements
   (a) Weight
   (b) Height
   (c) Waist and hip circumferences
   (d) Body fat measurement using an impedance meter
   (e) Arm circumference (for blood pressure measurements)

(2) Examination of the following
   (a) Lungs
   (b) Pulses - posterior tibial and dorsalis pedal
   (c) Bruits - Carotid and femoral

(3) Blood Pressure Measurements:
   (a) Sitting with conventional sphygmomanometer(3 times) -right arm
   (b) Right brachial and both ankles using doppler in supine position
(4) Twelve-lead ECG measurement

(5) Glucose Tolerance Test (GTT). The GTT will be given to participants excluding the following:

(a) Insulin requiring diabetics
(b) Diabetics who are on oral agents and the previous record indicated at least two values of random blood glucose above 250 mg/dl, or fasting glucose 225 mg/dl. by One Touch.
(c) Non-diabetics with a fasting glucose 225 mg/dl. by One Touch.

(6) Fasting blood samples for measurements of total triglyceride and cholesterol, LDL and HDL Cholesterol, VLDL Cholesterol and TG, Plasma Fibrinogen, and PAI-1, RBC type, and DNA isolation, glucose, creatinine, insulin, and HbA1c. No fasting blood samples will be taken from patients who are on renal dialysis or have had a kidney transplant, except tubes for isolation of DNA assay and RBC type.

(7) Urine collection at beginning of physical examination for measurement of albumin and creatinine.

(8) Peripheral sensitivity as measured by monofilaments.

(9) Echocardiography

(10) Gallbladder ultrasound

(11) Pulmonary function test

(12) Tuberculin skin testing

(13) Coccidiomycosis skin testing (Arizona only)

The IHS medical records will also be reviewed to determine whether the participant experienced hospitalization for stroke, myocardial infraction, in 1988-94.

A checklist to be used for the physical examination and a reminder of post examination activities are given in Appendix 2 (a) and (b).

The clinical examination will last approximately three hours. The participant will arrive at the clinic fasting in the morning. After registration, a study staff member will explain the study and procedures to the participant, answer questions, if any, and have the
consent form signed. The participant will then be instructed to go to the laboratory for blood drawing, to drink the glucose preparation (Glutol), and to obtain the urine specimen. The nurse clinician and other staff will then conduct the personal interview, examination of the lungs, obtain anthropometric measurements, blood pressure, impedance measurement for body fat composition, and ECG measurements. At exactly two hours after the ingestion of the glucose preparation, the participant will have another blood sample drawn for the glucose tolerance test. If the above procedures are not completed before the 2-hour sample is drawn, they may be continued and completed after the participant consumes a light snack. After all the procedures are completed, the participant will receive the payment or sign the payment form and be thanked for his/her participation. A flowchart that describes the process is given in Appendix 2 (c).

If possible, all of the components, except for the dietary survey and echo exams, should be completed in one visit. If an individual leaves before the examination is completed, it must be completed before the study is completed. The personal interview and consent may be completed up to two weeks prior to the physical examination if such arrangements are more convenient.

1.2.2 Endpoints and Risk Factors

A. MORBIDITY EVENT CRITERIA

1. Definite Myocardial Infarction (MI)

Minnesota codes 1.1.x or 1.2.x except 1.26. and 1.28 with no 7.1 or 7.4
History of MI verified by chart review as definite MI

2. Possible Myocardial Infarction

Minnesota codes 1.3.x, 1.2.6, or 1.2.8 with no 7.1 or 7.4
History of MI verified by chart review as possible MI

3. Definite Coronary Heart Disease (CHD)

Definite MI,
Definite CHD verified by chart review to include cardiac cath, proven coronary artery disease, PTCA, coronary artery bypass grafting, or abnormal stress ECG plus abnormal imaging (i.e., both must be abnormal),
Angina Pectoris plus LBBB (7.1.1) or
ST changes (4.1) or
T wave changes (5.1) or
verified possible MI,
4. **Possible Coronary Heart Disease**

   Possible ECG MI (1.3.x, 1.2.6, 1.2.8)
   Angina Pectoris
   Minnesota codes 7.1, 4.1, 4.2, 5.1, 5.2, 7.4
   Unconfirmed history of MI
   Positive functional test of ischemia (such as treadmill) without invasive confirmation
   Possible ECG or imaging in scintigraphic studies (not both).

5. **Definite Cardiovascular Disease (CVD)**

   Definite CHD
   Congestive Heart Failure
   Cardiomyopathy
   Valvular Heart Disease
   Left ventricular Hypertrophy by Echocardiogram
   Left ventricular Hypertrophy by ECG (3.1 or 3.3 plus 4.1-4.3 or 5.1-5.3)
   Ankle Arm Index <= 0.8
   Atrial Fibrillation
   Minnesota codes 4.1, 5.1, 6.1, 6.2, 6.8, 7.1, 7.2, 7.4
   Noncoronary heart surgery or carotid or other vascular surgery
   Pacemaker implantation
   Bruits by physical examination
   Intermittent Claudication by Rose Questionnaire
   Positive non-coronary angiography

**DEFINITION OF ANGINA PECTORIS AND HISTORY OF MI:**

1. **ANGINA PECTORIS - DEFINED BY THE ROSE QUESTIONNAIRE:**

   ROSEAP=1 (YES):  ROSE1='1' AND (ROSE2='1' OR ROSE2='3') AND ROSE4='1'
                     AND ROSE5='1' AND ROSE6='1' AND (ROSE7A='1' OR
                     ROSE7B='1' OR (ROSE7C='1' AND ROSE7D='1')), ELSE
   ROSEAP=0 (NO)

2. **MYOCARDIAL INFARCTION**

   A. **MEDICAL HISTORY**

   1. HISTORY OF MI: Q31 IN MEDICAL HISTORY QUESTIONNAIRE
      MED37='1';
   2. POSSIBLE MI FROM ROSE QUESTIONNAIRE: Q9
      ROSE9='1'.
B. DEFINITION OF HYPERTENSION

1. BLOOD PRESSURE: AVERAGE OF THE LAST TWO SITTING BLOOD PRESSURE FROM PHYSICAL EXAM, Q17, Q18, Q19, AND Q20
   SYSTOLIC BLOOD PRESSURE - SBP = (EXAM27 + EXAM29) / 2
   DIASTOLIC BLOOD PRESSURE - DBP = (EXAM28 + EXAM30) / 2
   MEAN BLOOD PRESSURE - MBP = (2/3 SBP) + (1/3 DBP)

2. HYPERTENSION

   a. WHO CRITERIA

   HYPERTENSION:
   i. TAKING ANTIHYPERTENSIVE DRUG (MEDICATION CODE='2408') OR
   ii. TAKING (DIURETICS ('4028'), OR BETA-BLOCKERS ('1216')) AND HISTORY OF HYPERTENSION (MED19='1') OR
   iii. SYSTOLIC BLOOD PRESSURE ≥ 160 mmhg OR
   iv. DIASTOLIC BLOOD PRESSURE ≥ 95 mmHg

   BORDERLINE HYPERTENSION:
   140 mmHg ≤ SBP < 165 mmHg OR
   90 mmHg ≤ DBP < 95 mmHg

   NORMOTENSIVE:
   SBP < 140 AND DBP < 90 AND NO ANTIHYPERTENSIVE TREATMENT.

   b. US CRITERIA:
   HYPERTENSION: WHO HYPERTENSION OR BORDERLINE HYPERTENSION
   NORMOTENSIVE: SAME AS WHO NORMOTENSIVE.

   HYPERTENSION CONTROL, FOR HYPERTENSIVE PARTICIPANTS ONLY:

1. UNCONTROLLED HYPERTENSION: DBP ≥ 90 OR SBP ≥ 140

C. DEFINITION OF RENAL DISEASE:

1. RENAL FUNCTION, PLASMA CREATININE:
a. CATEGORICAL VARIABLE:
   1 (RENAL INSUFFICIENCY)  PLASMA CREATININE ≥ 2.0 mg/dl
   0 (NORMAL)              PLASMA CREATININE < 2.0 mg/dl
b. CONTINUOUS VARIABLE, ADJUSTED FOR BMI

2. ALBUMINURIA (ACRATIO):
   ESTIMATED BY URINARY ALBUMIN - URINARY CREATININE RATIO
   2 (MACROALBUMINURIA)    ACRATIO ≥ 300 mg/g
   1 (MICROALBUMINURIA)    ACRATIO 30 - 299 mg/g
   0 (NORMAL)              ACRATIO < 30 mg/g

3. END STAGE RENAL DISEASE (ESRD)
   1 (YES)= ON RENAL DIALYSIS, MEDICAL HISTORY FORM, Q4a, MED42='1',
            OR
            HAD KIDNEY TRANSPLANT, MEDICAL HISTORY, Q4b,
            MED43='1', OR
            KIDNEY FAILURE, MEDICAL HISTORY, Q3g, MED29='1'
   0 (NO)=  NONE OF ABOVE

D. DEFINITION OF PERIPHERAL VASCULAR DISEASE (PVD)

1. ANKLE-BRACHIAL RATIO (PVD_ABR), PHYSICAL EXAM, Q44, Q45, AND Q46
   RIGHT ANKLE BP: MEAN OF FIRST AND SECOND DOPPLER SBP OF RT
                   ANKLE.
   RANKBP=(EXAM66 + EXAM68) / 2
   LEFT ANKLE BP:   MEAN OF FIRST AND SECOND DOPPLER SBP OF LT
                    ANKLE.
   LANKBP=(EXAM70 + EXAM72) / 2
   RIGHT ARMBP:    MEAN OF FIRST AND SECOND DOPPLER SBP OF RT
                    ARM.
   RARMBP=(EXAM74 + EXAM75) / 2
   RPVD_ABR = RANKBP / RARMBP
   LPVD_ABR = LANKBP / RARMBP

   PVD_ABR:
   1 (YES):   IF (RPVD_ABR < 0.8) OR (LPVD_ABR < 0.8) OR THE ANKLE
              DOPPLER BP s WERE NOT AUDIBLE (EXAM70, EXAM72, EXAM74,
              OR EXAM75 WAS '0')
   0 (NO):    IF PVD_ABR ≥ 0.8.

2. PERIPHERAL OCCLUSION (PERIOCC):
   ABSENCE OF DORSALIS PEDIS PULSE AND POSTERIOR TIBIAL PULSE ON
   EITHER FOOT.
(PHYSICAL EXAM Q36-Q39),
PERIOCC=1 (YES): (EXAM58=’2’ AND EXAM60=’2’) OR (EXAM59=’2’ AND EXAM61=’2’)
PERIOCC=0 (NO): EXAM58=’1’ AND EXAM59=’1’ AND EXAM60=’1’ AND EXAM61=’1’

3. PRESENCE OF FEMORAL BRUIT(S) (BRUIT)
(PHYSICAL EXAM Q40-Q41)
BRUIT=1 (YES): EXAM62=’1’ OR EXAM63=’1’
BRUIT=0 (NO): EXAM62=’2’ AND EXAM63=’2’

4. INTERMITTENT CLAUDICATION (MEDICAL HISTORY - ROSE QUESTIONNAIRE)
ROSE1C=1 (YES): ROSE10=’1’ AND ROSE11=’1’ AND ROSE12=’1’ AND (ROSE13=’1’ OR ROSE13=’3’) AND ROSE15=’2’ AND ROSE16=’1’ AND ROSE17=’1’ AND ROSE18=’1’, ELSE
ROSE1C=0 (NO):

5. COMPOSITE PVD (PVD_COMP)
PVD_COMP 1 (YES): PVD_ABR=1 OR PERIOCC=1 OR BRUIT=1 OR ROSE1C=1
PVD_COMP 0 (NO): PVD_ABR=0 AND PERIOCC=0 AND BRUIT=0 AND ROSE1C=0

E. DEFINITION OF OBESITY INDICES, PHYSICAL EXAM:

a. BODY MASS INDEX, Q1 AND Q2, (WEIGHT IN KILOGRAM) / (HEIGHT IN METER)^2

\[ BMI = \frac{EXAM94}{(EXAM03/100)^2} \]

b. WAIST-HIP RATIO, Q33 AND Q9:

\[ WHR = \frac{EXAM51}{EXAM13} \]

c. PERCENT BODY FAT (PCTFAT):

PCTFAT is calculated by using Rising's equation as following:

fat-free mass:
\[ FFT = 13.74 + 0.25 \times (\text{height}^2 / \text{resistance}) + 0.30 \times \text{weight} - 0.14 \times \text{age} + 6.18 \times \text{sex} \]
where: height in cm, weight in kg, age in years, sex (0=female, 1=male)

fat mass (FM) = weight - FFT
PCTFAT = (FM / weight) * 100%

RESISTANCE: Q35a IN PHYSICAL EXAM

1.2.2 DEFINITION OF RISK FACTORS

1. CIGARETTE SMOKING (PERSONAL INTERVIEW II, Q24-Q29):

A. SMOKING (NEVER, EX-SMOKER, CURRENT)
   0 (NEVER) IF INT2_34='2' OR INT2_35=0
   1 (EX-) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='2'
   2 (CURRENT) IF (INT2_34 = '1' AND INT2_35 NE 0) AND INT2_36='1'
   9 (UNKNOWN) NONE OF ABOVE

IF GROUP INTO SMOKER VS NONSMOKER,
(SMOKING=0 OR SMOKING=1) CAN BE COMBINED AS NON-CURRENT SMOKER;

OR

(SMOKING=1 OR SMOKING=2) CAN BE COMBINED AS EVER SMOKED.

B. SMOKING AMOUNT (FOR SMOKER ONLY):
   1. DURATION OF SMOKING: Q29 (INT2_39)

   2. AGE STARTED SMOKING:
      CURRENT SMOKER: AGE AT EXAM - DURATION OF SMOKING
      EX-SMOKER: AGE STOPPED SMOKING (Q27) - DURATION OF SMOKING

   3. DAILY SMOKING AMOUNT (Q28): INT2_38

   4. TOTAL SMOKING AMOUNT (PER PACK YEAR):
      PPy= (DAILY SMOKING AMOUNT * DURATION OF SMOKING) / 20
           = (INT2_38 * INT2_39) / 20

C. OTHER TYPE OF SMOKING: INTERVIEW II, Q30-Q32
   0 (NO) IF (INT2_40='2' AND INT2_41='2' AND INT2_42='2')
   1 (YES) IF (INT2_40='1' OR INT2_41='1' OR INT2_42='1')
D. PASSIVE SMOKING
0 (NO) IF INT2_33=0
1 (YES) IF INT2_33 > 0
DAILY EXPOSURE TIME (IN HOURS): INT2_33.

E. PARENTAL SMOKING:
0 (NONE) (INT2_31=2 OR INT2_31=3) AND (INT2_32=2 OR INT2_32=3)
1 (ONE) INT2_31=1 OR INT2_32=1
2 (BOTH) INT2_31=1 AND INT2_32=1

2. EDUCATION: PERSONAL INTERVIEW FORM II, Q15 - INT2_4

A. CONTINUOUS: INT2_4 (YEARS)

B. CATEGORICAL:

i. THREE CATEGORIES (EDUCAT1):
  1 (LESS THAN HIGH SCHOOL) 0 <= INT2_4 < 12
  2 (HIGH SCHOOL GRADUATE AND/OR SOME COLLEGE) 12 <= INT2_4 < 16
  3 (COLLEGE GRADUATE) INT2_4 >= 16

ii. FOUR CATEGORIES (EDUCAT2):
  1 (LESS THAN NINE YEARS) 0 <= INT2_4 <= 9
  2 (SOME HIGH SCHOOL) 10 <= INT2_4 <= 12
  3 (SOME COLLEGE) 13 <= INT2_4 <= 16
  4 (COLLEGE GRADUATE) INT2_4 >= 16

3. TOTAL DEGREE OF INDIAN BLOOD: INTERVIEW II, Q16

A. CONTINUOUS: INDIAN = (INT2_5 / INT2_6) * 100%

B. CATEGORICAL:
  0 (LESS THAN 25%) 0 < INDIAN < 25%
  1 (LESS THAN 50%) 25 <= INDIAN < 50%
  2 (50-74.9%) 50 <= INDIAN < 75%
  3 (75-99.9%) 75 <= INDIAN < 100%
  4 (FULL BLOODED) INDIAN = 100%

4. INDIAN TRADITION: INTERVIEW II, Q35-Q38

A. SPEAK NATIVE LANGUAGE, INDYLANG
  0 (NO) INT2_45='3' OR INT2_46='5'
1 (YES) \[\text{INT2} \_45=1' \text{ OR '2'} \text{ AND (INT2} \_46=1' \text{ OR '2'} \text{ OR '3'} \text{ OR '4')}

B. USE TRADITIONAL MEDICINE/HERBS, INDYMED
0 (NO) \[\text{INT2} \_47=5' \text{ OR '9'}
1 (YES) \[\text{INT2} \_47=1' \text{ OR '2'} \text{ OR '3'} \text{ OR '4'}

C. TRADITIONAL CEREMONIES, INDYCERE
0 (NO) \[\text{INT2} \_48=5' \text{ OR '9'}
1 (YES) \[\text{INT2} \_48=1' \text{ OR '2'} \text{ OR '3'} \text{ OR '4'}

5. STRESS: INTERVIEW II, Q42-Q46

A. SLEEP LOSS, Q42, SLEPLOSS
0 (NO) \[\text{INT2} \_52=1'
1 (YES) \[\text{INT2} \_52=2' \text{ OR '3'}

B. STRAIN OR STRESS, Q43, STRAIN
0 (NO) \[\text{INT2} \_53=1'
1 (YES) \[\text{INT2} \_53=2' \text{ OR '3'}

C. OPEN ARGUMENTS, Q44, QUARREL
0 (NO) \[\text{INT2} \_54=1' \text{ OR '2'}
1 (YES) \[\text{INT2} \_54=3' \text{ OR '4'} \text{ OR '5'}

D. ALCOHOL PROBLEM OF HOUSEHOLD, Q45, HOUSETOH
0 (NO) \[\text{INT2} \_53=1'
1 (YES) \[\text{INT2} \_53=2'

E. SIZE OF HOUSEHOLD, Q46, HOUSSIZE
1 (SMALL) \[\text{INT2} \_54 \leq 4
2 (MEDIAN) \[4 < \text{INT2} \_54 < 10
3 (LARGE) \[\text{INT2} \_54 \geq 10

6. ALCOHOL USE

A. ALCOHOL DRINKING STATUS, ETOHOUSE, Q47-Q48
0 (NEVER) \[\text{INT2} \_57=2'
1 (EX-DRINKER) \[\text{INT2} \_57=1' \text{ AND (INT2} \_59 \geq 12 \text{ OR INT2} \_60 \geq 1)
2 (CURRENT) \[\text{INT2} \_57=1' \text{ AND } \text{INT2} \_60 = 0

B. BINGE DRINK
1. DURING THE PAST MONTH, Q52
0 (NO) \[0 \leq \text{INT2} \_64 < 5
1 (YES) \[\text{INT2}_{64} \geq 5\]

2. DURING THE PAST YEAR, Q53
   0 (NO) \[0 \leq \text{INT2}_{65} < 5\]
   1 (YES) \[\text{INT2}_{65} \geq 5\]

C. AMOUNT OF ALCOHOL INTAKE

7. SOCIOECONOMIC STATUS (SES)

   A. RECEIVING FEDERAL ASSISTANCE:
      1. FOOD STAMPS / WIC, Q56
         0 (NO) \[\text{INT2}_{68} = 0\]
         1 (YES) \[\text{INT2}_{68} > 0\]

      2. COMMODITY FOOD, Q57
         0 (NO) \[\text{INT2}_{69} = 0\]
         1 (YES) \[\text{INT2}_{69} > 0\]

      3. FEDERAL ASSISTANCE, FEDHELP
         0 (NO) \[\text{INT2}_{68} = 0 \text{ AND } \text{INT2}_{69} = 0\]
         1 (YES) \[\text{INT2}_{68} > 0 \text{ OR } \text{INT2}_{69} > 0\]

   B. SES (EDUCATION, FAMILY INCOME, ...)

      1. HOUSEHOLD INCOME, Q58: USE THE CATEGORIES LISTED IN THE QUESTIONNAIRE.

8. FAMILY HISTORY OF DISEASES - PERSONAL INTERVIEW II, FAMILY HISTORY

   A. CLASSIFICATION:
      1. PARENTAL, FOR RELATIONSHIP CODE 1 AND 2 (FH1 AND FH14)
      2. FIRST DEGREE FULL-BLOOD RELATIVES:
         RELATIONSHIP CODE: 1 (MOTHER), 2 (FATHER), 3 (SISTER), 5 (BROTHER), 7 (DAUGHTER), AND 8 (SON).
      3. ALL FIRST DEGREE RELATIVES, ALL CODES.

   B. DISEASE HISTORY
      1. HEART DISEASE: MI AND HD
      2. CARDIOVASCULAR DISEASE: MI, HD, HBP, CVA
      3. DIABETES: DM
      4. KIDNEY FAILURE: KF
      5. ARTHRITIS: AT
6. CANCER

9. MEDICAL HISTORY, MEDICAL HISTORY FORM

A. PRESCRIBED MEDICATIONS: USE CATEGORIES IN THE MANUAL (p. 282)

<table>
<thead>
<tr>
<th>#</th>
<th>Medication</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ANTIHISTAMINE (400)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>ANTIBIOTICS (812)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>ANTINEOPLASTIC RX (1000)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>BETA-BLOCKERS (1216)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>ANTICOAGULANTS (2000)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>CARDIAC DRUGS (2404)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>HYPOLIPIDEMIC (2406)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>HYPOTENSIVE (2408)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>ANALEGISITIC (2808)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>ASPIRIN (280892)</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>ANTICONVULSANTS (2812)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>PSYCHOTHERAPY (2816)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>ADRENALS (6804)</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>ORAL CONTRACEPTIVE (6812)</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>DIURETICS (4028)</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>GI DRUGS (5600)</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>MENOPAUSAL ESTROGEN (6816)</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>INSULIN (682008)</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>SULFONYUREAS (682020)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>THYROID AGENTS (6836)</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>OINTMENTS (8400)</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>VITAMINS (8800)</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>UNCLASSIFIED (9200)</td>
<td></td>
</tr>
</tbody>
</table>

B. HISTORY OF:

1. GALLSTONE, Q3c
   - 0 (NO) MED22='2'
   - 1 (YES) MED22='1'

2. ARTHRITIS, Q3d
   - 0 (NO) MED23='2'
   - 1 (YES) MED23='1'

3. CANCER, Q3e
   - 0 (NO) MED24='2'
   - 1 (YES) MED24='1'

4. KIDNEY FAILURE, Q3g
   - 0 (NO) MED28='2'
   - 1 (YES) MED28='1'

5. EMPHYSEMA, Q3h
   - 0 (NO) MED31='2'
   - 1 (YES) MED31='1'

6. LIVER CIRRHOSIS, Q3i
   - 0 (NO) MED32='2'
1 (YES)  MED32='1'

7.  RENAL DIALYSIS, Q4a
   0 (NO)  MED42='2'
   1 (YES)  MED42='1'

8.  KIDNEY TRANSPLANT, Q4b
   0 (NO)  MED43='2'
   1 (YES)  MED43='1'

10.  REPRODUCTION AND HORMONE USE (FEMALE ONLY), MEDICAL HISTORY

A.  REPRODUCTION:
   1.  TIMES PREGNANT, Q7-1, REPRO1
   2.  NUMBER OF LIVE BIRTH, Q7-2, REPRO2
   3.  NUMBER OF LOST PREGNANCIES, Q7-3, REPRO3
   4.  NUMBER OF LIVING CHILDREN, Q7-4, REPRO4
   5.  MENOPAUSAL, Q8
       0 (NO)  REPRO5='2'
       1 (YES)  REPRO5='1'
   6.  AGE AT MENOPAUSE, Q9, REPRO6

B.  HORMONE USE
   1.  ORAL CONTRACEPTIVE, Q11
       0 (NO)  REPRO9='2'
       1 (YES)  REPRO9='1'
   2.  AGE STARTED TO USE OC PILLS, Q12, REPRO10
   3.  TOTAL DURATION OF USING OC PILLS, Q13, REPRO11
   4.  EVER USE OF ESTROGEN OTHER THAN OC PILLS, Q14
       0 (NO)  REPRO12='2'
       1 (YES)  REPRO12='1' OR MEDICATION CODE (Q1a-Q1h) CONTAINS '6816' (POST MENOPAUSAL ESTROGEN)
   5.  AGE STARTED TO USE ESTROGEN, Q15, REPRO13

Strong Heart Study II  1/20/94
6. TOTAL DURATION OF USING ESTROGEN, Q16, REPRO14

11. LAB DATA

A. LIPID - CONTINUOUS VARIABLE
   1. TOTAL TRIGLYCERIDE, ln(TRIG)
   2. TOTAL CHOLESTEROL, CHOLEST
   3. HDL CHOLESTEROL, HDL_CHOL
   4. LDL CHOLESTEROL, LDL_CHOL
   5. VLDL TRIGLYCERIDE, VTRIG
   6. VLDL CHOLESTEROL, VCHOL
   7. RATIOS:
      i. VCHOL/VTRIG
      ii. HDL_CHOL/CHOLEST
      iii. HDL_CHOL/LDL_CHOL
      iv. APOB/(CHOLEST-HDL_CHOL)
      v. APOA1/HDL_CHOL
      vi. APOB/LDL_CHOL

B. APOLIPOPROTEINS: APOA1, APOB

C. GLUCOSE:
   1. FASTING BLOOD GLUCOSE, GLUC_0
   2. 2-HR BLOOD GLUCOSE, GLUC_2

D. FIBRINOGEN

E. PLASMA INSULIN

F. FIBRINOGEN

G. APO E PHENOTYPE

H. PLASMA CREATININE

I. URINARY ALBUMIN AND CREATININE

J. GLYCATED LDL

K. LP(a)

L. LDL SIZE
M. LDL TYPE

CUT POINTS FOR CONTINUOUS VARIABLES:

<table>
<thead>
<tr>
<th>VARIABLES</th>
<th>LOW (0)</th>
<th>MEDIUM (1)</th>
<th>HIGH (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE GP</td>
<td>45-54</td>
<td>55-64</td>
<td>65-74</td>
</tr>
<tr>
<td>OBESITY:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBSESE (95%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEMALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI ≥ 32.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI ≥ 31.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OVERWT (85%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEMALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32.3 &gt; BMI ≥ 27.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.1 &gt; BMI ≥ 27.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBES_FAT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEMALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCTFAT &lt; 41%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCTFAT &lt; 29%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBES_WHR (65%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEMALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHR ≤ 0.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MALE:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHR ≤ 0.96</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL CHOLESTEROL (NCEP GUIDELINE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHOLEST &lt; 200(mg/dl)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL TRIGLYCERIDES</td>
<td>TRIG &lt; 250 (mg/dl)</td>
<td>TRIG ≥ 250</td>
<td></td>
</tr>
<tr>
<td>HDL CHOLESTEROL (NCEP GUIDELINE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL_CHOL &lt; 35 (mg/dl)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL CHOLESTEROL (NCEP GUIDELINE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL_CHOL &lt; 130(mg/dl)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In order to facilitate publicity and recruiting efforts in the community, it has been determined that individuals who participated in the Phase II exam are eligible for the clinical examination.

Eligible study participants are identified through the tribal population lists. Individuals will be contacted in an order convenient for each center. Local publicity campaigns and mailed information will alert participants before participation is requested.

When contacting an eligible examinee, the interviewer introduces the Strong Heart Study and explains its purpose and importance. A brochure and a letter explaining the purpose of the study and exam are used for recruitment. The voluntary nature of the study and the confidentiality of the collected data are stressed. If the subject is not at home at the time of the phone call or visit, call backs are made as necessary to meet the individual and schedule the clinic appointment. 100% participation is the goal.

In all areas, the recruiter should wear an identification badge. When scheduling appointments the recruiter should emphasize the following:

1. That the volunteer should not eat breakfast the morning of the visit to the exam; and should not eat or drink anything but water after 9:00 p.m. the previous evening.

2. That the volunteer should bring with him/her all medications which he/she has been prescribed and is currently taking;

3. That the volunteer should not take their morning diabetes medication until blood drawing is completed;

4. No tobacco or vigorous activity before the clinic visit;

5. Volunteer should be instructed to wear loose clothing and ladies to wear a skirt and blouse or pants and shirt, rather than a dress

In case the volunteer might be retarded or otherwise mentally incapacitated, a surrogate must accompany him/her to the examination, preferably someone who is very familiar with the medical and family history.

The recruiter schedules the appointment with the clinic for each subject. Whenever possible, eligible members of a single household are scheduled on the same day. The recruiter should also verify name, address, and social security number at the time of the recruiting visit. When possible, participants should be reminded by phone or in person the day prior to the visit.
After the visit appointment is made, the clinic staff should assemble all forms and labels necessary for the exam and arrange to have the hospital chart for that participant available the morning of the clinic visit. The chart may also be reviewed to see if the participant satisfies the exclusion criteria for the glucose tolerance test.

1.4 PERSONAL INTERVIEW

1.4.1 Components of the Personal Interview

The personal interview is designed to obtain demographic information, medical history, health behavior, acculturation and stress data that are considered important in identifying risk factors for cardiovascular disease. A total of five questionnaires will be administered during the clinical examination:

1. Personal Interview Form (I and II)
2. Medical History Form
3. Dietary Form
4. Psychosocial Form
5. Quality of Life

Personal living habits such as dietary, cigarette smoking and alcohol consumption, and stress have been considered as important risk factors for cardiovascular disease. Data on these factors as well as demographic information and the degree of acculturation will be collected by using the Personal Interview Forms (I and II) given in Appendix 3. Appendix 4 gives the Medical History Form which consists of questions on medical conditions, medications used and the Rose Questionnaire for angina pectoris and intermittent claudication.

Note: The Personal Interview Form I contains personal identification information. For confidentiality purposes, it should be sent to the Coordinating Center separately.

1.4.2 Guidelines for Interviewers

1. Introduction

The personal interview is probably one of the most important procedure for data collection in epidemiologic research. The personal interview has been shown to increase response over self-administered questionnaires, and when rapport is established between the interviewer and the interviewee it has been shown to be an excellent source of high quality information for epidemiologic research purposes. However, the interviewer must be able to show tact, care, and sensitivity, to be effective. Not everyone can become a successful interviewer.
Also, the personal interview can lead to a lack of standardization in the data collected, particularly in a multicenter study such as the Strong Heart Study. Since the interviewer is known to have a large effect on the quality of the data obtained, therefore interviewer training is very important. Please read this interviewer's manual frequently, and refer to it as needed during the study. It is also recommended that each Study Coordinator, hold monthly interviewer meetings, to go over common problems and clear up any questions about the interview procedures and the interview forms in the Strong Heart Study.

2. Types of Interviews

Structured versus Unstructured Interviews

In an unstructured interview the responses to questions are open-ended, and information given is to be recorded as given. In a structured interview the questions are usually closed, with a specific set of answers provided in the questionnaire.

For the Strong Heart Study we are using both structured and unstructured interviews. The use of structured interviews is the best way to maintain consistency in the data being collected. Interviewer training is important in order to maintain as much consistency in the interviews between study centers as possible.

Because we are using structured and unstructured interviews, we can achieve even more consistency if all interviewers conduct the interviews in a similar way. Therefore, ask each question as it is written. Do not reword the question. Also, ask the questions in the order they are given in the interview form. Hopefully, by following these procedures we can achieve a high degree of consistency in the way the interviews are conducted.

3. Style of the Interview

The interview style is also important and some of the components of what is generally considered to be acceptable interview style are listed below. In addition to the components of style listed below, the following interviewer characteristics are also very important: Politeness is very important since we will be asking sensitive questions to strangers, in a situation where they may be uncomfortable. Sensitivity on the part of the interviewer is also important, in order to know how and when to be more or less assertive in asking for information. Besides these qualities, listed below are what we expect our interviewer's style to approach, so please try to develop your style in accordance with these guidelines:
a. Non-judgmental, non-evaluative style. A large portion of the impression which the respondent has of the interviewer is based solely on the interviewer's voice and the manner with which the interviewer responds to the respondent's comments. A judgmental or evaluative response would indicate that the interviewer has made a judgement of the relative goodness, appropriateness, effectiveness, or rightness of the respondent's statement. The interviewer should not, in response to the respondent's statements, state what the respondent should or should not do in a given situation. The interviewers task is simply to record the information provided, and to elicit the desired response.

b. Non-interpretive style. As above, the interviewer should not use a style that might be considered teaching or preaching. An interpretive response is one which indicates that the interviewer's intent is to teach. We are interested in the respondent's impression of what was happening, not in the interviewer's impression.

c. Allow for respondent to complete sentences. Do not try to help the respondent by answering the questions for him/her. No matter how slowly the respondent is speaking, putting words in the respondent's mouth or not allowing the respondent to finish thoughts will generally alter the information which the respondent is attempting to give. However, long hesitations may be bridged by asking appropriate questions.

d. Supportive remarks. Remarks which indicate that the intent of the interviewer is to reassure, to pacify, or to reduce the intensity of the respondent's feelings are appropriate. However, these should be in keeping with local terms and expressions, and should be short so as not to detract from the interview itself.

e. Probing. This is an important response style which will be discussed further. A probe is a response which indicates that the interviewer's intent is to seek further information, to provoke further discussion along a certain line, or to question the respondent. Direct probes will be specific questions about details of what the respondent said.

f. Non-directive, or understanding. A typical non-directive response might be "I see". This is the general idea of understanding murmuring or clucking. The interviewer might also repeat what the respondent just said. This may prompt the respondent to elaborate.

4. Gain Rapport with the Interviewee before Commencing Interview
The first step in gaining the confidence of the respondent is a straightforward, believable introduction of the interview and the reason for this contact. It may help in gaining rapport with the respondent if you tell him/her a little about yourself, such as where you are from, and your background, etc. If the respondent seems to hesitate or has some questions the interviewer must be prepared with a more detailed explanation of why the information is needed. Also, if the respondent raises the issue of the confidentiality of the information collected, the interviewer must be prepared to reassure him/her of the precautions taken to respect their privacy.

5. Interviewer Error

We should try to minimize interviewer error during this study. The primary objectives of epidemiologic research are (1) to obtain measurements of exposure and disease variables relevant to the objectives of the study, and (2) to minimize error in these measurements. The presence of an interviewer may both reduce error and increase error. It may reduce error by increasing the response rate, motivating the subject to respond well and probing to obtain complete data when the responses volunteered fall short of what is desired. The presence of an interviewer may increase error if by his or her appearance, manner, method of administration of the questionnaire, or method of recording of the responses he or she exerts a qualitative influence on the subject's responses. Possible sources of error in the interview for data collection include (1) conditions of administration (heat, light, ventilation, freedom from distraction, lack of time, etc.); (2) interaction of the personality (sex or race of the interviewer with that of the subject); and, (3) performance by the interviewer (questioning, prompting and recording of responses).

The following are the common interviewer errors:

- a. Asking errors. Omitting questions or changing the wording of questions.
- b. Probing errors. Failing to probe when necessary, biased probing, irrelevant probing, inadequate probing, preventing the respondent from saying all he or she wishes to say.
- c. Recording errors. Recording something not said, not recording something said, incorrectly recording response.
- d. Flagrant cheating. Not asking a question but recording a response, recording a response when the respondent does not answer the question asked. These kinds of errors do occur and this has been amply documented by various studies. Cheating has been shown to be more common when the
interviewer is in an uncomfortable situation with the interviewee, i.e., he/she is difficult. We should try to be aware of these situations to avoid the interviewer errors above.

6. Circumstances for the Interview

We will not have very much control over the circumstances for the interviews. However the following should be considered in arranging for conducting interviews:

a. Time. There will be little control over the time of the interviews, since we will have many different interviews to carry out over a short period of time. However, it is desirable not to interview until after the breakfast has been served, otherwise the interviewee may tend to be somewhat uncomfortable.

b. Place. The place for the interview should be chosen where there are as few distractions as possible. Try to select a place where the location is quiet and comfortable. If it is possible, it is ideal to sit at a table, with the interviewer facing the interviewee, so that the interviewer can organize the papers. Privacy is also important. If the respondent will need to refer to records during the interview, be sure that the records are available before the interview begins.

7. Asking Procedures

In general the rules for asking questions in structured interviews can be summarized as follows:

a. Questions must be asked according to the instructions for each form. Be sure to read and re-read the instructions for each questionnaire you are using, and to ask all the questions in the same way to each person interviewed.

b. Read the questions exactly as they are worded in the questionnaire. If the question is misunderstood, then it may be repeated, interchanging local terms, if necessary for understanding.

c. Read each question slowly.

d. Use correct intonation and emphasis.

e. Ask the questions in the order that they are presented in the questionnaire.
f. Ask every question that applies to the respondent (all inapplicable questions will be identified as such by skip instructions in the questionnaire).

g. Repeat questions IN FULL that are misheard or misunderstood.

h. Read all linking or transitional statements exactly as they are printed.

i. Do not add apologies or explanations for questions unless they are printed in the questionnaire.

PROBING: Probes are additional questions asked or statements made by the interviewer when the answer given by a respondent is incomplete or irrelevant. Probing has two major functions: (1) To motivate the respondent to reply more fully; (2) to help the respondent focus on the specific content of the question. It must fulfill these functions without biasing the respondent's answers. However, probes, when they are used, MUST be neutral. Probing can introduce bias, such as by summarizing your understanding of the response to the subject when an unclear response has been given, or by offering some alternative interpretations from which the respondent can choose, and this must be guarded against.

The following are NON-DIRECTIVE methods of probing:

a. Repeat the question (RQ). All that may be required to clear up a vague answer may be to repeat the question. You may begin by saying "I am not sure that I understood you, let me just repeat the question so that I can be sure to get your answer right."

b. The expectant pause. Waiting expectantly will tell the respondent that the interviewer is expecting more information than has been provided.

c. Repeat the reply. Repeating the reply aloud while recording it may stimulate the respondent to provide more details.

d. Neutral questions or comments. Various neutral probes may be used for purposes such as clarification, specificity, or completeness: "What do you mean exactly?", "In what way?", "Could you be more specific about that?", "Anything else?", "Can you tell me more about it?"

e. Interpretation. Make sure that the question was understood, since that may be the reason for incomplete answers. You may need to ask the question again, perhaps substituting some local terms, If there is a problem in interpretation.

FEEDBACK: The provision of feedback by the interviewer to the respondent about his or her performance has been the subject of much research. Some studies have shown that the use of feedback in health-related surveys increased the amount of reporting of most events. Your decision about whether to provide feedback may depend upon
the performance of the person you are interviewing, and your experience in the benefits of providing feedback.

8. Specific Instructions for Telephone Interviewing

While it is generally held that the principles outlined above, which have been derived solely from research into and experience of face-to-face interviewing, apply to telephone interviewing, the evidence that this is true is very limited. Telephone interviewing is probably not simply the transfer of face-to-face techniques to the telephone. Use of visual cues, such as "show cards", is impossible on the telephone and must be compensated for in questionnaire design. There is evidence that this compensation may lead to response differences. In addition, other non-verbal communication, both from the interviewer to respondent and respondent to interviewer, is absent. The "expectant pause", for example, may be much more difficult to use as a probe for additional information on the telephone. It is also more difficult for the interviewer to establish the legitimacy of the interview on the telephone and the pace of the interview may be faster (because of the need to keep talking) leading to hurried and, perhaps, less thoughtful responses. On the positive side, the telephone should eliminate non-verbal biasing activity by the interviewer, and may encourage more honest reporting of threatening behaviors. Empirical data, however, have not shown consistent evidence of these effects.

9. Instructions for Recording Responses

In the study manual, each interview and form contains a set of question by question instructions for filling out the interview form, to clearly describe the information that is being solicited. These instructions should be read carefully and understood before attempting to fill out an interview form.

In addition, see the attached instructions for filling out forms. The following are some additional guidelines for recording responses:

a. Make sure that you understand each response.

b. Make sure that the response is adequate.

c. Do not answer for the respondent (i.e., do not infer a response from an incomplete or inadequate reply).

d. Begin writing as soon as the respondent begins talking. (The respondent's interest may be held by repeating the response aloud as you are writing).
e. Use the respondent's own words and record the answers verbatim.

f. Include everything that pertains to the question's objectives.

g. Note in the questionnaire the nature and place of each probe used.

h. Do not erase anything. If a response is wrong, strike it out and enter the correct response.

i. Write "refused" beside any question that the respondent refused to answer.

1.4.3 Training & Quality Control of Interviewers

1. Training

Interviewers will be centrally trained in July, 1993 at the training session in South Dakota using a standardized procedure for administering each questionnaire. Training will include instructions in research interviewing techniques and in completing each form. Interviewer skill training will include:

(a) adherence to the standardized protocol
(b) use of non-judgmental attitudes
(c) degree and nature of prompting permitted
(d) dealing with problem interviewing situations
(e) handling participants comments and recording relevant information on the note logs
(f) post interview responsibility for the data

2. Quality control of interviewers

To insure consistency and accuracy and to minimize inter- and intra-interviewer differences, study coordinators will monitor 5% of the interviews done by each interviewer.