YEAR 5 MEDICAL AND PERSONAL HISTORY

1 Background and Purpose

See Baseline Medical History and Year 3 Personal History in Manual of Operations.

2 **Definitions and Alerts**

• <u>Pain of possible infarction</u> is defined as being present in participants who answer as follows:

Question 18= yes

NOTE: When the answer to Question 18H, "Did you see a doctor because of this pain?" is negative, especially in the presence of a positive Rose Questionnaire, the participant should be seen by the clinic physician at that visit for subsequent disposition.

• <u>Congestive heart failure</u> is suggested when:

Question 22 = yes, and Question 23 = yes, and Question 24 = yes, and Question 24a = yes.

Confirmatory evidence is obtained from participant's reported history as outlined in the protocol for CHS events.

• <u>Claudication</u> is defined as positive in participants who answer as follows:

Question 25 = yes, and Question 25a = no, and Question 25b = yes, and Question 25c or 25d = yes, and Question 25c = no, and Question 25f = stop or slow down, and Question 25g = relieved within 10 minutes.

2.1 <u>Alerts</u>

At the end of the clinic visit, positive responses of potential medical significance are summarized on the CHS Exit Summary form. Positive symptoms and/or signs which should trigger medical follow-up or referral are verified during the Exit Summary Interview. (Questions from the Medical History Form that constitute an alert are reviewed and written onto the Check-off Sheet if an alert is indicated.)

2.2 <u>Definitions</u>

- <u>Physician</u> A licensed medical doctor (MD) or osteopath (DO).
- The London School of Hygiene Questionnaire (The Rose Questionnaire) is administered according to the standardized instructions and interviewer training recommended by Rose and Blackburn.
- The word "never" is interpreted literally and does not include responses such as "almost never" or "rarely".

3 Methods

3.1 <u>Home Questionnaire Packet</u>

The Medical History and Personal History forms are combined into one Medical History Form for the Third Follow-up Visit. The form is to be mailed to the participant after contact has been made and the Third Follow-Up Visit has been scheduled. Instructions for completing the form have been standardized and an individual sheet has been prepared which includes the name of a contact person and the telephone number that the participant should call if help is needed. If the Field Center elects not to send this form to the participant and the form is administered during the visit (e.g., there is concern about the percent of illiteracy in the population), the instruction form is not needed.

The Medical History Form is primarily designed as a self-administered questionnaire. When an interviewer perceives that the participant will not be able to complete the selfadministered form, the form should be administered by an interviewer.

3.2 A CHS Interviewer reviews the form to identify any questions which were not answered, were marked in an unclear fashion, or were skipped inappropriately. (Participant need not be present during the review, but could be interviewed later to clarify any ambiguities.)

The responses to Question 21e must be coded using the information on Interviewer Card 19-S.

When inconsistencies or errors are noted, the CHS Interviewer discusses these questions with the participant to determine the correct response(s).

- 3.3 The following guidelines are provided to assist the interviewer and/or analyst.
 - Unless otherwise noted, the participant's response choices are "yes," "no," or "don't know."

- When two spaces are provided for a number, use a leading "0" if only one space is needed (for example, "02" for two).
- If participant responds "yes" to any question that begins, "Have you been told by a doctor...", confirm that it was a doctor who gave the participant the information.
- Question 1 Would you say, in general, your health is:

Response choices are:

- 1-Excellent 2-Very good 3-Good 4-Fair 5-Poor
- Question 2 How would you say your health compares to other persons your age?

Response choices are:

- 1-Better than others your age2-About the same as others your age3-Worse than others your age4-Don't know
- Question 3 During the past two weeks, how many days have you stayed in bed all or most of the day because of illness or injury? (Do not include days in a hospital or nursing home. If you do not remember the exact number of days, please estimate as closely as possible.) Answer "0" if you haven't spent any days in bed in the last two weeks.

Response choices are 00 to 14.

Script: The next set of questions have to do with diseases or procedures you may have had in the past six months. We are looking for changes in your health since we last contacted you.

Questions 4 to 9 - Has a doctor told you that you had...since we spoke to you on the phone about six months ago?

Read each condition and wait for a response before continuing to the next condition.

- Question 4 A new myocardial infarction or heart attack
- Question 5 A new incident of angina pectoris or chest pain
- Question 6 A new incident of heart failure or congestive heart failure
- Question 7 A new incident of intermittent claudication or pain in your legs from a blockage of the arteries
- Question 8 A new stroke or cerebrovascular accident
- Question 9 A new transient ischemic attack or TIA or silent stroke

If the participant answers "no" or "don't know" to any question, skip the remainder of that question and continue with the next one.

• Part A: What was the doctor's name and address?

For any condition checked "yes", record the doctor's name and address.

• Part B: Date of the event or diagnosis:

Ask the participant to estimate if the exact date is not known. If the participant is unable to supply complete information, record all available but urge him/her to help you with an estimate if at all possible.

If the event involves a hospitalization, the date is the admission date to the hospital. If the event is non-hospitalized, the date is the date of the diagnosis by the physician (e.g., office visit).

• Part C: How many times altogether did you see a doctor for this condition since we last spoke to you?

Count the number of physician office or outpatient visits made FOR THIS DIAGNOSIS or problem only. Record in the space provided.

• Part D: Were you in the hospital at least one night for this condition since we last spoke to you?

If participant responds "no," skip to the next question. If the participant responds "yes," continue to subquestion E.

• Part E: How many different times were you in the hospital for this condition?

Record the number of different hospitalizations FOR THIS DIAGNOSIS OR CONDITION ONLY. This number should reflect the number of admissions for this condition IN THE LAST SIX MONTHS ONLY.

• Part F: Please record the admission date of each hospitalization and the name and location of the hospital.

If the exact date is not know, ask the participant to estimate the approximate date. An estimate is better than missing information. If the participant will not provide a day, fill in the month and year given and fill in '99' in the area for each 'day'.

Record the name and city/state of the hospital into which the participant was admitted for each admission.

• Part G: How many days altogether were you hospitalized for this condition?

Record sum of all days hospitalized for this condition.

■ Question 10 - Have you stayed overnight as a patient in a hospital for any other reasons not reported in Questions 4 through 9 since we spoke to you on the phone about six months ago?

This question will collect data on non-cardiovascular hospitalizations. If there are no additional hospitalizations, skip to Question 11.

For each non-cardiovascular hospitalization, record:

- reason for admission
- hospital name and location (city/state)
- date of hospitalization (i.e., admission)

There is space to record information for up to two hospitalizations on the form itself. If there have been more than two stays, record the additional information on a separate piece of paper and attach to the questionnaire.

If the participant reports having been hospitalized, send the data from Questions 4 through 10 to the site Events Coordinator for investigation and implementation of event procedures.

Question 11 - Have you stayed overnight as a patient in a nursing home or rehabilitation center since we spoke to you on the phone about six months ago?

If "no," skip to Question 10. If "yes," complete the following:

- Part A For each nursing home/rehab center stay, record:
 - reason for admission
 - facility name and location (city/state)
 - date of admission

There is space to record information for one stay on the form itself. If there has been more than one admission, record the additional information on a separate piece of paper and attach to the questionnaire.

- Part B Are you currently staying in a nursing home?
- Question 12 Have you had pneumonia since we saw you last year?
- Question 13 Have you had an attack of bronchitis since we saw you last year?

If "no," skip to Question 14.

- Part A If "yes," ask: Was it confirmed by a doctor?
- Question 14 Has a doctor ever told you that you had any of the following conditions or diseases; and if so, when were you FIRST told that you had the condition?

Valid responses are:

- 1-Never told2-First told during the past year3-First told more than one year ago
- Question 15 Has a doctor told you that you had other heart or circulatory problems since we saw you last year?

If "yes," specify.

- Question 16 Are you currently taking medication prescribed by a doctor for any of the following conditions?
- Question 17 Have you had coronary angiography or heart catheterization as an outpatient procedure since we saw you last year?

Question 18 - Rose Questionnaire for Angina and Possible Myocardial Infarction

In this exam, the original wording of the Rose Questionnaire has been used. It will collect any episodes of pain - not just that which occurred in the past year.

Question 18 - Have you ever had any pain or discomfort in your chest?

Record "Yes" if the participant reported having had chest pain, no matter how infrequent or how seemingly unrelated to the heart.

Record " No" if the participant has not had chest pain. Skip the remainder of Question 18 and go directly to Question 19.

• Part A - Do you feel the pain when you walk uphill or hurry?

Record "no" if participant states that the symptom occurred during other activities, but not while walking uphill or hurrying.

Note that response choices include "Never hurries or walks uphill".

If "no" or "never hurries or walks uphill," skip to Part I.

• Part B - Do you feel the pain when you walk at an ordinary pace on the level?

Record "No" if participant states that the pain occurred during other activities, but not while walking at a normal pace on the level.

• Part C - What do you do if you feel it while you are walking?

This is an open-ended question with "stop" and "slow down" being positive responses. NOTE: Record "stop or slow down" when participant "continues at same pace" after taking nitroglycerin. This includes responses such as "I suck on my pill and keep on going."

- Part D If you stand still, what happens to the pain?
- Part E Where do you get this pain or discomfort?

Allow participant to point to area on diagram.

• Part F - Have you had this pain in the past two weeks?

If "Yes," ask: "How many times in the past two weeks have you had this

pain?" If "No," skip to Part H.

- Part G Has there been an increase in the frequency or severity in the past two weeks?
- Part H Have you seen a doctor about this pain?
- Part I Have you ever had a severe pain across the front of your chest lasting for half an hour or more?

Record "no" when the participant did not have the pain, and skip to Question 19.

Record "Yes" when the participant reported having had the pain, no matter how infrequent, how long ago, or how seemingly unrelated to the heart. Continue with Parts J through K.

• Part J - Did you see a doctor because of this pain?

If "No", skip to Question 13.

• Part K - If you saw a doctor, what did your doctor say it was?

If "other," specify in space provided.

Questions 19 through 22 - Questionnaire for Congestive Heart Failure

Question 19 - Have you had to sleep on 2 or more pillows to help you breathe since we saw you last year?

Record "Yes" if the participant reported having had the symptom, no matter how infrequent, how long ago, or how seemingly unrelated to the heart.

- Question 20 Have you been awakened at night by trouble breathing since we saw you last year?
- Question 21 Do you get short of breath...

Record the participant's response for each of the following situations:

A. While resting in a chair?

- B. When walking on level ground?
- C. When walking quickly or uphill?

D. With light physical activity such as walking down a flight of stairs, dressing or showering without stopping, cleaning windows, stripping and making the bed, mopping floors, hanging washed clothes, pushing a power lawn mower, bowling, or playing golf (walk and carry club)?
E. With moderate physical activity such as carrying anything up a flight of stairs without stopping, dancing a foxtrot, gardening, raking, weeding, having sexual intercourse, or walking 4 miles an hour over level ground?
F. With strenuous physical activity such as doing outdoor work (shoveling snow, spading soil), playing squash or handball, jogging or walking 5 miles an hour, or carrying objects that weigh at least 80 pounds?

Question 22 - Have you had swelling of your feet or ankles since we saw you last year?

NOTE: Minor swelling of feet in hot weather only should not be considered a positive response. If response is "no", skip to Question 23.

• Part A - Did it tend to come on during the day and go down overnight?

Question 23 - Rose Questionnaire for Intermittent Claudication

Question 23 - Do you get pain in either leg when walking?

If "no," skip to Question 24. Record "yes" if participant reports ever having had pain in either leg, no matter how infrequent, how long ago, or how seemingly unrelated to claudication. If "yes," record participant's response for each of the following:

- Part A Does this pain ever begin when you are standing still or sitting?
- Part B Do you feel this pain in your calf or calves?
- Part C Do you feel it when you walk uphill or hurry?
- Part D Do you feel it when you walk at an ordinary pace on the level?
- Part E Does this pain ever disappear while you are walking?
- Part F What do you do if you feel it while you are walking?

Response choices are:

1-Stop or slow down2-Continue at same pace

• Part G - What happens to the pain if you stand still?

Response choices are:

1-Relieved in 10 minutes or less2-Takes longer than 10 minutes to be relieved3-Not relieved9-Don't know

Question 24 - Have you been told by a doctor that you currently have any of the following?

Record participant's response for each of the following:

- A. Arthritis of hands
- B. Arthritis of shoulder
- C. Arthritis of hips or knees
- D. Osteoporosis
- E. Liver disease, cirrhosis or hepatitis
- F. Kidney (renal) disease or failure
- Question 25 During the last year, have you had pain in any bones or joints for at least half the days of a month?

If "no," skip to Question 26. If "yes," record response for each of the following:

A. Hands
B. Feet
C. Knees
D. Hips
E. Neck
F. Back
G. Shoulders
H. Other (If "yes," specify location of pain.)

Question 26 - Have you been told by a doctor that you currently have cancer?

If "no," skip to Question 27. If "yes," record response for each of the following:

- A. Breast cancer
- B. Blood cancer, leukemia or lymphoma
- C. Colon (bowel) or rectum cancer
- D. Lung cancer
- E. Malignant melanoma
- F. Other skin cancer
- G. Prostate cancer
- H. Pancreatic cancer
- I. Esophageal cancer
- J. Other cancer (If "yes," specify type of cancer.)
- Question 27 Have you been treated by a doctor for any of the following since we saw you last year?

Record participant's response for each of the following:

- A. Broken hip (fracture)
- B. Broken lower leg (fracture)
- C. Broken arm, wrist or shoulder (fracture)
- D. Spine (vertebral) compression fracture
- E. Other injury (If "yes," specify type of injury.)
- F. Did you have arthritis that was treated with medication?
- Question 28 During the last year, have you had any sudden spells of dizziness, loss of balance, or sensation of spinning?
- Question 29 Have you ever accidentally lost control of your urine (wet yourself) more than one time in a month?
- Question 30 Do you wake up to urinate more than three nights per week?
- Question 31 During the last year, have you had a fall? (Do not include falls during skiing, skating or other activities that may affect balance.)

If "no," skip to Question 32. If "yes," ask:

- Part A How many times have you fallen during the last year?
- Question 32 During the last year, have you gained or lost more than 10 pounds?

Response choices are:

1-Lost more than 10 pounds2-Gained more than 10 pounds3-Both lost and gained more than 10 pounds4-No change9-Don't know

If the answer is "no change" or "don't know," skip to Question 33. If the answer is "lost more than 10 pounds," "gained more than 10 pounds," or "both lost and gained more than 10 pounds," record participant's response for the following:

- Part A Was diet for the purpose of losing or gaining weight a major factor in your weight change?
- Part B Was surgery, illness or medication a major factor in your weight change?
- Part C Was exercise a major factor in your weight change?
- Question 33 How would you compare your TOTAL average daily intake of food this year to your intake when we saw you last year?

Response choices are:

1-Eat a lot more2-Eat a little more3-Eat about the same4-Eat a little less5-Eat a lot less

If "Eat about the same," skip to Question 34. If "Eat a lot more" or "Eat a little more," record participant's response to the following:

• Part A - If you answered "Eat a lot more" or "Eat a little more," the main reason is:

1-A doctor recommended that I eat more
2-I am taking medicine that increases my appetite
3-My physical activity has increased
4-I am more able to shop or prepare food than before
5-A medical or dental problem has been resolved
6-My appetite has increased for other reasons (If "other reasons," specify.)

• Part B - If you answered "Eat a lot less" or "Eat a little less," the main reason is:

1-A doctor recommended that I eat less
2-I am taking medicine that decreases my appetite
3-My physical activity has decreased
4-I am less able to shop or prepare food than before
5-A medical or dental problem interferes with eating
6-My appetite has decreased for other reasons (If "other reasons," specify.)

Question 34 - Are you following a special diet?

If "no" or "don't know," skip to Question 35. If "yes," record participant's response to the following:

• Part A - What is the purpose of the diet?

Record participant's response to each item listed. If "yes" to "other reasons," specify reason(s).

• Part B - What kind of diet is it?

Record participant's response to each item listed. If "yes" to "other diet," specify kind of diet.

• Part C - About how long have you been following this diet?

Use "0" to fill unused spaces (for instance, "00" years, "06" months).

- Part D Was this diet recommended by your physician?
- Question 35 Have you gone off a special diet since we saw you last year?

If "no," skip to Question 36. If "yes," record participant's response to the following:

• Part A - What was the purpose of the diet?

Record participant's response to each item. If "yes" to "For other reasons," specify reason(s) for diet in space provided.

• Part B - What kind of diet was it?

Record participant's response to each item. If "Other diet," specify kind of diet.

• Part C - About how long had you been following this diet?

Record the number of years and months. Use "0" to fill unused spaces (for instance, "00" years, "06" months).

- Part D Was this diet recommended by your physician?
- Question 36 During the past two weeks, have you taken a multiple vitamin or any other vitamin supplements?

NOTE: This question refers to over-the-counter or prescription vitamins taken orally or by injection. Those administered as a cream are not included.

If "no" or "don't know," skip to Question 37. If "yes," record response to each of the following. If response is "yes," record number of days taken.

- Part A Multiple vitamin
- Part B Vitamin A or beta-carotene
- Part C Vitamin C
- Part D Vitamin E
- Question 37 Are you usually sleepy in the daytime? (Do not include taking a regular daily nap as "feeling sleepy.")
- Question 38 Do you feel groggy and unrefreshed for more than a half hour after waking up in the morning?
- Question 39 Has your spouse or roommate complained about your loud snoring?

Note that "live alone" is included in response choices.

■ Question 40 - Has anyone observed you while sleeping to have episodes where you stop breathing for a while and then snore or snort loudly?

- Question 41 Do you usually have trouble falling asleep?
- Question 42 Do you usually wake up several times at night?
- Question 43 Do you usually wake up far too early?
- Question 44 Can you see well enough to drive, with or without glasses? Note that "don't drive" is included in response choices.
- Question 45 Can you see well enough to watch TV, with or without glasses?
- Question 46 Can you see well enough to recognize someone across the room, with or without glasses?
- Question 47 Can you see well enough to read the newspaper, with or without glasses?
- Question 48 Can you hear well enough to use the telephone, with or without glasses?
- Question 49 Can you hear well enough to listen to a radio, with or without a hearing aid?
- Question 50 Can you hear well enough to carry on a conversation in a crowded room, with or without a hearing aid?
- Question 51 Have you smoked cigarettes during the last 30 days?

If "no" or "don't know," skip to Question 52. If "yes," complete the following:

- Part A On average, how many cigarettes do you usually smoke per day?
- Question 52 Which of the following best describes your current smoking status?

Response choices are:

1-Never smoked2-Former smoker, quit more than 1 year ago3-Former smoker, quit less than 1 year ago4-Current smoker9-Don't know

- Question 53 Does anyone living with you smoke cigarettes regularly? (This includes any other member of your household.)
- Question 54 Do you ever use snuff or smokeless tobacco?
- Question 55 Do you ever drink beer?

If "no" or "don't know," skip to Question 56. If "yes," record responses to the following:

• Part A - About how often do you drink beer?

Response choices are:

- 1-Daily 2-Weekly 3-Monthly 4-Yearly 0-Rarely/never
- Part B How many 12-ounce cans or bottles of beer do you usually drink on one occasion?
- Question 56 Do you ever drink wine?

If "no" or "don't know," skip to Question 57. If "yes," record responses to the following:

• Part A - About how often do you drink wine?

Response choices are:

- 1-Daily 2-Weekly 3-Monthly 4-Yearly 9-Rarely/never
- Part B How many medium, six-ounce glasses of wine do you usually drink on one occasion?
- Question 57 Do you ever drink liquor?

If "no" or "don't know," skip to Question 58. If "yes," record responses to the following:

• Part A - About how often do you drink liquor?

Response choices are:

- 1-Daily 2-Weekly 3-Monthly 4-Yearly 5-Rarely/never
- Part B How many drinks, equal to one shot of liquor, do you usually drink on one occasion?
- Question 58 Are you currently involved in any medical studies other than CHS?

If "yes," specify the name of the study.

The remainder of the form is to be completed for female participants only. If you are interviewing a male participant, thank him for his time and participation in CHS. If you are interviewing a female participant, continue with the following script and questions.

<u>Script:</u> "Women sometimes take female hormones after menopause. They may be taken for a variety of reasons, including hot flashes or other symptoms, and sometimes for the prevention of bone loss in women. These hormones are usually estrogens such as Premarin (conjugated estrogens), Estrace (estradiol) or Ogen (estrace). Sometimes women take progestins such as Provera (medoxyprogesterone) or Norlutate (norethindrone). We are interested in whether you are currently using or did use these hormones for any reason."

Question 59 - Are you currently taking estrogens such as Premarin, Estrace, Ogen or any other estrogen?

If "no" or "don't know," skip to Question 60. If "yes," record responses to the following:

- Part A How many days per month do you take estrogen?
- Part B For how long have you been taking estrogen?
- Part C Why are you taking estrogen?

Record participant's response to each of the following:

To prevent hot flashes To prevent other post-menopausal symptoms To prevent osteoporosis or bone loss To prevent heart disease For other reasons (If "yes," specify reasons in space provided.)

If participant answered "yes" to Question 59, skip to Question 61. If "no" or "don't know" to Question 59, record responses to the following:

■ Question 60 - If you are NOT currently taking estrogens such as Premarin, Estrace, Ogen or any other estrogen, have you taken estrogen in the past?

If "no" or "don't know," skip to Question 61. If "yes," record responses to the following:

- Part A How many days per month did you take estrogen?
- Part B When did you stop? (state year OR age when stopped)

Record either the year the participant stopped taking estrogen, or participant's age when estrogen was stopped. Do not record both.

- Part C For how long did you take estrogen?
- Part D Why did you take estrogen?

Record responses to each of the following:

To prevent hot flashes To prevent other post-menopausal symptoms To prevent osteoporosis or bone loss To prevent heart disease For other reasons (If "yes," record reasons in space provided).

Question 61 - Are you currently taking progestins such as Provera or Norlutate?

If "no" or "don't know," skip to Question 62. If "yes," record responses to the following:

- Part A How many days per month do you take progestin?
- Part B For how long have you been taking progestin?

If participant answered "yes" to Question 61, the interview is complete. Thank her for her participation in CHS. If participant answered "no" to Question 61, proceed with the following:

Question 62 - If you are NOT currently taking progestin such as Provera or Norlutate, have you taken progestin in the past?

If "no" or "don't know," the interview is complete. Thank the participant for her participation in CHS. If "yes," record responses to the following:

- Part A If you answered YES, how many days per month did you take progestin?
- Part B When did you stop? (State year OR age when stopped.

Record either year or participant's age when stopped, not both.

• Part C - For how long did you take progestin?

This completes the interview. Thank the participant for her time and participation in CHS.

- 3.4 "For CHS Field Center Use Only" box
 - If the form was self-administered, the CHS staff member who reviews the form will complete these items.

- Mark the box coded "0 Self-administered".
- Code your ID in the blanks for "Interviewer or Reviewer".
- Fill in the date the form was reviewed.
- If the form was interviewer-administered, the interviewer will complete these items.
 - Mark the box coded "1 Interviewer-administered".
 - Code your ID in the blanks for "Interviewer or Reviewer".
 - Fill in the date the interview occurred.