

Chapter 12

Medical and Personal History

BACKGROUND

This is a questionnaire designed to capture a wide range of medical and personal history from the subject. The questionnaire is to be administered by an interviewer. It includes information about medical and surgical history for heart and vascular disease, stroke, lung disease, arthritis, endocrine/GI/kidney disease, neurological disorders, cancer, hearing, vision fractures, recent falls, hospitalizations and weight history. For women, there are detailed questions on female reproductive history, menopause, hysterectomy and use of hormone pills.

For in-person Visit 3, the questions on Panel 5 will be self-administered except Question 2 for all participants. For Returning Participants questions will be anchored to any changes **since the last administration of Panel 5-II during an extended annual follow-up** (See Prefill forms for each participant for dates). For Newly Enrolled Participants questions will be anchored to the past year or have you ever been told. See specific questions for details.

METHODS: Medical History

Question 1: Read the question and record the response using the appropriate response form if this is an 'in-person' interview. Mark the correct response on the questionnaire.

Question 2: During Visit 3, this question will be completed by an interviewer during the in-person visit.

Script: *"I am going to read you a list of conditions. Please respond 'yes' or 'no' if you have been told by a doctor that you had this condition since we last interviewed you on [insert date of last contact or have you EVER been told by a doctor (newly enrolled)]."*

- If the participant responds Never told or No, mark "No" and continue on to the next item on the list.
- If the participant responds Yes, mark "Yes" and then ask the age they were first told they had the condition and whether or not they currently have the condition before moving on to the next condition. If they don't know the age, ask them to make their best guess. If the participant cannot estimate the age of diagnosis, put "D" in the appropriate box.
- If the participant refuses to respond, mark "Refused" and continue on to the next item on the list.
- If the participant responds Don't know, mark "Don't know" and continue on to the next item on the list.
- If the participant answers "yes" to heart valve problems, chest or abdominal surgery, other cancer, other fractures, and/or other illness, ask him/her to specify what type. If the participant does not know the specific type, record "unknown" and continue to the next item on the list. For any person reporting an "other cancer" in section 3g, please probe as to whether this cancer was malignant or not. For example, if the participant says "growth", follow-up by asking "What type of growth was it, and was this growth a malignant cancer"? Or, if the person says "pre-cancerous lesion", follow-up by asking "Was this a malignant cancer?" In the margin of the form write down all the information that the participant provides. If study staff is unsure as to whether this truly is a cancer or not, please bring this to the attention of your clinic coordinator immediately following the visit, and they will determine if this entry should be included under "other cancer".

Clarifications about administration of the Medical History questionnaire:

- Diagnoses of medical conditions refer only to those conditions that have been diagnosed FOR THE FIRST TIME since the previous administration of the Medical History or EVER for new enrollees. Recurrences of medical conditions such as depression should not be recorded if they have been previously noted. Subsequent episodes of medical conditions should not be reported (e.g., a second heart attack).
- Cataracts – If the participant has already reported cataract surgery in one eye and now reports cataract surgery in the second eye, then mark as Cataract Surgery in Both Eyes.
- Discrepancies in participant reported age of diagnosis should not be corrected in subsequent years. Age of diagnosis is considered to be most valid at the earliest reported time point (i.e., the first year reported).

Question 3: **Q3a** asks about falls, Panel 5 or Panel 5-II. Record the participant's answer. If the participant responds "yes", please continue to **Q3b** and **Q3c**. If s/he does not know for sure how many times s/he has fallen, record his/her best guess.

Question 3d-3e: **Q3d** asks about fainting episodes or loss of consciousness. Record the participant's answer. If the participant responds "yes", continue to Q3e. If s/he does not know for sure how many times s/he has fainted or lost consciousness, record his/her best guess.

Question 3f, 3f1, and 3f2: **Q3f** asks if you were told by a doctor that you had a heart attack, angina, or chest pain due to heart disease within the last year. If the participant responds "yes", please continue to **Q3f1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds "yes", please continue to **Q3f2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and subsequent ones under 'other hospitalizations', **Q4**.

Question 3g, 3g1, and 3g2: **Q3g** asks if you were told by a doctor that you had a stroke, mini-stroke, or TIA within the last year. If the participant responds "yes", please continue to **Q3g1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds "yes", please continue to **Q3g2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and subsequent ones under 'other hospitalizations', **Q4**.

Question 3h, 3h1, and 3h2: **Q3h** asks if you were told by a doctor that you had congestive heart failure within the last year. If the participant responds "yes", please continue to **Q3h1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds "yes", please continue to **Q3h2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and subsequent ones under 'other hospitalizations', **Q4**.

Question 3i, 3i1, and 3i2: **Q3i** asks if you were told by a doctor that you had cancer within the last year, specifically a cancer that was diagnosed for the first time within the last year. If the participant responds "yes", please continue to **Q3i1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds "yes", please continue to **Q3i2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and

subsequent ones under ‘other hospitalizations’, **Q4**.

Question 3j, 3j1, and 3j2: **Q3j** asks if you were told by a doctor that you had pneumonia within the last year. If the participant responds “yes”, please continue to **Q3j1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds “yes”, please continue to **Q3j2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and subsequent ones under ‘other hospitalizations’, **Q4**.

Question 3k, 3k1, and 3k2: **Q3k** asks if you were told by a doctor that you broke or fractured a bone(s) within the last year. If the participant responds “yes”, please continue to **Q3k1** which inquires if the participant was hospitalized overnight for this problem within the last year. If the participant responds “yes”, please continue to **Q3k2** which asks for the date of admission, date of discharge, name of hospital, and location of hospital (city and state). If there is more than one hospitalization for this condition, record first hospitalization here and subsequent ones under ‘other hospitalizations’, **Q4**.

Question 4: **Q4a** asks about overnight hospitalizations (previously stated only as hospitalizations) since the last interview. Emergency room visits and outpatient day surgeries are not considered hospitalizations. Record the participant's answer. If the participant responds "yes", continue to **Q4b**. If s/he does not know for sure how many times s/he has been hospitalized in the past year, record his/her best guess. For each hospitalization indicated in **Q4b**, record the date of hospital admission, date of discharge, diagnosis at discharge, name of hospital, and the city and state where the hospital is located. If the participant has been hospitalized more than 3 times, list additional hospitalizations on a separate sheet of paper. This section can be found after the Female Reproductive History questions.

Question 5: **Q5** asks about current weight. Record the participant's answer. If s/he does not know for sure, record his/her best guess.

Question 6: **Q6a** asks about weight change over the last year. If the weight change was greater than 5 pounds or 2.27 kilograms, complete **Q6b**, **Q6c**, and **Q6d**. For **Q6d**, emphasize that this is the **overall** weight lost or gained. So, if the person gained 10lbs and then lost 5lbs in the past year, the correct response will be a weight gain of 5lbs. If the participant seems uncertain about the amount of weight gained or lost, ask him/her to estimate.

Question 7: **Q7** asks about participant's usual body weight at about age 50 if the participant has turned 50 since Visit 2. This question is only asked of all NEW participants and RETURNING participants that turned 50 years old since Visit 2. If s/he does not remember exactly, record his/her best guess. If s/he cannot provide an answer, mark "Don't know/don't remember". If s/he refuses, mark "Refused".

Female Reproductive History

The section is to be asked of women participants only; if the participant is a man, conclude the interview at this time.

Question 8: For returning participants, we do not ask Q8a-Q8b (questions were already asked at Visit 2 and will not be repeated). We will ask all NEW enrolled participants all parts of Q8. **Q8** asks about pregnancy history. Pregnancies include all live births, still births, and miscarriages. If the participants replies that she has ever been pregnant in **Q8a**, complete **Q8a1** that asks about the number of pregnancies, and **Q8b** that asks how many pregnancies resulted in the birth of a live child. This includes all live births; excludes stillbirths, miscarriages and adopted children. **Q8c** asks new participants their age when their first child was born. **Q8c1** asks returning participants if they have

been pregnant since Visit 2. If yes, ask **Q8d** to establish age at last child. Do not include adopted children. If she does not remember exactly, record her best guess. **Q8e-g** ask about medical conditions diagnosed during pregnancy.

Question 9: **Q9** asks newly enrolled female participants the age at their first menses (period). Returning participants answered this in Visit 1 and will not be asked again.

Question 10a-10c: **Q10a** asks if the participant has reached menopause. If "Yes", proceed to **Q10b**; if "No", go to **Q11**. **Q10b** asks how old she was at the time she reached menopause. By definition, menopause is the cessation of a period for at least one year. Participants are not to include menstrual bleeding due to taking female hormone pills. If she does not remember exactly, record her best guess. If the participant is unable to provide the year in which she reached menopause, she may respond by either providing the age she was at that time OR by choosing one of the five age categories provided under **Q10b**. Then ask all women who answer **Q10b** the cause of their menopause in **Q10c**.

Question 11-11c: **Q11-11c** asks the participant about removal of ovaries. **Q11** will only be asked of participants who did NOT respond 'Two ovaries' to **Q11b** at Visit 2 (Refer to Prefill form to verify). **Q11a** asks the age when ovary removal surgery was completed. In **Q11b**, we ask the number of ovaries removed. **Q11b** will be asked of participants that responded 'Yes' to **Q11** at Visit 3. **Q11c** asks about female hormone pill use after having an ovary removed. If she answers "yes", **Q11d** asks for how many years the participant took estrogen or female hormone pills every day or nearly every day. If she does not remember exactly, record her best guess. **Q11e** asks when she started taking estrogen. If she is unsure of the age or year, ask her to make her best guess.

Question 12a: **Q12a** asks the participant if she ever had a hysterectomy, that is, surgery to remove the uterus or womb, since Visit 2. If she answers "no", "don't know" or "refused", please skip to **Q13a**. If she answers "yes", please complete **Q12b** which asks the age or year of this surgery. If she does not remember exactly, record her best guess.

If the participant previously indicated the onset of menopause (obtained from the PreFill form prior to the visit), go to Q14.

Question 13a: **Q13a** asks the participant if since menopause she has ever taken estrogen or female hormone pills. If the participant answered that they have not reached menopause in Q10a, the answer to this question should be marked "not applicable", and the questionnaire is finished. If she answers "yes", please complete **Q13b** which asks the age or year she started taking estrogen or female hormone pills. If she does not remember exactly, record her best guess and proceed to **Q13c** which asks for how many years the participant took estrogen or female hormone pills every day or nearly every day. If she does not remember exactly, record her best guess. If the participant answers "no" to **Q13a**, the questionnaire is finished.

Question 14: **Q14** is asked of participants who had reached menopause prior to Visit 2. This question asks whether the participant has taken estrogen or female hormone pills since Visit 2. Mark "yes, now" if the participant is currently taking estrogen or female hormone pills, "yes, not now" if the participant has taken estrogen or female hormone pills since Visit 2 but is not currently taking them, and "no" if she has not taken them since Visit 2.

AGE GUIDELINES

This addresses the issue of participants indicating their family members' ages as "mid 80s" or "late 70s", etc., without providing a specific number. Because estimates are not useful for data analysis, guidelines

have been developed as to how to code the data consistently (please see the chart below).

If a Participant Says/Writes:	You Should Enter as:
70s (number with 's' on end)	75
Early 70s	73
Mid 70s	75
Late 70s	78
70-75 (or any other range, two #s separated by a hyphen)	73 (the midpoint of the range)
< 75 (or any number with a '<' sign before it)	75
> 75 (or any number with a '>' sign before it)	75
75 ? (or any number with a '?' after it)	75
~ 75 (or any number with a '~' before it)	75
75 or 76 (any 'or' combination)	75 (use the lower number)
75+ (or any number with a '+' before it)	75
'Died when elderly'	80
'Died as a young adult'	25
'Died young'	15
'Died in childhood'	5
Between 11 mos. and 1 year	1
'Died in infancy' (or any age between 1 mo old and < 11 mos old)	0.5
< 1	0.5
'Died at birth' (or any age < 1 month old)	0.1
Stillborn	0.1

METHODS: Personal History (Smoking and Alcohol Consumption)

Background: For Visit 3, we will ask the same questions as Visit 2. Panel 4 will be mailed in advance of the in-person visit and self-administered..

Smoking

Question 1: **Q1a** asks if the participant has smoked cigarettes regularly in the last year. “No” means less than 1 cigarette a day for 1 year. If “no”, go to **Q2a**. **Q1b** asks if the participant smokes cigarettes now (as of 1 month ago). If s/he answers “no”, proceed to **Q1d**. If s/he answers “yes”, proceed to **Q1c** which asks how many cigarettes s/he smokes per day now. Record their answer. If s/he is unsure, ask him/her to make their best guess. **Q1d** asks during the time the participant was smoking, on average how many cigarettes per day s/he smoked. Record the participant’s answer. If s/he is unsure, ask him/her to make their best guess. Note that this number may differ than the number of cigarettes per day s/he smokes now, as “now” refers to the past month. **Q1e** asks for the age or year in which s/he stopped smoking cigarettes completely. Record “N” in the date field if s/he has not stopped smoking cigarettes completely. **Q1f** asks the participant if s/he ever stopped smoking for more than 6 months during the time that s/he smoked. If s/he answers “yes”, go to **Q1g**, which asks how many years total the participant stopped smoking cigarettes. If s/he is unsure, ask him/her to make their best guess. If s/he answers “no”, proceed to **Q2a**.

Question 2: **Q2a** asks if since the date of the last in-person visit the participant has regularly smoked a pipe or cigar. If s/he answers “no” proceed to **Q3a**. If s/he answers “yes” proceed to **Q2b** which asks if

the participant smokes a pipe or cigar now.

Alcohol Consumption:

Question 3a: **Q3a** asks if the participant regularly drinks beer, wine, and liquor/spirits. Each type of alcohol is recorded separately. If the participant answers “yes” to any type of alcohol, proceed to **Q3b**. If the participant answers “no” to each type of alcohol, proceed to **Q3c**.

Question 3b: **Q3b** asks the average number of servings of each type of alcohol s/he drinks in a typical week *or* month over the past year. A single serving of alcohol is considered a 12oz bottle, glass, or can of beer; a 4oz glass of red or white wine; or a 1oz cocktail/highball of liquor/spirits. Code alcohol intake as either weekly or monthly as appropriate. If the participant is unsure of the number of servings s/he consumed, ask him/her to make their best guess.

Question 3c: **Q3c** asks the age at which the participant stopped drinking alcohol. Record his/her response. If s/he is unsure, ask him/her to make their best guess. If the participant has not stopped drinking alcohol or if s/he never drank alcohol, record “N” for not applicable.

Question 3d: **Q3d** asks the average number of days per week the participant drank an alcoholic beverage of any type over the past year. Record his/her response. If s/he is unsure, ask him/her to make their best guess. If the participant has not had any drinks, record “0”. If he/she drank on 1 or less days, record “1”.

Question 3e: **Q3e** asks the number of drinks the participant had on a typical day over the past year. Record his/her response. If s/he is unsure, ask him/her to make their best guess. If the participant has not had any drinks, record “0”. If he/she drank 1 alcoholic beverage or less, record “1”.

Question 3f: **Q3f** asks the maximum number of drinks s/he had in a 24-hour period during the past month. Record his/her response. If s/he is unsure, ask him/her to make their best guess. If the participant has not had any drinks, record “0”. If he/she drank 1 alcoholic beverage or less, record “1”.

Question 3g: **Q3g** asks if since the date of the last in-person visit there has been a time when the participant drank 5 or more alcoholic drinks of any kind almost daily. Record his/her response.

Question 3f: Check the box if over the past year the participant drank less than one alcoholic beverage of any type per month.

Study Documentation referred to in this Chapter:

Panel 5: Medical History Returning Participants

Panel 5: Medical History New Participants

Panel 4: Personal History ALL Participants