Framingham Heart Study

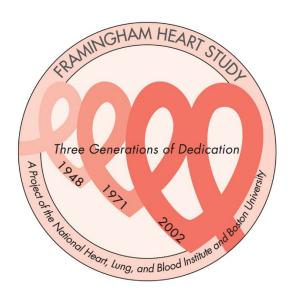
Manual of Procedures

MOP-version 1.0 August 22, 2018

Research Examination Center

Generation 3, Omni 2, NOS Cohorts Examination 3

Section #4 Self-Administered Questionnaires





Tracking of Revisions to this FHS Protocol MOP

Revised Section	Date (s) of Revisions; source	Approved by, Date	Revisions	Previous Pages #s section changed	Distribution Date

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1.0 Sociodemographic and Subjective Health

This is a self-reported form. The participant will fill this questionnaire out in clinic. Once the participant is done with the form a clinic staff member will review the form for completeness. If any blanks are left the question will be flagged and the participant will be asked to fill in the blank.

Question 1: What is your current marital status?

1=single/never married,

2=married/living as married/living with partner

3=separated

4=divorced

5=widowed

9=prefer not to answer

Question 2: What is the highest degree or level of school you have completed? (if currently enrolled, mark the highest grade completed, degree received)

0= no schooling

1=grades 1-8

2=grades 9-11

3=completed high school (12th grade) or GED

4=some college but no degree

5=technical school certificate

6=associate degree (Junior college AA, AS)

7=Bachelor's degree (BA, AB, BS)

8=graduate or professional degree (master's, doctorate, MD, etc.)

9=prefer not to answer

Question 3: Please choose which of the following best describes your current employment status?

0=homemaker, not working outside the home

1=employed (or self-employed) full time

2=employed (or self-employed) part time

3=employed, but on leave for health reasons

4=employed, but temporarily away from my job

5=unemployed or laid off

6=retired from my usual occupation and not working

7= retired from my usual occupation but working for pay

8= retired from my usual occupation but volunteering

9=prefer not to answer

10=unemployed due to disability

11= full-time student

Question 5: Using the occupation drop down list, choose the code that best describes your occupation.

Question 6: Please select which income group best represents your combined family income for the past 12 months.

1=under \$20,000

2 = \$20,000 - \$34,999

3 = \$35,000 - \$54,999

4 = \$55,000 - \$74,999

5 = \$75,000 - \$100.000

6 =over \$100,000

99=prefer not to answer

Question 7: How many people are supported by this income?

Question 8: Do you have some form of health insurance? 0=No, 1=Yes If the participant answers yes, make sure that the participant circles what type of insurance they have from the insurance plan list.

Question 9: Do you have prescription drug coverage

1.1 OCCUPATION CODING

- 01= Homemaker
- 02= Retired
- 03= Self Employed Business Owner
- 04= M.D. / Dentist
- 05=Lawyer/Judge
- 06= Psychologist / Social Worker / Mental Health Counselor
- 07= Scientist / Research
- 08= Engineer / Computer Science
- 09= Banker / Accountant
- 10= Manager / Consultant (e.g. Production Manager)
- 11= Administer (e.g. Personnel)
- 12= Educator
- 13= Nurse / Medical Personnel
- 14= Laboratory Technician
- 15= Physical / Occupational / Speech Therapist
- 16= Secretary/ Clerk / Data Entry
- 17= Retail / Cashier
- 18= Sales / Marketing / Insurance
- 19= Realtor
- 20= Writer / Editor
- 21= Artist / Graphic Designer / Craftsperson
- 22= Musician
- 23= Police / Fire / Security / Military
- 24= Factory / Assembly
- 25= Mechanic
- 26= Restaurant / Food Worker
- 27= Skilled Labor (e.g. Plumber, Carpenter, Painter, Hairdresser)
- 28= General Labor (e.g. Custodian, Delivery, Mailman, Truck Driver)
- 29= Heavy Labor (e.g. Construction, Landscaping)
- 30= Clergy (minister, Priest, Rabbi)
- 31= Sports Pro / Coach / Exercise Instructor
- 32= Statistician
- 33= Student
- 88= Other

1.2 SF-12 Health Survey

The Quality of Life form has twelve questions and is designed to collect information about the participant's perceived physical and emotional health, as they relate to quality of daily living.

Q1 asks the participant to rank his/her general health on a five-point response scale: *Excellent, Very Good, Good, Fair, Poor.*

Q2 and Q3 address the extent to which a participant's health limits his/her activities regarding moderate activities and climbing stairs, using a three-point response scale: *No-not limited, Yes-limited a little, Yes-limited a lot.*

Q4-Q7 ask the participant to assess whether physical and emotional problems have impacted his/her ability to perform work tasks or regular daily activities during the previous four weeks. A *Yes* or *No* response is required.

Q8 asks the participant how much pain interfered with his/her normal work during the previous four weeks, using a five-point response scale: *Not at all, A little bit, Moderately, Quite a bit, Extremely*.

Q9-Q12 ask the participant how he/she has felt during the previous four weeks, using a six point response scale: All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time.

1.3 Training and Certification of Staff

New Staff

- Given Protocol to read, understand, ask questions to Supervisor
- Protocol is demonstrated by Supervisor
- New Staff observes other Techs performing Protocol
- New Staff practices Protocol on staff and volunteers
- New Staff performs Protocol on participant with Supervisor or Certified Tech observing
- When Supervisor feels New Staff is proficient in Protocol, Supervisor will certify New Staff
- Certified New Staff will perform Protocol on own
- Certification date is noted in Certification Log

Recertification of Staff

- Occurs when there is a major deviation on Supervisor Observations or a new study with a new protocol is introduced into the exam
- Protocol is demonstrated by Supervisor
- Staff observes other Techs performing Protocol
- When Supervisor feels Staff is proficient in Protocol, Supervisor will recertify Staff
- Recertification date is noted in Certification Log

2.0 SF12 Health Survey

The Quality of Life form has twelve questions and is designed to collect information about the participant's perceived physical and emotional health, as they relate to quality of daily living.

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2.1 Training and Certification of Staff

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3.0 Bleeding Questionnaire

The FHS Bleeding Questionnaire was adapted from the long ISTH-BAT (International Society for Thrombosis and Hemostasis-Bleeding Assessment Tool) in consultation with hematologists and platelet researchers. The time to complete the questionnaire is expected to be <5 minutes for the vast majority of individuals. The question will be self-administered via RedCap. The focus of the Questionnaire is on collecting participant lifetime bleeding history and identifying in particular individuals with serious clinical bleeding conditions, with or without family history. A major emphasis is abnormal bleeding that caused or required significant medical intervention. This information will be compared with cell counts, platelet function tests and records follow-up later. The Questionnaire will be scored as described in a later section.

This self-administered Bleeding Questionnaire can be found under: Section 16: Platelet Aggregation