

Supporting Statement B

for

The Framingham Study (FHS), NHLBI

February 24, 2016

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List of Attachments

Attachment 1 – Examination Forms for Third Generation & NOS Cohort and
Omni Group 2 Cohort

Attachment 3 – Medical History

B. Collection of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The respondent universe consists of the surviving men and women of the Framingham Study cohorts (Original, Offspring, Generation Three & New Offspring Spouses (NOS), and Omni Groups 1 and 2 Cohorts). The collection of information does not employ statistical sampling methods since this is an ongoing study of participants previously enrolled in The Framingham Heart Study. All participants have been examined before, and thus, the study deals with a stable and already approached sample.

The response rate for the Original Cohort's previous examination (Exam 32) was 48 percent of the 166 surviving participants. The response rate for the Offspring Cohort's previous examination (Exam 9) and Omni Group 1 was 70 percent of the 3,894 surviving participants. In addition, the response rate for follow-up surveys was 88% of the 7,281 surviving participants in all cohorts. Vital status is known on most participants, with less than one percent totally lost to follow-up.

B.2. Procedures for the Collection of Information

The 32nd examination of the Original Cohort was completed, as were the ninth the Offspring Cohort and the 4th examination of Omni Group 1 Cohort in April, 2014. Both were previously approved by OMB (0925-0216). We are requesting approval to continue surveillance (Follow Up) for the Original Cohort and the Offspring Cohort and the Omni Group 1 Cohort during 2015-2019 using the Medical History Update Form (**Attachment 2**). We request approval for the third examination of the Generation Three & NOS Cohort and Omni Group 2 Cohort participants as a main component of this OMB submission. The participants were informed at their previous visit that a repeat visit would take place. The Framingham participants are contacted by telephone to schedule their appointment. A letter is then sent to confirm their appointment. For the

Generation Three & NOS Cohort and the Omni Group 2 Cohort, a questionnaire asking the participant to list current medications, hospitalizations since last examination, and physician visits since last examination is included with this letter (**Attachment 3**). In addition, a bag is sent along with a request that all the participant's currently medications be placed into the bag and brought to the clinic. Any participants unwilling or unable to participate in an examination are sent a Medical History Update Form to complete. Participants who are unreachable by telephone are sent a postcard and subsequently the Medical History Update Form (**Attachment 3**).

Data collection during the examination for the Generation Three & NOS Cohort and the Omni Group 2 Cohort includes an interview and will be conducted using the integrated Generation Three & NOS and Omni Group 2 Exam 3 Form (**Attachment 1**) by the cohort coordinator, by medical technicians, and by Framingham Heart Study investigators who are physicians, for those participants who come to the FHS examination center. At the visit, each participant will go through the following examination procedures: consent at reception, blood pressure measurement, anthropometric measurements, electrocardiogram, and medical history interview. Exam 3 also includes venipuncture for blood tests and DNA collection (in cases where it was not previously collected in adequate amounts. For those participants who are residing in the Framingham area and are not physically capable of coming to the clinic, an abbreviated data collection will occur at their place of residence (home or nursing home) and will be conducted by a medical assistant. (**Attachment 1**) The total response burden time associated with the examination at the Framingham Study center is 1.7 hours for the Generation Three & NOS Cohort and Omni Group 2. The total response burden associated with the at-home examination is 1 hour, for those Study participants unable to travel. There are no plans at this time for an examination of the Offspring cohort and Omni Group 1 as part of this program. The components of the Generation Three & NOS cohort and Omni Group 2 cohort examination are

listed in Table B.2 – 1

TABLE B.2-1 COMPONENTS OF GEN3 OMNI GROUP2 EXAM 3
PRE-EXAM <ul style="list-style-type: none">• Telephone contact for appointment• Scheduling, Reminder and Instructions
EXAM <ul style="list-style-type: none">• Informed consent• Blood draw/urine• ECG• Anthropometry• Physician-administered medical hx• Resting BP x 2• Lifestyle questionnaires• Exit interview• Change into gown• Bleeding Questionnaire and Platelet reactivity
POST EXAM Intramural Study <ul style="list-style-type: none">• eFHS App questionnaire

Aside from the examinations, participants from all the cohorts will be contacted annually via mail in order to identify their current contact information by means of a newsletter and by mail and/or telephone for medical history updates, and interim hospitalizations (**Attachment 3**). The procedure for obtaining updated medical releases from a participant or the family member of a participant is accomplished by sending a letter to either the participant or to a family member. Accompanying this letter is a medical release form (**Attachment 3**); once the release is obtained, a copy of it is enclosed with the appropriate records request form. Phone calls will be made and mortality records will be ascertained for those who fail to respond initially. Records may be requested from health care providers including personal physicians, hospitals and nursing homes to validate medical events. The recipient of the contract who is collecting and analyzing the data in conjunction with NHLBI is the Boston University Medical Center. The principal investigator is Ramachandran Vasan, M.D.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

The response rate will be calculated using the number of individuals examined as the numerator and the number of surviving members of the cohorts as the denominator. The expected response rate to the examination is 70 percent for all cohorts combined. This rate is estimated by extrapolating actual response rates from 1947 through Examination 32 of the Original Cohort, Examination 8 of the Offspring Cohort, and Examination 3 of the Omni Group 1. The response rate for health history follow-up was 88 percent. Response rates are maximized by offering three modes of response for follow-up surveys (paper survey by mail, web survey or telephone interview), by sending reminder phone messages, and by checking mail addressed annually with address correction feature on newsletter mailings.

When a participant arrives at the Framingham clinic for his or her examination, one of the first items on the agenda is the update of information to be used for maintaining future contact with the participant: his or her home address, email address and phone number, as well as similar information for participant's physician, employer, relative, and close friend. The patient coordinator works diligently to contact the participant for his or her next examination, using this information when needed. To date, less than one percent of the combined cohort has been lost to follow-up. The other participants who are considered non-respondents are: 1) those who have refused examination for any reason, e.g. illness, distance, or disinterest and 2) those for whom the address and phone number are correct, but the participant does not respond to contact attempts made. Other methods to promote response are the home or nursing home examinations for those who are not physically able to make it into the clinic and provision of taxi transportation for participants who are unable to get to the clinic otherwise.

B.4. Test of Procedures or Methods to be Undertaken

Many of the procedures and methods of data collection have been refined previously to minimize burden and improve utility. Some components from previous examinations will be omitted from the Generation Three, New Offspring Spouse and Omni Group 2 Examination 3, e.g., spirometry, neck girth and walking speed. Other components will be added, such as web-based collection of dietary and social network data. Wherever feasible, paper recording of data collection will be replaced by direct electronic capture of responses and measures.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing

Data

Those consulted on statistical aspects:

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