Supporting Statement B
for
The Framingham Study (FHS), NHLBI

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LIST OF ATTACHMENTS

a. Attachment 7 - Generation 3 Exam Scheduling Form (also to be used for Offspring and Omni Group 1 Exam).

b. Attachment 4 - Letter to Participants Not Taking Exam (now called “Medical History Update Form”)

c. Attachment 2 – Original Cohort Exam Forms

d. Attachment 1 - Offspring Cohort and Omni Group 1 Cohort Exam Form

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, 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 31) was 74 percent and for the Offspring Cohort's previous examination (Exam 8) was 81 percent. The overall response rate, combining these two populations, was 81 percent. Over the 64 years of The Framingham Study in general, the response rate for the original cohort has been declining very slowly (less than two percent per cycle), primarily due to participants moving away from the Framingham area and not making return visits. In particular, the original cohort is now very elderly (all are over 90 years of age), and a considerable number of those who have moved away are not well enough to return to Framingham for visits. However, 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 clinical visit of the Original Cohort is ongoing and the ninth and fourth clinical visits of the Offspring Cohort and Omni Group 1 Cohort will be completed by March 31, 2014 and both were previously approved by OMB (0925-0216). We are requesting approval to complete Exam 32 for the Original Cohort. We are also requesting approval to complete Exam 9 of the Offspring Cohort and Exam 4 of the Omni Group 1 Cohort during 2014-2016. We note that a great majority of the Offspring and Omni Group 1 cohorts will have already completed their examination cycles by the end of 2013. Therefore, only a small number of Offspring and Omni

Group 1 participants will remain to be examined for 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 Original 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 6a)**. For the Offspring and Omni Group 1 Cohorts, a dietary questionnaire **(Attachment 3)** and the same questionnaire as the Original Cohort requesting the participant to list current hospitalizations, emergency room visits, day surgery and physician's visits are sent with the appointment confirmation letter **(Attachment 6a)**; 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.

If the participants are unwilling or unable to participate in an examination, they 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 4)**.

Data collection for Original Cohort Exam 32 includes an interview and blood pressure determination and will be conducted using the integrated Original Cohort Exam Form **(Attachment 2)** by the cohort coordinator, by medical technicians, and by Framingham Heart Study investigators who are physicians, for those participants who come to the clinic. At the clinic, each original cohort participant will go through the following examination procedures: reception, blood pressure measurement, anthropometric measurements, electrocardiogram, strength and ambulation measures, cognitive and physical activity questionnaire, and medical history interview. Offspring Cohort Exam 9 and Omni Group 1 Cohort Exam 4 also includes reception, venipuncture for blood tests and DNA collection (in cases where it was not previously

collected in adequate amounts), blood pressure measurement, electrocardiogram, medical history, physical exam, anthropometrics, pulmonary function test, ankle doppler blood pressure , and cognitive and physical activity questionnaires conducted using the integrated Offspring and Omni Group 1 Exam Form **(Attachment 1a)** by the cohort coordinator, by medical technicians, and by Framingham Heart Study investigators who are physicians. 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 1b)** The total response burden time associated with the clinic examination is 0.75 hour for the original cohort and 3 hours for the Offspring Cohort and Omni Group 1. The total response burden associated with the at-home examination is 1.1 hours, for members of the Original Cohort unable to travel. The Generation Three Cohort and Omni Group 2 will not be having a full examination during the coming three years. A summary of the components of the Original Cohort Cycles 32 is found in Table B.2 -1. The components of the Offspring Cohort and Omni Group examination are listed in Table B.2 - 2.

Table B2-1 Components of Original Cohort Examination Cycles 31 and 32

Information sheet reviewing exam procedures

1) HIPPA-Release of Health Information for Research Purpose
2) FHS Follow-up by Proxy
3) Tracking Information Form (Salmon Sheet)

Anthropometrics

a. Height
b. Weight
c. Blood Pressure

Observed Physical Performance

a. Handgrip
b. Chair Stands
c. Balance
d. Timed Walk

Cognitive and Physical Function Questionnaires:

1) The Mini-Mental Status Examination
2) Sociodemographics and Subjective Health
3) Self Reported Physical Function:
   a. Rosow-Breslau
   b. NAGI Scale
   c. KATZ-Activities of Daily Living
4) IADL'S (Instrumental Activities of Daily Living)
5) CES-D (Center for Epidemiologic Studies Depression Scale)
6) Berkman Social Network Questionnaire
7) Other
   a. Use of Nursing and Community Services
   b. Falls and Fractures
   c. Procedure Sheet & Exit Interview

Medical History

1) Resting Blood Pressure (2)
2) Referral Tracking

Exit interview

Table B2-2 Components of the Offspring Cohort Examination 9 and Omni Group 1 Cohort Examination 4

Informed consent, tracking information
Phlebotomy, urine specimen
Anthropometry (weight, height, neck/waist/hip/thigh girth, sagittal abdominal diameter)
ECG
Physician administered medical history and physical exam
Ankle-brachial blood pressure
Pulmonary function testing (postbronchodilator spirometry- Subset) and respiratory disease Questionnaire
Tech-administered questionnaires: Neuro-cognitive and physical function ; exercise habits; CES-D
Self-administered questionnaires (Food frequency questionnaire, sociodemographics, SF-12)
Observed performance battery: chair stands, tandem stand, walking speed, Hand grip strength
Change clothing
Downtime (snack, wait between exam stations)

Aside from the examinations, participants from all the cohorts will be contacted annually via mail in order to identify their current contact information, medical history, and interim hospitalizations **(Attachment 4).** The procedure for obtaining 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 **(Attachments 6a and 6b)**; 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 Philip A. Wolf, 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 is 70 percent for the Original Cohort, Offspring Cohort, and Omni Group 1 combined. This rate is estimated by extrapolating actual response rates from 1947 through Examination 31 of the Original Cohort, Examination 8 of the Offspring Cohort, and Examination 3 of the Omni Group 1.

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 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 nonrespondents 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

There are no new procedures or methods of data collections being undertaken during the period of data collections being herein requested. The procedures and methods of data collection have all been refined previously to minimize burden and improve utility.

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

Those consulted on statistical aspects:

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