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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 Day Comment Request; The Framingham Heart Study (NHLBI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Paul Sorlie, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892, or call non-toll-

free number (301) 435-0456, or E-mail your request to: sorliep@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Framingham Heart Study, Revision, 0925-0216 Expiration Date: 10/31/2016, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: This proposal is to extend the Framingham Study to examine the Generation Three Cohort, New Offspring Spouses and Omni Group 2 Cohort, as well as to continue to monitor the morbidity and mortality which occurs in all Framingham Cohorts. The contractor, with the collaborative assistance of NHLBI Intramural staff, will invite study participants, schedule appointments, administer examinations and testing, enter information into computer databases for editing, and prepare scientific reports of the information for publication in appropriate scientific journals. All participants have been examined previously and thus the study deals with a stable, carefully described group. Data are collected in the form of an observational health examination involving such components as blood pressure measurements, venipuncture, electrocardiography and a health interview, including questions about lifestyles and daily living situations. The National Heart, Lung, and Blood Institute uses the results of the Framingham Study to: 1) characterize risk factors for cardiovascular and lung diseases so that national prevention programs can be designed and implemented; 2) evaluate trends in cardiovascular diseases and risk factors over time to measure

the impact of overall preventive measures; and 3) understand the etiology of cardiovascular and lung diseases so that effective treatment and preventive modalities can be developed and tested.

Most of the reports of study results have been published in peer reviewed medical journals and books.

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 8,382.

Estimated Annualized Burden Hours

Table A.12-1.1
ESTIMATE OF RESPONDENT BURDEN, ORIGINAL COHORT
ANNUALIZED

| Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Time per Response (in hours) | Total Annual Burden Hour |
|---|------------------------------|---|---|---------------------------------|
| I. PARTICIPANT COMPONENTS | | | | |
| ANNUAL FOLLOW-UP | | | | |
| a. Records Request | 30 | 1 | 15/60 | 8 |
| b. Health Status Update | 30 | 1 | 15/60 | 8 |
| SUB-TOTAL: PARTICIPANT COMPONENTS | 30* | ----- | ----- | 15 |
| II. NON- PARTICIPANT COMPONENTS | | | | |
| A. Informant Contact (Pre-exam and Annual Follow-up) | 15 | 1 | 10/60 | 3 |
| B. Records Request (Annual follow-up) | 30 | 1 | 15/60 | 8 |
| SUB-TOTAL: NON-PARTICIPANT COMPONENTS | 45 | ----- | ----- | 10 |
| TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS | 75 | | | 25 |

* Number of participants as reflected in Row I.b. above

Table A.12-1.2
ESTIMATE OF RESPONDENT BURDEN, OFFSPRING
COHORT and OMNI GROUP 1 COHORT
ANNUALIZED

| Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Time per Response (in hours) | Total Annual Burden Hour |
|---|------------------------------|---|---|---------------------------------|
| I. PARTICIPANT COMPONENTS | | | | |
| ANNUAL FOLLOW-UP | | | | |
| a. Records Request | 1500 | 1 | 15/60 | 375 |
| b. Health Status Update | 1700 | 1 | 15/60 | 425 |
| SUB-TOTAL: PARTICIPANT COMPONENTS | 1700* | ----- | ----- | 800 |
| | | | | |
| II. NON- PARTICIPANT COMPONENTS | | | | |
| A. Informant contact (Pre-exam and Annual Follow-up) | 150 | 1 | 10/60 | 25 |
| B. Records Request (Annual follow-up) | 1500 | 1 | 15/60 | 375 |
| SUB-TOTAL:NON-PARTICIPANT COMPONENTS | 1650 | ----- | ----- | 400 |
| | | | | |
| TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS | 3350 | | | 1200 |

* Number of participants as reflected in Row I.b. above

Table A.12-1.3
ESTIMATE OF RESPONDENT BURDEN, GENERATION 3
COHORT, NOS and OMNI GROUP 2 COHORT
ANNUALIZED

| Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Time per Response (hours per year) | Total Annual Burden Hour |
|---|-----------------------|------------------------------------|--|--------------------------|
| I. PARTICIPANT COMPONENTS | | | | |
| A. PRE-EXAM | | | | |
| 1. Telephone contact for appointment | 1,450 | 1 | 10/60 | 242 |
| 2. Exam appointment, scheduling, reminder and instructions | 1,270 | 1 | 35/60 | 741 |
| B. EXAM CYCLE 3 | | | | |
| 1. Exam at study center | 1,200 | 1 | 110/60 | 2,200 |
| 2. Home or nursing home visit | 35 | 1 | 60/60 | 35 |
| C. POST-EXAM eFHS Mobile Technology for Collection of CVD Risks | 1,100 | 18 | 9/60 | 2,970 |
| D. ANNUAL FOLLOW-UP | | | | |
| 1. Records Request | 1,200 | 1 | 15/60 | 300 |
| 2. Health Status Update | 1,400 | 1 | 15/60 | 350 |
| SUB-TOTAL: PARTICIPANT COMPONENTS | 2,850* | ----- | ----- | 6,830 |
| II. NON- PARTICIPANT COMPONENTS – ANNUAL FOLLOW-UP | | | | |
| A. INFORMANT CONTACTS | 180 | 1 | 10/60 | 30 |
| B. RECORD REQUEST | 1,155 | 1 | 15/60 | 289 |
| SUB-TOTAL:NON-PARTICIPANT COMPONENTS | 1,335 | ----- | ----- | 319 |
| TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS | 4,185 | | | 7,157 |

* Number of participants as reflected in Rows I.A.1 and I.D.2 above

Dated: December 22, 2015.

Valery Gheen,

NHLBI Project Clearance Liaison,

National Institutes of Health.

[NIH Billing Code 4140-01-P]

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