[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; Women's Health Initiative (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 4, 2016, Pages: 19207-19208. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Shari Ludlam, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892, or call non-toll-free number (301) 435-6667, or E-mail your request to: ludlams@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Women's Health Initiative, 0925-0414, Revision, Exp. 7/31/2016, 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 Women's Health Initiative (WHI), which comprises a group of research studies that will address critical issues about the most common causes of frailty, disability, and death among post-menopausal women aged 50 to 79 years. This Initiative is comprised of two main investigational approaches: 1) A large clinical trial (CT) to evaluate the clinical efficacy of promising, but unproven preventive approaches for specific diseases common among older women; and 2) a companion observational study (OS) comprised of women

ineligible or unwilling to participate in the CT, to evaluate risk factors for chronic diseases by following this large cohort of women and relating subsequent disease development to baseline assessments of historical, physical, and physiologic characteristics. The WHI provides new information on health and risk of disease among older post-menopausal women to inform development of approaches to disease prevention. The specific objectives of the OS are to provide reliable estimates of the extent to which known risk factors predict heart disease, cancers and fractures; identify new risk factors for these and other diseases in women; compare risk factors, presence of disease at the start of the study, and new occurrences of disease during the WHI in all study components; and create a future resource to identify biological indicators of disease, especially substances and factors found in the blood. Continued follow-up of medical outcome occurrences will enhance achievement of the WHI original goals and increase the range of scientific issues that can be examined. Specific biomarkers will be assessed based on current and future hypotheses related to clinical endpoints. The WHI study/protocol allows for analysis and presentation of results in aggregate form only, thus all data including biological samples are void of personal identifiers.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,796.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Medical History Update	Participants	40203	1	7/60	4690
Activities of Daily Life	Participants	40203	1	6/60	4020
Personal Information Update	Participants	40203	1	3/60	2010
Initial Notification of Death	Next of Kin	900	1	5/60	75
Initial Notification of Death	Physician/ Office Staff	15	1	5/60	1
TOTAL		41,118	121,524		10,796

Dated: June 9, 2016.

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Valery Gheen,

NHLBI Project Clearance Liaison,

National Institutes of Health.

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