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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 Day Comment Request; Women's Health Initiative (NHLBI)

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.

TO SUBMIT COMMENTS AND 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.

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 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.

A.12-1 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
Form 33 Medical History Update	OS Participants	40203	1	7/60	4690

Form 151 Activities of Daily Life	OS Participants	40203	1	6/60	4020
Form 20 Personal Information Update	OS Participants	40203	1	3/60	2010
Form 120 Initial Notification of Death	Next of Kin	900	1	5/60	75
Form 120 Initial Notification of Death	Physician/ Office Staff	15	1	5/60	1
TOTAL		41,118	41,118		10,796

Dated: March 23, 2016.

Valery Gheen,

NHLBI Project Clearance Liaison,

National Institutes of Health.

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