



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-Day comment request

The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer (NIEHS)

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 Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted 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: contact Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919)-541-4668 or E-mail your request, including your address to: sandler@niehs.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 Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer, Revision OMB#0925-0522 Expiration Date: 2/29/2016, National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH).

Need and Use of Information Collection: This is to continue the long-term follow-up of the Sister Study — a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The

etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 2,904 participants have reported being diagnosed with breast cancer.

Activity	Estimated Annual Number of Respondents	Number of Responses per Respondent	Average Burden per response(in hours)	Total Burden Hours per year
Annual Update	32,215	1	10/60	5,369
Follow-Up III (triennial)	16,108	1	40/60	10,739

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 16,108.

Dated: November 23, 2015

Laurie K. Johnson

Acting Deputy Associate Director for Management

NIEHS

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