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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

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

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 02 December 2015, Vol. 80, page 75465 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), 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 or request more information on the proposed project 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.

PROPOSED COLLECTION: REVISION: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer, 0925-0522, National Institute of Environmental Health Sciences (NIEHS), 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 16,350.

Estimated Annualized Burden Hours

Activity	Annual Number of Respondents	Number of Responses per Respondent	Average Burden per response (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
Follow-Up III Telephone Prompting Script	4,832*	1	3/60	242
TOTAL per year	48,323			16,350

**These Respondents are included in the 16,108 for Follow-Up III, thus not added into TOTAL Respondents per year.*

Dated: February 19, 2016.

Jane Lambert,

Project Clearance Liaison, NIEHS.

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