

**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.

**DATES: 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 CONTACT:** 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, P.O. Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919)-541-4668 or Email 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
<b>Total per year .....</b>	<b>48,323</b>	<b>.....</b>	<b>.....</b>	<b>16,350</b>

\* 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.

[FR Doc. 2016-04179 Filed 2-25-16; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request: A Clearance for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Data and Specimen Hub (DASH)**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Eunice

Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health, 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 October 30, 2015 on pages 66913-4 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 *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), 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.

**DATES:** *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 CONTACT:** To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Rohan Hazra, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6100 Executive Blvd., Room 4B11, Bethesda, MD 20892-7510, or call non-toll-free number (301)-435-6868 or Email your request, including your address to: *hazrar@mail.nih.gov*. Formal requests for additional plans and

instruments must be requested in writing.

**Proposed Collection:** Data and Specimen Hub (DASH), 0925-NEW, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The NICHD Data and Specimen Hub (DASH) is being established by NICHD as a data sharing mechanism for biomedical research investigators. It will serve as a centralized resource for investigators to store and access de-identified data from studies funded by NICHD. The potential for public benefit to be achieved through sharing research study data for secondary analysis is significant. NICHD DASH supports NICHD's mission to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. Data sharing and reuse will promote testing of new hypotheses from data already collected, facilitate trans-disciplinary collaboration, accelerate scientific findings and enable NICHD to maximize the return on its investments in research.

Anyone can access NICHD DASH to browse and view descriptive

information about the studies and data archived in NICHD DASH without creating an account. Users who wish to submit or request research study data must register for an account.

Information will be collected from those wishing to create an account, sufficient to identify them as unique Users. Those submitting or requesting data will be required to provide additional supporting information to ensure proper use and security of NICHD DASH data. The information collected is limited to the essential data required to ensure that the management of Users in NICHD DASH is efficient and the sharing of data among investigators is effective. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users with regards to their data submission or requests
- Monitor data submissions and data requests
- Notify interested recipients of updates to data stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH data by the research community

There is no plan to publish the data collected under this request.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 142.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hour
User Registration .....	120	1	5/60	10
Data Submission .....	36	1	2	72
Data Request .....	60	1	1	60
<b>Total</b> .....	<b>120</b>	<b>216</b>	.....	<b>142</b>

Dated: February 17, 2016.  
**Sarah L. Glavin,**  
*Project Clearance Liaison, NICHD, NIH.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (<http://videocast.nih.gov/>).

**Name of Committee:** National Cancer Institute Board of Scientific Advisors.  
**Date:** March 29, 2016.  
**Time:** 8:30 a.m. to 5:00 p.m.  
**Agenda:** Director's Report; Ongoing and New Business; Reports of Program Review Group(s); Budget Presentations; Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.  
**Place:** National Institutes of Health, 31 Center Drive, Building 31, C-Wing, 6th Floor, Room 10, Bethesda, MD 20892.  
**Contact Person:** Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Rm. 7W444,