


Dated: November 1, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

RE: Submission for OMB Review; Comment Request The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), 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 15 August 2012 on page 48993 and allowed 60-days for public comment. 1 public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements)

Type of Information Collection Request: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. Type of Information Collection Request: Revision. Need and Use of Information Collection: This is to continue the Phase II 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 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 each year of follow-up. Thus far 1,634 participants have reported being diagnosed with breast cancer. Frequency of Response: For the remainder of the study, women will be contacted once each year (when not scheduled for “triennial”) to update contact information and health status (10 minutes per response); and asked to complete short (75 minutes per response) follow-up interviews or questionnaires (“triennial”) every three years. Follow-up and validation of reported incident breast cancer and other health outcomes is conducted under Clinical Exemption CE 2009–09–004. Affected Public: Study participants, next-of-kin/proxies. Type of Responses: Participants enrolled in high-risk cohort study of risk factors for breast cancer, next-of-kin/proxies. The annual reporting burden is as follows: Estimated Number of Respondents: 50,884 study participants or next-of-kin/proxies. Estimated Number of Responses per Respondent: See annualized table below:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Estimated number of respondents</th>
<th>Estimated responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Updates</td>
<td>33,923</td>
<td>1</td>
<td>10/60</td>
<td>5,654</td>
</tr>
<tr>
<td>Follow-Up (triennial)</td>
<td>16,961</td>
<td>1</td>
<td>1.25</td>
<td>21,202</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>26,856</td>
</tr>
</tbody>
</table>

Average Burden Hours Per Response: 42 minutes; and Estimated Total Annual Burden Hours Requested: 26,856. The estimated total annualized cost to respondents $537,120 (assuming $20 hourly wage x 26,856). There are no capital, operating, or maintenance costs.

Request For Comments: 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.

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: Desk Officer for NIH. To request more information on the project or to obtain a copy of the data collection plans and instruments, 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.

Comments 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.

Joellen M. Austin, Associate Director for Management.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Hazardous Waste Worker Training

AGENCY: National Institute of Environmental Health Sciences, Division of Extramural Research and Training, NIH, HHS.

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), 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 May 14, 2012, pages 28395–28396 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 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.

Proposed Collection: Title: Hazardous Waste Worker Training—42 CFR part 65. Type of Information Collection Request: Revision of OMB No. 0925–0348 and expiration date November 30, 2012. Need and Use of Information Collection: This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In twenty-four years (FY 1987–2011), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained more than 2.7 million workers across the country and presented over 160,913 classroom and hands-on training courses, which have accounted for nearly 36 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with 65.4 (a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees’ qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA’s Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to provide their information in hard copy as well as enter information into the WETP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards. Frequency of Response: Biannual. Affected Public: Non-profit organizations. Public reporting burden for this collection of information is estimated to average 14 hours per year, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The annual reporting hour burden is as follows: number of respondents: 20; number of responses per respondent: 2; and annual hour burden per response: 560. The average time per response is 14 hours per year. The estimated hour burden for each respondent includes nine hours to create documents and five hours for support staff to compile the documents. The annualized cost to respondents is estimated at: $18,200.00.

The table below presents the estimated annualized burden hours for the proposed information collection:

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average time per response (in hours)</th>
<th>Total hour burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grantees</td>
<td></td>
<td>20</td>
<td>2</td>
<td>560</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>20</td>
<td>2</td>
<td>560</td>
</tr>
</tbody>
</table>