Seleda Perryman,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

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.

Proposed Collection: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision of OMB No. 0925–0522 and expiration date 30 September 2009. *Need and Use of Information Collection:* The purpose of the Sister Study is to study 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. In the United States, approximately 192,370 new cases of invasive breast cancer are anticipated in 2009. 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. We have enrolled a cohort of 50,000 women who have not had breast cancer. Recruitment took place from August 2003 through July 2009. We estimate that in the cohort of 50,000 sisters, aged 35–74 at enrollment, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. *Frequency of Response:* For the remainder of the study, women will be contacted once each year to update contact information and health status (10 minutes per response); and asked to complete short (60–75 minutes, total) follow-up interviews or questionnaires every two to three years. Women diagnosed with breast cancer or other health outcomes of interest are asked to provide additional information about their diagnosis (20 minutes per response) and their doctors will be contacted to provide medical records related to diagnosis and treatments (15 minutes per response). *Affected Public:* Study participants; medical office staff. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,000 study participants and 2100 medical office staff. *Estimated Number of Responses per Respondent:* See table below:

Activity (3–yrs)	Estimated number of respondents	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
Annual Updates	50,000	1	0.17	8,500
Biennial Follow-Up Questionnaire	50,000	1	1.25	62,500
Incident BC Case Follow-Up	1800	1	0.33	594
Incident Other Case Follow-Up	300	1	0.33	99
Incident Case Medical Office Contact	2100	1	0.25	525
Total				72,218

Average Burden Hours per Response: 0.7 hour; and *Estimated Total Burden Hours Requested:* 72,218 (over 3 years). The average annual burden hours requested is 24,073. The annualized cost to respondents is estimated at $14 (assuming $20 hourly wage × 0.7 hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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.

FOR FURTHER INFORMATION CONTACT: 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, 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.*''

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.

Dated: July 1, 2009.

Marc S. Hollander,

Associate Director for Management.

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