

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Care Financing Administration**

[Document Identifier: HCFA-SP1]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request****AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Post-Eligibility Preprint and Supporting Regulations in 42 CFR 435.310; *Form No.:* HCFA-SP-0001 (OMB# 0938-0673); *Use:* The post-eligibility preprint is part of the comprehensive statement that a State submits to show that it is meeting the requirements for Federal funding of its Medicaid program. It comprises part of each State's Plan which outlines the mandatory and optional aspects of a State's Medicaid program. Accurate submission of this information is necessary in order for States to receive federal funding; *Frequency:* On occasion; *Affected Public:* State, local or tribal government; *Number of Respondents:* 13; *Total Annual Responses:* 5; *Total Annual Hours:* 15.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/reg/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports

Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 29, 2001.

**John P. Burke, III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Environmental Health Sciences; 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:* NEW. *Need and Use of Information Collection:* We are proposing to study genetic and environmental risk factors for the development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, there were approximately 180,000 new cases in 1997, accounting for 30% of all new cancer cases among women. 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 about 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. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. The sister design will also facilitate study of sib-pairs to evaluate similarities in tumor characteristics, prognosis, and risk factors. We propose to enroll a cohort of 50,000 women who have not had breast cancer. In addition, we will enroll 500 of the index sisters whose breast cancer diagnosis was within the past four months. Initial recruitment of the first 2,000 women will take place from October 2001-January 2002 before beginning recruitment in earnest in April 2002. The data collected in the initial phase will allow us to evaluate subject recruitment and data collection procedures, and collect other data that will help us better target our recruitment efforts. We estimate that a cohort of 50,000 sisters aged 30-74 years would provide about 1,500 breast cancer cases over five years.

*Frequency of Response:* On occasion (one initial 15-minute screening [either on the telephone OR on the internet], followed by an hour and a half-long telephone interview, one mailed self-administered questionnaire, and some biological specimens collection). Women will be advised that subsequent shorter interviews or questionnaires will be sought every 1-2 years for follow-up.

*Affected Public:* Individuals or households.

*Type of Respondents:* Unaffected sisters of women diagnosed with breast cancer, aged 30-74, from all socioeconomic backgrounds and ethnicities and women with recently diagnosed breast cancer. The annual reporting burden is as follows:

*Estimated Number of Respondents:* 63,000 (20,833 unaffected sisters per year, on average, plus a total of 500 index sisters with incident breast cancer).

*Estimated Number of Responses per Respondent:* See table below.

*Average Burden Hours Per Response:* 4.6; and

*Estimated Total Burden Hours Requested:* 293,500 (over 3 years). The average annual burden hours requested is 97,833. The annualized cost to respondents is estimated at \$115 (assuming \$20 hourly wage × 5 hours + \$15 babysitting/travel allowance). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours requested
Women calling in (Eligibility Screening) .....	63,000	1	0.25	15,750
Telephone Interview (CATI) .....	50,500	1	1.5	75,750
Questionnaires (self-administered) .....	50,500	1	1.0	50,500
Biological Collections .....	50,500	1	3.0 <sup>2</sup>	151,500
<b>Total</b> .....	<b>1 63,000</b>	.....	.....	<b>293,500</b>

<sup>1</sup> Expect 20% (12,500) ineligible after screening, + 500 incident cases.  
<sup>2</sup> Includes waiting and travel time, and scheduling appointment for blood draw.

*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 proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale P. Sandler, Acting Chief, Epidemiology Branch, NIEHS, Building 101, A-304, P.O. 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 on or before August 20, 2001.

Dated: June 12, 2001.

**Francine Little,**  
 NIEHS, Associate Director for Management.  
 [FR Doc. 01-15460 Filed 6-19-01; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Environmental Health Sciences; Division of Extramural Research and Training; Proposed Collection; Comment Request; Hazardous Waste Worker Training**

**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:* Hazardous Waste Worker Training—42 CFR part 65. *Type of Information Collection Request:* Revision of OMB No. 0925-0348 and expiration date 10/31/2001. *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 curricular to target populations of hazardous waste workers and emergency responders has been developed. In thirteen years (FY 1987-2000), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained nearly 1 million workers across the country and presented over 54,000

classroom and hands-on training courses, which have accounted for nearly 16 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 S65.4(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. *Type of Respondents:* Grantees. The annual reporting burden is as follows: *Estimated Number of Respondents:* 18; *Estimated Number of Responses per Respondent:* 2; *Average Burden Hours Per Response:* 10; and *Estimated Total Annual Burden Hours Requested:* 360. The annualized costs to respondents is estimated at: \$9,180. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of