

*Background and Brief Description*

Since its establishment in 1970 by the Occupational Safety and Health Act, the National Institute for Occupational Safety and Health (NIOSH) has been at the forefront of research and innovation on methods to help eliminate workplace injuries, illnesses and exposures. At Mine Safety and Health Research laboratories in Pittsburgh, Pennsylvania and Spokane, Washington, NIOSH employs engineers and scientists with experience and expertise in mine safety and health issues. These laboratories and their researchers have gained an international reputation for innovative solutions to many mining safety and health problems.

Although the NIOSH Mining Program widely disseminates and publicizes research results, recommendations, techniques and products that emerge from the work of these laboratories, the agency has limited knowledge about the extent to which their innovations in mine safety and health have been implemented by individual mine operators. This is particularly true of methods and practices that are not mandated by formal regulations. The overarching goal of the proposed survey of NIOSH Recommended Safety and Health Practices for Coal Mines is to

gather data from working coal mines on the adoption and implementation of NIOSH practices to mitigate safety and occupational hazards (e.g., explosions, falls of ground). Survey results will provide NIOSH with knowledge about which recommended practices, tools and methods have been most widely embraced by the industry, which have not been adopted, and why. The survey results will provide needed insight from the perspective of mine operators on the practical barriers that may prevent wider adoption of NIOSH recommendations and practices designed to safeguard mine workers.

In the Spring of 2007, NIOSH conducted a pretest of the survey questionnaire with nine underground coal mine operators. The pretest instrument contained 81 questions, including five questions which measured the respondents' impressions of the clarity, burden level and relevance of the survey. The pretest served several important functions, including gaining feedback on the flow of items and their relevance to the respondents' experience, assessing the effectiveness of the questionnaire instructions, and obtaining recommendations for improving the questions. Data captured in the pretest

were used to identify areas for questionnaire improvement and recommendations for maximizing the performance of the full survey.

The proposed survey will be based upon a probability sample of approximately 300 of the 675 underground coal mines in the United States. A stratified random sample of mines will be drawn to ensure representativeness on important dimensions such as mine size and region of the country. Sampling a large proportion of the underground coal mines will ensure low rates of sampling error and increase confidence in the resulting survey estimates. Oversampling some kinds of mines, such as those operating longwall sections, will be necessary to ensure enough cases are available to conduct meaningful analysis of these mine types.

Once the study is completed, NIOSH will provide a copy of the final report to each sampled mining operation, and use the survey data to improve the adoption of important safety and health practices throughout the coal mine industry. There is no cost to respondents other than their time. The total estimated annual burden hours are 142.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Respondents                                               | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|-----------------------------------------------------------|-----------------------|------------------------------------|----------------------------------------|
| Initial telephone screening contact with coal mines ..... | 300                   | 1                                  | 5/60                                   |
| Respondents completing paper survey .....                 | 144                   | 1                                  | 30/60                                  |
| Respondents completing web survey .....                   | 96                    | 1                                  | 25/60                                  |
| Non-respondent follow-up .....                            | 60                    | 1                                  | 5/60                                   |

Dated: March 29, 2010.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; Women's Health Initiative Observational Study**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, the National Heart, Lung, and Blood Institute (NHLBI), 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 January 20, 2010, page 3237 and allowed 60 days for public comment. Two comments were received and appropriate responses were given. 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 current valid OMB control number.

*Proposed Collection: Title:* Women's Health Initiative (WHI) Observational Study. *Type of Information Collection*

*Request: REVISION: OMB No. 0925-0414, Expiration date: 05/31/2009. Need and Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up years for ascertainment of medical

history update forms will provide essential data for outcomes assessment for this population of aging women.

*Frequency of Response:* Annually.  
*Affected Public:* Individuals and physicians.  
*Type of Respondents:*

Women, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

ESTIMATE OF ANNUAL HOUR BURDEN

| Type of response                         | Number of respondents | Frequency of response | Average hours per response | Annual hour burden |
|------------------------------------------|-----------------------|-----------------------|----------------------------|--------------------|
| Observational Study Participants .....   | 42,550                | 1.12                  | .4155                      | 19,801             |
| Next of Kin <sup>1</sup> .....           | 941                   | 1                     | .083                       | 78                 |
| Health Care Providers <sup>1</sup> ..... | 8                     | 1                     | .085                       | .68                |
| <b>Total</b> .....                       | <b>43,499</b>         | .....                 | .....                      | <b>19,880</b>      |

<sup>1</sup> Annual burden is placed on health care providers and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

The annualized cost burden to respondents is estimated at \$397,617. 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 is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Shari Eason Ludlam, Project Officer, Women's Health Initiative Program Office, 6701 Rockledge Drive, 2 Rockledge Centre, Room 9188, MSC 7913, Bethesda, MD 20892-7936, or call non-toll-free number (301) 402-2900 or E-mail your request, including your address to: [ludlams@mail.nih.gov](mailto:ludlams@mail.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.

Dated: March 23, 2010.

**Michael S. Lauer,**

*Director, Division of Cardiovascular Science, NHLBI, National Institutes of Health.*

Dated: March 24, 2010.

**Suzanne Freeman,**

*Chief, FOIA, NHLBI, National Institutes of Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Cancer Therapy Evaluation Program Intellectual Property Option to Collaborator**

**AGENCY:** National Cancer Institute (NCI), National Institutes of Health (NIH), DHHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The National Cancer Institute, Division of Cancer Treatment and Diagnosis, is seeking comments on a proposed revision to its policy on intellectual property agreements with certain funding recipients, entitled the Cancer Therapy Evaluation Program (CTEP) INTELLECTUAL PROPERTY OPTION. The proposed policy, if finalized, would establish that potential applicants for CTEP funding should include an assurance of agreement with the recommended Intellectual Property Option and Institution Notification if they wish to be considered for funding support to carry out any CTEP-sponsored clinical trial for which CTEP holds the investigational new drug (IND) application.

**DATES:** Comments must be received by NIH on or before May 6, 2010.

**ADDRESSES:** The NIH welcomes public comment on the full text of the CTEP IP

option, set forth below. Comments should be addressed to: CTEP IP Option Project, [nciipoption@mail.nih.gov](mailto:nciipoption@mail.nih.gov).

**FOR FURTHER INFORMATION CONTACT:**

Jason Vittorio Cristofaro, J.D., PhD, Intellectual Property Advisor, National Cancer Institute/NIH/DHHS, Division of Cancer Treatment and Diagnosis, 31 Center Drive, Room 3A44, Bethesda, MD 20892-2580, telephone 301-594-5318, fax 301-496-0826, e-mail [cristofaroj@mail.nih.gov](mailto:cristofaroj@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains proprietary "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI CTEP-supported clinical trials under funding agreements. As part of the arrangement with these Collaborators to use their proprietary Agents and to make funding clinical research possible, Collaborators will often require, as a condition of collaboration, that the NCI CTEP funding recipients receiving the Agent ("Institutions") agree to certain conditions, including the willingness to provide notice of and grant options to certain intellectual property rights arising from research involving the Agent under the scope of an NCI CTEP funding agreement.

The current IP option language is silent as to the disposition of intellectual property developed from data and Agent-treated samples. As a result, both Collaborators and Institutions have claimed an ownership interest in inventions generated from these data and materials. This lack of clarity has become a major impediment in NCI CTEP's ability to obtain proprietary Agents from collaborators for use in CTEP-sponsored clinical studies, which has resulted in delays