

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the second meeting of the HIT Standards Committee in accordance with the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.).

DATES: June 23, 2009, from 9 a.m. to 12 p.m. [Eastern]

ADDRESSES: The Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC 20008, Diplomat Ballroom.

FOR FURTHER INFORMATION CONTACT: <http://healthit.hhs.gov>.

SUPPLEMENTARY INFORMATION:

The meeting will include presentations from the HIT Standards Committee Workgroups. The meeting is a Web-based meeting with

teleconference dial-in. If you have special needs for the meeting, please contact (202) 690-7151.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI)

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 Cancer Institute, the National Cancer Institute (NIH) will publish periodic summaries to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI). *Type of Information Collection Request:* Existing Collection in use without an OMB Control Number. *Need and Use of Information Collection:* Food and Drug Administration (FDA) regulations require sponsors to obtain information from the investigator before permitting the investigator to begin participation in investigational studies. The National

Cancer Institute (NCI), as a sponsor of investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are qualified by training and experience as appropriate experts to investigate the drug. In order to fulfill these requirements, a standard Statement of Investigator (FDA Form 1572 modified), Supplemental Investigator Data Form, Financial Disclosure Form and Curriculum vitae (CV) are required. The data obtained from these forms allows the NCI to evaluate the qualifications of the investigator, identify appropriate personnel to receive shipment of investigational agent, ensure supplies are not diverted for inappropriate protocol or patient use and identify financial conflicts of interest. Comparisons are done with the intention of ensuring protocol, patient safety and drug compliance for patient and drug compliance for patient safety and protections.

Frequency of Response: Annually.

Affected Public: Public sector, businesses other for-profit. Federal agencies or employees, non-profit institutions and a very small number of private practice physicians.

Type of Respondents: Health care investigators. The annual reporting burden is limited to those physicians who choose to participate in NCI sponsored investigational trials to identify new medicinal agents to treat and relieve those patients suffering from cancer. It is estimated that the total annual burden will be 8,564 hours, and include 17,128 investigators, for this project (see Table 1).

TABLE 1—ESTIMATES OF ANNUAL BURDEN

Type of respondents	Form	Number of respondents	Frequency of response	Average time per response	Total hour burden
Investigators and Designee ...	Statement of Investigator	17,128	1	0.25 (15 minutes)	4,282
	Supplemental Investigator	17,128	1	0.167 (10 minutes)	2,855
	Financial Disclosure	17,128	1	0.083 (5 minutes)	1,427
Totals	17,128	8,564

There is no capital, 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 proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301-496-5725 or E-