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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI)

SUMMARY: In compliance with the requirement of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected below. This proposed information collection was previously published in the **Federal Register** on June 10, 2009 (74 FR 27552), and allowed 60 days for public comment. One public comment was received regarding pharmaceutical testing. The submitter responded to the e-mail. 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 valid OMB control number.

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 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 NCI will accept the investigator's CV in any format. All investigators maintain a CV as part of their academic and professional practice. 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 or other for-profit that will include Federal agencies or employees, non-profit institutions and a very small number of private practice physicians. *Type of Respondents:* 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.

The annualized respondents' burden for record keeping is estimated to require 8,564 hours (see table below).

TABLE—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 are no capital costs, operating costs, and maintenance cost.

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 Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. 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-mail your request, including your address, to: *Hallch@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days following the date of this publication.

Dated: August 5, 2009.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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