[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request: Information Program on Clinical Trials; Maintaining a Registry and Results Databank

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), 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: Information Program on Clinical Trials: Maintaining a Registry and Results Databank

Type of Information Collection Request: Revision of OMB No. 0925-0586, expiration date April 30, 2012

Form Number: NA

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects

registration and results information for clinical trials and other types of clinical studies (e.g., observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events. As the existing PRA clearance for this information collection nears expiration, we are making a limited number of revisions to include additional data elements that may be voluntarily submitted to describe and aid in the interpretation of any submitted adverse event information and to facilitate the registration of patient registries.

Frequency of Response: For clinical trials that are subject to FDAAA, responsible parties must submit the required registration information not later than 21 days after enrolling the first subject. Results information is to be submitted not later than 12 months after the completion date (as defined in the law), but can be delayed under certain circumstances. Updates to most submitted information are required at least once a year, if there are changes to report, but changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. Other clinical studies register once, at their inception, and are requested to update information annually, as necessary.

Description of Respondents: Respondents include sponsors or principal investigators of clinical studies. Those subject to FDAAA are referred to as "responsible parties," which are defined as sponsors of the clinical trial (as defined in 21 CFR 50.3) or designated principal investigators who meet requirements specified in the law.

Estimate of Burden: The burden associated with this information collection consists of the burden associated with registration of clinical studies and the burden associated with the submission of results information (including adverse events). These information collections will occur at different times, but submitted information is integrated into a single record for each clinical trial. To estimate the annual reporting burden for registration, we examined the number of clinical studies registered annually with ClinicalTrials.gov and found an average of 17,000 registrations per year since the enactment of FDAAA. From this total, we estimate that approximately 5,000 studies would be applicable clinical trials of drugs (including biological products) and 500 would be applicable trials of devices subject to FDAAA. The remaining 11,500 studies would be registered voluntarily. We estimate the time to complete an initial registration to be 7 hours (including time to extract, reformat and submit information which has already been produced for other purposes). This estimate is consistent with that used on the previous PRA clearance and incorporates 4 hours for data extraction and 3 hours for reformatting. Based on previous experience, we estimate that each registration record will be updated an average of eight times and that each update takes approximately 2 hours. Applying these figures to the estimated number of trials to be registered per year produces an annual burden estimate of 391,000 hours. Of this total, 126,500 hours are associated with

the mandatory registration of trials subject to FDAAA, and 264,500 hours are associated with voluntary registrations.

The burden of results submission consists of the time and effort needed to summarize information from a clinical trial, format it, and enter it into the databank. We estimate that of the 5,500 applicable clinical trials that are registered each year, approximately 1,845 will be required to submit results each year (1,500 trials of drugs and biological products, and 345 trials of devices). We estimate that each results record will submitted once and updated twice to reflect changes in the data analysis, additional results of subsequent pre-specified outcome measures, or additional adverse event information. Based on information available from various organizations about results submission times, comments made at a public meeting held in April 2009, responses to estimates in previous OMB clearance documents (73 FR 58972, Oct. 8, 2008), and feedback from respondents who have submitted results to ClinicalTrials.gov, we have increased our estimate of the average response time to 25 hours from the 10 hour estimate included in the previous OMB clearance request. We estimate that updates take 8 hours, an increase over the 5 hour estimate included in the previous OMB clearance request for adverse event information. In addition, we estimate that 3,655 trials per year will submit certifications to ClinicalTrials.gov indicating that they qualify for delayed results submission, and another 200 trials will request extensions to the submission deadline for good cause, as permitted by FDAAA. We expect that it would take no more than 30 minutes for a responsible party to determine that a certification is required and to submit the necessary information through ClinicalTrials.gov. For extension requests, we

estimate that the time to prepare a request and submit it to ClinicalTrials.gov would be no more than 2 hours. Using these figures, we estimate the annualized hourly burden for submitting results information, certifications, and extension requests to be 77,872.5 hours. There are no capital 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 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.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301-402-9680 or E-mail your request to sharlipd@mail.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: February 2, 2012

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David H. Sharlip

OMB Project Clearance Liaison, National Library of Medicine

National Institutes of Health

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