[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request

Web-Based Assessment of the Clinical Studies Support Center (CSSC)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on March 12, 2011, Volume 77 No. 44, pages 14531-14533 and allowed 60-days for public comment. One comment was received. 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:* Web-Based Assessment of the Clinical Studies Support Center (CSSC). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Over the past decade Data Safety Monitoring Boards (DSMBs), Observational Safety Monitoring Boards (OSMBs), and Protocol Review Committees (PRCs) have become an important quality standard in clinical trials and research involving human subjects. The National Heart, Lung, and Blood Institute (NHLBI) alone currently has approximately 60 active review Committees. These include DSMBs, OSMBs, and PRCs which are independent groups convened to review study protocols developed under NHLBI funded Clinical Trial Networks. These committees are composed of members with expertise in biostatistics, clinical trials, bioethics, and other specific scientific and research areas. The NHLBI is charged with ensuring

the highest quality of each Institute-funded clinical research project and compliance with Department of Health and Human Services (DHHS)/National Institutes of Health (NIH)/NHLBI regulations regarding human subject protections and safety monitoring. To carry out this responsibility, the NHLBI program staff instituted a new methodology for supporting the administration of NHLBI-appointed Committees in 2009. The new methodology included the establishment of the Clinical Studies Support Center (CSSC) under the direction of Westat, Inc. The CSSC is a pilot program to support the operations of NHLBI's DSMBs, Observational OSMBs, and PRCs for the Division of Blood Diseases and Resources. Utilizing Executive Secretaries to support each NHLBI safety monitoring board, the CSSC is responsible for documenting standardized operating procedures related to the administration of monitoring committees and the support center in a CSSC Manual of Operations and Procedures (MOP); coordinating meeting space and logistics for in-person meetings, Web conferences, and teleconferences; managing distribution of adverse event notifications to DSMB chairs and members, new protocols, and proposed amendments; and providing Executive Secretaries who provide scientific and administrative support to document board recommendations related to the safety and efficacy of trial interventions and the quality and completeness of clinical research study data. To move forward with full knowledge of current Committee operations and to monitor the effect of newly established procedures, Westat is required, as part of this contract, to conduct an assessment of the efficiency and effectiveness of NHLBI CSSC committee operations. As part of this assessment, the NHLBI requires feedback and advice regarding the support provided by the CSSC for monitoring board operations. To this end, a Web-based questionnaire will be administered to Chairs and members of monitoring boards to learn about their opinions about specific CSSC activities and their satisfaction with the performance of CSSC staff.

Frequency of Response: Once *Affected Public:* Individuals *Type of Respondents:* Monitoring

board members. The annual reporting burden is a follows: *Estimated Number of Respondents:90*; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33 and *Estimated Total Annual Burden Hours Requested:* 30.36. The annualized cost to respondents is estimated at: $ 3.036 (based on $100 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Table 1-1 and 1-2: Estimate of requested burden hours and dollar value of burden hours

Table A.12.1. ESTIMATES OF HOUR BURDEN

Type of Respondents	Number of Respondents	Frequency of Responses	Average Time per Response	Annual Hour Burden
D/OSMB Chairs	10	1	0.33	3.3
D/OSMB Members	78	1	0.33	25.74
Members in two D/OSMB	2	2	0.33	1.32
Total	90			30.36

Table A.12-2. ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Number of Respondents	Frequency of Response	Average time per Response	Hourly Wage Rate	Respondent Cost
DSMB Chairs	10	1	.33	100	330
DSMB Members	78	1	.33	100	2,574
Members in two D/OSMB	2	2	.33	100	132
Totals	90				3,036

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.

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 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 plans and instruments, contact: Erin Smith, Contracting Officer Technical Representative, Room 9149, 6701 Rockledge Drive, Bethesda, MD 20892-7950, or call 301-435-0050, or E-mail your request to smithee@nhlbi.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: _May 1, 2012_____

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Keith Hoots,

Director, Division of Blood Diseases and Resources

National Heart, Lung, and Blood Institute, NIH

Dated: _May 14, 2012_____

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NHLBI Project Clearance Liaison

National Institutes of Health

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