

Supporting Statement A for

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

National Heart, Lung, and Blood Institute (NHLBI)

May 8, 2012

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ATTACHMENTS

Attachment #1:	Letter from NHLBI to DSMB/OSMB Board and Chair members
Attachment #2:	Email message from Jack Cahill, Westat CSSC Project Director to DSMB/OSMB Board and Chair members
Attachment #3:	DSMB Chair Questionnaire
Attachment #4:	DSMB Member Questionnaire
Attachment #5a:	Draft CSSC Assessment Screenshot- Chair
Attachment #5b:	Draft CSSC Assessment Screenshot- Member
Attachment #6:	Study Summary
Attachment #7:	Certification of the Westat Institutional Review Board

SUPPORTING STATEMENT

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

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. All responses will be kept secure to the extent provided by law.

The objective of this information collection is within the National Heart, Lung, and Blood Institute (NHLBI) mandate described in the Public Health Service Act, Section 421 (42 USC 285b-3 specifies the provision of: (A) investigation into the epidemiology, etiology and prevention of all forms and aspects of heart, blood vessel, lung and blood disease, including investigations into the social, environmental, behavioral, nutritional, biological and genetic determinants and influences involved in the epidemiology, etiology and prevention of such diseases.

A.2. Purpose and Use of Information Collection

By hiring Westat to streamline Committee operations NHLBI has introduced a completely new approach for the support of NHLBI-appointed Safety and Monitoring Committees. Outsourcing the administration of Committee operations clearly aims at providing workload relief for NHLBI, but it is also assumed to have the potential of increasing the independence and efficiency of Committee operations and encouraging the adoption of best practices for safety monitoring and adherence to Committee protocols, NIH and NHLBI policies, and regulations for human subjects' protections.

The primary purpose of the proposed web-based assessment of the CSSC is to objectively determine and quantify the value of the CSSC pilot program from the perspective of committee chairs and members. Although Westat has been collecting and analyzing administrative data on CSSC operations for the past two years, it was not been possible to receive feedback directly from the very people who interact directly with CSSC Executive Secretaries and are expected to benefit from the efficient and effective implementation of oversight committees. Thus, this web-based survey will provide considerable understanding of the value of outsourcing and of the CSSC approach, whether it will be useful to other Institutes, and how it can be improved over time.

A.3. Use of Information Technology and Burden Reduction

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. The following methodology will be used:

1. Initial communication Mass Mailing. Keith Hoots, MD, Director, Division of Blood Diseases and Resources and Simone Glynn, MD , Branch Chief, Transfusion Medicine

and Cellular Therapies Branch, Division of Blood Diseases and Resources will send an introductory letter telling potential respondents about the survey and that Westat will be contacting them (Attachment 1). The letter will describe the survey and why it is important.

2. Follow-up Message, Mass Mailing: Westat will follow up the letter from the NHLBI program office with an email from Westat signed by Jack Cahill, CSSC Westat Project Director (Attachment 2). A letter and email will be sent to all chairs and members from the boards currently supported by the CSSC project (12 Chairs and 78 members), and also contain a link to the respective questionnaire (Attachments 3 and 4) and survey password for online completion (Attachment 5).
3. Instructions: Participants will be asked to complete one online questionnaire for each board to which they belong. We have estimated 15 to 20 minutes to complete one questionnaire.
4. Hard Copy Option: For those who want to complete the questionnaire by hand, the appropriate type and number of questionnaires will be sent. There is a separate questionnaire for chairs and members (Attachment 3 and 4).
5. When sending out the questionnaire by hard copy, a self-addressed stamped envelope will be enclosed so participants can return the questionnaire. Once these are returned, the Westat system analyst will enter the data. We do not expect many hard copy questionnaires since this group of respondents is very comfortable working on their computer.

Efforts to minimize respondent burden are described below:

- Access to the web-based survey through a link attached to the email messages will help to reduce respondent burden.
- The questionnaire contains pre-tested question with a group of three former NHLBI DSMB members.
- Pre testing activities have indicated that it takes 15 to 20 minutes to complete the web-based survey.

A PIA has been completed for this web-based survey.

A.4. Efforts to Identify Duplication and Use of Similar Information

The web-based survey aims at evaluating the NHLBI CSSC pilot program and getting feedback for improvement. Since this is a new model of operation and organization of safety monitoring boards, currently there is no other source of information to assess the value of the program from the perspective of committee Chairs and members.

A.5. Impact on Small Business or Other Small Entities

Small business or entities are not involved. All respondents are individual NHLBI DSMB/OSMB committee members.

A.6. Consequences of Collecting the Information Less Frequently

Study participants will complete the Web-based survey only once. Participants who agree to complete the survey will use the link provided to the online questionnaire. There is no follow-up involved.

A.7. Special Circumstances Relating to the Guidelines of 5. CFR 1320.5

The proposed data collection is consistent with 5 CFR 1320.5

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult

Outside Agency

The 60-day Federal Register Notice was published on March 12, 2012, Volume 77 No. 44 , pages 14531-14533 and one comment was received. The web-based survey was pre-tested with 3 former DSMB members who provided feedback regarding the questions and response time. Revisions were made based on their feedback.

A.9. Explanation of any Payment of Gifts to Respondents

There are no payments, incentives or gifts that respondents will receive for completing the CSSC assessment survey.

A.10. Assurance of Confidentiality Provided to Respondents

Data gathered in this survey will not relate to participants as human subjects but only their opinions regarding the NHLBI CSSC program. No personal information will be collected. All information about the participants will be handled secure to the extent permitted by law. Participant name will not be used in any published report about this survey.

A.11. Justification for Sensitive Questions

Data gathered in this survey does not include sensitive information. Only opinions regarding the NHLBI CSSC program will be collected.

A.12. Estimates of Burden Hour Including Annualized Hourly Costs.

It is estimated that each respondent will spend about 15 to 20 minutes (0.33 burden hours) reading instructions and completing responses to the questions. Two participants are expected to complete the questionnaire two times as they belong to two committees. The annualized cost to respondents is estimated at \$3,036 based on \$100 per hour. The respondent population consists of specialty physicians, bio-statisticians, bioethics and qualified professional. Therefore, the \$100 per hour wage rate was selected based on reported hourly earnings in 2011. .

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

A.13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or start-up costs and no maintenance or service cost components to report.

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government for the proposed study is estimated to be approximately \$32,000 per year.

A.15. Explanation for program Changes or Adjustments

This submission constitutes a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The schedule for study activities is shown in Table A.16.

A.16-1 Project Time Schedule	
Task	Date of completion
Initial Communication, Introductory Letter	1 week after OMB approval
Mass mailing/emailing message and survey link	3 weeks after OMB approval
Follow-up Message	4 weeks after OMB approval
Data Compilation and QC	2 - 3 months after OMB approval
Data Analysis	3 - 6 months after OMB approval
Report writing	6 - 8 months after OMB approval

Subject to NHLBI approval, data will be disseminated to other branches of the NHLBI or other Institutes of the National Institutes of Health or the Human Subjects Protections and Bioethics community at presentations and professional meetings.

A.17. Reason(s) Display of OBM Expiration Date is Inappropriate

The OMB expiration date will be displayed in the upper-right hand corner of the questionnaire.

A.18. Exceptions to Certification of Paperwork Reduction Act Submissions

There are no exceptions to the certification for paperwork reduction act submissions.