

Supporting Statement B for

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

National Heart, Lung, and Blood Institute (NHLBI)

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Erin Smith
Room 9149
6701 Rockledge Drive
Bethesda, MD 20892
Phone: 301 -435-0050
Fax: 301-480-0867
Email: smithee@nhlbi.nih.gov

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B. Collection of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Respondents are all members of safety monitoring boards currently operating under the National heart Lung and Blood Institute (NHLBI) Clinical Studies Support Center (CSSC). Approximately 90 board members of currently operating or recently closed Data and Safety Monitoring Boards (DSMB) and Observational Study Monitoring Boards (OSMB) will be invited to participate.

Committee members will be asked to complete the questionnaire on line or in hard copy. The survey will consist of two slightly different questionnaires:

1. Board Chair Questionnaire (Attachment 3)
2. Board Member Questionnaire (Attachment 4)

The questionnaire is short and expected to take 15 to 20 minutes. Moreover, Committee members appear to be committed to the DSMB process. Thus, we expect nearly 100 percent participation in the survey. Two expected participants belong to two monitoring boards each. It is expected that they will complete two questionnaires each.

Table 1: Overall expected participation in the Web-Based Assessment of the Clinical Studies Support Center (CSSC) assuming all invited members agree to participate

Participant Type	Expected Number
Board Chair	10
Board Member	78
Members in two D/OSMB	2
Total	90

Sample Size Calculations:

As all board members of currently operating or recently closed CSSC monitoring board committees will be invited, there is no sample size calculation needed for this survey.

B.2. Procedures for the Collection of Information

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. This letter and email will be sent to all chairs and members from the boards currently supported by the CSSC project.
2. Follow-up Message: Westat will follow up the letter from the NHLBI program office with an email from Westat signed by Jack Cahill, CSSC Westat Project Director. The link to the web-survey will be embedded in the email. There is a separate questionnaire for chairs and members.
3. Instructions: Participants will be asked to complete one online questionnaire for each board they belong. We have estimated 15 to 20 minutes to complete. There will be a hard copy option for those participants who want to complete the questionnaire by hand. As requested, the appropriate type and number of questionnaires will be sent. 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. It is not expected to issue many hard copy questionnaires, since this group of respondents is very comfortable working with technology.

Data Analysis:

Responses to the web-based survey will be analyzed using descriptive statistics such as frequencies, means, standard deviations and medians.

B.3. Methods to Maximize Response Rates and Deal with Non-response.

To increase the response rate, this survey was designed as a Web-based questionnaire and kept as short as possible. One week after initial email message, Westat will send a follow-up reminder to those participants who have not responded.

B.4. Test of Procedures or Methods to be Undertaken

In order to assess the readability and understanding of the questions and the average time per response, four former DSMB members were asked to complete the questionnaire. Based on this pre-testing, it was concluded that the average time spent to understand and complete the questionnaire was 15 to 20 minutes (Used for burden hour calculations in Supporting Statement A).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.

Individuals consulted include the CSSC Assessment of Committee Operations Leader, a Westat Associate Director in Health Studies with more than 30 years experience in health related research and policy and extensive experience in assessment, evaluation, and epidemiology. The Project Director, project team members, and NHLBI technical team also participated in the development of the study tools. Data analysis will be performed by an independent analytical staff from Westat not involved in the day to day operations of the CSSC project. This team includes experts in qualitative data analysis along with assistance of the computer programmers and survey operations staff.