

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

**Study Number 8687.00**  
**Westat IRB summary**  
**November 21, 2011**

## **Introduction**

The National Heart, Lung, and Blood Institute (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, in 2009 the National Heart, Lung, and Blood Institute (NHLBI) established the Clinical Studies Support Center (CSSC) with Westat, Inc. as a pilot program to support the operations of NHLBI's Data and Safety Monitoring Committees (DSMBs), Observational Monitoring Boards (OSMBs), and Protocol Review Committees (PRCs) for the Division of Blood Diseases and Resources. As part of this contract, Westat is required to conduct an assessment of the efficiency and effectiveness of NHLBI Committee operations.

## **Purpose of the Survey**

The NHLBI program staff has instituted a new methodology for supporting the administration of NHLBI-appointed Committees. Instead of supporting the Committees with NHLBI staff, as they have in the past, program staff members have outsourced Committee support to Westat. The primary purpose of the assessment is to determine the value of such an approach, whether it will be useful to other Institutes, and how it can be improved over time. In other words, does it do what it is supposed to do, and does it help the Committee to do its job? Does this approach save time (result in less work, not more, for NHLBI program staff) and add value?

The NHLBI is interested in receiving 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.

## **Methodology for the Web-Survey:**

1. Initial communication. Introductory letter: A letter from Keith Hoots, MD and Simone Glynn, MD will be sent on NHLBI stationery telling

potential respondents about the survey and that Westat will be contacting them (See Attachment 1).

2. Mass Mailing: A letter and email will sent to all chairs and members from the boards currently supported by the CSSC project. (Listed in Survey Appendix A).
3. Follow-up Message: Westat will follow up the letter from the NHLBI program office with an email from Westat (See Attachment 2). Jack Cahill, CSSC Westat Project Director will sign it.
4. Instructions: Participants will be asked to complete one online questionnaire for each board they belong. We have estimated 15 to 20 minutes to complete
5. 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).
6. When sending out the questionnaire by hard copy, a self-addressed stamped envelope will be enclosed so participants can return the questionnaire.
7. When the hard copy questionnaires are returned, the Westat system analyst will enter the data. We do not expect many hard copy questionnaires since this group is very comfortable working on their computer.

### **Expected Participants:**

Approximately 90 board members from currently operating or recently closed monitoring boards will be invited to participate in the survey.

### **Human Subjects Considerations**

The proposed survey qualifies for exempt from Human Subjects regulations for the following reasons:

1. The survey aims at evaluating the CSSC pilot program and getting feedback for improvement. No generalizable knowledge is expected to come from this activity.
2. Data gathered will not relate to the survey participants as human subjects but only their opinions regarding the CSSC program will be collected.

As more than 30 participants are expected, the survey will be submitted for OMB approval

