

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NHLBI, Division of Blood Diseases and Resources, 6701 Rockledge Drive, Bethesda, MD 20892-7902, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

**CLINICAL STUDIES SUPPORT CENTER (CSSC)  
FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS\***

**Introduction**

In 2009-2011, the National Heart, Lung, and Blood Institute (NHLBI) established the Clinical Studies Support Center (CSSC) with Westat, Inc. in Rockville, MD. The purpose of the CSSC is to support the operations of NHLBI's Data and Safety Monitoring Boards (DSMBs), Observational Monitoring Boards (OSMBs) and Protocol Review Committees (PRCs) for the Division of Blood Diseases and Resources. As a Chair of a monitoring board who has been working with support from the CSSC, you are an important source of feedback and advice for the NHLBI on the support provided by the CSSC for board operations. We are asking your opinions about specific CSSC activities and your satisfaction with the performance of CSSC staff.

This survey will take about 15 minutes to complete.

Your participation in this survey is voluntary. You have the right to stop at any time or skip questions. All your answers are private and the information you provide will not be identified by your name, except as otherwise required by law. Your answers to these questions will provide NHLBI with important information to help improve monitoring board operations.

**A. NHLBI Board**

1. Which monitoring board do you chair [CHECK ONE. IF YOU CHAIR OR PARTICIPATE IN MORE THAN ONE BOARD, YOU WILL BE GIVEN A SEPARATE QUESTIONNAIRE FOR EACH ONE]?

\*Only Board Chairs will receive this questionnaire.

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**A. NHLBI Board (continued)**

Check one	Acronym	Board name
<input type="checkbox"/>	ATTRACT	Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT)
<input type="checkbox"/>	BABY HUG	Pediatric Hydroxyurea Phase III Clinical trial
<input type="checkbox"/>	BMT #1	Blood and Marrow Transplantation Clinical Trials Network
<input type="checkbox"/>	BMT #2	Blood and Marrow Transplantation Clinical Trials Network
<input type="checkbox"/>	BRIDGE	Bridging Anticoagulation in Patients who Require Temporary Interruption of Warfarin Therapy for an Elective Invasive Procedure of Surgery
<input type="checkbox"/>	GT/CT	Gene Therapy/Cell Therapy
<input type="checkbox"/>	RBC Storage	Immunomodulatory, Inflammatory, and Vasoregulatory Properties of Transfused Red Blood Cells as a Function of Storage (R01)
<input type="checkbox"/>	REDS III	Recipient Epidemiology and Donor Evaluation Study III
<input type="checkbox"/>	SCIRT	Sickle Cell Investigational Research Trials
<input type="checkbox"/>	TMH	Transfusion Medicine and Hemostasis Clinical Trials Network

**B. Liability Protection**

Please respond to the following questions on liability protection.

Please indicate the extent to which you **agree or disagree** with the following statements [SELECT ONE RESPONSE FOR EACH QUESTION].

Q no.	Question	Do you:	
2	Information provided to me on liability protection made it clear that as a member of a NHLBI monitoring board I have been automatically enrolled for professional liability insurance coverage through the Westat monitoring board Liability Insurance Coverage Plan at no cost to me.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
		Do not remember.....	5

CLINICAL STUDIES SUPPORT CENTER (CSSC)

FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS

**B. Liability Protection (continued)**

Q no.	Question	Do you:
3	Information provided to me on liability protection made it clear that this coverage is expected for committee activities performed for the duration of my service on an NHLBI monitoring board.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4 Do not remember..... 5
4	Information provided to me on liability protection made it clear that I can opt out of the insurance protection plan.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4 Do not remember..... 5
5	If I want to opt out of the insurance protection plan (e.g., if I have my own plan), I know what to do.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
6	If I receive notice of any claim related to my participation in NHLBI monitoring board activities, I am confident that I will know what to do.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
7	Having liability protection makes me more willing to be part of a NHLBI monitoring board.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**B. Liability Protection**

Q no.	Question	Do you:	
8	To implement liability protection for committee chairs and board members, the CSSC obtained an insurance plan that covers all board chairs and members. Thus, committee chairs and board members were automatically considered to be covered unless they opt out of the insurance plan. This approach was convenient for me.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
9.	Information on liability protection provided by the CSSC was clear and understandable.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
10.	The CSSC used an appropriate method (sending out a letter to the committee chair and board members) for presenting information on liability protection.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4

11 Please provide any comments you have on the liability protection provided by Westat through the CSSC.

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**C. Pre-Meeting/Call Activities**

CSSC staff is responsible for a variety of pre-meeting activities, including the scheduling of board meetings, development of the meeting agenda, meeting logistics, and orientation of new members. For each of the statements below on pre-meeting activities, please tell us the extent to which you **agree or disagree** with each one [SELECT ONE RESPONSE FOR EACH QUESTION].

Q no.	CSSC staff:	Do you:
12	Efficiently coordinates the scheduling of all board meetings at regular intervals as per the Charter.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
13	Provides email notices and reminders in enough time to ensure that you are sufficiently prepared for upcoming meetings.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
14	Creates well-planned agendas that address all necessary Board business, including review of study data and other pertinent issues.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
15	Clearly communicates with you concerning how you will receive or access meeting materials.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
16	Provides you with all the important materials and information that will prepare you for the meeting.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
17	Provides you with clear and accurate instructions for use of telecommunications and WebEx so you can easily access and communicate at meetings.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**C. Pre-Meeting/Call Activities (continued)**

Q no.	CSSC staff:	Do you:
18	Coordinates communication between you and NHLBI program staff and the study staff/protocol team in a manner that maintains the independence of the board.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
19	Communicates in a professional manner.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
20	Facilitated your orientation to ensure that you understood your roles and responsibilities.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
21	Works with you, as Chair, for selection of the best/most convenient dates and times for meetings.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
22	Obtains your input, as Chair, into meeting agendas as often as necessary.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4

23. Please provide any additional comments you have on pre-meeting activities organized or facilitated by the CSSC.

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**D. Meeting/Call Activities**

This section focuses on activities that take place during the meetings or that facilitate efficient and effective meetings.

Please indicate how frequently CSSC staff assigned to your board carries out the meeting activities listed below [SELECT ONE RESPONSE FOR EACH QUESTION].

Q no.	CSSC staff:	How frequently?
24	Is present at meetings.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
25	Makes Call to Order remarks at meetings.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
26	Makes Call to Order remarks that include confidentiality reminders.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
27	Makes Call to Order remarks that include an opportunity to disclose new conflicts of interest.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
28	Assists the board in recalling past discussions and recommendations.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
29	Assists the board in formulating recommendations.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**D. Meeting/Call Activities (continued)**

Q no.	CSSC staff:	How frequently?
30	Assists the board in complying with the DSMB Charter.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4
31	Ensures proper attendance at the different types of sessions (Open, Closed, Executive) of board meetings.	Always..... 1
		Frequently..... 2
		Sometimes..... 3
		Never..... 4

Please indicate the extent to which you **agree or disagree** with these statements [SELECT ONE RESPONSE FOR EACH QUESTION].

Q no.	CSSC staff:	Do you:
32	Uses technology (email, Webex, teleconferencing) appropriately – that is, the technology used suits the objectives of each meeting.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
		Not applicable..... 5
33	Makes logistical arrangements for in-person meetings so they run smoothly and efficiently.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
		Not applicable..... 5
34	Provides all necessary services (space, tables, sound system, projectors, teleconference, WebEx, internet connection, food service, etc.) in Westat's Conference Center.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
		Not applicable..... 5



**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**E. Meeting/Call Activities (continued)**

Q no.	CSSC staff:	Do you:	
35	Works closely with you, as Chair, to ensure achievement of meeting objectives.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
		Not applicable.....	5

36. Please provide any additional comments you have on meeting activities organized or facilitated by the CSSC.

**E. Post-Meeting/Call Activities and Activities between Meetings.**

Post-meeting activities focus on the preparation of minutes and recommendations. Activities between meetings concern adverse events (AE)/serious adverse events (SAE)/Unanticipated Problems (UPS) notification and reviews of new protocols and protocol amendments when they must be addressed by the board before the next regularly scheduled meeting.

Please tell us the extent to which you **agree or disagree** with the following statements on post meeting activities and activities between meetings [SELECT ONE RESPONSE FOR EACH QUESTION].

CLINICAL STUDIES SUPPORT CENTER (CSSC)

FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS

E. Post-Meeting/Call Activities and Activities between Meetings

Q no.	CSSC staff:	Do you:
37	Prepares minutes that are clear and comprehensive.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
38	Integrates comments and editorial suggestions into a single set of accurate, thorough, and well-organized minutes.	Strongly agree..... 1 Agree..... 2 ..... 3 Disagree..... 4 Strongly disagree..... 4
39	As per NHLBI policy, always includes minutes from the last meeting with materials for the next meeting.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
40	Always provides minutes to you, as chair, for review, corrections, and approval in a timely manner.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
41	Efficiently coordinates requests for preliminary comments for new protocols and protocol amendments.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
42	Assists in the identification of salient issues relevant to protocol and amendment reviews on which the board should focus.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4
43	Notifies you, as Chair, about adverse events (AEs)/serious adverse events (SAEs)/unanticipated problems (UPs) in a timely manner and in accordance with NHLBI policy.	Strongly agree..... 1 Agree..... 2 Disagree..... 3 Strongly disagree..... 4

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**E. Post-Meeting/Call Activities and Activities between Meetings (continued)**

Q no.	CSSC staff:	Do you:
44	Communicates your review comments and requests for additional information on AEs, SAEs, and UPs to the NHLBI Program Office.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
		Not applicable..... 5

45. Please provide any additional comments you have on post meeting activities and activities that occur between meetings.

**F. Your Role and Responsibilities to Protect Study Participants**

Please indicate the extent to which you agree or disagree with the following statements. [SELECT ONE RESPONSE FOR EACH QUESTION].

Q no.	Statement	Do you:
46	I am clear about my roles and responsibilities as a monitoring board Chair.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4
47	I am clear regarding the expectations, functioning and responsibilities of my monitoring board.	Strongly agree..... 1
		Agree..... 2
		Disagree..... 3
		Strongly disagree..... 4

**CLINICAL STUDIES SUPPORT CENTER (CSSC)**

**FEEDBACK ON CSSC OPERATIONS FROM BOARD CHAIRS**

**F. Your Role and Responsibilities to Protect Study Participants (continued)**

Q no.	Statement	Do you:	
48	The way the monitoring board is being administered by the CSSC helps me to carry out my responsibilities as a monitoring board Chair.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
49	I can count on the support of the CSSC staff to communicate and address concerns I have regarding safety of study participants.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4
		Not applicable.....	5
50	The methods used for adverse event notification helps me to assess the safety of study participants.	Strongly agree.....	1
		Agree.....	2
		Disagree.....	3
		Strongly disagree.....	4

51. Please provide any additional comments you have on the CSSC.

**Thank you for completing this questionnaire. Please return in the stamped, self-addressed envelope.**