

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

OMB Control # XXXX
Expiration Date: xx/xx/20xx

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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 or a member 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 survey questions will provide NHLBI with important information to help improve monitoring board operations.

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

A. NHLBI Board and CSSC Staff

1. Indicate your **role** in the monitoring board.

- Chair
- Regular member
- Ad hoc member

2. On which monitoring **board** do you participate?

- ATTRACT - Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis
 - BABY HUG - Pediatric Hydroxyurea Phase III Clinical trial
 - BMT #1 - Blood and Marrow Transplantation Clinical Trials Network
 - BMT #2 - Blood and Marrow Transplantation Clinical Trials Network
 - BRIDGE - Bridging Anticoagulation in Patients who Require Temporary Interruption of Warfarin Therapy for an Elective Invasive Procedure of Surgery
 - GT/CT - Gene Therapy/Cell Therapy
 - RBC Storage - Immunomodulatory, Inflammatory, and Vasoregulatory Properties of Transfused Red Blood Cells as a Function of Storage (R01)
 - REDS III - Recipient Epidemiology and Donor Evaluation Study III
 - SCIRT - Sickle Cell Investigational Research Trials
 - TCRN - Thalassemia Clinical Research Network
 - TMH - Transfusion Medicine and Hemostasis Clinical Trials Network
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Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

B. Liability Protection (for the ATTRACT Monitoring Board)

Please respond to the following questions on liability protection.

Please indicate the extent to which you agree or disagree with the following statements.

	Strongly agree	Agree	Disagree	Strongly disagree	Do not remember
3. 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Information provided to me on liability protection made it clear that I can opt out of the insurance protection plan.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Board name autofills based on response to 2nd question.

Previous Page

Next Page

(2 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

	Strongly agree	Agree	Disagree	Strongly disagree
6. If I want to opt out of the insurance protection plan (e.g., if I have my own plan), I know what to do.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Having liability protection makes me more willing to be part of a NHLBI monitoring board.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. 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 opted out of the insurance plan. This approach was convenient for me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Information on liability protection provided by the CSSC was clear and understandable .	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. The CSSC used an appropriate method (sending out a letter to the committee chair and board members) for presenting information on liability protection.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

12. Please provide any comments you have on the liability protection provided by Westat through the CSSC (for the ATTRACT Monitoring Board).

[Previous Page](#)

[Next Page](#)

(4 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

C. Pre-Meeting/Call Activities (for the ATTRACT Monitoring Board)

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.

Does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree
13. Efficiently coordinates the scheduling of all board meetings at regular intervals as per the Charter.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Provides email notices and reminders in enough time to ensure that you are sufficiently prepared for upcoming meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Creates well-planned agendas that address all necessary Board business, including review of study data and other pertinent issues.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Clearly communicates with you concerning how you will receive or access meeting materials.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Provides you with all the important materials and information that will prepare you for the meeting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Provides you with clear and accurate instructions for use of telecommunications and WebEx so you can easily access and communicate at meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Coordinates communication between you and NHLBI program staff and the study staff/protocol team in a manner that maintains the independence of the board.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Communicates in a professional manner.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Facilitated your orientation to ensure that you understood your roles and responsibilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Only presented and asked of persons who respond to their role on the board as chair.

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

As Chair for the ATTRACT Monitoring Board, does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree
22. Works with you, as Chair, for selection of the best/most convenient dates and times for meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Obtains your input, as Chair, into meeting agendas as often as necessary.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Previous Page](#)

[Next Page](#)

(6 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

24. Please provide any additional comments you have on pre-meeting activities organized or facilitated by the CSSC (for the ATTRACT Monitoring Board).

Previous Page

Next Page

(7 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

D. Meeting/Call Activities (for the ATTRACT Monitoring Board)

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 carried out the meeting activities listed below.

How frequently is the CSSC staff ...

	Always	Frequently	Sometimes	Never
25. Is present at meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. Makes Call to Order remarks at meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Makes Call to Order remarks that include confidentiality reminders.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. Makes Call to Order remarks that include an opportunity to disclose new conflicts of interest.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. Assists the board in recalling past discussions and recommendations.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. Assists the board in formulating recommendations.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. Assists the board in complying with the DSMB Charter.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. Ensures proper attendance at the different types of sessions (Open, Closed, Executive) of board meetings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

Please indicate the extent to which you **agree or disagree** with these statements about the CSSC staff.

Does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree	Not applicable
33. Uses technology (email, Webex, teleconferencing) appropriately – that is, the technology used suits the objectives of each meeting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. Makes logistical arrangements for in-person meetings so they run smoothly and efficiently.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. Provides all necessary services (space, tables, sound system, projectors, teleconference, WebEx, internet connection, food service, etc.) in Westat's Conference Center.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Previous Page

Next Page

(9 of 17)

Only presented and asked of persons who respond to their role on the board as chair.

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

As Chair for the ATTRACT Monitoring Board, does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree	Not applicable
36. Works closely with you, as Chair, to ensure achievement of meeting objectives.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Previous Page](#)

[Next Page](#)

(10 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

37. Please provide any additional comments you have on meeting activities organized or facilitated by the CSSC (for the ATTRACT Monitoring Board).

[Previous Page](#)

[Next Page](#)

(11 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

E. Post-Meeting/Call Activities and Activities between Meetings (for the ATTRACT Monitoring Board)

Post-Meeting activities focus on the preparation of minutes and recommendations. Activities between meetings concern adverse events (AES)/serious adverse events (SAES)/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.

Does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree
38. Prepares minutes that are clear and comprehensive.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39. Integrates comments and editorial suggestions into a single set of accurate, thorough, and well-organized minutes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40. As per NHLBI policy, always includes minutes from the last meeting with materials for the next meeting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41. Assists in the identification of salient issues relevant to protocol and amendment reviews on which the board should focus.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Only presented and asked of persons who respond to their role on the board as chair.

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

As Chair for the ATTRACT Monitoring Board, does the CSSC staff ...

	Strongly agree	Agree	Disagree	Strongly disagree
42. Always provides minutes to you, as chair, for review, corrections, and approval in a timely manner.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43. Efficiently coordinates requests for preliminary comments for new protocols and protocol amendments.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44. 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45. Communicates your review comments and requests for additional information on AEs, SAEs, and UPs to the NHLBI Program Office.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Previous Page](#)

[Next Page](#)

(13 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

46. Please provide any additional comments you have on post meeting activities and activities that occur between meetings (for the ATTRACT Monitoring Board).

[Previous Page](#)

[Next Page](#)

(14 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

F. Your Role and Responsibilities to Protect Study Participants (for the ATTRACT Monitoring Board)

Please indicate the extent to which you agree or disagree with the following statements.

	Strongly agree	Agree	Disagree	Strongly disagree
47. I am clear about my roles and responsibilities as a monitoring board Chair.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48. I am clear regarding the expectations, functioning and responsibilities of my monitoring board.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49. The way the monitoring board is being administered by the CSSC helps me to carry out my responsibilities as a monitoring board Chair.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
50. I can count on the support of the CSSC staff to communicate and address concerns I have regarding safety of study participants.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Only presented and asked of persons who respond to their role on the board as chair.

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

As Chair for the ATTRACT Monitoring Board, ...

	Strongly agree	Agree	Disagree	Strongly disagree
51. The methods used for adverse event notification helps me to assess the safety of study participants.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Previous Page](#)

[Next Page](#)

(16 of 17)

Clinical Studies Support Center (CSSC): Feedback to NHLBI on CSSC Operations

52. Please provide any additional comments you have on the CSSC (for the ATTRACT Monitoring Board).

Thank you for completing this questionnaire.

[Previous Page](#)

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(17 of 17)