

DRAFT - Memorandum of Understanding

To: [Board Member Name]
From: Rob Rengel, DSMB Program Manager and Faith Kline, Administrative Director- Center for Clinical and Translational Science
Date: [Date]
Trial Name: [Name of trial]

Purpose

- To outline an agreement between two teams within the Ohio State University:
 - [College Name], [Department and Division]
 - OSU, Center for Clinical and Translational Science
 - [Board Member Name]
- This agreement relates to the following:
 - Data Safety and Monitoring Board (DSMB) committee membership
- Reporting Relationship
 - PI must report their safety information to the DSMB Program Manager
 - DSMB Program Manager will then report information to the board
 - Board members will review data and safety information as provided by the PI and DSMB Program Manager

Scope of Work

- [College Name], [Department, Division], [# of Meetings per year]
 - Participation in meetings for unbiased review of data and safety information for the trial listed above
 - Example work includes: analysis of statistics and data safety monitoring report
- Center for Clinical and Translational Science (CCTS)
 - Schedules meetings
 - Provides meeting material for review prior to the meeting
 - Provides for billing and reimbursement
 - Example work includes: billing, schedule meetings, record meeting minutes, distribute outcome letter

Cost Estimate Summary

- DSMB Administrative costs funded through grant or internal OSU funds from Lead PI
- DSMB Board members time compensated through charge-back through the CCTS
- Estimated total reimbursement per meeting [amount], estimated overall reimbursement [amount]

Work Process and Agreements

To improve collaboration and ensure that all members of the University and OSU Wexner Medical Center receive best service from the CCTS DSMB, we ask that all teams respect the following agreements.

Definitions

“**Board Member**” is defined here as a member of the DSMB.

“**DSMB Resource**” is defined as the CCTS DSMB.

10.9.17 Version

Accepted:

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Agreements

1. **Board Member** will complete a Conflict of Interest (COI) and submit to DSMB Program Manager prior to participation on the board.
2. Upon request, **Board Member** will submit availability to DSMB Program Manager for upcoming meetings.
3. **Board Member** will attend scheduled meetings.
4. **Board Member** will put in approx. 2 hours of work outside of each meeting.
5. The **DSMB Resource** is responsible for all administrative functions of the DSMB meetings.
 - a. Recruiting committee members
 - b. Meeting minutes
 - c. Meeting final report/outcomes
 - d. Scheduling DSMB meetings
 - e. Billing and reimbursement
6. The **DSMB Resource** will provide all meeting materials 48 hours prior to scheduled meeting.
7. **Board Member** and **DSMB Resource** will meet at least [bi/semi/annually] to review safety data.

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Term and Termination

The term of this Agreement will commence once the CCTS has received confirmation of IRB approval, and will continue in full force and effect, unless terminated or modified by mutual written agreement of all parties until **June 30, 2016**.

- **[College Name]**, **[Department and Division]**
- OSU, Center for Clinical and Translational Science
- **[Board Member Name]**

Review of the contents or the term of this agreement may be initiated by either party at any time during the course of this agreement. This document will automatically renew at the end of the agreement period unless thirty (30) days prior written notice has been given by either party.

Approvals

_____ Date _____

[Board Member Name]

_____ Date _____

[Name]

Administrative Director of the Center for Clinical and Translational Science

_____ Date _____

[Name]

DSMB Program Manager