

DRAFT - Memorandum of Understanding

To: [Lead PI Name]
From: Rob Rengel, DSMB Program Manager and Faith Kline, Administrative Director- Center for Clinical and Translational Science
Date: [Date]

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
 - [Lead PI Name]
- This agreement relates to the following:
 - A Data Safety and Monitoring Board (DSMB)
- Reporting Relationship
 - PI must submit their data safety monitoring report to the DSMB Program Manager
 - DSMB Program Manager will then report information to the board
 - PI must report any serious adverse events related to the trial to the DSMB Program Manager

Scope of Work

- [College Name], [Department, Division], [# of Meetings per year]
 - Data report submitted to DSMB Program Manager
 - Example work includes: statistical analysis, data safety monitoring meeting report
- Center for Clinical and Translational Science (CCTS)
 - Will focus on conduct and administration of DSMB
 - Example work includes: development of Data Safety Monitoring Plan (DSMP), development and conduct of DSMB, record meeting minutes, distribute meeting outcome letter

Cost Estimate Summary

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

Work Process and Agreements

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

Definitions

“**Customer**” is defined here as the Lead PI for the trial under consideration.

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

Agreements

- Customer** will submit to **DSMB Resource** confirmation of IRB approval before first DSMB meeting is scheduled.

10.9.17 Version

Accepted:

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2. **Customer** will submit DSMB Meeting Report two weeks before scheduling any meeting.
 - DSMB Meeting Report Components
 - Title of protocol
 - Principal Investigator Name
 - Time Period
 - Report prepared by [Name]
 - Enrollment Data
 1. Number screened
 2. Number enrolled
 - List of Protocol Deviations
 - List of adverse events
 - Trial Summary
3. **Customer** will provide availability for each meeting through online polling.
4. The **DSMB Resource** is responsible for all conduct of DSMB meetings.
5. The **DSMB Resource** is responsible for all administrative functions of the DSMB meetings.
 - Recruiting committee members
 - Scheduling DSMB meetings
 - Meeting minutes
 - Meeting final report/outcomes
 - Billing
6. The **Customer** will submit, when appropriate, data and safety information in the case of a serious/adverse event.
7. **Customer** 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
- [Lead PI 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 _____

[PI Name]

_____ Date _____

[Name]

Administrative Director of the Center for Clinical and Translational Science

_____ Date _____

[Name]

DSMB Program Manager