

SOP - Management of Panel Member Conflicts of Interest

Version #: 003

Effective Date: 03/12/15

Supersedes Version: 002

This Policy Pertains to: All COMIRB Staff, Panel members and Chairpersons

Responsibility for executing this policy: All Panel Members, Chairpersons, Each Staff Member, Sr. IRB Manager

Last Reviewed on 03/12/15

Result: updated

Approval Authority: Director

Approved by: Meredith Mealer

Date: 3/12/15

1. PURPOSE

This policy describes how potential panel member conflict of interest (financial or non-financial) is managed as it relates to their role in COMIRB.

2. POLICY

Management of panel members and chairpersons potential conflicts of interest is critical if the COMIRB is to fulfill its mandate to protect the rights and welfare of research subjects in a compliant and ethical manner.

COMIRB Chairpersons and panel members will adhere to applicable institutional policy to manage conflicts of interest as they relate to activities outside of COMIRB.

3. SPECIFIC POLICIES

3.1 Financial or non-financial conflicts of interest

3.1.1 COMIRB Chairpersons and panel members who declare any financial (significant financial interest \geq \$5,000) or a non-financial conflict of interest that overlaps with a COMIRB protocol being reviewed at a panel meeting or by expedited/exempt process must recuse themselves from involvement in the review of that protocol.

3.1.2 The Director and Assistant Director under the direction of the Vice Chancellor of Regulatory Compliance establish the policy and process for ensuring that COMIRB Chairpersons and panel members who review biomedical and behavioral research involving human subjects have not declared a conflict of interest that overlaps with that protocol. The Panel Coordinator and Senior IRB staff are responsible for ensuring that these requirements are tracked and followed.

3.1.3 Panel Members:

3.1.3.1 Potential new panel members are required to:

Complete the Member Information Sheet (CF-027) outlining their expertise and any non-financial conflicts of interest.

The new panel member must also complete or update their conflict of interest declaration on file with the UCD Conflict of Interest and Commitment Office.

3.1.3.2 Current panel members must:

- Update their conflict of interest declaration in accordance with UCD policy or more frequently as needed.
- Update the non-financial conflict of interest declaration to COMIRB as needed, but at least annually.

Any panel member who does not update their conflict of interest declaration in accordance with UCD collection policy will be removed from the roster until the issue has been addressed.

3.1.3.3 The Senior IRB staff will review the declarations with the Director, then enter the information on the Panel COI tracking sheet. The updated tracking sheet will then be distributed to all Panel Coordinators and Senior IRB staff.

3.1.3.4 The Panel Coordinator will develop the assignment sheet including the sponsor of each protocol to be reviewed. The tracking sheet will be consulted prior to assigning reviewers to ensure that the primary reviewer does not have a declared conflict of interest with the protocol being assigned.

For expedited/exempt reviews, the Panel Coordinator will consult the tracking sheet prior to assigning the reviewer.

3.1.3.5 Prior to the panel meeting, the Senior IRB staff will review the tracking sheet and compare to the assignment sheet. Any conflicts of interest will be discussed with the committee at the beginning of the meeting and noted in the administrative items by the Senior IRB staff.

3.1.3.6 At the beginning of each panel meeting, the Chair or Senior IRB staff reviews known conflicts of interest for the meeting and solicits any additional conflict of interest declarations from the panel members attending.

3.1.3.7 Any panel member who has a potential conflict of interest with a protocol being reviewed may remain in the room to answer any questions during the discussion but must leave the room prior to the deliberation and vote.

3.1.3.8 The recusal is recorded by the Panel Coordinator and Senior IRB staff as it is being managed. The Panel Coordinator will add a note to the comment section of the minutes for that protocol indicating that the conflict was managed.

4. RESPONSIBILITY

The COMIRB Director and Assistant Director are responsible for establishing, conducting and/or supervising implementation of this policy.

The Conflict of Interest and Commitment Office is responsible for the collection of annual conflict of interest declarations.

Senior IRB staff is responsible for soliciting and tracking non-financial conflict of interest updates at least annually.

Chairpersons and all IRB staff are responsible for ensuring that the policy is followed at the panel meeting.

Chairpersons and panel members are responsible for updating their conflict of interest declaration within 30 days of any change.

5. APPLICABLE REGULATIONS AND GUIDELINES

- 45 CFR 46.103 (b) 3
- 45 CFR 46.107 (e)
- 21 CFR 56.107 (e)
- 21 CFR 56.115 (5)
- UCD Conflict of Interest and Commitment policies and procedures
- COMIRB policy and procedures "Conflict of Interest"

6. ATTACHMENTS

- CF-027 - Member Information Sheet
- UCD Financial Conflict of Interest and Commitment Declaration form
- COMIRB panel member conflict of interest tracking sheet
- Panel assignment sheet

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
Institutional Official	Evaluates the performance of the COMIRB Director and panel Chairs at least annually.
COI manager	Sets the COI declaration collection date and processes the responses in accordance with UCD policy.
Sr. IRB Staff	Ensures that all panel members and consultants are given to the COI office to be included in the COI collection. Maintains the COI tracking sheet and collects copies of all panel member declarations for the panel members' files.
Director and Assistant Director or other Sr. IRB Staff	Reconciles the tracking sheet with the assignment sheet prior to the meeting. Documents that the COI was appropriately managed on the meeting template.
Chair	Ensures that the conflict is appropriately managed.
Minute taker	Ensures that the management of the conflict is documented in the comment section of the protocol minutes.
Panel Coordinators	Develops assignment sheet prior to each meeting and ensures that the assigned reviewers do not have a conflict with their assigned reviews. Ensures that there will be quorum for the meeting when the individual is recused.