

University of Colorado Denver  
Colorado Multiple Institutional Review Board  
Standard Operating Procedures

SOP - Management of Panel Member Conflicts of Interest

Version #: 004	Effective Date: 1/7/2020	Supersedes Version: 003
This Policy Pertains to: All COMIRB Staff, Panel members and Chairpersons		
Responsibility for executing this policy: All Panel Members, Chairpersons, IRB Staff		
Last Reviewed on 1/7/20	Result: updated	
Approval Authority: Director		
Approved by: <u>John Heldens</u>	Date: <u>1/7/2020</u>	

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

4.1. Financial or non-financial conflicts of interest

3.2.1. 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.

3.2.2. 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 IRB

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Manager and Panel Coordinators are responsible for ensuring that these requirements are tracked and followed.

4.2. Panel Members:

3.2.1. Potential new panel members are required to complete the Member Information Sheet (CF-027), which includes disclosures of any non-financial conflicts of interest, and complete or update their University Conflict of Interest Disclosure with the University Conflict of Interest and Commitment Office.

3.2.2. Current panel members must update their University Conflict of Interest Disclosure in accordance with University policy. Any panel member who does not update their Disclosure as required by University policy will be removed from the IRB roster until the Disclosure has been submitted.

3.2.3. Current panel members will be required to update their non-financial disclosures at least annually.

3.2.4. Current panel members must disclose any financial and non-financial conflicts of interest with any studies on the agenda before and at every meeting they attend.

3.2.5. IRB Managers will review the declarations and enter the information on the Panel COI tracking sheet. The updated information will then be distributed to all IRB staff.

3.2.6. Prior to convened IRB meetings, the Panel Coordinator will develop the assignment sheet including the sponsor of each protocol to be reviewed. The Panel Coordinator will review the COI tracking sheet prior to assigning reviewers to ensure that the primary reviewer does not have a declared conflict of interest with the protocol being assigned. The Panel Coordinator will also ensure quorum will be maintained if a member with a conflict must recuse themselves.

3.2.7. For expedited/exempt reviews, the Panel Coordinator will consult the tracking sheet prior to assigning the reviewer to ensure that the reviewer does not have a declared conflict of interest with the protocol being assigned.

3.2.8. Prior to the panel meeting, the IRB Manager will review the COI tracking sheet and compare to the assignment sheet.

3.2.9. At the beginning of each panel meeting, the Chair or Compliance Officer reviews known conflicts of interest for the meeting and solicits any additional conflict of interest declarations from the panel members attending. Any conflicts of interest will be discussed with the committee at the beginning of the meeting and noted in the administrative items by the Compliance Officer.

3.2.10. Any panel member who has a potential conflict of interest with a protocol being reviewed may remain in the room to answer any questions

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during the discussion but must leave the room prior to the deliberation and vote.

3.2.11. The recusal will be recorded in the minutes of the meeting.

4. RESPONSIBILITY

- 4.1. The COMIRB Director and Assistant Director are responsible for establishing, conducting and/or supervising implementation of this policy.
- 4.2. The Conflict of Interest and Commitment Office is responsible for the collection of annual conflict of interest declarations.
- 4.3. IRB Managers are responsible for soliciting and tracking non-financial conflict of interest updates at least annually.
- 4.4. Chairpersons and all IRB staff are responsible for ensuring that the policy is followed at the panel meeting.
- 4.5. 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.
IRB Managers	Assist COI Office in making sure all panel members complete annual financial disclosures. Maintain the COI tracking sheet and collects copies of all panel member declarations for the panel members' files.

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Compliance Officer	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.
Panel Coordinators	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.