

Management of Institutional Review Board (IRB) Member and Consultant Conflict of Interest (COI) Policy

Scope

Applies to Mayo Clinic Human Research Protection Program personnel when identifying and managing an IRB member's conflict of interest.

Purpose

To describe the mechanisms for disclosure and management of possible COI for Mayo Clinic IRB members and Consultants who review research involving human subjects.

Policy

IRB Member's Disclosure of a Conflicting Interest

- No IRB member, whether serving in the role as a Convened IRB member or when serving as an Expedited reviewer, with a declared conflict of interest may participate in the review except to provide information as requested.
- This includes review of any materials submitted over the course of the research project or the duration of the member's service on the IRB, such as:
 - Initial IRB applications
 - Continuing Review reports
 - Modifications to approved research
 - Reportable Events
 - Allegations of non-compliance with regulations or requirements of the IRB
- An Expedited reviewer, who recognizes a conflicting interest with an item he or she is assessing under expedited review procedures, must have the item reassigned to a non-conflicted reviewer.
- Convened IRB members who realize they have a conflicting interest when first assigned an item for review at an upcoming IRB meeting must notify the meeting staff or IRB Chairperson immediately so that the item can be reassigned prior to the meeting.
- The IRB Chairperson begins each meeting with a reminder that each member must disclose any conflicting interest and recuse him or herself from the vote on the project by leaving the room.
- If the IRB Chairperson has a conflict, he or she may not chair the meeting during the consideration of the item in which the conflict resides must leave the room during the final discussion and vote.
- If an IRB member recognizes a conflicting interest in an item under review at the IRB meeting, the IRB member must inform the Chairperson of the conflicting interest and leave the room during the final discussion and vote on the item.
- If other IRB members need to request information about the item from the IRB member with the conflicting interest, the IRB member may remain in the room during the presentation of the item, however, the IRB member must leave the room during the IRB's final discussion and vote.

Consultant's Disclosure of a Conflicting Interest

- The definition of conflicting interest as defined above extends to any Consultant who may be asked to review an item under the review by the IRB.
- The IRB member who contacts a Consultant to inquire about assisting with a review is responsible for asking if the Consultant has a conflicting interest in the project. If such a conflict exists, the individual may not serve as a consultant.

Convened IRB Deliberation and Documentation

- A Convened IRB member or Chairperson with a conflicting interest is required to leave the room (i.e. recuse) for the final discussion and voting on the item under review.
- The IRB member who must recuse due to a conflict of interest is not counted towards quorum.
- When the IRB member recuses due to conflict of interest, the meeting minutes will reflect the name of the IRB member, and his/her absence from the vote due to a conflict of interest. Meeting minutes are recorded in the IRB electronic system.

Policy Notes

- Federal regulations prohibit IRB members from participating in the review of any research project in which they have a conflicting interest, except to provide information that is requested by the IRB (45 CFR 46.107(e) and 21 CFR 56.107(e)). Mayo Clinic IRB members must comply with Mayo Clinic institutional policies for the reporting and management of conflicts of interest. The Mayo Clinic IRB works in conjunction with the Mayo Clinic Conflict of Interest Review Board which serves in an advisory capacity, to interpret conflict of interest.
- Upon appointment and annually thereafter, each IRB member will complete the Mayo Clinic Institutional Review Board Disclosure Form.
- When an IRB member discloses a relevant interest through the initial/annual disclosure form or other mechanism, the IRB Member Recusal List is updated to make this information available for management of reviewer assignments and convened IRB meetings.
- Completed IRB member disclosure forms are maintained in accordance with the Mayo Clinic IRB policy IRB Records and Retention.

Related Procedures

N/A

Related Documents

Mayo Clinic Institutional Review Board Member Disclosure Form - Each year a link is sent to IRB Board Members via email.

[Committee Member Recusal List](#) (IRB 10223)

Definitions

Conflict of Interest: Any interest that could reasonably be expected to affect the objectivity of an IRB member or Consultant in relation to an application or other matter

under IRB review. An IRB member or Consultant has a conflict of interest if the individual:

- Is or will be an investigator or member of the research team (i.e. listed on the IRB application)
- Has an immediate family member (i.e. spouse, dependent children) or personal relationship with an individual serving as the Principal Investigator (PI) or co-Principal Investigator (co-PI) of the research
- Has a financial or managerial interest in a sponsoring entity or product being evaluated or provided by a commercial entity in the research, as defined by Mayo Clinic Conflict of Interest Policy
- Has received or will receive compensation with value (as defined by Mayo Clinic Conflict of Interest Policy) that may be affected by the outcome of the research project
- Has a proprietary interest in the research, such as a non-provisional patent application, patent, trademark, copyright, or licensing agreement as defined by Mayo Clinic Conflict of Interest Policy
- Has a nonfinancial interest (personal circumstance, ethical belief, or other factor) that may be conflicting, e.g., the IRB member has an interest that he/she believes conflicts with his/her ability to review a project objectively.
- Has responsibility for Institutional business development, such as raising funds or garnering support for research or as an officer within the Department of Development.

Consultant: A scientist or non-scientist from within or external to Mayo Clinic who has special expertise, to act – at the request of the IRB - as an ad hoc reviewer of a human research application. These individuals have access to all documents relevant to the specific project under review, may participate in the deliberations and make recommendations on the project, but may not vote and are not counted towards quorum.

References

[Mayo Clinic Conflict of Interest Policy](#)

[21 CFR 56.107\(e\) - IRB membership & 45 CFR 46.107\(e\) - IRB Membership](#)

Owner

[Michelle K. Daiss](#) on behalf of Office for Human Subject Research Protection

Contact

[Heidi M. Hanf](#)

Revision History

Date	Synopsis of Change
06/14/2022	Scheduled review. Converted Procedure into Policy. Transferred to standardized template and made minor edits. Updated Owner to Michelle Daiss and Contact to Heidi Hanf.

03/07/2019	Clarified the Chair with a conflict of interest must also leave room during vote of the item. Clarified COI definition (second bullet) as having an immediate family member or personal relationship with an individual serving as PI or co-PI of the research.
02/12/2018	Scheduled review - updated to new template no other changes at this time due to AAHRPP Accreditation cycle.
03/01/2016	Scheduled review - 1) Removed links to Related Documents and 2) Added "Revision History" to end of document.
04/28/2010	Approval for need to establish document: IRB