Management of IRB Member and Consultant Conflicts of Interest

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

This document describes the guidelines for the management of possible conflicts of interest (COI) for IRB Chairpersons, IRB members, IRB staff and Consultants who review research studies involving human subjects.

Background

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)).

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, assess the need for disclosure, and develop an appropriate management strategy if necessary.

Key Terms

Conflict of Interest: Any interest that could reasonably be expected to affect the objectivity of an IRB member with regards to a research project. A conflicting interest includes financial interests and may include non-financial interests such as personal or ethical beliefs, or other factors.

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 research project 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.

Definition of Conflicting Interest

A conflicting interest of an IRB member or Consultant includes the following:

- 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 who is one of the investigators
- 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 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.

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 term on the IRB Committee.
    - Initial IRB application
    - Continuing review reports
    - Modifications to approved research
    - Reportable Events
    - Non-compliance with regulations or requirements of the IRB
- IRB members who realize they have a conflicting interest when they are first assigned an application for review must notify the IRB staff or IRB Chairperson immediately so that the protocol can be reassigned.
- The IRB Chairperson begins each meeting with a reminder that proceedings are confidential. This is followed by a reminder of the requirement 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.
- If an IRB member recognizes a conflicting interest in a project at the IRB meeting, the IRB member must inform the Chairperson of the conflicting interest and leave the room during the discussion and vote on the project.
- If other IRB members need to request information about the project from the IRB member with the conflicting interest, the IRB member may remain in the room during the presentation of the project, however, the IRB member must leave the room during the IRB's 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 a protocol.
- The IRB Member who contacts a Consultant to inquire about review of a project 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.

Committee Deliberation and Documentation

- An IRB member with a conflicting interest is required to leave the room (i.e. recusal) for the final discussion and voting on the protocol or item under review.
- An IRB member who must recuse him or herself due to a conflict of interest is not counted towards quorum.
- When the IRB member leaves the room for a 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.

Procedural Notes

- Upon appointment to a Convened IRB committee, the member will be asked to complete the *Conflict of Interest Annual Disclosure for Selected Leadership Groups, Committees, and Work Areas form* (MC0219-12). Financial disclosures are reviewed by the Conflict of Interest Review Board to determine whether any reported interest constitutes a conflict.
- Upon identification of an IRB member conflict of interest disclosure, the IRB Member Recusal List is updated to reflect the type of conflicting interest.
- IRB members must comply with the Mayo Clinic Institutional policies for the reporting and management of financial conflicts of interest.

Related Documents

Conflict of Interest Disclosure – Annual Disclosure for Selected Leadership Groups, Committees, and Work Areas, Form MC0219

IRB Member Recusal List IRB 10223

References

Mayo Clinic Conflict of Interest Policy

45 CFR 46.107(e) - Protection of Human Subjects

21 CFR 56.107(e) - Institutional Review Boards

Approval Date

December 26, 2012