

Tip Sheet 13: IRB or EC Member and Consultant Conflict of Interest

Related Accreditation Elements: II.1.D.

IRB or EC members are prohibited from participating in the review of a research protocol or plan in which they have a conflict of interest, except to provide information requested by the IRB or EC. Implementation of this process requires defining, identifying, and acting upon IRB or EC member conflict of interest. Such procedures should also be applied to consultants.

Recommended Content:

Define the circumstances under which an IRB or EC member or consultant is considered to have a conflict of interest:

1. Include in the definition the interests of immediate family members of IRB or EC members and consultants.
2. Define immediate family members.
3. Write a definition of financial conflict of interest that is at least as stringent as that used for defining financial conflict of interest of Researchers and Research Staff.
4. Include financial and non-financial criteria in the definition, such as the IRB or EC member or consultant:
 - a. Is a member of the research team.
 - b. Has a financial interest in the research with value that cannot be readily determined.
 - c. Has a financial interest in the research with value that exceeds a specified monetary threshold.
 - d. Has received or will receive compensation with value that may be affected by the outcome of the study.
 - e. Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement.
 - f. Has received payments from the sponsor that exceed a specified monetary threshold in the past year.
 - g. Is an executive or director of the agency or company sponsoring the research.
 - h. Has an interest that the IRB or EC member believes conflict with his or her ability to objectively review a protocol.
5. Include additional criteria relevant to the local context.

Describe how conflicts of interest are identified:

1. For IRB or EC members:
Describe the process for identifying conflict of interest for each type of review conducted by the IRB or EC.
2. For consultants:
Describe the process for identifying conflict of interest when a consultant is asked to review a protocol.

Describe the actions taken when an IRB or EC member declares a conflict of interest:

1. Describe the circumstances under which an IRB or EC member with a conflict of interest is allowed in the meeting room to provide information requested by the IRB or EC.
2. Indicate that an IRB or EC member with a conflict of interest will be asked to leave the meeting room before the final discussion and voting on the research protocol or plan with which the IRB or EC member has a conflict.
3. Describe how the actions taken in response to an IRB or EC member with a conflict of interest are documented.

Describe the actions taken when a consultant declares a conflict of interest:

1. Describe the circumstances under which a consultant with a conflict of interest is allowed to provide information to the IRB or EC.
2. Describe how the actions taken in response to a consultant's conflict of interest are documented.

Other Suggestions:

1. In policies and procedures for writing IRB or EC minutes, indicate that the name of the person with a conflict of interest must be recorded for each applicable vote.
2. In policies and procedures for writing IRB or EC minutes, indicate that IRB or EC members with conflict of interest do not count towards quorum.