

Managing conflict of interest in Ethics Committee

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Abstract The article discusses conflict of interest (COI) situations and how to manage COI in ethics committee (EC).

Keywords: Conflict, Ethics Committee, Interest

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DEFINITION

Conflict of interest (COI) is a set of conditions where professional judgment concerning a primary interest such as participant's welfare or the validity of research tends to be unduly influenced by a secondary interest, financial, or nonfinancial.^[1]

A COI can arise when activities or situations place an individual or institution in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests.^[2] These interests include, financial or nonfinancial interests pertaining to the institution and/or the individual, their family members, friends, or their professional associates.^[2]

CONFLICT OF INTEREST SITUATIONS

An ethics committee (EC) member's primary responsibility is to ensure the protection of the rights, safety and well-being of human subjects participating in a trial and to provide public assurance of that protection.^[2,3] If an EC member has other responsibility or interest, in conflict with the primary responsibility, all the processes

of EC function, submission, review, discussion, approval, continuing oversight, and monitoring, could be affected.

- Investigator of a clinical research project in an institution
 - Financial^[2,4]
 - Financial interest in the commercial sponsor of clinical research/clinical trial in the following manner:
 - Holding a position, for example, director
 - Holding stock or stock options
 - Holding patents (or invention reports) for the product(s) being evaluated
 - Receiving compensation/honoraria as consultant/advisor
 - Obtaining royalties
 - Receiving payments based on the research recruitment or outcomes.
- Nonfinancial^[2,4]
 - Personal relationship with the protocol's principal investigator or investigator or another member of the research team, for example, spouse, children
 - Voting on a protocol when the member of EC is the protocol's principal investigator,

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- investigator, co-investigator, sub-investigator, or study coordinator
- Voting on a protocol when the member of the EC is a spouse, child, household member, or any other individual with whom the protocol's principal investigator, investigator, co-investigator, sub-investigator, or study coordinator has the appearance of a COI.
- Institution
 - Financial^[2,4]
 - Institutional officer, for example, Director, Dean, Head of Department, Head of Institute, Administration, Head of Research, who has financial interest in the commercial sponsor of clinical research/clinical trial as per the conditions listed above
 - Institute sponsoring a research project
 - Institute managing the intellectual property that forms the basis of a research project or stand to benefit from intellectual property resulting from the research
 - Institute holding equity in companies and/or receive major donations.
 - Nonfinancial^[2,4]
 - Responsibility for promoting research/institution image, protect institution, for example, Director, Dean, Head of Department, Head of Institute, Head of Research, Grant office, research administration, and site management organization
 - Responsibility for industry agreements/public-private partnerships
 - Voting on a protocol when the protocol's principal investigator or investigator is the EC member's supervisor, for example, Director, Dean, Head of Department, Head of Institute, Head of Research.

All the above conflict situations are relevant to

- Investigator of a clinical research project, who owns the institution/hospital, whose EC reviews his/her clinical research projects
- Investigator in a multi-centric trial, who is chairperson of EC of another institution where the same trial is submitted for review
- Independent EC or noninstitutional EC
- Invited subject matter experts/consultants.

IMPLICATIONS

When an EC reviews and approves a clinical research project and if an EC member with COI participates in

the review process, there is likelihood of compromise of^[2]

- Ethical responsibilities
- Independence of EC functioning
- Objectivity, fairness, and transparency of research ethics review
- Trust of human subjects participating in clinical trial
- Trust of society

Such a COI situation will be considered regulatory noncompliance during registration, accreditation or audit of EC^[5,6]

MANAGING CONFLICT OF INTEREST^[1,2,4,7]

- Policy
 - COI should not compromise the rights, safety and wellbeing of clinical research participants or the integrity of the research review process
 - Institutions should make written COI policies and procedures publicly available to all members of the research organization, including participants, ECs, research investigators, administrators, and research sponsors.
- Composition
 - COI should be avoided while selecting EC members
 - Any institution officers/administrators should not serve as members of EC. The mere presence of an institutional administrator, for example, Director at EC meetings can undermine the independence of the EC by unduly influencing EC discussions and decisions
 - Investigator of a clinical research project, who owns the institution/hospital, should not serve as member of EC.
- Process
 - Every EC member should sign a COI agreement before ethical review tasks of the EC commence
 - EC members should disclose in writing to the member secretary/designee all real, potential, or perceived COI interest for themselves and their family members— spouse, children, friends, or their professional associates when submitting a proposal
 - Such disclosure shall be sufficiently detailed and timely to allow the IEC administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet quorum
 - If an investigator is a member of the EC, he/she cannot participate in the review and approval process for any project in which he/she is involved as principal investigator, investigator,

co-investigator, or sub-investigator or has any other potential COI

- It will also be a best practice for the EC member who is the investigator to send another e-mail to the member secretary/designee to remind about his/her COI when the proposal comes up for EC deliberation
- At the beginning of each convened EC meeting, the chairperson/member-secretary will ask the EC members if anyone has a financial or nonfinancial COI with regard to any of the research projects on the agenda for reviewed at the meeting
- The chairperson/member-secretary should review disclosures, to determine whether a COI exists and to determine appropriate management of the COI
- Any EC member, who has COI in a clinical research project, should abstain from deliberations and the decision-making process, except to provide information as requested by the EC. Such abstentions should be documented in the minutes
- If any unanticipated COI affects quorum, that project proposal should not be discussed and should be deferred to the next scheduled meeting
- In case the member-secretary of the EC is principal investigator, investigator, co-investigator, or sub-investigator for project under discussion, he/she should declare COI and leave the meeting room. Another EC member nominated as Acting Member Secretary will perform the function of the secretary
- Care should also be taken that all queries (e.g., from patients, others) on the project during its life are managed by the acting member secretary
- In case of several projects being discussed in the

meeting, the minutes should clearly delineate the projects where the members secretary had a COI and hence was not part of the decision-making process. Ideally, separate minutes for these projects should be issued with the acting member secretary signing the minutes

- The EC should not approve a clinical research study where a COI is not eliminated.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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