

	FERCI MODEL SOPs <i>Handling Conflict of Interest among Ethics Committee Members</i>	SOP 03/V1: Effective Date: aa/bb/cccc
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Title: Handling Conflict of Interest among Ethics Committee Members

SOP Code: SOP 03/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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1. Purpose

The purpose of this SOP is to describe the process to identify and manage conflict of interest among Institutional Ethics Committee (IEC) members.

2. Scope

This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all IEC members.

3. Responsibility

All IEC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

4. Definitions and Mandate

Definitions

- Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain. [http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015].

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- Types of COI

- A personal COI is said to exist when
 - there is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an IEC member or consultant or who receives 50% or more support from an IEC member, regardless of age) or other close personal relationship (“step” relationships included) with the investigator, or with co-investigators.
 - IEC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financier.
 - research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)
- A professional COI means the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
- A financial COI for IEC members and immediate family exists the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated)..

Mandate

- *G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th February 2013*
[http://www.cdsc0.nic.in/writereaddata/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdsc0.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf)
accessed on 23rd Nov 2015

2h. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes

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conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

- <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> accessed on 3rd December 2015.

2.4.2.6. “A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed”.

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107> accessed on 23rd Nov 2015.

56.107 “No Institutional review board (IRB) may have a member participate in the IRB's initial or continuing review of any project in which the member *has* a conflicting interest, except to provide information requested by the IRB. [45 CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 IEC membership”.

5. Detailed Instructions

- Voluntary disclosure regarding COI by IEC member - The IEC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.

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- IEC members should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.
 - a) If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC Seretariat and return the documents.
 - b) If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC secretariat so that the review is re-assigned to other members.
 - c) If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
 - d) Recusal - IEC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.

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- e) If an IEC member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.
- At the beginning of each meeting, the IEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
 - If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion on such a project.
 - When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by IEC member with the help of IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)
 - The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
 - The IEC shall not approve a research study proposal where a COI is not managed or eliminated
 - Management of CO – In case of a COI ,
 - IEC members will disclose the COI as discussed above
 - IEC members will not serve as reviewers
 - IEC members will not influence the discussion and decision making of the concerned study by staying away during the IEC meeting.
 - IEC Member Secretary and the Secretariat will record the points related to disclosure and management of COI of IEC members in the IEC minutes.

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7. Flow Chart

No.	Activity	Responsibility
1	Determination of Conflict of Interest (COI)	IEC Member
2	Disclosure and management of COI	IEC Member
3	Ensuring declaration and management of COI during review process	IEC Chairperson
4	Recording of COI in minutes of IEC meeting	IEC Member Secretary/ Secretariat

8. References:

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1. **Part 56 -institutional review boards**, Subpart B--Organization and Personnel, Sec. 56.107 IRB membership, 45 CFR 46.107(e) and 21 CFR 56.107(e) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107> accessed on 23rdNov 2015.
2. https://ouhsc.edu/irb/IRB_SOP_2014/104B_COI_BoardMembers_FINAL_123114.pdf accessed on 23rdNov 2015.
3. <http://irb.northwestern.edu/sites/default/files/documents/hrp-050-sop-conflicting-interests-members.pdf> accessed on 23rdNov 2015.