



**IHEC – MGMCRI SOPs
Handling Conflict of Interest among Ethics
Committee Members**

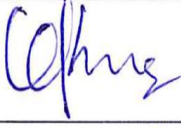

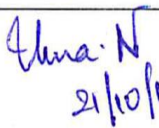

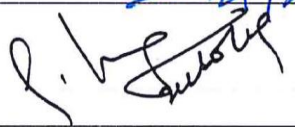


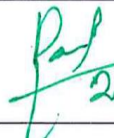
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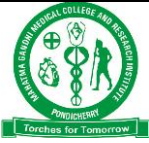
Title: Handling Conflict of Interest among Ethics Committee Members

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Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
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Reviewed by:	Signature and Date:
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1. Purpose

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

2. Scope

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

3. Responsibility

All IHEC members (regular and alternate) are responsible for understanding the definition of Conflict of Interest (CoI) and for self-identifying and disclosing the same. 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

4.1 Definition:

Conflict of Interest

"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. (*ICMR guidelines for Biomedical research, 2017*)

4.1.1 Types of CoI

(a) 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 IHEC member or consultant or who receives 50% or more support from an IHEC member, regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators.
- ♥ IHEC member or his/her immediate family member serves as a contributor to the research



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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)

(b) A professional CoI is said to exist when

- IHEC 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 IHEC members and immediate family exists
- IHEC 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).

4.2 Mandate

- 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 conflict of interest which may be indicated in writing to the chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
- A member must voluntarily withdraw from the IHEC 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.
- No IHEC member will participate in the IHECs initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IHEC

5. Detailed Instructions

5.1 Voluntary disclosure regarding CoI by IHEC member

- The IHEC member should determine whether he/she has a CoI before reviewing



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research and declare all certain or potential conflicts of interest prior to engaging in any review process.

- IHEC 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 IHEC.
- a) If an IHEC member has a CoI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IHEC Secretariat and return the documents.
- b) If an IHEC member has a CoI for a study for which he or she has been assigned as a reviewer, he or she will inform the IHEC secretariat so that the review is re-assigned to other members.
- c) If an IHEC 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 IHEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.
- d) Recusal - IHEC 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.
- e) If an IHEC member finds that he/she has a COI during the conduct of a research project approved by IHEC, he/she shall report the conflict to the IHEC at the next IHEC meeting.
 - At the beginning of each meeting, the IHEC chairperson asks the members to disclose any CoI concerning any of the items on the agenda. During the meeting, IHEC 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



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gathered from relevant sources and determination is done by IHEC member with the help of IHEC Chairperson/Co-Chairperson / member secretary/Additional Member Secretary (as applicable)

- The IHEC Chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately for research participant protection.
- The IHEC shall not approve a research study proposal where a CoI is not managed or eliminated

5.2 Management of CoI

In case of a CoI,

- IHEC members will disclose the CoI as discussed above
- IHEC members will not serve as reviewers
- IHEC members will not participate in the discussion and decision making for the concerned study

5.3. IHEC Member Secretary/Additional Member Secretary and the Secretariat will record the points related to disclosure and management of CoI of IHEC members in the IHEC minutes.

6. Glossary

Conflict of Interest (CoI)	Conflict of interest (COI) is a set of conditions where professional judgment concerning
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7. Annexure

Annexure 1: AX 01/SOP 03/V2–Conflict of Interest Form/ Declaration for IHEC Members



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Annexure 1: AX 01/SOP 03/V2

Conflict of Interest Form/ Declaration for IHEC Members

I am aware of the policy of the IHEC regarding Conflict of Interest (CoI) and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IHEC.

I declare _____ (actual or potential CoI) in relation to the proposal entitled “_____” submitted for review to the IHEC. The reason for CoI is _____

I will refrain from the review process and /or discussion at the IHEC meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

_____ Signature of IHEC Member _____ Date

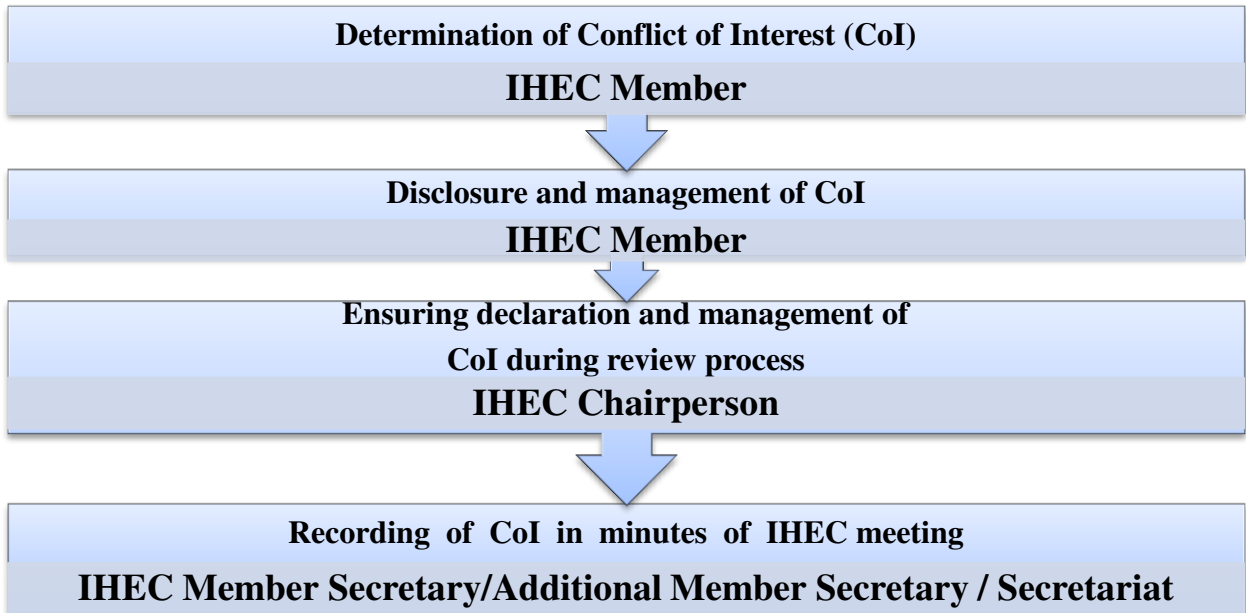
_____ Chairperson’s Signature _____ Date



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8. Flow Chart



9. References:

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*
