

	Institutional Ethics Committee Title: Handling Confidentiality and Conflict of Interest among Ethics Committee Members	SOP 03/V1 Effective from September 2019 Valid till September 2022
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3.1. Purpose

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

3.2. Scope

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

3.3. 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.

3.4. Definitions

- Confidentiality is obligation of the stakeholders to prevent disclosure of information and documents related to IEC to other than authorised individuals.
- 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 financial or non-financial (personal, academic or political) gain..
- Types of COI
 - A personal COI is said to exist when -
 - there is immediate family relationship (spouse, parent or parent of 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 current personal relationship ("step" relationships included) with the investigator, or with co-investigators;
 - IEC member or her/his immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff; and
 - 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 her/his 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 when the IEC member or the spouse or dependent of a member receives monetary benefits

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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).

3.5. Detailed Instructions

- Voluntary disclosure regarding COI by IEC member - The IEC member should determine whether she/he has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.
- IEC members should not participate in discussing, or decision making while reviewing research proposal applications at any level (exempt, expedited, or full-board) if they have conflicts of interest except to provide information requested by the IEC.
 - a) At the time of becoming a IEC member, she/he should sign a confidentiality and COI agreement.
 - b) If an IEC member has a COI with regard to a proposal, she or he should notify the IEC Secretariat and return the documents.
 - c) If an IEC member has a COI for a study for which she or he has been assigned the task of a primary reviewer, she or he should inform the IEC secretariat so that the review is reassigned to other members.
 - d) If an IEC member has a COI for review of research study at a meeting, she or he should inform the Chairperson and leave the meeting room while decision about the study is being taken. She/he 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.
 - e) Recusal - IEC member who declares COI and leaves the meeting does not count as part of the quorum for the decision making process either by consensus/vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence, which should be recorded in the minutes of the meeting.
 - f) If an IEC member finds that she/he 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 that just before the review of the relevant item begins.

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- 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/ Vice-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, or by IEC Chairperson / Member Secretary (as applicable)
- The UEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The UEC shall not approve a research study proposal where a COI is not managed or eliminated
- Management of 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 despite staying away during the IEC meeting.
 - Experts/consultants – Proposal will not be sent if COI is declared.
 - IEC Member Secretary and the Secretariat will record the points related to disclosure and management of COI in the minutes of the meeting of the IEC.

3. 6. Annexure

Annexure 1 AX 01/SOP03/V1 – Conflict of Interest Declaration for IEC members when joining as members/Consultants

Annexure 2 AX 02/SOP03/V1 - Conflict of Interest Declaration Form for IEC Members/Non-members (Guests/Observers) when attending meeting.

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Annexure 1: AX 01/SOP 03/V1

Conflict of Interest Declaration Form for IEC Members when joining as members

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

☐ I have no conflict of interest to report.

☐ I have the following conflict of interest to report

- i. Personal
- ii. Professional
- iii. Financial

Please describe any relationships, transactions, positions you hold (volunteer or otherwise), or circumstances that you believe could contribute to a conflict of interest:

(Please specify other non-profit and for-profit boards you (and your spouse) sit on, any for-profit businesses for which you or an immediate family member are an officer or director, or a majority shareholder, get speaking fees and the name of your employer and any businesses you or a family member own)

In accordance to the policy of the IEC, I will also immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee. I shall abstain from participating in decision-making process related to such proposals and inform the committee that I cannot be a part of the quorum for consensus or voting.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

I, _____(name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ Signature of IEC Member _____ Date

_____ Chairperson's Signature _____ Date

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Annexure 2: AX 02/SOP 03/IV

Conflict of Interest form to be signed by IEC member during Committee Meeting

Date:

To,

The Chairperson,

IEC, AVP Research Foundation

I hereby declare the conflict of interest for the project no. IEC/ _____ /
entitled, _____

_____ as:

1. I am the investigator / co-investigator/Author/member of research team
2. I have the following interest in the subject matter of the study under review

1) _____

2) _____

3) _____

4) _____

Member, IEC

Countersigned

Chairperson, IEC

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3.7. 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