

**Title: Handling Conflict of Interest among Ethics Committee Members**

**SOP Code: SOP03/v2**

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**Table of Contents:**

No.	Content	Page No.
1	Purpose	3
2	Scope	3
3	Responsibilities	3
4	Definitions & Mandate	4
5	Detailed instructions	5
6	Annexures	7
7	Flowchart	8

## **1. Purpose**

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

## **2. Scope**

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

## **3. Responsibility**

All YUEC members (regular and independent consultants) 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**

### **4.1 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 or appears to be unduly influenced by secondary interest - personal, academic, political or financial gain<sup>1</sup>.

### **4.2 Types of CoI**

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

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<sup>1</sup> Thompson DF. *Understanding Conflict of Interest*. *N Engl J Med*. 1993 Aug 19; 329: 573-76

- Research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)
- 2. A professional CoI means YUEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring research.
- 3. A financial CoI for YUEC members and immediate family exists if the YUEC 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)..

### 4.3 Mandate

The mandate for recording and reporting of conflict of interest is provided by the Government of India and is binding on the ethics committee<sup>2</sup>.

“There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the Chairperson prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest<sup>3</sup>.”

“A member must voluntarily withdraw from the YUEC 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<sup>4</sup>.”

“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<sup>5</sup>.

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<sup>2</sup> G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8<sup>th</sup> February 2013 [http://www.cdsc.nic.in/writereaddata/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdsc.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf) accessed on 8 July 2016 at 9.50 AM

<sup>3</sup> <http://cdsc.nic.in/writereaddata/ethic%20committee/268.pdf> accessed on 8 July 2016 at 2235 hrs

<sup>4</sup> [http://www.icmr.nic.in/ethical\\_guidelines.pdf](http://www.icmr.nic.in/ethical_guidelines.pdf) accessed on 8 July 2016 at 2242 hrs.

<sup>5</sup> 45 CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 YUEC membership

## 5. Detailed Instructions

### 5.1 Voluntary disclosure regarding CoI by YUEC member:

- 5.1.1 The YUEC 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.
- 5.1.2 YUEC members should not participate in discussing, or decision-making on research proposals reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by YUEC.
- 5.1.3 If a YUEC member has a CoI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the YUEC Secretariat and return the documents.
- 5.1.4 If a YUEC 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 YUEC Secretariat so that the review is re-assigned to other members.
- 5.1.5 If a YUEC member has a CoI for review of research study at a meeting, he or she will inform the Chairperson in writing 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 YUEC meetings at which discussion on serious adverse events, deviations/violations, amendments/continuing review reports related to studies are done.
- 5.1.6 Recusal – A YUEC 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.
- 5.1.7 If a YUEC member finds that he/she has a CoI during the conduct of a research project approved by YUEC, he/she shall report the conflict to the YUEC at the next YUEC meeting.
- 5.1.8 At the beginning of each meeting, the YUEC Chairperson asks the members to disclose any CoI concerning any of the items on the agenda. During the meeting, the YUEC member having conflict discloses the existence of the conflict just before the review of

the relevant item begins.

- 5.1.9 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.
- 5.1.10 When determination regarding existence of CoI is uncertain, more information is gathered from relevant sources and determination is done by YUEC member with the help of YUEC Chairperson/Member Secretary.
- 5.1.11 The YUEC Chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately for research participant protection.
- 5.1.12 The YUEC 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 ,**

- 5.2.1 YUEC members will disclose the CoI as discussed above.
- 5.2.2 YUEC members will not serve as reviewers.
- 5.2.3 YUEC members will not influence the discussion and decision-making of the concerned study by staying away during the YUEC meeting.
- 5.2.4 YUEC Member Secretary and the Secretariat will record the points related to disclosure and management of CoI of YUEC members in the YUEC minutes.

## 6. Annexure

### Ann01/SOP03/v2: Conflict of Interest Form/Declaration for YUEC Members

#### Conflict of Interest Form/ Declaration for YUEC Members

I am aware of the policy of the YUEC regarding conflict of interest 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 (CoI) except to provide information as requested by the YUEC.

I declare actual/potential CoI (*strike out whichever is not applicable*) in relation to the proposal entitled

“ \_\_\_\_\_ ” submitted for review to the YUEC. The reason for CoI is \_\_\_\_\_.

I am returning this protocol document package. I will refrain from the review process and/or discussion at the YUEC meeting/and also will not

take part in ongoing and periodic review and monitoring of this study.

Signature of YUEC Member

Date:

Signature of Chairperson

Date:

## 7. Flow Chart

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