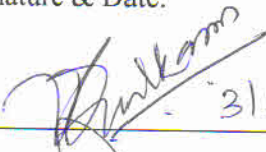


Title: Handling Conflict of Interest among Ethics Committee Members


SOP Code: SOP3A/v3

Effective Date: 03/10/2019

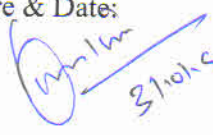
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature & Date:  31/10/19
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Notified by:

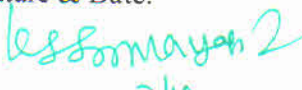
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1. **Purpose:** The purpose of this SOP is to describe the process to identify and manage conflict of interest (CoI) among Yenepoya Ethics Committee – 1 (YEC-1) members.
2. **Scope:** This SOP covers the policy related to identification, declaration and management of CoI and is applicable to all YEC-1 members, secretariat staff, independent consultants, guest observers (as defined in SOP05/v3) to the YEC-1.
3. **Responsibility:**
 - 3.1. **The Chairperson will:**
 - 3.1.1. Ensure that the CoI policy of the YEC-1 is followed at all times
 - 3.1.2. Ensure that the YEC-1 members declare any CoI at the time of review, during deliberation of the concerned protocol and during the post-approval activities
 - 3.1.3. Ensure that the members with CoI for a protocol will not take part in the deliberation and decision on such protocols
 - 3.2. **The Secretariat will:**
 - 3.2.1. Send the CoI forms to the reviewer-members along with the protocols
 - 3.2.2. File the CoI forms in the respective protocol files
 - 3.3. **The YEC-1 Member(s) will:**
 - 3.3.1. Understand the definition of CoI, identify the presence of CoI and declare it
 - 3.3.2. Manage the CoI by declaring the CoI, and not taking part in the review, decision making and post-approval activities of the protocols
 - 3.4. **The Independent Consultant will:**
 - 3.4.1. Understand the definition of CoI, identify the presence of CoI and declare it
 - 3.4.2. Manage the CoI by declaring the CoI, and not taking part in the review of those protocols
 - 3.5. **The guest/observer will:**
 - 3.5.1. Understand the definition of conflict of interest (CoI), identify the presence of CoI and declare it
 - 3.5.2. Manage the CoI by declaring the CoI, and not taking part in the meeting of the YEC-1, if the concerned protocol is included in that meeting.

4. Definition & Mandate:

4.1. **Definition:** CoI 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 gain¹.

4.2. Types of CoI:

4.2.1. A personal CoI is said to exist when

4.2.1.1. 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 YEC-1 member or an independent consultant or who receives financial support from a YEC-1 member (regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators, or with any other research team member, or with any employee of the sponsor.

4.2.1.2. YEC-1 member or his/her immediate family member (as defined above) serves as a contributor to the research project as a collaborator, consultant, research staff or financier.

4.2.1.3. A research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)

4.2.2. A professional CoI is said to exist when

4.2.2.1. A YEC-1 member or immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring research.

4.2.3. A financial CoI for YEC-1 members exists if

4.2.3.1. The YEC-1 member or the spouse or dependent or immediate family member (as defined above) of a member receives – or has received – 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) from the sponsor or any of its sister concerns or subsidiaries,

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

or from the principal investigator, or any of the research team members.

4.3. **Mandate:**

- 4.3.1. The mandate for recording and reporting of CoI is provided by the Government of India and is binding on the ethics committee². “There should be no CoI. The members shall voluntarily withdraw from the Ethics committee meeting while making a decision on an application which evokes CoI which may be indicated in writing (either in the prescribed format – Ann01/SOP03/v3 – or failing which by an email) to the Chairperson/Member-Secretary prior to the review and to be recorded so in the minutes. All members shall sign a declaration on CoI³.”
- 4.3.2. “A member must voluntarily withdraw from the EC while making a decision on an application which evokes a CoI 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 or a decision taken⁴.”
- 4.3.3. “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 IRB⁵.”

5. **Detailed Instructions:**

5.1. **YEC-1 Members:**

5.1.1. **Declaration at the time joining YEC-1:**

- 5.1.1.1. All YEC-1 members (including the Chairperson and Member-Secretary) and the staff of the YEC-1 secretariat shall sign a declaration – at the time of joining the service of the ethics committee – that they will disclose CoI as and when the same arises, for their entire tenure as ethics committee members.

5.1.2. **Voluntary disclosure regarding CoI by YEC-1 member**

- 5.1.2.1. The YEC-1 member should determine whether he/she has a CoI before

² G.S.R. 227(E). New Drugs and Clinical Trials Rules 2019. Ministry of Health and Family Welfare notification dated 20th March 2019 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ== accessed on 28 September 2019 at 1155 AM

³ <http://cdsco.nic.in/writereaddata/ethic%20committee/268.pdf> accessed on 28 September 2019 at 2235 hrs – modified from original

⁴ http://www.icmr.nic.in/ethical_guidelines.pdf accessed on 8 July 2016 at 2242 hrs.

⁵ 45 CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 YEC-1 membership

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

5.1.2.2. The YEC-1 member should determine whether he/she has a CoI for any protocol that is kept for discussion in the YEC-1 meeting before the meeting begins

5.1.2.3. The YEC-1 member should determine whether he/she has a CoI for any protocol that he/she has been assigned to review the continuing review application/ interim report/ closure report/ SAE/ take part in the SAE meeting or in the Site monitoring or any other activity related to such protocols.

5.1.3. **Managing CoI:**

5.1.3.1. If the Member-Secretary has a CoI, then he/she will hand over the responsibility of the protocols to the Joint-Secretary/another member and will not take part in the categorization, review or decision making or signing of the approval letters or post-approval activities.

5.1.3.2. YEC-1 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 YEC-1.

5.1.3.3. If a YEC-1 member has a CoI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the YEC-1 Secretariat and return the documents, within the stipulated time period as specified in SOP07/v3.

5.1.3.4. If a YEC-1 member has a CoI for a study for which he or she has been assigned as a primary reviewer/lead discussant, he or she will inform the YEC-1 Secretariat so that the review is re- assigned to other members.

5.1.3.5. If a YEC-1 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 YEC-1 meetings at which discussion on serious adverse events, deviations/violations, amendments/continuing review reports related to studies are done.

- 5.1.3.6. If a YEC-1 member finds that he/she has a CoI during the conduct of a research project approved by YEC-1, he/she shall report the conflict to the YEC-1 at the next YEC-1 meeting.
- 5.1.3.7. At the beginning of each meeting, the YEC-1 Chairperson will ask the members to disclose any CoI concerning any of the items on the agenda. During the meeting, the YEC-1 member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
- 5.1.3.8. If the Chairperson has a CoI for a particular project, this should be so declared and handled like any other member's conflict is handled. The Co-chairperson or the acting Chairperson should be appointed for discussion on such a project proposal.
- 5.1.3.9. The YEC-1 shall not approve a research study proposal where a CoI is not managed or eliminated

5.1.4. **Uncertain CoI:**

- 5.1.4.1. When determination regarding the existence of CoI is uncertain, more information is gathered from relevant sources and a final determination is done by YEC-1 member with the help of YEC-1 Chairperson/Member Secretary.
- 5.1.4.2. The YEC-1 Chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately.

5.2. **Independent consultants:**

5.2.1. **Declaration at the time joining YEC-1 as IC:**

- 5.2.1.1. An IC shall sign a declaration at the time of joining the panel of ICs for the YEC-1 that he/she will disclose the CoI as and when the same arises, for their entire tenure as ethics committee members.

5.2.2. **Managing CoI:**

- 5.2.2.1. An IC will declare CoI for a protocol when it is sent for review within the stipulated time

5.3. **Guest observer:**

5.3.1. Declaration at the time requesting the YEC-1 to visit as guest observer:

- 5.3.1.1. A Guest observer will declare CoI for any protocol that is included in the YEC-1 meeting

5.3.1.2. The YEC-1 Secretariat will confirm the same

5.3.2. Managing the CoI

5.3.2.1. The Guest observer will refrain from attending that meeting.

5.4. **Recusal:**

5.4.1. A YEC-1 member who declares CoI and leaves the meeting does not count towards the quorum for the vote.

5.4.2. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.

5.5. **Recording of the CoI:**

5.5.1. YEC-1 Member-Secretary and the Secretariat will record the points related to disclosure and management of CoI of YEC-1 members/ Independent consultants in the YEC-1 minutes.

5.5.2. YEC-1 Member-Secretary and the Secretariat will record the points related to disclosure and management of CoI of YEC-1 members in the approval letter.

6. **Annexures:**

6.1.1. **Ann01/SOP03/v3:** CoI Form/Declaration for YEC-1 Members/ Independent consultants

Ann01/SOP3/v3

Conflict of Interest (CoI) Form/ Declaration for YEC-1 Members/ Independent consultants

To

The Chairperson,

YEC-1

Sir/ Madam,

I am aware of the policy of the YEC-1 regarding conflict of interest and that no member/reviewer may participate in the review, comment or participate in decision-making of any activity in which he/she has actual/potential CoI except to provide information as requested by the YEC-1.

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

Protocol Number:	
Protocol Title:	

Principal Investigator:	
Funding agency:	

I declare CoI for the following reason (s): Tick whichever applicable

I am a member of the research team	
My immediate family member is a part of the research team	
I have a direct/indirect financial interest	
Any other: (Specify	

To manage the CoI (Tick after agreeing to the following points), I declare that:

I will return the protocol document package	
I will refrain from the review process	
I will not be present in the YEC-1 meeting room during the discussion and decision-making on this protocol	
I will not participate in any of the post-approval activities like ongoing review/ site monitoring/ audit/ SAE review/ and others pertaining to this protocol.	

Date:

Signature of the YEC-1 member/ Independent consultant
 Name and date

Signature of the Chairperson/Member-Secretary with date

7. Flow Chart

