


Title: Handling Conflict of Interest among Ethics Committee Members

SOP Code: SOP3A/v4

Effective Date: 01/07/2023


Prepared by

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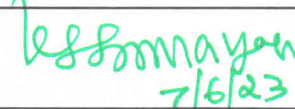
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Notified by:

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Details of superseded SOP3A

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP3A/v4

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Updated definition of CoI and removed redundancies 2. Glossary section added in the SOP 3. Added option of review of protocols by YEC-2 in case more than 2-3 YEC-1 members have CoI for the same protocol.

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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, Secretarial staff, Independent Consultants, Guests and Observers..
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/v4) to the YEC-1.
3. **Definition & Mandate:**
 - 3.1. **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.
 - 3.2. **Types of CoI:**
 - 3.2.1. A personal (non-financial) CoI is said to exist when
 - 3.2.1.1. There is a first degree family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse) between a YEC-1 member, secretarial staff, independent consultant, guest or observer and any person who is a stakeholder in the concerned research protocol (investigator, co-investigators, any other research team member, collaborator, consultant, any person from the sponsor or funding agency) submitted to YEC-1 for review.
 - 3.2.1.2. In addition, it will be deemed to exist in the case of any person (part of the research team) who resides with, or receives financial support from, or is in a close personal relationship with, a YEC-1 member.
 - 3.2.1.3. YEC-1 member himself/herself serves as a contributor to the research proposal in any role as described above.
 - 3.2.2. A financial CoI for YEC-1 members exists if
 - 3.2.2.1. 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, or from the principal investigator, or any of the research team members.
 - 3.3. **Mandate:**
 - 3.3.1. The mandate for recording and reporting of CoI is provided by the Government of India and is binding on the ethics committee. “There should be no CoI. The

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

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/SOP3A/v4) to the Chairperson/ Member-Secretary prior to the review and to be recorded so in the minutes. All members shall sign a declaration on CoI”.²

- 3.3.2. “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 taken”.³
- 3.3.3. “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 IRB⁴.”

4. Responsibility:

4.1. The Chairperson will:

- 4.1.1. Ensure that the CoI policy of the YEC-1 is followed at all times
- 4.1.2. Ensure that the YEC-1 members declare any CoI at the time of review, during deliberation of the concerned protocol, during decision-making and during the post-approval activities.

4.2. The Secretariat will:

- 4.2.1. Send the CoI forms to the reviewers along with the protocols
- 4.2.2. File the CoI forms in the respective protocol files
- 4.2.3. Report the CoI for the relevant protocol in the minutes of the meeting

4.3. The YEC-1 Member(s) will:

- 4.3.1. Understand the definition of CoI, identify its presence and declare it
- 4.3.2. Manage the CoI by declaring it, and not taking part in the review, deliberation, decision making and post-approval activities of the protocols

4.4. The Independent Consultant/Guest/Observer will:

- 4.4.1. Understand the definition of CoI, identify and declare it
- 4.4.2. Declare the CoI and not take part in the review and deliberation of the protocol

5. Detailed Instructions:

5.1. YEC-1 Members:

² https://cdsco.gov.in/openems/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf accessed 28 Apr 2023

³ https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf accessed on 28 Apr 2023

⁴ <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107> accessed on 28 Apr 2023

5.1.1. Declaration at the time of 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 (Ann01/SOP3A/v4) – at the time of joining the ethics committee – that they will disclose CoI as and when the same arises, for their entire tenure as ethics committee members, and beyond, if necessary.

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 reviewing a research protocol and declare all actual or potential (financial or non-financial) 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, or a continuing review/ interim report/closure report/SAE, and not 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 (if any) or another member and will not take part in the categorization, review or decision making or signing of the approval letters or any post-approval activities.

5.1.3.2. YEC-1 members should not participate in discussion, 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 member has a CoI for review outside a meeting (e.g., the expedited procedure/ amendments), he/she should notify the Secretariat and return the documents, within the stipulated time as specified in SOP07/v4.

5.1.3.4. If a member has a CoI for a full-review study for which he/she has been assigned as primary reviewer/lead discussant, he/she will inform YEC-1 Secretariat in writing so that the review is reassigned to another member.

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, at the beginning of the meeting when the Chairperson is asking for declaration of CoI and leave the meeting room at the time when the discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the

research protocol, if needed. 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 acting Chairperson should be appointed for discussion on such a project proposal.
- 5.1.3.9. YEC-1 approval of a research proposal shall be deemed invalid, where a CoI is not managed or eliminated, or subsequently discovered so.
- 5.1.3.10. If more than 2-3 members of YEC-1 have CoI for the same protocol, the protocol may be considered for review by YEC-2 after discussion with the Chairperson, YEC-1.

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, and may permit the said member to continue attending the meeting, if the CoI is perceived as negligible or uncertain. The Chairperson's decision is final and binding.

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.

5.2.2.2. All other conditions mentioned for members will apply to ICs.

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. The YEC-1 Secretariat will confirm the same

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

5.3.1.3. All other conditions mentioned for members will apply to guest observers.

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.

5.4.3. After said member recuses himself/herself, the quorum may be reassessed, and recorded as such, in the minutes.

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. References:

- 6.1. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTR_ules_2019.pdf accessed on 28 Apr 2023
- 6.2. https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf accessed on 28 Apr 2023
- 6.3. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107> accessed on 28 Apr 2023

7. Annexures:

7.1.1. **Ann01/SOP3A/v4: CoI Form/Declaration for Members/ Independent consultants**

Ann01/SOP3A/v4

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 financial/ non-financial 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:

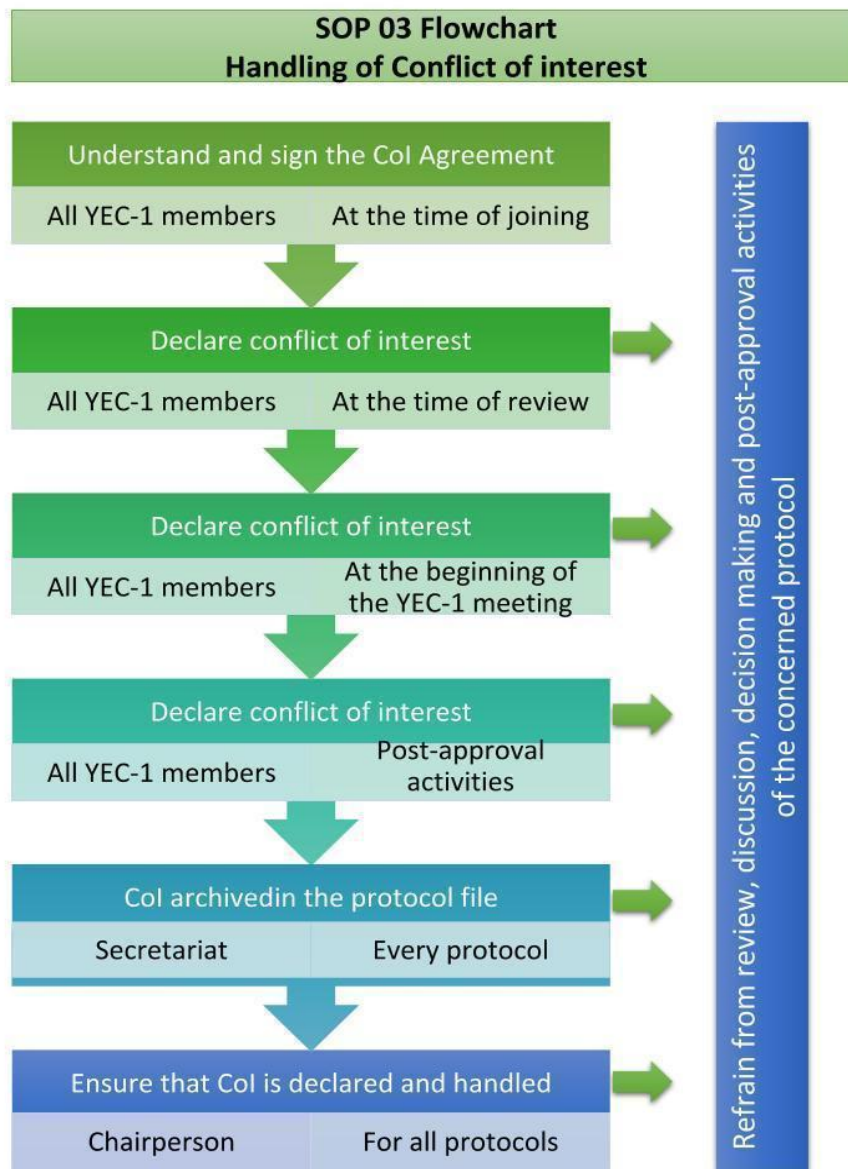
I will return the protocol document package	
I will refrain from the review process	
I will not be present in the YEC-1 meeting room during the discussion and decision-making on this protocol	
I will not participate in any post-approval activities like ongoing review/ site monitoring/ audit/ SAE review/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

Date:

Signature and name of the YEC-1 member/ Independent consultant

Signature of the Chairperson/Member-Secretary with date

8. Flow Chart



9. Glossary:

- CDSCO: Central Drugs Standard Control Organization
- CoI: Conflict of Interest
- CFR: Code of Federal Regulations
- ICMR: Indian Council of Medical Research
- NDCTR-19: New Drugs and Clinical Trials Rules, 2019
- SOP: Standard Operating Procedure
- IC: Independent Consultant