


Title: Handling Conflict of Interest among Ethics Committee Members

SOP Code: SOP03/v2

Effective Date: 01/08/2016

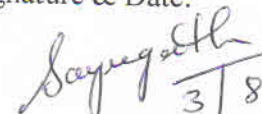
Prepared by:

Dr. Ravi Vaswani, YUEC Member	Signature & Date:  30/7/16
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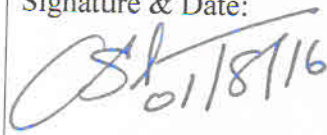
Reviewed by:

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Approved by:

Dr. Sayeegeetha Hegde, Chairperson, YUEC	Signature & Date:  3/8/16
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Registrar, Yenepeya University vide Notification No. YUreg/ACA/YUEC/FERCAP/01/2016	Signature & Date:  01/8/16 Dr. G. Shreebhar Menon Registrar
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Yenepeya University
Mangaluru - 575 018

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Registrar, Yenepoya University vide Notification No. YU/REG/ACA/YEC- 1/FERCAP/01/2016 dated 01/08/2016	Signature & 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 Yenepoya Ethics Committee - 1 (YEC-1) members.

2. Scope

This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all YEC-1 members.

3. Responsibility

All YEC-1 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 gain¹.

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

¹ 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 YEC-1 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 YEC-1 members and immediate family exists if the YEC-1 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 committee².

“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 interest³.”

“A member must voluntarily withdraw from the YEC-1 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 discussed⁴.”

“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.

² G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th 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

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

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

5. Detailed Instructions

5.1 Voluntary disclosure regarding CoI by YEC-1 member:

- 5.1.1 The YEC-1 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 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 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.
- 5.1.4 If a YEC-1 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 YEC-1 Secretariat so that the review is re-assigned to other members.
- 5.1.5 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.
- 5.1.6 Recusal – A YEC-1 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 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.
- 5.1.8 At the beginning of each meeting, the YEC-1 Chairperson asks 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.

- 5.1.9 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 YEC-1 member with the help of YEC-1 Chairperson/Member-Secretary.
- 5.1.11 The YEC-1 Chairperson has the final authority to determine whether a CoI has been managed or eliminated appropriately for research participant protection.
- 5.1.12 The YEC-1 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 YEC-1 members will disclose the CoI as discussed above.
- 5.2.2 YEC-1 members will not serve as reviewers.
- 5.2.3 YEC-1 members will not influence the discussion and decision-making of the concerned study by staying away during the YEC-1 meeting.
- 5.2.4 YEC-1 Member-Secretary and the Secretariat will record the points related to disclosure and management of CoI of YEC-1 members in the YEC-1 minutes.

6. Annexure

Ann01/SOP03/v2: Conflict of Interest Form/Declaration for YEC-1 Members

Conflict of Interest Form/ Declaration for YEC-1 Members

I am aware of the policy of the YEC-1 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 YEC-1.

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

“_____” submitted for review to the YEC-1. The reason for CoI is _____.

I am returning this protocol document package. I will refrain from the review process and/or discussion at the YEC-1 meeting/and also will not

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

Signature of YEC-1 Member

Date:

Signature of Chairperson

Date:

7. Flow Chart

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