


TAGORE MEDICAL COLLEGE & HOSPITAL 	Confidentiality / Conflict of Interest Agreements		Institutional Ethics Committee
			TMCH/IEC/SOP/13
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Confidentiality / Conflict of Interest Agreements

For Institutional Ethics Committee

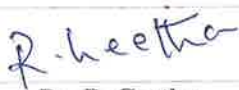

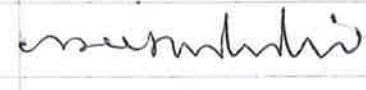
Tagore Medical College and Hospital




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Issue No : 01
Issue Date : 02.11.2020
Copy No : 01/10
Copy Holder Name and Designation : Dr. R. Geetha, Member Secretary, IEC

Prepared By	Reviewed By	Approved By
 Dr. R. Geetha Member secretary of IEC	 Dr. I. Kannan Member of IEC	 Dr. S. Seethalakshmi Chairperson of IEC

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1. Purpose

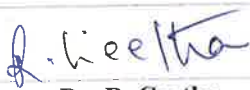


The purpose of this SOP is to describe the process to identify and manage confidentiality / conflict of interest among Institutional Ethics Committee (IEC) members.


2. Scope

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Institutional Ethics Committee (IEC)

3. Responsibility

- a. It is responsibility of each IEC member reviewing research project or attending IEC meeting to read, understand, accept and sign the agreement contained in the confidentiality / Conflict of Interest Form. The form should be read, understood, accepted and signed by each IEC member at the beginning of the tenure of his/her membership
- b. It is the responsibility of each and every newly-appointed member of IEC to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning ethical and/or scientific review tasks and prior to his/her attending IEC meetings held to review research studies to protect the rights of study participants.
- c. It is the responsibility of the guest/observers intending to attend an IEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form prior to attending an IEC meeting and/or before ethical review tasks with the Institutional Ethics Committee are commenced.
- d. It is the responsibility of the Independent Consultant (IC) to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the IEC and/or attending a meeting of IEC.

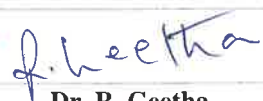


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- e. The Secretariat will ensure that the Confidentiality / Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests or observers for IEC meetings or Independent Consultants prior to attending an IEC meeting, accessing IEC documents or undertaking review processes (as applicable) and notify to the IEC Chairperson. The Secretariat will file signed Confidentiality/ Conflict of Interest Agreement forms in the files entitled 'Confidentiality /Conflict of Interest Agreement Forms'

4. Flow chart

No.	Activity	Responsibility
1.	Provide appropriate forms to IEC member, Guest attendees, Observers, Independent Consultant	IEC Secretariat
2	Read the text carefully and thoroughly	IEC members / guest attendees / observers / Independent Consultant
3	Clarification of doubts, if any	IEC members / guest attendees / observers / Independent Consultant
4	Sign and indicate consent	IEC members / guest attendees / observers / Independent Consultant
5	Keep the agreement in mind	IEC members / guest attendees / observers / Independent Consultant

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Mandate

G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th February 2013 2h. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

2.4.2.6. “A member must voluntarily withdraw from the IEC 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”.

56.107 “No Institutional Ethics Committee (IEC) may have a member participate in the IEC's initial or continuing review of any project in which the member *has* a conflicting interest, except to provide information requested by the IRB. [45CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 IEC membership”.




5. Detailed instructions


5.1 Provide appropriate forms to IEC member, Guest attendees, Observers, Independent Consultant

The appropriate Confidentiality and / or Conflict of Interest Agreement Form will be provided to the IEC member, Guest attendee, Observer and Independent Consultant

5.1.1 Read the text carefully and thoroughly

- Every member at beginning of the tenure and before he/she commences to review research

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- projects submitted to IEC and before he/she starts to function as an IEC member and before he/she starts attending IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form, carefully and thoroughly.
- Every observer or guest for IEC meeting: before initiating ethical review and / or before commencement of the meeting will read the Confidentiality / Conflict of Interest Agreement Form carefully and thoroughly
- Every Independent Consultant / advisory committee/ board member before initiating ethical review and / or before commencement of IEC meeting will read the Confidentiality / Conflict of Interest Agreement Form carefully and thoroughly




IEC member, Guest attendee, observer, Independent Consultant, advisory committee/ board member will fill up the details such as name, designation and official address.


5.1.2 Clarification of doubts, if any.

If any of the IEC members/Guests /observers for IEC meetings/Independent Consultants have any doubts, need clarifications or if any part or sentences is not clear, they will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications. If any further explanations are needed, they can be provided by the Chairperson / Legal expert/other IEC members.

5.1.3 Sign to indicate consent.

- a. The newly appointed IEC member, before the beginning of their tenure, Guests /observers for IEC meetings, Independent Consultants / advisory committee/ board member will sign and date the document before a member of the Secretariat.
- b. They will give the signed form back to the Secretariat.
- c. The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality /Conflict of Interest Agreement Form.

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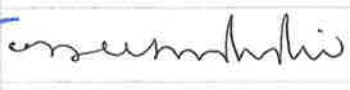
- d. The secretariat will provide IEC member, Guests or observers for IEC meetings, Independent Consultants a photocopy of the Confidentiality /Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement by their signature.
- e. The Secretariat keeps the original copies of the signed Agreements at the Institutional Ethics Committee office in the files entitled 'Confidentiality/Conflict of Interest Agreement file for members, guests, observers, Independent Consultants (IC)'
- f. The Secretariat will store the file in a secure cabinet with limited key holders.

5.1.4 Keep the Agreement in mind

The IEC members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants / advisory committee/ board member must implement the clauses of the signed Confidentiality Agreement Form.

6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22nd October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22nd October 2020).
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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