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|  | Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu | SOP 03/V5.1 Effective from 1st July 2018 Valid up to 30th June 2020 |
| | Confidentiality / Conflict of Interest Agreements | |


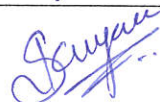
Title: Confidentiality / Conflict of Interest Agreements

SOP Code: SOP 03/V5.1 dated 2nd April 2018

Authors:

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|---|---|
| Dr. Sharmila Jalgaonkar (Member Secretary, IEC-I) |  |
| Dr. Snehalata Gajbhiye (Member Secretary, IEC-II) |  |

Reviewed by:

| | |
|--------------------------------------|--|
| Dr. Yashashri Shetty (Member, IEC-I) |  |
| Dr. Sunil Kuyare (Member, IEC-II) |  |

Approved by:




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|  Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date) |  Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date) |
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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

- 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
- 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.
- 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.
- 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.
- 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 |

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| 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 |

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

5.2 Read the text carefully and thoroughly.

- Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC members and before he/she starts attending IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form - *AX 01/SOP 03/V5.1 and AX 02/SOP 03/V5.1*, 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 *AX 03/SOP 03/V5.1* carefully and thoroughly

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- 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 -AX 04/SOP 03/V5.1 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.

5.3 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.

5.4 Sign to indicate consent.

- 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.
- They will give the signed form back to the Secretariat
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality /Conflict of Interest Agreement Form.
- 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.
- 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)'
- The Secretariat will store the file in a secure cabinet with limited key holders.

5.5 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 as in AX 01/SOP 03/V5.1, AX 03/SOP 03/V5.1 and AX 04/SOP 03/V5.1 respectively.

6. Glossary

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| Confidentiality | The nonoccurrence of unauthorized disclosure of information |
| Confidentiality Agreement | Sometimes called Secrecy or Non-disclosure agreement An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from |




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| | <p>the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.</p> |
| <p>Conflict of Interest</p> | <p>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 to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain. <i>[http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015].</i></p> <p>Types of COI</p> <ul style="list-style-type: none"> • A personal COI is said to exist when <ul style="list-style-type: none"> ➤ 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 an IEC member or consultant or who receives 50% or more support from an IEC member, regardless of age) or other close personal relationship (“step” relationships included) with the investigator, or with co-investigators. ➤ IEC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financier. ➤ research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable) • A professional COI means the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research. • A financial COI for IEC members and immediate family exists the IEC 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).. |

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7. References

- [1] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - <http://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 31st July 2017)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st July 2017)
- [3] Registration of Ethics Committees. GSR72E, February 8. 2013. [Last accessed on July 2017]. Available from: [http://www.cdscsco.nic.in/writereaddata/G.S.R%2072\(E\)%20dated%2008.02.2013.pdf](http://www.cdscsco.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf). (last accessed 31st July 2017)
- [4] <http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf> (last accessed 31st July 2017)
- [5] <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107> (last accessed 31st July 2017)

8. Annexure

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| Annexure 1 | <i>AX 01/SOP 03/V5.1</i> | Confidentiality Agreement Form for IEC members |
| Annexure 2 | <i>AX 02/SOP 03/V5.1</i> | Conflict of Interest Agreement Form for IEC Members |
| Annexure 3 | <i>AX 03/SOP 03/V5.1</i> | Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings |
| Annexure 4 | <i>AX 04/SOP 03/V5.1</i> | Confidentiality Agreement Form for Subject Experts (Affiliated / nonaffiliated to the institution) |


Annexure 1

AX 01/SOP 03/V5.1

Confidentiality Agreement Form for IEC Members

In recognition of the fact, that I _____

(*Member's name, and his/her affiliation*) herein referred to as the "undersigned", have been appointed as a member of the IEC, have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

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Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets (“information”) in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.


The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute’s policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

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Signature

Date

Chairperson's Signature

Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

Signature

Date

Annexure 2

AX 02/SOP 03/V5.1

Conflict of Interest Agreement Form for IEC Members

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.


When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

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Confidentiality Agreement Form for Institutional Funding Societies

I, _____
 _____ (Name and Designation) as a member/ staff of Funding Society (DJST/DDF/Research Society) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

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| _____ Signature of the member/ staff of Funding Society | _____ Date |
| _____ Chairperson of IEC-I | _____ Date |
| _____ Chairperson of IEC-II | _____ Date |

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

Signature

Date