

	IEC POLICY ON CONFIDENTIALITY & CONFLICT OF INTEREST		
	Policy Code: HAHCH/IEC/02	Prepared Date: 01.06.2026	Revision Number: 00
	IEC SOP on Confidentiality & Conflict of Interest Agreement	Review Due Date: 31.05.2029	Number of pages: 10

1. Purpose

The purpose of this SOP is to describe the process to identify and manage confidentiality and 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 IEC 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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Member Secretary, IEC

Ashaikh

APPROVED BY
Chairperson, IEC

[Signature]



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Mandate:

G.S.R. 72(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th February 2013.

- 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 interest.
- 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"
- 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.

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 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 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 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 will sign and date the document before a member of the Secretariat.
- They will give the signed form back to the Secretariat.

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- 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 must implement the clauses of the signed Confidentiality Agreement Forms.

6. Glossary

Confidentiality

The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities.

Confidentiality Agreement

An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. The standard by which confidential information will be handled depends on existing Acts, Rules, Policies and Guidelines in force.

Researcher

A person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Sponsor

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of research.

Conflict of Interest

Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like research participants' 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.

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Types of COI

Personal COI

A personal COI is said to exist when

- there is an 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 / post graduate or PhD student of the reviewer (may be regarded as a personal conflicting interest if applicable)

Professional COI

A professional COI means the IEC member or his/her/their immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

Financial COI

A financial COI for IEC members and immediate family exists when 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).

7. References

1. Indian Council of Medical Research. National ethical guidelines for biomedical and health research involving human participants. New Delhi: Indian Council of Medical Research; 2017. Available from: https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf
2. World Health Organization. Standards and operational guidance for ethics review of health-related research with human participants. Geneva: World Health Organization; 2011 [cited 29th May 2026]. Available from: <https://www.who.int/publications/i/item/9789241502948>
3. World Health Organization. Handbook for good clinical research practice (GCP): guidance for implementation. Geneva: World Health Organization; 2005. Available from: <https://iris.who.int/handle/10665/43392>
4. International Council for Harmonisation. ICH harmonised guideline: guideline for good clinical practice E6(R3). Final version. Geneva: ICH; 2025 [cited 29th May 2027]. Available from: [ich.org](https://www.ich.org)
5. Ministry of Health and Family Welfare (IN), Department of Health. Notification G.S.R. 72(E): Registration of Ethics Committee. New Delhi: Ministry of Health and Family Welfare; 2013 Feb 8.

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Chairperson, IEC

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Annexures:

Annexure	Description
Annexure 1	Confidentiality Agreement Form for IEC Members
Annexure 2	Conflict of Interest Agreement Form for IEC Members
Annexure 3	Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings
Annexure 4	Confidentiality Agreement Form for Subject Experts
Annexure 5	Confidentiality Agreement Form for Institutional Funding Societies

Terms and Conditions regarding Confidentiality:

In recognition of the fact, that I,

_____ (Member's name, and his/her/their 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;

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;

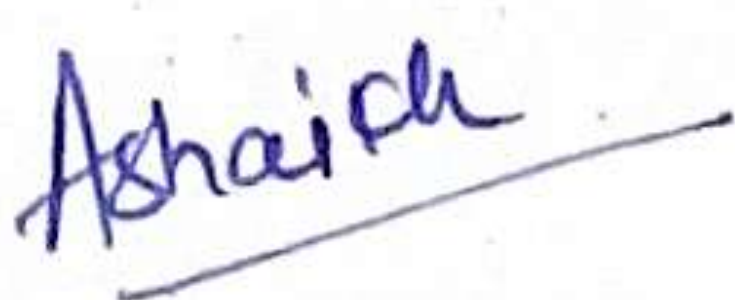
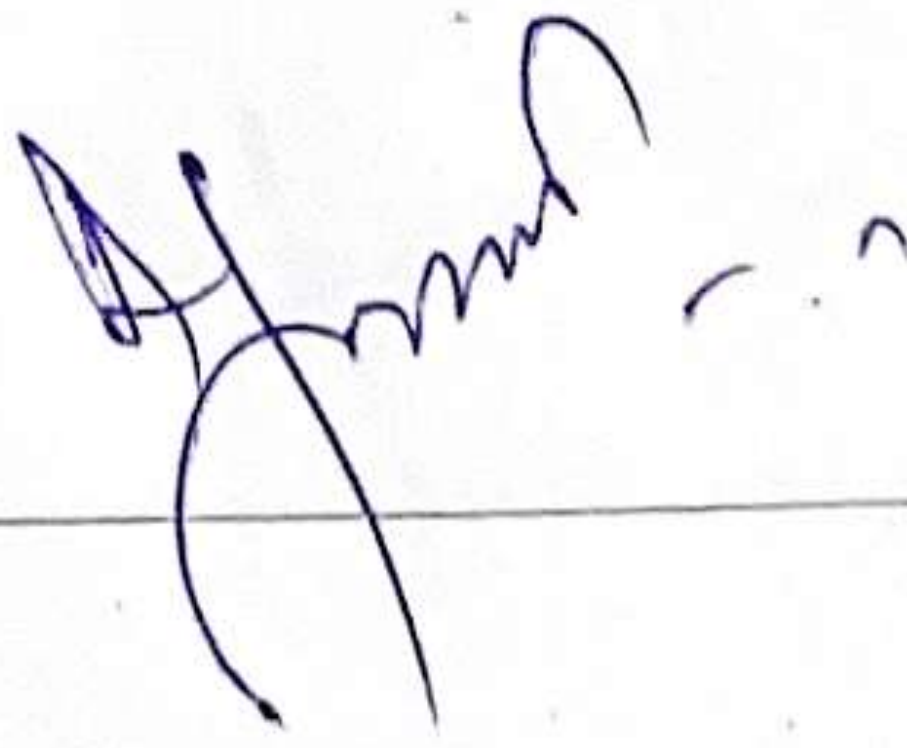
Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

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.

PREPARED BY:- Member Secretary, IEC 	APPROVED BY Chairperson, IEC 
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Annexure 1 – Confidentiality Agreement Form for IEC Members

I, _____ (Member's name and affiliation), have been appointed as a member of the Institutional Ethics Committee (IEC), Hamdard Institute of Medical Sciences and Research (HIMSR).

I understand that my duty is to independently review both scientific and ethical aspects of research involving human participants and maintain the highest ethical standards.

I agree to hold all Confidential or Proprietary information in trust and confidence and not disclose such information to any third party.

I agree not to use Confidential Information for personal benefit or outside the mandate of the IEC.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions.

Signature of Member	Signature of IEC Chairperson
Date	Date

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APPROVED BY
Chairperson, IEC

A. H. H.



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Terms and Conditions regarding Conflict of Interest:

In recognition of the fact, that I, _____ (Member's name, and his/her/their 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;

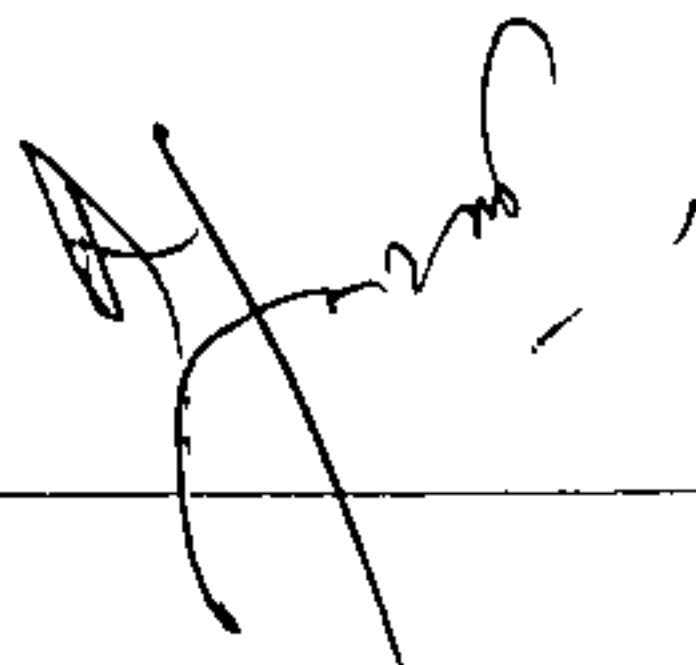
Whereas, it is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

Whereas, 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.

Whereas, 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.

Whereas, 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.

Whereas, 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.

PREPARED BY:- Member Secretary, IEC 	APPROVED BY Chairperson, IEC 
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Annexure 2 – Conflict of Interest Agreement Form for IEC Members

Conflict of Interest Agreement Form for IEC Members

I understand that conflict of interest may arise and I agree to disclose any actual or potential conflict to the Chairperson of the IEC.

I shall abstain from discussion, review, recommendation or decision-making where conflict of interest exists.

I, _____ have read and accept the aforementioned terms and conditions.

Signature of Member	Signature of IEC Chairperson
Date	Date

Annexure 3 – Conflict of Interest Agreement Form for Guest / Observer Attendees to IEC Meetings

I, _____ understand that I am attending the IEC meeting of HIMSR as a Guest/Observer.

I understand that confidential information may be discussed during the meeting and I agree to maintain confidentiality.

Signature of Guest / Observer	Signature of IEC Chairperson
Date	Date

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Annexure 4 – Conflict of Interest Agreement Form for Subject Experts

I, _____ (Name and Designation), understand that the documents provided to me by the IEC of HIMSR are confidential.
I shall not duplicate or distribute these documents without prior permission from the IEC.

Signature of Subject Expert	Signature of IEC Chairperson
Date	Date

Annexure 5 – Conflict of Interest Agreement Form for Institutional Funding Societies

Confidentiality Agreement Form for Institutional Funding Societies

I, _____ (Name and Designation), understand that the documents provided to me by the IEC are confidential.

I agree to maintain confidentiality and use the information only for the stated purpose.

Signature of Representative	Signature of IEC Member Secretary
Date	Date

PREPARED BY:-
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APPROVED BY
Chairperson, IEC

[Signature]



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Annexure 6 – Conflict of Interest Agreement Form for Non-Members Requesting Copies of IEC Documents Confidentiality Agreement Form for Non-members Requesting Copies of IEC Documents

I, _____ (Name and Designation understand that the copy (i.es) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Institutional Ethics Committee and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential. I have received copies of the following IEC documents:
.....

Signature of Non-Member	Signature of IEC Member Secretary
Date	Date

PREPARED BY:-
Member Secretary, IEC

Ashaith

APPROVED BY
Chairperson, IEC

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