

Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRH Ethics Committee for Human Studies

Title: Confidentiality/ Conflict of Interest Agreement

SOP Code: 03/V1.3 Dated 8th November 2024 Page Nos: 31 to 41

3.1. Purpose and Application:

The purpose of this section is to provide a form of Confidentiality/Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign, and date the form. The procedure provides details on when and where to sign as well as how the signed document should be kept.

The policy principles and procedures contained in this SOPs applied to:

1. Ethics Committee members;
2. Permanent/ temporary and part time employees of Ethics Committee; Contractual staff;
3. “Independent” persons engaged from outside the Institute to provide “expert and/ or scientific/technical” advice;
4. Observers or visitors/Guests

3.2. Scope

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the ICMR-NIRRH Ethics Committee for Human Studies.

3.3. Responsibility

As it is mandatory to maintain the confidentiality of study protocols, IEC documents, and correspondence with experts, it is the responsibility of all newly appointed ICMR-NIRRH Ethics Committee members to read, understand, accept, and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the ICMR-NIRRH Ethics Committee for Human Studies to protect the rights of study participants. If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff to take confidentiality and conflict of interest agreement forms duly signed and dated.

It will be the responsibility of the Secretariat to maintain EC office access limited to institutional scientists/students and staff for the purpose of submissions. The affiliated members will have to come to the EC office to review any proposals or documents, except the agenda packet that will be given to the affiliated members in sealed packets.

3.4. Flow chart

Sr. No.	Activity	Responsibility
1	Read the text carefully and thoroughly	IEC members/Independent consultants/ guest attendees
2	Ask questions, if any	IEC members/guest attendees

3	Sign to indicate consent	IEC members/guest attendees/observers
4	Keep the Agreement in mind	IEC members/guest attendees
5	Copy Confidential documents	IEC Secretariat
6	File log of Certified Copies	IEC Secretariat

3.5. Detailed instructions:

It will be the policy of the ICMR-NIRRH Ethics Committee that every member including the Chairperson, the alternate Chairperson, and the alternate members sign the Confidentiality/Conflict of Interest Agreement with a date. Even though the member discontinues being a part of the ICMR-NIRRH Ethics Committee for Human Studies, she/he will have to maintain confidentiality which will be valid for all the protocol-related information for which she/ he had access to.

Observation of functioning of ICMR-NIRRH Ethics Committee for Human Studies meetings / Departmental visits by Guest Attendees/ Staff of Other Ethics Committees/Interns

Permission to observe the ICMR-NIRRH Ethics Committee meetings/ visit to the Office of ICMR-NIRRH Ethics Committee for Human Studies will be given only after a formal written request addressed to the Director/Director-in-charge/ Member Secretary. Permission will be granted for academic purposes and other reasons at the discretion of the Director/Director-in-charge / Member Secretary. Individuals working in the field of Bio-ethics and of other specialties (at the discretion of the Director/Director-in-charge / Member Secretary) or interns and observers with prior formal permission will be permitted.

1. They will be requested to sign a Confidentiality Agreement Form and Conflict of Interest for Guest Attendees to ICMR-NIRRH Ethics Committee Meetings/ Departmental visits.
2. They will be escorted by staff of the ICMR-NIRRH Ethics Committee for Human Studies.
3. Care will be taken to see only the necessary documents are given access while the proposals will be stored under lock and key.

3.5.1 Read the text carefully and thoroughly:

1. Newly appointed members obtain two copies of the Agreement Form AF/EC/01/03/V1.2
2. The member is expected to read through the text of the form very carefully.
3. The members fill in their names and their office on the blank area.

3.5.2 Ask questions, if any

1. Direct questions to the Secretariat, if any part or sentence is not clear.
2. Let the Member Secretary explain or clarify the contents of the document.

3.5.3 Sign with consent.

1. Sign and date both copies of the document before a member of the Secretariat.
2. Give the forms back to a Member Secretary/ Secretariat to sign and date.
3. The members keep a copy as their records.

3.5.4 Keep the Agreement in mind.

1. The Secretariat in the Ethics Committee office keeps a copy of the signed Agreement as the Institute's records.
2. The original copies should be kept in a Confidentiality/Conflict of Interest Agreement file while a certified copy should be kept along with the CV file which will contain in addition letter of invitation by the Director/Director-in-charge, and an acceptance letter by the EC member.
3. Store the register in a secure cabinet with limited access to it.

3.6. ANNEX

ANNEX 1	AF/01/03/V1.3	Confidentiality Agreement Form for Ethics Committee Members
ANNEX 2	AF/02/03/V1.3	Conflict of Interest Agreement Form for Ethics Committee Members
ANNEX 3	AF/03/03/V1.3	Confidentiality Agreement Form for Guest Attendees to IEC- ICMR-NIRRH Meetings
ANNEX 4	AF/04/03/V1.3	Confidentiality Agreement Form for Independent Consultants
ANNEX 5	AF/05/03/V1.3	Confidentiality Agreement for Non-members Requesting Copy (ies) of IEC Documents
ANNEX 6	AF/06/03/V1.3	Log of Requests for Copies of IEC Documents
ANNEX 7	AF/07/03/V1.3	Log of Requests for Original Documents
ANNEX 8	AF/08/03/V1.3	Document History

Confidentiality Agreement Form for Ethics Committee members/ Secretariat Staff

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 ICMR-NIRRH Ethics Committee for Human Studies has been asked to assess research studies involving human participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the ICMR-NIRRH Ethics Committee for Human Studies is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

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

Whereas, the ICMR-NIRRH Ethics Committee for Human Studies 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 human participants;

The undersigned, as a member of the ICMR-NIRRH Ethics Committee for Human Studies, 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 ICMR-NIRRH Ethics Committee. 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 information/ data in trust or confidence and agrees that it shall be used only for contemplated purposes, 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 ICMR-NIRRH Ethics Committee.

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.

Confidential information includes any information submitted by the Scientists in connection with Ethics Committee review, whether written or oral, including, but not limited to technical, scientific, financial, strategic, marketing or product information. It also includes, but is not limited to, information concerning EC's computer processes, programs and codes, financial

information, pending projects and proposals, standard operating procedures, legal and regulatory affairs. Confidential and proprietary information includes the above information even when it is not marked as such.

“Confidential information” does not include information that:

- (a) was already in my possession, as evidenced by written records;
- (b) becomes publicly available through no fault of my own; or
- (c) is lawfully and in good faith made available to me by a third party.

Where I am required by law, regulation, or court order to disclose confidential and proprietary information, I will provide EC with a notice of such request(s) immediately, but in no event later than two (2) business days after receipt of such request. I agree to cooperate with Ethics Committee if Ethics Committee wishes to seek a protective order.

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 ICMR-NIRRH Ethics Committee..... A copy will be given to you for your records.

In the course of my activities as a member of the Committee, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to 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 return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

I also understand that as a member I will be given copies of the study proposals/necessary documents to be evaluated. I will return these to the ICMR-NIRRH Ethics Committee during the meetings or whenever requested. I also understand that these documents are confidential, hence every effort will be taken to prevent access to anyone other than me or the office staff of the ICMR-NIRRH Ethics Committee. Sometimes documents/proposals in soft copy format will be given/sent to me. I will ensure that these documents/proposals will be password protected.

I,, have read and accept the aforementioned terms and conditions as explained in this Agreement

Undersigned Signature

Date

Chairperson's signature

Date

**Conflict of Interest Agreement Form for Ethics Committee Members/Observer or
Intern/Guest Attendees**

It is recognized that the potential for conflict of interest will always exist but has faith in the ICMR-NIRRH Ethics Committee and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

It is the policy of the ICMR-NIRRH Ethics Committee 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 ICMR-NIRRH Ethics Committee for Human Studies.

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

While signing the attendance register, the member documents the proposal for which he/she has a Conflict of Interest

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

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

- i A member is involved in a potentially competing research program.
- ii 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 ICMR-NIRRH Ethics Committee. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I,, have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

Undersigned Signature

Date

Chairperson's signature

Date

**Confidentiality Agreement Form for Guest Attendees/ Observers/ Intern to
ICMR-NIRRCH Ethics Committee for Human Studies Meetings**

I, from understand that I am allowed to attend the ICMR-NIRRCH Ethics Committee meeting as a guest or an observer. In the course of the meeting of the ICMR-NIRRCH Ethics Committee , some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of the ICMR-NIRRCH Ethics Committee Meeting attended:

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.....
.....

Signature of the Guest **Attendees/
Observer or Intern**

Date

Member Secretary
ICMR-NIRRCH Ethics Committee for Human Studies

Date

Signature of the Chairperson

Date

Confidentiality Agreement/Conflict of interest Form for Independent Consultants

I,....., from.....as a non-member of ICMR-NIRRH Ethics Committee for Human Studies, understand that the copy (ies) given to me by the ICMR-NIRRH Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described by the ICMR-NIRRH Ethics Committee. I shall not duplicate, give, or distribute these documents to any person(s) without permission from the ICMR-NIRRH Ethics Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

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 ICMR-NIRRH Ethics Committee. A copy will be given to you for your records.

Signature of the Independent Consultant

Date

Member Secretary
ICMR-NIRRH Ethics Committee for Human Studies

Date

Signature of the Chairperson

Date

Confidentiality Agreement Form
For non-members Requesting Copies of IEC Documents

I,..... from.....as a non-member of ICMR-NIRRH Ethics Committee for Human Studies, understand that the copy (ies) given to me by the ICMR-NIRRH Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose described by the ICMR-NIRRH Ethics Committee. I shall not duplicate, give, or distribute these documents to any person(s) without permission from the IEC/IRB. Upon signing this form, I agree to take reasonable measures and full responsibility in keeping the information Confidential.

I have received copies of the following IEC documents:

.....
.....
.....
.....

Signature of the recipient

Date

Member Secretary,
ICMR-NIRRH Ethics Committee for Human Studies

Date

Signature of Chairperson

Date

ANNEX 6**AF/06/03/V1.3****Log of Requests for Copies of IEC Documents**

Sr. No	Date	Name of the Receiver	Documents Requested	Signature of the Receiver	Reason for Request

ANNEX 7**AF/07/03/V1.3****Log of Requests for Original Documents**

Sr. No	Date	Name of the Receiver	Documents Requested	Signature of the Receiver	Reason for Request

ANNEX 8**AF/08/03/V1.3****Document History**

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20 th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	7 th November 2017	Annex 4 – deleted ‘whenever I have a conflict of interestVoting
Dr. Beena Joshi	Version 1.2	1 st May 2019	Reference to annex changed appropriately ANNEX 3, AF/EC/03/03/V1.2, observer/ intern were added in Guest Attendees
Dr. Vikrant Bhor	Version 1.3	8 th November 2024	All bullets are numbered. Modifications done in following points: Annex 1: Secretariat staff is added along with the EC members