Title: Confidentiality/Conflict of Interest Agreement

SOP Code : SOP/03/V1.2

Effective date: 1st May 2019

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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 provide details when and where to sign as well as how the signed document should be kept.

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

- Ethics Committee members;
- Permanent, temporary and part time employees of Ethics Committee;
- Contracted staff;
- "Independent" persons engaged from outside the Institute to provide "expert and/ or scientific/technical" advice;
- Observers or visitors/Guests

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 Clinical Studies.

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

4. Flow chart

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
4	Keep the Agreement in mind ↓	IEC members / guest attendees
5	Copy Confidential documents ↓	IEC Secretariat

6	File log of Copies	IEC Secretariat

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 date. Even though the member discontinues being a part of the ICMR-NIRRH Ethics Committee for Clinical Studies, he/she will have to maintain confidentiality which will be valid for all the protocol related information for which he/she had access to.

Observation of functioning of ICMR-NIRRH Ethics Committee for Clinical Studies meetings / Departmental visit 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 Clinical Studies will be given only after a formal written request addressed to the Director/Officer-in-Charge/ Member Secretary.

Permission will be granted for academic purposes and other reasons at the discretion of the Director/Officer-in-Charge / Member Secretary. Individuals working in the field of Bio-ethics and of other specialties (at the discretion of the Director/Officer-in-Charge / Member Secretary) or interns and observers with prior formal permission will be permitted.

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

5.1 Read the text carefully and thoroughly:

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

5.2 Ask questions, if any.

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

5.3 Sign with consent.

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

5.4 Keep the Agreement in mind.

- The Secretariat in the Ethics Committee office keeps a copy of the signed Agreement as the Institute's records.
- The original copies should be kept in a Confidentiality/Conflict of Interest Agreement file while a copy should be kept along with the CV file which will contain in addition

letter of invitation by the Director/Officer-in-Charge, acceptance letter by the EC member.

- Store the register in a secure cabinet with limited key holders.

6. Glossary

Confidentiality: The nonoccurrence of unauthorized disclosure of information:

Confidentiality Agreement:(Secrecy or Nondisclosure agreements).
An agreement designed to protect, information, data 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 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.

Conflict of Interest: A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.
Conflict of interest is present and interferes with ability to make an objective evaluation when ethics committee members

- Have their own research projects under review by the Ethics Committee, when they are a investigator, co-investigator, or when they are in a supervisory or mentoring relationship with a Principal Investigator.
- Members whose spouse/relative is a Principal Investigator or co-investigator, for any project under review is also considered to have conflict of interest.
- Members may also be in a conflict of interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, organization that may be the sponsor of the research project, or that may be substantially affected by the research.

To maintain the independence and integrity of research ethics review, members must identify, eliminate, minimize or otherwise manage real, potential or perceived conflicts of interest. If a member has a personal or financial conflict of interest the members must disclose the nature of the conflict and absent themselves from any discussion or decision regarding that research project. In the event that a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the Committee can ensure that an alternate member be in attendance to maintain quorum. There are three key elements in this definition: financial interest; official duties; professional and personal interest.

Strategies to manage Conflict of Interest:

- Disclose conflict of interest
- Document the conflict of interest in attendance register /minutes of the meeting

- Refrain from taking part in any discussion/review/ debate about the proposal;
- Refrain from participating in the review process of project proposal by leaving the meeting room.

A conflict of interest occurs when:

- An individual's private interest differs from his or her professional obligations to the institute.
- Professional actions or decisions occur that an independent observer might reasonably question.
- A conflict depends upon situation and not on the character or actions of the individual.
- Potential conflicts of interest must be disclosed and managed as per policy.

7. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapter 7/
4. http://www.cancerinstitute.org.au/media/64618/CINSW_POLICY-conflict-of-interest.pdf
5. http://www.iecindia.org/pdf/sop20_m.pdf
6. Forum for Ethical Review Committees in Asia and the Western Pacificac SOPs 2006

8. ANNEX

ANNEX 1	AF/EC/01/03/V1.2	Confidentiality Agreement Form for Ethics committee members
ANNEX 2	AF/EC/02/03/V1.2	Conflict of Interest Agreement Form for Ethics committee members
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ANNEX 1 **AF/EC/01/03/V1.2**

Confidentiality Agreement Form for Ethics Committee 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 ICMR-NIRRH Ethics Committee for Clinical 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 Clinical 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 Clinical 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 Clinical 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. These will be duly returned by me to the ICMR-NIRRH Ethics Committee during the meetings/as and when requested for. I also understand that these documents are confidential, hence every effort will be taken to prevent access to any other person other than me or the office staff of the ICMR-NIRRH Ethics Committee. At times documents/proposal in soft copy format will be given/send to me. I will assure that theses 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

ANNEX 2 **AF/EC/02/03/V1.2**

Conflict of Interest Agreement Form for Ethics committee members

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 Clinical 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 in relation to any particular proposal submitted for review by the Committee, and to 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 Conflict Of Intertest
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:

- 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 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

ANNEX 3 **AF/EC/03/03/V1.2**

Confidentiality Agreement Form for Guest Attendees/ Observers/ Intern to ICMR-NIRRH Ethics Committee for Clinical Studies Meetings

I,…….from …….understand that I am allowed to attend the ICMR-NIRRH Ethics Committee meeting as a guest or an observer. In the course of the meeting of the ICMR-NIRRH 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-NIRRH Ethics Committee Meeting attended:

……

……

……

_____ _____

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

_____ _____

Member Secretary Date
ICMR-NIRRH Ethics Committee for Clinical Studies

_____ _____

Signature of the Chairperson Date

ANNEX 4 **AF/EC/04/03/V1.2**

Confidentiality Agreement/Conflict of interest Form for independent Consultants

I,……..., from……..as a non-member of ICMR-NIRRH Ethics Committee for Clinical 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 to the ICMR-NIRRH Ethics Committee and 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 Date

ICMR-NIRRH Ethics Committee for Clinical Studies

_____ _____

Signature of the Chairperson Date

ANNEX 5 **AF/EC/05/03/V1.2**

Confidentiality Agreement Form
for Non-members Requesting Copies of IEC Documents

I,……..,..,., from……..as a non-member of ICMR-NIRRH Ethics Committee for Clinical 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 to the ICMR-NIRRH Ethics Committee and 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 to keep the information as Confidential.

I have received copies of the following IEC documents:

……
……
……
……

_____ _____
Signature of the recipient Date

_____ _____
Member Secretary, Date
ICMR-NIRRH Ethics Committee for Clinical Studies

_____ _____
Signature of Chairperson Date

ANNEX 6 **AF/EC/06/03/V1.2**

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/EC/07/03/V1.2**

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/EC/08/03/V1.2**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	7th November 2017	Annex 4 – deleted 'whenever I have conflict of interest ….Voting
Dr. Beena Joshi	Version 1.2	1st May 2019	Reference to annex chaged appropriately ANNEX 3, AF/EC/03/03/V1.2, observer/ intern were added in Guest Attendees