

## **Standard Operating Procedures of Institutional Ethics Committee**

### **ICMR – NIRRH Ethics Committee for Human Studies**

#### **Title: Selection and Responsibilities of Independent Consultants**

**SOP Code: 05/V1.2**

**Dated: 08<sup>th</sup> November 2024**

**Page Nos: 46 to 49**

### 5.1. Purpose

The purpose of this SOP section is to provide procedures for engaging the expertise of a professional as a consultant to the ICMR-NIRRH Ethics Committee for Human Studies

### 5.2. Scope

If the Chairperson or the ICMR-NIRRH Ethics Committee for Human Studies determines that a study will involve procedures or information that is not within the area of expertise of the committee members, the Chairperson of the committee in consultation with the Member Secretary and/or members suggests individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the committee and appointed by the Director/ Director-in-charge.

### 5.3. Responsibility

Upon the advice or recommendation of the Secretariat, Chairperson or any member of the ICMR-NIRRH ethics committee for Human Studies, it is the responsibility of the ICMR-NIRRH ethics committee for Human Studies to nominate and approve the name of the special consultants to be endorsed by the Director/ Director-in-charge.

### 5.4. Flow chart

Sr. No.	Activity	Responsibility
1	Maintaining a specialty-wise list/roster of independent Consultants	Secretariat
2	Suggestions of Independent Consultants	IEC Members / Member Secretary or Chairperson
3	Appointment of Independent Consultants	Director/ Director-in-charge
4	Consultation Services	IEC Secretariat/ Consultant
5	Termination of the Services	Consultant / IEC

### 5.5. Detailed instructions

#### 5.5.1. Selection and Appointment of Independent Consultants (ICs)

1. Identify the experts and maintain a list of consultants approved by the Chairperson at the Ethics Committee secretariat. Appointment of consultants will be as mentioned in SOP 2, (2.5.5 according to Pg.No.71). Invite the consultants.

The Chairperson/ Member Secretary on behalf of the Ethics committee will invite IC(s) selected by the committee in writing to assist in the review of the project and provide her/his independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through any mode of communication.

2. Make decisions based on expertise, availability, and independence criteria
3. Get approval from the Ethics Committee.
4. Contact the consultant.
5. Invite the consultant to attend the meeting by sending an appointment letter signed by the Director/ Director-in-charge of the Institute.
6. The Secretariat will request IC to declare competing interests, if any, and sign a confidentiality agreement. The Secretariat may obtain and retain a copy of the updated curriculum vitae of ICs in the ECRHS office for records and future reference. The Secretariat will maintain and provide a specialty-wise roster of consultants.

#### **5.5.2 Co-ordination with Independent Consultants for fulfilling administrative requirements**

The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to IC(s) (See ANNEX 4, AF/04/03/V1.3) for careful reading, understanding and signing.

The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the Independent Consultant(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert Ethics Committee.

#### **5.5.3 Reading, understanding, and signing the Conflict-of-Interest document and Confidentiality Agreement**

1. The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement document.
2. The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to the Chairperson.
3. The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC (s).
4. The Independent Consultant is expected to implement the clauses of the signed Confidentiality/Conflict of Interest Agreement Form AF/04/03/V1.3

#### **5.5.4. Consultation Services**

IEC provides study protocol documents to the appropriate consultant for review. In case the project has been presented to the Ethics Committee and needs further modifications/ revisions/amendments, the project has to be submitted to IC along with the Review Report (Assessment) Form for comments purpose. The consultant will review the study protocol, and send comments or attend the Ethics committee meeting, and participate in the discussion but *cannot vote or be par of decision making process*. Reimbursement will be given to the Consultant as per rules of the Institute.

The Review Report Form will be filed with the project proposal in the respective file.

#### **5.5.5 Termination of the Services**

Consultation services may be terminated by either the consultants themselves or by the IEC.

Upon termination of the consultant's services, a member of the Secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are documented and filed with the administrative documents.

## 5.6. ANNEX

### ANNEX 1

AF/01/05/V1.2

#### Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20 <sup>th</sup> March 2013	<ul style="list-style-type: none"> <li>First approved copy</li> </ul>
Dr. Beena Joshi	Version 1.1	1 <sup>st</sup> May 2019	<ul style="list-style-type: none"> <li>Points 5.2 &amp; 5.3 Reference details of annex nos for Conflict of Interest agreement updated</li> </ul>
Dr. Vikrant Bhor	Version 1.2	8 <sup>th</sup> November 2024	All bullets are numbered.