

**Title: Selection and Responsibilities of Independent Consultants
(IC)**

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1. Purpose

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

2. Scope

If the Chairperson or the NIRRH Ethics Committee for clinical studies determines that a study will involve procedures or information that is not within the area of expertise of the committee members, Chairperson of the committee in consultation with the Member Secretary 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/ Officer-in-Charge.

3. Responsibility

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

4. Flow chart

No.	Activity	Responsibility
1	Maintaining a speciality –wise list/roster of independent Consultants ↓	Secretariat
2	Suggestions of Independent Consultants ↓	IEC Members / Secretariat or Chairperson
3	Appointment of Independent Consultants ↓	Director/ Officer-in-Charge
3	Consultation Services ↓	IEC/IRB Secretariat/ Consultant
4	Termination of the Services	Consultant / IEC/IRB

5. Detailed instructions

5.1. Selection and Appointment of Independent Consultants (ICs)

- Identify the experts from the list of the independent consultants/roster maintained by the secretariat or by the Ethics Committee Members, Secretariat and Chairperson
- 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 his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through any mode of communication.

- Make decision based on expertise, availability and independence criteria
- Get approval from the Ethics Committee.
- Contact the consultant.
- Invite the consultant to attend the meeting by sending an appointment letter signed by the Director/ Officer-in-Charge of the Institute.
- 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.

5.2 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/EC/04/03/V1.0) 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 Members

5.3 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement document.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- 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).
- The Independent Consultant is expected to implement the clauses of the signed Confidentiality/Conflict of interest Agreement Form AF/EC/ 04/03/V1.0

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 has further modifications/ revisions/amendment the project has to be submitted alongwith the Review Report Form for comments purpose. The consultant will review the study protocol, attend the Ethics committee meeting, and participate in the discussion but *cannot vote*. 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 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 filed with the administrative documents.

6. Glossary

Independent consultant An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

7. Reference

7.1 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006