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1. Purpose

The purpose of this SOP is to provide procedures for engaging the expertise of a professional as a consultant to the IRB.

2. Scope

This SOP covers the procedures for selecting, appointing Independent Consultant and getting their expert opinion during the IRB review process. It also defines the responsibilities of Independent Consultant.

3. Responsibility

Upon the advice or recommendation of the secretariat or any IRB member, it is the responsibility of the Chairperson to nominate and approve the special consultants.

4. Flow chart

No.	Activity	Responsibility
1	Selection of Independent Consultant	Chairperson
	↓	
2	Signing of COI and Confidentiality Agreement forms	Independent Consultant, Chairperson
	↓	
3	Receive protocol and other relevant documents for reviewing	Consultant
	↓	
4	Review study protocol based on the assessment form	Consultant
	↓	
5	Communicate with secretariat office	Consultant and IRB secretariat
	↓	
6	Termination of the services	Consultant /Chair person

5. Detailed instructions

5.1. Selection of Independent Consultant

- Identify the experts by the IRB member and Secretariat from the roster, or otherwise

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- Make nomination based on expertise, availability and independence criteria
- Secretariat will issue an appointment letter to the independent consultant after confirming their willingness through telephonic/ electronic communication
- Get approval from the chairperson

5.2. Signing of COI and Confidentiality Agreement forms

- The independent consultant will sign and date the Confidentiality and Conflict of Interest Agreement Form (EPHI-IRB AF 06-004/02.0)
- 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 another copy will be sent to the independent consultant

5.3. Receive protocol and other relevant documents for reviewing

- The independent consultant will receive the protocol and other relevant documents from the IRB secretariat
- Check the received packages for completeness
- Sign and date an acknowledgement form upon receiving the packages.
- Return the receipt form back to the IRB secretariat

5.4. Review study protocol based on the assessment form

- The Secretariat will provide study protocol documents for Independent Consultant (s)
- The Independent Consultant will be requested to complete the Assessment Form (EPHI-IRB AF 01-008/02.0) and his/her remarks using an assessment report form (EPHI-IRB AF 02-008/02.0) and provide to the Secretariat within a stipulated period or by a stipulated date
- The assessment report provided by the Independent Consultant becomes a permanent part of the study file
- The assessment report will be reviewed by the secretary in the IRB meeting when the concerned study is being discussed
- If deemed necessary, the Chairperson or secretary may seek additional information or clarifications from the Independent Consultant in writing. Additional Information provided by the Independent Consultant will be considered as part of the Assessment Report (EPHI-IRB AF 02-008/02.0)

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- If deemed necessary, the Chairperson or Member-secretary may invite the Independent Consultant to attend an IRB meeting for providing additional information or clarifications that may be sought by IRB members or Chairperson. However, the Independent Consultant will not participate in the decision-making process on the research study.

5.5. Communicate with secretariat office

- Consultant sends his/her comments made using the assessment form on the protocol to the secretariat
- Principal investigator/designee requested to provide clarifications or answer to unclear issues, if there is/are any, to the secretariat
- Secretariat sends protocol & other relevant documents to IRB members at least three days prior to the IRB meeting for their preparation to convened IRB meeting

5.6. Termination of the Services

- Consultation services may be terminated by either the consultants themselves or by IRB secretariat
- Upon termination of the consultant's services, a member of the secretariat, ensures that 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 conflict of interest with the protocols.

7. References

1. FDRE Ministry of Science and Technology, National Research Ethics Review Guideline, 2014.
2. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.

8. Annex

None