

CHAPTER 2.4

SELECTION OF INDEPENDENT CONSULTANT

SOP NUMBER: SOP/006/01



**INSTITUTIONAL REVIEW BOARD
(IRB)**

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

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

2. SCOPE

The SOP shall cover the process of selecting and appointing the independent consultant, and the requirement of the consultation service.

This SOP shall be applicable to the IRB and the selected independent consultant.

3. RESPONSIBILITY

Once a study involves procedures or information that is not within the area of expertise of the IRB members, it is the responsibility of the Chairperson or any IRB member to nominate a consultant with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the IRB. The qualification review shall be conducted by the IRB. The appointment shall be approved by the Chairperson.

4. FLOW CHART

No.	Activity	Responsibility
1	Selection of Independent Consultants ↓	IRB Members / Secretariat
2	Consultation Services ↓	IRB Secretariat / Consultant
3	Termination of the Services	Consultant / IRB

5. DETAILED INSTRUCTIONS

5.1. Selection of Independent Consultants

- 5.1.1. Identify the experts by the Chairperson/Secretariat/IRB members.
- 5.1.2. Conduct a qualification review of the prospective consultant
- 5.1.3. Recommend the identified consultants to the KGUMSB and seek approval
- 5.1.4. The consultant provides:
 - 5.1.4.1. A curriculum vitae
 - 5.1.4.2. A signed Professional Services Agreement
 - 5.1.4.3. A signed Confidentiality/Conflict of Interest Agreement (*Form AF/01-004/01*)
- 5.1.5. The Secretariat keeps the documents in a consultant's file and creates a roster of consultants with the areas of their expertise.
- 5.1.6. Fees, if any, shall be as per the COS and/or RGOB rules.

5.2. Consultation Services

- 5.2.1. The IRB Secretariat provides study protocol documents to the appropriate consultant for review.
- 5.2.2. The consultant shall complete a consultative report to be reviewed by the IRB at the time the study is reviewed.
- 5.2.3. The consultant may attend the IRB meeting, present the report and participate in the discussion but cannot vote.
- 5.2.4. The report becomes a permanent part of the study file.

5.3. Termination of the Services

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

5.3.2. 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.
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