CHAPTER 2.1

CONSTITUTING A INSTITUTIONAL REVIEW BOARD

SOP NUMBER: SOP/003/01

Institutional Review Board (IRB)

Khesar Gyalpo University of Medical Sciences Of Bhutan

www.kgumsb.edu.bt

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Author: SOP Team — Date: September 29, 2021
Approved by: Chairperson, IRB — Date: September 30, 2021
Name: ***Dr. Karma Tenzin***

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1. PURPOSE

The IRB was established on 2nd July, 2021 with its formal ceremonial launch observed on the day, in order to provide independent guidance, advice, and decision (in the form of "approval/recommendation/stipulation/ disapproval") on health research or other specific research protocols involving human subjects.

The IRB is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

These Standard Operating Procedures (SOPs) describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the IRB.

2. SCOPE

The SOP shall apply to all activities under the IRB.

3. RESPONSIBILITY

The IRB members & the Secretariat shall be responsible to read, understand and respect the rules set by the IRB.

4. FLOW CHART

No.	Activity	Responsibility
1	Ethical basis / Guidelines ↓	IRB Members, Secretariat
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5. DETAILED INSTRUCTIONS

5.1. Ethical Basis

5.1.1. The IRB recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities.

5.1.2. In evaluating protocols and ethical issues, the IRB is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.

5.1.3. It attempts to inform itself, where possible, of the requirements and conditions of the various localities where proposed Health research is being considered.

5.1.4. The IRB also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.

5.1.5. The IRB shall be guided in its reflection, advice, and decision by the ethical principles expressed in the Declaration of Helsinki (1964 and subsequent revisions).

5.1.6. It makes further reference to the National and International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), the Belmont Report, and the European Convention on Human Rights and Biomedicine.

5.1.7. The IRB establishes its own SOPs based on the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO), the WHO & ICH Guidelines for Good Clinical Practice and the local regulations *(Bhutan Health Research Guideline - to be developed)*.

5.1.8. The IRB shall seek to fulfil the requirements for international assurances and is established and functions in accordance with the national law and regulations.

5.2. Composition of the IRB

5.2.1. The IRB shall be composed of sixteen members excluding the IRB Member Secretary who shall not be the board member.

5.2.2. The composition of the IRB shall ensure diversity of background for complete and adequate review.

5.2.3. At least one member from non-medical/non-scientific area, one member from outside the health sector and one non-affiliated member.

5.2.4. Professional qualifications may include physician, pharmacist, nurse, behavioural or social scientist, lawyer, statistician, paramedic and/or layperson.

5.2.5. The IRB shall include representation from all genders.

5.2.6. The IRB shall include representation from the older and younger generations.

5.2.7. The IRB can have Alternate Member(s) in addition to the regular board members.

5.3. Membership requirements

5.3.1. The President of the KGUMSB shall be responsible for making the appointment of regular board members.

5.3.2. IRB Secretariat shall be responsible for seeking nominations of board members.

5.3.3. IRB Secretariat shall maintain a list of former IRB Board members as alternate members with their consent.

5.3.4. Members shall serve in their personal capacities, based on their interest, qualification, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IRB's work.

5.3.5. Members shall disclose, in writing, any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

5.3.6. The IRB shall decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision; refer to *SOP/004/01* – Confidentiality / Conflict of Interest Agreement.

5.3.7. Members shall be required to sign a confidentiality agreement at the start of their term.

5.3.8. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work.
5.3.9. Members shall be appointed for a period of 4 years.
5.3.10. The Chairperson and the vice-chairperson shall be elected by the IRB members for two-year term. They may be re-elected but not for more than two consecutive terms. Should they resign or be disqualified, the IRB members elect a replacement until the completion of the normal term. If both the Chairperson and Vice Chairperson declare Conflict of Interests with any protocol then the board members shall nominate an acting Chairperson among themselves to manage the review of such protocols.
5.3.11. The members' appointments may be renewed by the President, KGUMSB, for up to two consecutive terms, upon recommendation by the Chairperson. The renewal of membership of the Chairperson (as a member of IRB) shall be recommended by the Vice Chairperson.

5.4. Roles and responsibilities of IRB members

5.4.1. Participate in the IRB meeting
5.4.2. Review, discuss and consider research proposals submitted for evaluation
5.4.3. Monitor serious adverse event reports and recommend appropriate action(s) *(SOP/020/01)*
5.4.4. Review the progress reports and monitor ongoing studies as appropriate
5.4.5. Evaluate final reports and outcomes
5.4.6. Review, develop and update guidelines on research and ethics
5.4.7. Maintain confidentiality of the documents and deliberations of IRB meetings *(SOP/027/01)*
5.4.8. Declare any conflict of interest
5.4.9. Participate in continuing education activities in biomedical ethics and biomedical research
5.4.10. Collaborate with the KGUMSB on all research-related activities

5.5. Resignation, Disqualification, Replacement of Members

5.5.1. Members may resign from their positions by submitting a letter of resignation to the Chairperson.
5.5.2. Members may also be disqualified from continuance should the Chairperson provide written arguments to the (other) members, according to IRB members' responsibilities listed in *Section 5.4*, and there is unanimous agreement.
5.5.3. Members that have resigned or have been disqualified may be replaced by the Head of the organization upon recommendation by the Chairperson.
5.5.4. Members may be disqualified if he/she fails to attend two consecutive meeting without proper leave of absence which is acceptable to the Chairperson.
5.5.5. An appropriate replacement for the disqualified member/resigned member shall be made by the President, KGUMSB upon recommendation by the Chairperson.

5.6. Independent Consultants

5.6.1. The IRB may be further supported in its reflections on specific protocols or requests for advice on specific ethical/ technical issues by Independent Consultants.
5.6.2. Independent Consultants are appointed by the Chairperson of the IRB.
5.6.3. Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, religion. Independent Consultants are appointed for the duration of the period sought *(see SOP/006/01)*.

5.7. Conditions of Appointment

5.7.1. Members and Independent Consultants are appointed to the IRB under the following conditions:

5.7.1.1. Willingness to publicize his/her full name, profession, and affiliation;

5.7.1.2. All financial accountability, reimbursement for work and expenses, if any, within or related to the IRB shall be recorded and made available to the public upon request;

5.7.1.3. All IRB Members, Alternate Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

5.8. Officers

5.8.1. The following officers through their respective responsibilities contribute to the good functioning of the IRB:

Chairperson	Responsible to chair the meetings and liaise directly with the Head of the organization, report the meeting outcomes to the Head, and invite independent consultants to provide special expertise to the IRB on proposed research protocol. He/she shall also be a member of the National Health Research Board/Council,
Vice-Chairperson	Responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson,
Secretariat	Responsible for the administrative aspect of the IRB *(see 5.9 – below)*

5.9. Secretariat

5.9.1. The Research and Innovation Unit of the Medical Education Centre for Research Innovation and Training (MECRIT), KGUMSB shall be the secretariat for the IRB.

5.9.2. The Research and Innovation Unit of the MECRIT shall appoint a member secretary to the IRB.

5.9.3. All Secretariat staff have to sign Confidentiality/Conflict of Interest Agreements.

5.9.4. The Secretariat shall have the following functions:

5.9.4.1. Organizing an effective and efficient tracking procedure for each proposal received *(see SOP/008/01, SOP/026/01)*.

5.9.4.2. Preparation, maintenance and distribution of study files *(see SOP/025/01)*

5.9.4.3. Organizing IRB meetings regularly *(SOP/022/01).*

5.9.4.4. Preparation and maintenance of meeting agenda and *minutes (see SOP/021/01)*

5.9.4.5. Maintaining the IRB's documentation and Archive *(See SOP/025/01 and SOP/026/01)*

5.9.4.6. Communicating with the IRB members and applicants *(SOP/023/01)*

5.9.4.7. Arrangement of training for personnel and IRB members *(see SOP/005/01)*

5.9.4.8. Organizing the preparation, review, revision and distribution of SOPs and guidelines *(see SOP/001/01 and SOP/026/01)*

5.9.4.9. Providing the necessary administrative support for IRB related activities to the Chairperson of the Board (e.g. communicating a decision to the applicant) – *(SOP/008/01 – SOP/022/01)*

5.9.4.10. Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Board members.

5.9.4.11. Maintain budget for the regular meetings, and any other requirements.

5.10. DISSOLVING OF THE IRB

5.10.1. At any point in time, should the Organization cease to exist, the IRB shall be automatically dissolved.

5.10.2. The IRB may also be dissolved at any time by the **President, KGUMSB,** following written notification to each of the members.

6. GLOSSARY

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IRB's information and documents
IRB	IRB is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection. The board shall review both technical and ethical issues related to the research proposal.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed
Affiliated member	Members working under the **KGUMSB**
Non-affiliated member	Members from outside the **KGUMSB**
Scientific member	Members with masters or higher degrees; or members with sufficient research experience
Non-scientific member	Members with qualification below master degree
Alternate member	An individual appointed to the IRB to serve in the same capacity as the specific IRB member(s), who substitutes for members at convened meetings when the member is not in attendance.
Head of organization	President, KGUMSB, Thimphu, Bhutan
Secretariat	Research and Innovation Unit, MECRIT, KGUMSB
Member Secretary	A person nominated by the Secretariat and responsible for IRB activities.

7. REFERENCES

7.1. WHO. Standards and operational guidance for ethics review of health-related research with human participants (2011). (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf - accessed 28 October 2017)

7.2. ICH HARMONISED GUIDELINE. INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Current Step 4 version dated 9 November 2016 (https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf - accessed 28 October 2017)

7.3. Associated SOPs: SOP/001/01, SOP/004/01-005/01, SOP/008/01-011/01, and SOP/013/01-026/01.