INSTITUTIONAL
REVIEW BOARD

TERMS OF REFERENCE

ToR Version (v1.3)

Research & Innovation Unit

MECRIT, KGUMSB, THIMPHU

22 June, 2021

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Contents

PREAMBLE

The Institutional Review Board (IRB) is a Human Research Ethics Committee, established under the auspices of Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB, referred to hereafter as **the University**) responsible for reviewing the ethical acceptability of research, while ensuring compliance with the University research policy & guideline(s) relating to ***responsible conduct of human research***, University of Medical Sciences Act of Bhutan 2012, National Health Policy and other national regulatory and/or legislative requirements.

It has a special responsibility for oversight of the conduct of ethical reviews so that quality and consistency of its processes are maintained in compliance with professional and ethical standards.

The primary role of IRB is to safeguard the rights, safety, dignity and well-being of all actual and potential research participants. This includes protecting participants from physical, psychological, social/cultural, economic and legal risks of harm.

The main responsibility of each member is to decide, independently, whether in his or her opinion, the conduct of each research proposal submitted to the IRB, will so protect the participants. The guiding principles in making this decision are those of:

- **I**=Integrity;
- **R**=Respect for persons;
- **B**=Beneficence; and
- **J**=Justice.

STANDARDS:

Notwithstanding, KGUMSB-IRB policy for responsible conduct of human research and relevant national policies (such as the National Health Policy) and regulations (Bhutan Medical & Health Council, Drug Regulatory Authority, etc.), the University IRB also endeavours in reviewing all submitted research protocols against recognized international ethical standards, such as the Belmont Report (1979), World Medical Association's Declaration of Helsinki (1964, as amended (currently 2013)), ICH Good Clinical Practice (R1-1997 & R2-2018), International Ethical Guidelines for Health-related Research involving Humans (2016 & 2017), Standards and operational guidance for ethics review of health-related research with human participants (2011), as well as other established standards in biomedical research. Links to these guidelines are included in the references.

DEFINITIONS:

For the purpose of this Terms of Reference the following words have the following definitions:

0.1 **Primary Investigator** - *means the researcher or research student who is principally responsible for conducting a research or study.*

0.2 **Human Research** - *is defined as the attempt to derive generalisable new knowledge, and includes studies that aim to generate hypotheses as well as studies that aim to test them. Notwithstanding, any investigation with or about people or their data or tissue, where such investigation is undertaken to gain knowledge and understanding. It does not include routine testing and analysis, quality control, and the development of teaching materials.*

0.3 **Ethics Committee** - *means the IRB.*

0.4 **Researchers** - *includes Primary Investigators, co-investigators, and research students (who can be co-investigators or primary investigator) with the latter including, postgraduate, undergraduate (Honours) and higher degree by research students (doctoral or masters by research only) who is principally responsible for conducting a research or study. Also includes students-exchange, honorary staff, visiting staff, and volunteers.*

0.5 **Staff or Faculty** - *means regular staff and/or faculty of KGUMSB, staff of teaching hospitals, ex officio faculties (affiliated universities, colleges and institutes), honorary academic appointments comprising visiting appointments, adjunct appointments and volunteers.*

0.6 **Lay person/member** - *means someone who is not currently and professionally qualified in healthcare or works in healthcare research or as a faculty*.

*The above definitions are neither exhaustive nor restrictive as defined, but subject to necessary amendment(s) as deemed required!

1 BACKGROUND

The Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB) is the only medical university in the country with affiliations and collaborations with various renowned international universities. The University has faculties both full time and designated in a wide array of medical and health field's expertise, who would implement the activities professionally. Therefore, the stature of the University and its faculties should be able to provide quality training, research and other activities, such as medical innovations and development, among others.

Accordingly, the **University of Medical Sciences Act of Bhutan 2012**, in particular the Chapter-6 highlights and emphasizes on the *"Conduct of Medical Education and Research."* In the same chapter, the section pertaining *"examination and treatment of patient"* in particular, the ***article 53(b)****-(sub-article: iii, iv & v)*, does states as follows:

a. Students obtain prior informed consent from patient or patient party;

b. Students exercise due care and diligence in dealing with patient; and

c. Students conduct research as per the accepted ethical protocols and code of conduct.

In addition, the section on *"Medical Health & Research,"* specifically the ***article 58*** reassures on the importance of research for evidence-based decision and policy making, whereby stating that: *"the University shall encourage, promote, support and conduct research activities to enhance evidence-based health care for which the University may collaborate with other institutions within or outside the country."*

While endeavoring promotion and expansion of medical researches, the University felt the need to institute its own Research Ethics Committee, so-called the IRB to facilitate academic as well as the faculty's primordial requirements for ethics reviews and considerations in the conduct of any research/study involving human participant(s).

To this end, the University has approached the MoH for the necessary dialogue and approval, mainly to delineate precise scope of responsibilities and functions of IRB, while not conflicting with the already established Research Ethics Board of Health (REBH) at the MoH. To this end, the MoH has accorded permission to the University for establishing IRB as proposed vide approval, **Ref.No: MoH/Research/Gen/01/2017/4494, dated June 2, 2017**.

The IRB establishment in the University anticipates to supplement in addressing increasing demand or need for ethical reviews and issuance of ethical clearances within the University students and/or faculties, and academia originating from its affiliated institutions.

2 SCOPE OF RESPONSIBILITY

The IRB is responsible for considering the ethics of human research, whether it be clinical, epidemiological, physical, behavioural, attitudinal, social, economic or psychological. **Note:** *This list is not exhaustive, as it will depend on the nature of the research and its population.*

Any research/study involving national policy implications or attentions and require approval beyond the University's jurisdiction, such as study involving randomized controlled trials (RCTs) of complex interventions, will be cautiously considered in close consultation with the Research Ethics Board of Health (REBH) in the Ministry of Health.

The IRB at KGUMSB is independent of all institutional, faculty, departmental and financial interests. This ToR is aimed at ensuring a quality and consistent ethical review of researches undertaken by and for KGUMSB staff, faculty, students and its affiliated institutional academia.

2.1 The purview of the IRB will include research undertaken by staff/faculty and students (including students-exchange programme) of KGUMSB. The staff/faculty includes core and adjunct faculty members, academic staff from teaching hospitals, affiliated colleges and/or institutions, and visiting academics. Research students, as defined in the section **DEFINITIONS# 0.4**, includes students of KGUMSB, affiliated colleges, institutions and those under the student-exchange programme.

2.2 Reviewing, confirming ethical suitability, social values, scientific merits and monitoring of research protocols involving humans where the research:

2.2.1 is carried out by any person (either independently or collaboratively with others) who is a full-time, part-time or student-exchange and staff member of the University, visiting academics, or a person formally recognized by the University;

2.2.2 involves human participants who are students or faculty and/or staff members of the University, or are otherwise connected with the University in any way;

2.2.3 is carried out using equipment, facilities or premises owned by the University or otherwise under the control of the University.

2.3 Determine whether or not proposed research involving human participants are acceptable on ethical grounds, while ensuring that no research or study may proceed without prior consideration and approval of a written protocol by the IRB.

2.4 This scope does not prohibit the University from accepting another Ethics Committee's ethical approval as sufficient to allow both the release of funds held by the University and commencement of the research, provided that such other Research Committee is properly constituted and registered and/or accredited, such as from the Forum for Ethical Review Committees in the Asia & the Western Pacific Region

(FERCAP) or from the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), among others;

2.5 Reviewing, confirming ethical suitability, and monitoring, of research undertaken by individuals who are not affiliated with the University, provided that an agreement (MOU) exists between the University and the external researcher(s) that defines the role of the IRB in providing ethical approval and ethical monitoring of the research. The agreement will specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the Ethics Committee, and will also specify that the researcher or his/her institution/organisation (not the University) is responsible for liabilities arising from the conduct of the research.

3 OBJECTIVES

The IRB is expected to deal with all of the ethical aspects of procedures where humans participate in research and in teaching projects; these include confidentiality and privacy issues in addition to the physical and psychological welfare of participants.

Therefore, key objectives of the IRB are to:

3.1 Ensure that a participant's inclusion in a research study complies with the principles of ethical conduct, which mainly includes: **Research Merit and Integrity**; **Justice**; **Beneficence**; and **Respect**, including the themes: **risk and benefit**; and **participant's consent**.

3.2 Protect and safeguard the mental and physical welfare, rights, dignity and safety of participants involved in health research. In general, minimizing the risk of harm arising from research studies involving humans;

3.3 Facilitate ethical research through efficient and effective review processes including review of low or negligible risk research proposals through expedited review;

3.4 Ensure that all research is conducted responsibly and in the interests of the wider community;

4 FUNCTIONS

In general, the IRB will endeavour to:

4.1 Protect the rights and welfare of research participants and minimise the risk of harm arising from research studies involving humans;

4.2 Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data collected during the conduct of research involving humans;

4.3 Provide independent, timely and unbiased review of research activities involving human participants and/or their data in respect to their ethical acceptability and scientific merit;

4.4 Facilitate ethical human research through efficient and effective review processes;

4.5 Obtain expert opinions (internal or external) as and when required to provide scientific/technical assessment and safety evaluation of research activities;

In addition, the IRB Secretariat as mandated will strive to:

4.6 Promote ethical standards of human research and awareness by educating academic community;

4.7 Routinely report to the Director of Medical Education Centre for Research, Innovation & Training (MECRIT), the activities of the IRB via the Chairperson;

4.8 Provide report to the Chairperson of any significant events, complications and protocol violations that occur at any time during the conduct of research;

4.9 Provide annual progress reports to the Chairperson and the board members at intervals specified by the Board and at completion of any research;

4.10 Submit yearly report on the ethical reviews, IRB status and progress to the Research Ethics Board of Health (REBH), Ministry of Health (MoH);

4.11 Monitor the conduct of approved research through the receipt of progress, annual and completion reports;

4.12 Receive complaints from research participants, researchers or others on the conduct of human research, to deal with these in accordance with University policies and procedures, and where the content of the complaint constitutes a possible breach of the University Research Code of Conduct or policy, and accordingly report them to the Chairperson;

4.13 Shall maintain a register of proposed research involving human participants and communicate information on request to appropriate national bodies.

5 MEMBERSHIP

Recognizing that the IRB membership should reflect a balance of experience, views, expertise and gender, as well as representation from the different faculties and institutions within the University and outskirts of its premises (refer Table 1: IRB membership list); the University IRB will be constituted according to the following criteria:

5.1 Composition

i. Chairperson - shall be nominated and elected in fair and transparent manner;

ii. The Vice Chairperson - shall be nominated and elected in fair and transparent manner;

iii. One member who is a lay people - who have no affiliation with the University, and who is not involved currently in medical, scientific, legal, or academic work;

iv. Two members with knowledge of, and current experience in the areas of research and ethics - one each from (REBH, MoH) and Medical Education & Research Unit (MERU, JDWNRH);

v. One member with knowledge of, and current experience in the professional care, counselling or treatment of people;

vi. At least one representative from each faculty as nominated by the relevant Deans or Deputy Deans;

vii. One member who is a legal officer/lawyer;

viii. One member with statistical expertise (NSB);

ix. One member with traditional medicine background;

x. One member with social science/studies background;

xi. One member with public health background;

xii. The Member Secretary of the IRB who shall normally be a staff member of the University Research Office.

* Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion. Gender balance and multi-professional representation are desirable.

5.2 Membership conditions

The following membership conditions prevail:

i. Ideally, the membership of Ethics Committee ranges from 9 to 15 or 20 on a need basis. However, IRB for the University will consists of 14 core members, with additional alternate members as deem required;

ii. No member shall represent in more than one of the membership categories;

iii. At least one third of the members should be appointed from outside the University;

iv. The IRB shall co-opt additional members and/or seek additional advice where required to provide expertise, subject to that person(s) having no conflict of interest (COI) and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter;

v. No member shall adjudicate on research in which s/he COI.

vi. Membership will lapse if a member fails without notifying the Chairperson to attend three consecutive meetings or if the member fails to attend in full at least two thirds of all scheduled meetings in each year, unless there are exceptional circumstances. The Chairperson will notify the member, in writing, of such lapse of membership. The Chair will initiate the process to appoint a new member to fill the vacancy of the lapsed member;

vii. A member may resign giving one month prior notice in writing to the Chairperson. The Chairperson will initiate the process to appoint a new member to fill the vacancy of the former member. Where a member resigns, the appointment of the new member will be for the remaining term of the fixed term position.

5.3 Liability coverage

a) The University will provide indemnity for members of IRB, in respect of liability that may arise in the course of the bona fide conduct or exercising his or her duties as a member in good faith. Indemnity may be provided in accordance with the Condition of Services (COS 2018, clause# 2.8), Bhutan Civil Service Rules & Regulations (BCSR 2018, clause# 6.7), and other pertinent service regulations;

b) The risk of legal liability affecting board members will be minimised by requiring applicants upon approval of the research/study to complete a signed declaration agreeing to comply with the conditions prescribed by the IRB, and to accept responsibility for legal liability arising from any aspect of the study.

5.4 Termination of membership

The Chairperson may terminate the appointment of any member of the IRB if s/he believes it to be necessary for the proper and smooth functioning of the Board - failure to attend the required attendance, performance - upon written notice and justifications provided by the Secretariat.

6 APPOINTMENT OF IRB MEMBERS

6.1 The IRB member(s) will be formally sought for nomination via written notice/ letter to the concern agency or organization with set criteria to fulfilling the membership composition requirements;

6.2 Members will agree to their name and category of membership being made available to the public, including being published online;

6.3 All members upon appointment are required to provide the Secretariat with recent CV, passport photo, current details of contact, including, as appropriate, telephone and fax numbers, email and postal addresses. All communications with individual board members will be made through this contact information;

6.4 Prior to appointment, members should acknowledge in writing their acceptance of the IRB Terms of Reference and any requirements for confidentiality and COI required by the University;

6.5 New members should be provided induction material for individual mentoring, and must undertake **online research ethics integrity test** arranged by the IRB Secretariat;

6.6 Each member should become familiar with the University's research policy for the responsible conduct of human research and where necessary consult other guidelines (such as Council for International Organizations of Medical Sciences (CIOMS)) and Standard Operating Procedures (IRB SOPs, among others);

6.7 Members should attend continuing education and training in research ethics at least every 3-5 years;

6.8 Throughout their tenure, members will be provided with equitable access to education sessions, conferences, workshops and training related to technology and/or skills development relevant to the work and responsibilities of the IRB, at the expense of the University;

6.9 Where applicable, all essential and necessary expenses incurred by members in carrying out their IRB duties will be paid for or reimbursed by the KGUMSB on production of original receipts, as per the prevailing financial norms or rules;

6.10 As appropriate, entitlements (Travel & Daily Allowances) and refreshments will be provided at the IRB Full-Board rendezvous to facilitate members' attendance at meetings;

6.11 All appointments to the IRB shall be for a term of three (3) years, and may be renewed for a another term. - After completion of 2 terms, member will have to resign. S/he can be re-nominated after 3 years;

7 APPLICATIONS AND SUBMISSIONS

7.1 The IRB for the University requires submission of research protocols through a standard format using the online KGU Research Information Enterprise System (KRIES). No other forms of application submission will be entertained or accepted;

7.2 To facilitate timely submission and appropriate planning and review of Thesis protocol pertaining to KGUMSB students, a minimum of 3 months should be allocated prior to data collection; In consultation with the concerned Academic Deans, the date of submission will be uploaded on MECRIT website and faculty;

7.3 All researchers should be aware of the submission process and requirements. The system (KRIES) will not accept the application if the requirements are not fulfilled. This may delay the review process and timely collection of data;

Following are some key tips or information to be considered while preparing your ethical clearance proposal which will be assessed for:

7.3.1 Correctly quoting your system generated/assigned protocol number, date and versions;

7.3.2 Duly sign (wherever required or stated) to put your/Supervisor(s) digital signature;

7.3.3 Upload all required documents in support of your protocol, such as project description or research proposal along with implementation plan, administrative clearance from the MoH, relevant agencies/departments or study sites, CVs, among others. This feature to upload required documents is accessible on KRIES;

7.3.4 Informed consent should address adequately some of its crucial aspects, such as participants recruitment process, voluntariness, how to provide care & protection of research participants, maintaining confidentiality, minimizing any potential harm, involvement of children as participants and process, among others;

7.3.5 Guidelines to assist applicants in their preparation of submissions will be made available by posting on MECRIT website and as well as on KRIES webpage, in the format approved from time to time by the Board.

7.4 The Chairperson in consultation with the board members will determine if any expert advice is required in the process of initial application review;

8 LEVELS OF ETHICAL REVIEW TO BE FOLLOWED

8.1 **Waivers:** Requests for exemption or waiver shall be considered by the IRB Secertariat and noted by the Chairperson for consideration;

8.2 **Expedited Review:** Research involving low or negligible risk, such as use of existing collections of data or records that contain only non-identifiable data about persons, including ratifications of applications and amendments, may be considered by the Chairperson and delegated to at least two members for further review and ratified at the next scheduled meeting;

8.3 **Full-Board Review:** Research which involves more than low or negligible risk will be reviewed at the next full-board meeting of IRB. Each such application will be allocated to at least two IRB members for in-depth review;

8.4 **Minor amendments,** revisions and extensions of approval may be reviewed and approved by the Chairperson between meetings; Substantial amendments and revisions may require full-board review and/or ratification.

8.5 **Exceptional circumstances:** In exceptional circumstances, where as a matter of public policy, and in the national interest, it is essential that an application should be reviewed urgently to allow health related research to commence as soon as possible, the Chairperson may grant approval under exceptional circumstances for a protocol where:

8.5.1 Another Ethical Committee has approved the protocol and the protocol appears to conform to the requirements of the IRB; and

8.5.2 Clinical need necessitates urgent approval of the protocol.

9 REVIEW OF APPLICATIONS AND PROCESS

9.1 No review process will be considered or commenced for incomplete application as described in the earlier section.

9.2 Before forwarding to the Chairperson, the IRB Secretariat will attempt to “triage” completed applications to assign the level of review in terms of risk and complexity of the research and accordingly submit it to the Chairperson. Subsequently, the Chairperson will further evaluate and allocate protocol(s) to a prospective reviewer(s) for reviews;

9.3 All applications submitted to IRB for review must be prospective, which means that the research/study should not have started yet in any fashion, without prior approval from the IRB;

9.4 Deadlines for review will be strictly adhered to; for example, minimum of 6 months period to review Postgraduate students' Theses (in the case of bulk submissions) - includes submission, reviews, re-submissions and to grant of approvals.

9.5 For non-thesis research protocols, the assigned, (usually 1 week [7 working days] period for the review) by the Chairperson during the task assignment will be followed;

9.6 The review process will be documented via the online KRIES application system;

9.7 The review process will be undertaken and automated via online system (KRIES) and reports will normally take place electronically, unless an issue requires specific consideration at a meeting.

10 OPERATIONAL COST

In order to meet the Board's operational cost (time and resources spent, board meetings and other proceedings expenses, among others):

10.1 A nominal fees will be charged for consideration of research proposals from students (ex. PG Thesis/study as a part and parcel of their academic requirements);

10.2 Minimal fees will be charged for any proposals other than university academic requirements, applies to both students and staff/faculty members of KGUMSB;

10.3 Fees will be levied for applications submitted for assessment by the IRB from external researchers or scholars who have no formal affiliation with the University;

10.4 In addition, these researchers will also be required to sign a contract with the University detailing the terms and conditions under which the IRB will review the application and monitor the research/study, once approved.

10.5 Review fees, wherever applicable will be charged in accordance to the IRB Fees Schedule effective from 01 July, 2021 (which is subject to periodic revisions) as illustrated below:

- Students - Intitial review - **Nu. 2000/-** per protocol;
- Faculty/Staff - Intitial review - **Nu. 3000/-** per protocol;
- Other than faculty/staff - Intitial review - **Nu. 5000/-** per protocol review;
- International/collaborative (external funded) - Intitial review - **5% of the research grant or fund/-** per protocol;

11 BOARD MEETINGS

11.1 Full-Board meetings will be held 4 times in a year, on a quarterly basis;

11.2 Meetings will be held at dates and times as determined by the Board. Meeting dates will be set judiciously (not coinciding with the REBH meeting dates) by the end of each calendar year for the ensuing 12 months. These dates will be made available on the www.mecrit.bt and/or KRIES;

11.3 Reminder of meeting will be given at least two weeks prior to meeting;

11.4 The Chairperson upon apprisal from the Member Secretary may reschedule a meeting and convene additional meetings to consider urgent matters. Should a situation call for such additional meetings, provided that 7 days notice is given to the Board members.

12 PROCESS AND CONDUCT OF BOARD MEETINGS

12.1 The IRB Secretariat will consider every correctly and fully completed application which it receives at its next available meeting following receipt, provided that the application is received on time and considered for the forthcoming meeting's agenda;

12.2 The members must as soon as practicable disclose any conflict of interest (COI) in relation to matters on the agenda prior to discussion of the item. In such instances the Board will determine whether, and to what extent, the member will be excluded from deliberations, until the Board's consideration of the relevant matter has been completed. All such declarations will be minuted and documented;

12.3 If need arises to invite external expert(s) to attend the meeting, s/he will be required to declare an absence of COI and sign a confidentiality agreement prior to review proceedings;

12.4 Where there is less than required quorate of the minimum membership (50%+1 of the members) at a meeting, the Chairperson must be satisfied, before a decision is reached, that members from all membership categories have had an opportunity to contribute their views and that these have been recorded and considered in the decision making process;

12.5 Efforts or attempts should be made to reach decisions by general consensus. Failure to agree may require an extension of time to reconsider the application and its possible modification, especially when any member is not satisfied that the welfare and rights of participants are protected;

12.6 Dissenting and supporting opinions should be summarised in the minutes, including those submitted by absent members. If necessary, the decision will be by simple majority. However, the Board may impose conditions to take into account the dissenting views;

12.7 If need be, and to ensure informed consideration of studies/issues the IRB Secertariat may request the investigator(s) to furnish further information or may invite to attend the face-to-face meeting with the board members to discuss a proposal. However, the applicant will be required to leave the meeting before any outcome is decided;

12.8 Decisions will be communicated to researchers in writing. Letters of approval to applicants will specify conditions of the approval, reporting and monitoring requirements, and the duration of the approval;

12.9 Members who are unable to attend a meeting in person may arrange to participate via tele/video conference and/or forward their reviews in writing to the IRB Secertariat or Chairperson prior to the meeting;

12.10 Members must inform the Chairperson if a leave of absence is required. If unable to attend three or more consecutive meetings, members should consider their availability to remain on the Board;

12.11 In the absence of the Chairperson and Vice Chairperson, the Chairperson/Member Secretary may appoint an Acting Chairperson;

12.12 Where ever possible, members shall maintain confidentiality of the content of applications and the deliberations of IRB matters;

13 DOCUMENTATIONS AND RECORDS

13.1 The Member Secretary will document minutes of the meetings, including a summary of the discussion, any dissenting views and the conclusions/recommendations/actions agreed at the meeting; The Minutes will be ratified or endorsed after one week of the completion of a meeting;

13.2 The IRB Secretariat will prepare and retain written records of:

13.2.1 All IRB's activities, including agendas and minutes of all relevant meetings;

13.2.2 Individual applicant received protocol (the Project File) including copies of applications submitted, all associated documents and correspondence between applicant and the IRB Secretariat;

13.2.3 All these files will be kept securely and confidentially (password protected for electronic storage and under lock and key for hard copies); and only accessible to Secretariat and Chairperson IRB - after completion of reviews;

13.2.4 Maintain a database with appropriate backups of all applications received and reviewed;

13.2.5 Records will be retained for minimum 5 years to allow for future references;

13.2.6 Maintain record of all complaints related to activities of the Board and its outcomes incuding record of all complaints received regarding research conduct and as well as outcome of those complaints;

13.2.7 Maintain a record of any breaches of the University research policy and code of conduct, stated otherwise in the University responsible conduct of human research policy;

13.3 All matters relating to protocols and Board proceedings will be considered confidential. For example, after use, any sensitive and confidential papers will be disposed of through a confidential recycling bin. IRB members may leave papers for confidential disposal after meetings.

14 QUORUM

14.1 Unless otherwise prescribed by external regulatory requirements, the quorate for Board meetings shall be (50% + 1) of the core members, including the Chairperson, provided that members unable to attend have had sufficient opportunity to consider agenda items and provide their views. The Chair must be satisfied, before a decision is reached, that the views of an absent core member(s) have been received and considered.

15 MONITORING

15.1 The Primary Investigator (PI) must annually provide the IRB Secretariat with a project/study report using the online form provided on KRIES. The prime objective of the report is to verify that the conduct of research confirms to the approved process;

15.2 The IRB may adopt any additional procedures for monitoring research that it considers appropriate;

15.3 PI must immediately report to IRB Secretariat on any changes or events that may warrant review of the ethical approval for their research proposal, including proposed changes to the protocol and/or unforeseen events. In such unfavourable situations, PI may seek prior advice from the IRB.

16 COMPLAINTS

i. IRB provides platform for complaints about the process of ethical review, but does not provide for an appeal against a final decision to reject a proposal;

ii. To obtain further clarity on the research protocol, the Board can invite the PI to provide further information related to the protocol;

iii. The decision by the IRB to reject an application will be final.

16.1 Complaints concerning the IRB's review process

i. Complaints about the process of ethical review must be made in writing and directed to the Chairperson through IRB Secretariat. These complaints may be referred to the Director, MECRIT and investigate and/or attempt to resolve the matter harmoniously;

ii. Researchers have the right to attend one meeting of the IRB to present their complaint in person.

16.2 Complaints concerning the conduct of research

i. Complaints about the conduct of an approved IRB-reviewed research/study, whether from research participants or researchers should be lodged/made through IRB Secretariat to the Chairperson for resolution;

ii. If the complainant provides consent, their contact details are to be recorded in the Complaints Log held in the IRB Secretariat so that the outcome of the investigation can be reported to the complainant;

iii. The Chairperson will consider the complaint and will take what action he/she deems appropriate within one week after intimidation or being informed. The process will usually involve verification that the protocol approved by the Board has been followed and subsequent action may include temporary withholding of ethics approval.

iv. Complaints considered as serious by the IRB or any potential breaches of the KGUMSB's Research Code of Conduct will be referred immediately to the Director (MECRIT) by the Chairperson for resolving the matters.

17 REVIEW AND AMENDMENTS OF TOR

The Terms of Reference will be reviewed by the Board every three (2) years and necessary amendments made at the first meeting of the calendar year, unless requested earlier by a member of the IRB or Secretariat in conjunction with the IRB Chairperson. The date of next review is July 2023.

Table 1: IRB Members

Current Membership				
Sl#	IRB Role	Title, Name & Expertise	Appointment Type	Terms of Office
1.	Chairperson	Dr Karma Tenzin, Medical Educationist	Member	3 years + renewal for 3 yrs.
2.	Vice Chair	Mr. Zimba Letho, Researcher	Member	-do-
3.	Board Member	Drg. Choegyel Dorji, Traditional Medicine	Member	-do-
4.	Board Member	Drg. Karma Ugyen, Traditional Medicine	Member	-do-
5.	Board Member	Mr. Jigme Phuntsho, Social Studies	Member	-do-
6.	Board Member	Dr. Tika Ram Adhikari, Clinician	Member	-do-
7.	Board Member	Mr. Wangchuk, Public Health	Member	-do-
8.	Board Member	Ms. Tshering Nidup, Lawyer/Attorney	Member	–

Table 1...Contd/-: IRB Members

Current Membership				
Sl#	IRB Role	Title, Name & Expertise	Appointment Type	Terms of Office
9.	Board Member	Mr. Cheda Jamtsho, Researcher	Member	-do-
10.	Board Member	Ms. Pema Lhamo, Social Worker	Member	-do-
11.	Board Member	Mr. Ugyen Tashi, Pharmacist	Member	-do-
12.	Board Member	Ms. Sonam Wangmo, Researcher	Member	-do-
13.	Board Member	Mr. Mongal Singh Gurung, Statistician	Member	-do-
14.	Board Member	Mr. Tashi Norbu, Public Health	Member	-do-
15.	Board Member	Ms. Lila Maya Adhikari, Disease Control Laboratory	Member	-do-
16.	Board Member	Mr. Kuenzang, Nursing & Midwifery	Member	-do-

Table 2: Document history and version control

Document History	
Last Amendment (minor):	22-06-2021
Amended:	14-04-2021
Reviewed:	12-03-2021
Amended:	08-03-2021
Reviewed:	11-02-2021
Contact Office:	Research & Innovation Unit, MECRIT, KGUMSB, Thimphu [Tele(O): +975-2-328990; Email: irb@kgumsb.edu.bt]

Version Control			
Version No.	Date Approved	Approved By	Brief Description
v1.3	14/04/2021	PRESIDENT, KGUMSB	Approved during UHRC with minor revisions.
v1.2	12/03/2021	-NA-	Reviewed during MECRIT (CPD & IRB) Retreat at Rogchopel, Thimphu.
v1.1	08/03/2021	-NA-	Final draft - Under amendment based on recommendations
v1.0	11/02/2021	President with recommendations.	First draft - Reviewed by Hon'ble President, Registrar, Directors, Deans and other Senior Faculties of the University.

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