CHAPTER 11

GLOSSARY

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Table of Contents

1. PURPOSE

This SOP shall provide guidance regarding definition of terms, abbreviations and titles used by the *IRB* and its administrators to facilitate use and understanding of the *IRB* Standard Operating Procedures and activities

The definitions are divided into two sections:
1.1. Description/definition of individual roles as used in the *IRB* SOPs
1.2. Description/definition of terms and abbreviation used in the *IRB* SOPs

2. SCOPE

This section shall apply to all *IRB* SOPs and activities in addition to persons preparing and/or using the SOPs.

3. RESPONSIBILITY

The *IRB* members shall be responsible to define or determine and approve the appropriateness of the description.

4. FLOW CHART

No.	Activity	Responsibility
1	Description of individual titles and roles	*IRB* members and Secretariat
2	Definition of terms	*IRB* members and Secretariat
3	Addition / Correction of new titles and terms	*IRB* members and Secretariat
4	Approval of the new addendum	*IRB* members / Chairperson

5. DETAILED INSTRUCTIONS

5.1. Description of individual roles

5.1.1. KGUMSB

The Khesar Gyalpo University of Medical Sciences Of Bhutan.

5.1.2. Chairperson

A member of the *IRB* who presides over a board meeting He/she is responsible for expedited approvals on behalf of the Board.

5.1.3. Vice Chairperson

A member of the *IRB* who assist the Chairperson or presides over a board meeting in absence of the chairperson. He/she is responsible for expedited approvals on behalf of the Board.

5.1.4. Supervisor

The person at the study site who is responsible for managing the study. Sometimes, the Principal Investigator is also the site coordinator and manager.

5.1.5. IRB

The *IRB* is a body established to review and monitor health research involving human subjects. The primary purpose of such a review is the protection of the rights and welfare of the human subjects. In accordance with applicable national/international regulations, the *IRB* has the authority to approve, require modifications to, or disapprove research.

The *IRB* consists of at least five voting members in addition to the other members during the session. The composition of the membership must reflect a diversity of backgrounds sufficient to assure:

5.1.5.1. expertise and experience to provide adequate review of research activities
5.1.5.2. consideration of race, gender, and cultural backgrounds
5.1.5.3. sensitivity to attitudes and concerns of the community and the patient population
5.1.5.4. knowledge of applicable regulation, laws and standards of professional conduct and practice
5.1.5.5. no member participates in the review process of any study project in which he/she has a conflicting interest
5.1.5.6. no gender discrimination

5.1.6. IRB Members

Individuals who have agreed to become a member of the *IRB* after being nominated by the *KGUMSB*.

5.1.7. Investigational New Drug (IND)

Investigational new drug means a new substance/medicine or biological product that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this part.

Principal Investigator

Individual responsible for implementing and coordinating an investigational study

5.1.8. Secretariat

The *IRB* staff who are responsible for the day-to-day administrative functions and duties which support the activities and responsibilities of the *IRB* members.

5.1.9. SOP Team

A selected group of *individuals* and administrative staff who oversee the preparation, review and periodic revision of the *IRB* SOPs

5.1.10. Vulnerable subjects

A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence

5.2. Definition of Terms

5.2.1. Active study files

Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the *IRB.*

5.2.2. Administrative documents

Documents include official minutes of Board meetings as described in SOP... *IRB* meeting minutes and voting records and the standard operating procedures, both historical files and Master Files as described in the SOP, SOP distribution, implementation and file maintenance.

5.2.3. Deviation

Any instance in which the current approved *IRB* SOP has not been followed.

5.2.4. Expedited approval

An *IRB* approval granted only by the Chairperson of the *IRB* or a designated *individual or IRB* member (not the full Board) for "minor" changes to current *IRB*-approved research activities and for research which involves no more than minimal risk

5.2.5. Final report

An obligatory review of study activities presented as a written report to the *IRB* after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Complete, comprehensive written description of a completed trial that describes the experimental materials and statistical design, presentation and evaluation of the trial results and statistical analyses.

5.2.6. Historical file

A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

5.2.7. Inactive study files

Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communication and correspondence with the investigator, and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *IRB* for which a final report has been reviewed and accepted Inactive study files are archived for a minimum of five years following the completion of the study. These files can be retrieved as needed.

5.2.8. Investigational medical device

A medical device which is the object of clinical research to determine its safety or effectiveness.

5.2.9. Master files

Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

5.2.10. Medical Device

A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-occular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kids for *in vitro* diagnosis of disease and other conditions, (for example, pregnancy).

5.2.11. Minutes

The official record of events, activities, and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The board votes separately on each collective set or each item submitted for review: protocol, consent form, investigator, and advertisement(s). The record notes the number for, number against, the number of abstaining votes, and the reason for the abstention(s), without identifying the individual member's names.

5.2.12. New Study

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to *IRB* for approval for the first time and not previously approved by this board. This includes re-application for those studies denied approval by *IRB*.

5.2.13. Non-compliance record

A list containing the identity of investigators who are considered by the *IRB* to be non-compliant with national/international regulations or who fail to respond to the committee's requests, and the incident(s) justifying the reason for the determination of non-compliance.

5.2.14. Non-significant Risk Device (NSR)

A non-significant risk device is an investigational device that does not pose a significant risk.

5.2.15. Progress Report

An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the *IRB*. Generally, these reports are due annually with the *IRB* sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the *IRB*.

5.2.16. Protocol Amendment

A change to the study protocol during the planning or course of the trial or the amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

5.2.17. Quorum

Attendance required arriving at a decision at any convened meeting of the board i.e. 50% of the members including the five voting members.

5.2.18. Significant Risk Device (SR)

A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.

5.3. Addition / Correction of terms

5.3.1. Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time, if he/she feels clarification should be made.

5.3.2. Write your proposal.

5.3.3. Submit your proposal to the *IRB* secretariat.

5.4. Approval of the addendum

5.4.1. *IRB* secretariat shall bring the proposal to a meeting.

5.4.2. The proposal shall be discussed for further opinion.

5.4.3. Agreement and approval shall be made at the meeting.

6. REFERENCES

6.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

6.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.