CHAPTER 8.1

AGENDA PREPARATION, MEETING PROCEDURES AND MINUTES

SOP NUMBER: SOP/022/01

INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Effective Date: October 1,2021
Supersedes: SOP/021/yy

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

Table of Contents

1. PURPOSE

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of IRB.

2. SCOPE

This SOP shall apply to administrative processes concerning the preparation of the agenda for all regular IRB meetings, divided into three stages: before, during and after the meeting.

3. RESPONSIBILITY

The IRB Secretariat staff shall be responsible to prepare the agenda for the IRB meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson shall review and approve the agenda and the minutes sent to him/her.

4. FLOW CHART

No.	Activity	Responsibility
1	Before each Board Meeting ↓	IRB Secretariat / Chairperson
2	During the Meeting ↓	IRB Secretariat, Members and Chairperson
3	Voting ↓	IRB Members without conflict of interest / Chairperson
4	After the Board Meeting ↓	IRB Secretariat / Chairperson
5	Storage of the documents	IRB Secretariat staff

5. DETAILED INSTRUCTIONS

5.1. Before each Board meeting

5.1.1. Check for filled up forms for completeness.

5.1.1.1. The Secretariat shall:

5.1.1.1.1. Review the new study application for completeness.

5.1.1.1.2. Document the review by completing the appropriate checklist. If incomplete, the staff member attempts to obtain the information from the person who submitted the application package.

5.1.2. Consider the appropriate review channel of each protocol

5.1.2.1. Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel.

5.1.2.1.1. SOP/009/01 for Expedited Review

5.1.2.1.2. SOP/010/01 for Initial Review of Submitted Protocols

5.1.2.1.3. SOP/013/01 for Review of Resubmitted Protocols

5.1.2.1.4. SOP/014/01 for Review of Protocol Amendments

5.1.2.1.5. SOP/015/01 for Management of protocol continuing Reviews

5.1.2.1.6. SOP/016/01 for Review of Final Reports

5.1.2.1.7. SOP/019/01 for Management of study termination.
5.1.2.1.8. SOP/020/01 for Review of Serious Adverse Event Reports

5.1.3. Assign protocol reviewers

5.1.3.1. Assign at least two to three reviewers (for technical and ethical reviews) for initial review of each submitted protocol by the IRB Chairperson.
5.1.3.1.1. The technical reviewer shall prepare a brief protocol summary, including a statement of the purposes, the evaluation parameters, and the methodology of the protocol. The ethical reviewer examines the consent form for completeness of information and protection of human subjects.
5.1.3.1.2. The assignment shall be based on the information provided in SOP/005/01 and SOP/006/01

5.1.4. Prepare meeting agenda

5.1.4.1. Schedule the review as soon as possible after submission, either at the time of the next scheduled meeting or within 4 weeks after submission.
5.1.4.1.1. Arrange extra IRB meetings to accommodate protocol reviews.
5.1.4.2. Consult the Chairperson to schedule the meeting date.
5.1.4.3. Prepare the meeting agenda, according to the ANNEX - AF/01-021/01
5.1.4.4. Schedule protocols in the agenda on a first-come first-serve basis.
5.1.4.5. Include "request to appeal" items in the agenda, upon receipt of the correspondence, preferably during the next convened Board meeting.
5.1.4.6. Prepare invitation letters to the reviewers and the members.
5.1.4.6.1. Allow at least 3 weeks for the review process.
5.1.4.7. Specify the due date for the return of comments.
5.1.4.7.1. Allow at least 5 working days to the IRB Member Secretary to process the documents
5.1.4.8. Include an Application form for Initial Review, ANNEX - AF/01-008/01 with the protocol package along with the invitation letter, a response form and the meeting agenda.
5.1.4.9. Prepare the package for delivery.
5.1.4.10. Record the name of the assigned reviewers in the appropriate database or the review assignment file.

5.1.5. Distribution of Protocol Packages to the IRB Members

5.1.5.1. Keep in mind Procedure for Maintaining Confidentiality of IRB documents (SOP/027/01) when preparing and distributing documents.
5.1.5.2. Distribute copies of the protocol submission packages to the assigned reviewers and IRB members by either electronic mail (if electronic submission protocols), telefax, or by post *one week* in advance of the scheduled meeting.
5.1.5.3. Keep copies of "sent" e-mail, fax cover memos and/or letters accompanying posted materials in the Correspondence section of the respective protocol file.
5.1.5.4. Verify (verbally, by e-mail, by fax or by mail) with the members whether the protocol packages are received.

5.1.6. Prepare for the meeting

5.1.6.1. Make a room reservation on the schedule meeting date and time.
5.1.6.2. Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.

5.2. During the meeting

5.2.1. The IRB may allow investigators, project managers, sponsors, etc., to attend the portion of the Board meeting related to their studies.

5.2.2. At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
5.2.3. These guests may include a potential client, students, etc.
5.2.4. Guests shall be required to sign a confidentiality agreement form, ANNEX- AF/02-004/01
5.2.5. The Secretariat shall report on the minutes of the previous meeting and presents the agenda for discussion.
5.2.6. The Secretariat shall record the discussions and the decisions made during the meeting.
5.2.7. The Chairperson may inform members and attendees of the rules being followed during meetings. .
5.2.8. The meeting proceeds in the order organized in the agenda; however, the Chairperson in discussion with the IRB may allow some amendments.
5.2.9. The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments.
5.2.10. In case the reviewer cannot be present during the meeting, a member of the Secretariat or an IRB member may give the briefing about the study by reading the comments and evaluation of the reviewers.
5.2.11. The other members shall give their comments right after the presentation and the discussion about the study takes place.
5.2.12. Investigators may be allowed to present their projects in brief and clarify any questions the IRB members may have.

5.2.13. Quorum Requirements

5.2.13.1. A minimum of ***"50%+1"*** of the members must be present at a meeting in order to issue a valid advice and/or decision.

5.2.13.2. Professional qualifications of the quorum requirements shall consist of at least one member whose primary area of expertise is in a non-scientific area, one medical scientist and at least one member who is independent of the institution/research site.

5.2.13.3. A provision for a maximum of 3 alternate members is kept for each board meeting.

5.2.14. Frequency of the meeting

5.2.14.1. The IRB shall meet at least 2 times a year in July and January.

5.2.14.2. Emergency meeting may be convened if required, wherein the secretariat shall notify the members upon approval from the Chairperson.

5.3. Voting

5.3.1. In order to avoid conflict of interest, only those Board members and alternate members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
5.3.2. All voting will take place after the observers / presenters / Board members with a conflict of interest leave the meeting room.
5.3.3. The Chair shall determine if the number of voting Board members is sufficient to constitute a quorum (refer 5.2.13) and proceeds accordingly.
5.3.4. A board member shall make a motion to recommend action on a protocol or issue being discussed.
5.3.5. The motion is seconded and voting takes place.
5.3.6. A motion is carried out once the majority of IRB members vote in favour of the motion.

5.4. After the Board meeting,

5.4.1. Preparing the Minutes and the Decision Forms

5.4.1.1. Assembling the meeting minutes and the decision form

5.4.1.1.1. Use the format as shown in ANNEX - AF/02-022/01to write a minute.

5.4.1.1.2. Compose the summary of each meeting discussion and decision in a concise and easy-to-read style.

5.4.1.1.3. Make sure to cover all contents in each particular category.

5.4.1.1.4. Check spelling, grammar and context of the written minutes.

5.4.1.1.5. Finish the minutes within five working days after the meeting.

5.4.1.2. Contents of the IRB Meeting Minutes

5.4.1.2.1. The official minutes of the Board meeting consist of, but are not limited to, the following:

5.4.1.2.1.1. Name of person preparing the minutes

5.4.1.2.1.2. Location where the meeting was held (city, state)

5.4.1.2.1.3. Meeting date

5.4.1.2.1.4. Attending Board members and guests

5.4.1.2.1.5. Agenda items

5.4.1.2.1.6. Individual serving as Chairperson of the meeting

5.4.1.2.1.7. Determination of a duly constituted quorum by the Chairperson to proceed with the meeting

5.4.1.2.2. Requirements for each study or activity requesting Approval:

5.4.1.2.2.1. Sponsor's name;

5.4.1.2.2.2. Protocol number/date/version of protocol, when available;

5.4.1.2.2.3. Investigator's name;

5.4.1.2.2.4. Advertisements;

5.4.1.2.2.5. Name of Board member presenting study materials;

5.4.1.2.2.6. Discussion as deemed appropriate by the Chairperson

5.4.1.2.2.7. Number of members voting 'yes', 'no', or 'abstention'

5.4.1.2.2.8. Number of abstentions and the reason for the abstention;

5.4.1.2.2.9. Reference to the investigator approval letter that lists all changes requested by the Board;

5.4.1.2.2.10. Determination of the next requested continuing review.

5.4.1.2.3. Requirements for each study or activity requesting Expedited Review:

5.4.1.2.3.1. Sponsor's name;

5.4.1.2.3.2. Protocol number, if applicable;

5.4.1.2.3.3. Investigator's name;

5.4.1.2.3.4. Lists of expedited approval requests and outcomes.

5.4.1.2.4. Required for each Continuing Review Report:

5.4.1.2.4.1. Sponsor's name;

5.4.1.2.4.2. Protocol number, if applicable;

5.4.1.2.4.3. Investigator's name;

5.4.1.2.4.4. Indication of the Board's determination to continue, terminate, or amend the study;

5.4.1.2.4.5. Lists of recommendations or actions to be taken up with the investigator, if applicable.

5.4.1.2.5. Required for each Adverse Event notification and Final Report:

5.4.1.2.5.1. Sponsor's name;

5.4.1.2.5.2. Protocol number, if applicable;

5.4.1.2.5.3. Investigator's name;

5.4.1.2.5.4. Actions deemed appropriate by the Board's review.

5.4.1.2.6. Required for Termination of Approval:

5.4.1.2.6.1. Sponsor name's;

5.4.1.2.6.2. Protocol number, if applicable;

5.4.1.2.6.3. Investigator's name; reason for termination

5.4.2. Approval of the minutes and the decision

5.4.2.1. Circulate the draft minutes to all IRB Board Members, Chairperson, Vice Chairperson, IRB Member Secretary and Secretariat within three working days after each meeting for review and comments.

5.4.2.1.1. As soon as possible after each meeting, a copy of the minutes is sent to a senior administrative staff member for quality control and review Allow up to two working days for review and comments.

5.4.2.2. The IRB Member Secretary shall check the correctness and completeness of the minutes, indicating review by signing and dating the minutes.

5.4.2.3. Following review, the minutes shall be given to the Chairperson or designee for review and approval.

5.4.2.4. The Chairperson shall indicate approval by signing and dating the minutes.

5.4.3. Distribute the Decision and the minutes

5.4.3.1. Send the approved Action Letter to the applicants informing them of the IRB's decisions and recommendations.

5.4.3.2. Record the receiver and the delivery date of the Action Letter

5.4.3.3. Send the approved minutes to the IRB members.

5.4.4. Storage of the documents

5.4.4.1. Place the original version of the minutes and the signed decision form in the IRB files for the specific protocol.

5.4.4.2. Place all correspondence in the appropriate file.

5.4.4.3. Place a copy of the approval letter in the "minutes" file to inform the Board Members of the Expedited approval.

5.4.4.4. Document the appeal requests in the meeting minutes.

6. GLOSSARY

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number of IRB members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum vote in its favour.

7. REFERENCES

7.1. World Health Organization, Operational Guidelines for Ethics Boards that Review Biomedical Research, 2000

7.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

7.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants Guidance document, 2011

7.4. Associated SOP/004/01-SOP/006/01, SOP/008/01, SOP/010/01-SOP/016/01, SOP/012/01, and SOP/027/01.

8. ANNEX

ANNEX 1	AF/01-022/01	Agenda format
ANNEX 2	AF/02-022/01	Form of IRB Meeting Minutes
ANNEX 3	AF/03-022/01	IRB Meeting Minutes Template

ANNEX 1
AF/01-022/01

Format of an Agenda

Tentative agenda for xth IRB Full Board Meeting
dth Month, 2021

Sl. No.	AGENDA	TIME	PRESENTER
DD/MM/YYYY			
1	Opening remarks	9:00 am	Chairperson
2	Agenda adoption and quorum determination		
3	Review and endorsement of minutes of wth IRB Board meeting		IRB Member Secretary
4	Updates by IRB Member Secretary		IRB Member Secretary
Initial Full Board Review			
5	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
6	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
Expedited Review, Continuing Review & Resubmitted Review			
14	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
15	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
Reports for closure			
17	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
18	PN/YYYY/VVV xxxx _ Mr AZ		Primary Reviewers
	Next Board Meeting date		IRB Member Secretary
	Any other issues		
	Closing Remarks		Chairperson

ANNEX 2
AF/02-022/01

Form of IRB Meeting Minutes

Meeting No.:	Meeting date:
☐ Regular meeting	☐ Emergency meeting
Venue of meeting:	
Agenda items:	
Starting time:	Adjourned time :

Attending board members and guests:

1. 10.
2. 11.
3. 12.
4. 13.
5. 14.
6. 15.
7. 16.
8. 17.
9. 18.

Chairperson/Vice Chairperson:

Was there sufficient voting member representative for the session met?

☐ Yes ☐ No

Prepared by:…… Reviewed by:……..

Date: …… Date: ……..

Approved by: ……

Date: ……..

ANNEX 3
AF/03-022/01 IRB Meeting Minutes Template

Agenda Item 1: Opening Remarks
Agenda Item 2: Adoption of Agenda
Agenda Item 3: Updates by IRB Member Secretary on the status of Protocols
Agenda Item 4: Declaration of Conflict of Interest (CoI)
Protocols for Initial Full Board Review
Agenda Item 5:
Protocol Number: Title: PI: Primary Reviewer 1: Primary Reviewer 2: Discussion: Decision: Recommendations/Clarifications:
Protocols for Resubmission Agenda Item 6: Protocol Number: Title: PI: Primary Reviewer 1: Primary Reviewer 2: Discussion: Decision: Recommendations/Clarifications:
Protocols for Final Report Review Agenda Item 7: Protocol Number: Title: PI: Primary Reviewer 1: Primary Reviewer 2: Discussion: Decision: Recommendations/Clarifications:
Agenda Item 8: Any other Issues
Agenda Item 9: Next Board Meeting Date
Agenda Item 10: Closing Remarks