CHAPTER 4.3

MANAGEMENT OF PROTOCOL CONTINUING REVIEWS

SOP NUMBER: SOP/015/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

This procedure describes how continuing reviews of previously approved *IRB* protocols shall be managed by the Ethics Board.

The purpose of the continuing review shall be to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless (1) the study was eligible for, and initially reviewed by, an expedited review procedure; or (2) the study has changed such that only the activities that are eligible for expedited review are remaining; or (3) Continuing review with no modifications /amendment to the original protocol and no additional risks have been identified.

2. SCOPE

This SOP shall apply to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but *not less than once a year.* Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

3. RESPONSIBILITY

The IRB Secretariat shall be responsible to remind the IRB and the principal investigators regarding study protocols that shall be continuously reviewed. *The frequency of continuing review is based on the IRB decision during the approval of the study protocol.*

The IRB shall be responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol informed consent documents and assent documents shall be examined to ensure that the information remains accurate and unchanged from the original approved protocol.

The IRB has the same options for decision making on a continuing review package as for an initial review package. The decision shall be made as *approved; approved with recommendations; resubmission and disapproved.*

4. FLOW CHART

No.	Activity	Responsibility
1	Determine the date of continuing review ↓	Members and Chairperson
2	Notify the study team ↓	IRB Secretariat
3	Manage continuing review package upon receipt ↓	IRB Secretariat

No.	Activity	Responsibility
4	Notify the members of the IRB ↓	IRB Secretariat
5	Continuing review process ↓	IRB Secretariat, Members and Chairperson
6	Communicate the decision to the investigator ↓	IRB Secretariat
7	Storage of the Documents	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1 Determine the date of continuing review.

5.1.1 The Members and Chairperson shall be responsible for determining the date of continuing review.

5.1.2 Once the date of continuing review is determined, add it to the "database tracking system" under the column 'continuing review date'.

5.1.3 Look through the approval letter and/or database tracking system for the due date of continuing reviews. Plan for continuing review at least two months ahead and as close as possible to the due date of continuing reviews or in the first quarter of the study period.

5.2 Notify the principal investigator or the study team

5.2.1 Inform the Study Team at least two months in advance of the due date for the continuing review by fax, post, e-mail or other appropriate means.

5.2.2 Fax, mail or e-mail also a Continuing Review Application Form, ANNEX - AF/01-015/01 to the Study Team to fill up.

5.2.3 Keep the informed notice in the protocol file.

5.2.4 Allow the Study Team sufficient time to collate the information and to prepare a report package required for the continuing review.

5.3 Manage continuing review package upon receipt.

5.3.1 Receive a package of continuing review for each protocol prepared and submitted by the Study Team.

5.3.2 Upon receipt of the package, the Secretariat of the IRB shall perform the following:

5.3.2.1 Initial and date the submission package

5.3.2.1.1 See SOP/008/01 for procedures on receipt of submitted packages.

5.3.2.2 Verify the contents of the package.

5.3.2.2.1 Make sure that the contents of the package include:

5.3.2.2.1.1 Continuing Review Application Form

5.3.2.2.1.1.1 Check for complete information and for the presence of the required signatures (investigator and the chairperson of IRB).

5.3.2.2.1.1.2 See the Continuing Review Application Form, ANNEX - AF/01-015/01.

5.3.2.3 Continuing Review Memorandum with progress report

5.3.2.3.1 Summarize the progress of the protocol since the time of the last review.

5.3.2.3.2 Include information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" answers on the application form

and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.

5.3.2.4 Current Informed Consent Document

5.3.2.4.1 - Ensure that the version of the informed consent document is the most recently approved informed consent document.

5.3.3 Photocopy the package.

5.3.3.1 Make sufficient copies (for both members and reviewers) of the original continuing review package in accordance with IRB SOP/ Procedures for Maintaining Confidentiality of IRB Documents.

5.3.4 Store the continuing review package.

5.3.4.1 Store the original package in the protocol specific file.

5.4 Notify the Members of the IRB.

5.4.1 Distribute the protocol progress report and the informed consent document to the IRB members.

5.5 Prepare meeting agenda.

5.5.1 See SOP/022/01 for procedures on the preparation of meeting agenda.

5.5.2 Place the review on the agenda for the meeting of the IRB which coincides with the first quarter of the study period or nearest next regular IRB scheduled meeting.

5.5.3 Distribute the materials to the IRB members by electronic mail (e-mail), or fax or by post, according to SOP/027/01 (Procedures for Maintaining Confidentiality of IRB Documents) at least one and a half to two weeks in advance of the scheduled meeting.

5.5.4 Keep copies of "sent" e-mail, fax cover memos and/or letter accompanying posted materials in the Correspondence Section of the protocol specific file.

5.5.5 Record and keep the IRB members' response upon receipt of the agenda in the member correspondence file.

5.6 Continuing Review Process

Continuing Review Application Form

5.6.1 Use the Continuing Review Application Form, ANNEX - AF/01-015/01 to guide the review and deliberation process.

5.6.2 If there are amendments or changes then "Review of Protocol Amendments" SOP/014 applies.

5.6.3 Sign and date the Continuing Review Application Form by the Chairperson of the IRB after a decision has been reached.

5.6.3.1 The completed Continuing Review Applications Form is the official record of the decision reached by the IRB for the protocol.

5.6.4 Maintain and keep the form and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.7 Communicate the decision to the investigator

5.7.1 Send the action letter to the Principal Investigator within *5 working days*

5.8 Store original documents.

5.8.1 Place the original completed documents with the other documents in the Continuing Review Package in the protocol file.

6 GLOSSARY

Approved Protocols	Protocols that have been *approved without stipulations* or *approved with recommendations* by the IRB may proceed. Protocols that have been *approved with stipulations* by the IRB may not proceed until the conditions set by the IRB in the decision have been met. Protocols shall be amended and submitted to the IRB within *one* month for re-review.

7 REFERENCES

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

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

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

7.4 Associated SOP/008/01, SOP/022/01 and SOP/027/01.

8 ANNEX

ANNEX1 AF/01-015/01 Continuing Review Application Form (2 pages)

ANNEX – 1
AF/01-015/01

Continuing Review Application Form

PROTOCOL No.:	PROTOCOL TITLE:
Principal Investigator:	Site……

Action Requested:
- ❑ Renew - New Participant Accrual To Continue
- ❑ Renew - Enrolled Participant Follow Up Only
- ❑ Terminate - Protocol Discontinued

Have There Been Any Amendments Since The Last Review?
- ❑ No
- ❑ Yes (Describe Briefly In Attached Narrative)

Summary of Protocol Participants:
- _____ Accrual Ceiling Set By IRB
- _____ New Participants Accrued Since Last Review
- _____ Total Participants Accrued since Protocol Began

Accrual Exclusions
- ❑ None
- ❑ Male
- ❑ Female
- ❑ Other (Specify: _____)

Impaired Participants
- ❑ None
- ❑ Physically
- ❑ Cognitively
- ❑ Both

Have There Been Any Changes In The Participant Population, Recruitment Or Selection Criteria Since The Last Review?
- ❑ No
- ❑ Yes (Explain Changes In Attached Narrative)

Have There Been Any Changes In The Informed Consent Process Or Documentation Since The Last Review?
- ❑ No
- ❑ Yes (Explain Changes In Attached Narrative)

Has Any Information Appeared In The Literature, Or Evolved From This Or Similar Research That Might Affect The IRB's Evaluation Of The Risk/Benefit Analysis Of Human Subjects Involved In This Protocol?
- ❑ No
- ❑ Yes (Discuss In The Attached Narrative)

Have Any Unexpected Complications Or Side Effects Been Noted Since Last Review?
- ❑ No
- ❑ Yes (Discuss In The Attached Narrative)

Have Any Participants Withdrawn From This Study Since The Last IRB Approval?
- ❑ No
- ❑ Yes (Discuss In The Attached Narrative)

Investigational New Drug/Device
☐ None ☐ Ind ☐ Ide
Dra No. ……..
Name: ……
Sponsor: ……
Holder: ……

Ionizing Radiation Use (X-Rays, Radioisotopes, Etc)
- ❑ None
- ❑ Medically Indicated Only

Have Any Participating Investigators Been Added Or Deleted Since Last Review?
- ❑ No
- ❑ Yes (Identify all changes in the attached narrative and submit the CV of the new investigator(s)

Have Any New Collaborating Sites (Institutions) Been Added Or Deleted Since The Last Review?
- ❑ No
- ❑ Yes (Identify All Changes And Provide An Explanation Of Changes In The Attached Narrative)

HAVE THERE BEEN ANY CHANGES IN SUPERVISOR / INVESTIGATOR? ❑ NONE ❑ DELETE:…… ❑ ADD: ……..	HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? ❑ NO ❑ YES (Append A Statement Of Disclosure)

SIGNATURES:

_____Date: ……

Protocol Chairperson (if applicable)

_____ Date: ……

INSTITUTE.... SUPERVISOR

_____ Date: ……

INSTITUTE.... Director

_____

(For use by IRB)

COMPLETION

_____ Date:……

Member Secretary, IRB

(For IRB use)

Complete the following section if there are no changes or amendments. If there are changes or amendments refer "Review of Protocol Amendments" SOP/013.

Member's Recommendation:

☐ Approved ☐ Approved with Recommendation

☐ Resubmission ☐ Disapproved

Comments, if any: .....

.....

FINAL DECISION of IRB:

A. By Chairperson

☐ Approved ☐ Approved with Recommendation

☐ Resubmission ☐ Disapproved

Comments, if any: .....

.....

B. By Full Board

☐ Approved ☐ Approved with Recommendation

☐ Resubmission ☐ Disapproved

Comments, if any: .....

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