CHAPTER 5.2

RESPONSE TO RESEARCH PARTICIPANTS' REQUEST

SOP NUMBER: SOP/018/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Effective Date: October 1, 2021 Supersedes: SOP/0017/yy 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 KGUMSB considers protection of the rights and welfare of the human subjects participating in a clinical investigation/research approved by the IRB as its primary responsibility. Therefore, the IRB should make sure that the Informed Consent documents reviewed by the IRB should contain the statement, "Questions regarding the rights of a participant/patient may be addressed to the IRB Chairperson" and should also make sure to provide with the contact name and phone number of the responsible official of the IRB.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant in any approved research study.

2. SCOPE

This SOP shall apply to all requests concerning the rights and well-being of the research participants participating in studies approved by the IRB.

3. RESPONSIBILITY

The KGUMSB's policy designates the Chairperson of the IRB as the person responsible for communicating with participants/patients regarding their rights as study participants. Delegation of this responsibility to another IRB member or IRB Member Secretary shall be acceptable as long as the delegation is documented (in writing). Delegation to non-IRB members shall not be permitted.

All Staff and IRB members acting on behalf of the IRB shall be responsible to facilitate participant/patient requests within the scope of their responsibilities.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the request ↓	IRB Members and Secretariat
2	Take action ↓	IRB Members and Chairperson
3	File the request document	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive the request.

5.1.1. The IRB secretariat or member shall receive the inquiry or request from research participants/patients.

5.1.2. Record the request and information in the request record form, ANNEX - AF/01-018/01

5.1.3. Refer the inquiry to the IRB Chairperson in writing.

5.1.4. The Chairperson shall:

5.1.4.1. document the communication for the IRB study file,

5.1.4.2. request follow-up information,

5.1.4.3. provide advice as required,

5.1.4.4. inform the other IRB members about the inquiry,
5.1.4.5. Follow-up at the next IRB meeting, or
5.1.4.6. Delegate these tasks to IRB Secretariat or members.

5.2. Take Action

5.2.1. Investigate the fact.
5.2.2. Record information and any action or follow-up taken in the form, ANNEX - AF/01-018/01
5.2.3. Sign and date the form.
5.2.4. Report to the IRB about the action taken and the outcomes.

5.3. File the request document

5.3.1. Keep the record form in the "response" file.
5.3.2. Keep a copy in the study file.
5.3.3. Store the file in the appropriately labelled shelf.

6. GLOSSARY

Participants' rights	Any study participants has the right not to participate in any study, withdraw at any point of time from the study and to receive standard care if she/he withdraws from a study.

7. ANNEX

ANNEX 1 AF/01-018/01 Request Record Form

8. REFERENCES

8.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
8.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.
8.3. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants, 2011.

ANNEX 1
AF/01-018/01

Request Record Form

Date Received:	
Received by :	
Request from :	❑ Telephone call No……... ❑ Fax No……..… ❑ Mailed letter / Date…… ……. ❑ E-mail / Date…… ❑ Walk-in / Date / Time…….. ❑ Other, specify …….
Participant's Name:	
Contact Address: Phone:	
Title of the Participating Study	
Starting date of participation:	
What is requested?	
Action taken: Outcome:	

Signature

_____
Member Secretary, IRB