CHAPTER 3.1

DETERMINATION OF RESEARCH QUALIFYING FOR EXEMPTION FROM ETHICS REVIEW

SOP NUMBER: SOP/007/01

INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Effective Date: October 1, 2021
Supersedes: SOP/007a/yy

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

Table of Contents

5. PURPOSE

The purpose of this SOP shall be to provide guidance to IRB to decide if the proposed study qualifies for exemption from ethics review under the requirements of the National Health Policy, 2011.

6. SCOPE

This SOP shall apply to decide if the proposed study qualifies for exemption from ethics review.

7. RESPONSIBILITY

The IRB Secretariat and Chairperson shall be responsible to decide if the proposed study qualifies for exemption from ethics review.

8. FLOW CHART

No.	Activity	Responsibility
1.	Determination. ↓	IRB Member-Secretary /Chairperson
2.	Exemption Letter ↓	Chairperson
3.	Communicate the review result to the investigator. ↓	IRB Member-Secretary
4.	Report the exemption during the IRB meeting ↓	IRB Member-Secretary
5.	Storage of the documents	IRB Member-Secretary

9. DETAILED INSTRUCTIONS

9.1. Determine protocols for exemption from ethics review.

9.1.1. IRB Member-Secretary/IRB Chairperson determines if the proposed study qualifies for exemption from ethics review with the help of checklist (*AF/01-007/01*). Following are the criteria for exemptions;

9.1.1.1. The study does not involve human subjects.
9.1.1.2. Research about public behaviour (voting trends, opinion surveys, etc.)
9.1.1.3. Program evaluation of public programs
9.1.1.4. Surveillance functions of KGUMSB/ Faculties/ Affiliated Institutes
9.1.1.5. Public health practices
9.1.1.6. Historical and cultural events
9.1.1.7. Research involving large statistical data without identifiers
9.1.1.8. Research involving educational methods remain exempt, but only if the research is not likely to adversely affect classroom instruction time or student performance.
9.1.1.9. Curriculum development and educational testing remains exempt as long as;
9.1.1.9.1. any recorded information is completely de-identified
9.1.1.9.2. any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm
9.1.1.10. Secondary research involving identifiable private information, if
9.1.1.10.1. the identifiable information is already available to the public

9.1.1.10.2. the information is not re-identified, and the researcher does not attempt to re-identify it

9.1.1.11. The use of non-identifiable bio-specimens in research does not, on its own, require ethics review.

9.2. If the proposed study doesn't qualify for exemption from ethics review, such study has to be reviewed by IRB for ethical clearance. Follow *SOP/008/01* MANAGEMENT OF PROTOCOL SUBMISSION.

9.3. Exemption Letter

9.3.1. If a proposed study qualifies for exemption from ethics review then an **exemption** letter duly signed by the Chairperson shall be sent to the applicant/ Investigator within two working days after receiving the application.

9.4. Communicate the review result to the investigator

9.4.1. The Secretariat shall prepare the exemption letter and send it with the duly filled checklist (*AF/01-007/01*) to the Chairperson.

9.4.2. The Chairperson shall approve the exemption by signing on the letter (*AF/01-007/01*).

9.4.3. The Secretariat shall send the letter to the investigator.

9.5. Report the Exemption to the full board

9.5.1. Report the list of studies that are granted exemption of ethical approval to the full board during the board meeting.

9.6. Storage of the document

9.6.1. The checklist and the related meeting minutes shall be kept with the protocol file.

9.6.2. The copy of the exemption letter shall be kept in the protocol file.

9.6.3. Store the file on an appropriate shelf in the designated cabinet.

10. GLOSSARY

Research	Research refers to a class of activity designed to develop or contribute to generalizable knowledge through a systematic investigation. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.
Research involving human subjects	Research involving human subjects includes: 1. Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or patients; 2. Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation; 3. Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures; 4. Studies concerning human health-related behaviour in a variety of circumstances and environments; 5. Research involving human subjects may employ either observation or physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other private information about individuals who may or may not be identifiable from the records or information; and

	6. Definition of "human subject" does not include the use of non-identifiable biospecimens.

7. REFERENCES

7.1. CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002
7.2. CIOMS, International Ethical Guidelines for Epidemiological Studies, 2009
7.3. The Office for Human Research Protections (OHRP). Human Subject Regulations Decision Charts. https://www.hhs.gov/ohrp/sites/default/files/full-2016-decision-charts.pdf)
7.4. Associated SOPs: SOP/008/01

8. Annex

8.1. ANNEX 1 *AF/01-007/01* Checklist to determine whether the research is a biomedical research involving human subjects
8.2. ANNEX 2 *AF/02/007/01* Exemption Letter Templates
8.3. ANNEX 3 *AF/03-007/01* APPLICATION FORM for Exemption

ANNEX 1
AF/01-007/01

Checklist to determine if a proposed protocol qualifies for exemption from ethics review

STEP 1: Does the proposed study involve human participants[1]?

☐Yes ☐ No

STEP 2: Does the proposed study fulfils the criteria for exemptions specified under SOP/007/03 (9.1.1.1 to 9.1.1.11[2])

☐ Yes ☐ No

STEP 3: Decision making;

1. If 'No' for STEP 1 then the proposed study doesn't require ethical clearance from IRB.
2. If 'Yes' for STEP 1 and 'Yes' for STEP 2 then the proposed study doesn't require ethical clearance from IRB.
3. If 'Yes' for STEP 1 and 'No' for STEP 2 then the study has to be reviewed by IRB.

Recommendation: ☐ Exempt ☐ the study has to be reviewed by IRB for Clearance

Name and signature of the Reviewer/IRB Secretary:

DECISION TO BE MADE BY THE CHAIRPERSON
Decision: ☐ Exempt ☐ the study has to be reviewed by IRB for Clearance

Name and signature of the Chairperson:

[1] Research involving human subjects includes:

1. Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or patients;
2. Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation;
3. Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures;
4. Studies concerning human health-related behaviour in a variety of circumstances and environments;
5. Research involving human subjects may employ either observation or physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information; and
6. Definition of "human subject" does not include the use of non-identifiable biospecimens.

[2] Following are the criteria for exemptions:

1. 9.1.1.1. The study does not involve human subjects.
2. 9.1.1.2. Research about public behaviour (voting trends, opinion surveys, etc.)
3. 9.1.1.3. Program evaluation of public programs
4. 9.1.1.4. Surveillance functions of KGUMSB/ Affiliated Institutes/ Ministry of Health
5. 9.1.1.5. Public health practices
6. 9.1.1.6. Historical and cultural events
7. 9.1.1.7. Research involving large statistical data without identifiers
8. 9.1.1.8. Research involving educational methods remain exempt, but only if the research is not likely to adversely affect classroom instruction time or student performance.
9. 9.1.1.9. Curriculum development and educational testing remains exempt as long as;
10. 9.1.1.9.1. any recorded information is completely de-identified
11. 9.1.1.9.2. any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm
12. 9.1.1.10. Secondary research involving identifiable private information, if
13. 9.1.1.10.1. the identifiable information is already available to the public
14. 9.1.1.10.2. the information is not re-identified, and the researcher does not attempt to re-identify it
15. 9.1.1.11. The use of non-identifiable biospecimens in research does not, on its own, require ethics review.

ANNEX 2
Form AF/02-007/01 Exemption Letter Template

གཞི་སར་རྒྱལ་པོ་གསོ་རིག་གཙུག་ལག་སློབ་སྡེ།།

Khesar Gyalpo University of Medical Sciences of Bhutan
Royal Government of Bhutan

Ref. No. IRB/ / / Date:

EXEMPTION LETTER

Protocol No: PN/ /
Protocol Title:
Version Number: "...", dated: DD/MM/YYYY
Principal Investigator:
Institute:
Co-Investigators:

This is to state that Research Review board of Health (IRB) has determined that the above protocol, submitted to IRB for ethical approval, qualify for exemption from ethics review based on the criteria specified in the Standard Operating Procedures (SOP) of IRB - SOP/007 DETERMINATION OF RESEARCH QUALIFYING FOR EXEMPTION FROM ETHICS REVIEW and application form AF/03-007/01 APPLICATION FORM for Exemption.

Therefore, the need for IRB approval is exempted for the protocol. Nonetheless, the investigator(s) shall be responsible to;

1. Seek all other clearances/approvals required by law/policy including permission from the study sites before conducting the study/project,
2. Submit Final Report of the study/project, at the end of the study/project, for review and protocol file closure.
3.

Note: Technical and ethical soundness of protocols are not assessed by IRB for the protocols that qualify for exemptions of IRB review.

( )
Chairperson

For further information please contact: *.....@kgumsb.edu.bt; IRB Member-Secretary*

ANNEX 3
Form AF/03-007/01

APPLICATION FORM for EXEMPTION

Instructions: This form has 8 items. Follow the item specific instructions and fill all applicable items from 2 through 8. (To mark "✓" the given options double click on the first half of the box "☐")

1.	Protocol Number (*Protocol Number will be assigned by IRB Secretariat*):
2.	Protocol Title:
3.	Protocol Version Number:
4.	PARTICULARS OF THE PRINCIPAL INVESTIGATOR (PI) Name: …….. Address: ..... Contact Number: ..... Fax: ..... E-mail: …….....
5.	Proponent of the study: …….....

6. CO-INVESTIGATOR(S)

Name and Institution	BMHC No.	Role in the study	Does s/he meet or will meet authorship criteria* (Yes/ No)	Contact Number
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

* The ICMJE recommends that authorship be based on the following 4 criteria:
1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

7.	Mark "✓" for the following sub-items 7.1 to 7.13 as appropriate 7.1. The study does not involve human subjects[3]. ☐Yes ☐ No Comments: ……

[3] Research involving human subjects includes:
1. Studies of a physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or patients;
2. Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation;
3. Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures;
4. Studies concerning human health-related behaviour in a variety of circumstances and environments;
5. Research involving human subjects may employ either observation or physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information; and
6. Definition of "human subject" does not include the use of non-identifiable biospecimens.

	7.2. Research is about public behaviour (voting trends, opinion surveys, etc.) ☐Yes ☐ No Comments: …… 7.3. The project is a program evaluation of public programs ☐Yes ☐ No Comments: …… 7.4. The project is a surveillance functions of KGUMSB/ Affiliated Institutes/ Ministry of Health ☐Yes ☐ No Comments: …… 7.5. The project is a public health practices ☐Yes ☐ No Comments: …… 7.6. The project is about historical and cultural events ☐Yes ☐ No Comments: …… 7.7. The project is a research involving large statistical data without identifiers ☐Yes ☐ No Comments: …… 7.8. The project is a research involving educational methods and the research is not likely to adversely affect classroom instruction time or student performance. ☐Yes ☐ No Comments: …… 7.9. The project is a curriculum development and educational testing and any recorded information is completely de-identified ☐Yes ☐ No Comments: …… 7.10. The project is a curriculum development and educational testing and any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm ☐Yes ☐ No Comments: …… 7.11. The project is a secondary research involving identifiable private information and the identifiable information is already available to the public, the information is not re-identified, and the researcher does not attempt to re-identify it ☐Yes ☐ No Comments: …… 7.12. The project is a research involving use of non-identifiable bio-specimens. ☐Yes ☐ No Comments: ……
8.	**SIGNATURES:** _____ Date: …….. Principal Investigator _____ Date:…… Protocol Chairperson (if applicable)