3.3. Exemption of Protocol Review

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3.3. Exemption of Protocol Review

1.Purpose

The SOP describes criteria for determination of which study protocols can be exempted from reviewand describe the process for exemption fromreview of a protocol.

2.Scope

This SOP applies to protocols which qualify the criteria for exemption from review. Any protocol that carries less than minimal risk and fulfills criteria for exemption from review is covered in this SOP.

3.Responsibility

It is the responsibility of the IRBchair-personto decide which study protocols should be exempted from review.

4.Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents.	IRB Secretariat
	↓	
2	Determine protocols for exemption.	Chairperson
	↓	
3	Exemption Process and Communication	IRB Secretariat/ Chairperson

5.Detailed instructions

5.1.Receive the submitted documents.

- Receive the application documents submitted by investigators.
- Get the initial review application form, EPHI-IRB AF-01/010/02.0 (see Annex 1 of SOP/007/02.0), to check items received.
- Stamp the receiving date on the letter and the documents.
- Sign the receiver's name on the receiving documents.
- Hand the received documents to the IRB secretariat

5.2. Determine protocols for exemption

IRBChairperson determines whether a study is qualified for exemption from review (EPHI-IRB AF 02-010/02.0) according to the following criteria:

- Project to be conducted in established or commonly accepted educational settings, involving normal educational practices.
- Project involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) surveys, interviews, or observation of public behavior, provided the study participants cannot be identified.
- Project involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or recorded without identifiers. Or if the information is recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the subjects.
- Evaluation or examination of government projects or programs designed to explore public benefit or service programs, procedures for obtaining benefits or services under those projects or programs, possible changes in or alternatives to those programs or procedures.
- Taste and food quality evaluation and consumer acceptance.
- Quality assurance activities.

5.3. ExemptionProcess and Communication

- The Chairperson will sign and date letter conveying the decision.
- The exemptionfrom review should not take longer than ten working days.
- The IRB Secretariat communicates the decision to the investigator.
- Inform the IRBof the proposals exempted from review at its regular meetings.

6.Glossary

Exempt from review	A review and decision process by the chairperson for projects with less than minimal risk and qualifies the criteria for exemption from review.
Project	Research or non-research investigations planned to be

executed with a specific objectives and time frame.

7.References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP)E6(R2), 2016.
3. FDRE Ministry of Science and Technology, National Research Ethics Review Guideline, 2014.
4. Amdur R and Bankert EA, Institutional Review Board: Member Handbook, Jones and Bartlett Publishers, Boston, Toronto, London and Singapore pp. 215, 2011.
5. Relevant SOP: EPHI-IRB SOP 007/02.0, EPHI-IRB SOP/026/02.0, EPHI-IRB 027/02.0.

8.Annex

3.3. Exemption of Protocol Review

Annex1: Exemption Assessment Form
(EPHI-IRB AF 01/009/02.0)

Protocol Title: ….....
Principal Investigator's name: ……..
Protocol number: ……..

Research activities involving human study participants in one or more of the following categories can be considered for exemption

- ☐ The research is conducted in established or commonly accepted educational settings
- ☐ The research specifically involves normal educational practices that are NOT likely to adversely impactstudents' opportunity to learn, required educational content or the assessment of educators who provideinstruction.
- ☐ Project involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or recorded without identifiers. Or if the information is recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the subjects
- ☐ Evaluation or examination of government projects or programs designed to explore public benefit or service programs, procedures for obtaining benefits or services under those projects or programs, possible changes in or alternatives to those programs or procedures
- ☐ Health systems research whereby public officials are interviewed in their official capacity on issues that are in the public domain
- ☐ Taste and food quality evaluation and consumer acceptancestudies
- ☐ Emergency conditions of national or regional importance, such as epidemics
- ☐ Quality assurance activities.

Assessor's (Chairperson) name: …….

Signature: ……..

Date: ……

3.3. Exemption of Protocol Review

Annex 2: Exemption Notification
(EPHI-IRB AF 02/009/02.0)

Protocol number:EPHI-IRB-☐☐☐-☐☐☐☐

Protocol Title:		
Investigators:		
Institute:		
Study site/s		
Exemption Assessment Form	☐ Attached	☐ Not attached
Exempted Protocol	☐ Attached	☐ Not attached

I. Elements approved:1. Protocol Version No.: ……

2. Protocol Version Date: …..…….….

3. Informed Consent Form Version No.: ……

4. Informed Consent Form Version Date: ……..……

II. Obligation of the PI:

1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs IRB approval
3. The PI should report unexpected SAEs & AEs within 48 hrs and 10 days after the event, respectively
4. End of the study, including final report, manuscripts and thesis works should be reported to the IRB

Decision date: ……..

Name of EPHI-IRB chairperson: …….
Signature: …….
Date**:** ……..

CC:
Director General Office
Other offices as appropriate
EPHI