	Salale University Institutional Research Ethics Review Committee (SIU-IRERC)		Document No: SIU-IRERC/SOP-002/01.0
	Preparation of Guidelines		Version No: 01
			Page 1 of 10 Effective date: 25/09/2024

Principle

The preparation of guidelines should be grounded in the principles of clarity, evidence-based reasoning, inclusivity, and practicality. It is essential that the guidelines are designed to be relevant, accessible, and actionable for their intended audience. The preparation of research ethics review guidelines should be guided by the following principles: evidence-based reasoning, clarity and precision, relevance, transparency, stakeholder involvement, flexibility, accountability, up-to-date and dynamic practices, equity and fairness, and sustainability.

Purpose

This procedure describes how to prepare a new guideline or update an existing one as well as the layout and format of each guideline.

Scope

This SOP applies to any SIU-IRERC guidelines and their amendment versions published and distributed by the institute.

The SIU-IRERC works according to internal rules that must be described in written standard operating procedures (SOPs). The SOPs are confidential but may be disclosed to authorities upon request. However, in order to maintain a transparent relationship with non-members of the SIU-IRERC, certain procedures will form guidelines for use by investigators, scientific experts and by the university personnel.

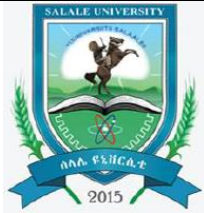
Responsibility

It is the responsibility of the SIU-IRERC delegate committee to prepare or amend the guidelines as and when required. The designated committee will manage the preparation/amendment of the guidelines with the assistance of the main SIU-IRERC.

Flow chart

Authority for Issue: Salale University Institutional Research Ethics Review Committee	Authorized date: DD, MM, YY
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Step	Activity	Responsibility
1	Numbering of Guidelines	SIU-IRERC Secretariat
2	Numbering of the Version	SIU-IRERC Secretariat
3	Contents and Layout of A Guideline	SIU-IRERC Secretariat
4	Approval of New and Updated Guidelines	SIU-IRERC Chairperson / Member
5	Information for Personnel	SIU-IRERC Members / Secretariat
6	Distribution of Guidelines	SIU-IRERC Secretariat

Detailed instructions

Provide the number of the guidelines

- Procedure SOP# SIU-IRERC 002/01.0 lists all procedures and guidelines used by the SIU-IRERC of the university.
- When a new guideline will be created, a subsequent number should be allocated at the end of the list of existing Guidelines.
- When a guideline is no longer used, its status is changed to “inactive”. It is not allowed to reuse the guideline number of an inactive guideline.
- All guidelines are named and numbered in the following way: Guideline (GL) 01 to GL 99

Provide the version of the guideline

- Number guideline versions as follows:
 - Draft versions:

All draft versions are always indicated as “version 1.0” followed by the word “draft”.

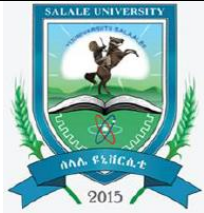
For example: Version 1.0, draft

- For minor changes on a final version:
Version V.0, final to Version V.n, final

For example, the third update concerning minor issues on “version 2.2, final” will be indicated as “version 2.3, final”.

- For major changes on a final version:

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Version V.n, final to Version (V+1).0, final

For example, major changes on “version 2.3, final” will be indicated as “version 3.0, final”.

Define contents and layout of a guideline

A new or updated guideline has four sections:

1. Cover page
2. Table of contents
3. Main text
4. References
5. Appendices

- Sections 1 to 4 are mandatory. The “Appendices” section is not mandatory.

Cover page

The cover page should contain the following information:

- Logo of the SIU, if any, university and related information (address, telephone number, fax number, email address).
- Title and number of the guideline date of implementation of the guideline
- Date of the previous issues. If not applicable, the date of pervious issue is indicated by “N/A” (= not applicable).
- Name (directory names and path included) of the corresponding computer document, if relevant.
- Name of the editors and address of the contact office.
- A copyright declaration.
- Refer to annex (SIU-IRERC 01-002/01.0) for an example of a cover page.

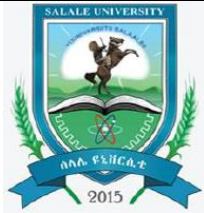
Table of contents

The table of contents lists all major headers and subheadings of the guideline, including the appendices and page numbers on which these appear in the guideline.

Main text

- **Introduction**

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- Summarize and explain the purpose of the guideline.
- A short note on how the guideline was prepared.
- A short note on how to use the guideline.

• **Detailed description**

- The final text should be short and clear.
- Long guidelines should be split into shorter ones.
- Wherever possible and relevant references should be added
- Limitation of the guidelines may be mentioned

Appendices

- Replace long and complex descriptions.
- “Descriptions-by-example” are always recommended to avoid writing difficult and hard to understand texts.
- Glossary
- Full form of abbreviations

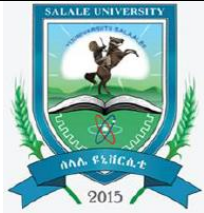
Approval of new and updated guidelines

- The members of the SIU-IRERC shall prepare a new guideline or update an existing guideline.
- The Chairperson of the SIU-IRERC and the president of the university should approve each new or updated guideline.
- The final version is the one to be implemented.

Communicate the new version guideline to the personnel

- All members of the SIU-IRERC must read and understand a new or updated guideline.
- Each member will sign a form indicating that they have read and understood each new or updated guideline.
- Refer to Annex 2 (SIU-IRERC 02-002/01.0) for an example.
- If the guideline is for investigators/students/institute personnel then they should be given a copy of the

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guideline after taking their signature.

Distribution of guidelines

- Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and SIU-IRERC members.
- A log of guideline distribution should be maintained for inventory records (Annex 3, SIU-IREC-03-002/01.0).

Glossary

Guideline: Any suggestion, rules, procedures intended as a guide for specific practice

Annex

Annex 1: SIU-IRERC 01-002/01.0: Cover page of a Guideline (2 pages)

Annex 2: SIU-IRERC 02-002/01.0:List of signatures

Annex 3: SIU-IRERC 03-002/01.0: Log of guideline distribution

References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Annex 1: SIU-IRERC-01-002/01.0: Cover page of a guideline

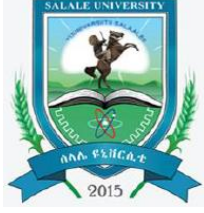
Guideline forSalaleUniversity Institutional Research Ethics Review Committee

Version No SIU-IRERC 01-002/01.0 (First edition)

Address:

Salale University Institutional Research Ethics Review Committee

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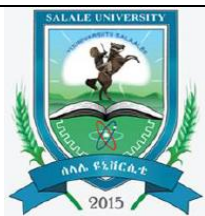
Email:

Information on the back of the cover page

- Number of copies printed
- Title of the guideline
- Number of Version
- Month/Year of publication
- ISBN:
- Author:
- Editor:
- Publisher:
- Computer record (Folder name and online link)

Annex 2: SIU-IRERC-02-002/01.0: List of signatures

Title of the guideline:



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Number of the Guideline: GL: _____

The following listed persons with their signatures have read this guideline.

No.	Full name of SIU-IRERC Member	Signature	Date

Annex 3: SIU-IRERC-03-002/01.0

Log of guideline distribution

Authority for Issue: Salale University Institutional Research Ethics
Review Committee

Authorized date: DD, MM, YY

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