SALALE UNIVERSITY

Institutional Research Ethics Review Guideline

SlU-IRER-Committee

SlU-IRERC	Nº. 002/01.0	Version No: 01	Effective date: 25/09/2024

Contents

ACRONYMS

AAUMFIRERC: Addis Ababa University Medical Faculty Institutional Research Ethics Review Committee

ABS: Access and Benefiting Sharing

AE: Adverse Event

AHRI: Armauer Hansen Research Institute

CAB: Community Advisory Board

CBD: Convention on Biological Diversity

CIOMS: Council for International Organization of Medical Sciences

COI: Conflict of Interest

CV: Curriculum Vitae

DACA: Drug Administration and Control Authority

DNA: Deoxyribonucleic Acid

DSMB: Data and Safety Monitoring Board

EC: Ethics Committee

EERB: Environment Ethical Review Boards

EFDA: Ethiopian Food and Drug Administration Authority

EgRERP: Engineering Research Ethical Review Board

EIAR: Ethiopian Institute of Agricultural Research

EPHA: Ethiopian Public Health Association

EPHI: Ethiopian Public Health Institute

ERC: Ethics Review Committee

ESTA: Ethiopian Science and Technology Agency

ESTC: Ethiopian Science and Technology Commission

EvRERB: Environmental Research Ethical Review Board

FDRE: Federal Democratic Republic of Ethiopia

FMHACA: Food Medicine and Health Care Administration and Control Authority

GCP: Good Clinical Practice

GDP: Gross Domestic Product

GMP: Good Manufacturing Practice

GNI: Gross National Income

HIE: Higher Education Institution

HRE: Health Research Ethics

HS&T: Health Science and Technology

IBC: Institutional Biosafety Committee

IoT: Institute of Technology

IRERC: Institutional Research Ethics Review Committee

LAR: Legally Authorized Representative

MoE: Ministry of Education

MoSHE: Ministry of Science and Higher Education

MoST: Ministry of Science and Technology

MTA: Materials Transfer Agreement

NRERB: National Research Ethics Review Board

NGO: Non-Governmental Organization

SlU-IRERC: Salale University Institutional Research Ethics Review

PI: Principal Investigator

S&T: Science & Technology

SAE: Serious Adverse Event

SOP: Standard Operating Procedures

TOR: Terms of Reference

UK: United Kingdom

UN: United Nations

UNISA: University of South Africa

WHO: World Health Organization

ACKNOWLEDGEMENTS

We would like to express our deepest gratitude to Salale University for its unwavering support and provision of all the necessary assistances including logistics and accommodations throughout the process of developing the Salale University Institutional Research Ethics Review Guideline. The University's commitment to academic excellence and ethical research practices has been instrumental in making this initiative a success.

In this regard, special thank go to Dr. GenanewGofe, President of Salale University, and Dr. TsegayeDeyou, Vice President for Academic and Research, for their leadership and encouragement throughout this process.

As the Chairperson of the SlU-IRERC, I would like to express my sincere appreciation to the dedicated members of the committee for their tireless efforts in reviewing, contextualizing, and adapting the National Research Ethics Technical Guideline, along with various international research ethics standards, to suit the unique needs and context of Salale University. Your professionalism, critical insights, and collaborative spirit have laid a strong foundation for ethically grounded research practices at our institution.

We are also grateful to the Ministry of Education (MoE) for providing the adaptable National Research Ethics Guideline, which served as a vital reference in our institutional adaptation process. The Ministry also deserves special acknowledgment for the continuous training and capacity-building efforts extended to the SlU-IRERC. These efforts have significantly enhanced our understanding of research ethics and our ability to institutionalize them effectively.

Finally, we acknowledge the contributions of all stakeholders who, in one way or another, supported this endeavor. Your commitment to fostering an ethical research environment at Salale University is deeply appreciated.

SECTION 1: INTRODUCTION

Salale University (SlU) is a comprehensive public university established in 2015, located in Fiche town, North Shewa Zone, Oromia Regional State, Ethiopia. Currently, the university offers 43 undergraduate and 33 postgraduate academic programs, both in regular and extension modes, organized under six colleges and one school:

1. College of Natural Sciences
2. College of Agriculture and Natural Resources
3. College of Health Sciences
4. College of Social Sciences and Humanities
5. College of Business and Economics
6. College of Engineering and Technology
7. School of Law

With the support of its dedicated staff, Salale University strives to conduct impactful research addressing national priorities, benefiting the local community, and contributing to the country's economic development. The institution emphasizes solving community problems through research and services in various sectors, including health, environment, agriculture, engineering, and technology. Its overarching goal is to foster innovation, knowledge creation, and community advancement while actively participating in local, national, and global economies.

To achieve these goals, Salale University is committed to adhering to ethical standards in all its research and community service endeavors.

As a key stakeholder institution, Salale University established the SlU Institutional Research Ethics Review Committee (SlU-IRERC) three years ago, in line with directives from the former Federal Democratic Republic of Ethiopia Ministry of Science and Higher Education (FDRE-MoSHE), now the Ministry of Education (FDRE-MoE). The primary objective of SlU-IRERC is to ensure a balance between research and community service activities and the welfare of the surrounding community.

To actively contribute to the university's mission, the SlU-IRERC is presenting working guideline. This guideline aligns with the National Research Ethics Review Technical Guideline (2022) of the FDRE-Ministry of Education and focuses on supporting ethical research practices and appropriate community services. In doing so it helpundertakes research related activities to help the university achieve its vision and mission.

1.2 Mission, Vision, Core Values, and Motto

1.2.1. Mission

- To provide quality education that produces competent, ethical, and innovative graduates across diversified fields/programs,
- Conduct problem-solving research,
- Promote technology transfer, and
- Deliver demand-driven community engagement.

1.2.2. Vision

- Aspire to be a leading comprehensive university in Ethiopia by 2030.

1.2.3. Motto

- Co-creating Quality

1.2.4. Core Values

- Quality
- Diversity
- Innovation
- Collaborative/Team Spirit
- Professionalism
- Transparency and Accountability

1.2.5. Focus Areas

1. Agriculture and Natural Resources
2. Health and Medical Sciences
3. Natural Science and Computing
4. Social and Business
5. Engineering and Technology

1.3. Purpose

- Reviews scientific validity and ethical acceptability of research project proposals

- Ensures the safety and benefits of humans, animals, Plants and the environment while conducting research via applying ethical procedures and principles.
- Advise University management, staff and students, as appropriate, on all matters pertaining to the research ethics and scientific conduct.
- Issue guidelines and codes of practice, where appropriate on any matter pertaining to research ethics and scientific conduct.
- Monitor and audit the implementation of policy, procedures, guidelines and codes of practice related to scientific integrity and research ethics across the University.
- Recommend the necessary administrative arrangements for operating the policies and procedures of research ethics.
- Form and delegated research and ethical committees at each college if necessary.
- Approve the terms of reference and guideline prepared and membership of delegated committees at college levels.
- Act as an appeal body for delegated committees at college level.
- Monitor the activities of delegated committees at college level.
- Communicate with National and other external research ethics committees.
- Plan, review and present an annual report on the activities conducted to the University research Vice-president for Academics and research.
- Raise awareness of scientific research integrity and ethics amongst staff and students across the University.

1.4. Shorttitle

- ThisguidelinemaybecitedasSalaleUniversity Institutional Research Review Guideline, 2025

1.5.Definitions

In thisguideline,unless the contextrequiresotherwise:

1. **University: Means Salale University**
2. **Ministry:**meansMinisterof Education;
3. **Research:**meansanysystematicinvestigationdesignedtodeveloporcontribute to generalizable knowledge, skill and attitudes.
4. **ResearchEthics:** means moral principles that guide researchers to conduct and reportresearchwithoutdeceptionorintentiontoharmtheparticipantsofthestudy or members of the society as a whole, whether knowingly or unknowingly.
5. **Ethicsreviewinresearch**:meanstheprocessofassessing and examining theethicsofresearch

involving research subjects timely and in compliance with the guideline.

6. **National Research Ethics Review Board (NRERB)**: means the ethics review committeeestablishedundertheMinistryofEducation(MoE)andmandatedto conduct ethical reviews at the national level.
7. **SalaleUniversity Institutional Research Ethics Review Committee (SlU-IRERC)** means an independent committees established atSalaleuniversity to conduct initial and continuing review of research projects with the primary goal of protecting the rights, safety and welfare of research participants.
8. **Researcher**:meansapersonor an individual who isableandresponsibletocarryoutacademicor scientific research in different discipline.
9. **Institute:**meanslegalorganizationsthatareassignedtoperformresearchand publish the result in reputable journals.
10. **Protocol:**means the formal design or plan of a data collection activity; specifically, the plan submitted to a reviewing authority such asSlU-IRERC. The protocol includes a description of the design or methods for conducting the data gathering, description of the study population, methods for data handling and analysis, procedures for handling incidents, and methods for notification and dissemination of results.
11. **Community**: means a group of people living in the particular place or having a particular characteristic in common.
12. **Research conducted on animals** means research conducted on animals after verifying that the results of the research has benefit for society.

1.6.Objectives

General objective

The general objective of this guideline is to set a framework that ensures the safety and benefits of humans, animals, Plants, engineering and technology, and the environment while conducting research via applying ethical procedures and principles.

SpecificObjectives:

- To undergo research ethics activities and review systems with sense of accountability and loyalty, and
- Tosafeguardthecommunityfromeconomic,cultural,andsocialinfluencesdueto lack of ethical compliances

1.7.IssuingAuthority

- Based on the powers vested in it under Article Proclamation No.1152/2019, the SalaleUniversity has issued this guideline.

1.8.ScopeofApplication

- ThisSalale University research ethics guideline is applicable to all types of research that involves human as well as animal, plant, science, technology and engineering fields, environment. The guideline is applicable in research proposed to be conducted by Salale university's staff, students, and affiliated researches. Theseinclude,butarenotlimitedto,public,privateandnon- governmental organizations (NGOs), bilateral, multilateral, and United Nations'agencies.

SECTION 2:*ETHICALPRINCIPLES*

2.1. Fundamental Principles of Research Ethics

2.1.1. Respect for Persons (Autonomy)

- **Informed Consent**: Participants must be fully informed about the nature, purpose, risks, and benefits of the research and must voluntarily agree to participate.
- **Privacy and Confidentiality**: Protect the identity and personal information of participants.
- **Right to Withdraw**: Participants can withdraw at any time without penalty.

*2.1.1.*2. Beneficence

- **Do No Harm**: Minimize the risk of harm (physical, psychological, social, or legal).
- **Maximize Benefits**: Ensure the research contributes to the well-being of participants and society.
- **Risk-Benefit Assessment**: Evaluate whether the benefits of the research outweigh the risks.

2.1.1.3. Justice

- **Fair Participant Selection**: Ensure equitable recruitment across different groups. Avoid exploiting vulnerable populations.
- **Equal Access to Benefits**: Ensure that all populations benefit fairly from the outcomes of the research.
- **Avoid Discrimination**: Do not exclude or include individuals unfairly.

*2.1.1.*4. Integrity and Honesty

- **Truthful Reporting**: Report data accurately without fabrication, falsification, or misrepresentation.
- **Transparency**: Disclose funding sources, conflicts of interest, and research purpose.

- **Plagiarism**: Avoid copying others' work without proper attribution.

*2.1.1.*5. Accountability and Responsibility

- **Researcher Accountability**: Take full responsibility for the ethical conduct of the research.
- **Compliance with Laws and Guidelines**: Follow national and institutional ethical guidelines and obtain necessary approvals (e.g., from an ethics committee).
- **Data Management**: Store, analyze, and dispose of data responsibly and securely.

*2.1.1.*6. Respect for Communities

- **Community Engagement**: Involve communities in the design and implementation of research, especially in cross-cultural or indigenous contexts.
- **Cultural Sensitivity**: Respect local customs, norms, and values.
- **Benefit Sharing**: Ensure findings benefit the community where the research was conducted.

In preparing a research proposal or ethics application, these principles should be clearly reflected in researchers:

- Informed consent and assent forms
- Methodology
- Risk assessment
- Data handling procedures
- Dissemination plan

2.2. Human

High ethical standards in human health research can be achieved only when investigators aspire to high ethical standards in their research activities. To safeguard the rights, safety and welfare of human subjects in research, SlU-IRERC shall promote three basic ethical principles: 1) respect for persons 2) beneficence/non-maleficence 3) justice 4)Integrity and Honesty and 5) Respect for Community. In general, SlU-IRERC shall ensure that investigators have thought of ethical issues, specifically that a minimized harm shall be done while the research is executed. However, in certain circumstances, the weight given to each of these three basic ethical principles may differ in accordance with the type of the research and the setting where the research is conducted. Nevertheless, SlU-IRERC should ensure that the following basic ethics principles are met.

2.2.1. RespectforPersons

Out of respect, participants must be informed about the research and allowed to decide about participation. Research participants unable to make decisions independently deserve extra protection.

2.2.2. Autonomy

This principle aspires to protect the interests of human research participants from physical, psychological, and cultural harm. It refers to the obligation on the part of the investigator to respect each research participant as a person capable of making an informed decision regarding participation in the research. It obligates investigators to respect the rights ofhuman subjects to hold their views, make choices and take actions without controlling influences. For human subjects who are not capable of making an informed decision because of age, mental, or medical capacity, the next of kin or guardian shall make the decision in the best interest of the research participant.

2.2.3. InformedConsent

The importance of informed consent of research participants is unquestionable and the informed consent should be analyzed for content in terms of the basic elements of information, comprehension, competence, disclosure, and voluntarism. Information shall be giveninwritingandsignedorverballyapprovedbytheresearchparticipant.Theinformationto be provided should be written or verbal in a way that considers the local culture and values, as well as the level of understanding of the research participant. The information provided should weigh theresearch participants' competence. When informedconsent is sought froma third party (proxy; parent, next-of-kin, or legally authorized representative (LAR)), the reasons for the indirect approach shall be stated and become part of the protocol.

Research participants or persons giving proxy consent cannot give full informed consent unless the consent process/form contains adequate information. All such information shall be expressed in a language that is understandable to the participant or proxy.

2.2.4. Beneficence/Non-maleficence

The principle of beneficence refers to the obligation on the part of the investigator to attempt to maximize benefits for the individual participant and/or community, while minimizing risk or harm to the individual/community. As much as possible, beneficence also considers inflicting

no harm and removing harm. An honest and thorough risk/benefit assessment must be performed. Balancing the risk and benefit of the research is indispensable in the designand conduct of the research.

Risk is the probability and magnitude of some future occurrence of harm. Harm is injury and setback to interests as a result of being a research participant. Risks and harm can be known or presumed. Although no specific regulations exist, risks and harms may include physical, psychological, emotional, economic, educational, legal and social.

In addition, beneficence includes whether the usual care is changed or manipulated to inflict noharm, minimize harm,remove harm, andmaximize the benefittoresearchparticipantsand to the community, or both.

Researchers should always abide by non-maleficence and no intentional harm should be inflicted on participants.

2.2.5. Justice

Justiceconnotes fairness and equityin the distribution of the benefits and burdens of research to participants. Justice demands equitable selection of participants, particularly with populations that may be unfairly coerced into participating, including but not limited to, prisoners, pregnant women, fetuses, newborns, children, people with mental and physical disabilities,immigrants, refugees, small ethnicgroups, marginalized groupsandinstitutionalizedpersons. There must be a justificationforinclusionof thesevulnerable groupsinthe research. There should be no disproportionate use of vulnerable populations. The same recruitment approach should be used in all populations. Injustice may arise when selecting participants from a specific socio-economic class, age, sex, racial, cultural, religious, creed, and institutional make up.

The principle of justice requires equality in the distribution of benefits and burdens amongthe population groups likely to benefit from the research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes obligations toward individuals who are vulnerable and unable to protect their own interests. Conversely, distributive justice imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.

Justicealsodemandsbalancingthebenefitsandburdenstothe communitywherethe research is undertaken.

In addition, investigators shall assure that information obtained during investigations remains confidential to protect participants from possible harm. Data unlinked from individuals or groups does not jeopardize confidentiality. The privacy of individual participants also needs to

be protected throughout the investigation by the investigators.

2.3.Animal

Animals (be it laboratory, domestic or wild) deserve respect when used for research and specific ethical principles like respect for life, societal benefit and non-maleficence are applied. Even before using animals for research, there are five freedoms that animals have to experience.These are freedomfromhunger or thirst,freedomfromdiscomfort,freedomfrom pain, injury or disease, freedom to express normal behavior and freedom from fear and distress.

Since 1950, researchers conducting studies on animals are advised to follow the three Rs research ethics principles that include:

- **Replacement**:replacingexperimentsonanimalswithalternative techniques.
- **Reduction:**minimizingthenumberof animalsneededtoperform anexperimentorteach a concept.
- **Refinement:** refining experimental protocols to minimize pain or distress in the animal under experiment.

These principles are fair enough and are consistent with ethical principles to guide investigatorstominimizeuseof animalsandminimizepainanddistresscausedinperforming experiments.

2.3.1 Respectforanimals'dignityandtheirgeneticresources

Researchers must have respect for animals regardless of their utility value, and for animals' interestsasliving,sentientcreatures.Researchers shouldbeconcernedabouttheconservation and sustainable utilization of the genetic resources and benefit of the farming communitywho conserved the biodiversity. Researchers must be respectful of as‘dignitywhen choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

Generally this principle requires that animals used in research should be of an appropriate species and health status and should involve the minimum number required to obtain valid scientific results.It also recognizes that the use of different species may raise differentethical concerns.

2.3.2. Responsibilityforconsideringoptions(Replace)

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritized if the same knowledge can be acquired without

using laboratory animals. If no good options are available, researchers should consider whether the research can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

2.3.3. Theprincipleof proportionality

Responsibilities for considering and balancing suffer and benefit. Researchers mustconsider the risk that animals experience pain and other suffering and assess them in relation to the value of the research for animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiatedandspecifiedinboththeshortandthelongterm.Theresponsibilityalsoentailsan obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits. Access to animal genetic resources and the fair and equitable sharing of the benefits arising from their utilization is one of the objectives of the Convention on Biological Diversity (CBD). Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment.

There are many different methods for analyzing harm and benefit. Research institutions should provide trainingon suitable models/methods, and researchers are responsible forusing such methods of analysis when planning experiments on animals.

2.3.4. Responsibilityforconsideringreducingthenumberofanimals (Reduce)

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the experiments and the relevance of the results. This means, among other things,researchers must conduct literature studies, consider alternative experimental designs and perform design calculations (sample size) before beginning experiments.

2.3.5. Responsibility for minimizing the risk

Researchers are responsible for assessing the expected effect of research undertakings on laboratoryanimals. Researchers must minimize the risk of sufferingand provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally.

A researcher's assessment of what is considered acceptable suffering should be based on knowledge of the animals under consideration; if there are doubts regarding any perceived

suffering, re-designing the planned studies with alternative methods is recommended.

Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetizing, breeding, transportation, stabling and euthanizing. This means that researchers must also take account of the need for periods of adaptation beforeand after the experiment.

2.3.6. Responsibilityformaintainingbiological diversity

Researchers are responsible for ensuring that the use of laboratory animals and their genetic resource does not endanger biological diversity. This means that researchers must considerthe consequences to the stock and to the ecosystem. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain, knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem, researchers must observe the precautionary principle.

2.3.7. Responsibility when intervening in natural habitat

Researchersare responsiblefor reducingdisruption and anyimpact on thenatural behaviorof individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and theirliving conditions, forexamplebecause of installingradarmasts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality and minimize the possible negative impact.

2.3.8. Responsibilityforopennessandsharingofdataandmaterial

Researchers are responsible for ensuring that there is transparency about research findingsand facilitating the sharing of data and material from experiments on animals and genetic resources. Such transparency and sharing are important to avoid unnecessary repetition of experiments. Transparencyis also important to ensure that thepublic areinformed and is part of researchers' responsibility for dissemination.

In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of

animals in research.

2.3.8. Requirementforexpertiseonanimalsandtheirgeneticresources

Researchers and other parties who handle live animals and their genetic resources must have adequatelyupdatedanddocumentedexpertiseonanimalsandtheirgeneticresources.Thisincludes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

- **Requirementofduecare**

There arenational laws and rules and international conventions and agreements regardingthe use of laboratory animals, and their genetic material that both researchers and research managers must comply with. Any person who plans to use animals in experiments must familiarize themselves with the current rules (this guideline).

- **SocietalBenefit**

This principle entails that where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal good, the populations affected, and the burdens that are expected to be borne by the subjects of the research. In addition, the obligations related to accessing genetic resources include the fair and equitable sharing of benefits arising out of genetic resources, as well as compliance with prior informed consent and mutually agreed terms.

- **Non-maleficence**

This principle entails that the minimization of distress, pain, and suffering is a moral imperative.Unless the contrary is established, investigators should consider that any procedures that can cause pain or distress in humans may cause pain or distress in other sentient animals.

2.4.Plant

High ethical standards in Plant research can be only achieved when investigators aspire to such standards in their research activities. For the conservation and sustainable utilization of Plant in research in general, SlU-IRERC shall ensure that investigators have thought of ethical issues, specifically that no harm will be done and no damage of the genetic resources in the name of research, regardless of the research question planned for exploration. However, in certain circumstances, the weight given to each of these three basic ethical principles may differ in

accordance with the type of the research and the setting where the research is conducted. Nevertheless, the SlU-IRERC should ensure that the following basic ethics principles are met:

- **Properdeploymentofgenetic materials**

The research activities should always be in line with the conservation and sustainable utilization of the genetic resources. Besides, the researcher should respect the benefit of the farming community who conserved the biodiversity to be used in the research activities and should provide benefits for society after the research activities completed. Respecting the Plant and microbial genetic resources should be an integral and important part of the researchers since all the agricultural activities and society is highly dependent on this resource.

- **Benefit sharing**

Access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization is one of the three objectives of the Convention on Biological Diversity (CBD, 2024).Nagoya Protocol(2014) on Access to Genetic Resources and the Fair and Equitable Sharingof Benefits Arising from their Utilization. This agreement created a framework that balances access to genetic resources, including those related to traditional knowledge of indigenousand local communities, on the basis of prior informed consent and mutually agreed terms, with the fair and equitable sharing of benefits, thereby contributing to the conservation and sustainable use of biodiversity.

TheNagoyaProtocol is thefirst international instrument ofparticularrelevanceto indigenous and local communities negotiated since the adoption of the UN Declaration on the rights of indigenous peoples. As such it is a significant step in mainstreaming indigenous rights as a cross-cutting issue in international negotiations.

- **Justice**

Justice connotesfairness and equityin thedistribution ofthebenefits and burdens of research to the farming community.

At the core of the Nagoya Protocol(2014) are obligations related to access to genetic resources, the fair and equitable sharing of benefits arising out of genetic resources, as well as compliance with prior informed consent and mutually agreed terms.

The principle of justice requires equality in the distribution of benefits and burdens amongthe population groups likely to benefit from the research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests. Conversely, distributive justice imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Justicealso demands balancingthe benefits and burdens to thecommunitywhere the research is undertaken.

In addition, the investigators shall assure that information obtained in the course of the investigation remains confidential to protect participants from possible harm. Data unlinked from individuals or groups does not jeopardize confidentiality. The privacy of individual participants also needs to be protected throughout the investigation by the investigators.

4.5. Environment

The living and non-living things around us that make up the environment continuously challenge human duties and responsibilities in avoiding major problems which affect communities. There should be ethical principles while conducting research in theenvironment so that werespect the well-being of the natural world. Of these basic ethical principles, the major ones are: justice and sustainability; sufficiency and compassion; solidarity and participation.

Some of the guiding principles of environmental ethics that govern the attitude and behavior of human beings in their interaction with the environment are non-maleficence, noninterference, fidelity, and justice. In conducting research in the environment, basic precautionary principles have to be adhered in order to avoid harm to the environment and prevent environmental degradation. These principles are termed as movement, minimization, maximization and modification.

2.5.1. Guiding Principles

Theseguidingprinciplesofenvironmentalethicsthatgoverntheattitudeandbehaviorof human beings in their interaction with the environment are stated below:

- **Non-maleficence**

The principle of no harm (non-maleficence) states that no harm be done to the environment; and humans should not destroy species or biotic communities.

- **Noninterference**

The principle of no interference (noninterference) states that barriers should not be imposed on the freedom of organisms, namely freedom to find food, shelter, and breeding.

- **Fidelity**

The principle of loyalty (fidelity) states that living things should not be trapped, deceived, or obstacles set against them only for the sake of human interests.

- **Justice**

The principle of justice states that people should restore what we have damaged or make compensation.

2.5.2. PrecautionaryPrinciples

The precautionary principle states that research activities which may lead to morally unacceptable harm to the environment, and which are scientifically plausible but uncertain, should lead to actions that avoid or prevent environmental degradation. Morallyunacceptable harm refers to harm to humans, other living things, or to the environment that is threatening human life or health or leads to serious and effectively irreversible or inequitable impacts on the present or future generations of those affected. The _Precautionary Principle‘ should constrain all environmental research, and that within these limitations the researcher should design experiments according to four maxims:

- **Movement:** This refers to a preference for locating experimental sites away from environmentally sensitive areas or to the use of non-invasive techniques such as computer modeling.

- **Minimization:** which refers to a preference for experiments with fewer observations where statistical significance can still be preserved.
- **Modification:** This refers to a preference for experiments that have been adapted to minimize impact on ecosystems.
- **Maximizing:**whichrefers topreference forexperimentswherethe scientific outputis as significant as possible.

2.6.Engineeringand technology

Inadditiontothegeneralethicalprinciplesthatholdstrueforhealthresearchethics, engineering research is required to maintain and promote the following ethical standards:

- **Accuracyand rigor**

Researchers should ensure that they acquire and use the knowledge that is relevant to the engineering skills needed. They should not knowingly mislead or allow others to be misled about engineering matters. They should also identify and evaluate and, where possible, quantify risks.

- **Honesty and Integrity**

Researchers should be alert to the ways in which their work might affect others and duly respect the rights and reputations of other parties. Theyshould also avoid deceptive acts, take

steps to prevent corrupt practices or misconduct, and declare conflicts of interest.

- **Respectfor life,lawandthe publicgood**

The research should give due weight to all relevant law, facts and published guidance, andthe wider public interest. They should ensure that all work is lawful and justified, with minimal adverse effect on societyorthenatural environment. The researchersshould actively promote public awareness and understanding of the impact and benefits of engineering achievements.

SECTION 3:ORGANIZATIONAL STRUCTURE AND MANDATES

3.1. OrganizationalStructure

The SalaleUniversity, as part of its mandate in regulating research ethics at national level, oversees research activities to be carried out in accordance with ethical procedures and with the highest priority to maintaining high standards of integrity, responsibility, and accountabilityin all research conducted in Ethiopia. In addition, there is a need to ensure existence of proper ethics review mechanisms for networking and cooperation among national, regional, continental, and global institutions. Therefore, there is a need to establish an organizational structure, where this research ethics guideline is properly implemented both at national and institutional levels.Todeliverresearch ethicsreviewservices effectivelyandefficiently,functionalandstructural arrangements are necessary at the national and institutional levels in conformity with the organizational shown below (Figure 1).

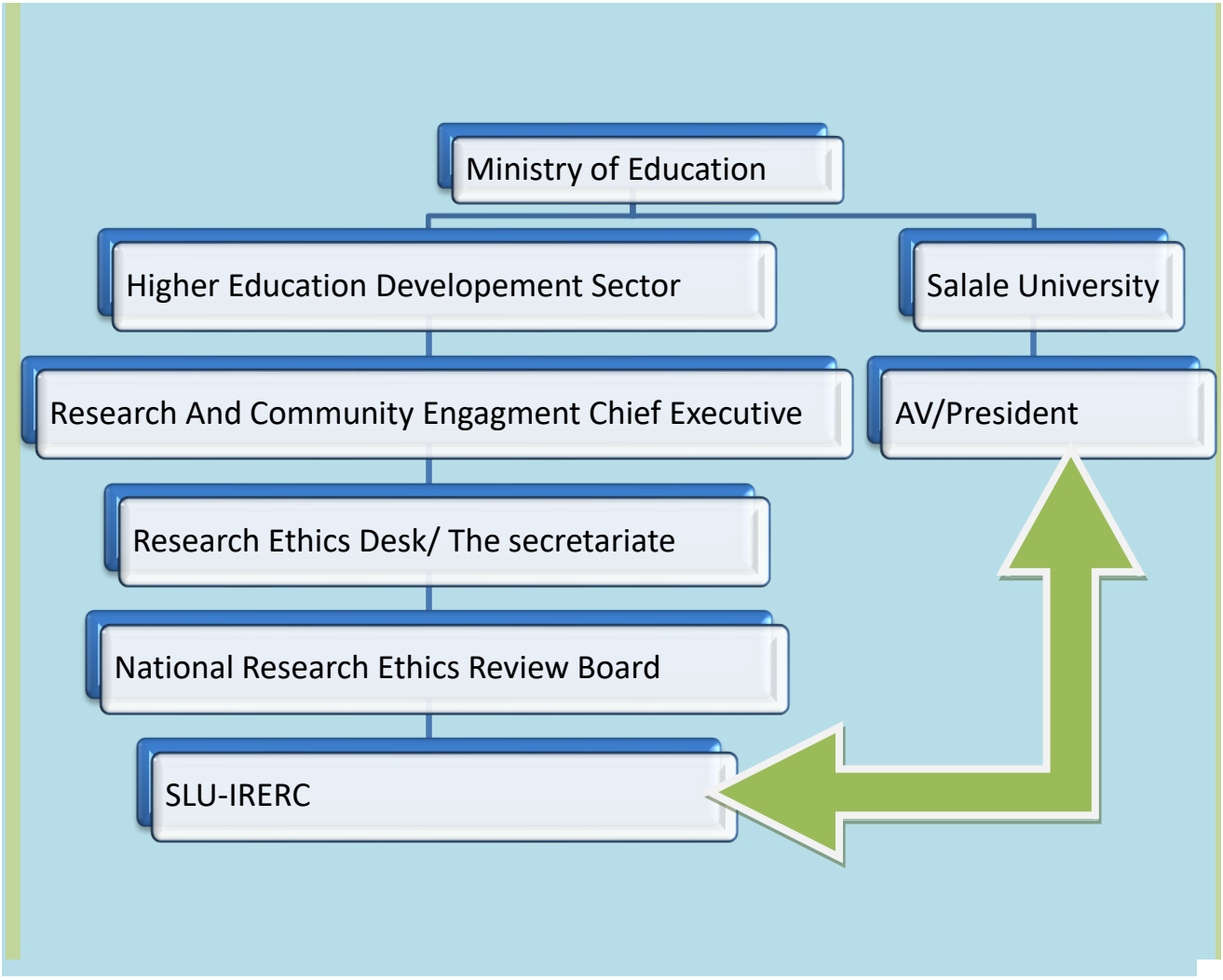

Figure 1.OrganizationalStructureof theSlU-IRERC

3.1.1SlU-IRERC-Chair person

TheSlU-IRERC-Chairpersonwillhavethefollowing responsibilities

- Overseepropercompletenessofresearchethicsreview activitiesat university level;
- Guide and properly follow works of the Research Ethics Desk are completed asper the plan;
- Checkwhether researchethicsprotocolapplicationsatuniversitylevelandunder the Secretariat as well as the SlU-IRERC are performed properly and timely;
- Network the University's IRERC professional activities with college as well as others research collaborators;
- Coordinate researchethics capacitybuilding programsat university level

3.1.2. TheSlU-IRERC

- The main role of the SlU- IRERC is to review and approves research protocols that are submitted to it from the research staff, students and affiliated stakeholders of the SalaleUniversity. In doing so, it safeguard the dignity, rights, safety, and welfare of actual or potential research participants and/or communities.

The SlU-IRERC will establish the following panels when appropriate:

- Human Health Research Ethics Review Panel,
- Animal Research Ethics Review Panel,
- Plant Research Ethics Review Panel,
- Environmental Research Ethics Review Panel, and
- Engineering Research Ethics Review Panel.

3.1.3. Mandatesandfunctionsof SlU-IRERC

3.1.5. SlU-IRERC

The SlU-IRERC is established under the Salale University and it is in charge of reviewing specific tasks as per the mandates shownbelowin this guideline.Allthe research the Salale universityconductinvolvinghumans,animalsandotheraspects of life and environment should governed in accordance with this guideline. The Salale University has the authority responsible for the appointment ofSlU- IRERC members.

Members are selected in their personal capacities based on their scientific knowledge and expertise, as well as on their commitment and willingness to dedicate the necessary time and effortsfortheCommittee‘sfunction.Besides,appointmentsshouldconsider,age,gender,and professional mixes. The appointment letter should indicate the term of service.Members will sign a confidentiality agreement and conflict of interest (CoI) form.At Salale University, the IRERCs ismandated for/expectedto:

- Ethicaldecisionsonexperimentalresearchactivitiesthatdonotinvolvematerials transfer;
- Referringofemergency/humanitariancrisisresearchprojectsthatareofnational interest and priority;
- DevelopsSOPsand guideline thatgoverntheIRERC‘sresearch reviewprocedures;
- Reviewofr e s e a r c h protocolsthat involve minimal riskandaboveminimal risk;
- SubmittingprogressreportstotheNRERB;
- Conducting joint ethical review with the NRERB on specific research activities thatrequire joint decisions and
- Solicitingfundsto buildits capacity.

3.1.6. Composition and Terms of the SlU-IRERC andSlU-

3.1.6.1. IRERC Composition

- The SlU-IRERC shall have members with professional competence and mix of varying backgrounds from human, animal, plant, microbiology, environment, engineering, and social science fields; gender representation, balanced age, a community representative, and have research ethics training and experience.
- Thenumber of SlU-IRERC members shall be from 11-15
- The SlU-IRERC shall have onecommunityrepresentative,whodoes not necessarilyhaveto have any scientific expertise but who could represent the interests and concerns of members of the community and is familiar with the community‘s values, customs, traditions, and culture.
- If SlU-IRERC regularly reviews research that involves vulnerable populations, or which requires special expertise, the SlU-IRERC shall in ad hoc arrangements involve or co-opt one or more individuals who are knowledgeable about and experienced in working with these research participants of such nature.
- The SlU-IRERC members, including the community representative, should at a minimum take one basic training on research ethics within one year of appointment.
- The chairperson and vice-chair shall be elected by the members through a process of nominationsandvotingbyasecretballotmechanism. Inthe absenceofthechairperson,the vice-chair shall lead the SlU-IRERC meeting.
- Whenthechairpersondecidestostepdown,he/sheshouldinformthe Salale Universityinwritingat least one month in advance.
- Membership becomes effective upon accepting an invitation from the appointing authority, the Salale University.Acceptance must be indicated by the member‘s dated signature.
- A member should be willingto have his/her full name, profession and affiliation(s) published in the public domain.
- Members are responsible for reviewing protocols to safeguard the rights, safety and welfareof study participants.
- Membersare responsiblefor reviewing progressreports.
- Membersare responsiblefor oversightvisitstomonitor ongoingstudies.
- Members are obliged to read protocols, including ancillary documents (e.g., patientbrochures, informed consent forms, project reports and Serious AdverseEvent

(SAE) reports given to them by the Secretariat) in advance of an arising from themeeting.

- Membersare obligedtokeepdocuments secure, private,andconfidential.
- Membersshouldattendmeetingsregularlyandparticipate fullyandactivelyin deliberations.
- Members must declare conflict of interest, if any, when reviewing protocols and withdraw from the review of that protocol.
- Members must maintain privacy and confidentiality of documents and deliberations of meetings.
- New members should undergo orientation and training to familiarize them with basicresearch ethics. Such training should be organized by the Secretariat, the host institutions and/or any other players involved in such training.
- UpdatedCVs and records of trainingof allmembers shallbearchived in theoffice.

3.1.6.2. Termsofoffice

- The term of SlU-IRERC members should be three years.
- Membership may be renewed only for a second term if a majority vote is secured.
- The Secretariat for the SlU-IRERC should be assigned from the University, and serves full time in the office; while terms for the Secretary for SlU-IRERC shall be for a period of three years, with possibilities of renewal as stated above.

3.1.6.3. Terminationofmembership

- Membership may be terminated voluntarily. A member who seeks to terminate membership should submit a resignation letter to the Salale University at least in a one-month notice.
- Membership should be terminated by Salale Universityon the advice of the SlU-IRERC, and if a member is known to be away for three consecutive meetings. However, a member who for acceptable reasons (approved by the Salale University) is not on duty for a periodof three months could maintain his membership and join upon return to his duty.
- MembershipshouldbeterminatedbytheSalale Universityformisconductorcriminal offence recorded and verified by majority of the members.

3.2. Registration and Accreditation of SlU-IRERC

- SlU-IRERC will beregistered and accredited bytheNRERBSecretariat.

- Renewal of registration and accreditation of SlU-IRERC shall be done every two years from the date of registration or renewal of the SlU-IRERC. Following registration, a letter of registration shall be issued by the NRERB secretariat.
- When SlU-IRERC members are replaced for any reason, these outgoing members shall be notified in writing. The reason for replacement of membership shall be clearly described in the letter. Review procedures, ToRs, and the review forms should be standardized.
- SlU-IRERC can have odd numbered members for the sake of decisions, particularly when there is a need to vote.
- SlU-IRERC shall have members with a varied professional mix, gender and age balance and community representation. No SlU-IRERC can be composed entirely of a single profession, similar gender, or without a community representative.

3.2.1.SlU-IRERCRegistrationRequirements

SlU-IRERC shall apply in writing for approval and registration to the Secretariat of NRERB at MoE, and include the following requirements:

- StatementthattheSlU-IRERCwillfollowthe national guideline and other law, and relevant regulations related to research ethics.
- AlistofSlU-IRERCmembersidentifiedbyname,qualifications,profession,updated Curriculum Vitae, and representative capacity..
- ClassificationtoLevelAorLevelBshallbeaccordingtoo u r research review performances and detailed criteria will be indicated in the SOP.
- WrittenSOPsand guideline forthe activitiesoftheSlU-IRERC,whichshould include:
  - ShouldhaveSOPsand guideline forallreviewprocesses.
  - The SlU-IRERC Secretariat presents the application to the national research ethics review Broadwho shall examinethe institution‘s application, and if satisfied, will facilitate the approval of the registration by MoE.

3.2.2. TheReview ProcessesandMechanisms

- The main function of SlU-IRERC is to contribute to safeguarding the rights, safety, and well-being of all actual or potential research participants, by making an independent scientific and ethicalreview of researchbefore commencementof researchactivities. Thegoalsof research, while important, should never be permitted to override the health, well-being, and care of research participants.
- SlU-IRERC should provide independent, competent, and timely review of the ethics of

proposed studies. In their composition, procedures, and decision-making, SlU-IRERC needs to have independence from political, institutional, professional, and market influences. They need to demonstrate their competence and efficiency in their work. They also need to ensure thatthere is regular evaluation of the ethics of ongoing studies that received a positive decision.

- The SlU-IRERC must be independent from the appointing authority, hosting institution, investigators, sponsors and any other stakeholders in its review and decision-making processes. The functions of the SlU-IRERC are the following:

i. Initial review

TheSlU-IRERCmustdeterminethatthefollowingrequirementsaresatisfiedbeforeitapprovesa research protocol:

- Riskstoparticipantsareminimizedandanticipatedbenefits(ifany)andthe knowledge that will be gained from the research is justified by risk benefit assessments.
- Selection ofstudyparticipants is equitable.
- Determine that informed consent will be sought from each prospective study participant or the participants' parentsorlegallyrecognizedguardianasappropriate.
- Determinethatassentissoughtwhere appropriate.
- Determinethatinformedconsent willbeappropriatelydocumented.
- Determine that there are adequate provisions to protect privacy of study participants and mechanisms for maintaining confidentiality is in place.
- Determine that there are additional safeguards included in the study to protect the safety and welfare of study subjects who are likely to be vulnerable to coercion or undue influence such as children, prisoners, mentally disabled people, etc.

ii. Expedited reviewof proposals

- A proposal is circulated for expedited review when the research procedures present no more than minimal harm to the research participants, the environment specifically, and communities at large.
- In this case, the proposal is sent to two SlU-IRERC members who are required to provide their feedback to the secretariat within 10 working days. As appropriate, the proposal is then either approved or returned to the PI for further action.

iii. ExemptionfromERCreview

- Proposals are exempt from SlU-IRERC review when there is no possibility of harm arising as a result of the conduct of the research project or when the information collected is available from the public domain.

iv. Acceleratedreview

- In the event of a public health emergency, such as the investigation of a disease outbreak or a disaster relief operation, a protocol may be submitted for accelerated review.

v. Amendment

- A material change to study procedures including minor changes must be reviewed by anSlU-IRERC before they may be implemented.

vi. Continuing Review

- The SlU-IRERC conducts continuing review of all approved studies at intervals of time appropriate to the degree of risk that the study participants are exposed, and at least once a year.
- The SlU-IRERC will require continuing progress reports annually, unless it designates otherwise.
- All amendments (all changes in approved research projects) should be reported and approved by the SlU-IRERC before implementation, except where necessary to eliminate immediate apparent risks.

vii. Suspension or Termination of Approval

TheSlU-IRERChastheauthoritytoterminateorsuspenditsapprovalfor researchprojectsifit considers it appropriate such as:

- Theresearchisnotbeingconductedaccordingtotheapprovedprotocol,or according to applicable guidelines;
- Theresearchhasbeenassociated withseriousharmto subjects;
- Theresearchcreatesapotentialthreattothesafetyandwelfareofresearch participants or the community.
- Theterminationorsuspensionofapprovalshould includeastatementofthereasonsverifying the SlU-IRERC decision and be reported to the investigator, the sponsor of the research and appropriate institutional officials.
- Upon notification of the suspension or termination of the research, the investigator must promptly inform the research participants about the status of the research with assurance of continuing care and treatment.

viii. **ExternalReviewers**

- If a protocol requires expertise that is beyond the competence of the SlU-IRERC

members or the SlU-IRERC needs additional opinion in the review process, independent experts may be engaged in the review of such protocols.

- The Secretariat of SlU-IRERC should keep an updated list of experts along with their CVs, which should be reviewed and updated annually.
- Independent experts must sign privacyand confidentialityagreements and conflict of interest forms to ensure that the information in the protocol is protected and that reviewers do not have any conflicts of interest.
- The expert maybe invited to attend a particular convened meeting or consulted bytelephone, but he/she cannot vote in the meeting

ix. DeclarationofConflictof InterestbySlU-IRERC

- If there is any conflict of interest regarding a particular protocol, SlU-IRERC members must declare the same and excuse themselves from the review process of that research protocol.
- This is critical to ensure an objective assessment of the protocol.
- CoI can be declared at the time research protocols aresubmitted, upon receivingthe SlU-IRERC agenda prior to the meeting and at the beginning of each meeting.
- SlU-IRERC members who have a CoI related to any research protocol must not participate in any initial or continuing review of that specific protocol or related matters except to provide relevant information which maybe requested by the SlU-IRERC.
- AnSlU-IRERC memberdeclaring CoIcannot deliberate or voteon thoseprotocols or related matters.
- AnSlU-IRERC member or invited expert who has declared a CoI will be required to excuse himself/ herself from the meeting during discussion and decision.
- The CoI and action taken should be included in the minutes of the meeting of SlU-IRERC.
- AnSlU-IRERC member or invited expert assigned to carry out an expedited review on a protocol (or related matter)for which aconflict has been identifiedmust notifythe SlU-IRERC Chairpersonor Secretary so that the protocol may be reassigned to another person.
- TheUniversity requires all research involvinghumanparticipants orhumanbiological materials be reviewed and approved by SlU-IRERC prior to initiation of any research-related activities, including recruitment and screening of participants.
- The SlU-IRERC has the authority to ensure that research conducted under their jurisdiction is designed and conducted in a manner that protects the rights, welfare and privacy of research participants. Specifically:

- The SlU-IRERC has the authority to approve, require modification in, or disapprove all research activities that fall within their jurisdiction.
- The SlU-IRERC has the authority to conduct continuing review as it deemed necessary to protect the rights, welfare, and privacy of research participants, including requiring progress reports from investigators.
- The SlU-IRERC maysuspend or terminate approval of a studynot being conducted in accordance with the SlU-IRERC's requirements or in studies associated with unexpected serious harm to participants or others.
- The SlU-IRERC has the authority to observe or have a third party observe the informed consent process and/or audit the progress of any study in its jurisdiction as it deemed necessary to protect the rights and welfare of human participants.
- TheSlU-IRERC mayplacerestrictionson astudy.
- The SlU-IRERC have a duty of informing and assisting investigators and advisorsof students on ethical and procedural standards related to the use of human participants, animals or the environment in research, and to ensure compliance with this guideline, thelaws of the country, and international regulations.
- However, the primary responsibility for assuring that the rights and welfare of individuals are protected rests upon the investigators conducting the research. Others engaged in the conduct of the research including host institutions and sponsors share this responsibility.
- Collegein the Universities who supervise students have an obligation to carefully consider whether the students are qualified to safeguard the rights and welfare of participants.
- SlU-IRERC is the ultimate entity that reviews and gives opinion on research proposals when required as a matter of mandate as described in this guideline. Research on high-up societal problems and sensitive issues might be deferred to SlU-IRERC.The organogramshown below outlinesthe setting ofSlU-IRERCthat maybeputin placeas required.
- SlU-IRERCis front-lineentities reviewing and giving oversight on research processes. SlU-IRERCreview and oversee research carried out in human participants or animals to ensure that research undertakings meet the ethical principles upheld by this guideline and EFDA regulations as applicable; and that it complies with legal requirements and other pertinent regulations, guidance, and local laws. Any academic/research institution or entity mandatedto sponsor or carry out research can establish SlU-IRERC.
- Registration of SlU-IRERCat MoE is mandatory. SlU-IRERCwill review and approve

research protocols when proposals fall under their mandate; or send proposal for higher-up review by SLU-IRERC.

3.3. Use of Policies and Procedures

The SlU-IRERCmembers and its Secretariat must maintain and follow all written policies and procedures consistent with Ethiopian regulations, good clinical practices, and biomedical ethics when reviewing proposed research.

3.3.1. InformedConsent,Assent,andwaivers

- The SlU-IRERC must determine that the Study Information Sheet (SIS) and Informed Consent Form (ICF) are documented using a written or verbal form. The SIS and ICF should be approved by the SlU-IRERC (SlU-IRERC).
- Both should be translated to relevant local language(s) where the study is going to be conducted.
- The ICF must be signed by the participant, or a parent, or next-of-kin or a guardian and by the individual authorized to conduct the informed consent process. In case the participant cannot read or write, a witness should sign that the consent process was carried out appropriately.
- A copy of the SIS and signed ICF should be given to the study participant.
- Research participants or persons giving proxy consent cannot give full informed consent unless the consent process/form contains adequate information.
- All such information shall be expressed in a language that is understandable to the participant. Generally, the SIS should explicitly indicate the following:
    - Astatement that thestudyinvolves research, the purposeofthe research, theexpected duration of participants‘involvement.
    - Identificationofanystudyprocedures.
    - Foreseeablerisksanddiscomforts.
    - Reasonablyexpectedbenefitsto theparticipantsaswellasthe community.
    - Disclosureofappropriate alternativeproceduresor treatments.
    - Extentto whichconfidentialitywill bemaintained.
- Compensation for possible injury if the research is greater than minimal risk; if so, an explanation is needed as to whether any medical treatments are available if injury occurs and what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related

injury to the participant.

- A statement that participation is voluntary, that refusal to participate will involve no penalty orloss ofbenefits to which theparticipant is otherwiseentitled. The consent form should also clearly indicate that research participants are free to withdraw from the study at any time and thattheparticipantmaydiscontinueparticipationatanytimewithoutpenaltyorlossofbenefits.
- Research participants also are not obliged to respond to all questions in a study questionnaire.

3.3.1.1.E-consentforinternet-basedresearch

- Informed consent (e-consent):after participants are given information, it can include "I agree" or "I do not agree" buttons.
- If the SlU-IRERC requires documented informed consent, the researcher may email the consent form to participants, who may then type their name and date and send it back to the researcher.

3.3.1.2 Assent

- Assent will be sought from a study participant from 8 up to 18 years old. The minor child should be given appropriate information based on the child‘s level of comprehension whatever the complexity of the research procedures, in addition to the consent of a parent, next-of-kin, or guardian.

3.3.1.3. WaiverofInformedConsent

Waiver of informed consent should be approved by the SlU-IRERC. The investigator must secure an explicit waiver of consent from the SlU-IRERC. The SlU-IRERC may waive some or all the elements of an informed consent, if the SlU-IRERC determines that:

- The research project carries no more than minimal risk; if the research or demonstration project is to be conducted or approved and is designed to study, evaluate, or otherwiseexplore public benefit or service programs; possible changes in or alternatives to those programs; possible changes in methods or levels of payment for benefits or services under those programs.
- The research project could not practically be carried out without the waiver or alteration (whenever appropriate the research participants will be provided with additional pertinent information after participation); in emergency/ acute conditions where a new drug (or new combination of drugs) or a new procedure(s) potentially holds a direct

benefit but theresearch participant cannot give or refuse informed consent because of the acute condition, the SlU-IRERCmay give waiver for informed consent. However, it is the responsibility of the investigatorandthesponsortopublicizesuchastudytothecommunitybeforecommencement of any research activity.

- The SlU-IRERC should monitor such publicity to ascertain the community‘s awareness.
- Each SlU-IRERC must have written standard operating procedures (SOPs), including procedures to be followed in their review mechanism. The following are the minimum requirements for anSlU-IRERC review mechanism.

3.4. GeneralRequirement for research ethics review

- The SlU-IRERC shall review proposed research at convened meetings at which morethan 50%of the members are present, including at least one member who represents the interests of the community.

- For the research project to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The exceptions to this procedure include exempted review as outlined in this new guideline.
- SlU-IRERCshalldecide thefrequencyofitsmeetings,whichshouldbeannounced.
- The SlU-IRERC shall require that information given to research participants as part of informed consent complies with the general requirements for informed consent as prescribed by the guidelines.
- SlU-IRERC shall notify investigators in writing of the outcome of the review of the research project. Such notice shallbe provided to the investigator within 3 workingdays from the date of SlU-IRERC meeting and decision on the applied research protocol.

3.4.1.ExemptedReview Procedures

- Research activities in which the only involvement of human participants will be in one or more of the specific categories stated below can be considered as exempt:
- Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior, provided the research participants cannot be identified.
- Research involving the collection or study of existing data, documents, records,

pathological specimens, or diagnostic specimens, if these sources are publicly available or recorded without identifiers.

- Evaluation or examination of government projects or programs designed to explore publicbenefitorservice programs;proceduresforobtainingbenefitsorservicesunder those projects or programs; possible changes in or alternatives to those programs or procedures.
- Taste and food quality evaluation and consumer acceptance studies where the foods are free of additives and where the ingredients are known to be safe.
- All research including that in the exempt categories must meet, at a minimum, the principles of respect for persons, beneficence and justice. The exemption determination other than mentioned above will be based on regulatory and institutional criteria.

3.4.2.. ExemptStudySubmissionRequirements

- Researchactivitiesthatmeettherequirementsforoneormoreexemptresearchcategories must be endorsed by the SlU-IRERC.
- The investigator must complete the appropriate _Exempt Application Form‘ and submit the application along with (if appropriate):
- Questionnaires,surveys, assessments,interviewquestions,andtools.
- Consentstatements,informedconsentforms/scripts,andassentforms/scripts.
- Advertisementsand lettersof permission.

3.4.3. ExemptionCategoriesandDeterminations

Research activities, in which the only involvement of human participants will be in one or more of the exempt categories, can be approved as exempt. The Chair or the Chair‘sdesignee, the SlU-IRERC Secretary/Administrator, will complete the appropriate Exempt Category Form to review the protocol and make a recommendation.

3.4.4. Assessmentoftheresearch:

Thereview ofthe researchwill also include:

- Whethertheresearchhasasoundresearchdesign.
- Assuringthereis minimal risk to participants.
- Ensuring that the investigator has the resources, time, and expertise to conduct the study.
- The reviewer may require additional protections to meet the principles, including a level of informed consent appropriate to the research, or review by the full (convened) SlU-

IRERC.

- Policies do not allow exemption of research involving video or digital recordings, andsurveys or interviews that are extremely sensitive or personal. Allowance of audio recording is dependent on the research and is determined on a case-by-case basis and must be documented.

3.4.5. ApprovalPeriod:

- At the one-year anniversaryof the approval, an email is sent to the investigator requesting an update on the status of the study. During the approval period, the investigator needs to keep the SlU-IRERC informedofanychanges in thestudy, so that the SlU-IRERC can ensure that thestudy continues to meet the exempt criteria. The investigator may close the study when data collection has ended or contact with the subject is complete.

3.4.6. DocumentationofExemptReview

- If the study qualifies for exempt review, the reviewer will complete the appropriate Exempt Category Form which will be documented.

3.4.7. Notificationof exemptionstoInvestigatorandSlU-IRERCmembers

- The investigator will be notified by appropriate medium of the exempt determination. Each month claims of exemptions and notifications made of the same will be listed on the SlU-IRERC meeting agenda.

3.4.8. ExpeditedReviewProcedures

- Expedited reviewis reviewofaprotocol that need not beseen bythefull (convened) SlU-IRERC, but carried out by one or two SlU-IRERC members assigned by the chairperson.

3.4.9. EligibilityforExpeditedReview

- For the review of a protocol to be expedited, the proposed research must demonstrate that:No morethan minimalrisks areexpected (meaningthatthe probabilityandmagnitude ofharmor discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests); Adequateness of mechanisms for protection of privacy/confidentiality; and

Theproposedworkfallsinto oneofthe followingcategories:

- Research employing survey, interview, oral history, focus group, or human factors evaluation.
- Research involving materials (data, document, records, or specimens) that were originally

collected for non-research purposes.

- Collection of data from voice, video, digital or image recordings previously made for research purposes.
- Research on individual orgroupcharacteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).

3.4.10. Follow-uponchanges,amendmentsandannualrenewals:

- Follow-up on changes or information requested by the Review Committee as a condition of approval by expedited review mechanism will be assessed during implementation and upon requests for annual renewal. The review committee determines and documents at a convened meeting that the research involves no greater than minimal risk (and there are no proposed changes that involve additional risk). The considerations for approval of renewals will include:
  - Minoramendments topreviouslyapproved research;
  - Verificationsiftheoriginalapprovalwasthroughexpeditedreview;
  - Verificationsthatremainingactivitiesinvolveonlylong-termfollow-upof previously enrolled participants or only data analysis is remaining.

3.4.11. ApplyingforanExpeditedReview

- Requests for an expedited review can be submitted at any time to the Secretariat. An investigator who wishes to solicit an expedited review should apply indicating the reason(s) for the eligibility of the study for expedited review. Upon receiving an application for expedited review, the SlU-IRERC Secretary/Administrator in consultation with the Chairperson/Vice Chair makes the initial assessment to determine if it qualifies for expedited review. If the study qualifies for expedited review, SLU-IRERCchairperson or one or more experienced reviewers designated bythe chairperson from amongthe membersof the SlU-IRERC should be assigned to review the protocol. If the review involves a study amendment, the selected SlU-IRERC member should be one who reviewed the previous version of the protocol. When the protocol is approved, the investigator(s) will be notified immediately through the Secretariat. Approval or disapproval of protocols through the expedited review mechanism will be accompanied by the following course of (or follow-up) actions:

- Asummaryoftheprotocolsreviewedthroughtheexpeditedprocessshouldbesubmittedto

the full (convened) SlU-IRERC at its next meeting.

- Adecisionarisingfromanexpeditedreviewwillbeprovisionalpendingapprovalfromthe SlU-IRERC. Such decisions should be communicated to the investigator in writing.
- Should a protocol be disapproved by the expedited review, it should be submitted for a full (convened) SlU-IRERC review. The full (convened) Committee has the authority to endorse, modify or reverse the decision of the expedited reviewer. If the decision of the full(convened) SlU-IRERC is contrary to the decision of the expedited review, detailed reasons and explanations should be recorded in the minutes. The applicant should be informed of any modifications that the full (convened) SlU-IRERC recommends and the ethical justification forthe decisions taken.

3.4.12. ExpeditedReviewProcedure

- Anexpeditedreview coversthesameissuesasafull(convened) review.Thereviewerhasthe same options as the full (convened) review committee, i.e., to approve, or request modifications of a protocol. If the protocol is not approved, it will be referred to the full board.The chairperson shouldnotifythe SlU-IRERC -IRERC membersaboutdecisionsmadepertainingto such research using a suitable medium (full board meeting, internet, post, telephone). At that time, any member or the committee may request a re-review of the approved protocol at the full (convened) committee meeting. If this were to occur, the investigator would be notified and asked to suspend the study pending full review. Reviewers involved in the expedited review process refer the issue to the full committee if there is any question about the level of risk or the applicability of any category of activities before approving the protocol.

3.4.13.SLU-IRERC/decisions

- SlU-SLU-IRERCmayreachthefollowingdecisionsafterreviewingtheresearch protocol:
- **Approved:** ifaprotocolfulfillsallrequirementsas stipulatedinthis guideline.
- **Protocol Requires Minor revision:** if a protocol needs minor modifications, which can be verified if commentsare addressed anddulyaccommodated bythe secretariat.The secretariat however can refer to the board meeting if needed.
- **Protocol Requires Major revision**: if a protocol needs major modifications the revisions are required to be reviewed by the reviewers and be presented to the SlU-IRERCto verify if the comments were duly accommodated.
- **ProtocolNot approved:** ifaprotocol isfoundtobeunscientificand/or unethical.

3.4.14. DecisionMakingProcedures

- TheSlU-IRERC can onlymakedecisions ifa quorumis met.
- Amemberwithconflictofinterestmustexcusehimself/herselffromthereview process and voting.
- Non-members such as project PIs and independent experts may be consulted as partof the review process, but do not vote.
- OnlySlU-IRERCmemberswhoparticipatedinthereviewprocessanddeliberationsshould take part in the decision-making process.
- SlU-IRERC decisions shall be either unanimous or by consensus where there is a majority decision. If the decision is by voting the number for and against should be recorded in the minutes.

3.4.15. CommunicatingDecisionsto Applicants

- Decisions regarding protocols should be officially communicated, in writing, to the applicant within 3 working days of the meeting where the decision was made.

- Communicationof the SlU-IRERCdecisionshallinclude butnotbe limitedtothe following:
- Thename, title, and address of the applicant.
- Theexact title ofthe protocol.
- Thenameofthe studysite(s)orstudyarea.
- Thenamesandidentificationnumbers(versionsnumbers/dates)ofthereviewеddocuments.
- Aclearstatement ofthedecisionreached bytheSlU-IRERC.
- The name of the SlU-IRERC making the decision (letter head of the SlU-IRERC suffices); and list of SlU-IRERC /IEC members who attended the meeting.
- The date of the decision and the signature of the Secretary/Administrator or Chairperson/Vice Chairperson.
- In case of a conditional decision (approved on condition), any requirements by the SlU-IRERC, including suggestions for revisions, should be clearly explained in writing to the applicant.
- In case of a positive decision (approval), a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the ERC.

3.4.16. Thevalidityperiodofthe approval

- The final approval certificate/letter shall be countersigned by the Chairperson/ Vice Chairperson.

3.5. SlU-IRERC Records

3.5.1. Documentation

- The SlU-IRERC and SlU-IRERC should maintain adequate documentation of all its activities, including all the following:

3.5.2. FileofdetailedwrittenproceduresfortheSlU-IRERC

- File of each protocol, containing all versions of protocols submitted and accompanying documents such as informed consent, approved versions, approval letters, progress reports submitted by investigators, reports of injuries to research participants, and other relevant documents.
- Agenda and minutes of the meetings; the minutes shall be in sufficient detail to show attendance at the meetings; actions taken; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
- Recordsofcontinuingreviewactivities.
- Updatedmemberfiles withCVs, trainingdocuments, etc.
- SAEreportssubmittedbyinvestigators.
- Finalreportsfrominvestigators.

3.5.3. *Archiving*

- All closed files shall be retained for, at least, five (5) years after completion of the research project. All documents should be kept in a secure system that ensures confidentiality. All records shall be accessible for inspection by authorized personnel.

3.5.4. RequirementsforSubmissionofProtocolsto SlU-IRERC

- For a research protocol to be processed by SlU-IRERC, administrative and technical requirements must be met. This is verified at the Secretariat level during submission. Additional requirements may be needed for special categories of research.

3.5.5. Administrativerequirements

- TheapplicantmustbethePrincipal Investigator(PI)orco-PIoftheproposedresearch study.
- A Protocol Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee.
- A signed cover letter from the PI or co-PI and the institutional details where the investigator is based (which should include a physical address, fax number, telephone number, mobile number and email address) also must be submitted.
- The applicant should submit hard copies of the full research protocol and/or an electronic version.

- Allmaterialstobeusedin—advertising‖theresearchstudy(e.g.,campaign materials, brochures, etc.) should be submitted along with the protocol.
- Up-to-date signed and dated CVs of the PI and/or co-PI should be submitted. Also, bio-sketches of co-investigators should be submitted although full CVs may be requested by SlU-IRERC.
- AllapplicationsshouldfirstbesubmittedtoSlU-IRERCofinstitutionsthatthePIis affiliated with, and ultimately to SlU-IRERC if applicable.
- SlU-IRERCshallgivefinalofficialapprovalforstudiesundertheirmandate;SlU-IRERC will be responsible for the same.
- Uponreceiptofcompleteapplications,preliminaryscreeningshallbedonebythe SlU-IRERC Secretariat.

3.5.6. Technical requirements

- All research protocols and related documents submitted to the SlU-IRERC for review and approval must at the least include the following:
  - Titleofthe study,
  - Purposeofthe study,
  - Sponsor ofthe study,
  - Backgroundoftheproject,
  - Arationalewith full justification ofthestudyand that thereis no otheralternativeand less risky way of obtaining the data,
  - Descriptionofthestudy population,
  - Participantsinclusion/exclusioncriteria,
  - Precisedescriptionofallproposedproceduresandinterventions,includingthe duration of the study,
  - Provisionsforprotectingprivacyandconfidentiality,
  - Provisionsformanagingadverseevents,
  - Plansfordatamanagement includingplanforstatistical analysisandpublication,and
  - Budget,
  - Vulnerablepopulationinvolvementrequiresfurtherexplanationtojustifythatno alternative approaches exist to carry out the planned research.

3.5.7. Documentstobesubmittedforreview include:

- Studyprotocol, protocolamendments,
- Study/participantinformationsheetandinformedconsent form,

- Upto date CV ofinvestigators,
- Investigator‘sbrochure(wheneverapplicable),andothermaterials,
- The studyinformed consent process/form and information sheet, in both the official language and, when necessary, its translation into the local language (N.B. a back translation into the official language may be requested by the SlU-IRERC, contact addresses of the PI, and the SlU-IRERC that approved the research protocol must be included in the study information sheet,
- Data collection tools such as questionnaires, interviews /discussion guides, check lists and case report forms, and
- Anyother materials tobeusedin studyparticipant recruitment (includingadvertisements).
- Special documents accompanying protocol submissions (to be described in detail in appropriate sections).

If the proposed study is a clinical trial, the investigator‘s brochure which provides anadequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of the clinical experience of thestudy product (e.g., recent investigator‘s brochure, published data, summary of the product‘s characteristics etc.), must also be submitted. Further, a certificate of Human Participant Protection, Good Clinical Practice, of at least one of the investigators, and a certificate of GoodManufacturingPracticebasedonthenatureoftheresearch,mustbeattached.Anotherimport ant document required is certificate of insurance/indemnification for the proposed clinical trial, and description of plans for compensation of expenses.

- In studies that need transportofhuman biological substances, arequest for amaterial transfer agreement, the type of biological material, how it is going to be processed and stored, howthe material is intended to be analyzed, intent for possible future analysis (if there is one), as well as how and when it will be disposed, must be included in the study protocol.

3.6. ResearchProtocolswithSpecialConsiderations/Populations

- Special categories of research that possess unique characteristics require emphasis in some aspects of ethical considerations.

3.6.1. Collaborativeresearch

- Collaborative research is research that is conducted by investigators from more than one institution. If one of the collaborating institutions or investigators is based outside

ofEthiopia, then, the research is termed ―international collaborative research.

- There are different potential reasons for conducting collaborative research. The reasons may includegreaterprevalence, convenienceof, orfamiliaritywith thesetting and theresearchers, scientific or public health justification, and the research question or intervention is only relevant to the type of health problem in Ethiopia. Hence, the reason for choosing to conduct the research in Ethiopia should be explicitly stated.

3.6.2. Requirements

- International collaborative research should be in line with the health research priorities of Ethiopia and be consistent with the health science and technology policy. Importantly, the proposed research must be responsive to the health needs of Ethiopians. The research should also contribute towards strengthening national research capacity to carry out similar research independently, including providing research ethics training to members of the investigation team. Adoption of a paternalistic approach by research sponsors/donors towards collegesin University or the research priorities of the government, is unacceptable.
- In all collaborative research, all Colleges involved in a proposed study are required to review and write a recommendation of approval before submission to SlU-IRERC(SlU-IRERC).Intheeventthecollegesdo nothaveafunctioningSlU-IRERC,theresearchprotocol and other documents can be submitted directly to any of the SlU-RERCmandated to review and approve collaborative research. However, to avoid duplication of review effortsby SlU-IRERC, the SlU-IRERC may choose to conduct joint reviews in part or in whole, accept the review of another qualified SlU-IRERC, or make other arrangements toestablish oversight responsibilities.

Thefollowingrequirementsapplytocollaborativeresearch proposals:

- The sponsor/donor should agree in advance that products will be made reasonably available after completion of the study, and the community must have access to the fruits of research.
- All collaborative research must have a Principal Investigator or a Co-PI actively working in Ethiopia. Also, the PI or Co-PI must be employed or affiliated to a recognized institution or organization in Ethiopia. The research procedure should consider, to the extent possible, socio-cultural conditions in the community where the research is proposed to be conducted.

3.6.3. Monitoring

- When conducting collaborative research studies, each institution is responsible for

safeguarding the safety, rights and welfare of human participants and for complying with all applicable regulations. The SlU-IRERC that reviewed and approved the collaborative research is primarily responsible for monitoring the ethical conduct of the research procedures.However, the SlU-IRERC can monitor the conduct of the research whenever it deems further oversight is necessary. Any modification, amendment, or change in the approved collaborative research protocol should be made at each collaborating institution. Material transfer agreements must be obtained whenever applicable.

3.6.4. Communityengagement

Communityengagement is a component of scientific research, policymaking, ethical review, and technology design. Effective community engagement is essential for ensuring both instrumental objectives and moral ideals of scientific research. Engagement has the potential to redress past harms; dissolve long-standing mistrust and suspicion; minimize the risk of further exploitation; compensate for or resolve existing differences in power, privilege, and positionality; allow for marginalized voices and experiences to be represented in the production of scientific knowledge; and ensure that research is relevant and impactful. Engagementactivitiesmustaimtocreatemeaningfulpartnershipsbetweenresearchersandthe local community. Ongoing dialogue and collaboration are important in shaping study design and implementation.

- Researchers are encouraged to involve the community in decision-making about the design and conduct of the study. Investigators should consider the local customs, traditions, culture and religious practices of the community where the research is proposed to be conducted. Involvementof communitystakeholdersshallnotoverridethe rightsof individualstoconsent voluntarily for participation in a research project. Community engagement is to be treated as an ongoingprocess until completion ofresearch. Communitydialogues need to becarried out to promote understanding, research participation and ownership. Researchers should develop plans for providing feedback on the research results and outcomes of the research process.

3.6.5. Internetbased research

- Data collectiontakesplace over the Internetusingmethodssuch asemail,listservs, electronic bulletin boards and web surveys. Approval of, or certification of exemption from, SlU-IRERC review is necessarywhenever conductingresearch involvinghuman participants.Researchers should identify and manage risks during data collection,

processing and dissemination. The existence of data and information already online does not relieve the researcher from the obligation to respect privacy and mitigate risks that could result from combining data from multiple sources and their subsequent use and publication. Researchers should identify and manage risks during data collection, processing and dissemination.

SlU-IRERCshallascertainthat:

- Riskssuchasviolation ofprivacy,legalrisks, andpsychosocialstressare minimized,
- Provisionofsimilarlevelsofprotectiontoresearchactivitiesthatposesimilarprivacy risks,
- Participants'participationisvoluntary,
- Informedconsentrequirementsaremet,
- Informationobtainedfromorabouthumanparticipantsiskeptconfidential,
- Methodandproceduresfordatacollectionandsecurityarereliableand secure,
- Materials used for posting recruitment materials on the internet, e.g., through a website,abanneradvertisement,oranemailsolicitationareappropriatelywordedand free from statements that implicate undue influence.

3.7. Vulnerable populations

Vulnerable populations are those segments of the population whose capacity to safeguard their welfare, demand their rights and satisfy their interests, is compromised. Because ofthese limitations, they cannot provide or refuse consent. Vulnerable populations are particularly subject to undue influence, manipulation, coercion, and intimidation. Hence, vulnerable populations deserve special protection by SlU-IRERC and other regulatory authorities.

3.7.1. Children

Children are persons who have not attained the legal age of 18 years (Ethiopian Law).The following apply in research involving children:

The child should provide assent (8-18 years) in addition to the informed consent by a parent or guardian.

The research presents a realistic opportunity and clearly justifies that the research contributes to further understanding, prevention, or alleviation of problems affecting the welfare of children.

Clinical trials that recruit children should justify that these trials had been conducted in animals and adult conditions.

In disease conditions specific to children, clinical trials can be allowed based on risk-benefit analysis, public health issues, etc.

Emancipated minors who are working or earning their living, or are married, or parentingmay be allowed to give an informed consent; or SlU-IRERC may decide on a waiver of consent.

In research related to sensitive topics like drug use and abuse, sexuality, reproduction, STIs, where obtaining consent from a parent, next-of-kin, or guardian is challenging and may be problematic to the minor because of the nature of the research, assent with waiver of consent may be applicable.

Ininstitutionalchildren,alegallyapproved guardianmaygiveconsent.

3.7.2. Prisoners

- Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary decision about participating in research which is notcoerced. Therefore, additional safeguards should be included in the studyto protect the rights and welfare of these subjects, as follows:
- If SlU-IRERC regularly reviews research that involves these vulnerable populations, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- Where possible, a prisoner or an ex-prisoner can be co-opted into the SlU-IRERC for reviewing the proposed research project.
- Research on health and social conditions particularly affecting prisoners with reasonable probability of improving the health and well-being of the research participants should be permissible.
- The SlU-IRERC shall determine that the informed consent process is properly applied with adequate assurance that a prisoner‘s participation or refusal to participate will not be considered in decisions regarding his/her legal status (release or further detention) and each prisoner is clearly informed about this in advance.

3.7.3. PersonswithDisability(PWD)

- Persons with a disability need special attention because they are prone to being socially marginalized. Therefore, their dignity, rights and well-being in research must be

respected. Careful consideration should be made where proxy consent is to be used, and where the useof signed consent forms is not feasible, alternative viable methods should be employed.

- Persons with disabilities (mental or physical) should not be unfairly excluded from participating in research. Researchers should try to address communication, disability and comprehension constraints that often are the excuse for exclusion.
- Individuals with mental disabilities or substance abuse related disorders include those people with psychiatric, cognitive, or developmental disorders. These groups of individuals are usually institutionalized, and institutionalization may further compromise their ability tomake voluntary decisions to participate in a research project. Therefore, research on persons with cognitive disabilities or with substance abuse related disorders should:
  - Providesufficientjustificationforinvolvingsuchpeople,
  - Have appropriate evaluation procedures adapted to an Ethiopian situation or context for ascertaining research participants‘ ability to give informed consent,
  - Have an informed consent process that is free from coercion; and if research participants are deemed unable to understand and to make an informed decision, then an appropriate proxy should be identified, and
  - Be of no more than minimal risk, or if minimal risk is involved, the risk is outweighed bythe anticipated benefits of the research project to the research participant.

3.7.4. Olderpeople

In Ethiopia, the number of elderly people (age over 65 years) is significant (accounted for about 5% of the population in 2019). It is imperative to adopt a healthy ageing approach in health research to better understand and recommend interventions for healthy ageing. It is therefore necessary to consider the following while doing research in older people:

- Ensurethatthebasicethicalprinciplesare applied,
- Use all available mechanisms to collect gender and age differentiated health data on older persons, and
- Disorders that usually come with old age like problems in vision, hearing, orthopedic andjointsshouldbeaddressedwithprovisionofsupportinginstrumentsas applicable.

3.7.5. Geographicallydisadvantagedpopulations

Due to limited health care resources in such regions, special care needs to be taken to ensure

the provision of health care services for research participants residing in rural areas or inthose who are identified as disadvantaged to ensure protection from undue inducement to volunteer for the study. The burdens and benefits of research should be fairly distributed between rural and urban populations.

3.7.6. Research that involves ethnicity and minority ethniccommunity

Data on ethnicityis considered as sensitive data and collection of such data must be done after the review and approval by the SlU-RIRERC.Additionally, minority groups tend to be marginalized so special care should be taken to ensure research does not further disadvantage them.

3.7.7. Researchinemergencies(outbreaks,pandemicsand disasters)

Research that is conducted in the context of public health emergencies includes but is not limited to: i) outbreaks, ii) tsunamis, iii) displacements, iv) infectious disease outbreaks, v) natural disasters, and vi) human-made disasters such as conflict, bioterrorism, and industrial accidents, etc. Types of research conducted during emergencies fall in the range of epidemiologic, behavioral, socio-economic, ethnographic, clinical trials, and other interventions.

Research can play an essential role in improving the effectiveness of the health-related or other response mechanisms to those affected by such emergencies but is often ethically contested because of the highly challenging environment in which it takes place.

In this context, vulnerability is affected by power imbalances. The voices of those who are most affected by emergencies are often not meaningfully included in deciding what research takes place, where and how. Affected populations include those whose lives, health, and livelihoods are threatened by the emergency, people within those populations who take partin research, and front-line research workers. Finding ways to ensure front-line research workers are better supported in addressing the ethical dilemmas theyface is important. Issues that lead to ethical dilemmas or override the ethical applications of research in such populations include:

- Significantly raised risks to physical or mental well-being at both individual and population level,
- Pressures of time, creating tensions between research and response timescales, and exacerbating the challenges of multidisciplinary working,

- Uncertainty that makes decision-making in these time-limited contexts particularly difficult for all concerned,
- Fear, distress, and sometimes panic, potentially undermining populations‘ ability or desire to engage with research,
- Inability to implement appropriate study designs and review systems that are sensitive to the difficult contexts in which research is taking place, and
- Achievingmeaningfulconsentprocesses withinawiderethicalsystemof governance.

3.8. Addressingethicalconsiderationforresearchduringemergencies

- All research conducted during emergencies must have scientific validity and social value. Research should be conducted only if it does not impede emergency response efforts. This means that research should not be conducted if it can be expected to take away personnel, equipment, facilities, and other resources from those required for outbreak response.Research projects should be coordinated to avoid wasteful duplication and underpowered studies, and to ensure that priorities and activities are consistent with response efforts. The appropriateness of any research design should be informed by the context in which the research is to be conducted, and that unnecessary risks to study participants and researchers should be avoided.
- In considering the conduct of research during emergencies; upholding independent ethical review (both in the country affected and, where relevant, in other countries) can ensure safeguards for research participants. The established research ethics review mechanisms and processes should not be compromised in any way. However, the following recommendations are hints for planning research and managing research ethics review during emergency situations.
- Flexibility and adjustments in schedules and time frames to review multiple protocols withina short time span,
- Establishment of sub-committees to focus specifically on the review of protocols related to the disaster under considerations,
- Putting in place an accelerated review system for approval within an average of3-5 working days, and quick turnaround time (12-24 hours) for issuing comments, guidance, and approval letters,
- IRERC responsiveness might include the use of phone or online meetings, willingness to discuss protocols with researchers at development stage and provide informal feedback, and the ability to respond quickly to protocol modifications, for example in response to community feedback,
- The need for the availability of SOPs for running remote meetings or for triaging a series of protocols to facilitate expedited reviews,

- Depending on the nature and gravity of the issues (issues calling for immediate national interest or security), some of the protocols would require national review by NRERB e.g., if the conduct of a Clinical Trial becomes a matter of urgency and some studies/investigations might require international sample transportations.
- SlU-IRERC should clearly communicate any emergency procedures for researchers and stakeholders.Rapid sharing of information generated during research—subject to ethical requirements such as maintaining the confidentiality and privacy of personal information—with those participating in the response efforts can also help strike an effective and mutually beneficial balance between research and response. To ensure that research is responsive and sensitive to local realities, needs, values, and cultures, it is imperative that communities and researchers from local contexts be engaged at all stages of research.
- Developing community engagement networks to facilitate relationships is a key part of emergency preparedness. Research during an emergency requires fair and meaningful community engagement and inclusive decision-making. The most inclusive level of engagement is one in which local stakeholders are not only consulted but also take part in decision-making processes with respect to research design, implementation, and evaluation. This involves inclusive and accountable decision-making. It requires that all reasonable steps are taken to ensure that all those concerned, including those who are the most vulnerable and marginalized, are not left out.
- Routine public health or other humanitarian activities not constituting research do not require independent ethics review but should still proceed with due attention to ethicalconsiderations, as outlined in part in the WHO‘s Guidelines on Ethical Issues in PublicHealth Surveillance.
- To minimize duplication of ethics review and oversight, in most cases independent ethics review should proceed collaboratively between one local and one international review body, with at least one being well-versed in research ethics.
- To facilitate expeditious ethical review in emergency situations without compromisinghuman participants‘ protection, generic advance protocols (which can be rapidly adapted and reviewed), templates, and other tools for the ethical review of research can be employed. Pregnant women, minorities, children, and other groups considered to be _vulnerable‘ should notberoutinelyexcludedfromresearchparticipationduringemergencysituationswithoutareasonable scientific and ethical justification. Any exclusion from participation in research should be justified byrobust and current scientific evidence, such as an unfavourable benefit- risk

ratio.

- Cultural and linguistic differences, as well as confusions about the dual role of the clinician/researcher, may be heightened for research conducted in this context, and so processes for obtaining informed consent, including the wording of documents and methods of obtaining and recording consent, should be developed in consultation with local communities. Finally, researchers should inform potential participants about the circumstances under which their data or samples might be shared. Participants and stakeholders should be fully informed about the collection, storage, future use, bio-banking and export of human biological material. Researchers generating information that has the potentialtoaidresponseeffortshaveanethicalobligationtosharethatinformationassoonas it is quality-controlled for release (e.g., peer-reviewed).

- To ensure the greatest impact of the research, information should be shared with those involved in response efforts in addition to research participants, affected populations, and the global community. Researchers should share this information without waiting for publication in scientific journals. Journals can facilitate this by ensuring that data or preprints shared ahead of submission will not pre-empt publication in their journals.

- Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of vulnerable groups.

- Ongoing research which may increase risks to the participants and/or the research team (e.g.,COVID-19) may have to be stopped and amendments sought on how to continue ensuring protective mechanisms or in a modified approach (e.g., phone or web-based interview instead of face-to-face encounters).

3.9. Biological Materials

Biological materials are defined as any materials of biological origin that are collected through a formal agreement (in the form of consent/assent or other contractual agreement). Biological materials usuallycontain genetic information and maybe capable of reproduction, unless stated otherwise.

Thelists below arematerialscategorizedasbiologicalmaterials:

- Human products, including blood, tissues, bodily fluids, clinical specimens, nail clippings, skin, microorganisms, and other associated bio-products obtained from human

research participants

- Live animals, animal carcasses, or animal products including tissues, cells, blood, or other bodily fluids
- Pathogenicmicroorganisms(includinghuman, animal,orplant pathogens)
- Plants,animals,insects,microorganisms,orcells thatproducetoxiccompounds
- Recombinant or synthetic DNA/RNA (plasmids, cloned materials, oligonucleotides, siRNA)
- Viralvectors(e.g.,lentivirus,retrovirus,adenovirus,AAV)
- Genetically-modifiedorganisms(animals,microorganisms,plants,insects,cells/cell lines)
- SelectAgentsorSelectToxins

3.9.1. Acquisition,StorageandSecondaryUseof BiologicalSamples

- The acquisition, storage, and future use of biological samples from research participants in Ethiopia shall be guided by the following procedures:
- Collection of biological samples should follow acceptable standard procedures by adequately trained personnel with proper research plans that exhibits risk minimization;
- There should be a separate informed consent process for obtaining human biological samples for storage and for future use;
- Research participants should know the purpose of sample storage, quantities of samples to be stored, place where samples will be stored, duration of storage, measures to protect confidentiality, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future research, and any other information deemed necessary by the Investigators, or SlU-IRERC;
- After explaining the need to store the samples, the research participant should be offered to choose whether their samples should or should not be stored for future studies;

- The host institution in Ethiopia should hold the samples in trust on behalf of the research participant;
- Research participants should reserve the right to withdraw their samples from storage if the samples are linked;
- Where samples have not been obtained as part of research (for example as part of routine surveillance, emergency procedures, laboratory quality control, notifiable diseases, routine counseling and testing, etc.), the institution that collected the samples takes custodianship of the samples. Any future research study on such samples must be reviewed by an IRERC;
- Upon justification, stored samples may be used to address research questions not included in the approved protocol after getting anSlU-IRERC approval.

3.9.2. BiologicalMaterialTransferandDissemination

Biological samples may be transferred for the purpose of generation of data or for quality control and laboratory reference. In order to justify transfer of biological materials overseas, investigators should demonstrate that in-country capacity to perform investigations/tests doesn‘t exist or is inadequate.Dissemination of biological material refers to multiplication and distribution of biological materials both within and across countries, for research purposes.For the transfer/dissemination/delivery of biological materials within a country,the organizations/institutes described are legally obliged to grant permission. For the transfer of biological materials overseas, the following procedure is to be adhered:

3.9.3. Procedureformaterialtransfer

- To justify transfer of biological materials overseas, investigators should demonstrate that in- country capacity to perform investigations/tests does not exit. However, samples may be transferred for quality control and laboratory reference purpose.
- When it is necessary to transfer samples overseas, the host institution shall negotiate an appropriatecontractwiththerecipientinstitution.ThiscontractshallbeintheformofaMaterials Transfer Agreement (MTA).
- The specific details of the MTA should include, among other things, the purpose for the transfer/export, clear arrangements for collaboration and benefit sharing, a framework for accessing and sharing data, restrictions to third party transfer,dateforterminationoftheuseofthematerial,disposalplanandannualreportstothe host institution on the status of the samples.
- When the sample is none human origin, MTA prepared by Ethiopian Biodiversity Institute

(EBI) should be used, and the host institution should get export permit from EBI.

- It is required that Ethiopian institutions retain ownership of the materials, and an Ethiopian scientist must be included as co-investigator in all future studies using the human biological materials collected from Ethiopia.
- The NRERB, or the SlU-IRERC when designated by the NRERB, should review all research studies involving stored human biological samples

3.9.4 Open data access, data ownership, sharing, and result dissemination

Ethiopiahas clear policy and guidelines on data sharing and access in general and the use of open data. All researchers who receive public funding must submit their data management plans for approval, to confirm that data will be handled according to international FAIR data principles.FAIRdataaredatathatmeetstandardsof end ability, accessibility, interoperability and reusability.

3.9.4.1. Data ownership

Dataownership and associated intellectual propertyrights shall bediscussed and agreed upon bycollaborating partners at the inception of a research project while respecting the law of the country.Collaboratingresearchpartnersshallnegotiatedataownershipanduseinaccordance with the host organization‘s data use and ownership policies.The national ownership of data shall be clearly stated in the research protocol or collaborative research agreements, which shall be reviewed by NRERB or by SlU- IRERC up on designation by NRERB.

3.9.4.2. Data sharing

- Collaboratingresearch partnersshall agreeon appropriatedata access anduserightsbefore commencement of the study. Researchers shall have in place mechanisms for maintaining confidentiality of research participants and their communities.
- A collaborating research partner shall not transfer data to a third party without the written consent of the other partner.
- Local researchers shall have unrestricted access rights to data sets collected through a collaborative research project which has to be clearly indicated in the research proposal.

- Researchers shall ensure that documentation/records from which the data have been obtained are available at the research site for at least five years after completion of the research project. Electronic records are acceptable.
- Datasharingrequestrequires NRERBor IRERCs approval.

3.9.4.3. Exception

Data deposited in public domain repositories areopen access, and not necessarily governed by data sharing agreements.

3.9.4.4. Results dissemination

a) Researchers shall, as appropriate, make all reasonable efforts to share findings (following the open data policy of the country) of research with the host organization, research participants, key stakeholders and communities in which research was done.
b) Researchers shall describe in the protocol, plans for research results dissemination and ensure its execution.
c) Researchersshallbesensitiveabouttheethicalimplicationsoftheresearchresultsandtake appropriate measures to protect research participants and their communities.

3 . 1 0 . Regulatory oversightofresearch

Regulatory oversight of research in Ethiopia is exercised at various levels. At the country level,theNRERBistheprimaryorganforethics oversight. AttheSalale University level, SlU-IRERC oversee all research being conducted under specific jurisdictions. For research involving experimental/clinicaltrials,authorization toimportandusetheinvestigationalproductshould be solicited from EFDA.

The legal obligations concerning oversight and regulation in research shall be overseen by MoEandEFDA,thelaterconcerningclinical trials. SlU-IRERC,and Data & SafetyMonitoring Board‘ (DSMB) are primarily responsible for safeguarding research participant safety. The Institutional BiosafetyCommittee(IBC)and CommunityAdvisoryBoard (CAB)shall ensure public/community wellbeing.

3.10.1 MinistryofEducation(MoE)

MoE,establishedbyProclamation No.1263/2021is bestowed with thepowers and duties to:

- Forwardrecommendationsbasedonstudiesforadoptingandrevisinghigher education policies, strategies, laws and directives.
- Prepare national research and research ethics policy; provide guidelines for programs and projects; monitor and evaluate their implementation.
- Setprioritiesforhighereducationresearchactivities.
- Supportandstrengtheninstitutionsthatundertakeresearchethicsactivities.

3.10.2. TheEthiopianFoodandDrugAuthority(EFDA)

TheEthiopianFood and drugAuthority‘sobjectives are to protect thehealth ofconsumersby ensuring: 1) food safety and quality 2) the safety, efficacy, quality, and proper use of medicines 3) competence and ethics of health professionals, medical practitioners and pharmacy professionals.

The authority is responsible to protect the safety and rights of the subjects participating in a trial and to ensure that trials are adequately designed and are carried out using scientifically sound methodologies. The mandate of the Authority is to review clinical trial protocols, and where necessary to protect the safety of subjects, to require protocol revisions and/or termination of trials.

Any clinical trial conducted in the country on human beings and/or on animals other than laboratory animals should have received prior permission before the commencement of the trial. Furthermore, the Authority demands that findings from a clinical trial need its approval before publishing. Besides, the responsibilities of the investigator, the sponsor, and the monitor should be stated clearly in the research protocol.

The authority also requires that a specific application form for clinical trials shall be completed and submitted for authorization.

3.10.3. EthiopianBiodiversityInstitute(EBI)

The Ethiopian Biodiversity Institute was established in 1976. The Institute is mandated to undertake study and research on the conservation of Ethiopia‘s Biodiversity and associated indigenous knowledge through establishment of participatory conservation mechanisms. The Institutewas giventhemandateofconservation, sustainableutilizationand its communityget fairandequitableshareofthebenefitsarisingfromtheirutilizationofallformsofbiological

resources including plants, animals and microbial genetic resources as well as associated indigenous knowledge.

3.10.4. EnvironmentalProtectionAuthority(EPA)

Environmental Protection Authority (EPA) was established as an autonomous government agencyat the Federal level byProclamation 1263/2021. The EPA is responsible to ensure the realizationoftheenvironmentalrights,goals, objectives,andbasicprinciplesenshrinedinthe Constitution. It is also responsible for environment policy of Ethiopia through coordinating appropriate measures, establishing systems, developing programs and mechanisms for the welfare of humans and the safety of the environment.

3.10.5. InstitutionalBio-SafetyCommittee

Institutional Biosafety Committee (IBC) evaluates research projects that use any of these: recombinant DNA; agents that are infectious to humans, animals and plants; and other potentially harmful materials, select agents and biological toxins. IBCs are established by institutions that undertake research on potentially hazardous substances of a physical, chemical, biological, or any other nature. Any institution involved in or planning to conduct research with potentially hazardous substances is required to set up or designate a competent IBC. Each IBC once formed shall consist of a bio-safety officer and at least three other officers with appropriate expertise in DNA, biological safety and physical containment.

Members of the IBC shall protect confidentiality of all information given to them in the course of their work and shall sign confidentiality agreements with their institutions.

3.10.5.1. Functionsof anIBC

- The IBC‘s function is to minimize potential human and environmental harm that may be associated with research on/or with potentially hazardous substances such as pathogens, biological toxins, radioactive material and applications of biotechnology, especially recombinant DNA techniques and processes.
- The purpose of an IBC is to ensure adequate containment of potentiallyhazardous biological agents, by adding a platform for expert review of, and monitoring of potentially hazardous experiments, and provide a means of communication among researchers and healthcare providers about potentially hazardous protocols.

- IBCsshall**:**NotifyIRERCofanyresearchwithpotentiallyhazardoussubstancesintheir institutions.
- Conduct bio-safety review and approval of research proposals involving recombinant DNAand potentially hazardous substances.
- Carryout continuedreviewofapproved researchprojects.
- Ensuretheprovisionofsuitableandsafestorageanddisposalfacilitiesforallresearch undertakings that utilize potentially hazardous substances.
- Ensurethatallappropriatetechnicalpersonneloftheinstitutionhaveadequatetrainingin biosafety.
- Establishahealth-monitoringplan forallhigh-riskpersonnelinvolvedin application,useand production of potentially hazardous substances.

3.10.5.2. CommunityAdvisory Boards

Community Advisory Boards (CABs) are established by the investigator team. They are indispensable in orienting the investigator team about the local customs, traditions, terminologies, culture, and attitude towards research and development. Besides, CABs are important bridges to liaise the researchers with the community. CABs are critical forums to facilitate dialogue between community members, research participants and investigators.

CAB members shall be selected from the community where research is to be undertaken through a stakeholder consultative process. The CAB‘s role and expectations should be explicitlydescribed in their terms of reference. Members of the CAB may include but are not limited tothe following: 1) Individuals familiar with local laws, customs, cultural values, and gender issues, 2) Elders, opinion leaders, local chiefs, 3) Peer leaders, women leaders, 4) Religious leaders, 5) Representatives of the study population, 6) Media personnel, and 7) Professionals who understand research or science issues

3.10.5.3 Functions of CAB

- The main function of a CAB is to assist investigators with understanding and incorporating community concerns into their research procedures. The functions are expressed through different ways like advising on issues central to the informed consent process.

- The responsibilities of the CABs may vary according to the study location, size, complexity, and familiarity of the investigators with the local setting. To mention just a few, CABs‘ functions are to:
- Provide information on traditional beliefs and needs of the study population and their concerns regarding the research project.
- Provide input into the design of the research protocol as appropriate, especially in the recruitment and the informed consent process.
- Advise investigators on acceptable and effective methods for disseminating informationabout the research project and its outcomes.
- Provide advice and support regarding retention of research participants including gender equity.

3.10.6Monitoringand ReportingbySlU-IRERC

- Monitoring essentially encompasses four activities: continuing review, review of the consent process, review for adherence to an approved protocol and review to identify unapproved activities. Continuing review is the most common approach in monitoring and reporting of research undertaking by SlU-RERC.
- The primary function of monitoring is ensuring participant safety through assuring compliance with regulations and adherence to approved research protocols. In clinical trials, data monitoring is conducted to ensure data quality and safety. The DSMB is designated by the sponsor upon the recommendation of the IRERC primarily to periodically monitor data quality and participant safety. Moreover, interim analysis of risks and benefits should be a component of monitoring to ensure safety, whenever applicable.
- In multi-center research, monitoring at each of the research centers should primarily be carried out by the SlU- IRERC. However, the NRERB is also responsible for oversight at selected, representative research centers.
- In international collaborative research, periodic progress report must be submitted, and all adverse events must be notified to the NRERB. The investigator bears the major responsibility for regular reporting of adverse events to the SlU-IRERC. The sponsor is also obligated to report, or otherwise ascertain, that the adverse events are reported to the SlU-IRERC.
- Based on monitoring and reporting that includes Adverse Events (AEs) as applicable, the IRERC may allow continuation, suspension, or termination of the research or recommend an amendment (a change) in the research procedure. Besides, if the research involves a drug

or investigational product, the investigator must notify the EFDA.

3.10.6. ComplianceMonitoring

Principal investigators should submit progress reports at regular intervals stipulated by the IRERC as a condition for renewal of ongoing research. Periodic progress reports enable IRERCs to determinewhetherthe research is progressing accordingto the approved protocol. In clinical trials, the progress report should include reports of the DSMB.

SlU-IRERC shall establish a follow-up mechanism to monitor the progress of all ethically approved research. The follow-up review shall be done taking note of the following prefaces:

a) Validityperiod of ethicsapproval

- Ethicsapproval isvalid foroneyear.For research that takes more than a year to complete, a renewal (continuation) application shouldbesubmittedtotheSecretariatwithafullprogressreportandjustificationfor SlU-IRERC approval.
- Anyamendmentintheprotocolatanytimeshould bereportedtotheSecretariatandapproval secured from the SlU-IRERC.
- Serious and unexpected AEs shall be reported to the Secretariat as stipulated inthe clinicaltrials of this guideline.
- In case of premature suspension or termination of a research project, the investigator should notifytheSecretariat includingthe reasons forthe prematuresuspension or termination ofthe research and summary of the research findings.

b) **Monitoring and Oversight Visits**

Approved research programs should be actively monitored through various mechanisms to ensure adherence to ethics principles, as considered necessary by SlU-IRERCs. Monitoring and oversightmechanismsandplansaredrawnupbyeach SlU-IRERCandoftenrelyuponreviewof reportsandsitevisits.Therearemany reasonsthatpromptthe needforsitevisits,someof which are:

- Some unexpected information becomes available from whistleblowers or discovered from information circulating in the community.
- Increased frequencyof SAE reports.
- Unavailabilityofprogress reportsorafinalreportin time.
- Reportsofsuspectedresearchmisconduct.
- Continuation of researchby investigators beyond the end of approval dates

withoutsoliciting formal request for extension.

- Studiesthatcontinuetobecarriedoutwithnewormodifiedobjectives/designswithout approval from SlU-IRERC.
- AnyotherreasonthattheIRERC feelswarrantsfurtherfollow-up.

c) Monitoring visits

SlU-IRERCemploystwo typesofmonitoringvisits,

i. Passive(SlU-IRERCreceivesinformationabout theresearchthatithasapprovedandusesthatinformation toassessthestudy‘s progress),and
ii. Active(SlU-IRERCmembersphysicallyvisittheresearchsite(s)).Activemonitoringnecessitates the use of checklists to ensure appropriate issues are assessed during the visit.

d) Oversight Visits

Oversight visits by SlU-IRERC could be planned as announced (pre-arranged and notified to the site investigators) or unannounced (by way of unarranged visits).The type and frequency of oversight visits should depend on the level of risk and complexity of the research. SlU-IRERC can carry out announced or unannounced oversight visits. The number of SlU-IRERC members needed to conduct an oversight visit depends on the workload of the monitoring team. To maximize objectivity, at least two members of the SlU-IRERC or delegated persons with diverse expertise and drawn from different institutions should make up the monitoring team. A monitoring team may include the community representative of SlU-IRERC.

3.11. ResearchMisconduct,andpossibleactionsagainstmisconduct

All researchers are obliged to respect the requirements set in these guidelines and the laws of thecountryandthepertinentlocalregulationsrelatedtoresearch.Misconductinresearchis one of the aspects that make research unethical. Research misconduct includes but is not limited to:

- Conducting research that involves humans, animals or the ecosystem that comprise human and animal life (ecological, environmental, agricultural, engineering, etc.) without proof of ethical approval or waiver by a competent body.
- Collecting samples or information from study participants without first obtaining valid, voluntary informed consent except in conditions where waiver of informed consent is applicable.
- Sharing with other investigators samples collected from study participants or institutions without ethical approval and without a signed Material Transfer Agreement.

- Sharing samples collected prospectively from study participants with other investigators or institutions without the informed consent of the participant (Note: IRERC may waive the requirement for informed consent in the case of archived and anonymized samples if the justifications are considered ethically and scientifically sound).
- Failure to submit mandatory reports such as SAE reports, progress reports and final reports to the SlU-IRERC.
- Failure to renew approval or conducting research after the approval period hasexpired.
- Failure to uphold the confidentiality of research participant's information including informed consent documents.
- Failure to report deviations from the approved protocol procedure(s) in time. Deviation from approved protocol procedure(s) should not be made without the agreement of the IRERC that approved the protocol except when it is necessary to avoid immediate danger to a research participant.
- Unjustifiable deviations.
- Fabricatingor falsifyingdata, orknowinglyplagiarizingothers'work.
- Misuseofresearchfunds.
- Forgery of SlU-IRERC documents (e.g., alteration of approval letter/certificate, Material Transfer Agreement, etc.).

IRERCsmayreceivereportsofmisconductviainvestigators,communitymembers,voluntary whistle-blowers,researchparticipants,orthroughitsoversightactivities.Uponreceiving

such reports, the SlU-IRERC should confirm the validity of the alleged misconduct before deciding on an appropriate course of action. The actions that SlU-IRERC may take after confirming the misconduct include:

- A letter of warning written to the PI by the SlU-IRERC Chair with instructions for the misconduct to be stopped and/or rectified. The head of the institution, partners, and sponsors should be copied.
- Correctiveoreducational measures.
- Frequentmonitoringofresearchactivities.
- Recommendations on more frequent reporting by the investigator about his/her research activities.
- Suspension of eligibility to receive research grants. SlU-IRERC may blacklist the investigator for a fixed period. (N.B., IRERC should not approve any research protocol submitted by the blacklisted investigators). The list should be copied to the relevant authorities.
- Intheeventseriousharm/injurywascausedtoparticipants becauseofthemisconduct, compensation for the harm/injury should be made by the investigators, or the host institution, or both. All research-related harm or injury because of ethically unapproved research shall be compensated by the investigator, the host institution, or both. The compensation package should be determined by qualified and relevant authorities.
- Temporary or permanent suspension of the PI and other investigators from research and/or professional practice.
- Suspensionof allresearchbeing conductedbytheinvestigator.
- Terminationoftheresearch.
- Thehost institution mayalso be suspendedtemporarilyfrom research activities.
- Editors of journals should refuse publication of manuscripts from unethically conducted research and retract articles that are alreadypublished but eventuallyfound to be conducted unethically.
- Inthe caseofcriminalmisconduct,informalegalauthority.

3.12. ResponsibilitiesofInvestigators,Salale University, andSponsors/donors

Responsible conduct of research requires that all stakeholders discharge duties expectedofthem according to this guideline and the law and regulations of Ethiopia.

3.12.1. Investigators

The investigator is responsible for overall conduct of the research according to the approved research protocol/procedures. More specifically, the investigator:

- Shallmaintainadherencetobasicethicsprinciples,
- Shallpossessappropriatescientificandhuman ethicsstandards,
- Shall ensure the highest possible standard of ethics, within the limit of investigators‘ and the sponsors‘ capacity,
- Shall ensure availability of care to study participants during the study and ifapplicable for a variable period after the completion of the research based on the researched problem, condition or instrument,
- Shall ensure privacy of study participants and confidentiality of information about themandshallkeeprecordsofinformedconsent documentsconfidentiallyinalocked cabinet; and investigator‘s file has the necessary documents to guide the research, but also to facilitate oversight,
- The investigator shall ensure that hard data is kept in locked cabinets and electronic data is password protected and accessible only to appropriate personnel,
- Monitor research staff to ensure the research is carried out according to the approved research protocol/procedures,
- Periodically submit a progress report to the IRERC. The frequency of the report is to be determined according to the level of risk inherent in the research, i.e., the higher the risk the shorter the reporting interval,
- Shall promptly investigate serious adverse events and take appropriate measures to safeguard the safety of study participants. The investigator shall inform the IRERC, theclinicalmonitorand thesponsor about such adverse eventsand measurestaken,if any,
- Shall inform the IRERC and obtain approval for any changes or amendments in the approvedprotocol/proceduresexceptincircumstanceswhereanincidenceofanimmediate hazard or danger to study participant necessitates prompt actions to be taken by the investigator without the need for amendment. Any amendment shall be appended to the approved research protocol,

- Shall inform the SlU-IRERC, clinical monitor, the sponsor and the participants if thestudy is terminated or suspended at any time during the research process,
- Shall be responsible for periodic assessment of the quality of data management as well as reporting an interim analysis whenever appropriate,
- In caseofclinical/experimentaltrials,shall ensureatleastoneoftheinvestigators has a certificate of Good Clinical Practice (GCP) and that the investigational product has certificate of Good Manufacturing Practice (GMP),
- Shall ensure that beneficial investigational products are available to the community after the research is completed,
- ShallreporttotheDSMB,asapplicable,
- In collaborative research, shall consider the cultures and ethnic diversities of communities and should make the research objectives transparent and easily understandable/comprehendible so that the welfare of the individuals or communities is unaffected,
- Shall provide adequate information in all publications so that the methods and findings can be replicated or verified by a community of researchers and/or policy makers.Limits of reliability and applicability should be made clear,
- Shallsubmitfinalreportand findingstothe IRERC, and
- Shallensurethecommunityreceivesinformationaboutresearchfindings.

3.12.2. Salale University Responsibilities

The Salale University‘s culture in which research is conducted strongly influences whether ethical conduct of research is supported or valued. The Salale University must work closely with investigators. The Salale University shall monitor the investigators‘ research activities; more specifically, the it shall:

- Ensurethat the studydesign is scientificandethical.
- Ensureethicalimplementationof the research.
- Complywith legalrequirements and ethicsregulations as stipulatedin thisguideline.
- Ensurethattheinvestigatorsconductingthestudyarescientificallyqualifiedand competent to carry out the research at the institution.

- Facilitateandprovidesupportforsmoothandethicalimplementationoftheresearch.
- Makesurethat theresults ofthestudyareproperlyand publiclydisseminated.
- Ensurethatguidelines,ethicalprinciples,andrelatedmaterialsreachtheendusers and the investigators.
- ProvideperiodicreportsofethicalimplementationofthestudytotheIRERC‘sSecretariat.
- Takedisciplinaryactionontheinvestigatorsforbreachofanyofthisguideline,or regulatory and legal requirements.

3.12.3. Sponsors/donors

Sponsors/Donors are responsible for providing an environment that promotes integrity, objectivity and the highest ethical standards of research, including standards for design, implementation and reporting. Particularly, sponsors must commit to protect participants in all research. Besides, sponsors are expected to ensure research subjects and communities are not made worse during or after completion of the research. Sponsors can accomplish these goals in the following ways:

- Ensure appropriate review and approval by SlU-IRERC or appropriate IRERCs is carried out as required by local and international regulations. If the sponsor is based outside of Ethiopia, the sponsor must in addition produce approval from an appropriate IRERC. If the sponsor is an international organization, the review of protocol must maintain rigor in accordance with its own independent IRERC.
- Monitortheresearch accordingto aplanapproved bytheIRERC.
- Select qualified investigators and institutions that can competently lead or co-lead the research undertakings.
- Providetrainingonethical guidelinestoall investigators.
- Complyingwiththelocalethical,regulatoryandlegalrequirements.
- Promoteresearchintegrity, and refrainfrom actionsthatbreachintegrity.
- Ensure the local relevance of the research by involving local partners during research protocol development.
- Securefundsforfinancingthe study.
- Ensureadequate safetyand efficacyof investigational products, if applicable.

- Ensure safety and efficacy of investigational products, if applicable; the sponsor shall ensure investigational products are manufactured following good manufacturing practice,
- Supplyingandhandlinginvestigational products,
- Updateinvestigator'sbrochureassignificantnewinformationismade available.
- EstablishaDSMB,if applicable,
- Assignclinicalmonitors,ifapplicable,
- Provideinsurancetostudyparticipantsandindemnificationtothestudywhen applicable/as required by local regulations,
- InformNRERB/IRERCifitsuspendsorterminatesaresearchwithdetailed explanation for the termination or suspension, and
- Ensurethe communitywherethe research isconductedisinformed abouttheresearch findings.

3.12.4 Networking and envisioning online research ethics review management platform Networking and creating a dynamic relationship among SlU-IRERC are essential forharmonizing research processes and to establish a strong research database system. The national research ethics review guideline has as its core activities the task of establishing a strong and standardized research ethical review and reporting system in Ethiopia. MoEaspires to foster partnership among SlU-IRERC of local institutions and forge collaboration with international IRERC. Efforts are underway to facilitate the processes, and toultimately establish a central web-based repository and registration of ongoing research in Ethiopia. Pre-conceived principles and networking mechanisms/modalities for building the necessary capacity for these efforts to be realized include:

- Informationflowshould bemultidirectional.
- All SlU-IRERC shallsubmitreportstoNRERB.
- ReportsofSlU-IRERC shallincludeataminimum:i.activitiesperformed,ii.Support needed, and iii. Problems encountered, etc.
- Forurgentmatters,SlU-IRERC shouldseekinformationortechnicalsupportfrom NRERB.

The SlU-IRERC will distribute appropriate guidelines and other related information to all colleges and request feedback.

SECTION 4: HUMAN HEALTH RESEARCH ETHICS

Introduction: High ethical standards in health research are possible when investigators aspire to such standards in their research activities. To safeguard the rights, safety and welfare of human subjects in research, SlU-IRERC, shall promote three basic ethical principles: i) respect for persons, ii) beneficence/non-maleficence, and iii) justice. In general, SlU-IRERC shall ensure that investigators havethought of ethical issues, specificallythat no ethicallyacceptableharm will be done, and no resources are wasted in the name of research, regardless of the research question planned for exploration.However, in certain circumstances, the weight given to each of these three basic ethical principles may differ in accordance with the type of the research and the setting where the research is taking place.

4.1.Typesanddescriptionsofethicalproceduresin humanhealth research

There are special categories of research in human health that possess characteristics and demand special emphasis in ethical considerations. These types of research include clinical/experimental trials, genetic studies, socio-behavioral, and collaborative research, etc.

4.1.1. Clinical trials Submissionrequirements

An investigator‘s brochure which provides an adequate summary of all safety, approval and permissiononpharmacological,pharmaceutical,andtoxicologicaldata available onthe study product, together with a summary of the clinical experience of the study product (e.g., recent investigator‘s brochure, published data, summary of the product‘s characteristics, etc.), must be submitted.

The principal investigator (PI) should attach a certificate of Good Clinical Practice (GCP), and a certificate of Good ManufacturingPractice (GMP), based on the nature of the research. The PI must assure that the clinical monitor and the SlU-IRERC have access to the participant‘s file to verify trial procedures and archiving data in accordance with the approved protocol. This information must be included in the participant information sheet. Additionally, the research participant by signing the informed consent is permitting access to the file by the clinical monitor and the SlU-IRERC.

Theinvestigator shouldaffirmthathe/she hassufficienttime toconductand monitor the trial, as well as to submit progress reports on time. If the study involves a new intervention, investigators need to give an assurance, when applicable, that post-trial benefits will be provided to the community where the study is to be conducted and the country at large.

4.1.2. Investigator'sFile

The investigator must prepare a file containing documents related to the trial. During the study, the investigator is responsible for updating the file and adding trial-related documents. It is possible to archive identification codes of participants up to 10 years.

- TheInvestigator'sFile should contain,ata minimum:
  a) Localregulatoryrequirements
  b) SlU-IRERC andotherauthorities'writtenapprovalforalldocuments
  c) SlU-IRERCandotherauthorities'writtenapprovalforprotocolamendments correspondencewith theSlU-IRERC
  d) Approvedprotocoland amendments
  e) Allsignedand datedinformedconsent forms
  f) Investigators'andCo-investigators'CVs
  g) Copyof theinsurancecertificate/otherinsurances
  h) Investigator'sSOPs
  i) Notificationanddocumentationofseriousadverseevents
  j) Specimenmanagementprocedures,trialsupplies/equipment
  k) Participantidentification list
  l) Investigator'sinterim andfinalreport/summaryofthetrial.

4.1.3. ParticipantFile

Theparticipant fileshould contain at aminimum the followingoriginal information:

a) Subjectidentification:familyname,givenname,dateofbirth,sex,andidentification number in the trial
b) Protocolidentificationnumber/studyreference
c) Datesoffirstscreeningand/or enrolmentinthetrial

d) Nameofdrugorinvestigationalproduct orprocedureon test
e) Datesofproduct administrationanddosage,andprocedure(s)
f) Datesof assessment visitand name ofindividual responsible formakingthe assessment
g) Seriousadverseeventandrelatedtreatmentormedication
h) Dates oflaboratoryspecimen/samplecollection.

4.2. DataSafetyandMonitoringBoard(DSMB)

- A Data and Safety Monitoring Board (DSMB) is an independent committee composed of a multidisciplinary group of experts established by the research sponsors to assess and report the ongoing scientific and ethical integrity of a study by reviewing and evaluating (unblinded as necessary) data at regular intervals.
- The DSMB should ensure that the data are handled in accordance with the provisions of the research protocol and monitors adverse events and safety data.
- A DSMB should be established before the commencement of a clinical trial and its composition submitted to the SlU-IRERC
- All phase I, phase II, and phase III, including drug efficacy and clinical trials proposed to be conducted in Ethiopia should have a safety monitoring plan, and a DSMB as recommended by an SlU-IRERC.
- DSMBs should be established in studies where interim data analysis is required to ensure the safetyof research participants. Other interventional studies, such as communitytrials, maybe required to set up DSMBs on a case-by-case basis.
- Sponsors should consider the need for establishing a DSMB prior to undertaking a particular study. An ethics review committee may also suggest to the sponsor that a DSMB is mandatory for a particular study. Recommendations of a DSMB are communicated directlyto the sponsor, but the sponsor should notify other relevant parties and ensure that the recommendations are communicated to, and acted upon by, the various parties involved inthe research.

4.2.1. Composition

A Data Safety and Monitoring Board is composed of people external to the research team. The members of the Board should:

a) Beindependent of the sponsor and themanufacturer oftheinvestigational drugor product;
b) Havenoconflict ofinterest inthe researchtheyare monitoring;
c) Receive no scientific recognition in the form of publications or promotions from the

results;

d) Have relevant expertise (clinician with relevant specialization, clinical pharmacology and/ortoxicology,epidemiology,statistics,ethics andadditionaltypesofexpertisedepending on the type of the research, e.g., anthropologists or community members for research which involve assessing cultural sensitivities);
e) Havefair representation fromparticipatingcountries inmulti-center studies;
f) Be composed of at least three members and the size and necessary expertise of the DSMB will depend upon the research design.

4.2.2.ConstitutingaDSMB

When required by the nature of a study, a sponsor should ensure the establishment of DSMB to ensure the broadest possible coverage of potential research participants, and the validity and scientific integrity of the data. To generate competent reviews and sound recommendations, the DSMB should be multidisciplinary and include, as appropriate, expertise in medicine (physicians with relevant backgrounds), clinical pharmacology and/or toxicology, epidemiology, statistics, clinical trial process, and ethics. The suitability of members of a board should be determined according to the nature of the study to be monitored.

The sponsor is responsible for establishing the DSMB‘s charter that defines the relationship between the sponsor and DSMB, which should be included (or referred to) in the research protocol.Members shouldnotbe affiliatedwiththe sponsor, investigators, ethicscommittees, regulatory authorities, sites, or study staff. Members should also not have vested interest(e.g., a financial or other interest in an intervention or product similar to the intervention being studied).

A procedure should be established concerning the requirements for candidacy, including an outline of the duties and responsibilities of DSMB members. Procedures for reporting and addressing potential or real conflicts of interest for members and independent consultants should be clearly defined in the charter.

4.2.3. Responsibilities

- Review research protocol, informed consent documents and plans for data safety and monitoring.
- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus

benefit, performance of the trial site, and other factors that can affect the study outcome.

- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial.
- Review clinical center performance, make recommendations and assist in the resolution of problems reported by the PI.
- Protect the safetyofthestudyparticipants.
- Conduct interim analysis of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis.
- Ensuretheconfidentialityofthetrial data andtheresultsof monitoring.
- Assist the sponsor through remarking on any problems related with study conduct, enrollment, sample size, and/or data collection.
- Report on the safety and progress of the trial and make recommendations to the SlU-IRERC and the sponsor regarding continuation, termination, or other modifications of the trial based on the observed benefits or adverse effects.
- Report the decisions to investigators who must submit those reports to the SlU-IRERC, which shall further report to the SlU-IRERC.

4.3. AdverseEvents:Definition,Grading,Follow-up,Reporting

4.3.1. Definitionof GradingforanAdverse Event (AE)

Adverse events are serious when they are fatal, life threatening, cause serious or permanent disability, cause or protract hospitalization, cause congenital anomaly, or lead to death.

An AE is related to the research procedure, drug and/or an investigational product based on temporal association with and response pattern to the procedure, drug or product, and the relationship, or otherwise, to the research participant‘s clinical state, or other interventions unrelated to the research or concomitant therapy.

An AE shall be considered unexpected if the event has not been observed or documented in similar research involving humans; the characteristics or severity of the event is inconsistent with information in the investigators‘ brochure; or the event is observed with higher frequency or severity than previously documented.

An adverse eventisgradedas:

a) **Mild**: if the event does not interfere with day-to-dayactivities and does not require

treatment.

b) **Moderate**: if the event marginally affects the day-to-dayactivities but can be tolerated by the participant or require out-patient treatment.

c) **Severe**: if the event significantly interferes with daily activities and demands hospitalization or procedures for relief.

4.3.2. Follow-uponanAdverseEvent

OnceanAEhas occurred,theinvestigatorshall:

- Monitorthe AE closely.
- Provide a standard care to manage the AE and follow the AE until completeresolution of the AE. Thoroughly investigate the likelihood and extent of the relationship of the AE to the research procedure, drug and/or investigational product. The details of the AE, from occurrence to complete resolution, must be recorded and attached to the participant‘s file.

4.3.3. AE Reporting

- A SeriousAdverseEvent (SAE) andthe measures takentomanage the SAE must be reported bytheinvestigatorthroughemailtotheSlU-IRERCsecretariatwithintwoworkingdaysoftheoccurrence of the event, even if the SAE is considered not to be related to the research procedures. Other adverse events should be reported with the progress report and submission of a renewal or an extension of an approval.
- The SlU-IRERC examines the AE report and the appropriateness, or otherwise, of the measures taken, and whether the measures are in accordance with the approved protocol. Measures beyondthe approvedprotocolshallbe documentedintheparticipant‘sfile andreportedtothe SlU-IRERC. The SlU-IRERC ultimately decides on the need for additional action.
- The medium for SAE reporting should be according to the communication means/channel described in the approved protocol. Anonymity of the research participant shall be respected when all information is sent/reported.

4.3.4. ComplianceMonitoring

Progress reports – Principal investigator (PI) should submit progress reports at regular intervals

stipulated by the SlU-IRERC as a condition for renewal of ongoing research. Periodic progress reports enable the SlU-IRERC to determine whether the research is progressingaccording to the approved protocol. In clinical trials, the progress report should include reports of the DSMB.

The SlU-IRERC shall establish a follow-up mechanism to monitor the progress of all ethically approved research. The follow-up review shall be done in the following manner:

- Ethics approval is valid for one year. For research that takes more than a year to complete, a renewal (continuation) application should be submitted to the Secretariat with a full progress report and justification for SlU-IRERC approval. Any amendment in the protocol at any time should be reported to the Secretariat and approval secured from the SlU-IRERC.
- Seriousandunexpected AEsshallbe reported to theSecretariat asstated abovein this guideline. In case of a premature suspension or termination of a research, the investigator should notify the Secretariat including the reasons for the premature suspension or termination of the research and summary of the research findings.

4.3.5. Monitoring

To observe compliance with an approved protocol, a site visit is necessary during the research. Deviation from the protocol is acceptable only to manage/treat a serious adverse event that endangers the participant‘s life or cause serious or permanent disability.In such acceptable cases of protocol deviation, the investigator must notify the SlU-IRERC, clinical monitor and sponsor immediately. Then, the content of protocol deviation must be recorded and inserted into the already approved protocol. Finally, the investigator should subsequently make a request for protocol amendment while applying for renewal of the research. The investigator should regularly submit a progress report; the progress report should include reports of the DSMB.

4.4. MedicalCarefor TrialSubjects

- The highest available standard of care in the country must be provided for trial participants.In international collaborative research, the care should be equivalent and uniform to the care provided in the country where the sponsor or the collaborating institution is functioning.
- Adequate/standardmedicalcare should be providedto participantsforadverse events.
- In caseof thetrial prematurelyterminated orsuspended, for anyreason:
- Theresearchparticipantswithassurancewillbeinformedandreceivecontinuingcareand treatment. The investigator must inform the SlU-IRERC and the sponsor as soon as

possible.

- Randomized,double-blinded trials,prematureun-blinding:the code may be broken because of a serious adverse event, if deemed necessary by the DSMB during interim report. This will be documented in the file and reported to the clinical monitor immediately.

4.5. GeneticResearch

- **Genetic Research**: is research conducted to generate scientific knowledge about genesand/or the genetic basis of disease.
- **Genomics Research:** the study of the genome, its action, and related techniques to understand the inter-relationships of all genes to identify their combined influence on the organisms,incontrasttogeneticswhichinvestigatesthefunctioningandcompositionofsingle genes. However,theterm geneticresearch in this guidelineencompassesboth genomic and genetic investigations.
- **Genetic Counseling**: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences. It takes place before and after genetic testing and screening.

4.5.1. Collection,storage,and handlingofgenomicdata

- In genetic studies involving the acquisition of biological samples, the procedure used to obtain samples, the type and amount/size must be clearly stated.
- The collection, processing, handling, storage, transfer, and destruction of human biological materials (data) must be conducted consistent with the principles of protection of privacyand confidentiality of specimen archives and data.

4.5.2. PrivacyandConfidentiality

- The protocol must state the use of appropriate coding techniques as well as security and access procedures at each step of sample collection, transport, analysis, and storage.
- The institute/organization where the data are deposited must have appropriate data protection andconfidentialityguidelines.
- Providingaccessshouldconsider the riskof compromisingthe privacy of individual study participants as well as risks of compromising data quality and interpretation.
- Data protection should be reassured in terms of secured physical or computational infrastructure.

4.5.3. Informedconsentconcerninggeneticresearch.

- In theinformed consent process, thereshould be aclearstatement that the studyis for genetic research purposes. Informed consent should describe, in simple language, the type and quantity of biological material, the collection procedures, and the plan for returning genomic data.
- The informed consent process should cover the human biological materials and data to be collected, data anticipated to be derived from the analysis of samples (including the possibility of incidental findings that were not initially intended to explore), and the health and other records to be accessed, their intended uses, storage, and duration of storage.
- The participants are informed that specific information resulting from the study will not be available to participants and their families unless there are existing standard medical interventions or locally acceptable social/legal norms. Explanation must be provided if the samples are shared with third parties and that in these cases the samples will be anonymous.
- If there are opportunities to obtain genetic counseling, it is desirable to include the information in the informed consent form. The consents should clearly state the use of broad or specific consent. If broad consent is sought, the protocol should clearly indicate relevance, risk, and benefit and otherissues. It must disclose that thedatawill be stripped of identifiable data or clearly indicate that the identity of those with access to secondary use will remain unspecified. Either of these consent options can be used as appropriate for the study nature and context.

a) **Broad consent:** is a consent where participants are given an option to consent to verybroadly described research possibilities with no further future re-consenting required.
b) **Tiered consent**: is consent where participants are given an option to consent to limited research possibilitieswith an additional option to bere-contacted for research proposed in the future or in a form of waiver of consent, where ethics committees decide on their behalf for other research.
c) **Opt-out consent:** is consent where participants are given an option to consent to limited research but specifically decline to research beyond the described purposes or timelines.

- When subsequent use of human biological materials or data previously collected that would not be consistent with the original informed consent, application for ethical approval is required. A new informed consent form developed has to be signed by participant/guardian/LAR or request for waiver of consent from SlU-IRERC.

4.6. Communicationof Findings

- Research institutions/sponsors that generate genomic data in a study are encouraged to adopt mechanisms regarding return of data to subjects, as appropriate. The protocol should clearly state the possibility of discovering _incidental findings‘and must ensure participants have proper understanding of this concept.
- Offering genetic results depends on ethical and local issues including the clinicalsignificance.Thepotentiallackofaccuracyandunderstandingofresultsobtainedintheresearch require adequate review. Thus, assessment of analytic and clinical validity is necessary, which includes evaluation of the strength of genotype-phenotype data association.
- The protocol should describe the timing of such communication, by whom (e.g., researcher, physician, or genetic counselor), and to whom (subjects, or the primary caregiver or legal guardian). A valid justification is necessary for each of the above-mentioned points.
- Ethics review committees/boards need to be consulted before communicating clinicallyuseful findings. The committee/board will decide whether communication is needed or not after reviewing the clinical utility of the finding and cost-effectiveness of the available medical intervention.

4.7. Biorepository/Biobanks

- **Biorepositories/Biobanks** are systematic collections of human biological samples that are linked to associated personal health information used for anypossible future research. Unlike standard biological research, research based on biobanks could involve many researchers, who might not have direct contact with participants and may encompass a large range of research questions of which some are undefined at the point of sample collection.Researchers and companies requesting to access repository specimens and data need to go through a review process with emphasis on justifiable local benefit sharing.
- All principles described above in the genetic research section will apply when reviewing studies involving biorepository samples/biobanks.
- Ownership of specimens and linked data primarily belongs to the research participant. However, institutionscouldtakeresponsibilityandcustodianshipover collected specimensor linked data forappropriate and controlled use,safe-keeping, responsible sharing and eventual disposal of the specimens or linked data.
- Whenstoringbiological materials(withlinked health-related data), institutionsor researchers must have a governance system to obtain authorization for future use of these materials in research, how the quality of the materials is controlled, and how privacyof

studyparticipants and confidentiality of the data derived are maintained.

4.8. Biotechnologyandstemcellresearch

- Medical biotechnology is a branch of medicine that uses living cells and cell materials in researchwiththeaimofproducingpharmaceuticalanddiagnosticproducts.Itcomprisesvarious techniques that exploit the application of biological organisms, systems or processes for the benefit of human beings. Some of the most recent uses of medical biotechnology includegenetictesting, and development oftherapeutics suchas biosimilar, geneeditingand artificial tissue growth.
- Such products help to diagnose, treat or prevent diseases, making huge advancements and helping millions of people around the world. However, with the much advancement in this technology, there are medical and ethical issues that require attention.
- When conducting clinical trials on biotech products where safety is a concern, theinformation sheet should clearly indicate the likelihood that unknown risk‘might occur because the effect of genetically modified/manipulated products (such as stem cells, gene editing, etc.) might not be determined within a short period of time or during the trial period. In such situations, insurance to trial participants must be available accordingly.
- Stem cell research (tissue engineering), especially embryonic stem cell research, is not allowed for various reasons at this stage, but somatic/adult stem cell research may be considered, given that all fundamental research ethics principles are observed.

4.9. Researchonthedeadbody

Research on the dead body, heart beating cadavers and cadavers should receive scientific and ethical review and oversight. The following ethical concerns need attention, including:

a) Useof procedures respectfulof thedeadbody
b) Protectconfidentiality
c) Getproxyconsent for bodyor organ donation
d) Getauthorizationfrom legalauthoritieswhere applicable
e) Request possibilityofwaiverofconsent
f) Haveplans fordisclosureoffindings
g) Getclear guidancefor ultimate disposalofthe body
h) Trytocomplywith thereligiousand cultural beliefs ofthe community.

4.10. SocialandBehavioralResearch

Social and behavioral science researchers encounter unique ethical challenges that warrant serious consideration. One of the key criteria used to review and approve protocols is to determineasatisfactoryrisk/benefitratio,toensurethattherisksbornebyparticipantsare well-balanced by adequate benefits. Social science research may cause non-physical harm in the form of emotional distress, stigma and other social harm such as destabilization of social and relational systems, and violation of privacy or confidentiality.

Social and behavioral research is often context dependent and not easily generalizable. This throws doubt on the societal benefit of this kind of research.

4.10.1. Informedconsentinsocialandbehavioralresearch

- Social and behavioral research can involve most-at-risk or hard-to-reach and legally unprotected communities. Permission can be obtained from gatekeepers such as community leaders, government authorities or heads of households.
- In situations where deception is required to achieve the objectives of the study, there needs to be a plan for assuring that there will be debriefing at the end of the study. SlU-IRERC need to be vigilant about the use of deception by ensuring that the debriefing includes adequate disclosure of the rationale for deception and be aware of the expected risks/harms that the participants may face from the deception process.
- Depending on the nature of the research protocol, waiver of consent or waiver of documentation of consent is possible to be approved by SlU-IRERC.
- Engaging communities in research can also facilitate the conduct of a given study in safeguarding and empowering vulnerable groups, fair distribution of benefits and burdens, and minimizing the potential conflicts of interest.
- Given that obtaining consent is a process that should be subject to negotiation during and even after the end of an interview, the informed consent process should include authorization for recording (audio, video) of interviews, focus group discussions, and observations.

4.10.2. Privacyandconfidentiality

- Depending on the nature of the study, the use of pseudonyms is allowed to hide the participant‘s identifiers or study site locations. Anonymity is ethically appropriate forresearch with those who are better off and better known.
- Research participants‘confidentiality is to be maintained on sensitive topics that involve discussion of private matters through interviews, phone calls, and home

visits.Psychosocialharmand interventions

- Social and behavioral studies are usuallyperceived to pose minimal risk to participants in the application of ethical principles. However, in social and behavioral research, the followingare potential risks to participants that all stakeholders should know and take into account:

a) **Anxiety and distress**: Responses are intimately dependent upon the context of the participants' beliefs, values, behaviors and actions. The differing experience of the participants can make it a daunting task to predict who may experience anxiety and distress and if it will be difficult/problematic.

b) **Intrusion in life**: exploringbehavior relatedto health mayrequire observation ofparticipants atvarious placesincludingthe household,workplace, privatetimeand maytake long periods.

c) **Exploitation**: Power imbalances between the researcher and the study participants orexerting undue influence.

d) **Misrepresentation**: Participants' opinions are sometimes taken out of context or interpreted from the researcher's perspective. Dynamics of the qualitative interviews and the nature of data collection can be affected by the professional background of the researcher.

e) **Identification of participant**: Any clues given (by self or others or in published papers) can inadvertentlyidentifystudyparticipants' identities. Thismayhappen when cluesareprovided to describe the participants' age, gender, educational and economic status, place of residence, profession, etc.

Hence, to minimize these risks of harm, the followingethical issues deserve special emphasis during protocol review, conduct, and monitoring of qualitative research:

- Ensuringscientific soundness.
- Providingcounselingandrehabilitationsupportwhereappropriate.
- Ensuringconfidentialitythroughsecuringstorageofaudioandvideotapesand transcripts.
- Conducting_respondentvalidation' oftheresearcher'sanalysisbeforedissemination of the research findings.
- Publicizingtheresearchbeforecommencementsuchthatthecommunityisawareof the observation that can be made in public domains: at marketplaces, sport events,brothels,theatres,etc. Insuchcases,the SlU-IRERCmaydecide waiverofconsentand

documentation of consent.

4.10.3. Pregnantwomenand Fetuses

Toconductresearchon pregnantwomen,thefollowingmustbefulfilled:

- Thereshouldbeevidencefromstudiesonpregnantwomenandnon-pregnantwomen that studies are safe.
- Theresearchshouldholdtheprospectofdirectbenefittothepregnantwomanandthe fetus.
- Thereshould beno inducementto terminatea pregnancy.
- Iftheprospectofbenefitsisforbothpregnantwomanandfetus,aninformedconsent must be obtained from the mother to enroll the woman into the research.
- Iftheprospectofbenefitissolelytothefetus,informedconsentshouldbeobtained from both parents, provided they are competent to give or refuse consent.
- Theforeseeablerisksoftheresearchonthefetusortheneonatemustbethoroughly explained.
- Anindependenthealthcareproviderwhoisnotamemberoftheresearchteamshould follow care of the fetus.

Newborns/Neonates

In researchinvolvingneonateswithuncertainviability,the following mustbemet:

- Previousresearchprovidesdatatoassesspotentialriskstoneonates.
- Viabilityofthefetusshouldbeassessedbyahealthcareproviderwhoisnota member of the investigators' team.
- Thereshouldbenoothermeansofobtainingtheknowledgetobederivedfromthe research.
- Thereshould benoadded risk totheneonate dueto theresearch.
- Theresearch is likelytoenhanceviabilityand survival.
- Informedconsentshouldbeobtainedfromeitherofthe parents.

Forresearchinvolving deadfetuses, or organsortissuesofthedead fetus:

- Thereshouldbeaprospectofimportantknowledgethatcan possiblybeusedinthe prevention and treatment of similar or related conditions.
- Informedconsentshould beobtainedfromeitherof theparentsof thedead fetus.

4.11. Traditional and Complementary Medicine (alternative medicine) (T&CM)

- TraditionalandComplementaryMedicine(T&CM):T&CMmergesthetermstraditional medicine (TM) and Complementary Medicine (CM), encompassing products, practices andpractitioners. In principle, traditional and complementary medicines research is subject to the same ethical standards as conventional research practices.

- The research should follow scientifically sound procedures and observe the fundamental ethical principles of autonomy, beneficence and justice and the ethical review processes outlined in these guidelines.
- It is important to balance the need to protect the intellectual property rights of indigenous peoples and local communities and their health careheritage while ensuringaccess to T&CM and fostering research, development and innovation.
- All herbal medicinal product processes must be conducted based on standard techniques and theseagainhave tobe accordingtoapplicable legalandenvironmentalrequirementsandwith the ethical codes or norms prevailing in the communityand the country. To ensure safetyand efficacy of herbal medicines, proper scientific studies (phases) are necessary to be conducted on healthy volunteer populations. Unique characteristics in these areas of research which require dueconsideration suchas inclusion/exclusion criteria, useof placebos and the general principles and requirements for a clinical trial should be similar to conventional drugs.

4.12. HealthSystemsResearch

- **Synonyms**: Health Systems Research, Operations Research, Implementation Research,Health Systems and PolicyResearch (HSPR). Health Systems andPolicyResearch (HSPR) is recognized as a hybrid, or trans-disciplinary' field, drawing on different disciplinary traditions and methodological approaches. Applied research is undertaken with an orientation towards influencing policy and wider action to improve the performance of health systems.
- Health systems research (HSR) is a subset of public health and is defined by the WorldHealth Organization (WHO) as the purposeful generation of knowledge that enables societiestoorganizethemselvestoimprovehealthoutcomesandhealthservices.HSRis necessary to ensure health systems strengthening, quality of care, and evidence-informed public policy creation. HSR researchers must carefully define their intent and goals and openly clarify the

values that may influence the premises and design of their protocols.

- Implementation Research (IR) addresses different aspects of implementation including social and contextual factors (poverty, environment, and culture), the process of implementation (which approach best answers the implementation issue?) or the outcomes of implementation (clinical/process end points).IR questions cover a broad range of topics that focus on improving health system functioning and improving equitable and just access to effective health care interventions. In short, HPSR has close interconnections with health policy with social and political implications and employs a range of study designs.
  - **Ethical Issues:**HSR and IR involve a range of ethical considerations that have not yet been comprehensively covered in international guidelines on health research ethics. The fundamental ethical principles governing clinical research apply equally in HSR and IR, but the application of these principles may differ depending on the research question, context,and the nature of the proposed intervention.
  - **Identification**: The definition of HSR varies depending on the type of research, location, or source considered and these often leave grayzones between research and non-research which are currently considered as part of the HSR agenda in LMIC.
  - **Distinction of research**: A clear operational definition is required of what counts as health research and therefore is subjected to ethical review and what does not count as health research or counts merely as quality improvement, monitoring and evaluation exercises.
  - **Community engagement**: Meaningful engagement with all stakeholders including communities and research participants is a fundamental ethical requirement that cuts across all study phases of IR.
  - **Balance between the risks and benefits:** The benefits of IR may not accrue to the same groups whoparticipateintheresearch,thereforejustifyingthe risksversusbenefitsof IRmay be ethically challenging but investigators should aim to balance these.
  - **Autonomy and informed consent**: Challenges in operationalizing informed consent in the context of IR include whether the beneficiaries are individuals or populations, andappropriateidentificationofwhotheactualresearchparticipantsare.Theinformedconsentprocessin IRthereforemaybequitedifferentfromthatinclinicalresearchandrequires thorough consideration to ensure optimal ethical conduct of IR.
  - **Dataownershipandsharing:**donororsponsoroftenownsdata,regulatesandrestricts further handling of the data.

4.12.1.Recommendations to SlU-IRERC on HSR

HSRmayposeethicalissuestohumanparticipants,andtheethicalreview processes of research ethics committees (RECs) and **Salale University Institutional Research Ethics review committee (SlU-IRERC)**. The following are recommendations to ethics reviewers, committees.

- Realize that the ethical concerns differ from other types of research; therefore, its ethicalreviewshouldarguablybetailoredtoaddressthefeaturesanduniqueethical challenges that are particularly salient (though not exclusive) to HSR.
- RECsneedtodistinguishprogramandqualitymonitoringandevaluationexercises from implementation and health research. Health system research which is merely quality improvement, monitoring and evaluation exercises are programmatic interventions.These,therefore,donotrequireclassicalethicalreviewassessments.
- RECsneedtohaveanSOPandchecklisttoreviewHSRintheguidelines/SOP, including a review checklist or SOP for this type of research.
- Health systems research is not reviewed by the same ethical standards as clinical research.HSRdoesnotimposethesameriskstostudyparticipantsasothertypesof clinical or public health research.

a) **Justification and responsiveness:** Research problems addressed by IR must be of high local priority to justify the research. Engagement with local health experts and communities is therefore essential in the planning stages of IR to determine whether a health problem is indeed perceived to be a local priority.

b) **Equipoise:** Itisrequiredtojustifyanypotentialrisktoresearchparticipanti.e., whetherthere remains genuine doubt whether a new and untested package of interventions will work in a specific context.To justify IR, therefore, equipoise regarding the effectiveness of the implementation processes must be preserved.

c) **Stakeholder and community engagement**: Key stakeholders in IR may include the government,policymakers,publichealthfunctionaries,healthcareproviders,healthcaremanagers, financing mechanisms, health care industry, and the community (community representative).

d) **Privacy and confidentiality**: In most HSR informed consent is not possible; it is the responsibility of the researcher to obtain a waiver of consent from the respective institutional research ethics review committee.In research, specifically dealing with qualityimprovement, it is necessary to inform patients and ensure privacy and confidentiality, and use the opportunity to strengthen the patient-researcher partnership and build trust.

e) **Standard of care or prevention**: There are two approaches to deciding on standard of

careor prevention services for a control group: either de facto or de jure. De facto standard refers to allocating the local de facto existing standard, which in some situations may be grossly insufficient, making it ethically unacceptable based on justice and fairness principles.For example, having a placebo control arm is not acceptable despite the local de facto care being no treatment, if effective treatment is available.De jure standard refers to provide the local de jure standard of care or prevention, which is agreed upon by public health experts of that region and is acceptable to the community.

f) **Dissemination of researchfindings**:Giventhe importantpublic healthimpactof IR,thereis an ethical obligation to disseminate the research findings (both positive and negative) widely, including feeding back to the communities and stakeholders who participated in the research.

g) **Data ownership and sharing**:an ethical oversight of the data ownership process is required to ensure appropriate access to the research findings bythe relevant stake-holders post-study, including the local researchers and communities when appropriate, to maximize the utility of the knowledge generated.

h) **Translating findings into public health action**: there should be an ethical obligation for IR findings to be used to inform effective and equitable public health action. Prompt communicationof findingsbyresearcherstopolicymakers isimportant,as wellasworkingto establish and support a culture of evidence-based decision-making.

4.12.2. Digital Health

Synonyms: Electronic Health, mHealth, Artificial Intelligence (AI), and Big Data. With the increasing use of mobile and wearable devices, new opportunities have arisen for personalized health (tailored care to the needs of an individual), crowd sourcing, participatory surveillance, and movement of individuals pledgingtobecome datadonors‘‘andthequantified self‘‘ initiative (where citizens share data through mobile device-connected technologies). These initiatives create large volumes of data with considerable potential for research through open data initiatives. The range of data sources include Electronic Health Records (EHRs), data from mobile health (mHealth) applications, medical blogs and web- networks, healthcare robotics, medical internet of things, as well as direct-to-consumer genetic and screening tests. Additionally, health-related information is not derived only from digital health applications, but also from non-strictly medical data sources such as online personal dietaryprograms, fitness club memberships and Twitter hashtags. Health-related big data is the umbrella term used to describe extremely large and heterogeneous data sets that have the potential for analyses to reveal

patterns, trends, and correlations, that have relevance for human health.

- Digital Health research is a broad area of research, which encompasses electronic health records, mobile health applications, social-media, medical artificial intelligence and health related big data. The mainstay being use of interrelated and interconnected online datasources for generation of knowledge and medical application.Digital health is a rapidly expanding medical field premised on the availability of ever-increasing amounts of dataabout people‘s lifestyles, habits, clinical histories and path physiological characteristics.
- Digital health, entails connecting health-related data, including data generated by patients themselves, and harnessing the medical potential of technological tools of common usage, such as smart-phones, wellness bands, apps, social media and sensing devices disseminatedin our dwelling environment. It generates a seamless flow of critical medical data between patients, their families and their physicians. Given their volume, complexity, variety and propensity to be analyzed through data-mining techniques, such data qualify as big data or, more precisely, as biomedical big data.
- **Ethical Issues:** The methodological novelty and computational complexity of big data health research raises new challenges in ethical review. For digital health to materialize, it is better to realize that several ethical and policy challenges exist.

  Issues of concern include ownership of personal data, privacy, and confidentiality breaches with increased likelihood of privacy threats to data sets that are not readily identifiable. The clinical development of digital health applications is premised on the creation of large data, including the recording of sensitive personal data.

  There is increased risk of (re)identification of individuals and/or a weakening of the security that data masking techniques appear to provide. The privacy model ensures that the privacyof data from contributors is protected well while at the same time ensuring that data is not rendered useless because of privacy protection efforts.
- **Open data movement and commercial exploitation**: striking the balance between an individual‘s desire for privacy and the desire for good evidence to drive healthcare, may sometimes be in conflict. Moreover, bodies with a commercial interest in selling health-related goods and services may be able to use shared data to pressure people into purchasing them.
- **Risks to privacy and personal autonomy:** conflicts with the intentions of solidarity-based

approaches to healthcare funding. The increasing public demand for transparency, trust, and fairness while using big data is an expressed opinion by society.Lack of appropriate infrastructures for data storage is a critical technical and infrastructural issue that might endanger a big-data-driven healthcare.

- **Informed consent**: Heavy reliance on consent is becoming increasingly impracticable in the big data context. Nowadays, big data can be used within and across ecosystems to look into different health agendas within and among countries.

- **Data security (personal, institutional and national):** some of the data collected and stored electronically may pose data security threats.

- Recommendationsto **IRERC**: Due to the existing and emergent critical ethical issues mentioned above, digital health research protocols need to be reviewed by research ethics committees as there is no implicit exemption. Issues of data ownership, group-level ethical harms and the distinction between academic and commercial uses of big data must be taken into considerations in the review of digital health research.

Digitalhealthresearchers and reviewers shouldscrutinizemorecarefullythefollowing:

- Whetherandhoweachprojectattemptstoaddressthesocialbenefits,ifany,of research?
- Howsubjectsinvolvedinthestudycanexercisecontrolovertheirdata(datacontrol problem)?
- Whichmeasuresof accountabilityarebeingemployedbythe researchers,and
- Whethercollecteddatacanbereusedforsecondary,includingmalevolent,purposes (dual use problem) and what measures are implemented to prevent that?

Ethics review committees need to have access to expertise during the review process. Data scientists, security experts, and bioinformatics experts should complement the expertise of clinicians, ethicists and other traditional IRERC/**SlU-IRERC** /ERC members.

Adequacy of privacy models should consider the attributes of a dataset and specify the conditions that the data must satisfy for the disclosure risk to be minimized to an acceptable risk level, such as:

a) data likability (the ability for anonymized data to remain relatively linkable so the value of the data is not significantly diminished),
b) Composability (the privacy guarantees that can be given when data from multiple

sources to which the same or different privacy models have been applied is integrated into one data- rich source), and

c) Low computation (algorithmic efficiency i.e., the algorithm uses a low number of computational resources, such as time or space).

The researchers need to demonstrate and present (attach/annex) clearly written data sharing policies for Data Repositories and Electronic Medical Records and Online Data Platforms.

- **Data security**: Researchers should refer to and cite comprehensive regulatory policies and safeguards to address public concerns, such as the protection of individually identifiable information. However, in absence of specific guidelines and comprehensive evaluation studies, ERCs might be facing uncertainty on how to review health-related big data projects and according to which evaluative criteria.
- **Informed consent**: depending on data type, data source and context, there should be a mechanism to seek informed consent for collecting and sharing data. The researchers need to explain in what terms data were collected from the originators of the data. Informed consentis often not practical to obtain for studies involving a retrospective access to data from millions of individuals.
- **Accountability**: Data generators and data managers take responsibility for the proper and ethicaluse ofdata. Inaddition,inthe areasof ArtificialIntelligence (AI),there shouldalways be human supervision and monitoring.
- **Co-governance**could giveacollaborativeplatform to address issues ofbigdatavulnerability by ensuring that all stakeholders have a say in decision-making over how data are gathered, stored, and distributed.

SECTION 5:ANIMAL RESEARCH ETHICS

5.1. Management of conflict and arbitration mechanism

Addressing research ethics issues by peer-based mechanisms will uphold scientificautonomy, be more cost-effective, and likely resolve issues in a peaceful way therebycreating a more harmonious atmosphere. In case a conflict arises at any stage of the review process an independent one-time committee of arbitration shall be installed. The committee members must display impartiality, independence and objectivity in an arbitration tribunal which is crucial during the process of resolution. The committee member or invited expert with a Co I will be required to excuse himself/herself from the meeting during discussion and decision of any arbitration process. Upon calling an independent expert as a committee member for arbitration he/she shall sign privacy and confidentiality agreements and Co Iforms to ensure that the

information in the protocol is protected and that consultants do not have any conflicts.

5.2. Mandate and types of proposals to be reviewed by SlU-IRERC

NRERB'sintentionisnot to hinder research; itsobjective is to ensure that the welfare of animal is protected and that the project complies with federal/country standards. The review panel is composed of experienced and educated researchers from different areas in the biological sciences.

Thefollowingare thelist of research protocols mandated to bereviewed by**SlU-IRERC**:

- Zoonotic diseases (Emerging and reemerging diseases of public health significance), exotic zoonotic diseases, research involving highly pathogenic organisms.
- Economicallyimportanttrans-boundarydiseases havingnational interest.
- Researchinvolvinganimalgeneticresourcesandgeneticallymodifiedanimal research/organisms.
- Researchinvolvingendangeredanimalspecies.
- Researchinvolvingrecombinantvaccines.
- Internationallycollaborativeresearchinvolvingmulti-sectoralagencies.

5.3.GeneralGuidelinesforreviewof researchinvolvinganimals

The work of SlU-IRERCcomplieswiththeregulationsandrecommendations for the care and ethical treatment of animal involved in research throughthe animal welfare act and other related acts and regulations and directives on animals & animal products of the country.

Additional regulations may provide protection for animal species. All appropriate state and federal permits must be obtained prior to conducting field or laboratory research on animals protected bythe Endangered Species Act for Wildlife and Fisheries, and other state and local regulations.

The Institutional Animal Care and Use Committee (IACUC) for the protection of animal is charged with the responsibility for reviewing, prior to its initiation, all research involving animals (whether the project is funded or not). The IACUC is concerned with evaluating the care and treatment of participants in research ensuring the ethical treatment of experimental animal.

5.3.1. ReviewCriteria

The national ethics review system shall oversee the humane care and use of animals in research in accordance with federal and institutional regulations, and sponsoring agency policies and

procedures. Key personnel involved in animal and animal genetics related research need to have basic training on the humane care and use of animals or supported by co-investigators who are trained as such.

SlU-IRERC supports and endorses cooperation with institutions to ascertain compliance and monitoring efforts related to animal welfare, and reports instances of noncompliance to the appropriate compliance office.

All research involving vertebrate animals (i.e., exploratory, descriptive, and experimental) must be reviewed by the **SlU-IRERC**/IACUC and when appropriate by **SlU-IRERC**.Approval must be sought when the research plans are complete and before the involvement of animals in the project.

Although review of research involving non-vertebrate animals is not required, it is recommended that the spirit of the Animal Welfare Act and other federal guidelines be considered as partof the ethical responsibilityoftheresearcher.Tothis end, the **SlU-IRERC** will conduct a Courtesy Review of such proposals at the request of the researcher and provide recommendations.

While the ultimate responsibility for conducting research in an ethical manner that complies with federal, state, and local regulations rests with the researcher, the **SlU-IRERC** reviewers will seek to determine that:

- The transportation, care, and use of animals are in accordance with the Animal Welfare Act and other applicable federal laws, guidelines, and policies.
- Procedures involving animals and their genetic resources should be designed and performed with due consideration of their relevance to animal health and production, the advancement of knowledge, and for the good of society.
- The animals selected for a procedure should be of an appropriate species and quality, and only the minimum number required to obtain valid results are used.
- Methods such as mathematical models, computer simulations, and in vitro biological systems when appropriate can possibly be used in lieu of animals.
- Proper use of animals, including the avoidance and minimization of discomfort, distress, and pain combined with sound scientific practices are taken into consideration.Procedureswithanimalsthatmaycausemorethanmomentaryorslight pain or distress should are performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures are not to be performed on unanesthetized animals.
- Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved are painlessly killed at the end of the procedure or, if appropriate, during the

procedure.

- The livingconditions ofanimals areappropriate for the species and contribute to their health and comfort.
- The investigators and other personnel are appropriately qualified and experienced for conducting procedures on living animals.

5.3.2. Theresponsibilitiesoftheprincipalinvestigators

- Choosingthemostappropriatemethodsfortheirwork,inconsultationwithveterinarians and other experts as needed.
- Detailingallanimal-basedmethodsinwritingtotheethicscommitteewithinthe animal use protocol forms provided for this purpose by the ethics committee.
- Answering questions from the research ethics committee on any aspect of animal- based work, including: i) why animals cannot be replaced, if this is the case; ii) why the animal model and proposed numbers of animals have been chosen; iii) what refinements to animal use are proposed and what additional ones could be considered (in some specific cases, certain elements that would normally be refinements may not be appropriate, in which case the principal investigator should provide justification of the proposed choice); and iv) what can be learned from previous, similar work.
- Reporting serious violations of approved protocol, particularly any violations thatmay affect animal safety, to the **SlU-IRERC**/IACUC and if required to **SlU-IRERC**.
- Prepares and submits animal studies protocols or changes in accordance with federal regulations and institution and sponsoring agency policies and procedures.
- Submits proposed changes to the protocol for approval as required and assures that changes are not implemented prior to approval.
- Reviews protocols at inception and as required thereafter for completeness, accuracy, and improvement opportunities.

Considerationsduringscientific review shall include the following:

- Importance andnoveltyofthescientificquestion.
- Strengthofthescientific designandmethodology.
- Feasibilityof theresearch as designed.
- Appropriatenessofthestatisticalanalysisplan.
- Estimateof theprobabilityofmeetingtheenrollment goals.
- Assessmentofthethoroughnessoftheproponent‘sevaluationoftherelevant literature and previous studies, if available.
- Appropriateness of the qualifications of the investigator to carry out the protocol and

the facilities available to him or her.

- Appropriatenessoftheinclusion/exclusioncriteria.
- Disseminationplan(torelevantstakeholdersandthrough formalpublication).

Therearethreepossiblemechanismsbywhichinitialresearchproposalsinvolvinganimal subjectsandanimalgeneticresourcesarereviewed:i)exemptionofreview,ii)fullboardreview, and iii) expedited review. Exempt review is conducted by the Chair/Vice-Chair of **SlU-IRERC** while full and expedited reviews are conducted by the **SlU-IRERC**.

5.4.Typesof researchprojectseligibleforexemptreview

Projects that involve non-vertebrate species or non-living vertebrate specimens such as museum specimens, preserved specimens, or other animals that arenot euthanized to conduct a project are not subject to review, nor are projects that consist solely of field observations of animals in their natural habitats. Only projects that involve hands-on work with vertebrate specimens that are alive during or immediately prior to the project require expedited or full- board reviewing.

Research with animal subjects may qualify for exemption if, and only if, all research proceduresfallwithintheexemptioncategories listed,and ii)theprojectdoesnotinvolveany of the animals or procedures listed under restrictions.

Researchcannot be exempted ifanyof thefollowingare involved:

- Procedureswhichexposeparticipantstogreaterthanminimalrisk.
- Researchinvolvingendangeredspecies.
- Experimentalresearchinvolvingallanimals.

5.5.Typesof researchprojectsrequiringfullboardreview

All research proposals that are not exempt and do not meet the criteria for expedited reviews arereviewedviafullboardreviewmechanismataregularlyconvenedmeeting.**SlU-IRERC**willreview all proposalsthatdo notfallinto the expeditedreviewcategory.

To approve a protocol, the **SlU-IRERC**, and when appropriate the **SlU-IRERC**, must have sufficientinformation to determine the following criteria have been met:

- Theresearchdesignisscientificallysoundandwillnotexposeanimalstounnecessary risk.
- Riskstoanimalsarereasonableinrelationtoanticipatedbenefitstotheanimalwelfare and to society.
- Risksto animals are minimized.
- Selection of number of animals is appropriate given the purpose of the research andthe setting in which it will be conducted.
- Additionalsafeguardsarein placetoprotect animalsthat arelikelyto be vulnerable.

- Adequate procedures are in place to protect the welfare of animals and maintain theconfidentiality of data.

5.6.Typesof researchprojectseligibleforexpeditedreview

This guideline allows certain types of research to be reviewed using "expedited" procedures. Protocols that are reviewed via an expedited process are evaluated by the same ethical standards and must meet the same approval criteria as those that receive full review. Thus,the same general application for **SlU-IRERC** reviewmust besubmitted when applying for expedited review. However, the review process does not require discussion at a convened **SlU-IRERC** meeting.

The chairperson of **SlU-IRERC** chooses a limited number of members to review the proposal. If the limited numbers of reviewers have significant concerns, a fullboard/committee review may be warranted. Informal consultation with **SlU-IRERC** chairperson may assist the applicant in determining the best type of review to be solicited.

Typically, the **SlU-IRERC** should be able to provide the investigators with the review outcome of an expedited review within 15 business days after submission. Investigators will be sent an email notifying them of the review outcome.

Level of risks, nature of participant population and type of research procedures are key elements of eligibility for expedited review as discussed below.

5.6.1. Levelof Risk

Tobeeligibleforexpeditedreview,researchmayhaveonlyminimalriskto participants.Some regulations define minimal risk‖ as follows: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.‘‘

In deciding whether to request expedited review, the researcher must make an initial determinationthatthestudyinvolvesminimalrisk‖toparticipants.Ultimately,however,the expedited reviewer will determine the risk level of the proposed research.If the expedited reviewer determines that the protocol involves greater than minimal risks, the proposalshould be re-channeled to a convening Full Board meeting.

5.6.2. NatureofParticipantPopulation

Researchtobe conductedonendangeredspecies, includingexperimentalresearchonrare and endemic animals, may not be reviewed under expedited procedures.

5.6.3. ResearchProcedures

For minimal risk research, some regulations designate certain categories of research procedures as being eligible for expedited review.

A committee member conducting expedited review has the authority to request additional information, to approvea project, to conditionallyapproveaproject and specifyconditions of approval, or to table a project for re-review. They do not, however, have the authority to disapprove a project. Expedited reviewers must refer any project which they would have disapproved to the full **SlU-IRERC** meeting. They may also refer any project to the full **SlU-IRERC** if, in their judgment, full review is warranted.

5.6.4. ContinuingReview

In its initial review of the proposal, the **SlU-IRERC** will consider the extent ofcontinuing review needed. All proposals shall be reviewed annually, but in certain research the participants are exposed to more than usual risk; such proposals may be reviewed at more frequent intervals appropriate to the research. This review interval will be determined at the time the research is approved and may be changed at the discretion of the **SlU-IRERC**. In each such review, the principal investigator will be required to promptly report the status of the research activity, and any proposed changes in the research activity. If the research is still in progress, the investigator will affirm that the approved research protocol involving animals is being followed.

SECTION 6:PLANT RESEARCH ETHICS REVIEW

Introduction: Plant-based research contributes significantly to Ethiopia's development in agriculture, biodiversity conservation, public health, and environmental sustainability. Given Ethiopia's unique and rich plant diversity - many of which are culturally and scientifically valuable - it is critical to ensure that plant research adheres to the highest ethical, legal, and environmental standards. This section outlines Salale University Institutional Research Ethics Review Committee (SlU-IRERC)'s requirements for the ethical oversight of plant research.

6.1 Indigenous Plant Use and Biodiversity Protection

1. **Recognition of Indigenous Knowledge**
   Researchers must respect and safeguard traditional ecological knowledge related to plant use, including medicinal, nutritional, cultural, and ecological applications.

2. **Prior Informed Consent (PIC)**

   Consent must be obtained in writing from community representatives and appropriate local/regional government offices before initiating any research involving indigenous plant knowledge. PIC must be:

   - Voluntary and informed,
   - Based on accessible and understandable information,
   - Documented prior to data/sample collection.

3. **Access and Benefit Sharing (ABS)**

   All research must comply with the **Nagoya Protocol** and Ethiopia's Access and Benefit Sharing Proclamation (Proclamation No. 482/2006). Researchers must:

   - Ensure fair and equitable benefit sharing,
   - Sign clear agreements specifying intellectual property rights, benefit mechanisms, and local involvement.

4. **Protection of Endangered Species and Ecosystems**

   - Collection from endangered or protected species or ecosystems requires written approval from the **Ethiopian Biodiversity Institute (EBI)**.
   - Unsustainable harvesting and any research that could degrade biodiversity are strictly prohibited.

6.2. Biosecurity and Safety Standards

1. **Risk Assessment**

- All research involving invasive species, plant pathogens, or hazardous materials must include a comprehensive bio-risk assessment.
- Research involving **GMOs or genetic engineering** shall not be reviewed by SlU-IRERC instead referred to the **National Research Ethics Review Committee (NRERC)**.

2. **Containment and Handling Protocols**

- Field and lab-based plant research must follow institutional biosafety protocols.
- Researchers must be trained in proper handling, transportation, storage, and disposal of biological materials.

3. **Environmental Impact Mitigation**

   Research proposals must describe steps to:

- Minimize environmental harm,
- Rehabilitate disturbed ecosystems,
- Prevent unintended spread of introduced species.

4. **Compliance with National Regulations**

   All research must conform to relevant laws from:

- Ministry of Education,
- Ministry of Agriculture (MoA)
- Ministry of Environment, Forest and Climate Change,
- Ethiopian Biodiversity Institute (EBI).

6.3. Collaboration with Regulatory and Biodiversity Authorities

1. **Clearance and Permits**.

   - All field research involving plant collection in protected or agricultural areas requires permits from **EBI** and relevant local authorities
   - Researchers must submit copies of permits and collaboration agreements to SlU-IRERC.

2. **Data Sharing and Reporting**

   Researchers must submit:

   - Annual or final reports to SlU-IRERC, EBI, and other institution as appropriate.
   - Data relevant to conservation and biodiversity management to local stakeholders, as appropriate.

3. **Capacity Building and Community Engagement**

   Research must promote:

   - Training for local researchers and students,
   - Knowledge transfer through workshops or field demonstrations,
   - Collaborative monitoring where applicable.

4. **Sustainability and Ethical Practice**

   Collaborative projects must:

   - Align with national, environmental and agricultural policies,
   - Promote sustainable plant use,
   - Avoid harm to communities and ecosystems.

6.4 Proposal Types Requiring National Research Ethics Review (NRERC)

The following plant research protocols must be referred to NRERC for ethical review and approval:

1. **Research involving foreign genetic materials**:
   - Trials involving crossbreeding of exotic plant species, genetically engineered organisms, or use of imported agro-chemicals or biological agents.
   - Approval from EBI for import/export of genetic material is required before ethics submission.
2. **Multi-center or high-risk field trials**:

- Research conducted across multiple sites, especially those involving human participants (e.g., farmers) in participatory settings.

3. **Commercially funded research**:
   - Projects sponsored by companies for product testing in open environments.
4. **Transfer of biological materials**:
   - Any protocol involving the transfer of seeds, microbes, DNA samples, or other plant-related specimens.
5. **Research with breeding companies or NGOs**:
   - Proposals linked to private-sector breeding or propagation.

6.5. Conflict Management and Arbitration Mechanism

1. **Independent Arbitration**
   - In case of conflict or disputes during review, an independent ad hoc arbitration committee shall be established.
   - Members must be free of conflicts of interest (CoI) and must sign confidentiality and impartiality declarations.
2. **Conflict of Interest (CoI) Management**
   - Any SlU-IRERC member or external expert with a real or perceived CoI must recuse themselves from deliberations.
   - CoI disclosure forms are mandatory for all involved.
3. **Resolution Process**
   - Disputes will be resolved within **30 calendar days** from formal submission of a complaint or challenge.
   - Final decisions will be documented, and parties may request a written justification.
4. **Balancing Ethics and Scientific Progress**
   - Ethical values will be upheld while facilitating responsible scientific advancement. When conflicts arise, the committee will prioritize long-term societal and scientific benefits.

SECTION 7:PRINCIPLES OF ENVIRONMENTAL ETHICS

Environmental research contributes significantly to understanding ecological systems, biodiversity, climate change, and sustainable development. At Salale University, SlU-IRERC ensures that such research adheres to ethical standards that protect the environment, comply with national regulations, and support sustainable practices.

9.1. Exempted Review

Research activities that may be considered exempt from full SlU-IRERC review must meet specific environmental and ethical criteria:

- Natural Conservation: Studies promoting the protection of endangered species or habitats, without direct intervention in the ecosystem.
- Environmental Emergencies: Research conducted in response to national or regional disasters.

Conditions for Exemption:

- All exempt research must still comply with basic environmental ethics and SlU-IRERC principles.
- Investigators must submit an exemption application, including:
  - ✓ Research tools (questionnaires, assessments, etc.),
  - ✓ Consent statements,
  - ✓ Permission letters or advertisements as applicable.
- Exemptions are evaluated and documented per institutional and regulatory criteria.

Notification: Investigators will receive written confirmation regarding exemption status.

7.2. Ethical Assessment Criteria

All environmental research is subject to rigorous ethical review based on the following criteria:

- Scientific Quality:
  - ✓ Sound research design, appropriate methodology, and adequate statistical power.
  - ✓ Researcher qualifications and institutional capacity.
- Environmental and Social Risk Assessment:
  - ✓ Risks to soil, water, air, biodiversity, and human health.
  - ✓ Consideration of direct, indirect, cumulative, spatial, and temporal impacts.
  - ✓ Impacts on traditional, religious, or local community practices.
- Animal Welfare:
  - ✓ Avoidance of stressors (trapping, handling, etc.)
  - ✓ Risk of disease transmission and effects on non-target species.

- Transportation Impact:
  - ✓ Assessment of environmental harm from transport methods (e.g., vehicle noise, soil erosion).
  - ✓ Measures to prevent invasive species or biological contamination.
- Approval Period:
  - ✓ Approvals are valid for one year.
  - ✓ Amendments or study closure must be reported to SlU-IRERC.

7.3. Expedited Review Procedures

An expedited review may be granted for research involving minimal environmental risk. Criteria include:

- Minor protocol amendments,
- Data analysis from previously approved studies,
- Long-term follow-up activities,
- Committee-confirmed minimal risk designation.

One or two designated SlU-IRERC members will review expedited protocols.

7.4. Research Requiring Special Ethical Consideration

Certain types of environmental research necessitate heightened scrutiny and safety measures:

- Climate and Ecosystem Research:
  - ✓ Projects potentially impacting ecosystems or communities.
- Nanotechnology:
  - ✓ Prevent exposure to hazardous nanoparticles.
  - ✓ Ensure environmental safety.
- Air Quality Monitoring:
  - ✓ Human participant exposure to pollutants must be ethically justified.
- Animal Research:
  - ✓ Protection of free-living species and habitats.
  - ✓ Address risks related to disease, stressors, and biodiversity disruption.
- Environmental Biotechnology:
  - ✓ Use of genetically modified organisms (GMOs).
  - ✓ Bioremediation research (soil, aquatic).
- Exposure/Risk Assessment:

✓ Research involving humans or animals must detail safety and ethical protections.

- Sensitive Areas and Species:

- ✓ Research in protected areas, or on endangered species, must have NRERB approval.
- ✍ Water and Sanitation, Environmental Geology:
- ✓ Ethical review must address potential long-term environmental impacts.

7.5. Review of Environmental Impact Studies

- ✍ Mandatory Ethical Review:
- ✓ Required for research involving land use, pollutants, chemicals, or waste.
- ✓ Submission of a Preliminary Environmental Impact Statement (EIS) is mandatory.
- ✍ Risk Management:
- ✓ Research must identify risks and include mitigation/restoration plans and monitoring mechanisms.
- ✍ Legal and Policy Compliance:
- ✓ Researchers must follow Ethiopia's Environmental Impact Assessment Proclamation (No. 299/2002) and relevant directives from the national and local environmental offices.
- ✍ Stakeholder Engagement:
- ✓ Involvement of local communities and government agencies is required.

7.6. Research in Protected or Ecologically Sensitive Areas

- ✍ Authorization:
- ✓ Obtain permits from relevant national and local offices.
- ✍ Low-Impact Methods:
- ✓ Prioritize non-invasive and non-disruptive research techniques.
- ✍ Monitoring and Accountability:
- ✓ Submit periodic impact reports; report unanticipated harms immediately.
- ✍ Sensitive Data Handling:
- ✓ Comply with country regulations concerning drones, surveillance, and ecological imagery.

7.7. Waste Management and Eco-Compliance

- – Sustainable Waste Management Plans (SWMP):
- ✓ Address segregation, disposal, and use of biodegradable materials.
- – Institutional Responsibilities:
- ✓ Researchers must follow SlU-IRERC procedures and maintain waste disposal records.
- – Green Research Practices:
- ✓ Reduce emissions, avoid plastic waste, and prioritize sustainable sourcing.
- ✍ Compliance Monitoring: _High-impact projects may face environmental audits.
  - ― Violations may lead to suspension of ethical approval.

SECTION8: ENGINEERING AND ICT RESEARCH ETHICS

Introduction: Engineering and Information and Communication Technology (ICT) research are central to technological innovation, national development, and digital transformation. However, these disciplines also raise complex ethical questions around data use, artificial intelligence, surveillance, and intellectual property. This section outlines ethical standards for Engineering and ICT research under the SlU-IRERC.

8.1. Software and Algorithm Fairness and Data Use

1. **Responsible Data Collection and Use**

- Researchers must ensure that all personal and sensitive data used in software or algorithmic research is collected legally, with informed consent, and used in accordance with data protection laws (e.g., Ethiopia's Data Protection Proclamation).
- Anonymization or pseudonymization must be applied where applicable.

2. **Bias and Fairness in Algorithms**

- Researchers must identify, disclose, and mitigate algorithmic bias, especially in systems that influence human lives (e.g., health, finance, education).
- Research involving predictive analytics or machine learning must include fairness metrics and impact assessments.

3. **Transparency and Accountability**

- ✓ Software and algorithmic systems must be explainable, auditable, and include documentation that allows replication or review.

Clear logs of changes and decisions made during development must be maintained.

8.2.**Artificial Intelligence (AI),** Surveillance, and Automated Decision-Making Systems

1. **Ethical Design and Deployment**
    - ✓ AI systems must respect principles of human dignity, autonomy, and non-discrimination.
    - ✓ Researchers must ensure systems do not reinforce social inequalities or marginalize vulnerable groups.
2. **Consent and Awareness**
    - ✓ Individuals subject to AI-driven decisions or surveillance tools must be informed of their use, unless such disclosure is waived for legitimate legal or public safety reasons.
3. **Surveillance and Privacy Protection**

- ✓ Use of surveillance technologies (e.g., facial recognition, CCTV analysis) must comply with national privacy regulations and be justified with clear ethical rationale.
- ✓ All data collected must be stored securely and accessed only by authorized personnel.

4. **Human Oversight and Redress**
   - ✓ Automated systems must allow for human oversight and appeal mechanisms, especially in critical domains like health, justice, and public services.

8.3. Conflict of Interest and Transparency

1. **Disclosure Requirements**
   - All researchers must disclose financial, institutional, or personal interests that could unduly influence the research outcome.
   - Collaborations with private companies or government agencies must be declared at the proposal stage.
2. **Integrity in Research Collaboration**
   - Researchers should maintain independence in conducting and reporting results, even in funded projects.
   - Publication of results must not be suppressed due to commercial or political interests.
3. **Transparency in Methodology**
   - Research methodologies, tools, and datasets must be fully disclosed in publications, with limitations acknowledged.

8.4. Intellectual Property and Open Science

1. **Protection of Innovation**
   - Innovations developed under Salale University must follow institutional intellectual property (IP) policies.
   - Researchers must clarify patent rights, licensing agreements, and ownership before research begins.
2. **Open Access and Knowledge Sharing**
   - Wherever possible, researchers are encouraged to publish in open-access journals, deposit code in open repositories, and share datasets under FAIR principles (Findable, Accessible, Interoperable, and Reusable).
3. **Ethical Use of Third-Party Software and Code**
   - All third-party tools and software libraries must be used in accordance with their licenses.
   - Proper attribution must be provided, and researchers must not use pirated or unlicensed software.

4. **Student and Staffy Innovation Rights**
   - Projects involving students must have clear agreements regarding ownership and co-authorship.
   - Supervisors must not claim authorship or patent rights without substantial intellectual contribution.

Oversight and Review Mechanism

- The SlU-IRERC must ensure that proposals in Engineering and ICT undergo ethical screening, with technical review where required.
- Reviews must consider social impact, legal compliance, and institutional accountability.
- Any breach of these guidelines may result in suspension of approval.

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GLOSSARYOFTERMS

Academic research: Research conducted within academic institutions by undergraduate and graduate(i.e.,MScand PhD)studentsor staffmembers,irrespectiveof thesourceoffunding.

Access and benefit-sharing: One of the three objectives of the Convention on Biological Diversity (CBD), as set out in its Article 1, is the ―fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding‖. The CBD also has several articles (especially Article 15) regarding international aspects of access to genetic resources.

Adverse Event (AE): Any untoward health-related occurrence in a participant administereda health-research intervention and which does not necessarily have to have a causal relationship with this intervention. An AE can be any unfavorable and unintended sign, symptom, or condition temporally associated with the administration of the health-research intervention, whether or not considered related to the intervention. This also includes unfavorable deviations from baseline health.

Alternatives: An alternative is likely to mean an alternative method to replace the use of animals for research.

Amendment: A material change to study procedures/any change to the protocol. Such changes, including minor changes, must be reviewed by an IRERC before they may be implemented.

Animal: Any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, and wildlife.

Animal Welfare: An animal‘s quality of life based on an assessment of an animal‘s physical andpsychologicalstateasanindicatorofhowtheanimaliscopingwiththeongoingsituation as well as a judgement about how the animal feels.

Anonymous/anonymized: Lacking identification because identifiers or other information that could identify the individual were not collected or were removed. Information may or may not be considered anonymous if there is a reasonable basis to believe that one can usetheinformationtoidentifyanindividual,evenifonecannotreadilyascertaintheindividual's

identity; see further discussion at individually identifiable information. For example, it might be possible to determine a survey respondent's identity from a combination of demographic factors in a survey together with public or proprietary data sources, even if the surveyor did not jointly record the respondent's identity and those demographic characteristics.

Approval: The determination of the NRERB/IRERC that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRERC and by other institutional and federal requirements.

Assent: Child participant not of legal age (8-18 years old); affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

Autonomy: Self-rule that is free from both controlling interference by others and from limitations that prevent meaningful choice. See also respect for persons.

Basic research: Research with the primary purpose of advancing scientific knowledge.

Belmont Report: Statement of ethical principles and guidelines for the protection of human participants of research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published this report in 1979. The three principles are respect for persons, beneficence, and justice. These are clearly shown in https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

Beneficence: principle of ethical precept asserting an obligation to prevent harm, to remove harm, or to do or promote good; two-part rule: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

Benefit: A potential advantage or gain.

Breach of protocol: Material departure from approved procedures of the study, such as the consent process, violations of data confidentiality, or complaints by participants; may be a reportable incident.

Breeding: the mating and production of offspring by animals.

Biodiversity: short for biological diversity means the diversity of life in all its forms—the diversity of species, of genetic variations within one species, and of ecosystems.

Biotechnology: Any technology that is applied to living organisms to make them more valuable to people.

Child/children: Person who is under the age of 18 and has not attained the legal age for consent to treatments or procedures involved in the research.

Clinical trial: A prospective research study in human participants that is designed to answer specific questions about health-related interventions (such as medications, herbal supplements, nutritional strategies, physical interventions, behavioral interventions, prevention trials, or diagnostic tools), particularly to determine whether these interventions are safe, efficacious, and effective.

Close/closure: Proactively and permanently end both research-related intervention or interaction with participants and collection and use of identifiable private research information when study objectives have been met as specified in the protocol.

Coded: Replacement of identifying information (such as name or social security number that would enable one to readily ascertain the identity of the individual to whom the private information or specimens pertain) with a number, letter, symbol, or combination thereof where a key to decipher the code exists and links the identifying information to the private information or specimens. In contrast with linked, coded often means that the link exists butis unavailable, as through a nondisclosure arrangement.

Collaborative research: Research conducted by research/academic institutions inpartnership with more than one research/ academic institutions (local and/or international) as well as industries.

Compensation: Payment to cover actual research-related harm. Where understandability is an issue, use a simpler word like "payment". Contrast with incentive, reimbursement.

Completion of study: Point at which data analysis has ended or identifying information is removed from the data and biological specimens.

Comprehension:in thiscontext, understandingwhat thestudyis about.

Complementary medicine (CM): The terms ―complementary medicine‖ or ―alternative medicine‖refertoabroadsetofhealthcarepracticesthatarenotpartofthatcountry‘sown

tradition or conventional medicine and are not fully integrated into the dominant health-care system.

Conduct: To be engaged (in research) by obtaining data about living individuals through intervention or interaction with them for research purposes or by obtaining individually identifiable private information about living individuals for research purposes.

Conflict of interest: A situation wherethe goals or obligations of an investigator or reviewer conflict with an obligation to uphold another party's interest, thereby compromising objectivity and impartiality.

Confidential/confidentiality: The condition of honoring a request or expectation that information will be protected from disclosure.

Convened: Aformal,joint meetingor action ofa quorum ofthe IRERC/ NRERB.

Datafabrication:meansmakingupdataor resultsforresearch purpose.

Data falsification: means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Dataandsafetymonitoring: Structured,ongoingmonitoringofspecifiedcharacteristicsofa research protocol, generally by a small, independent body of experts appointed by the study sponsor. Sometimes incorrectly called "data safety and monitoring". Monitoring may pertain to study performance (such as rate of accrual), safety (such as occurrence of AEs), and efficacy (such as achievement of primary endpoints). A body that monitors all three characteristics is usually called a data monitoring committee (DMC) or a data and safety monitoring board (DSMB).

Documentation of consent: Consent that is documented bytheuseof awrittenconsent form approved by the IRERC and signed by the participant or the participant's legally authorized representative.

Endpoint: The stage in an experiment or test where the procedure is terminated. Where experiments increase suffering, animals should be killed as early as possible.

Emergency response: A public health activity undertaken in an urgent or emergency

situation,usuallybecauseofanidentifiedorsuspectedimminenthealththreattothe

population, but sometimes because the public or government authorities perceive animminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem.

Engineering: Engineering is a systematic and iterative approach to design and develop objects, processes, and systems using scientific and mathematical principles to meet human needs and wants.

Engineeringresearch: Researchinengineeringandtechnology.

Euthanasia: Literally:_gooddeath'.Theactofkillingahumanorotheranimalinaspainless a way as possible.

Expedited review: Review performed by the NRERB /IRERC Chair or a designated experienced member for research that involves no more than minimal risk and meets the criteria for expedited review or represents minor changes in approved research.

Expiration date: The expiration date is the daybefore the anniversaryof the approval date – unless the IRERC/ BRERB approves it for less than one year. For instance, a protocol approved on 12/4 has approval date of 12/4/06 and an expiration date of 12/3/07 midnight (which means research may be conducted on 12/3).

Gene: The functional unit of heredity; the part of the DNA molecule that encodes a single enzyme or structural protein unit.

Gene bank: A facility established for the ex-situ conservation of individuals (seeds), tissues, or reproductive cells of plants or animals.

Genetic diversity: The variety of genes within a particular population, species, variety, or breed.

Genetic Testing: A procedure to detect the presence or absence of, or change in, a particular geneorchromosome,includinganindirecttestforageneproductorotherspecificmetabolite that is primarily indicative of a specific genetic change.

Genetic Screening: Large-scale systematic genetic testing offered in a program to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people.

Good Clinical Practice (GCP): An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human participants. See alsohttps://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/good-clinical-practice

Guardian: An individual who is authorized under applicable local law to consent on behalf of a child to general medical care.

Harm: Injury, damage, orhurt; an experiencein which one's interests are thwarted, defeated, or set back, especially one's physical or psychological interests.

Human subject/human participant: A living person about whom an investigatorconducting research obtains (1) data through intervention or interaction with the individual,or (2) identifiable private information (e.g., medical records, employment records, or school records).

Identifiable private information: Information (data or biological specimens) such that the identityof a participant is or mayreadilybe ascertained bythe investigator or associated with the information, and either the information concerns behavior that occurs in a context in which an individual can reasonablyexpect that no observation orrecording is takingplace, or the information has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Incentive: Paymentorothergoodsorservicesoffered tomotivatestudyparticipation.

Incident: An instance of one of the following: an unanticipated problem involving risks to participants or others, serious or continuingnoncompliance, or suspension or termination (for reasons other than expiration).

Indigenous people: People whose ancestors inhabited a place or country when persons from another culture or ethnic background arrived on the scene and dominated them through conquest, settlement, or other means and who today live more in conformity with their own social, economic, and cultural customs and traditions than with those of the countryof which they now form a part (also: _native peoples‘ or _tribal peoples‘).

Industry research: Research conducted within the premises of research institutes or industries. Like projects, this research is usually conducted to solve existing problems using known approaches so that scientific novelty is less.

Informed consent: The free and informed decision by a prospective participant or participant's legally authorized representative to participate in research. The consent process should ensure that the participant has been provided full information regarding the research, the participant comprehends the research, and the participant is volunteering free of coercion and undue influence.

Injury: Physicalharmtoaparticipantina researchstudy.

Institutional ResearchEthics Review Committee(IRERC): Theformallyappointed ethics review committee established to ensure that research conforms to ethical principles at institutional level, which includes Research Institutes, Higher Education Institutes, and professional societies. Institutional Research Ethics Review Committees (IRERCs) are independent committees established in an institution to conduct initial and continuing review of research projects with the primary goal of protecting the rights, safety and welfare of research participants.

Intervention: Physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

Principles of Justice,: Ethical precept asserting an obligation to treat persons fairly and give to each person what she is due; two-part rule: (1) exhibit fairness and (2) distinguish between classes of participants that ought, and ought not, to participate in any particular kind of research.

Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable State law who may consent on behalf of another individual to participate in the procedure(s) involved in the research.

LocalIRERC:IRERClocatedinthe institutionwherethe research istobeconducted.

Medical device: Any instrument, apparatus, or other similar or related article, including component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease orotherconditions, orin the cure, mitigation, treatment, orprevention of disease, in humans or other animals; or (c) intended to affect the structure or any function of thehumanbodyorinanimals;anddoesnotachieveanyofitsprincipalintendedpurposes

through chemical action within or on the human body or in animals and is not dependentupon being metabolized for the achievement of its principal intended purposes.

Minimal risk: Risks such that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minor changes: Changes to a research protocol that do not result in a net increase in risk, a change in the harm-benefit balance, or provide minor clarification or correction. Minor changes may be reviewed under expedited review, even if the protocol has been deemed to pose more than minimal risk to participants.

National Research Ethics Review Board (NRERB): The ethics review committee established under the Ministry of Education (MoE) and mandated to conduct ethical reviews at the national level.

Noncompliance: Failure by investigators, research staff, IRERCmembers, or IRERCstaffto follow regulations for human research protections.

Parental permission: The agreement of a parent or guardian to the participation of theirchild in research.

Personal identifier: Information obtained and recorded in such a manner that human participants can be recognized, directlyor through links to the participants. Examples include names, social security numbers, and codes.

Pilot study: Preliminary study to determine the feasibility of a larger study, use of a test instrument, or other activity.

Plagiarism: means the unethical practice of using words or ideas (either planned or accidental) of another author/researcher or your own previous works without proper acknowledgment.

Pregnancy: The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

PrincipalInvestigator(PI): Leadscientistwhoisworkingonthedesign ofaresearchstudy, development of methods and procedures for the study, collection of data or specimens, analysis of data or specimens, or interpretation of data.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The termis intended to encompass individuals sentenced to suchan institution under acriminal or civil statute, individuals detained in other facilities byvirtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information: Information about individually identifiable behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes byan individual and which the individual can reasonably expect will not be made public (e.g., a medical record).

Private/privacy: Individual person's interest in preventing disclosure of information about himself or herself.

Procedure: A combination of one or more technical acts carried out on an animal for an experimental or other scientific purpose which maycause that animal pain, suffering, distress or lasting harm.

Project: Aplanned activityorcollection ofactivitiesconductedforaparticularpurpose; may encompass more than one protocol on the same subject matter.

Protocol: The formal design or plan of a data collection activity; specifically, the plan submitted to a reviewing authority such as an IRERC/ NRERB. The protocol includes a description of the design or methods for conducting the data collection, description of the study population, methods for data handling and analysis, procedures for handling incidents, and methods for notification and dissemination of results.

Quorum: The number of IRERC members required to be present at a convened meeting in order for the IRERCto transact business.

Reimbursement: Repaymentforcostsincurred byvirtueorparticipationinresearch, suchas for lost earnings or travel costs.

Related/relation: Pertaining to an AE, the likelihood that the event was caused by research procedures, usually relative to the likelihood it was caused by something other than research procedures.

Report: A written account of the IRERC 's findings, conditions for approval, or reasons for disapproval regarding human research protections in a research protocol.

Repository: An entity that collects, stores and manages, and distributes data or human tissue materials to recipient investigators for research and other purposes. See also http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm.

Research conducted on animals: means research conducted on animals after verifying that the results of the research to have benefit for society.

Research participant: means human or animal that participate directly or indirectly in the research.

Respect for persons: Principle of the requirement to treat individuals as autonomous agents and to provide additional protections to persons with diminished autonomy. Respect for persons requires that participants, to the degree that they are capable, be given theopportunity to choose what shall or shall not happen to them.

Response: An investigator'swritten replyto an IRERC/ NRERB report.

Responsible conduct of research (RCR): A collection of core areas for conductingscientific research with integrity: data acquisition, management, sharing and ownership; conflict of interest and commitment; human participants; animal welfare; research misconduct; publication practices and responsible authorship; mentor/trainee responsibilities; peer review; and collaborative science.

Risk: Exposure to injury, loss, or harm, expressed in terms of the probability and magnitude of that harm. Risks to participants must be minimized and must be reasonable in relation to anticipated benefits to participants and the importance the knowledge that may reasonably be expected to result.

Serious adverse event (SAE): An AE that results in death, is life-threatening (at the time of the event), requires inpatient hospitalization or prolongation of existing hospitalization,resultsinpersistentorsignificantdisabilityorincapacity,orisacongenitalanomalyo

rbirth

defect. An AE may also be considered serious if it jeopardizes the participant or requires intervention to prevent one of the other outcomes listed.

Serious noncompliance: Noncompliance that results in increased risk to participants or reflects a failure to apply substantial portions of governing regulations. Serious noncompliance must be reported promptly.

Severe/severity: The graded level of intensityof an AE and its interference with usual social and functional activities, often standardized in toxicity tables. Grade levels generally include normal, mild, moderate, severe, life-threatening, and fatal.

Social and behavioral research: Studies involving human participants that are not primarily seekingtounderstandorobservepurelyphysical processesrelatedtohealth,ortotestdevices or drugs in order to improve measurable health outcomes by means of biomarkers. More positively, social and behavioral research seeks through a wide variety of methodologies to understand human behavior, including psychological processes (cognition, emotion, temperament, and motivation), biosocial interactions, and social influences on individual and group behaviors. Terms such as _qualitative research‘ and _social and behavioral studies‘ are also used interchangeably to describe the same domain, though some social and behavioral studies can also incorporate quantitative approaches and involve direct interventions. While many social and behavioral studies are health related, they commonly use approaches standard and distinctive for the disciplines of, for example, anthropology, sociology, or psychology.

Species: A group of organisms capable of interbreeding freely with each other but not with members of other species.

Sponsor: A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation.

Suspend/suspension: Temporary cessation of research-related intervention or interaction with participants and obtaining or using identifiable private research information. Partial suspension halts some but not all such activities, for example when enrollment is stopped but follow-up continues with enrolled participants. A suspension must be reported promptly unless the suspension results from expiration of NRERB/ IRERC approval.

Technology: Any modification of the natural or designed world developed to fulfill human needs or desires.

Terminate/termination: Permanent cessation of research-related intervention or interaction with participants and obtaining and use of identifiable private research information. A termination must be reported promptly unless the termination results from expiration of IRERC approval or withdrawal or closure for reasons other than research risks.

Traditional medicine (TM): It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable ornot,used inthemaintenanceofhealthas well asintheprevention,diagnosis,improvement or treatment of physical and mental illness.

Understandable language: generally 8th grade reading level or lower/higher depending on targeted population.

Undue influence: An excessive, unwarranted, inappropriate, or improper reward intended to motivate study participation.

Unexpected: Pertaining to an AE, the event is previously unobserved or undocumented in humansundertheresearchintervention(oronesubstantiallysimilar),thenatureorseverityof the event is not consistent with information in the relevant source documents (e.g., investigator's brochure, package insert, or non-reportable events [NRE] list), or the event is observed with higher frequencythan previouslyobserved or documented. Expectedness does not entail the abilityto predict results from in vitro, animal, or otherpharmacological models.

Unlinked: The condition of data or specimens which had been coded but for which the key linking the code to direct personal identifiers has been destroyed.

Unrelated: Pertaining to an AE, the condition in which the event is due to a documented cause other than research procedures.

Verbal consent: Consent obtained only through speaking, generally in the absence of documentation of consent. See also documentation of consent, informed consent, verbalconsent.

Voluntary/voluntariness: Freedomfrom coercionandundueinfluence.

Vulnerable: Having reduced capacity to offer free and informed consent due to possible coercion, undue influence, or other diminished autonomy, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Vulnerability may be associated with other characteristics such as age, health status, or social standing. The IRERC must ensure additional safeguards protect the rights and welfare of vulnerable persons.

Vulnerable population: A group identified by one or more common characteristics associated with reduced capacity to offer free and informed consent.

Waive/waiver: Temporarily set aside the requirement of a particular rule, regulation, or condition in a protocol or consent document.

Withdraw/withdrawal: Permanently halt a research study after submission for review but before human participants become involved, whether or not the study has been reviewed by an IRERC . This term has been replaced by the term close/closure.

VARIOUS PROVISIONS

We have used some of the notions used in the 5th version of the guideline. Any guideline other than this new compressive guideline shall not be implemented or used.Based on this comprehensive guideline, higher education and research institutions can adopt and produce their own internal guideline.

ThisguidelineissubjecttobereviewedasdeemednecessarybytheMOE. This guideline will be effective starting from the date of signature.

Dr. FayeraDinsa

Salale University President