Title:

A DRAFT STANDARD OPERATING PROCEDURES (SOPs) MANUAL DEVELOPED FOR WOLLO UNIVERSITY INSTITUTIONAL RESEARCH ETHICS REVIEW COMMITTEE (WU-IRERC): UBUNTU PHILOSOPHY INTEGRATED FOR MULTI-DISCIPLINARY RESEARCH ETHICS REVIEW FRAMEWORK, WOLLO UNIVERSITY, ETHIOPIA

Author: Andualem Yimer (DVM, MSc, Associate Professor; IRERC Secretariat)

Affiliation: Wollo University, Dessie, Ethiopia

Contact Email: andualem.yimer@wu.edu.et; anduyimer007@gmail.com

Document Code: WU-IRERC-SOPs-001

Version: 2

Developed date: November, 2025

Status: Complete Draft

This is a preprint that has been submitted to journal AfricArXiv/OSF

SOPs DOCUMENT HISTORY: A brief Summary of the development process

History	Date	Creator/Author	Description of SOPs development
Version 1	Augst, 2025	Dr. Andualem Yimer	Initial draft created & developed, containing 10 chapters of standards, farmwork and guidance. This draft was circulated to IRERC members for comments
Version 2	September, 2025	Dr. Andualem Yimer	Document fully restructured to a manual containing 13 chapters for operational clarity. Added specialized standards and new discipline-specific guidance (Annex E) developed, which were circulated for IRERC comment
			Finalized the manual by creating standardized forms, templates, assessment tools and practical checklists

IRERC Reviews

Reviewers	Contributions
IRERC members	Comments on SOPs Structure, procedural clarity, organization and typography
IRERC Members	Expertise comments on discipline specific checklists (Annex, E)

Approval

Authority	Name	Signature with date
Wollo University Research and Technology Transfer office Vice President		

ACKNOWLEDGMENTS

I am grateful to Wollo University Research and Technology Transfer office Vice President for supporting me during the development of this manual. I also acknowledge the WU-IRERC members for their helpful comments on the structure, typography and feedback on expertise specific annexes to enhance this manual.

EXECUTIVE SUMMARY

The Wollo University Institutional Research Ethics Review Committee (WU-IRERC) Standard Operating Procedure Manual, Version 2, provides a comprehensive framework for ethical oversight of research involving human participants, animals, plants, communities and environmental systems within Wollo University jurisdiction. It harmonizes international ethical standards including the Declaration of Helsinki, CIOMS guidelines and WHO Minimum Standards for IRERCs in Low- and Middle-Income Countries (2022) with Ethiopian legal requirements under Proclamation No. 1130/2019 and the culturally significant Ubuntu philosophy, which emphasizes interconnectedness and collective responsibility. The manual promotes a multidisciplinary, integrated approach prioritizing community well-being, environmental stewardship and sustainable outcomes. It offers detailed, standardized procedures for ethical protocol review, post-approval monitoring, record keeping and continuous quality improvement, ensuring that all research is scientifically sound, ethically justified and culturally appropriate. This approach supports high-quality, multidisciplinary research across all Wollo university colleges and affiliated institutions, safeguarding the rights and welfare of all research subjects and ecosystems under the university's jurisdiction.

Key Features:

- **Risk-based review system**: Three-tier pathway (Exempt, Expedited, Full Board) based on systematic risk assessment
- **Ubuntu integration**: "I am because we are" philosophy embedded in all procedures
- **Integrated ethical framework**: Combines international principles (Autonomy, Beneficence, Justice) with Ubuntu principles (Interconnectedness, Solidarity, Compassion).
- **Multi-disciplinary framework**: Holistic assessment across all research domains
- **Community-centered approach**: Mandatory consultation and benefit-sharing (Community engagement) protocols
- **Practical tools**: Step-by-step procedures, checklists, templates for daily use and decision frameworks

Critical Requirements:

- All research requires IRERC approval before initiation
- Community consultation is mandatory for community-based researches
- Annual continuing review is required for all approved research
- Training certification is required for all researchers and IRERC members

- Benefit-sharing agreements are mandatory for research involving communities or traditional knowledge

TABLE OF CONTENTS PAGES

ACRONYMS

A	Administrative
ABS	Access and Benefiting Sharing
AE	Adverse Event
AT	Assessment Tools
CAB	Community Advisory Board
CIOMS	Council for International Organization of Medical Sciences
COI	Conflict of Interest
CV	Curriculum Vitae
DACA	Drug Administration and Control Authority
DC	Discipline Specific
DSMB	Data and Safety Monitoring Board
EC	Ethics Committee
EERB	Environment Ethical Review Boards
EFDA	Ethiopian Food and Drug administration Authority
EIAR	Ethiopian Institute of Agricultural Research
EPHI	Ethiopian Public Health Institute
ERC	Ethics Review Committee
ESTC A	Ethiopian Science and Technology Agency
F	Form
FDRE	Federal Democratic Republic of Ethiopia
IRERC	Institutional Research Ethics Review Committee
NEC	National Ethics Committee
NGO	Non-Governmental Organization
NRERB	National Research Ethics Review Board
PI	Principal Investigator
SAE	Serious Adverse Event
SPOs	Standard Operating Procedures
T	Template
TR	Terms of Reference
WHO	World Health Organization
WU	Wollo University

PART I: FOUNDATION AND FRAMEWORK

CHAPTER 1: INTRODUCTION AND SCOPE

Ethiopia's strong commitment to research ethics is highlighted through the National Research Ethics Review Guidelines (Fifth Edition), establishing a comprehensive framework for protecting research participants while promoting scientific advancement. The Wollo University Institutional Research Ethics Review Committee (WU-IRERC) serves as the official body ensuring that all research under the university's jurisdiction complies with rigorous ethical and scientific standards. The SOP, identified as WU-IRERC-SOP-001 (Version 2), mandates ethical oversight for all research involving human participants, animals, plants, the environment, and communities, aiming to safeguard the rights and welfare of all subjects while fostering ethically responsible and impactful research. This framework aligns with international ethical principles, Ethiopian national laws, and the African philosophy of Ubuntu, which stresses community, solidarity and mutual responsibility.

The SOP offers a clear and practical guide for researchers, committee members, and institutional officials to effectively manage the ethical review and approval process, ensuring full compliance with both national and international standards.

1.1. Purpose and Mission

1.1.1. Purpose statement

The Wollo University Institutional Research Ethics Review Committee (WU-IRERC) serves as an independent body and the institutional guardian of research ethics, ensuring that all research conducted under the auspices of Wollo University. Ensure research quality, relevance and public trust in Ethiopia while fostering ethically sound research across all university disciplines by**:**

1. Protects the rights, dignity and welfare of all participants (human, animal and environmental)
2. Promotes scientifically rigorous and ethically sound research
3. Preserves cultural values and traditional knowledge
4. Provides benefits to communities and society

1.1.2. Mission statement

To establish Wollo University as a leader in ethically rigorous, culturally responsive research that advances knowledge while respecting Ethiopian values, environmental stewardship, and community well-being through the integration of Ubuntu philosophy and multi-disciplinary approaches. The WU-IRERC is also committed to foster ethically sound research through education, collaborative review,

and ongoing oversight, aligning with Ethiopia's commitment to research integrity and sustainable development.

1.1.3. Core objectives

- **Participant protection:** Ensure comprehensive protection of human, animal, plants, and environmental and community participants
- **Ethical excellence:** maintain highest standards of research ethics across all disciplines
- **Cultural integration:** incorporate Ethiopian values and Ubuntu philosophy into ethical review
- **Community engagement:** facilitate meaningful community participation and benefit-sharing
- **Capacity building:** develop institutional expertise in research ethics
- **Regulatory compliance:** ensure adherence to national and international standards

1.2. Regulatory Foundation and Authority

1.2.1. Regulatory framework and hierarchy of standards

Level 1: Ethiopian National Law (Mandatory)

- Constitution Article 90 (Research for Development)
- Proclamation No. 1130/2019 on Research Ethics
- National Research Ethics Review Guidelines, 5th Edition
- Data Protection Proclamation No. 1183/2020
- Traditional Knowledge Protection Laws
- Environmental Protection Authority Guidelines

Level 2: International standards (Guiding)

- Declaration of Helsinki (World Medical Association, 2024)
- CIOMS International Ethical Guidelines (2016)
- WHO Standards for Research Ethics Committees (2022)
- UNESCO Universal Declaration on Bioethics and Human Rights
- International Council for Laboratory Animal Science Guidelines

Level 3: Institutional Requirements (Binding)

- Wollo university research policy
- Ubuntu Philosophy integration Framework
- Multi-disciplinary approach standards
- Community engagement protocol

1.2.2. The WU-IRERC legal authority and responsibilities

Primary authority: Ethiopian Proclamation No. 1130/2019 on research Ethics

Institutional mandate:

- Wollo university Senate legislation (Article 135/January, 2016)
- Research and Technology Transfer Office Directive
- Presidential decree on research ethics

The WU-IRERC granted its authority from the Office of the Vice President for Research and technology transfer office of Wollo university. **The IRERC holds delegated power to**:

- Review, approve, modify or disapprove all research protocols
- Conduct continuing review of ongoing research and suspend research activities that violate ethical standards
- Monitor compliance with approved protocols
- The WU-IRERC has the authority to suspend or terminate non-compliant research or any research activity that deviates from an approved protocol or violates the principles set forth in this SOPs
- Investigate allegations of non-compliance
- Require corrective actions and additional safeguards
- Issue binding directives on research ethics

Mandatory reporting to:

- University administration (quarterly)
- National Ethics Review Committee (annually)
- Funding agencies (as required)
- Regulatory authorities (serious violations)

1.3. Scope of Application

These SOPs apply to all research involving human participants, animals, plants, biodiversity or the environment conducted by Wollo University faculty, staff, students or external collaborators. Research may not commence without the WU-IRERC approval or a formal reliance agreement.

1.3.1. Mandatory review categories

Step 1: Determine if a research protocol requires review using this decision tree:

Research activity
↓
Involves human participants, animals,
plants, environmen, or communities?
↓
YES → Requires IRERC review
NO → May require other approvals

Table 1. Examples of research requiring mandatory IRERC review categories

Category	Examples of mandatory review
Human participant research	○ Clinical trials and medicine, ○ Social and behavioral studies, ○ Educational research involving data collection, ○ Survey and interview-based studies, Observational studies with intervention ○ Use of human biological specimens, Secondary data analysis (if identifiable)
Animal research	○ Vertebrate animal studies (all species) ○ Wildlife and conservation research, ○ Agricultural animal studies ○ Companion animal research
Environmental & community research	○ Research affecting community ecosystems ○ Traditional knowledge documentation ○ Biodiversity and conservation studies ○ Climate change research with community implications, Cultural heritage studies and Environmental impact research
Multi-disciplinary research	○ International collaborative projects ○ Multi-institutional studies ○ Cross-cultural research ○ Technology transfer research ○ Commercial research partnerships

1.3.2. Exempt categories (Requiring verification)

Category A: Educational research (Examples)

- Research in established educational settings
- Normal educational practices
- Standard curriculum evaluation
- Anonymous educational assessments

Category B: Anonymous surveys and interviews (Examples)

- No direct identifiers collected
- No sensitive topics
- No vulnerable populations
- Public behavior observation (no interaction)

Category C: Existing data research (Examples)

- Publicly available datasets
- De-identified secondary data
- No possibility of re-identification
- No contact with data subjects

1.3.3. Institutional coverage

To realize the responsibility of Wollo University to ensure the quality and integrity of research undertaken by its colleges, schools, institutes and students, the WU-IRERC has the mandate to ensure that proper research ethics governance is in place in the University. This SOPs applies specified guidance for all Wollo University **Colleges, Schools, Academic unities** and their **affiliated institutions** under**:**

- College of Medicine and Health Sciences
- College of Agriculture and Environmental Sciences
- College of Natural and Computational Sciences
- College of Social Sciences and Humanities
- College of Business and Economics
- Institute of Technology and Engineering
- School of Law
- School of Veterinary Medicine
- Institute of Teacher Education and Behavioral Sciences

Affiliated institutions: Research centers and institutes**,** teaching hospitals**,** agricultural research stations**,** community health programs and extension services.

External collaborations: Partner universities (via reliance agreements)**,** international research organizations**,** government agencies**,** NGOs and civil society organizations **and** private sector partners.

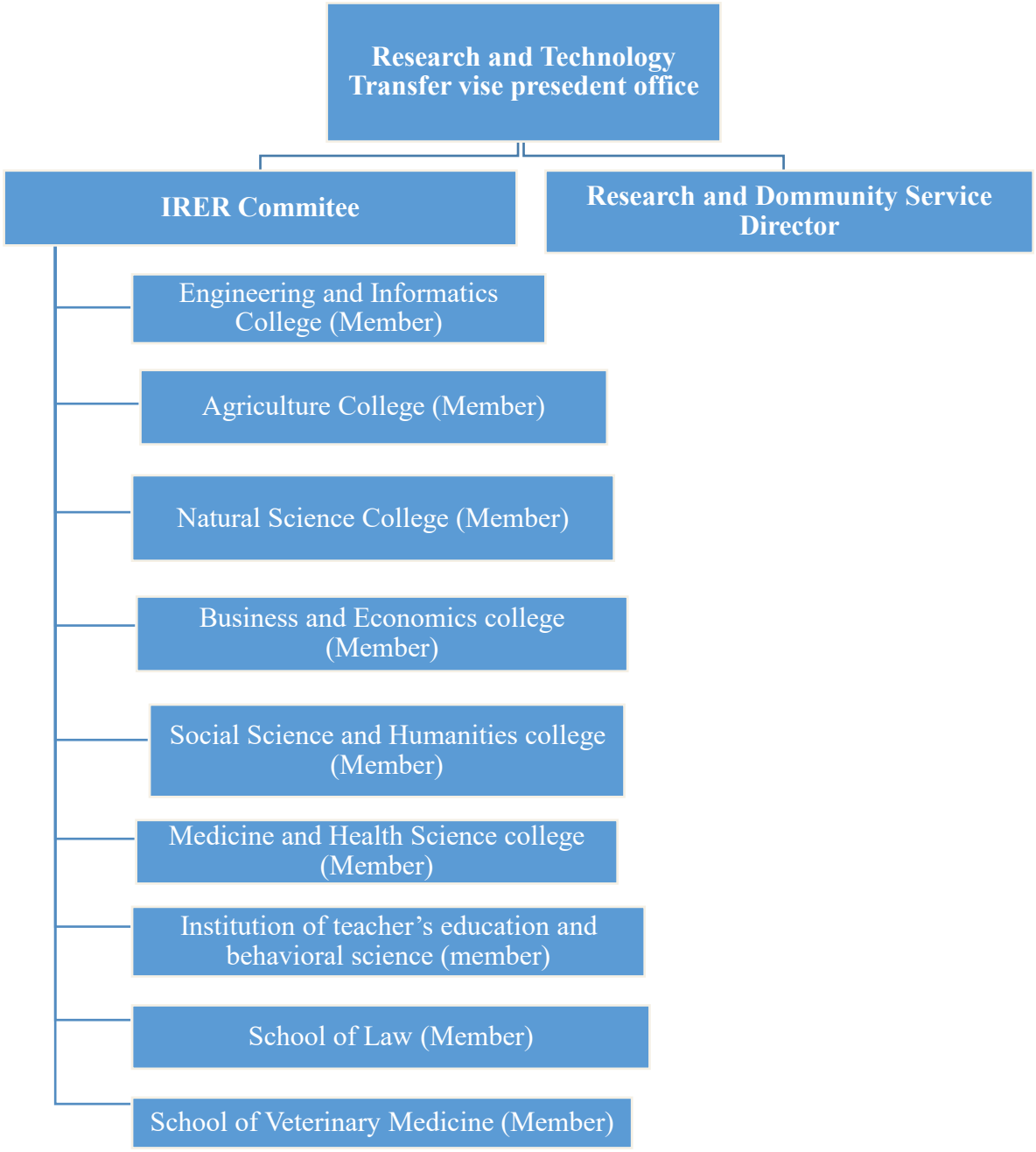


Figure 1 presents the Research Ethics review committee structure

The WU-RERC operates under the Vice president of Research and community service. Figure 1 presents the Research Ethics review committee structure.

1.4. Definitions and Key Concepts

1.4.1. Core research definitions

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes**.**

- **Examples considered as research:** Hypothesis-driven studies, data collection for publication, pilot studies for larger research, graduate student thesis research and faculty research projects
- **Excludes:** Quality improvement activities, program evaluation (internal use only), routine clinical care documentation and administrative data collection

Community engagement: Meaningful involvement of communities in research design, implementation and benefit-sharing.

Human participant: A living individual about whom an investigator (whether professional or student) conducting research obtains: Data through intervention or interaction with the individual, or identifiable private information

Intervention: Physical procedures, manipulations of subject or environment, communications or interpersonal contact

Interaction: communication or interpersonal contact between investigator and subject

Private information: Information about behavior in a context where individual reasonably expects no observation/recording will occur, OR information provided for specific purposes that individual reasonably expects will not be made public.

1.4.2. Risk assessment definitions

Minimal risk: 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.

- **Examples of minimal risk*:***
  - Anonymous questionnaires about non-sensitive topics
  - Non-invasive physiological monitoring
  - Collection of saliva samples
  - Brief interviews about educational experiences

Greater than minimal risk: any research where the probability and magnitude of harm or discomfort anticipated in the research exceed those ordinarily encountered in daily life.

- **Examples of greater than minimal risk:**

- Drug trials
- Invasive procedures
- Research on sensitive topics (trauma, illegal behavior)
- Studies with vulnerable populations
- Research with potential for psychological harm

1.4.3. Vulnerable populations

Definition: Individuals who may have compromised autonomy and therefore require additional protections to ensure voluntary participation**.**

Categories:

- **Minors (under 18 years)**: Children and adolescents
- **Cognitively impaired**: Individuals with mental disabilities, dementia
- **Economically disadvantaged**: Individuals whose economic situation might influence decision-making
- **Institutionalized persons**: Prisoners, residents of care facilities
- **Pregnant women:** Due to potential risks to fetus
- **Cultural/Linguistic minorities:** Groups with limited understanding of research processes.
- **Emergency situations**: Individuals unable to provide informed consent

1.5. Procedures for ensuring consideration of ethical issues in research

Wollo university is committed to maintaining high standards of ethics in research. This means abiding by the principles of ethical research and appropriate ethical. To this end, the following guidelines and procedures are designed to support researchers at all levels in conducting research according to relevant ethical, legal and professional obligations and standards, in whatever context and are therefore also drawn from and consistent with this IRERC-SOPs. According to this IRERC-SOPs there is common agreement that the basic principles of ethical research are:

- **Autonomy**. The participant must normally be as aware as possible of what the research is for and be free to take part in it without coercion or penalty for not taking part, and also free to withdraw at any time without giving a reason and without a threat of any adverse effect.
- **Beneficence.** The research must be worthwhile in itself and have beneficial effects that outweigh any risks; it follows that the methodology must be sound so that best results will be yielded.

- **Non-maleficence.** Any possible harm must be avoided or at least mitigated by robust precautions.
- **Confidentiality.** Personal data must remain unknown to all but the research team (unless the participant agrees otherwise or in cases where there is an overriding public interest, or where participants wish their voices to be heard and identified).
- **Integrity.** The researcher must be open about any actual or potential conflicts of interest, and conduct their research in a way that meets recognised standards of research integrity.

1.6. Guiding Ethical Frameworks

This Standard Operating Procedure (SOP) establishes a mandatory, unified framework for all research and teaching at Wollo University. The WU-IRB's ethical review is founded on a unique, integrated framework that combines global and national standards with a locally relevant philosophical approach.

- **Global & national alignment:** Adherence to Ethiopia's Proclamation No. 1130/2019, the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, and the World Health Organization (WHO) Minimum Standards for IRBs.
- **Ubuntu philosophy:** All ethical decisions are guided by the principle of **Ubuntu** ("I am because we are"), which emphasizes interconnectedness, collective responsibility, and communal well-being.
- **Multidisciplinary integrated approach:** The IRERC adopts a "**Holistic approach"** the inclusion of a cross-sectoral coordination and transdisciplinary research frameworks for **sustainable outcomes**.
    - Eg. "One Health" approach, recognizing the inseparable links between human, animal, and environmental health and requiring researchers to consider the impact of their work across all these domains.

CHAPTER 2: ETHICAL FRAMEWORK AND PRINCIPLES

This chapter lays out the core principles that guide WU-IRERC, ensuring that research is conducted responsibly and respectfully for everyone involved.

2.1. Foundational Ethical Principles

All research conducted under the auspices of Wollo University must adhere to the following ethical principles. The IRERC follow a set of essential ethical principles, both internationally recognized and deeply rooted in Ethiopian culture.

2.1.1. Core international principles: The global standard

A. Respect for Autonomy: Recognizing every individual's value

1. **Principle:**

- Recognition of individuals as autonomous agents capable of deliberation about personal goals and acting under their own direction. It also means the IRERC have a special responsibility to protect individuals who might have diminished autonomy, like children or those with certain cognitive impairments.

2. **Operational Implementation**

- **Informed consent requirements:**
  - Ensure comprehensive information disclosure, voluntary decision-making process, ongoing consent verification, guarantees the right to withdraw without penalty and the IRERC constantly check to protects diminished autonomy (e.g., assent for minors).
- **Autonomy protection measures**
  - IRERC make sure consent processes are **culturally appropriate** and that all information is **available in local languages**. Participants are given **adequate time to make their decisions** and there's absolutely **no room for coercion or undue influence**.
- **Safeguarding those with diminished autonomy:**
  - For individuals who might be more vulnerable, the IRERC provide **additional protections**. This includes using **assent processes for minors** (getting their agreement

in addition to parental consent) and involving **surrogate decision-makers** when necessary. The IRERC also offer **enhanced monitoring and support** for these groups.

3. **Review Criteria Checklist**

- When the IRERC evaluate a project/protocol, reviewers look for a clear description of the informed consent process, confirmation that information is provided in the right language and format, an emphasis on voluntary participation and specified withdrawal procedures. IRERC reviewers also ensure there are special protections for vulnerable populations.

B. Beneficence and Non-maleficence

1. **Principle**:

- Research must **maximize potential benefits** for participants and society while simultaneously **minimizing any possible harms**.

2. **Operational Implementation**

- **Maximizing benefits:**
  - The WU-IRERC ensure that research has clear scientific and social value, uses an appropriate study design and is conducted by qualified investigators with adequate resources and facilities.
- **Minimizing harm:**
  - This involves a comprehensive risk assessment to identify potential dangers, followed by risk mitigation strategies. We also put in place safety monitoring plans and clear emergency response procedures.
- **Careful risk-benefit analysis:**
  - The IRERC systematically weigh the potential harms against the potential benefits. This includes considering alternative approaches that might have lower risks, continuous monitoring and adjustment throughout the study and assessing the *impact on the wider community.*

3. Review Criteria Checklist:

- The IRERC confirm that the research demonstrates scientific merit and social value, that risks are identified and minimized and the *risk-benefit ratio is favorable*. We also check for adequate safety monitoring and emergency procedures.

C. Justice

1. **Principle**:

- Is about the *fair distribution of the benefits and burdens of research*. It ensures that no single group bears disproportionate risks or is unfairly excluded from potential benefits.

2. Operational Implementation

- **Equitable Participant Selection**
    - The IRERC insist on *fair recruitment procedures* and *inclusive eligibility criteria*. There must be *no exploitation of vulnerable groups*, and the research participants should be representative of the populations the study aims to help.
- **Fair benefit Distribution**
    - The benefits of the research should be *accessible to the participants* themselves. This can involve community benefit-sharing agreements, capacity-building components, and mechanisms for knowledge transfer.

- **Fair Burden Distribution**

  No group should experience an excessive burden. This means providing *compensation for participation costs*, minimizing inconvenience and demonstrating *cultural sensitivity in all procedures.*

3. **Review Criteria Checklist**

- The IRERC ensure participant selection criteria are fair, that there's no exploitation of vulnerable populations, and that benefits are accessible to participants and communities. We also verify that burdens are fairly distributed and that compensation is appropriate.

D. Confidentiality and integrity

- **Principle:** Protects personal data, secures data storage, and requires transparency regarding conflicts of interest
    - Personal data must be protected and accessible only to authorized personnel
    - Participants must be informed about data usage and storage
    - Plans must be in place for data security and breach response
    - Cultural considerations regarding data sharing must be respected
    - Researchers must be transparent about conflicts of interest
    - Research must be conducted honestly and responsibly

2.1.2. Ethiopian cultural integration: Blending global with local wisdom

This SOPs ethical framework isn't just about international standards; it's also deeply rooted in Ethiopian values and laws.

A. Constitutional Foundation

- The IRERC approach is guided by **Ethiopian Constitution Article 90**, which emphasizes research for national development. We also adhere to the *Cultural values protection* act, the *Community rights recognition framework* and *Traditional knowledge protection laws*.

B. Integrating Cultural Principles:

- **Community consultation:** The IRERC make mandatory engagement with traditional leaders a priority.
- **Intergenerational consideration:** The IRERC carefully consider the impact of research on future generations.
- **Cultural sensitivity:** The IRERC also have deep respect for religious and traditional practices.
- **Local ownership:** The IRERC ensure community participation in the research design itself

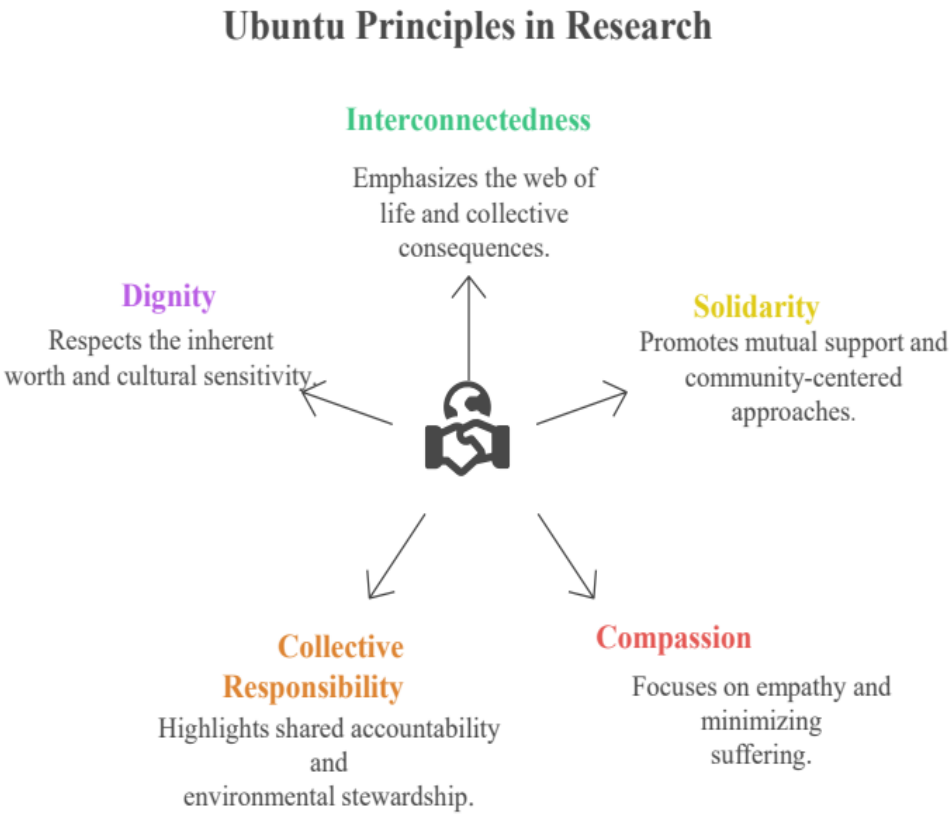
2.2. Ubuntu Philosophy Integration: "I Am Because We Are"

This philosophy demands a community-centered ethics where research decisions prioritize collective well-being

2.2.1. Ubuntu foundational concepts

The core principle of Ubuntu **"Umuntu ngumuntu ngabantu"**, which translates to **"I am because we are"**. is central to the ethical framework of the WU-IRERC. This philosophy highlights that all beings are fundamentally interconnected and share a collective responsibility for well-being. **In the context of research ethics, Ubuntu demands:**

- ***Recognition of interconnectedness*:** the IRERC understand that research impacts ripple far beyond individual participants.
- Collective Responsibility**:** there's a shared accountability for research outcomes and their consequences.
- ***Compassionate approach*:** the IRERC approach all aspects of research with empathy for everyone affected.
- ***Community-Centered ethics*:** decisions are made with the well-being of the entire community as the primary consideration.



2.2.2. Ubuntu operational framework

- To truly embody Ubuntu, the IRERC focus on four key operational pillars:

A. Interconnectedness (Ukuphila Ngokubambisana): Living in harmony

- **What** the IRERC **require:**
  1. **Ecosystem impact assessment:**
     - The IRERC evaluate environmental consequences and analyze the interconnectedness of humans, animals, and plants. Integrating with traditional ecological knowledge and develop sustainability plans.
  2. **Community network analysis:**

- This involves mapping all stakeholders, assessing their relationships, identifying power structures, establishing clear communication pathways and facilitating collective decision-making.

- **The IRERC tools:**
  - The IRERC member reviewers use an Interconnectedness Assessment Matrix, a Stakeholder mapping template and a community consultation record (see WU-IRERC-AT-003)
- **The IRERC review criteria:**
  - The IRERC check if the research impact on the broader community and environmental consequences has been assessed, if traditional knowledge was considered and if stakeholder relationships are mapped.

B. Solidarity (Ukusebenzisana): Working together

- **The** WU-IRERC **require:**
  1. **Collective benefit planning:** the IRERC identify community benefits, create shared ownership agreements, include capacity-building components, and establish resource-sharing mechanisms.
  2. **Participatory decision-making:** This means involving the community in the research design from the outset, ensuring ongoing consultation processes, building consensus, and having clear conflict resolution mechanisms.
- **The IRERC Tools:** the IRERC utilize a Benefit-Sharing Agreement Template, a Community Consultation Checklist and a Participatory Decision Record (WU-IRERC-T-004 and WU_IRERC-AT-003)
- The IRERC **Review Criteria:**
  - The IRERC look for clearly defined community benefits, established participatory processes, demonstrated shared decision-making, and procedures for conflict resolution.

C. Compassion (Ukuphila Ngothando): Living with love

- **The WU-IRERC require:**
  1. **Suffering minimization:** This involves a comprehensive harm assessment, protocols for reducing pain and distress, providing support services, and adopting trauma-informed approaches.
  2. **Empathetic engagement:** The IRERC mandate cultural sensitivity training, respectful communication protocols, emotional support systems, and healing-centered practices.

- **The** IRERC **Tools:**
    - The IRERC use a Compassion Assessment Checklist, a Cultural Sensitivity Protocol, and a Support Services Plan.
- **The** IRERC **Review Criteria:**
    - The IRERC ensure harm minimization strategies are comprehensive, cultural sensitivity is demonstrated, support services are available, and trauma-informed approaches are used.

D. Collective Responsibility (Ukuziphendulela Ngokubambisana): Being accountable together

- **The WU-IRERC require:**
    1. **Shared accountability systems:** This means involving the community in monitoring, transparent reporting mechanisms, joint oversight committees, and collective evaluation processes.
    2. **Intergenerational consideration:** We assess future impacts, work to preserve traditional knowledge, implement sustainable practices, and protect cultural continuity.
- **The IRERC tools:**
    - The IRERC employ a Collective Responsibility Framework, an Intergenerational Impact Assessment form, and a Community Monitoring Plan.
- **The IRERC review criteria:**
    - The IRERC verify that shared accountability mechanisms are established, community monitoring involvement is planned, intergenerational impacts are considered, and collective evaluation processes are defined.

2.3 A Multi-Disciplinary Integrated Approach: Holistic health for all

Our ethical framework culminates in an integrated approach that understands how everything is connected.

2.3.1 Conceptual framework: Understanding the whole picture

This is a collaborative, cross-sectoral, and transdisciplinary way of working that acknowledges the deep connections between human, animal, plant and environment within shared ecosystems.

WU-IRERC **core principles:**

- **Systems thinking:** The IRERC understand that complex interactions and feedback loops are at play.
- **Cross-sectoral collaboration:** The IRERC integrate efforts across health, agriculture, environment, and social sectors.

- **Transdisciplinary research:** The IRERC combine academic knowledge with invaluable community knowledge.
- **Sustainable outcomes:** The IRERC focus is always on long-term benefits for all stakeholders

2.3.2. Operational Implementation

A. Cross-Sectoral Coordination (Working as One Team)

- **The IRERC need:**
    - **Multi-sectoral teams:** These teams include representatives from various decalins or fields of specialty and crucially, community stakeholder participation.
    - **Integrated planning:** This involves setting joint objectives, developing coordinated methodologies, sharing resources, and establishing unified monitoring systems.
- **The IRERC tools:** The IRERC use a Multi-Sectoral Team Composition Matrix, an Integrated Planning Template, and a Cross-Sector Coordination Plan.

B. Sustainable Outcomes Framework: Building a better future

- The WU-IRERC use a "*Triple Bottom Line Assessment*" to ensure our projects benefit people, the planet and prosperity:
    - **Social sustainability:** research must focus on building community capacity, promoting social equity, preserving culture, and fostering education and awareness.
    - **Environmental sustainability:** This means protecting ecosystem health, conserving biodiversity, building climate resilience and conserving resources.
    - **Economic sustainability:** Our aim is to improve livelihoods, foster local economic development, find cost-effective solutions and ensure long-term financial viability.
- **The IRERC Tools:** the IRERC rely on a Sustainability Assessment Matrix, a Triple Bottom Line Evaluation form, and an Outcome Monitoring Framework.

CHAPTER 3: ORGANIZATION STRUCTURE FOR ETHICAL OVERSIGHT

3.1. Institutional structure: Organizational Hierarch

At the top is the Vise President for Research & Technology Transfer Office, under whom oversees the research director. Directly beneath the VP is the WU-IRERC, which is the central ethical review body.

3.1.1. The WU-IRERC

The IRERC operates at the institutional level under the Vise president for Research & technology transfer office and has the mandate to ensure that proper research ethics governance is in place throughout the university.

- Provides oversight of the IRB and other ethics review bodies
  - Ensures alignment of ethics review processes with university policies and national regulations
  - Addresses systemic issues in research ethics governance
  - Facilitates coordination between different ethics review bodies within the University particularly the College or School Research Review Committee (C/SRRCs)

3.1.2. College or School Research Review Committee (C/SRRCs)

Each college or school under Wollo university has its own Research Ethics Review committee (C/SRRC) to handle initial reviews. The C/SRRCs, are responsible for providing primary reviews for their respective disciplines **and local ethical oversight** within their respective colleges or schools.

A. The purpose and key functions of the C/SRRCs are:

1. **Primary Functions**

- C/SRRCs conduct the initial review of protocols specific to their college.
- They offer disciplinary expertise and guidance to researchers.
- They facilitate pre-submission consultations to aid researchers before formal applications.
- They monitor compliance with ethical standards within their respective colleges.

2. **Delegated authority**

- The C/SRRCs have delegated authority from the WU-IRERC for certain review procedures:
  - They can make **exempt determinations** for very low-risk studies.
  - They can perform **expedited reviews** for minimal risk research.
  - They can approve **minor amendments** to protocols.
  - They conduct **continuing review assessments**.

- Implement IRERC decisions and policies at the college/school level

B. Limitations and oversight

The C/SRRCs operate under the **supervisory oversight** of the central WU-IRERC, specifically regarding the ethical part of research. It is important to note the limitations of the C/SRRCs' authority:

- They cannot approve research with greater than minimal risk.
- They cannot approve research involving vulnerable populations.
- They must refer complex cases (such as multi-college collaboration, community controversy, or international involvement) to the full WU-IRERC.
- They cannot override decisions made by the WU-IRERC and must refer complex cases to the full WU-IRERC.

3.1.3. Reporting relationships: Staying connected

The WU-IRERC believes clear reporting lines ensure accountability and smooth operation.

- **Upward reporting:** The WU-IRERC chairperson reports monthly to Wollo University Research & Technology transfer Vise President. The VP Research reports quarterly to the University President, who then reports annually to the National Ethics Committee.
- **Horizontal coordination:** College RRC and the WU-IRERC are in ongoing communication. The community advisory members coordinate with the WU-IRERC monthly, and the IRERC members from the university continuously works with the colleges or schools they representing.
- **Downward oversight:** The WU-IRERC provides supervisory oversight to College or School Research Review Committees (RRC) related to ethical part of research.

3.2. WU-IRERC Composition and Membership

The WU-IRERC is a diverse and expert team, carefully selected to provide comprehensive ethical review.

Table 3.1. IRERC member roles and required qualifications detailed framework

Role	Qualifications	Commitment (hrs /Month
Chair	PhD in relevant field, minimum 10 years experience, ethics training certification, leadership experience	10–15
Vice-Chair	PhD/MSc degree; 7+ years' experience; ethics training.	8–12
Social scientist (Education/ Humanities)	PhD/MSc in social sciences + 5 years research experience	8–10
Natural/computational science expert	PhD/MSc and 5+ years of research experience and peer-reviewed publications are preferred	
Agriculture science expert		
Legal expert (Law School),	Law degree 5+ years experience in research law/regulation	8–10
Natural/Environmental Scientist	MSc/PhD in natural/environmental sciences + 5 years experience	8–10
Veterinarian	DVM+MSc, 5+ years field clinical and research experience; animal welfare certification.	8–10
Biomedical/Public health	PhD in biomedical sciences 5+ years research; published ethics work.	8–10
Community Representative	Respected and recognized community member, not affiliated with the university; non-scientist. leader; cultural expertise; local knowledge fluency and communication skill	8–10
Traditional Knowledge Keeper	Certified traditional healer; deep ecological knowledge.	6–8
Ethics expert	Advanced degree in ethics/bioethics 5+ years experience	8–10
Engineering and Informatic expert	PhD/MSc in technological l sciences 5+ years research experience	8–10
Business and economics expert	PhD/MSc in business filled, 5+ years research experience	8–10
Secretary	A minimum of MSc and administrative skills. Experience in research administration, database management and confidentiality training are preferred.	10–12

3.2.1. IRERC composition and expertise

The WU-IRERC's composition is carefully designed to ensure comprehensive and balanced reviews. The IRERC shall be composed of a minimum of nine (9) and a maximum of fifteen (15) members, appointed by the Office of the VP for Research & technology transfer office. The composition ensures comprehensive and balanced reviews by incorporating a diversity of scientific, ethical, a traditional knowledge keeper and community perspectives (see Table 3.1)

The IRERC membership shall reflect diversity in:

- Gender: Both men and women shall be represented, with efforts to achieve gender balance
- Disciplinary background: Multiple scientific disciplines and non-scientific areas
- Cultural and ethnic background: Representation of the diverse communities served by the university
- Professional experience: Mix of junior and senior members
- Community affiliation: Both university-affiliated and community member

3.2.2. Member selection process

Selection involves a formal nomination and review process. Internal members are nominated by departments and reference-checked. External members are selected through community consultation, stakeholder nominations and community validation. Selection criteria emphasize relevant qualifications, commitment to ethics, cultural sensitivity, communication skills, independence, integrity and availability.

Nomination process

- **Internal member nomination:**
  - **Department/College nomination:** Departments or colleges can nominate individuals by qualifications, including justification letter and confirming the nominee's availability and commitment.
- **External member nomination:**
  - **Community consultation:** by actively engage traditional leaders and elders, conduct community forums, seek recommendations from organizations and verify community standing.
  - **Stakeholder engagement:** reach out to professional associations, civil society organizations, religious and cultural groups and government representatives for nominations.

- **Reference checks:** Including professional, character, and community validation, along with conflict-of-interest screening.
- **Final approval:** The selection committee makes a recommendation, which requires approval from the VP Research and finally, community endorsement.

3.3. Member roles and responsibilities:

The specific roles within the Institutional Research Ethics Review Committee (IRERC) are designed to provide the necessary expertise, administrative structure, and leadership required for the IRERC to fulfill its overall functions of reviewing research, ensuring compliance, and upholding ethical principles. The contribution of specific roles can be categorized based on their impact on governance, expert review, compliance, and administration:

1. Leadership and governance

These roles ensure the smooth operation, direction, and representation necessary for the committee to manage its mandated responsibilities.

- **Chairperson**
    - Provides **leadership and direction** for the IRERC. This role contributes by presiding over meetings, ensuring timely review of protocols, overseeing operations, and assigning protocols to reviewers. The Chairperson also represents the IRERC to institutional officials and external bodies, and prepares annual reports on IRERC activities, fulfilling reporting requirements.
- **Vice-chairperson**
    - Contributes by assisting the Chairperson in all duties and presiding over meetings when the Chairperson is absent. They also help support educational and review functions by coordinating training programs and assisting in protocol assignment and review.

2. Expert review and assessment

These expert roles ensure that research protocols are assessed against scientific rigor, ethical soundness, cultural relevance, and potential risk to participants, directly supporting the core function of protocol review, modification, approval, or rejection.

- **Scientific Members**
    - Contribute technical and methodological vetting. Their responsibilities include reviewing the scientific merit and methodology of protocols, assessing risk-benefit

ratios, and evaluating researcher qualifications. They also provide scientific expertise during deliberations and participate in the continuing review of approved research.

- **Ethics expert**
    - Provides **essential ethical analysis and guidance** to the committee. This expert identifies ethical issues in protocols, ensures alignment with ethical principles, and advises on ethical dilemmas. They also contribute to the long-term functioning of the committee by providing ethics training and participating in the development of ethical guidelines.
- **Non-scientific members**
    - Contribute crucial context by providing **community and cultural perspectives**. This ensures the committee's decisions consider real-world impact. They assess community impact and benefit-sharing, evaluate cultural appropriateness, ensure protection of vulnerable populations, and advise on community engagement strategies.

3. Compliance and regulatory assurance

These roles are crucial for ensuring the research remains compliant with internal and external standards, which supports the IRERC's duties to monitor compliance, investigate non-compliance, and suspend/terminate research if necessary.

- **Legal expert**
    - Ensures the **legal compliance of research**. Their specific contributions include advising on regulatory requirements, identifying legal issues in protocols, reviewing consent forms and agreements, and assisting in the development of necessary policies and procedures. They also provide guidance on intellectual property issues.

4. Administration and documentation

The administrative role ensures that all actions and decisions of the committee are properly recorded, communicated, and tracked, which is central to the IRERC's overall responsibility to **maintain documentation of all IRERC activities**.

- **Secretary**
    - Manages the **logistics and essential documentation**. Their contributions include coordinating meeting schedules, preparing and distributing agendas and materials, recording and maintaining minutes of meetings, and managing correspondence. The Secretary also tracks protocol review timelines and outcomes and manages the IRERC databases and filing systems.

A. Chairperson responsibilities

- Provides strategic direction, ensures compliance, represents the IRERC, and facilitates effective decision-making.
- Plans and coordinates monthly meetings, ensures quorum, guides discussions, and maintains order.
- Supervises IRERC office operations, monitors performance, approves policies,

Specific duties: Reviews all protocols, prepares agendas, facilitates consensus, signs approval letters, represents the IRERC at university committees, conducts annual performance reviews, prepares quarterly reports and coordinates training programs.

B. Scientific member responsibilities (The Expert Reviewers)

Scientific members bring their disciplinary expertise to the review process.

- Conduct thorough scientific evaluations, assess methodology and design quality, evaluate feasibility and resources and provide expert input.
- Participate in multidisciplinary discussions, share expertise, mentor junior researchers, and contribute to policy development.

Specific duties: Completes assigned protocol reviews within 7 days, attends monthly meetings (at least 80% attendance), provides written comments, participates in continuing education, serves on subcommittees, maintains confidentiality and updates knowledge on ethical standards.

C. Community representative responsibilities

These members ensure the community's perspective is at the forefront.

- Represents broader community interests, assesses community impact and benefits, ensures cultural appropriateness, and advocates for participant protection.
- Facilitates community consultation, reports community concerns and feedback, builds trust and transparency, and promotes research understanding.

Specific Duties: Reviews protocols from a community perspective, attends monthly meetings and community forums, facilitates community consultation, reports feedback, participates in outreach, maintains community connections, and advocates for benefit-sharing.

3.3.1. Term structure and renewal

- A standard term is **3 years**, with a maximum of **2 consecutive terms (6 years total)**. Renewal is based on a performance review and reconfirmation. Emergency appointments can be made for up to 1 year to maintain quorum.

- To ensure continuity and preserve institutional memory, members are appointed in a staggered fashion: **5 members in Year 1, 5 in Year 2, and 5 in Year 3**.
- Members are assessed on attendance (minimum 80%), quality of reviews (timely and thorough), participation level (active engagement), professional development (continuing education) and ethical conduct.

3.3.2. Standard operating procedures for C/SRRCs: How They Operate

- **Review process:**
    - **Initial review:** Reviewers conduct preliminary evaluations, identify the review category, and prepare recommendations.
    - **Panel discussion:** Review findings are presented, concerns and recommendations are discussed, and a consensus decision is reached.
    - **Decision communication:** A decision letter is prepared, submitted to the WU-IRERC for ratification and the researcher is notified of the outcome.

3.4. Governance structure and procedural safeguards

The WU-IRERC reports upward through the VP Research & Technology Transfer office to the University President and annually to the National Ethics Review Committee. It provides supervisory oversight to College/School Research-Ethics Review Committees (C/SRRCs) related to the ethical part of research.

3.4.1. IRERC office administration

The IRER Office provides essential administrative and operational support for all ethical review processes.

3.4.1 Administrative Structure

- IRER Office: Provides overall administrative leadership, oversees policy implementation, coordinates external liaison, and supervises quality assurance.
- Administrative coordinator: Manages meeting coordination and scheduling, document management, communication, and database maintenance.
- Research ethics specialist: Coordinates protocol review, develops training programs, monitors compliance, and provides technical assistance.
- Community liaison: Coordinates community engagement, facilitates cultural consultation, protects traditional knowledge, and implements benefit-sharing initiatives.

3.4.2 Administrative procedures:

The IRB Office follows a structured routine to ensure efficiency:

- **Daily operations:** Monitoring protocol submissions, updating database records, responding to inquiries, preparing meeting materials, coordinating reviews, and maintaining correspondence.
- **Weekly activities:** Preparing meeting agendas, distributing review assignments, updating progress reports, conducting training sessions, and updating website content.
- **Monthly tasks:** Compiling performance metrics, preparing quarterly reports, conducting file audits, updating policy documents, coordinating community meetings, and planning training programs.
- **Annual responsibilities:** Preparing annual reports, conducting comprehensive audits, reviewing and updating SOPs (Standard Operating Procedures), planning strategic initiatives, evaluating performance and budget planning.

3.4.3. Conflict of interest management

- A conflict of interest exists when an IRERC member's personal, professional, financial, or other interests could interfere with their objective judgment in the review of a research protocol.

A, Types of Conflicts

- Financial interests (e.g. stock ownership, consulting fees, and honoraria), professional interests (e.g. collaboration with researchers, academic competition), personal interests (e.g. familial relationships and personal beliefs), institutional interests (e.g. departmental affiliations, administrative roles)

B. Disclosure Requirements:

- Any member with a direct or indirect interest in a research protocol must disclose this conflict and recuse themselves from the review, deliberation, and voting process for that specific protocol.
  - All IRERC members must complete a conflict-of-interest disclosure form annually
  - Members must disclose any potential conflicts prior to review of each protocol
  - Members must update their disclosure information whenever their circumstances change
  - This recusal must be documented in the meeting minutes as a crucial procedural safeguard.

C. Management of conflicts:

- For minor conflicts: Members may participate in discussion but must recuse themselves from voting
- For significant conflicts: Members must recuse themselves from both discussion and voting
- Members with conflicts must leave the room during deliberations on the relevant protocol
- The conflict and management approach must be documented in meeting minutes

D. Prohibited conflicts:

- IRERC members may not participate in the review of protocols in which they are investigators
- IRERC members may not review protocols from their immediate family members
- IRERC members may not review protocols in which they have a significant financial interest
- IRERC members may not review protocols from their department or direct supervisees

E. Violation

- Failure to disclose a conflict of interest may result in:
  - Removal from the IRERC member
  - Disciplinary action by the university
  - Reporting to appropriate oversight bodies
  - Re-evaluation of protocols reviewed while in conflict

3.4.4. IRERC meeting procedure

Meeting Types Schedule

The WU-IRERC meeting procedures are designed to ensure efficient and effective review of research ethics. The following types of meetings are convened:

- **Regular meetings**: Held monthly on the first Thursday of each month, these meetings are dedicated to reviewing research protocols and conducting IRERC business held at the IRERC office, with virtual participation options available. Notice sent at least 7 days in advance, including agenda, protocols to be reviewed, and supporting materials
- **Emergency meetings**: Called by the Chairperson or at least three members for urgent ethical issues that require immediate attention. Minimum 48-hour notice required, with a brief agenda and relevant materials.
- **Special meetings**: Quarterly community consultations, annual planning, and training sessions are held to foster collaboration and address specific topics. Held at community-accessible venues, with arrangements made for virtual participation as needed. Notice sent at least 14 days in advance, with a detailed agenda and supporting materials.

Agenda preparation: The Secretary, in consultation with the Chairperson, prepares a draft agenda, which is distributed to members at least 5 days before regular meetings. Members may request items to be added to the agenda.

3.4.5. Conduct of meetings and quorum management

- A quorum is the minimum number of members required to be present to conduct official IRERC business

Table 3.1 Rules governing attendance and quorum.

Step	Procedure	Requirement & Detail	Source
1	Verify Quorum	Secretary	Verification must occur *before* the meeting begins. Attendance is recorded in the meeting minutes.
2	Quorum Definition	A minimum of **60%** of total members (e.g., 9 of 15 members) must be present.	
3	Quorum Composition	Quorum must include: Chairperson or Vice-Chairperson; At least one community representative; At least one traditional knowledge keeper; At least one external/independent member; Both scientific and non-scientific members.	
4	Remote Participation	Remote participants are counted toward quorum if they are fully able to participate. Remote participation must be documented in the minutes.	
5	Note Attendance Issues	Late arrivals are noted but **do not count** toward the initial quorum count. Early departures are noted and the impact on quorum is assessed.	
7	Approve Final Agenda	IRERC Members	The final agenda must be approved by the members at the beginning of the meeting.
8	Conduct meetings /Dialogue	Chairperson/Members	The Chairperson presides over meetings, emphasizing **Ubuntu-based consensus building**, respectful

			dialogue, and active listening.
9	Manage Loss of Quorum	Chairperson/Secretary	If quorum is lost during the meeting, **no further official business may be conducted**. Decisions made before the loss of quorum remain valid. Remaining items are deferred to the next meeting with quorum. Emergency procedures may be initiated if urgent matters require attention.

3.4.6. Decision-making procedures

Table 3.2. The mandatory process, prioritizing consensus and specifying voting rules

Step	Procedure	Requirement & Detail	Source
1	Principle of Consensus	Decisions must be based on ethical principles, regulations, and policies. Consensus is preferred over voting.	
2	Consensus Building	Chairperson facilitates discussion to identify areas of agreement/disagreement. Members express views openly. **Consensus is defined as general agreement without substantial opposition.**	
3	Initiate Voting (If Necessary)	Chairperson	Voting is initiated **only** if consensus cannot be reached, or if further discussion is deemed unproductive by the Chairperson.
4	Call for Vote	Chairperson	Chairperson calls for a vote on specific motions.
5	Voting Method	Voting may be conducted by show of hands, voice vote, or secret ballot, as appropriate.	
6	Determine Outcome	**Simple Majority (50% + 1):** Required for most decisions. **Two-thirds (2/3) Majority:** Required for significant decisions (e.g., protocol approval or termination).	

7	Record Abstentions	Secretary	Abstentions must be allowed and recorded for conflicts of interest or lack of expertise.

3.4.7. Documentation and appeals

Table 3.3. Mandates documentation standards and outlines the official appeal process

Step	Procedure	Responsibility	Requirement & Detail
1	Record Minutes	Secretary	Minutes must be detailed, including attendance, discussion points, all decisions, and voting outcomes (if applicable).
2	Document Decision Rationale	Secretary	Rationale for all decisions must be documented. Minority opinions must be recorded if requested.
3	Approve Minutes	IRERC Members	Minutes must be approved by the IRB at the next meeting.
4	Maintain Records	Secretary	Approved minutes must be maintained in the IRB records.
5	Communicate Decisions	Secretary/Chairperson	Decisions must be communicated to relevant parties in writing.
6	Prepare Reports	Secretary/Designee	Summary reports must be prepared for institutional officials.
7	Receive Appeal	Researcher/Chairperson	Appeals must be submitted in writing to the IRERC Chairperson within **30 days** of the decision communication.
8	Review Appeal	IRERC Members/Designee	The appeal must be reviewed by IRERC members who **did not participate in the original decision**. External experts may be consulted for complex appeals.
9	Communicate Final Decision	Chairperson	The final decision on the appeal must be communicated in writing. No further appeal within the IRERC process is permitted.

.

PART II

WU-IRERC STANDARD OPERATING PROCEDURES.

This section is designed to guide researchers through the journey of preparing and submitting their research for ethical review, ensuring their project is not only scientifically sound but also deeply respectful of human dignity and community values.

CHAPTER 4: PROTOCOL REVIEW PROCESS

4.1. Pre-Application Consultation Concept Note

Purpose:

Not everyone *must* consult, but many researchers will find it mandatory or highly beneficial. Pre-application consultation is a mandatory step designed to ensure that proposed research aligns with ethical principles, Ubuntu philosophy, and WU institutional standards before formal submission.

Mandatory pre-submission consultation categories:

- First-time applicants and Student researchers
- Engaged in international collaborations
- Community-based research
- Traditional knowledge studies
- Multi-college projects
- Greater than minimal risk research and Vulnerable population research.

The IRERC strongly recommend consultation if research involves:

- Novel methodologies or procedures, sensitive or controversial topics, complex regulatory requirements, large-scale or multi-site studies and commercial or industry-sponsored research.

4.1.2. Consultation process

Step 1: Initial Contact: researchers should make initial contact to IRERC Office (Email/Phone) or in person at the administrative building (see Appendix F) **at least two weeks before** the research intended submission date.

The IRERC response timeline:

- An acknowledgment response within 24 hours.
- Consultation meeting will be held within 3 business days of scheduling.

Step 2: Concept note submission

Once meeting is scheduled, researcher (PI) will need to submit a **2–3-page concept notes** before meeting

The concept note should include detailing

- Principal Investigator name and affiliation and contact information for scheduling

- Research Overview**:** core research question, objectives, brief background, significance, expected outcomes and impact.
- Methodology summary**:** study design, participant population, recruitment strategy and data collection methods.
- Ethical considerations**:** Potential risks and benefits, any vulnerable populations and a community impact assessment.
- Community engagement plans and implementation plan **(**timeline, milestones, resources, funding and team composition)

Concept note format

- File Format: PDF or word document, font (12-point Times New Roman, spacing (Double-spaced), pages (Maximum 3 pages excluding references), language (English)

Step 3: Schedule and response

The IRERC office acknowledge receipt within 24 hours and schedule consultation meeting within 3 business days.

Step 4: The consultation meeting (60-90minute) to discuss about research directly with ethics experts.

Meeting structure:

- Opening & Introductions**:** Welcome, agenda review, introductions and confidentiality agreements.
- Research Presentation (20 min): The Principal Investigator (PI) presents the research concept and methodology, followed by a Q&A.
- Ethical Discussion (30 min): the IRERC will delve into risk assessment, community impact analysis, the application of the **Ubuntu principle** and regulatory compliance needed.
- Guidance & Recommendations (20 min**):** researchers will receive clear guidance on review pathway, a list of required documentation, community engagement requirements and next steps.
- Documentation & Follow-up (10 min): summarize recommendations and assign action items.

Who Attends the Meeting?

- Principal Investigator (REQUIRED**)**, Co-Investigators (recommended), IRERC Chairperson or designee and relevant collage or school RRC coordinator

Step 5. Consultation report & ongoing support

- Following consultation, the IRERC chairperson will provide a **written consultation report within 3 business days**. This report is a crucial guide for the formal application process.

Consultation report will include:

- Review Pathway Determination: Whether the project will likely undergo **Exempt, Expedited or Full Board Review**, with a rationale and any special requirements.
- Required documentation checklist**:** A detailed list of mandatory forms, templates and supporting documents.
- Community engagement requirements**:** Guidance on stakeholder identification, consultation procedures, and benefit-sharing expectations.
- Compliance guidance**:** Specific regulatory requirements, institutional policies and best practice recommendations.

4.2. Mandatory Community Consultation Requirement

For research involving communities, researchers must identify stakeholders, develop an engagement plan and meticulously document the consultation process. Document all consultation activities (including meeting dates, participants, concerns, and responses), and create a benefit-sharing plan. Evidence of community consultation (e.g., minutes from community meetings) is a mandatory component of the protocol.

Required documentation: Community Consultation Report (Appendix C, WU-IRB-T-004), Stakeholder Mapping (T-004 Section 4&5), Benefit-Sharing Agreement (T-004, Section 7) and Cultural Sensitivity Protocol.

CHAPTER 5: APPLICATION AND REVIEW PROCESS

5.1. Purpose

This chapter establishes the Standard Operating Procedures (SOPs) for the submission, processing, and ethical review of all research protocols submitted to the Wollo University Institutional Research Ethics Review Committee (WU-IRERC). This guide outlines the submission requirements for Principal Investigators (PIs) and the chronological review steps the WU-IRERC undertakes scientific standards.

5.2. Submission Requirements for Principal Investigators

5.2.1. PI Responsibility for completeness

The Principal Investigator (PI) is fully responsible for submitting a complete, detailed, and accurate application package to the WU-IRERC (Chairperson/Secretariat) by the posted submission deadline, using official university forms. Incomplete applications will not be processed and will be returned to the PI, which will delay the review.

5.2.2. Formatting and language standards

All submitted documents must adhere to the following standards. The WU-IRERC Secretariat will verify compliance during the administrative review.

- Format**:** All text must use Times New Roman, 12-point font, with 1.5 line spacing. Documents must be formatted for A4 size with 2.5 cm margins on all sides.
- Structure: The main research protocol and any attachments over 10 pages must include a cover page and a table of contents. All pages must be numbered.
- Citations**:** All references must follow the APA 7th edition style.
- Language**:** The primary language for all application materials is English. All participant-facing materials (e.g., consent forms, questionnaires) translated into Amharic or other local languages must be submitted alongside the English version and a certificate or declaration of translation accuracy.

5.3. The Complete Application Package

A complete application package consists of four categories of documentation. The specific forms and templates required are outlined in Chapter 11. The WU-IRERC Secretariat or Chairperson must

confirm that all necessary documentation is present and organized. The package must include:

1. **Core application forms:**
    - WU-IRB-F-001: Research Protocol Application Form and Principal Investigator Information (Appendix B.1.1)
    - WU-IRB-F-002: Protocol Summary Form (Appendix B.1.2)
2. **Primary research documents:**
    - The Research Protocol: A single, comprehensive document detailing the entire study (see **Section 5.4** for content requirements).
    - Research Instruments: All questionnaires, interview guides, data collection sheets, and other instruments to be used
    - Data Management Plan: A detailed plan for data collection, security, privacy, access, and long-term storage or destruction (see Section 8 of WU-IRERC-F-001)
3. **Ethical and Community Documentation:**
    - Informed Consent/Assent Forms: All consent forms (e.g., adult, parental) and assent forms (e.g., child, adolescent) for all participant groups (see Section 5.5 and Appendix B 2.1(WU-IRERC-T-001), B.2.2(T-002) and B.2.3(T-003).
    - WU-IRB-AT-003: Risk assessment matrix (Appendix C.3)
    - WU-IRB-AT-003, Section 6): Ubuntu impact assessment
    - WU-IRB-AT-004: Community consultation report (if applicable) (Appendix C.4)
    - Stakeholder Mapping (if applicable)
    - Benefit-sharing agreement (BSA): A copy of the draft or signed BSA (if applicable, see Chapter 10).
    - Cultural sensitivity protocol (if applicable)
    - Data safety monitoring plan (DSMP): Required for all research determined to be greater than minimal risk.
4. **Personnel and Supporting Documents:**
    - Curricula Vitae (CVs): Up-to-date CVs for the PI and all co-investigators.
    - Training certificates: Valid (current) research ethics training certificates for the PI and key personnel.
    - Supporting letters: Institutional affiliation letters, letters of support from collaborating sites, and documentation of scientific peer review (if applicable).

5.4. Research Protocol Content Detailed Requirements

The main research protocol (maximum 25 pages, excluding appendices) must be a comprehensive, standalone document that provides a complete understanding of the study. It must include the following sections:

- **Section 1: Research overview:** Project title, PI and team information, and a concise summary of the research question, objectives, and expected outcomes.
- **Section 2: Background and rationale:** A literature review establishing the research gap, a clear problem statement, and justification for the study's significance, particularly within the Ethiopian context.
- **Section 3: Research design and methodology:** A detailed description of the study design, target population, sample size justification, recruitment strategies, data collection procedures, and the data analysis plan.
- **Section 4: Ethical considerations:** A detailed risk-benefit analysis, justification for participant selection, and procedures for protecting privacy and confidentiality.
- **Section 5: Ubuntu and community integration:** An explanation of how the research applies Ubuntu principles (interconnectedness, collective responsibility, compassion), a summary of the community engagement process, and an outline of the benefit-sharing framework.
- **Section 6: Implementation and management:** A description of the research team's qualifications, required resources and facilities, funding source, and a realistic project timeline with key milestones.

5.5. Informed Consent Requirements

5.5.1. Core elements of informed consent

The informed consent process is a cornerstone of ethical research. All consent forms must be clear, non-coercive, and written in language the participant can understand. They must include:

1. **Study identification:** Research title, PI name, and contact details for the research team and the WU-IRERC.
2. **Purpose and procedures:** A clear explanation of the research purpose, the expected duration of participation, and a description of all procedures.
3. **Risks and discomforts:** An honest description of all reasonably foreseeable risks (physical, psychological, social, economic).

4. **Benefits:** A description of any potential benefits to the participant, community, or society. It must be stated if there is no direct benefit.
5. **Confidentiality:** An explanation of how privacy will be protected and how data will be kept confidential.
6. **Compensation:** Details on any payment, reimbursement, or costs to the participant.
7. **Voluntary participation:** A clear statement that participation is voluntary, and the participant has the right to refuse or withdraw at any time without penalty.
8. **Contact information:** Clear contact information for the PI (for study questions) and the WU-IRERC (for questions about rights as a participant).

5.5.2. Cultural and linguistic adaptation

To ensure consent is truly informed, all materials must be culturally and linguistically appropriate. This includes professional translation and verification, the use of local terms, respect for traditional authority structures in the consent process, and consideration for gender and age-based communication protocols.

5.5.3. Protections for special populations

- **Minors (Under 18):** Requires the documented, signed consent of at least one parent or legal guardian. In addition, the minor's own affirmative agreement (assent) must be obtained using an age-appropriate assent form (e.g., verbal assent for ages 7-11, simplified written assent for ages 12-17). The minor's decision to refuse participation must be respected.
- **Cognitively impaired individuals:** A formal capacity assessment is required. If a participant lacks the capacity to consent, permission must be obtained from a legally authorized representative or surrogate, focusing on the participant's best interests.
- **Emergency situations:** In rare, life-threatening situations where prospective consent is impossible, the protocol must detail a clear plan for exception from consent, including an independent physician's consultation and procedures for seeking consent from the participant or family as soon as feasible.

5.6. The WU-IRERC Review Process

All applications must be submitted through the IRERC online portal, along with one signed hard copy. This section describes the standard review process chronologically from receipt of the application through the final decision.

Step 1: Administrative triage (Days 1–2)

- **Responsibility:** WU-IRERC Secretariat
- **Action:** Upon receipt, the secretariat conducts an administrative review to ensure the application package is complete and all documents are correctly formatted per **Sections 5.2 and 5.3**. Incomplete applications are returned to the PI.

Step 2: Determination of Review Pathway (Days 3–4)

- **Responsibility:** WU-IRERC Chair or designated reviewer, in consultation with the Vice-Chair and Secretary.
- **Action:** Complete applications are triaged into one of three review pathways based on the level of risk, as detailed in Section 5.7.
    1. **Exempt review:** For research posing no more than minimal risk and fitting specific, defined categories.
    2. **Expedited review:** For research posing no more than minimal risk but not qualifying for exempt status.
    3. **Full board review:** For all research posing greater than minimal risk, or research involving vulnerable populations or sensitive topics.
- **Decision frame work:**

1. **Does the research involve human participants?**
    - **NO**: The project might need animal protocol review, environmental assessment or community consultation.
    - **YES,** if it does proceed to assess the risk level. **Risk level assessment**
        - **Minimal risk**?
            - **YES**, and it meets specific, well-defined categories (e.g., anonymous surveys, existing de-identified data): It's likely for **Exempt review**.
            - **YES**, minimal risk but does not meet exempt categories (e.g., standard clinical procedures, social/behavioral surveys requiring identifiers): It's likely for **Expedited Review**.
    - **Greater than minimal risk**? this always leads to **Full Board Review.**
        - Even if minimal risk, but involves ***Vulnerable Populations or Sensitive Topics***: this also leads to **Full board review**.

Step 3: Assignment of reviewers (Days 3-4)

- **Responsibility:** WU-IRERC Chair
- **Action:** For Expedited and Full Board reviews, the Chair assigns the protocol to a Primary

Reviewer and at least one Secondary Reviewer. Reviewers are selected based on expertise, workload, and conflict of interest checks. For multi-disciplinary studies, specialist reviewers from relevant fields will be assigned (see **Chapter 8**).

Step 4: Protocol evaluation

- **Responsibility:** Assigned Reviewers

Action: Reviewers conduct an in-depth evaluation of the protocol using the standardized review framework and scoring methodology detailed in **Chapter 6: Review criteria and evaluation framework**

- **Review Process and Decision-Making**. They assess scientific merit, ethical compliance, Ubuntu alignment, and multi-disciplinary integration.

Step 5: Committee Deliberation (Full Board Review)

- **Responsibility: Full IRERC committee**
- **Action:** At a convened meeting with a quorum present, the Primary Reviewer presents the protocol and their findings. The committee discusses the protocol, considers all reviewer reports, and collectively debates any ethical concerns. The PI may be invited to answer questions.

Step 6: Decision-making and communication

- **Responsibility:** Full IRERC Committee
- **Action:** The committee deliberates and reaches a formal decision, as detailed in **Chapter 6, Section 6.2**.
- **Communication:** The PI is notified of the decision in writing via a formal letter from the WU-IRERC Chair within 3-4 business days of the decision.

5.7. Categories of the IRERC Review Pathways

5.7.1. Exempt review

. **Eligibility**

- This pathway is for research that poses **no more than minimal risk** and falls into specific, well-defined low-risk categories. These studies are exempt from full IRERC review but not from ethical principles.

Qualifying categories (Examples)

- **Category 1: Educational research**
    - Conducted in established educational settings, involves normal educational practices (e.g., comparing instructional techniques, evaluating teaching methods, assessing

learning materials) and curricula, does not adversely impact students' opportunity to learn

- **Category 2: Anonymous surveys and interviews**
    - Collects no identifiable information, uses anonymous data, deals with non-sensitive topics, and does not involve vulnerable populations. Anonymous surveys, interviews, or focus groups
    - Information recorded cannot identify subjects and risk of disclosure would not place subjects at risk
- **Category 3: Secondary data research**
    - Uses publicly available datasets or previously collected, de-identified data where re-identification is impossible (e.g., secondary analysis of census data, published dataset analysis).
    - Analysis of existing data, documents, or specimens

Review process: The protocol is reviewed by the IRERC chair or a designated member**,** written documentation of exemption rationale required and annual reporting requirement for ongoing exempt research

Review Timeline: A decision is typically communicated within 3-4 business days of submission, notification provided to principal investigator within 5 business days

5.7.2. Expedited review

Eligibility:

This pathway is for research that poses **minimal risk**, uses well-established procedures, has limited potential for harm, and follows standard research protocols but not qualifying for exempt status

Qualifying categories (Examples):

Category 1: Minimal risk procedures

- **Clinical and biological:** E.g., collection of blood samples by finger/heel/ear stick or venipuncture (limited amount), collection of excreta/external secretions.
- Collection of data through noninvasive procedures from adults (18+), voice recordings, moderate exercise by healthy volunteers or studies with existing identifiable data
- Clinical studies of drugs with approved labeling, prospective collection of biological specimens for research
- **Social and behavioral:** research on individual/group characteristics or behavior, surveys, interviews, oral history, focus groups, program evaluations, research on educational practices.

Category 2: Minor protocol modifications

- These are administrative or limited-scope changes to an approved study, such as personnel changes, contact updates, minor clarifications, small increases in sample size (less than 20%), or extending data collection or minor amendments to existing protocols)

Review process:

- Review by Chair and 1-2 experienced members reviews the protocol, and the chair consolidates recommendations and their decision summary is reported to the full board at next meeting

Review Timeline: 5-7 business days, decision communicated within 7 business days

5.7.3. Full Board review

- **Eligibility**: This review is mandatory for any research that does not qualify for exempt or expedited review or research that poses *greater than minimal risk* to participants

Mandatory for categories (Examples):

- **Greater than minimal risk research:** initial clinical trials, invasive procedures, psychological interventions involving deception, studies with potential for physical or emotional harm.
- **Vulnerable population research:** Includes minors (under 18), pregnant women, prisoners, institutionalized individuals, cognitively impaired persons, economically disadvantaged populations, and cultural/linguistic minorities.
- **Sensitive topic research:** Involving illegal activities, sexual behavior, mental health, substance abuse, domestic violence, trauma, or political beliefs.
- **Community-based participatory research**
- **Complex or novel research:** International collaborative studies, multi-site protocols, first-in-human studies, gene therapy, stem cell research, or artificial intelligence studies.

Process: The protocol is reviewed by all members and discussed at a convened IRERC meeting.

Review Timeline: Applications are reviewed at the next convened meeting. The Secretariat will inform the PI of the meeting schedule and the expected timeline for a decision

CHAPTER 6: REVIEW CRITERIA AND EVALUATION FRAMEWORK

This chapter establishes the standard guideline for the evaluation framework, scoring methodology and decision-making criteria detailed in this SOP to ensure that all institutional research protocol applications are reviewed to the highest ethical and scientific standards.

6.1. Review Methodology and Criteria

6.1.1. Four domains of assessment

The WU-IRERC employs a multi-dimensional evaluation framework that assesses research protocols across four critical domains, each weighted 20-35% to ensure balanced and thorough review as described in table 6.1.

Table 6.1. Four domains of assessment

No.	**Domain**	**Weighting (%)**
1	Scientific Merit Assessment	25
2	Ethical Compliance Evaluation	35
3	Ubuntu Alignment Assessment	20
4	Multi-Disciplinary Integration Assessment	20

6.1.2. Scoring methodology

Each of the four domains is evaluated on a 100-point scale. The final decision is based on the total score and the individual domain scores.

Table 6.2: Scoring Scale

Score Range	Designation	Description
90-100	Exceptional	Exceeds all required standards.
80-89	Excellent	Meets all standards with distinction.
70-79	Good	Meets all standards adequately.
60-69	Satisfactory	Meets the minimum acceptable standards.
50-59	Needs Improvement	Falls below standards; significant revision is required.
Below 50	Inadequate	Fails to meet fundamental standards.

6.1.3. Required scoring and approval thresholds

The IRERC reviewers score the application on a 100-point scale. To be considered for approval, a research protocol must achieve:

- To receive approval, the application must achieve a minimum of 70 points overall.
- Crucially, the application must also receive a minimum score of 60 points in each of the four domains (Scientific Merit, Ethical Compliance, Ubuntu Alignment, and Multi-disciplinary Approach).

Note: *Applications scoring 50-59 points are considered 'Needs Improvement' and require revision, while those below 50 points are 'Inadequate'.*

6.1.4. Domain 1: Scientific merit assessment (25%)

This domain evaluates the scientific rigor, significance, and feasibility of the proposed research evaluated based on key evaluation criteria described in table 6.3. The total mark in 100% according to table 6.3 will be changed to 25%.

Table 6.3: Scientific merit evaluation components

Component (Weighting)	Key evaluation criteria
Research Significance & Innovation (30%)	Importance and relevance of the research question; originality of the approach; potential for knowledge advancement.
Methodology & Design Quality (40%)	Appropriateness and validity of the research design; rigor of data collection and analysis plans; mitigation of bias.
Feasibility & Resources (30%)	Qualifications of the research team; adequacy of the timeline, budget, facilities, and institutional support.

6.1.5. Domain 2: Ethical compliance evaluation (35%)

This domain assesses the protocol's adherence to core ethical principles for protecting participants and communities. Evaluated based on key evaluation criteria described in table 6.3, the total weighted mark in 100% should be changed to 35%.

Table 6.4: Ethical compliance evaluation components

Component (Weighting)	Key Evaluation Criteria

Risk-benefit analysis (35%)	Identification and mitigation of physical, psychological, social, and economic risks; clear justification of potential benefits to participants, communities, and society.
Informed consent adequacy (25%)	Clarity, comprehensiveness, and cultural appropriateness of the consent process and documents; specific protections for vulnerable populations.
Privacy & confidentiality (25%)	Robust procedures for secure data collection, storage, de-identification, and access control to protect participant privacy.
Regulatory compliance (15%)	Adherence to all relevant Ethiopian national regulations and applicable international standards (e.g., Declaration of Helsinki, CIOMS).

6.1.5. Domain 3: Ubuntu alignment assessment (20%)

This domain evaluates how the research embodies the principles of Ubuntu, ensuring it is culturally sensitive and promotes collective well-being. Evaluated based on key evaluation criteria described in table 6.5, the total weighted mark in 100% should be changed to 25%.

Table 6.5: Ubuntu alignment evaluation components

Component (Weighting)	Key evaluation criteria
Interconnectedness recognition (30%)	Acknowledgment of the complex relationships between individuals, communities, animals and the environment; integration of traditional ecological knowledge.
Collective responsibility (25%)	Demonstration of shared decision-making with the community; establishment of mutual accountability mechanisms and collective benefit-sharing agreements.
Compassion & solidarity (25%)	Empathetic consideration for all affected beings; clear strategies to minimize harm and provide support; evidence of cooperation and mutual support.
Cultural sensitivity & respect (20%)	Respect for traditional values, practices, and governance structures; observance of cultural protocols and protection of cultural heritage.

6.1.6. Domain 4: Multi-Disciplinary integration assessment (20%)

This domain assesses the protocol's integration of diverse knowledge systems and its planning for sustainable, holistic outcomes.

Table 6.6: Multi-Disciplinary integration evaluation components

Component (Weighting)	Key evaluation criteria

Cross-sectoral coordination (30%)	Meaningful collaboration across relevant sectors (e.g., health, agriculture, environment, social systems) with integrated planning and implementation
Sustainable outcomes planning (40%)	A "Triple Bottom Line" approach that includes clear plans for positive, long-term impacts on social (e.g., capacity building, equity), environmental (e.g., conservation, resilience) and economic sustainability (e.g., sustainable livelihoods)
Knowledge integration & sharing (30%)	Synthesis of traditional knowledge and modern science; development of accessible knowledge products and capacity-building activities for the community.

6.2. IRERC Meeting and Decision Procedures

The IRERC prefers consensus-building, but if voting is necessary, a two-thirds majority vote is required for approval. Abstentions are allowed for conflicts of interest, and minority opinions are recorded. For Full Board Reviews, the Principal Investigator may be invited to the meeting to answer questions.

6.2.1. Meeting requirements

Quorum requirements: Minimum of 50% of voting members present, member with scientific expertise, at least one member with non-scientific background and at least one community representative

Conflict of interest management: members must declare conflicts before discussion; conflicted members may provide information but must recuse themselves from voting, discussion or deliberation and recusals documented in minutes.

6.2.2. Deliberation process

Protocol presentation:

- Primary reviewer presents summary and assessment and secondary reviewer provides additional perspectives
- Community representative offers community impact assessment and ethics specialist highlights ethical considerations

Discussion procedures:

- Chair facilitates open discussion and scientific validity considered first. Ethical concerns addressed systematically, Ubuntu alignment evaluated and risk-benefit balance determined

Decision-making:

- Consensus preferred, voting if necessary (two-thirds majority required)

- Abstentions allowed for conflicts of interest and minority opinions recorded in minutes

6.2.3. Decision categories

- **Approved**:
    - The protocol meets all ethical, scientific, and procedural requirements and can proceed as proposed. This requires an overall score of **≥75/100 points**, with specific minimums (≥7.5/10) for Scientific merit, Ethical compliance, Ubuntu alignment, and multi-disciplinary integration, along with community consensus and support.
- **Approved with conditions**:
    - The protocol meets most requirements but requires minor modifications or additional conditions before implementation. This typically applies to protocols with an overall score of **≥65/100 points** (≥6.5/10 for individual criteria).
    - Minor changes are reviewed and verified by the Chair or a designated member, not requiring another full committee review.
- **Deferred**:
    - The protocol has **significant deficiencies** or raises substantial ethical or scientific concerns that prevent immediate approval. It requires major revisions or additional information (e.g., inadequate scientific justification, incomplete community consultation).
    - The protocol is returned with detailed feedback for formal revision and resubmission for a new Full Committee Review. This applies to protocols scoring **50-64/100 points**.
- **Disapproved**:
    - The IRB determines that the research **cannot be ethically or scientifically justified** as proposed due to fundamental ethical concerns or violations (e.g., studies without scientific merit, culturally inappropriate research, violation of community values, research without proper oversight). This decision is accompanied by a comprehensive written explanation and applies to protocols scoring **<50/100 points**.

6.3. Communication and Documentation

6.3.1. Decision communication

An initial notification (e.g., email, portal update) will be sent within 48 hours of the decision. A formal decision letter will be sent within 3-4 business days, detailing:

- Protocol identification information.

- The final decision category.
- A clear rationale for the decision.
- A detailed list of required modifications (if applicable).
- Information on the appeals process (if deferred or disapproved).

6.3.2. Approval documentation

Upon final approval, the PI will receive a formal Approval Certificate containing the protocol title, tracking number, PI name, approval date, and expiration date.

6.4. Appeals Process

6.4.1. Grounds for appeal

Researchers may appeal a "Deferred" or "Disapproved" decision on the following grounds:

- A significant procedural error by the IRERC that affected the outcome.
- Demonstrable bias or conflict of interest in the review process.
- A clear misinterpretation of facts or regulations by the committee.

6.4.2. Appeal procedures

1. **Submission:** The PI must submit a formal written appeal to the IRERC Chair within 30 days of receiving the decision, addressing the specific grounds for appeal.
2. **Assessment:** The IRERC Chair and Vice-Chair determine if the appeal meets the criteria.
3. **Committee review:** If the criteria are met, an appeal committee (composed of members not involved in the original review) is formed to examine all materials.
4. **Final decision:** The appeal committee provides a recommendation to the Vice President of Research and Technology Transfer, who issues a final, binding decision within 30 days of the appeal submission.

6.5. Prohibited Research

The WU-IRERC will not approve research that falls into the following categories:

- **Absolute prohibitions:** Studies determined to have no scientific merit, research that is culturally inappropriate or violates community values, and any research proposed to be conducted without proper oversight.
- **Conditional prohibitions (Requires special justification):** Research involving high risks (e.g., endangered species, severe pain/distress) or requiring enhanced oversight (e.g., genetic modification) is subject to additional requirements, such as independent expert review and special safety protocols, before it can be considered for approval.

CHAPTER 7. POST-APPROVAL MONITORING AND COMPLIANCE

7.1. Ongoing Monitoring Framework

The WU-IRERC emphasizes that IRERC approval is an ongoing process that necessitates continuous monitoring and compliance to ensure that all research adheres to or in full compliance with the approved protocols, national, and international ethical standards and university policies thereby ensuring the continuous protection of participants (human, animal, community) and the environment

Monitoring objectives: The WU-IRB's post-approval monitoring guidelines that ensures approved research:

- Continues to comply with ethical standards and approved protocols
- Maintains participant safety and welfare
- Fulfills community engagement and benefit-sharing commitments
- Adheres to regulatory requirements and institutional policies
- Achieves intended scientific and social outcomes

7.1.1. Monitoring activities

The WU-IRER conducts periodic, random audits of approved research projects to ensure compliance. Monitoring activities include:

- Review of research records, consent forms and regulatory documents.
- On-site inspections of research facilities and activities.
- Discussions with the research team and participants.
- Comparison of research data with source documents.
- Observation of research procedures.
- The Institutional Research Ethics Review Committee (IRERC) also conducts announced and unannounced inspections of facilities and procedures.

7.2. Compliance and Monitoring Procedures

7.2.1. Protocol duration and continuing review

- An approved research proposal or protocol is valid for a maximum period of three years from the date of initial approval.
- Despite the three-year validity, all approved research protocols must be reviewed at least once annually to ensure they continue to meet ethical standards.

- Researchers are required to submit an Annual Review Form (WU-IRERC-F-005) to the IRERC each year.
    - The IRERC notifies researchers 60 days before the anniversary of the approval date, prompting them to submit a **continuing review report** detailing the study's progress and any changes.
- Failure to submit the annual review on time will result in the automatic suspension of the protocol.

7.2.2. Principal Investigator (PI) Responsibilities

Ethical oversight is a shared and continuous responsibility. Upon receiving approval, the PI assumes the following obligations for the study:

7.2.3. Adherence to approved protocol

The PI must conduct the research exactly as described in the approved protocol. All research personnel must be trained on and must adhere to the approved protocol and ethical guidelines.

7.3. Amendments Review (Protocol modifications)

Any proposed change to an approved protocol must be submitted to and approved by the IRERC before the change is implemented. Changes are submitted using the Amendment Form (WU-IRERC-F-004).

7.3.1. Amendment categories and review process:

Minor amendments (Expedited review): Changes that do not significantly affect risk or ethical considerations (adding personnel, small changes in participants) typically undergo **expedited review** or designated **member review**. **Detailed classifications and examples**:

a. **Administrative changes:** Personnel additions or changes (no role change), contact information updates, minor clerical corrections, administrative procedure clarifications.
b. **Limited Scope changes:** Small sample size increases (<20%), minor timeline adjustments, non-substantial procedure modifications, additional non-invasive data collection
c. **Documentation updates:** Consent form clarifications, information sheet updates, protocol text corrections, reference updates

Major amendments (Full Board Review): Changes that substantially affect risk, participant population, or ethical considerations (e.g., changing study objectives, adding invasive procedures, changing species) require a full committee review (IRERC) (full board review). **Detailed classifications and examples**:

a. **Substantial protocol changes**: Research objective modifications, methodology or design changes, participant population changes and new procedure additions
b. **Risk-related changes**: Increased risk procedures, new vulnerable populations, additional invasive procedures and extended study duration
c. **Ethical consideration changes**: Consent process modifications, confidentiality procedure changes, community engagement alterations, benefit-sharing modifications

7.3.2. Amendment submission

Required documents:

- Amendment Request Form (WU-IRB-F-004), change description and justification
- Impact assessment on participants and communities, risk-benefit analysis update

Revised protocol documents

- Track-changed protocol version, updated consent forms (if applicable), modified data collection instruments and revised community engagement plans (if needed)

Supporting Documentation

- Scientific rationale for changes, community consultation records (if applicable) and safety data updates

7.3.3. Amendment review process and possible outcomes

Step 1. Amendment assessment: Change classification (minor vs. major), review pathway determination, reviewer assignment and timeline establishment

Step 2. Review conduct: Individual reviewer evaluation, risk-benefit reassessment, community impact analysis and compliance verification

Step 3. Decision and communication: Amendments can be approved, approved with modifications, deferred (additional information required), or denied.

Time line: decision will be notified for the researcher within 5-7 days for Minor and 7-10 days for major amendments type

7.4. IRERC Continuing Review Process

7.4.1. Scheduling and submission

All approved research protocols are subject to continuing review at least annually, based on the level of risk.

- The WU-IRERC Secretariat will send a reminder notice to the PI at least 60 days before the protocol's expiration date.

- The PI must submit the "Continuing Review Report" (see form WU-IRB-F-05), along with all necessary supporting documents, at least 30 days before the expiration date to guarantee a timely review.

7.4.2. Review pathway

- **Expedited review:** Continuing reviews for studies that are low-risk or in the data-analysis-only phase are typically reviewed via the Expedited pathway.
- **Full Board review:** Any high-risk study, any study with reported Serious Adverse Events or significant non-compliance, or any protocol that the initial reviewer feels warrants full committee discussion will be assigned to the Full Board for review.

7.4.3. Evaluation criteria

The IRERC review will focus on:

- **Research progress:** Verifying that progress (e.g., enrollment, data collection) is consistent with the study timeline.
- **Safety and welfare:** A thorough review of all adverse events, unanticipated problems, and participant complaints to reassess the risk-benefit balance.
- **Compliance:** Verifying that the research is being conducted in accordance with the approved protocol and that no unapproved changes have been implemented.
- **Community engagement:** Confirming that benefit-sharing and community consultation commitments are being met as planned.

7.4.4. Review outcomes

Following the review, the IRERC will issue one of the following decisions:

- **Approval:** The protocol is re-approved for another period, not to exceed one year.
- **Approval with modifications:** The protocol is re-approved, contingent on the PI addressing minor, specific issues.
- **Deferred:** The committee has substantial questions or concerns. The PI must provide additional information for review.
- **Suspension:** The committee orders a temporary halt to some or all research activities due to serious concerns.
- **Termination:** The committee orders a permanent halt to the research, and ethical approval is revoked.

7.5. IRERC-Initiated Monitoring (Audits)

In addition to reviewing PI-submitted reports, the WU-IRERC will conduct its own monitoring based on a risk-based approach.

7.5.1. Selection of protocols for audit

The IRERC Chair or a designated Quality Assurance officer will select protocols for audit based on the following:

- **Intensive monitoring (High-Risk):** Protocols deemed high-risk (e.g., involving vulnerable populations, novel interventions) will be prioritized for site visits.
- **Standard monitoring (Moderate-Risk):** A random selection of moderate-risk protocols will be audited annually.
- **For-cause audits:** Any protocol that is the subject of a complaint, a report of serious non-compliance, or has a high rate of adverse events will be immediately flagged for a "for-cause" audit.

7.5.2. The audit process

An audit may include a "desk audit" (review of all records, consent forms, and data) and/or a "site visit" (observation of study procedures, interviews with the PI and participants).

7.6. Non-Compliance Investigation and Response

The IRERC must investigate all credible allegations of non-compliance

- The IRERC is obligated to investigate all credible allegations of non-compliance with its Standard Operating Procedures (SOPs) and research ethics policies.
- Non-compliance can vary from minor administrative lapses to serious deviations from an approved protocol.
- Confirmed violations may lead to required corrective actions, additional training, or immediate suspension of the research protocol.
- If an investigation confirms serious or continuing non-compliance, the IRERC has the authority to suspend the research protocol and report the findings to university leadership and funding agencies as required.

7.6.1 Non-compliance categories

Table 7.1. Non-compliance category and response measures

Non-Compliance Category	Examples	Response Measures
Minor	Late submission, procedural oversight without safety impact, minor documentation deficiencies.	Educational intervention, Corrective Action Plan (CAP), Enhanced monitoring.

Serious	Failure to obtain informed consent, enrollment of ineligible participants, unreported adverse events, significant protocol deviations.	Immediate corrective action, Mandatory additional training, Temporary suspension.
Continuing	Pattern of ongoing non-compliance despite previous corrective actions.	**Research suspension or termination**, Investigator restriction, Regulatory agency reporting.

7.6.3. Identification and reporting

Any individual (e.g., research participant, community member, IRERC staff) who suspects non-compliance with ethical standards or the approved protocol may report their concerns to the IRERC Chair.

7.6.4. IRERC review and action

- The IRERC Chair will conduct a preliminary investigation of all credible allegations.
- If the allegation is serious, the Chair may immediately suspend the research to protect participants.
- All serious allegations of non-compliance will be presented to the Full Board for deliberation. The PI will be given an opportunity to respond to the allegations.

7.6.5. Communication of findings

Following its deliberation, the IRERC will issue a formal finding and may require corrective actions, suspend, or terminate the protocol. All findings will be communicated in writing to the PI, the relevant College Dean, and the Vice President for Research and Community Engagement.

7.7. Suspension and Termination of Research

7.7.1. Grounds for suspension

The IRB may suspend or terminate research for several critical reasons, including but not limited to:

- Failure to follow the approved protocol or ethical principles.
- Serious adverse events related to participation.
- Failure to properly manage risks to participants.
- Fraud or misrepresentation in research conduct or reporting.
- Failure to report required events or information.
- Withdrawal of community consent or support.
- Suspension or termination required by external authorities.

7.7.2. Termination criteria

- **Irremediable violations**: fundamental ethical violations, serious and continuing non-compliance, loss of scientific validity and community withdrawal of consent
- **Safety concerns**: unacceptable risk-benefit ratio, inability to ensure participant safety, serious adverse events pattern, and environmental or community harm

7.7.3. Termination process

- **Termination decision**: formal IRERC vote on termination, decision rationale documentation, appeal rights notification and immediate cessation order
- **Participant protection**: participant notification and withdrawal, community explanation, and consultation and institutional administration notification

PART III: SPECIALIZED GUIDANCE

CHAPTER 8: DISCIPLINE-SPECIFIC REVIEW AND MULTI-DISCIPLINARY PROTOCOLS

8.1. Purpose

This chapter establishes the framework for applying Wollo University's core ethical principles across all academic disciplines. It outlines the standardized documentation required for all protocols and provides the specific Standard Operating Procedure (SOP) for managing the review of multi-disciplinary research projects.

8.2. Standardized Approach to Discipline-Specific Ethics

8.2.1. Integration with core ethical principles

All research conducted under the authority of Wollo University, regardless of discipline, is governed by the core ethical principles outlined in Chapter 2 and the Ubuntu philosophy. The WU-IRERC recognizes that the *application* of these principles manifests differently depending on the research context. Reviewers shall evaluate protocols based on these context-specific applications.

Table 8.1: Application of core principles across research disciplines

Principle	Manifestation in Human-Centered Research	Manifestation in Animal Research	Manifestation in Environmental/Plant Research
Respect for Autonomy	Upholding participant dignity and ensuring a robust, voluntary informed consent process.	Ensuring species-appropriate welfare, and freedom from unnecessary distress.	Respecting ecosystem integrity, sustainability, and legal/community stewardship rights.
Beneficence & Non-Maleficence	Maximizing direct and societal benefits while minimizing physical, psychological, and social risks to participants.	Promoting animal health and well-being; minimizing all pain and distress (The 3 R's: Replacement, Reduction, Refinement).	Protecting biodiversity, preventing ecological harm, and promoting food security or sustainable production.
Justice	Ensuring the fair and equitable selection of participants and the just distribution of research burdens and benefits.	Ensuring animals are not over-used and that the burdens placed on them are justified by the potential benefit.	Ensuring that one community or ecosystem does not bear an unfair burden of environmental research for the benefit of others.

Ubuntu (Interconnectedness)	Recognizing that participant well-being is tied to community well-being; prioritizing collective benefit and community-based decision-making.	Recognizing the human-animal bond and our collective responsibility for the compassionate care of sentient beings.	Recognizing the deep connection between human, animal, and environmental health (One Health) and our intergenerational responsibility.

8.3. Standardized documentation requirements

To facilitate a consistent review, all research protocols submitted to the WU-IRERC must adhere to a standardized documentation structure.

8.3.1. Core documentation (Required for ALL protocols)

All submissions, regardless of discipline or review pathway, must include the following:

- WU-IRERC-F-001: Research Protocol Application Form
- The Main Research Protocol Document: (Utilizing the standardized university template).
- Informed Consent/Assent Forms: All consent, assent and information sheets for participants (see WU-IRERC-T-001, T-002 and T-003)
- WU-IRERC-AT-003: Risk Assessment Matrix
- WU-IRERC-AT-003, Section 6): Ubuntu Impact Assessment
- Data Management Plan: A description of data collection, security, privacy, and storage.
- Curricula Vitae (CVs): CVs for the Principal Investigator (PI) and all Co-Investigators.
- Ethics Training Certificates**:** Valid ethics training certificates for the PI and key personnel

8.3.2. Conditional documentation (based on research type)

Based on the specific nature of the research, one or more of the following documents are mandatory.

Table 8.2: Conditional documentation requirements

If the research involves...	Mandatory additional documentation
Multi-Disciplinary collaboration	Multi-Disciplinary Integration Plan (Section 8.4)
Human clinical trials	Detailed clinical trial protocol; Investigator's brochure; data safety monitoring plan (see WU-IRERC-DS-003)
Animal subjects	Animal care and use protocol (for animal research); Justification for animal numbers and species (see WU-IRERC-DS-006)
Environmental impact / biodiversity	Environmental impact assessment; Institutional/Governmental permissions (if applicable) (see WU-IRERC-DS-005)

Community engagement (for community-based research)	Community engagement and consultation documentation (see Chapter 10 and WU-IRERC-T-004)
Traditional knowledge	Traditional knowledge protection and benefit-sharing plan (see Chapter 10 and WU-IRERC-DS-008)
Genetic research	Genetic counseling plan; sample storage and future use protocols (see WU-IRERC-DS-007)
Social/Behavioral sciences	Specific protections for vulnerable populations; Certificate of Confidentiality (if applicable) (see WU-IRERC-DS-008)

(Note: Appendices E, contain the detailed, discipline-specific guidelines referenced in this chapter.)

8.4. Guide line for Multi-Disciplinary Research Protocols review

This SOP defines the procedure for managing protocols that span multiple disciplines or colleges (e.g., a project involving animal health, human sociology, and environmental science).

Step 1: Initial triage and classification

- **Responsibility:** WU-IRERC chair/delegate and secretariat
- **Action:** Upon receipt, the Secretariat screens the protocol (specifically forms WU-IRERC-F-001 and F-002) to identify it as multi-disciplinary.

Step 2: Determination of primary college and expertise

- **Responsibility:** WU-IRERC Chair, in consultation with the Secretariat.
- **Action:** The Chair determines the "Primary College" based on the PI's affiliation and the protocol's main scientific focus. The Chair also identifies *all* other relevant disciplines/colleges implicated in the protocol.

Step 3: Assignment of reviewers

- **Responsibility:** WU-IRERC Chair / Secretariat
- **Action:** A review team shall be assembled that includes:
    1. A primary reviewer from the Primary College.
    2. At least one specialist reviewer from *each* of the other identified disciplines (e.g., a veterinarian, a sociologist).
    3. A community representative (if community-based).
    4. An ethicist or other non-scientific member.

Step 4: Integrated evaluation

- **Responsibility:** Assigned Reviewers

- **Action:** All reviewers use the standardized review framework (Chapter 6). However, specialist reviewers are required to pay special attention to the protocol's adherence to their specific disciplinary guidelines (as defined in the Appendices E). Multi-Disciplinary Integration Plan is a key document for evaluating how the team will manage its integrated goals.

Step 5: Coordinated decision-making

- **Responsibility:** Full Committee at a convened meeting.
- **Action:** The protocol is presented by the primary reviewer. The specialist reviewers provide their analysis. A final decision (Approve, Modify, Defer, Disapprove) is only reached after the committee has formally considered the risks, merits, and ethical compliance *from all disciplinary perspectives*. All concerns raised by specialist reviewers must be satisfactorily resolved before final approval is granted.

CHAPTER 9: VULNERABLE POPULATIONS AND CONSIDERATIONS

9.1 Children and Adolescents

9.1.1 Regulatory framework

Research involving children requires additional protections based on:

- Risk level and potential benefit assessment, parental permission and child assent requirements (age 7 years), age-appropriate procedures, and materials and special attention to coercion and undue influence.

9.1.2. Consent and assent procedures

Parental/guardian permission requirements:

- Both parents: Required when both parents have legal custody
- Single parent: Sufficient when one parent has sole custody
- Guardian: Legal documentation of guardianship required
- Traditional authority: Community elder or traditional guardian involvement

Permission documentation:

- Signed parental consent form, cultural authority recognition and emergency contact information

Age-based child assent requirements:

- **Ages 7-11 Years (verbal Assent):**
    - Simple, age-appropriate explanation, use of visual aids and examples
    - Verbal agreement with witness documentation and ongoing assent verification
- **Ages 12-17 Years (Written Assent):**
    - Written assent form completion, age-appropriate language use, understanding verification, ongoing consent maintenance

9.1.3 Special protections and safeguards

Permitted Research (with appropriate safeguards):

- Research not involving greater than minimal risk
- Research involving greater than minimal risk but presenting prospect of direct benefit
- Research involving greater than minimal risk with no direct benefit but likely to yield generalizable knowledge about disorder or condition

Prohibited research:

- Research with no prospect of benefit and greater than minimal risk

- Research involving vulnerable children without additional protections
- Research that could harm child development
- Research violating cultural norms about childhood

9.3. Research With Pregnant Women

9.3.1 Ethical considerations

Requires assessment under the dual patient concept (**maternal and fetal considerations**) and respect for cultural pregnancy norms

Additional protections

- Risk assessment for maternal and fetal welfare, father's involvement when possible and appropriate, independent monitoring of maternal and fetal safety

Consent considerations

- Maternal autonomy in decision-making, information about pregnancy-specific risks, Specific fetal risks and benefits, pregnancy outcome considerations, long-term child development effects

9.4. Economically Disadvantaged Populations

9.4.1 Vulnerability assessment

Vulnerability factors (e.g., income, food insecurity, geographic isolation) must be assessed**.**

9.4.2. Exploitation prevention

- Compensation must be appropriate reimbursement not exceeding reasonable compensation to prevent undue influence/exploitation. Essential services not contingent and benefit-sharing emphasized

Community benefits

- Mandatory Components: Capacity building included, results shared with community, sustainable interventions, local employment opportunities, knowledge transfer commitment and sustainable outcome planning

Cultural Sensitivity:

- Local custom and practice respect, traditional authority involvement, community value alignment and dignity preservation

9.5. Research In Emergency Situations

9.5.1. Emergency research ethics

- **Exception from informed consent**, **criteria for exception:**
    - Life-threatening condition requiring intervention, available treatments unproven or unsatisfactory, research offers prospect of direct benefit or impossible to obtain prospective consent
    - Research could not practicably be carried out without exception
- **Community consultation requirements**
    - Community advisory consultation, public disclosure of research plans, community input integration, ongoing community involvement, resource coordination and benefit-sharing maintenance

9.5.2. Emergency consent procedures

Requires **Pre-research community engagement** and use of alternative consent mechanisms (Deferred or Witnessed Consent).

- **Deferred consent:** Intervention initiation without consent, consent seeking when capacity returns, Surrogate consultation when possible and continuation decision upon capacity.
- **Witnessed consent:** Independent witness involvement, verbal consent documentation, cultural witness appropriateness and traditional authority recognition
- **Follow-up requirements:** Participant welfare monitoring, psychological support provision, community impact assessment and resource access facilitation

CHAPTER 10: COMMUNITY ENGAGEMENT AND BENEFIT-SHARING

10.1. Purpose and Guiding Principles

This chapter establishes the SOPs for all research conducted under the purview of Wollo University that involves human communities or their resources. This includes social, clinical, biodiversity and environmental (including animals and biodiversity) studies. The purpose is to ensure that community engagement is meaningful, respectful, and equitable, and that the benefits of research are shared fairly. Adherence to this chapter is mandatory for securing ethical approval from the Wollo University Institutional Research Ethics Review Committee (WU-IRERC).

10.1.1. The community engagement Ethical framework: The Ubuntu philosophy

At Wollo University, community engagement is not just a requirement; it's a fundamental principle. The WU-IRERC's approach to community engagement is deeply rooted in the Ubuntu philosophy—"I am because we are." This principle of interconnectedness and collective responsibility serves as the ethical framework for all research activities. Researchers are expected to embody the following core tenets of Ubuntu:

- **Interconnectedness and collective Responsibility:**
  Recognizing that the well-being of individuals, the community, and the environment (including animals and biodiversity) are linked. Acknowledgment of research impact beyond direct participants and ensure community involvement in decision-making processes. Research must be a collaborative partnership with shared accountability for outcomes with joint ownership of benefits and risks
- **Solidarity and Compassion:**
  Conducting research with an empathetic understanding of the community's needs, values, and priorities, with a firm commitment to maximizing benefits and minimizing harm.
- **Respect and Dignity:**
  Upholding the dignity of all participants and their cultural heritage, including their traditional governance structures and knowledge systems.

10.2. Principal Investigator (PI) Responsibilities

The Principal Investigator (PI) is ultimately responsible for ensuring that all procedures outlined in this chapter are implemented and documented. This includes leading the community engagement process, negotiating agreements, and reporting progress to the WU-IRERC.

10.3. The Community Engagement principles

The PI must follow a structured, phased approach to community engagement. This process must be documented and submitted as part of the ethics review application.

10.3.1. Community identification and analysis

Before any contact, the PI must conduct a thorough analysis of the community.

Step 1: Stakeholder Analysis

Identify all individuals, groups, and organizations that may be affected by or have an interest in the research. Stakeholders should be categorized as:

- **Primary stakeholders:** Those directly affected by the research (e.g., research participants, local families, traditional leaders, local government officials).
- **Secondary stakeholders:** Those indirectly affected (e.g., neighboring communities, civil society organizations, regional government agencies).
- **Key influencers:** Individuals or groups with significant influence, but who may not be in formal leadership positions (e.g., traditional healers, women's group leaders, youth representatives, religious figures).

Action*: The PI must complete and submit a* ***Stakeholder Mapping Template*** *detailing the interest and influence of each group and outlining a tailored engagement strategy(seed WU-IRERC-T-004 and WU-IRERC-AT-002).*

Community dynamics analysis

Analyze the community's power structures and decision-making processes, including:

- Formal power structures**:** Official government and legal hierarchies.
- Informal power structures**:** Traditional authority (e.g., councils of elders), religious hierarchies, and social networks.
- Socio-demographic dynamics**:** Understand the roles of gender, age, and other social factors in decision-making to ensure inclusive participation.

10.3.2. The consultation and engagement plan: Stape 2

Engagement must be a transparent and iterative dialogue, not a one-time event.

Phase A: Initial Engagement & Formal Introduction

1. **Formal introduction:** The PI must submit an official letter to the relevant local authorities and traditional leaders, introducing the research team, outlining the study's purpose, and stating a commitment to the principles of community engagement and benefit-sharing.
2. **Cultural protocol:** The research team must observe all relevant cultural protocols regarding greetings, attire, gift-giving, and respect for sacred spaces or customs.
3. **Preliminary consultation meeting:** Schedule an initial meeting to formally introduce the project, discuss potential impacts (both positive and negative), and seek initial feedback. This meeting should be conducted in the local language(s), with professional translation and cultural interpretation as needed.

Phase B: Comprehensive consultation

Following the initial introduction, the PI must conduct in-depth consultations tailored to specific stakeholder groups:

- **Meetings with traditional leaders/Council of elders:** To formally seek their counsel, assess cultural appropriateness, and request permission to proceed with broader community consultations.
- **Community assembly:** A public meeting open to all community members for a transparent discussion of the research. This is the primary forum for obtaining formal community consent.
- **Meetings with special interest groups:** Focused discussions with groups such as women, youth, farmers, or others to ensure their specific concerns and perspectives are heard and integrated.

Phase C: Documentation of consultation

All consultations must be meticulously documented using the official WU-IRERC forms:

- Meeting minutes (Form WU-IRERC-AT-002): For every meeting held.
- Community consent documentation (Form WU-IRERC-AT-004): To record the collective consent obtained from the community assembly.
- Cultural appropriateness assessment (Form WU-IRERC-AT-0o4): To document how the research design respects and aligns with local cultural norms.

10.4. Community Consent and Collective Decision-Making

10.4.1. Framework for community consent

Community consent is a collective process that respects the community's autonomy. It must be obtained in addition to individual informed consent from participants. The process must include:

1. **Comprehensive information sharing:** All relevant information about the research (purpose, methods, duration, risks, benefits, and data use) must be provided in an accessible format.
2. **Sufficient time for deliberation:** The community must be given adequate time to discuss the information, ask questions, and reach a decision without pressure.
3. **Inclusive deliberation process:** The decision-making process must be inclusive and culturally appropriate, respecting traditional methods such as consensus-building.
4. **Formal documentation:** The final decision must be formally documented, endorsed by recognized community representatives, and witnessed.
5. **Right to withdraw:** The community must be informed of its right to withdraw collective consent at any stage of the research, and the procedures for doing so must be clear.

10.4.2. Conflict resolution

The PI must develop a proactive plan for resolving potential disagreements. This plan should prioritize traditional and community-based mechanisms for mediation. If internal resolution fails, an external neutral mediator may be required.

10.5. Benefit-Sharing Framework

10.5.1. The principle of reciprocity

All research must be designed to provide tangible and meaningful benefits to the participating community. These benefits should be co-determined with the community during the consultation phase.

10.5.2. Types of benefits

The WU-RERC framework outlines three categories of benefits, as described in the following tables and should be tailored to the community's priorities.

Table 10.5. Categories of community benefit sharing

Category	Examples
Direct benefits	Compensation for time, access to health services provided by the study, skill development and training for participants, educational materials.
Community benefits	Capacity building for local institutions, infrastructure improvements (e.g., water access), support for local schools or clinics, access to research equipment.
Long-Term benefits	Contribution to sustainable development goals, creation of economic opportunities, strengthening healthcare systems, joint publications, and acknowledgement in research outputs.

10.5.3. The Benefit-sharing agreement (BSA)

A formal, written Benefit-Sharing Agreement (BSA) is mandatory for all approved research projects. This agreement is a binding document co-developed with community representatives. The BSA must clearly define:

- All parties involved and their respective roles and responsibilities.
- The specific benefits to be provided (financial, in-kind, etc.).
- A detailed implementation framework and timeline.
- A monitoring and evaluation plan to track progress, with regular reports to the community and the WU-IRERC.
- A sustainability plan for benefits that continue after the research project concludes.

10.6. Protection of Traditional Knowledge (TK)

- **Legal protection framework:**
  Ethiopian traditional knowledge protection laws, international indigenous rights frameworks, customary law and traditional governance systems, and intellectual property rights and benefit-sharing agreements

10.6.1. Recognition and respect for TK

Researchers must recognize that communities are the owners and custodians of their traditional knowledge (TK), which includes:

- Medicinal plants and healing practices

- Agricultural techniques and crop varieties
- Environmental and ecological knowledge
- Cultural practices and spiritual beliefs

10.6.2. Ethical documentation and use of TK

The documentation or use of any TK requires the Free, Prior, and Informed Consent (FPIC) of the knowledge holders and the broader community. This process must:

- Ensure knowledge holders are fully attributed and recognized, traditional authority consultation and permission
- Knowledge holder consent and participation, community assembly deliberation and approval
- Preserve the cultural context and meaning of the knowledge.
- Specify any access and use restrictions determined by the community.

10.6.3. Intellectual property and commercialization

- **Non-commercial use:** The primary purpose of using TK in academic research should be for non-commercial applications that benefit the community and advance knowledge.
- **Commercial use restrictions:** Any potential commercial application of TK is strictly prohibited unless explicitly governed by a separate, detailed agreement that ensures substantial benefit-sharing with the community and complies with Ethiopian and international laws on access and benefit-sharing.

10.7. WU-IRERC Review and Monitoring

The WU-IRERC is responsible for:

- **Reviewing** the PI's Community Engagement Plan, Stakeholder Map, BSA, and TK protection measures as part of the ethics application (See WU-IRERC-AT-004) Approval is contingent on a satisfactory plan.
- **Monitoring** the implementation of the approved plan through annual progress reports and, if necessary, site visits. Failure to adhere to the approved plan may result in the suspension or termination of ethical approval.

PART IV: ADMINISTRATION AND QUALITY ASSURANCE

CHAPTER 11: DOCUMENTATION, RECORDS AND REPORTING

11.1. Purpose

This chapter outlines the SOPs for the documentation, management, retention, and reporting of all activities related to the WU-IRERC. These procedures ensure transparency, accountability, and compliance with national and institutional standards.

11.2. Record Management and Retention

11.2.1. Responsibility

The WU-IRERC secretariat is responsible for creating, maintaining, and archiving a complete and accurate record for every research protocol submitted for review.

11.2.2. Retention period

The IRERC must maintain comprehensive records (protocols, amendments, minutes, correspondence, adverse events, community feedback) including correspondence, must be maintained for a minimum of three years after the completion or termination of the research project.

11.2.3. Core documentation

The official file for each protocol must contain, at a minimum:

- The complete research protocol application file, including all initial submission forms.
- All subsequent submissions, including amendment requests, continuing review reports, and final reports.
- Official minutes of WU-IRERC meetings where the protocol was discussed.
- Copies of all official decisions, correspondence, and certificates sent to the Principal Investigator (PI).
- Records of community consultations and Benefit-Sharing Agreements (BSAs).
- Documentation of any adverse events, protocol violations, or participant complaints.

11.3. Official forms and templates

The WU-IRERC requires the use of standardized forms to ensure consistency and completeness of information. The official forms are categorized as follows:

Table 11.1: Application and assessment forms

Form ID	Form Title	Purpose
WU-IRB-F-001 (Appendix B.1.1)	Research protocol application form	The primary form for submitting a new research protocol for ethical review.
WU-IRB-F-002 (Appendix B.1.2)	Protocol summary form	Provides a concise overview for reviewers, highlighting key ethical considerations.
WU-IRB-F-001	Principal Investigator information Form	|Documents the PI's qualifications, experience, and potential conflicts of interest.
WU-IRB-AT-003 (Appendix C3)	Risk Assessment matrix	A structured tool for identifying, evaluating, and planning mitigation for potential risks.
WU-IRB-AT-004 (Appendix C4)	Ubuntu Impact assessment form	Assesses the research's alignment with Ubuntu principles, focusing on community impact and cultural sensitivity.

Table 11.2: Consent form templates

Template ID	Template title	Purpose
WU-IRERC-T-001 (Appendix B.2.1)	Adult informed consent form	Standard template for obtaining informed consent from adult participants.
WU-IRERC- T-002 (Appendix B.2.2)	Parental/Guardian consent form	Template for obtaining permission for the participation of minors or legally dependent adults.
WU-IRERC-T-003 (Appendix B.2.3)	Child assent form	Age-appropriate template for securing the affirmative agreement of a minor to participate
WU-IRERC-T-004 (Appendix B.2.4)	Community consent form	Used to document collective consent from a community and endorsement from traditional authorities
(WU_IRERC-T-004) (Appendix B.2.4)	Traditional knowledge consent form	For securing consent from knowledge holders regarding the use of their traditional knowledge.

Table 11.3: Review and decision forms

Form ID	Form title	Purpose
WU-IRB-AT-002 (Appendix C 2)	Individual protocol review form	A structured evaluation form used by primary reviewers to assess a protocol
WU-IRB-AT-004 (Appendix C4)	Community representative review form	A specialized form for community representatives to evaluate community engagement and cultural appropriateness
WU-IRB-A-005 (Appendix D5)	IRERC decision letter template	The official template for communicating the committee's decision, including any conditions or required modifications

WU-IRB-D-002	Approval certificate template	The official certificate issued upon final approval of a research protocol.

11.4. Reporting Requirements

11.4.1. Reporting by principal investigators

PIs are required to submit regular reports to the WU-IRERC, including:

- **Continuing review reports:** Submitted annually, or more frequently if required by the committee (see WU-IRERC-F-004)
- **Amendment reports:** For any proposed changes to the approved protocol (see WU-IRERC-F-003)
- **Adverse event reports:** Submitted immediately upon discovery of any serious adverse events (see WU-IRERC-F-005)
- **Final report:** Submitted upon completion of the research project. (see WU-IRERC-F-006)

11.4.2. Institutional and external reporting by WU-IRERC

The WU-IRERC is committed to transparency and will disseminate reports to various stakeholders:

- **Quarterly reports:** Submitted to the Vice President for Research and Technology Transfer office, summarizing protocol submissions, review statistics, and key activities.
- **Annual public report:** Published on the Wollo University website, summarizing the year's activities, performance metrics, and community impact outcomes. This report is also shared with the National Research Ethics Review Committee and the Ministry of Education.
- **Annual community accountability reports:** Culturally appropriate, and enhancement contributions summaries of research outcomes and benefits delivered to participating communities. Community capacity building and development achievements

11.5. Confidentiality and Transparency

11.5.1. Confidentiality principles

All WU-IRERC members and administrative staff must sign a confidentiality agreement to protect the privacy of researchers and the integrity of their work. While the IRER committee operations and annual summaries will be transparent, the following information will be kept strictly confidential/Information protection:

- Personal identifying information of research participants.
- Proprietary information or intellectual property of the researcher.
- Sensitive community information or restricted traditional knowledge.

- The individual deliberations of WU-IRERC members.

11.5.3. Information sharing protocols

IRERC members access: Protocol review document access for assigned reviewers, meeting materials and decision documentation, training and educational resource availability, policy and procedure document access.

11.5.4. External information sharing

Regulatory reporting: Required information sharing with regulatory agencies**,** compliance monitoring and inspection cooperation**,** legal and judicial proceeding information provision.

Research collaboration: Multi-institutional research partnership information sharing**,** international collaboration and data exchange**,** academic publication and dissemination**,** conference presentation and professional communication

CHAPTER 12: TRAINING AND CAPACITY BUILDING

12.1. Training Framework and Purpose

This chapter outlines the framework for training and capacity building for all members of the WU-IRERC, Principal Investigators and research staff. The program is grounded in the Ubuntu philosophy, aiming to cultivate ethical wisdom, cultural sensitivity and a deep commitment to community partnership. Training goes beyond regulatory compliance to cultivate ethical wisdom, cultural sensitivity and community commitment that extends beyond mere regulatory compliance.

Core training objectives: Ethical Competency, Cultural Sensitivity, Community Engagement Skills, Ubuntu Integration, and Regulatory Compliance. Continuing education is provided on topics such as Ubuntu philosophy, community engagement, and updates to national/international regulations

12.2. Training Program Structure

12.2.1. Mandatory foundational training

All newly appointed WU-IRERC members and all PIs submitting a protocol for the first time must complete a mandatory foundational training program. This program covers:

- The history and principles of research ethics.
- National and international research ethics regulations.
- A detailed review of all Wollo University Research Ethics SOPs.
- In-depth modules on the Ubuntu philosophy, community engagement, benefit-sharing, and the protection of traditional knowledge.

12.3. Multi-Level Capacity Building Strategy

The WU-IRERC will implement a holistic strategy that builds capacity at three levels:

- **Individual Level:** Fostering the professional growth of researchers and IRERC members through targeted training, mentorship programs, and access to resources for ethical reflection.
- **Institutional Level:** Promoting a university-wide culture of ethical research through seminars, policy development, and the integration of ethics into the academic curriculum.
- **Community Level:** Empowering community partners through workshops on research literacy, their rights as participants, and their role in the co-creation of knowledge. This ensures they can engage as equitable partners in the research process.

12.4. Documentation of Training

The WU-IRERC Secretariat will maintain a permanent record of all training and continuing education activities completed by IRERC members and PIs. Completion of mandatory training is a prerequisite for participation in review activities or for receiving final protocol approval.

CHAPTER 13: QUALITY ASSURANCE AND CONTINUOUS IMPROVEMENT

13.1. Purpose and Core Principles

This chapter establishes the Quality Assurance (QA) and Continuous Improvement (QI) framework for the WU-IRERC. The framework integrates Ubuntu principles with international best practices to ensure the ethics review process is effective, efficient, accountable and consistently centered on the well-being of the community by the internal and external evaluation of the WU-IRERC. The purpose of this framework is to ensure the IRERC's operations are effective, efficient, compliant with all regulations, and aligned with the core goal of continuous improvement.

The WU-IRB adopts a comprehensive quality management approach centered on community

13.2. Quality Assurance Performance Indicators

The performance of the WU-IRERC will be monitored using the following key indicators:

13.2.1. Internal audits and performance monitoring

The WU-IRERC Secretariat, under the direction of the Chair, shall conduct ongoing performance monitoring. Key metrics to be tracked include in Table 13.1. A summary of these metrics shall be reviewed monthly by the IRERC Chair and discussed with the full committee at its regular meetings to identify and address bottlenecks.

Table 13.1: Key Performance Indicators (KPIs)

Quality Dimension	KPI	Target
Review Process Efficiency	Average review turnaround time (Full Board)	< 30 business days
	First-review approval rate	> 60%
	IRERC meeting attendance rate	> 80%
Documentation Quality	Complete application submission rate on first attempt	> 80%
	Record retention compliance	100%
Training & Capacity	Completion rate for mandatory training	100%
	Annual participation in continuing education	100%
Stakeholder Satisfaction	Annual satisfaction score from researchers	> 4.0 / 5.0

13.2.2. Annual comprehensive self-assessment

The WU-IRERC shall conduct a comprehensive self-assessment at the end of each academic year. This assessment will:

- Analyze feedback collected from stakeholders (see Section 13.2.3).
- Assess the effectiveness of training programs.
- Review the committee's compliance with its own SOPs.
- Evaluate its performance against the KPIs listed in Table 13.1.
- Collect and analyze feedback from researchers and community representatives (see Section 3.2.6)
- Identify and prioritize areas for improvement for the upcoming year.

13.2.3. Stakeholder feedback mechanisms

The WU-IRERC shall actively solicit feedback from its stakeholders to guide its improvement process.

13.2.4. Investigator feedback

- **Post-review surveys**: The Secretariat will send a standardized satisfaction survey to all Principal Investigators (PIs) following the final decision on their protocol.
- **Annual focus groups:** The IRERC will host at least one annual focus group discussion with researchers from various colleges to gather qualitative feedback on the review process.

13.2.5. IRERC member feedback

The Chair will conduct an annual anonymous survey of all IRERC members to assess:

- Satisfaction and engagement with committee operations.
- Perceived effectiveness of training and resources.
- Feedback on workload, meeting management and administrative support.
- Identification of professional development needs.

13.2.6. Community input

- **Community advisory**: The IRERC shall maintain a Community Advisory Board (CAB) or utilize community representatives to provide feedback on IRERC policies and community engagement practices.
- **Public comment**: Any significant proposed changes to these SOPs will be made available for a public comment period before final adoption.

13.3. Continuous Improvement Cycle

The WU-IRERC will follow a structured cycle for continuous improvement based on the Plan-Do-Check-Act model.

13.3.1. Internal monitoring and evaluation (Check)

The IRERC will conduct an annual self-assessment to:

- Review its processes and procedures against the established SOPs.
- Assess the consistency and quality of its decisions.
- Evaluate its performance against the KPIs listed in Table 13.1.
- Collect and analyze feedback from researchers and community representatives.

13.3.2. External evaluation (Check)

An external review of the WU-IRERC SOPs will be conducted once every year. This review may be performed by the national regulatory authority, an accreditation body, or a panel of external ethics experts to provide an objective assessment of the committee's operations.

13.3.3. Corrective and preventive action (Act & Plan)

Findings from internal and external evaluations will be used to develop a formal Corrective and Preventive Action (CAPA) plan. This plan will identify root causes of issues, assign responsibilities from the members and set timelines for implementing improvements.

13.4. Accreditation and Registration

13.4.1. Requirement for national registration

As a mandated body overseeing ethical research practices, the (WU-IRERC is required to obtain and maintain official registration and accreditation from the Ethiopian Ministry of Education (MoE).

This accreditation confirms that the WU-IRERC, its processes, and its authority are recognized at the national level.

13.4.2. Purpose of accreditation

Accreditation ensures that the WU-IRERC operates in full compliance with the National Research Ethics Guidelines and all applicable national laws. This SOPs manual (Version 2.0) serves as the primary governing document to demonstrate this compliance. Maintaining this status is essential for the legal and ethical validity of the research approved by the committee.

13.4.3. Process for maintaining registration and accreditation

The WU-IRERC Chair and secretariat are jointly responsible for the proactive and timely maintenance of the committee's accredited status. The process for maintaining this status includes, but is not limited to, the following actions:

1. **Annual reporting:** Preparing and submitting a comprehensive annual report of all IRERC activities, membership, and protocol statistics to the MoE and its designated body, the National Research Ethics Review Committee (NRERC), as required.
2. **SOPs adherence:** Ensuring all review activities and operations strictly adhere to this approved SOP manual, which forms the basis of the accreditation.
3. **Periodic audits:** Cooperating fully and transparently with any periodic audits, compliance reviews, site visits, or requests for information initiated by the MoE or NRERC.
4. **Accreditation renewal:** Proactively managing the accreditation renewal process by submitting all required documentation (including the current SOPs, membership rosters, and activity logs) and paying any requisite fees within the stipulated timeframe.
5. **Notification of changes:** Formally notifying the MoE and NRERC of any significant changes to the IRERC's structure or procedures, such as the appointment of a new Chair, significant changes in committee membership, or major revisions to this SOP manual.

13.5. SOPs Implementation and Review

13.5.1. Administrative responsibility

The WU-IRERC Secretariat is responsible for the practical implementation of these SOPs, including:

- Establishing and maintaining all official file systems, tracking databases and administrative procedures described herein.
- Ensuring the most current version of the SOP manual and all associated forms are accessible to researchers and the public via the university website.
- Planning and scheduling all mandatory training programs for researchers and IRERC members.

13.5.2. Researcher and member responsibility

- **Researchers:** All Principal Investigators are required to read this manual and complete all mandatory training *before* submitting a protocol. Adherence to these SOPs is a condition of protocol approval.

- **IRERC members:** All committee members are required to complete certification training on these SOPs before participating in any review activities. Members must maintain strict confidentiality and adhere to all defined procedures.

13.5.3. Continuous support

The WU-IRERC is committed to supporting an institutional culture of ethical research. The Secretariat shall provide continuous support to researchers and committee members by:

- Offering regular training and refresher opportunities.
- Providing pre-submission consultation services to researchers.
- Routinely updating templates and guidance documents.
- Serving as a primary point of contact for policy clarifications.

13.6. SOP Review and Version Control

13.6.1. Document version

This document is **Version 2.0** of the WU-IRERC Standard Operating Procedures.

13.6.2. Review frequency

These SOPs will be reviewed comprehensively by the full IRERC committee at least once every year. An interim review may be triggered at any time by significant changes in national regulations, international best practices or institutional policy.

13.6.3. Amendment and approval process

- Proposed amendments to these SOPs can be submitted by any IRERC member or stakeholder.
- All proposed amendments will be discussed at a convened full board meeting. Adoption of amendments requires a two-thirds majority vote of the committee

14. REFERENCES

Congiunti, L., Lo Piccolo, F., Russo, A., Serio, M. (Eds.), 2023. Ethics in Research: Principles and Practical Considerations, UNIPA Springer Series. Springer Nature Switzerland, Cham. https://doi.org/10.1007/978-3-031-24060-7.

DE LA SALLE UNIVERSITY RESEARCH ETHICS OFFICE (2011). Operational Guidelines for Research Ethics Review Committees.

Ehni, H. J., & Wiesing, U. (2017). Research ethics for a globalised world: the revised CIOMS international guidelines. *Indian Journal of Medical Ethics*, *2*(3). https://doi.org/10.20529/IJME.2017.046.

Guidelines on the practice of ethics committees in medical research with human participants, 4th ed. ed, 2007. . Royal College of Physicians of London, London.

HHS. (2018). *Subpart A of 45 CFR Part 46: Basic HHS Policy for Protection of Human Subjects*. Office of the Assistant Secretary for Health, Office for Human Research https://doi.org/10.1007/978-3-031-69573-5_42.

Institutional Review Board - New Mexico Highlands University. (n.d.). Retrieved November 2, 2025, from https://www.nmhu.edu/institutional-review-board/.

International ethical guidelines for health-related research involving humans. (2017). CIOMS.

International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016 https://doi.org/10.56759/rgxl7405**.**

International Ethical Guidelines for Health-related Research involving Humans. (2016). https://doi.org/10.56759/RGXL7405.

IRB Actions to Approve or Disapprove Research – Institutional Review Board. (n.d.). Retrieved November 2, 2025, from https://irb.utah.edu/sops/407/.

Israel, M. (2015). Research Ethics and Integrity for Social Scientists: Beyond Regulatory Compliance. *Research Ethics and Integrity for Social Scientists: Beyond Regulatory Compliance*. https://doi.org/10.4135/9781473910096.

Kruger, M., Ndebele, P., Horn, L. (Eds.), 2014. Research Ethics in Africa: A Resource for Research Ethics Committees, 1st ed. SUN MeDIA. https://doi.org/10.18820/9781920689315

McAdam, K. (2004). THE ETHICS OF RESEARCH RELATED TO HEALTH CARE IN DEVELOPING COUNTRIES. *Acta Bioethica*, *10*(1). https://doi.org/10.4067/s1726-569x2004000100006..

Mkhize, N. (2018). Ubuntu-Botho Approach to Ethics: An Invitation to Dialogue. *Advancing Global Bioethics*, *13*, 25–48. https://doi.org/10.1007/978-3-319-93230-9_3.

National Research Ethics Review Technical Guideline Ethiopia Ministry of Education. (2022).

Nyika, A., Kilama, W., Tangwa, G. B., Chilengi, R., & Tindana, P. (2009). Capacity building of ethics review committees across africa based on the results of a comprehensive needs assessment survey. *Developing World Bioethics*, *9*(3), 149–156. https://doi.org/10.1111/J.1471-8847.2008.00243.X.

Panel on Research Ethics, TCPS Interpretations, [May 2024]. https://ethics.gc.ca/eng/policy-politique_interpretations.html.

Pentz, R. (2021). ES13.05 The Ethics of International Research. *Journal of Thoracic Oncology*, *16*(10). https://doi.org/10.1016/j.jtho.2021.08.748.

Research, U.S.N.C. for the P. of H.S. of B. and B., 1978. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research : Appendix. Department of Health, Education, and Welfare, National Commission for the Protection of Human Subjects

of Biomedical and Behavioral Research.
Saunders, J. (2003). Manual for research ethics committees. *Clinical Medicine*, *3*(5). https://doi.org/10.7861/clinmedicine.3-5-479.
Saunders, J., 2003. Manual for research ethics committees. Clinical Medicine 3. https://doi.org/10.7861/clinmedicine.3-5-479.
Sefotho, M. M., & Letseka, M. (2024). Botho/Ubuntu paradigm as cognitive justice in psychology. *School Psychology International*, *45*(3), 233–253. https://doi.org/10.1177/01430343241244748.
Silaigwana, B., & Wassenaar, D. (2015). Biomedical research ethics committees in sub-Saharan Africa: A collective review of their structure, functioning, and outcomes. *Journal of Empirical Research on Human Research Ethics*, *10*(2), 169–184. https://doi.org/10.1177/1556264615575511.
Tirone, V., Newman, E., Ouimette, P., & Kaier, E. (2013). Ethical considerations in conducting research on trauma, posttraumatic stress, and substance misuse and abuse. In *Trauma and substance abuse: Causes, consequences, and treatment of comorbid disorders (2nd ed.).* https://doi.org/10.1037/14273-005..
UERM MEMORIAL MEDICAL CENTER, INC. (2022). RESEARCH INSTITUTE FOR HEALTH SCIENCES ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURES
Ujomudike, P. O. (2016). Ubuntu Ethics. *Encyclopedia of Global Bioethics*, 2869–2881. https://doi.org/10.1007/978-3-319-09483-0_428.
UNESCO Universal Declaration on Bioethics and Human Rights (2005)
United States. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978. The Belmont report: ethical principles and guidelines for the protection of human subjects of research (Vol. 2). The Commission.
Vieira, B. O., Colbath, A., & Okyere-Manu, B. (2025). Ubuntu and Social Choice Theory: An Ethical Interrogation of Group Decision-Making from an African Perspective. *The Palgrave Handbook of Ubuntu, Inequality and Sustainable Development*, 685–705. https://doi.org/10.1007/978-3-031-69573-5_42.
Wassie, L., Gebre-Mariam, S., Tarekegne, G., & Rennie, S. (2019). Enhancing ethics review of social and behavioral research: developing a review template in Ethiopia. *Research Ethics*, *15*(3–4), 1–23. https://doi.org/10.1177/1747016119865731.
WHO, 29 September, 2011. Standards and operational guidance for ethics review of health-related research with human participants. World Health Organization (WHO), Geneva, Switzerland. (ISBN: 9789241502948).
World Medical Association. (2013). Declaration of Helsinki. Ethical principles for medical research involving human subjects.64th WMA General Assembly, Fortaleza, Brazil, October 2013. In *Journal of the Indian Medical Association* (Vol. 107, Issue 6).

15. ANNEXES

ANNEX A. Glossary of Terms

Key terms	Definition
Informed consent	The process of providing potential participants with information about research to allow them to make voluntary decisions about participation
Adverse event	Any untoward medical occurrence in a participant, which does not necessarily have a causal relationship with the research
Amendment	A material changes 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 welfare	An animal's quality of life based on an assessment of an animal's physical and psychological state as an indicator of how the animal is coping with the ongoing situation as well as a judgement about how the animal feels.
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.
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-sharing	The distribution of benefits derived from research to participating communities and individuals.
Collaborative research	Research involving coordination between the researchers, institutions, organizations, and/or communities.
Community consultation	The process of engaging with communities affected by research to seek their input and address their concerns
Compliance audit	The audit of the conduct and records of the approved research to verify compliance with REC-H requirements and conditions. Standard Operating Procedures
Confidential/confidentiality	The condition of honoring a request or expectation that information will be protected from disclosure
Conflict of interest .	A compromised situation as regards ethical conduct of research as a result of conflicting duties, responsibilities or interests (personal, professional or otherwise) on the part of the PI and/or PRP and/or participant recruiter and/or gatekeeper and/or sponsor of the study
Consent	Any record of voluntary, specific and informed expression of will in terms of which permission is given for the participation in the data collection process, and for the processing of personal information.

Expedited Review	Review of research by one or more experienced IRB members without convening a full committee meeting
Full Committee review	Review of research by a convened IRB with a quorum present
Institutional Ethics Review committee (IRERC)	A committee established to review and approve research to ensure their rights and welfare of participants. Research ethics committees review proposed studies with participants (or samples deriving from them) to ensure they conform to international and locally accepted international guidelines, monitor studies once they have begun and, where relevant, take part in follow-up action and surveillance after the end of research
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in research are not greater than those ordinarily encountered in daily life
Non-compliance	The result of deviating from approved processes.
Potential for Harm	Physical, social, psychological and all other types of harm are kept to an absolute minimum
Protocol	A detailed plan for conducting research, including objectives, methods, and procedures.
Results Communication	You ensure your work is free of plagiarism or research misconduct, and you accurately represent your results.
Research Misconduct	Making up or falsifying data, manipulating data analyses, or misrepresenting results in research reports.
Research Protocol	A document written by the investigator(s) which should typically contain a project summary; general information; background rationale; references and literature review; study goals and objectives; study design; methodology; safety considerations; follow up; data management considerations and statistical analysis; quality assurance; expected outcomes of the study; dissemination of results and publication policy; duration of the project; problems anticipated; project management structure and process; ethical considerations; informed consent documents; funding organization(s); collaborations; and qualifications of senior researchers.
Societal and/or Ethical value	Any possible benefit as a result of the study/data collection procedure that would be either temporarily or permanently transferred to the community from which participants are drawn.
Ubuntu Philosophy	An African philosophy emphasizing interconnectedness, collective responsibility, and compassion ("I am because we are")
Violation	That occurrence/process that fails to comply with the data collection procedures for which approval was granted
Vulnerable Populations	Groups with reduced ability to protect their own interests, including children, prisoners, pregnant women, and individuals with impaired decision-making capacity.

ANNEX C: REVIEW AND ASSESSMENT TOOLS (WU-IRERC-AT)

C.1. WU-IRERC-AT-001: Pre-Submission Checklist (For Researchers)

Instructions: Before you submit your application (F-001), check that you have included *everything* in this list. Incomplete applications will be returned without review.

Check	Document
[ ]	**WU-IRERC-F-001 (Initial Application Form):** Fully completed and signed.
[ ]	**Research Protocol:** The full, detailed study protocol.
[ ]	**Informed Consent Forms:** All templates (T-001, T-002, T-003) adapted for your study, in English AND local language(s).
[ ]	**Data Collection Tools:** All questionnaires, surveys, interview guides, or case report forms.
[ ]	**Recruitment Materials:** All posters, scripts, or advertisements.
[ ]	**CVs of PI and Co-Is:** Brief (2-3 page) curriculum vitae for all key researchers.
[ ]	**Ethics Training Certificates:** Proof of recent ethics training for the PI.
[ ]	**Permits & Approvals:** Copies of any other permits (e.g., Woreda, environmental).
[ ]	**Funder Documentation (if applicable):** Grant proposal or award letter.

C. 2. WU-IRERC-AT-002: Primary Reviewer Evaluation Form (For IRERC Members)

Instructions: To be completed by the assigned primary reviewer(s) and returned to the IRERC Secretariat before the full board meeting.

Project Title:	
IRERC Protocol No.:	
Primary Reviewer:	
Date of Review:	

Evaluation Criteria	**Assessment (Comments are Mandatory)**
1. Rationale & Scientific Merit: Is the research question clear? Is the design sound?	[ ] Acceptable [ ] Needs Revision Comments:
2. Risk/Benefit Assessment: Are risks minimized? Are they reasonable in relation to benefits?	[ ] Acceptable [ ] Needs Revision Comments:
3. Participant Selection: Is the selection equitable? Are there adequate protections for vulnerable groups?	[ ] Acceptable [ ] Needs Revision Comments:

4. Informed Consent: Is the consent process clear? Are the forms simple and complete (including verbal/local language)?	[ ] Acceptable [ ] Needs revision Comments:
5. Community Engagement: Is the plan for community entry, engagement, and benefit-sharing adequate and respectful? (Ref: Ubuntu)	[ ] Acceptable [ ] Needs revision Comments:
6. Data & Confidentiality: Is the plan for data security (especially offline) practical and sufficient?	[ ] Acceptable [ ] Needs revision Comments:
7. Animal/Environment (if applicable): Are the "3 Rs" (for animals) or impact minimization (for environment) adequately addressed?	[ ] N/A [ ] Acceptable [ ] Needs Revision Comments:

Section 3: Reviewer's Recommendation	
Recommended Action:	[ ] Approve: No changes needed. [ ] Minor Revisions: Approve pending minor, specific changes (reviewer does not need to see again). [ ] Major Revisions: Requires significant changes, must be re-reviewed by the full board. [ ] Disapprove: The protocol is ethically or scientifically unsound.
Required Revisions / Rationale:	*List all required changes or provide the rationale for disapproval. Be specific and constructive.*

Reviewer's Signature:……	**Date:……**

C.3. WU-IRERC-AT-003: Risk Assessment Matrix

Instructions: Complete this matrix for each research proposal to systematically identify and evaluate potential risks. This tool helps ensure comprehensive risk assessment across all research domains.

Study Title:

_____

Principal Investigator: _____
Reviewer Name: _____ **Date:** _____
RISK DOMAINS
For each domain, assess: (1) Likelihood of risk occurring, (2) Severity if it occurs, (3) Overall risk level, (4) Adequacy of mitigation
Rating Scales:
Likelihood: 1 = Rare, 2 = Unlikely, 3 = Possible, 4 = Likely, 5 = Almost Certain
Severity: 1 = Negligible, 2 = Minor, 3 = Moderate, 4 = Major, 5 = Catastrophic
Overall Risk: Low (score 1-6), Medium (score 7-12), High (score 13-18), Very High (score 19-25)
Mitigation: 1 = Inadequate, 2 = Needs Improvement, 3 = Adequate, 4 = Strong

DOMAIN 1: Physical Risks

Specific Risk	Likelihood (1-5)	Severity (1-5)	Overall Risk (L×S)	Risk Level	Mitigation Adequate? (1-4)	Comments
Injury from procedures						
Pain/discomfort						
Infection						
Adverse drug/intervention effects						
Environmental hazards (heat, terrain, etc.)						
Travel-related injuries						
Other:						

Domain 1 Summary:

- Highest risk identified: _____
- Overall physical risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 2: Psychological/Emotional Risks

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Distress from sensitive topics						
Anxiety about participation						

Triggering traumatic memories						
Guilt or shame						
Loss of self-esteem						
Fear of consequences						
Other:						

Domain 2 Summary:

- Highest risk: _____
- Overall psychological risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 3: Social Risks

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Stigmatization						
Discrimination						
Social isolation/ostracism						
Family/community conflict						
Loss of social status						
Relationship breakdown						
Reputational harm						
Gender-based backlash						
Other:						

Domain 3 Summary:

- Highest risk: _____
- Overall social risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 4: Economic Risks

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Lost income (time away from work)						
Healthcare costs						
Transportation costs						
Childcare costs						
Loss of employment						
Economic exploitation						
Dependency on research benefits						
Other:						

Domain 4 Summary:

- Highest risk: _____
- Overall economic risk level: ☐ Low ☐ Medium ☐ High ☐ Very High

- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 5: Legal/Regulatory Risks

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Criminal liability (disclosing illegal activity)						
Civil liability						
Immigration consequences						
Loss of legal status/benefits						
Legal action against researchers						
Other:						

Domain 5 Summary:

- Highest risk: _____
- Overall legal risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 6: PRIVACY/CONFIDENTIALITY RISKS

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Accidental disclosure of identity						
Data breach (electronic)						
Unauthorized access to paper records						
Loss/theft of data						
Identifiability in small communities						
Group setting confidentiality breach						
Third-party access (court, authorities)						
Other:						

Domain 6 Summary:

- Highest risk: _____
- Overall privacy risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 7: Community-Level Risks

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Community conflict/division						

Exacerbation of power imbalances						
Cultural disruption						
Negative publicity for community						
Exploitation of community resources						
Unfulfilled expectations/benefits						
Research fatigue						
Other:						

Domain 7 Summary:

- Highest risk: _____
- Overall community risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 8: Environmental/Ecological Risks (if applicable)

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Habitat disturbance						
Species population impact						
Introduction of invasive species						
Pollution/contamination						
Ecosystem disruption						
Climate impact						
Other:						

Domain 8 Summary:

- Highest risk: _____
- Overall environmental risk level: ☐ Low ☐ Medium ☐ High ☐ Very High
- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong

DOMAIN 9: Animal Welfare Risks (if applicable)

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Pain						
Distress						
Suffering						
Death						
Lasting harm						
Inadequate care						
Other:						

Domain 9 Summary:

- Highest risk: _____
- Overall animal welfare risk level: ☐ Low ☐ Medium ☐ High ☐ Very High

- Mitigation adequacy: ☐ Inadequate ☐ Needs improvement ☐ Adequate ☐ Strong
- 3Rs (Replacement, Reduction, Refinement) adequately addressed: ☐ Yes ☐ No ☐ Partially

DOMAIN 10: Vulnerable Population-Specific Risks

10.1. Children:

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Developmental harm						
Coercion/undue influence						
Inadequate understanding of consent						
Abuse reporting obligations						

10.2. Pregnant Women:

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Fetal harm						
Pregnancy complications						

10.3. Persons with Diminished Capacity:

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Exploitation						
Inadequate representation						

10.4. Economically Vulnerable:

Specific Risk	Likelihood	Severity	Overall Risk	Risk Level	Mitigation Adequate?	Comments
Undue inducement						
Economic coercion						

Domain 10 Summary:

- Highest vulnerable population risk: _____
- Additional safeguards needed: _____

OVERALL RISK ASSESSMENT SUMMARY

Highest Risk Domains:

1.
2.
3.

Overall Study Risk Classification:

Calculate: (Sum of all domain "Overall Risk" scores) ÷ (Number of applicable domains)

☐ **Minimal Risk** (Average <6) - No greater than daily life or routine examinations

☐ **More than Minimal Risk** (Average 6-12) - Greater than daily life but manageable with

appropriate safeguards
☐ **High Risk** (Average >12) - Significant potential for harm requiring extensive safeguards
Risk-Benefit Balance:
☐ **Favorable** - Expected benefits clearly outweigh risks
☐ **Acceptable** - Benefits likely outweigh risks with proper safeguards
☐ **Marginal** - Benefits and risks roughly balanced; requires close monitoring
☐ **Unfavorable** - Risks outweigh benefits; not approvable without major modifications

MITIGATION ASSESSMENT
Inadequate Mitigation Areas (domains scored 1-2):

_____

Required Improvements: _____

Strong Mitigation Practices (domains scored 4):_____

SPECIAL CONSIDERATIONS
Cumulative Risk:
Are participants exposed to multiple risk domains simultaneously that could compound harm?
☐ Yes (describe: _____) ☐ No
Delayed/Long-term Risks:
Are there risks that may emerge after study completion?
☐ Yes (describe: _____) ☐ No
Third-Party Risks:
Could research cause harm to non-participants (family, community)?
☐ Yes (describe: _____) ☐ No
Systemic/Structural Risks:
Could research reinforce harmful power structures or inequities?
☐ Yes (describe: _____) ☐ No

REVIEWER RECOMMENDATIONS
Overall Recommendation:
☐ **Approve** - Risks are minimal and adequately mitigated
☐ **Approve with Conditions** - Approvable if specified modifications made
☐ **Revisions Required** - Significant risk mitigation improvements needed
☐ **Disapprove** - Risks are unacceptable or cannot be adequately mitigated
Specific Required Modifications:

_____

_____

Suggested Enhancements (optional but recommended):

_____

_____

Monitoring Requirements:
☐ Standard monitoring

☐ Enhanced monitoring (specify: _____)
☐ Data Safety Monitoring Board required

_____

Reviewer Signature: _____ _____**Date:** _____
Reviewer Name: _____

C.4. WU-IRERC-AT-004: Community Engagement Assessment Tool

Instructions: Use this tool to evaluate the quality, depth, and authenticity of community engagement in research proposals. This is a core ethical requirement for research at Wollo University.

Study Title: _____

Principal Investigator: _____

Reviewer Name: _____ _____**Date:** _____

PART 1: COMMUNITY DEFINITION AND MAPPING

1.1 Community Definition

Is the "community" clearly and appropriately defined for this research?

☐ **Strong** (4 points) - Clear, specific, culturally appropriate definition; boundaries well-articulated

☐ **Adequate** (3 points) - Defined but could be more precise

☐ **Weak** (2 points) - Vague or overly broad definition

☐ **Inadequate** (1 point) - No clear community definition

☐ **N/A** (0 points) - Community-level engagement not applicable to this study

Score: ___ /4

Comments:

1.2 Stakeholder Mapping

Has the researcher identified key community stakeholders and their roles/relationships?

Assessed Elements:

- Formal leaders (elders, kebele officials, religious leaders): ☐ Yes ☐ No
- Informal influencers: ☐ Yes ☐ No
- Marginalized groups explicitly identified: ☐ Yes ☐ No
- Women's representation considered: ☐ Yes ☐ No
- Youth representation considered: ☐ Yes ☐ No
- Vulnerable subgroups identified: ☐ Yes ☐ No

Quality Rating:

☐ **Comprehensive** (4) - All key stakeholders identified with roles and relationships mapped

☐ **Good** (3) - Most stakeholders identified

☐ **Basic** (2) - Only formal leaders identified

☐ **Poor** (1) - Superficial or missing stakeholder analysis

Score: ___ /4

Comments:

SECTION 2: Pre-Research Consultation

2.1 Timing of Consultation

When was/will community consultation occur?

☐ **Optimal** (4) - Already completed; began in research design phase

☐ **Good** (3) - Completed before ethics submission

☐ **Acceptable** (2) - Planned before data collection

☐ **Poor** (1) - Planned after ethics approval or after research starts

☐ **None** (0) - No consultation planned

Score: ___ /4

Comments:

2.2 Consultation Process Quality

Assess each element:

Element	Present & Strong (2)	Present but Weak (1)	Absent (0)	Score
In-person meeting(s) held				
Sufficient notice given to community				
Information presented in local language				
Information presented in accessible format (oral, visual, etc.)				
Adequate time for discussion				
Questions encouraged and answered				
Documentation of meeting (minutes, attendance)				
Multiple consultations/iterative process				

Subtotal: ___ /16

Quality Rating:

- 13-16: Exemplary
- 9-12: Good
- 5-8: Needs improvement
- 0-4: Inadequate

Comments:

2.3 Breadth of Participation

Who participated in consultations?

☐ **Inclusive** (4) - Diverse representation including marginalized groups, women, youth

☐ **Moderately Inclusive** (3) - Some diversity but gaps in representation

☐ **Limited** (2) - Primarily formal leaders only

☐ **Very Limited** (1) - Single gatekeeper or individual

Evidence of active efforts to include:

- Women: ☐ Yes ☐ No
- Youth: ☐ Yes ☐ No
- Minority/marginalized groups: ☐ Yes ☐ No
- Persons with disabilities: ☐ Yes ☐ No

Score: ___ /4

Comments:

2.4 Community Input Integration

How was community feedback incorporated?

☐ **Fully Integrated** (4) - Specific examples of protocol changes based on community input
☐ **Partially Integrated** (3) - Some modifications made
☐ **Acknowledged** (2) - Feedback documented but minimal changes
☐ **Ignored** (1) - No evidence of responsiveness to feedback
☐ **N/A** (0) - Consultation not yet occurred
Examples of integration:

Score: ___ /4

2.5 Community Decision
What was the community's response to the proposed research?
☐ **Strong Support** (4) - Enthusiastic endorsement with documentation (e.g., letter of support)
☐ **Support** (3) - Positive response documented
☐ **Conditional Support** (2) - Support with conditions that are addressed
☐ **Ambivalent/Mixed** (1) - Divided opinions or unclear response
☐ **Opposition** (0) - Community does not support research
☐ **Pending** - Decision not yet made
Score: ___ /4
Comments:

SECTION 3: BENEFIT-SHARING PLAN
3.1 Directness and Relevance of Benefits
Are proposed benefits meaningful to the community?
☐ **Highly Relevant** (4) - Benefits directly address community-identified priorities
☐ **Relevant** (3) - Benefits align with community needs
☐ **Somewhat Relevant** (2) - Generic benefits not tailored to community
☐ **Irrelevant** (1) - Benefits don't match community needs/interests
☐ **None** (0) - No community benefits proposed
Evidence that benefits match community priorities:
☐ Based on community consultation
☐ Based on community needs assessment
☐ Based on researcher assumptions
☐ Not evident
Score: ___ /4
Comments:

3.2 Types of Benefits
Check ALL proposed benefit types and rate appropriateness:

Benefit Type	Proposed	Appropriate	Inappropriate	N/A

Research findings dissemination (accessible format)	☐	☐	☐	☐
Capacity building/training	☐	☐	☐	☐
Employment opportunities	☐	☐	☐	☐
Infrastructure improvements	☐	☐	☐	☐
Health services/screening	☐	☐	☐	☐
Educational materials	☐	☐	☐	☐
Agricultural inputs/technology	☐	☐	☐	☐
Cash/in-kind compensation	☐	☐	☐	☐
Community fund contribution	☐	☐	☐	☐
Co-authorship/knowledge ownership	☐	☐	☐	☐
Long-term partnership	☐	☐	☐	☐

Diversity of benefits:

☐ **Excellent** (4) - Multiple types including both immediate and long-term benefits

☐ **Good** (3) - 2-3 benefit types

☐ **Limited** (2) - Single benefit type

☐ **Minimal** (1) - Only research findings dissemination

☐ **None** (0) - No benefits

Score: ___ /4

3.3 Timeline and Sustainability

When will benefits be delivered?

During research: ☐ Yes ☐ No (specify: _____)

At completion: ☐ Yes ☐ No (specify: _____)

Long-term (beyond study): ☐ Yes ☐ No (specify: _____)

Sustainability Rating:

☐ **Sustainable** (4) - Benefits designed for lasting impact beyond research period

☐ **Moderately Sustainable** (3) - Some lasting benefits

☐ **Short-term** (2) - Benefits end with research

☐ **Unclear** (1) - Sustainability not addressed

Score: ___ /4

Comments:

_____

_____

3.4 Mechanism and Accountability

How will benefits be delivered and accountability ensured?

Elements Assessed:

Element	Yes (2)	Partial (1)	No (0)	Score
Clear mechanism for distribution/implementation				
Specific responsible parties identified				
Timeline specified				

Community role in oversight				
Monitoring/evaluation plan				

Subtotal: ___ /10
Comments:

_____

_____

3.5 Proportionality
Are benefits proportionate to community contribution and researcher gains?
☐ **Highly Proportionate** (4) - Significant benefits matching community input/risk
☐ **Proportionate** (3) - Reasonable balance
☐ **Somewhat Disproportionate** (2) - Benefits seem minimal relative to extraction
☐ **Highly Disproportionate** (1) - Exploitative; minimal return for significant contribution
Considerations:

- Level of community effort/time: _____
- Potential researcher career benefits (publications, funding, etc.): _____
- Cultural/intellectual resources accessed: _____

Score: ___ /4
Comments:

_____

_____

SECTION 4: ONGOING ENGAGEMENT
4.1 Communication Plan
How will community be kept informed during research?
Frequency: ☐ Monthly ☐ Quarterly ☐ At milestones ☐ Other: _____ ☐ Not specified
Methods:
☐ Community meetings
☐ Liaison person
☐ Written updates
☐ Radio
☐ Other: _____
Quality Rating:
☐ **Robust** (4) - Multiple methods, regular frequency, two-way communication
☐ **Adequate** (3) - Regular updates planned
☐ **Minimal** (2) - Infrequent or one-way communication
☐ **Absent** (1) - No ongoing communication plan
Score: ___ /4
4.2 Feedback and Grievance Mechanism
Is there a clear process for community to provide feedback or raise concerns?
Assessed Elements:

Element	Yes (1)	No (0)	Score
Dedicated contact person/mechanism identified			
Accessible (phone, in-person, etc.)			
Culturally appropriate			

Confidential option available			
Response timeline specified			
Process explained to community			

Subtotal: ___ /6

Quality:

- 5-6: Strong
- 3-4: Adequate
- 1-2: Weak
- 0: Absent

Comments:

_____

_____

4.3 Community Role in Research

Beyond participation, what role does community play?

☐ **Partnership** (4) - Community as co-researchers; decision-making role

☐ **Collaboration** (3) - Active involvement beyond data provision

☐ **Consultation** (2) - Input sought but researchers control process

☐ **Passive** (1) - Community as subjects/data sources only

Evidence:

☐ Community members employed as research team

☐ Community input on data interpretation

☐ Community co-authorship

☐ Community validation of findings

☐ Other: _____

Score: ___ /4

Comments:

_____

_____

SECTION 5: DISSEMINATION AND KNOWLEDGE SHARING

5.1 Plan for Sharing Results with Community

Timeline: ☐ <3 months post-completion ☐ 3-6 months ☐ 6-12 months ☐ >12 months ☐ Not specified

Format:

Format	Planned	Appropriate for Community	Score (0-2)
Community meeting/presentation	☐	☐	
Written summary (local language)	☐	☐	
Visual materials (poster, infographic)	☐	☐	
Radio/media broadcast	☐	☐	
Video	☐	☐	
Other:	☐	☐	

Accessibility:

☐ **Highly Accessible** (4) - Multiple formats, local language, low-literacy appropriate
☐ **Accessible** (3) - Local language, appropriate format
☐ **Limited Accessibility** (2) - English/academic format only
☐ **Inaccessible** (1) - No community-appropriate dissemination
Score: ___ /4

5.2 Community Intellectual Property Rights
Are community knowledge contributions and IP rights addressed?
☐ **Fully Addressed** (4) - Clear agreement on knowledge ownership, attribution, use
☐ **Partially Addressed** (3) - Some consideration of IP
☐ **Minimally Addressed** (2) - Acknowledgment but no formal agreement
☐ **Not Addressed** (1) - No consideration of community IP
☐ **N/A** (0) - No traditional/indigenous knowledge involved
Evidence:
☐ Formal agreement/MOU with community
☐ Community co-authorship planned
☐ Community attribution in publications
☐ Community consent for knowledge use
Score: ___ /4
Comments:

SECTION 6: UBUNTU PRINCIPLES INTEGRATION
6.1 Interconnectedness
Does the research recognize and honor the relational nature of knowledge and community?
☐ **Exemplary** (4) - Research design explicitly recognizes interconnections; uses relational approaches
☐ **Good** (3) - Evidence of relational awareness
☐ **Limited** (2) - Individual-focused but some community awareness
☐ **Absent** (1) - Purely extractive individual data collection
Evidence:

Score: ___ /4
6.2 Solidarity
Does the researcher demonstrate standing WITH the community, not just studying them?
☐ **Strong Solidarity** (4) - Clear commitment to community priorities; researcher as ally
☐ **Moderate Solidarity** (3) - Some alignment with community interests
☐ **Weak Solidarity** (2) - Researcher-driven agenda with community as means
☐ **No Solidarity** (1) - Purely extractive; no commitment to community
Evidence:

Score: ___ /4

6.3 Compassion
Does the research demonstrate genuine care for community well-being?
☐ **Deeply Compassionate** (4) - Well-being and dignity central to research design
☐ **Compassionate** (3) - Clear concern for avoiding harm, promoting good
☐ **Minimally Compassionate** (2) - Basic harm avoidance only
☐ **Lacking Compassion** (1) - Indifferent to community well-being
Evidence:

Score: ___ /4

6.4 Collective Responsibility
Does the research acknowledge shared accountability for outcomes?
☐ **Fully Embraced** (4) - Clear commitments to community; accountability mechanisms
☐ **Acknowledged** (3) - Recognition of responsibility
☐ **Minimally Addressed** (2) - Legal compliance only
☐ **Absent** (1) - No sense of accountability to community
Evidence:
☐ Long-term commitments articulated
☐ Accountability for benefit delivery
☐ Plan for addressing negative outcomes
☐ Follow-up/longitudinal engagement
Score: ___ /4
Comments:

SECTION 7: CONTEXTUAL APPROPRIATENESS
7.1 Cultural Sensitivity
Is the research culturally appropriate and respectful?
Assessed Elements:

Element	Strong (2)	Adequate (1)	Weak (0)	Score
Understanding of local customs/practices				
Gender norms respected				
Religious considerations addressed				
Language/communication appropriate				
Timing (seasonal, religious calendar) considered				

Subtotal: ___ /10
Comments:

7.2 Local Capacity and Resources
Does the research build on and strengthen local capacity?
☐ **Capacity Building** (4) - Explicit training, skills transfer, infrastructure
☐ **Some Capacity Building** (3) - Some local employment/training

☐ **Minimal** (2) - No local capacity contribution
☐ **Extractive** (1) - Uses local resources without reciprocity
Evidence:
☐ Local employment
☐ Training provided
☐ Equipment/infrastructure left for community use
☐ Skills that remain after research
Score: ___ /4

OVERALL COMMUNITY ENGAGEMENT ASSESSMENT
SCORING SUMMARY

Section	Possible Points	Actual Score
Part 1: Community Definition & Mapping	12	
Part 2: Pre-Research Consultation	32	
Part 3: Benefit-Sharing Plan	26	
Part 4: Ongoing Engagement	14	
Part 5: Dissemination & Knowledge Sharing	8	
Part 6: Ubuntu Principles	16	
Part 7: Contextual Appropriateness	14	
TOTAL	**122**	

Percentage Score: _____ %

OVERALL RATING
☐ **Exemplary (90-100%)** - Model of community-engaged research; exceeds standards
☐ **Strong (75-89%)** - Robust community engagement; meets all standards
☐ **Adequate (60-74%)** - Meets minimum standards; some areas for improvement
☐ **Needs Improvement (40-59%)** - Significant gaps; revisions required
☐ **Inadequate (<40%)** - Fails to meet community engagement standards; not approvable

Strengths:

_____

_____

Areas For Improvement:

_____

_____

Required Modifications:

_____

_____

Recommendations:
REVIEWER RECOMMENDATION:

☐ **Approve** - Exemplary or strong community engagement
☐ **Approve with Minor Conditions** - Adequate with specified improvements
☐ **Revisions Required** - Needs significant improvement before approval
☐ **Disapprove** - Inadequate community engagement; fundamental redesign needed

Reviewer Signature: _____ Date: _____
Reviewer Name: _____

ANNEX D: ADMINISTRATIVE FORMS (WU-IRERC-A)

D.1. WU-IRERC-A-001: Conflict of Interest Disclosure Form

Instructions: To be completed by all IRERC Members (annually) and all Principal Investigators (per application)

Name:	**Role**	**Project Title (if PI):**
	[ ] PI [ ] IRERC member	

A conflict of interest (COI) exists when a financial, professional, or personal interest may compromise (or appear to compromise) your judgment.

Disclosure Questions	**Yes / No**	**If yes, please explain:**
1. Do you or your immediate family have a financial interest (e.g., ownership, stocks, consulting fee) in the sponsor of this research or a product being tested?	[ ] Y [ ] N	
2. Are you an inventor on a patent related to this research?	[ ] Y [ ] N	
3. Do you have any personal or professional relationships (e.g., family, close colleague) that could be seen as affecting your objectivity on this protocol?	[ ] Y [ ] N	
4. (For IRERC Members) Are you an investigator or part of the study team for the protocol you are being asked to review? (If Yes, you must recuse yourself).	[ ] Y [ ] N	

Declaration
I certify that I have disclosed all potential conflicts of interest. I will update this form if my situation changes.
Signature:
Date:

D.2. WU-IRERC-A-002: Training Log

Instructions: For all researchers and IRERC members to maintain a record of their ethics training.

Name:	College:	Role:
		[ ] PI/Researcher [ ] IRERC Member

Date	Training Title / Provider (e.g., CITI, WU-IRERC Workshop, NUREM)	Certificate?
		[ ] Yes [ ] No
		[ ] Yes [ ] No
		[ ] Yes [ ] No
		[ ] Yes [ ] No

D.3. WU-IRERC-A-003: IRERC Meeting Minutes Template

Meeting Details	
Date:	
Time:	Start:
Location:	
Members Present:	
Members Absent:	
Quorum Met?	[ ] Yes [ ] No

Meeting Agenda	
1. Call to Order	
2. Approval of Previous Minutes	
3. New Protocols for Full Review	
Protocol number:	**PI:**
Discussion Summary:	
Conflicts:	(List any members who recused)
Motion:	Action: [ ] Approved [ ] Minor Rev [ ] Major Rev [ ] Disapproved Votes: For: __ Against: __ Abstain: __

D.4: WU-IRERC-A-004; SOP Revision Request Form

Complete this form whenever a problem or deficiency is identified in an SOP, and retain it with the SOP until an authorized replacement is implemented.

WU-IRERC-SOP-001, Version 2	
Title:	
Details of problems or deficiencies in the SOP:_____	
Identified by:	Date (D/M/Y):
Discussed with:_____	
SOP revision required: ☐ **Yes** ☐ **No**	
If yes, to whom will it be carried out, by whom?	
If not, why not?	
Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	

D.5. WU-IRERC-A-005: IRERC Decision Letter Template

Template guidance for IRERC secretariat

Customization: *Select the single appropriate* ***DECISION OUTCOME*** *section (1, 2, 3, or 4) and delete the other three sections before sending.*
Record keeping: *File a copy of the final, signed letter with the meeting minutes and protocol documentation.*

[Official WU-IRERC Letterhead / Logo]
Date: [Date Letter is Sent]
Subject: IRERC Protocol Decision — [Study Title / Protocol ID:…….[YEAR]/[NUMBER]]

Dear [Principal Investigator Name],
The Wollo University Institutional Research Ethics Review Committee (WU-IRERC) has completed the review of your research protocol, **[Study Title],** submitted on [Date of Submission].
The Committee acknowledges the multi-disciplinary scope of your research and specifically considered the protections related to human participants, animals, community engagement (Ubuntu principles), and environmental impact, based on your application (F-001).

DECISION OUTCOME 1: PROTOCOL APPROVAL
The WU-IRERC has **APPROVED** your research protocol.
- Review Category: [Exempt / Expedited / Full]
- IRERC Meeting Date: [Date of Meeting]
- Official Approval Start Date: [DD Month YYYY]
- Approval End Date (Expiration**):** [DD Month YYYY] (Maximum one year from approval date)

Documents Approved (Latest Versions):
- WU-IRERC-F-001: Initial Protocol Application Form (Version [X], Dated [DD/MM/YYYY])
- Research Protocol Document (Version [Y], Dated [DD/MM/YYYY])
- Informed Consent Template(s) (Version [Z], Dated [DD/MM/YYYY])
- [List all other approved documents: Community Assent, Questionnaires, Permits, etc.]

Conditions of Approval (If Any):
- [List any administrative or minor conditions that do not require further IRERC review (e.g., PI must submit current training certificate before enrollment starts).]
- [If no conditions, state: "No specific conditions apply to this approval."]

Compliance Requirements:
1. **Continuing review:** You must submit a Continuing Review Report (F-004) at least **30 days** before the Approval End Date to keep the study active.
2. **Amendments:** You must seek **prior written approval** (using F-003) for *any* changes to the approved protocol, consent forms, or recruitment materials.
3. **Reporting:** All Adverse Events or Unanticipated Problems must be reported immediately using the F-005 form, as per the SOP timelines.

DECISION OUTCOME 2: APPROVED WITH MINOR CONDITIONS
(*Use this section if approval can be granted by the Chair/Designee after minor revisions; delete all others***.)**

The WU-IRERC has determined that your protocol meets ethical standards but requires **MINOR REVISIONS** to secure final approval.
Action Required by You: Please address the following conditions and resubmit the revised documents by **[Date – typically 10 days]**.

	Required Condition / Revision
1	[Example: Correct the reading level of the consent form (T-001) to 6th grade, as per SOP guidance.]
2	[Example: Clarify the secure storage location for the paper records, as the current plan lacks specifics on physical security.]
3	[List all minor conditions here.]

Resubmission Process:

- Submit the revised documents with changes clearly **tracked/highlighted**.
- The Chair or a designated reviewer will confirm satisfactory completion of the conditions, and a final approval letter (Outcome 1) will be issued.

DECISION OUTCOME 3: DEFERRED PENDING MAJOR REVISIONS

(*Use this section if the protocol has substantive issues requiring re-review by the full board or a sub-committee; delete all others***.)**
The WU-IRERC has determined that the protocol review must be **DEFERRED** due to **Substantive Concerns** requiring significant clarification or methodological changes.
Major Concerns and Rationale:

- **Concern 1 (e.g., Consent/Community):** [Detail the concern, e.g., "The plan for Community Assent (T-002) is incomplete; the proposed benefit-sharing does not align with the scale of community resource use (Ubuntu principles)." **Protocol Section Affected:** [Section Reference]]
- **Concern 2 (e.g., Risk/Design):** [Detail the concern, e.g., "The justification for not using the '3 Rs' in the animal study is insufficient; the number of animals proposed is too high relative to the study's objective." **Protocol Section Affected:** [Section Reference]]
- [List all major concerns here.]

Action Required by You:

1. Prepare a detailed written response addressing each concern point-by-point.
2. Submit revised documents with changes clearly tracked/highlighted.
3. Your revised protocol will be reviewed at the next available full IRERC meeting.

DECISION OUTCOME 4: PROTOCOL DISAPPROVAL
(*Use this section if the protocol is ethically or scientifically unsound and cannot be approved; delete all others***)**

The WU-IRERC has reached a consensus decision that the protocol cannot be ethically or scientifically approved. The decision is **DISAPPROVAL**.
Reasons for disapproval:

- **Reason 1 (Core Conflict):** [State the fundamental conflict, e.g., "The risks associated with the procedure significantly outweigh any potential benefit to the participants or the community, violating the core principle of proportionality."]
- **Reason 2 (Unresolvable Issue):** [State an unresolvable issue, e.g., "The research design requires the enrollment of an extremely vulnerable population (e.g., children in an emergency setting) without providing any justification for not using a less vulnerable population."]

- [List all fundamental reasons for disapproval here.]

Next Steps:

You may request a meeting with the IRERC Chair to discuss the decision. However, the current protocol cannot be resubmitted. Substantially revised proposals that fully address the fundamental reasons for disapproval may be submitted as a new application.

For all inquiries, please contact:

[Chair/IRERC Office]

Sincerely,
[Signature]
[Name of IRERC Chair/Designee]
Chair, Wollo University Institutional Research Ethics Review Committee (WU-IRERC)

ANNEX F: CONTACT INFORMATION

F.1. IRERC Office

Location: Administrative Building, 4th Floor, Room 405

Wollo University Main Campus, Dessie, Ethiopia

Office Hours: Monday-Friday, 8:30 AM - 5:30 PM