

STANDARD OPERATING PROCEDURES: ETHICS CLEARANCE FOR RESEARCH INVOLVING HUMAN PARTICIPANTS (SOP – RE/3/2019)

The African Centre for Technology Studies (ACTS) conducts research, capacity building, policy analysis as well as knowledge and technology brokerage in the areas defined by respective strategic plans and as specified by its partners and stakeholders. This document defines the research ethics clearance procedures to be followed by researchers at the Centre and their collaborators prior to commencing all research. The provided procedures therefore ensure that all research conducted through the Centre comply with internationally recognized research standards and ethics. Further, ACTS has also been certified as a research institution by the Kenya's National Commission for Science Technology and Innovation (NACOSTI), vide a certificate dated 2nd April 2024.

As a minimum, ACTS research (including research conducted with collaborators), will comply with the following ethics principles and guidelines:

- a. **Cause no harm:** research shall not knowingly inflict harm to researchers, research participants or the beneficiaries of the research outputs.
 - b. **Free, prior and informed consent:** all research participants will be notified on the objectives, format, methods and impacts of research activities (negative or positive) and should be free to withdraw their consent to the research activities at any time.
 - c. **Confidentiality:** participant's confidentiality shall be maintained.
 - d. **Safety:** Utmost care shall be taken to ensure the safety of researchers and/or research participants.
 - e. **No coercion:** No inducement or other forms of coercion shall be used to gain participation of any person in the research activities.
 - f. **Involvement of children** (under 18years): where children are involved, signed consent will have to be issued by a parent/guardian. Parents/guardians shall be free to withdraw the participation of the minors at any given time.
 - g. **Gender:** research shall seek to promote gender equity and equality.
 - h. **Inclusivity:** research shall seek to ensure inclusion (for instance of persons with disability, women and other socially disadvantaged individuals).
1. It is the responsibility of the **principal investigator** of a specific research project to ensure that, with respect to research participants, the work is carried out ethically and as described in the project proposal and the rights of the research participants are fully protected.
 2. Research applications shall be evaluated and approved by a Research Ethics Committee (REC) constituted under the Directorate of Research and Innovation (DRI) and comprising of the Senior Management Team (SMT) who can co-opt any other person as appropriate (Annex 2).
 3. An application for research ethics approval shall be made using a prescribed Application form (Annex I).

ETHICS CLEARANCE FOR RESEARCH INVOLVING HUMAN PARTICIPANTS (APPLICATION FORM – ANNEX 1)

**ACTS RESEARCH ETHICS COMMITTEE
SOP Reference Number RE/3/2019**

SECTION A: General Information

Project Title:	
Principal Investigator:	
Co Investigators:	
Programme/Department	
Contact Details of Principal Investigator:	<i>Phone</i> <i>E-mail</i>
Funding Body	
If Project if Funded Provide:	Reference No. (if available) Project Duration
Project Location: <i>(Local, National or International - include sites)</i>	
Does this submission hold other ethical clearance? ((if YES, please provide Ethical clearance Reference no.) & Attach copy from Other Recognized Ethics Review Committee	

I (the researcher's name) hereby confirm that:

1. The information provided in this ethics clearance application to undertake research with human participants is accurate to the best of my knowledge;
2. I understand the principles of conducting ethical research;
3. I will endeavour to conduct all the research in an ethical manner as prescribed by ACTS Research Ethics Guidelines and;
4. I will inform the ACTS Research Ethics Committee (REC) of any substantive changes to the project should that happen prior to commencement of the project or during the project implementation.

Signature and Date

SECTION B: Brief Summary of the research project

RESEARCH METHODOLOGY

Please provide the relevant information.

1. Research Approach(es) (Tick as many as may apply)

- Qualitative
- Quantitative
- Mixed/Integrated Methods
- Philosophical/conceptual
- Other (please provide details)

[Click or tap here to enter text.](#)[Click or tap here to enter text.](#)

2. Research Method(s) and Instrument(s)

- Document analysis/Protocol
- Surveys/Questionnaires or other quantitative strategy (please provide details below)
- Individual interviews/Protocols
- Focus Group Interviews/Protocols
- Observations/Protocols
- Other (please provide details)

[Click or tap here to enter text.](#)

3. Outline who the participants of the study area

4. Selection of participants

- Random
- Targeted
- Purposeful
- Snow balling
- Other (please provide details)

OTHER RESEARCH PROJECT DETAILS

Background to the study including the nature of the research

Abstract of the project

Objective of the project

Clearly state the purpose of research in a sentence or two.

Procedures involved in the research

Explain in easy-to-understand language and short sentences what you expect from participants. Include information such as:

- The educational or scientific benefit of the study, and standard procedures that participants will be exposed to;
- How you will ensure "full disclosure" for informed consent.
- Who you will make this disclosure to (participants / communities / employers etc).
- How you will ensure understanding. Possible barriers to understanding (language, intelligence, maturity, level of trust, culture, religion, privacy).
- Possible problems in the informed consent process and how you will address these.
- Participant involvement, e.g selection/sampling, duration of participation /time required / frequency of

interactions (expectation of participation must be clearly defined ie. Who, what, when, how long?).

- Place where interactions will take place, types of interaction (e.g. interviews, focus groups, surveys).
- Data capture (written notes and/or voice/video recording) with additional measures to ensure informed consent to record. Recordings necessitate an approval hence the addition on the consent/assent form.

Potential Risks

Provide Risks and Mitigation measures.

Potential Benefits

Describe the benefits which should outweigh the risks. The intention should be to leave the participants better, or no worse off than before.

Informed consent

Attach/provide a concept form to be used for the research, See **Section C**.

Confidentiality

Every effort must be made to protect (guarantee) confidentiality and privacy of the participant/s. The consent form should factor this in.

Participation and withdrawal

The participation should be voluntary. The consent form should factor this in.

Future interest and Feedback

The participant should be provided with contact information (of a researcher) should they wish to seek any information related to the study, during or after the study. The consent form should factor this in.

Type researcher name and email address		Any other relevant person like project CO-PI name and email address
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SECTION C: INFORMED CONSENT/ASSENT

(For all participants, parents, guardians and other stakeholders)

INFORMED CONSENT/ASSENT FORM

Project Title _____

Name of Investigator/Researcher _____

Date _____

1. General Information (Add yes or no in the appropriate boxes next to the statement)

Agree to be involved in the above research project as a participant .	
Agree to be involved in the above research project as an observer to protect the rights of: <input type="checkbox"/> Children younger than 18 years of age; <input type="checkbox"/> Children younger than 18 years of age that might be vulnerable*; and/or <input type="checkbox"/> Children younger than 18 years of age who are part of a child-headed family.	
Agree that my child (provide name) may participate in the above research project.	
Agree that my employee/s may be involved in the above research project as participant/s. Provide name/s of employee/s.	

2. Taking part in the study (add yes or no in the appropriate boxes next to the statement)

I have read the research information sheet pertaining to this research project (or had it explained to me) and I have had the opportunity to ask questions about the project. I therefore understand the nature of the research and my role in it.	
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time during or after interview data has been collected, without having to give a reason. In addition, should I not wish to answer any particular question or questions, I am free to decline.	
I understand that taking part in the study will involve answering interview or survey questions.	
I agree to the being audio-/video-recorded.	
I willingly provide my consent/assent for the use of photographs in this study.	
I understand that other genuine researchers will have access to my personal details (and any identifying data) only if they agree to preserve the confidentiality of the information as requested in this form.	
I agree for the data collected from me to be stored and used or quoted in relevant future research.	
This consent forms will be kept in a digitized format at ACTS which will be encrypted to restrict access and will be kept for as long as the research data is retained by the Project Principal Investigator or a designated researcher.	

Name of participant (person taking the consent)	
Participant's signature	
Date	
Name of lead researcher	
Signature	
Date	