Responsible & Ethical Research Engagement
Policy

Zihi
Institute

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Department:	Research Dpt
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1. Introduction

The purpose of the Zihi Institute Responsible and Ethical Research Engagement Policy is to guide the acceptable standard procedures, and ways of conducting research. It serves as a framework to ensure research is conducted in a professional, responsible, ethical and accountable manner. Its main goal is to protect the dignity, rights and well-being of target communities, uphold the integrity of the research process and promote trust in scientific research endeavours. All Zihi Institute's research work will be universally governed by the policies outlined in this document.

Zihi Institute is committed to ensuring that all research work carried out upholds the utmost scientific and ethical integrity and respects the cultures, norms and behaviours of the target communities and participants. It also takes into account the community's contributions to research irrespective of their identifying factors and demographics.

2. Objectives:

1. Protect the dignity and rights of the communities and all stakeholders involved in research to ensure they are respected, protected and safeguarded.

2. Prevent target communities from exposure to socially, physically, emotionally and psychologically harmful procedures involved in the research process.

3. Create an autonomous, respectful and fair environment for communities to make informed and voluntary decisions without undue influence.

4. Promote responsibility, accountability and trust between the researchers and participants to ensure research integrity and validity.

5. To uphold honesty, integrity and credibility in the design, implementation and reporting of research findings on the target communities.

3. Scope

● Applies to all researchers including staff, volunteers, associates, students, interns as well as the international and local collaborating individuals and organizations.

● Covers all types of research work carried solely or collaboratively by the organization.

● Addresses all stages of research including research planning, implementation, results, dissemination, data storage and sharing.

4. Legal Frameworks

Research activities conducted by the Organization must adhere to **Kenyan national laws**, **regional regulations**, and **international ethical standards** to ensure responsible and legally

compliant research practices. The following legal and ethical frameworks will govern the organization's research engagements:

4.1 National Legal and Ethical Guidelines

- **The Kenyan Constitution (2010)** – Recognizes the right to human dignity, equality, and freedom from inhumane treatment, which must be upheld in research.

- **The Science, Technology, and Innovation Act (2013)** – Mandates research regulation through the National Commission for Science, Technology, and Innovation (NACOSTI) and ensures ethical research licensing.

- **The National Commission for Science, Technology, and Innovation (NACOSTI) Guidelines** – Sets the national framework for research approval, ethical review, and compliance.

- **The Kenya Data Protection Act (2019)** – Regulates the collection, processing, storage, and sharing of research data to ensure privacy and confidentiality.

- **The Penal Code of Kenya (Cap 63)** – Criminalizes fraudulent research practices, including falsification of data and exploitation of research participants.

- **The Children Act (2022)** – Establishes child protection measures, ensuring ethical engagement of minors in research, including obtaining informed consent from parents/guardians and assent from children.

- **The Public Health Act (Cap 242)** – Ensures ethical health research practices that protect public welfare.

4.2 International Ethical Guidelines

- **The Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)** – Establishes ethical principles for scientific research involving human subjects.

- **The Declaration of Helsinki (World Medical Association, 1964; latest revision 2013)** – Provides fundamental ethical principles for research involving human participants, emphasizing informed consent, risk-benefit analysis, and participant safety.

- **The Belmont Report (1979, U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research)** – Establishes the principles of respect for persons, beneficence, and justice in research ethics.

- **The International Ethical Guidelines for Health-Related Research Involving Humans (CIOMS, WHO, 2016)** – Provides a framework for conducting ethical research, particularly in low-resource settings, ensuring protections for vulnerable populations.

- **The ICMJE (International Committee of Medical Journal Editors) Authorship and Publication Ethics Guidelines** – Establishes ethical authorship, ensuring transparency, acknowledgment, and prevention of research fraud.

- **The General Data Protection Regulation (GDPR) (EU, 2018)** – Provides additional safeguards for international data handling and privacy standards where cross-border research is conducted.

4.O The Responsible and Ethical Research Engagement Policies:

4.1   Relevance and need assessment

Before the research is carried out, sufficient evidence has to be sought on the need to do such research. This is empirical in clearly identifying and understanding the problem to be addressed. The evidence can be obtained from the previous studies using the existing literature.

4.2   Community interest and of social justice

The interest of the public will be put into consideration when designing, planning and implementing research done at Zihi Institute. The target communities will also be involved in every stage of the research to take into account their knowledge and contributions.

Further, all the research work done by Zihi Institute will be carried out with the goal of generating solutions to the AMR and infectious diseases challenges affecting the communities. All research findings will be made available and accessible for the benefit of the general public.

4.3   Qualification, competence and ability

All the research work by Zihi Institute will be carried out by qualified and competent researchers. Before involvement in the research, the personnel have to be assessed to ascertain their experience and competence. Professionalism, commitment and dedication to the assigned responsibilities are essential prerequisites for good and ethical research.

4.4   Safeguarding participants' rights

All researchers involved in a particular study, shall agree to uphold participants' autonomy and safeguard the privacy, dignity and confidentiality of participants and shall never expose them to risks not associated with in part or entirety the research undertaken.

4.5   Autonomous and informed consent

Individuals' participation in a particular study should be freely given, and based on informed consent. There will be no direct nor indirect participant coercion and undue inducement to

participate in research, as this prevents autonomous decision-making resulting in people consenting against their better judgment to participate in studies involving risks.

4.6 Awareness and respect for cultural diversity

Researchers should be cognizant of participant's own cultures and shall be respectfully treated within the confines of their cultural systems and traditions. If the research work being undertaken may compromise the secrecy, value and dignity of the community's cultures, norms and beliefs, it may be modified for the benefit of the community, or its implementation stopped in such a given community. Where applicable, consent may be sought from the community leaders besides that of participants.

4.7 Inclusivity and fairness

Participants from the target communities will be given equal chances to participate in the research based on their consent. Selection of the target participants shall be fair irrespective of their demographics and other identifying factors. The contributions of the underprivileged participants will not be undermined at the expense of the privileged ones. Also, the participants shall not be burdened by over-participation in the research.

4.8 Transparency, trustworthiness and accountability

All research work done by Zihi Institute shall be carried out in a fair, transparent and honest manner by observing high levels of professionalism and accountability. The organization invests a lot in the recruitment process to make sure the selected researchers are highly qualified, competent and of high integrity to prevent research misconduct and abuse of positions and participants.

4.9 Risk mitigation

The research guidelines and protocols should be clearly outlined to ensure that the research and data collection methods shall not in any circumstance expose the participants to any potential risk. In a risky situation where the participants may be exposed to potential risks, the benefits of conducting the research to or in the community should outweigh the potential risks. Otherwise, the implementation of the study should not proceed. The researchers shall carry out pre-studies to determine the possible risks that could be encountered in the actual study. In the unfortunate circumstances that an injury, theft, loss has occurred, the affected communities will be compensated.

4.10 Respectful and ethical engagement

Researchers are expected to observe high standards of professionalism, integrity, responsibility and fairness in conducting the research. This is empirical in the avoidance of exploitation of research target participants and communities, research assistants, vulnerable people and other institutions before, during and after the implementation of the research. The expected outcomes

of the study should be beneficial to all stakeholders involved, including the target communities, and they should be informed prior to research implementation and after.

4.11 Research power balance

Communities will be considered as equal partners in research to promote autonomy, equity and ownership of interventions. Their rights, beliefs, views and opinions are paramount in the planning, implementation and dissemination of study findings; hence they shall be involved at every stage of the project. Among others, the organization will ensure this through Community-Based Participatory Research by involving target communities at every stage of the research process, respecting cultures. indigenous knowledge, provision of informed consent, and co-development of interventions.

4.12 Community's culture, economic and social behaviours

The economic, cultural behaviours, practices and beliefs of the target communities must be respected and taken into consideration during the planning and implementation of the study.

4.13 Research participants' selection

Study participants should be selected through well-defined criteria where applicable. The selection criteria should be clear, fair and just.

4.14 Research repetition and participants' rights

If a study similar to the first is to be conducted again, it should not involve the same participants. This may lead to over-exposure to potential risks, such as psychological, physical and ethical concerns or unfair advantage from the study's benefits. However, if the study is progressing into the second phase, engaging the same community may be appropriate. In such cases, clear ethical guidelines and study protocols should be followed to minimize risks and study burden, and equitable distribution of reasonable risks and benefits while maintaining the study's scientific integrity.

4.15 Participants' reimbursement

When compensating study participants for their involvement in research, it is essential to ensure that the process is fair, transparent, and equal for all participants. This will help to prevent disparities, undue influence and potential of conflicts among the participants. However, reimbursements are not mandatory in every research work and will only be provided where necessary. They are primarily meant to compensate study participants for the costs incurred in the research process. Reimbursement covers direct costs such as travel, registration and food as well as providing non-monetary compensation options such as training and vouchers to prevent it from causing undue influence on the participants. Voluntary participation will also be emphasized through informed consent.

4.16 Study communities' exploitation

The researchers should ensure that research work is conducted ethically, prioritizing the well-being of the communities involved. They should not focus on benefiting from these communities while exposing them to undue hardship or making them incur losses by unreasonably spending their resources and time.

4.17 Consent and ethical approval

All researchers must acquire ethical approval from the relevant and accredited institutions before conducting the study. Consent to participate in the study must also be sought from the study communities involved before collecting any data.

- **Written Consent:** Standard practice requires **signed written consent forms** from all participants.

- **Oral Consent:** In cases where literacy is a barrier, **oral consent** may be obtained, with a neutral third party witnessing the process.

- **Electronic Consent:** For digital and online research, consent can be obtained via **secure electronic forms**.

- **Translated Materials:** Consent forms must be **provided in a language understandable** to the participant.

- **Reconsent Process:** If there are significant changes to the study, participants must be **re-consented** with updated information.

4.18 Special Considerations for Vulnerable Populations

Research involving **vulnerable groups** requires additional ethical safeguards:

- **Children and Minors:**
    - Written **parental or guardian consent** is mandatory.
    - **Assent** (agreement from the child) must be obtained if the child is capable of understanding the study.
    - Researchers must ensure child-friendly, age-appropriate explanations.

- **Individuals with Disabilities or Impaired Decision-Making Capacity:**
    - Additional legal or family representative consent may be required.
    - The researcher must assess the individual's ability to comprehend and make decisions.

- **Indigenous and Marginalized Communities:**

- o Community gatekeepers, elders, or cultural leaders should be consulted.

- o Collective consent may be required alongside individual consent.

- **Refugees, Internally Displaced Persons (IDPs), and Prisoners:**

  - o Extra precautions must be taken to ensure that consent is truly voluntary, given their vulnerable status.

  - o Institutional approvals from the respective authorities may be required.

5.O Noncompliance and Reporting Ethical Issues in Research

Failure to adhere to this policy, ethical research standards, or applicable legal requirements will result in disciplinary action as per the organization's disciplinary measures. The Organization is committed to enforcing strict measures against violations to maintain the integrity and credibility of research activities. Disciplinary actions will be proportional to the nature and severity of the violation and will be carried out in alignment with Kenyan legal frameworks, and applicable international research ethics guidelines. In case you would like to report any issue concerning research we are engaged in, please write to us at: info@zihiinstitute.org with the subject, "Research".

5.O Conclusion

Through these policies, the organization is committed to ensuring that its research work upholds integrity, fairness and respect to all stakeholders involved. All stakeholders are highly encouraged to ensure the implementation of these policies.

6.O Acknowledgment

By signing any terms of reference, agreement, contract, job description documents or any other engagement with the organization, all staff, board members, and stakeholders acknowledge understanding and commitment to these policies.

7.0 Review and Amendments

The policies in this document are subject to regular modification to adapt to evolving and emerging developments. They will be reviewed every 2 years or as necessary to accommodate the emerging changes.

8.0 Approval

Approved by:

Daniel Waruingi

Executive Director, Zihi Institute

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