

**Research Integrity in Kenya, Current Status
and Future Directions subject to your
concurrence.**

By

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Introduction

- The National Commission for Science, Technology and Innovation (NACOSTI), is established by the Science, Technology and Innovation (ST&I) Act, 2013.
- NACOSTI is the successor the National Council for Science and Technology (NCST) which was established by the Science and Technology Act, Cap 250 of the Laws of Kenya in 1977

Mandate of NACOSTI

To **REGULATE** and **ASSURE QUALITY** in Science, Technology and Innovation sector and **ADVICE** Government on matters related thereto.

The Act also gives powers and guiding principles to the NACOSTI in the discharge of its functions.

Functions

Among Others:

- ✓ **Set the priorities in research, science and technology** in Kenya in relation to the economic and social policies of the Government, and the country's international commitments
- ✓ **Register and Accredite** research institutions in Kenya
- ✓ **Approve** all scientific research in Kenya
- ✓ **Assure relevance and quality of ST&I** programs in research institutes.

Functions Cont.d

- ✓ **Coordinate, monitor and evaluate**, as appropriate, activities related to scientific research and technology development
- ✓ **Promote and encourage** private sector involvement in scientific research and innovation development.
- ✓ **Develop and Enforce Codes, Guidelines and Regulations** in accordance with the policy determined under ST&I Act.
- ✓ **Undertake or cause to be undertaken, regular inspections, monitoring and evaluation** of research institutions to ensure compliance with set standards and guidelines.

Research Misconduct- Definitions

Generally **research misconduct** is defined as **fabrication, falsification, or plagiarism** in proposing, performing, or reviewing research, or in reporting research results.

Fabrication: making up data or results and recording or reporting them.

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

Research Misconduct- Definitions

Plagiarism: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

However, research misconduct does not include “honest error” or differences of opinion..

Research misconduct is committed intentionally or recklessly

Other forms of Research Misconduct

- Violation of laws or research regulations or policies
- Misuse of confidential information from peer reviews
- Failure to declare Conflict of interest
- Misrepresentation of qualifications/credentials
- Unethical authorship
- Violation of research subjects, materials etc.
- Unauthorized transfer of materials from the country

Who has the Responsibility of Research Misconduct?

- NACOSTI has the overall mandate of regulation of research in Kenya
- Research institutions/organization which include universities bear the primary responsibility of detection and prevention of research misconduct since this is where research takes place.
- General public
- Research participants/subjects has a responsibility to reporting

Legal Framework for Research Misconduct?- Constitution 2010

Article	Elements
31. Privacy	<ul style="list-style-type: none">• Every person has the right to privacy, which includes: the right not to have information related to their family or private affairs revealed
32 Freedom of Conscience, Religion, Believe and opinion	<ul style="list-style-type: none">• A person shall not be compelled to act, or engage in any act, that is contrary to the person's belief or religion.
33. Freedom of expression	<ul style="list-style-type: none">• Every person has the right to freedom of expression, which includes academic freedom and freedom of scientific research.

Legal Framework for Research Misconduct?- Constitution 2010

Article	Elements
40. Protection of right to property	<ul style="list-style-type: none">• The State shall support, promote and protect the intellectual property rights of the people of Kenya
42. Environment	<ul style="list-style-type: none">• Environment protection for the benefit of present and future generations through legislative and other measures
53. Children	<ul style="list-style-type: none">• Every child has the right to be protected from abuse, harmful cultural practices, hazardous or exploitative labor

Some Provisions of ST&I Act-Licensing of Research

Section	Provisions
12 (1) Requirement for licence to undertake research	<ul style="list-style-type: none">● No person shall undertake research in Kenya without obtaining a research license issued under the ST&I Act.
Section 12 (3)	<ul style="list-style-type: none">● Any person undertaking or intending to undertake research in science and technology in the country, or who accesses, handles, or transfers any material or technology or moves it within, from or into the country, shall apply to the Commission for the grant of a licence in accordance with ST&I Act
Section 14 Procedures, standards, ethics and guidelines	<ul style="list-style-type: none">● This requires a person issued with a license to adhere to such procedures, standards, code of ethics and guidelines as may be

Offences

Section	Provisions
Section 15 Offences	<p>(1) Any person who—</p> <ul style="list-style-type: none">• accesses, handles, transacts, transfers or moves any specified technology or any material necessary for scientific research within, into or from Kenya without a licence issued under this Act; or• contravenes the provisions of section 12, commits an offence and shall, in addition to any other penalty which may be provided for in this Act or any other written law, be liable on conviction to a fine not exceeding five million shillings or to imprisonment for a term not exceeding four years, or both.

Offences

Section	Provisions
Section 15 Offences	2) The Court convicting a person under subsection (1) may in addition to any penalty imposed thereunder, order the confiscation of the materials in respect of which the offence is committed, and may bar the person so convicted from undertaking any further research in the country or transferring or moving any substance or material in or out of the country.

Offences Cont.d

Section	Provisions
Section 15 (3)	<p>For the avoidance of doubt, the technologies or materials imported into or exported out of Kenya and declared under—</p> <ul style="list-style-type: none">(a) the Industrial Property Act (Cap. 509);(b) the Seeds and Plant Varieties Act (Cap. 326);(c) the Wildlife Conservation and Management Act, 2013;(d) the Customs and Excise Act (Cap. 472);(e) the Biosafety Act (Cap. 321A); <p>or any other written law shall be deemed to be technologies or materials to which this section applies.</p>

Registration of Research Institutions

Section	Provisions
Section 16(1) Establishment of research institutions	<ul style="list-style-type: none">• Provides for the establishment and grant of Certificate of Registration to research Institutions
Section 16 (3)	<ul style="list-style-type: none">• Provides that the institute established:<ul style="list-style-type: none">(a) shall have corporate personality;(b) Should specify the duties, powers and functions;(c) Specify the manner in which the institute shall be governed; and(d) such other matters with respect to the conduct and management of the institute, as the CS may find it necessary or desirable to provide for.

Registration of Research Institutions

Section	Provisions
Section 17 and 18	provides for application and grant of Certificate of Registration to established research Institution

Offences Cont.d

Section	Provisions
Section 21 (1) Offence to establish or operate research institutes without authority	Provides that “any person who establishes or operates a research institute without obtaining a Certificate of Registration commits an offence under this Act and shall be liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term of not exceeding than two years or to both.”
Section 21 (2)	Any property, equipment, material or other facilities used in a research institution in contravention of this Act shall be liable to be confiscated by the Commission and disposed of in the manner deemed appropriate by the Commission

Regulations

Section	Provisions
Section 45 (1)	Empowers the Cabinet Secretary to make Regulations for the better carrying out of the provisions of the Act.
45 (2)	Regulations shall prescribe: - (a) standards, guidelines and codes to ensure and maintain standards and ethics in research; (b) the forms to be used in connection with the issuance of licenses under the Act; (c) the manner and form of the registers to be kept; and (d) any other matter for the better carrying into effect of the provisions of the Act.

ST&I Regulations, 2014

The following are the Regulations under the Act:

- **LEGAL NOTICE No. 106:** Registration and Accreditation of Research Institutions Regulations, 2014
- **LEGAL NOTICE No. 107:** Relevance and Quality Assurance in Research Regulations, 2014
- **LEGAL NOTICE No. 108:** Research Licensing Regulations, 2014

National Bioethics Committee

Mandate of National Bioethics Committee

- The National Bioethics Committee (NBC) is established as an advisory committee in accordance with the provisions of sections 9 and 27 of ST&I Act.
- It is multidisciplinary and draws membership from the various institutions across the country.
- The core mandate of the committee is to ensure the highest ethical (professional, moral, social, cultural and legal) standard are maintained in research.

NBC- Composition

NBC was first established in Kenya in 2009. The committee is made up of 11 members constituted as follows:

- i. Experts from different scientific disciplines
- ii. Lawyer
- iii. Lay person

- There is gender and regional balances
- The tenure of each Committee is three (3) years and members could be reappointed
- Current Committee will serve for the period 2018-2021

NBC- functions

The Committee's functions are to:

- Ensure that the highest ethical (professional, moral, social, cultural and legal) standards are maintained in research;
- Consider and review accreditation applications for ethics committees in Kenya;
- Advise on Bioethical policy issues
- Prepare guidelines on bioethics
- Create and enhance awareness on bioethical issues of public concern

NBC- functions Cont.d

- Provide a forum for consultation and informed debate on bioethical issues of public concern;
- Review of protocols referred to the committee; and
- Promote training of Institutional Ethics Review Committees.

NBC- key Achievements

- In total NBC has recommended accredited twenty eight (29) Institutional Ethics Review Committees (IERCs).
- Ensures compliance of the Accredited IERCs through review of annual reports and M&E
- It reviewed and resolved several matters referred to it by the Commission.

NBC- Key Achievements

The committee has prepared a set of guidelines and other documents to be used in the country;

- Material Transfer Agreement (MTA) Guidelines
- Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya
- National Guidelines for the Care and Use of Animals in Research and Education in Kenya
- Curriculum for training IERC members.
- A tool for Monitoring and Evaluation for IERCs
- Guidelines for accreditation of IERCs

Institutional Ethics Review Committees

- NACOSTI has delegated the task of reviewing research proposals for ethical clearance to IERCs. This is to ensure that research conducted in the country observes high standards research ethics.
- 29 IERCs have been accredited by NACOSTI in hospitals, research institutions and universities.
- The number of IERCs is expected to increase given the increase in the number of registered research institutions and Universities.

The Role of IERCs

- Review ethical concerns and clear research protocols with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants;
- Monitor the research study;
- document procedures and prepare annual reports; and
- Examine compliance with all regulatory requirements, applicable guidelines and laws.

Observations- Challenges

- Inadequate mechanisms for protection of whistleblowers for research misconduct

Challenges

- Inadequate policies and guidelines for research misconduct at the institutional level
- Threshold of proof that misconduct was committed intentionally
- An allegation of research misconduct is a lengthy process consist of several steps including: inquiry, investigation and recommendation.
- Some institutions do not report research misconducts for fear of losing credibility

Conclusion

- There exist legal and institutional framework for addressing research misconduct.
- However, the legal framework requires strengthening if it's to effectively address the current and emerging research misconducts challenges.
- NACOSTI will work closely with the key stakeholders to review the legal framework. Discussions are on-going to review ST&I Act.
- Looking forward to the report from the workshop to inform the review process.

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Thanks



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