NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

NATIONAL GUIDELINES FOR ETHICAL CONDUCT OF BIOMEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS IN KENYA

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Foreword

The legal framework for research is provided by the Constitution of Kenya 2010 mainly through the Science Technology and Innovation Act No. 28 of 2013, Industrial Property Act 2001 and Copyright Act 2001. The National Commission for Science Technology and Technology (NACOSTI) oversees research in the country. Any research undertaken in the country therefore requires clearance and authorization by NACOSTI.

The Kenya Vision 2030 envisages significant growth in the knowledge generation. It is expected that growth in research will result in complexity in the management of scientific projects. As such, it is imperative that there is need for guidelines that are consistent with emerging issues so as to ensure quality, value and impact of research. This specific guideline will establish a uniform approach to ethical issues that invariably arise in biomedical research. Along with the existing legal framework, the National guideline for ethical conduct of Biomedical research involving human participants in Kenya will streamline ethical considerations by researchers and reviewers.

In this new edition, additional information on emerging issues in biomedical research such as stem cell research, biobanking among others have been included while recognizing international reference material. Adherence to these guidelines will ensure ethically sound biomedical research in Kenya. This document also provides guidance on research regulations and approval process by Institutional Ethics Research Committees (IERCs).

The guidelines are applicable to all research involving human participants in both conventional and alternative, medicine, social sciences and humanities. All research in public institutions, private institutions, non-governmental organizations or intergovernmental organizations are within the scope of these guidelines. Research conducted using human biological materials collected in Kenya shall also be guided by the provisions herein.

I, therefore, wish to thank NACOSTI for this important milestone and hope that the new edition of the guideline will make a significant contribution towards quality innovative biomedical research in the country.

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Preface to the Second Edition

The first edition of these guidelines was published in 2004, a time when the magnitude of research projects involving human participants was comparatively smaller than it is today. The revision has been necessary to address the developments that have since taken place. Emerging research areas such as stem cell research, biobanking, In Vitro Fertilization among others have led to the need to revise the earlier guidelines.

The Constitution of Kenya 2010 created a provision for academic freedom of scientific research that led to the enactment of Science, Technology and Innovation Act, 2013 with clear regulation of research and establishment of the National Research Fund. There have also been new encounters and greater demand for collaborative studies supported by foreign funding agencies, more foreign researchers coming into the country, occasioned by ever rising need to conduct clinical trials in new populations. This has also been accompanied by more requests for shipment of biological material for analysis, experimentation and storage for future use outside the country. Along with that, there is a rising awareness of the population about rights and demands for information from institutions carrying out research. NACOSTI has also taken cognizance of the developments in the global arena in research, human rights, bioethics and the social constructs of the society in which we live today. Most importantly, the guidelines have been anchored on a number of global normative instruments such as Council for International Organizations of Medical Sciences (CIOMs) and the Universal Declaration on Bioethics and Human Rights.

The above scenario has led to an avalanche of new ethical issues that need to be addressed in guidelines. The Kenyan National Bioethics Committee established in 2009 has risen to these challenges and revised the earlier guidelines prepared in 2004. This is part of the effort to streamline the conduct of research in line with the requirements of the ST&I Act. It is my belief that this guideline will make significant contribution to the quality of biomedical research in Kenya.

The production of this document could not have been possible without dedicated commitment of the members of National Bioethics Committee (2009-2012, 2012-2015, 2015-2018, 2018-2021) who took their time to consider and revise the guidelines in use.

National Commission for Science and Technology is grateful to the secretariat who organized the process particularly the staff of the then Health Science Schedule and the current Directorate of Research, Accreditation and Quality Assurance (DRAQA) for their administrative support: Dr Stephen Karimi, Mr. Boniface Wanyama, Mr. Simon Langat, Ms. Charity Musembi, Mr. Steve Indimuli, Ms. Joan Chepleting and Teresia Nyawira. Finally, NACOSTI is thankful to all the stakeholders who have contributed to this final guideline.

Dr. Moses K. Rugutt, PhD, OGW
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Abbreviations

CIOMS	Council for International Organizations of Medical Sciences
DNA	Deoxyribonucleic Acid
DRAQA	Directorate of Research, Accreditation and Quality Assurance
GCP	Good Clinical Practice
DG	Director General
HIV/AIDS	Human Immunodeficiency Virus, Acquired Immunodeficiency Syndrome
IERC	Institutional Ethics Research Committee
KEMRI	Kenya Medical Research Institute
KEPHIS	Kenya Plant Health Inspectorate Services
KNDI	Kenya Nutritionist and Dieticians Institute
KWS	Kenya Wildlife Services
MoH	Ministry of Health
MTA	Material Transfer Agreement
NACOSTI	National Commission for Science, Technology and Innovation
NBA	National Biosafety Authority
NBC	National Bioethics Committee
NCST	National Council for Science and Technology
NDA	Nutritionists and Dieticians Act
PI	Principal Investigator
PPB	Pharmacy and Poisons Board
TB	Tuberculosis
WHO	World Health Organization

Definitions

Benefit: A favourable consequence arising from a study, for example the demonstration that a vaccine is effective in a randomized controlled trial or the identification of a workplace hazard in an observational study.

Bio bank: A storage place for biological samples (such as human tissue, blood, or DNA) that may be used especially for future research (CDC, 2019).

Bio banking: The practice of creating large-scale repositories of human biological material (e.g. blood, urine, tissue samples, DNA, etc.) designed to further research.

Bioethics: It is a discipline that deals with ethical issues related to medicine, life sciences and associated technologies as applied to human beings, considering their social, legal and environmental dimensions UNESCO (2005).

Biomedical research: Is the broad area of science that involves the investigation of the biological process and the causes of disease and management through careful experimentation, observation, laboratory work, analysis, and testing.

Child: Is any human being under the age of eighteen years.

Compensation: Include offers to participants, monetary or otherwise, to offset the time and inconvenience for participating in research.

Confidentiality: The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities.

Conflict of interest: In the research context, scientists have a conflict of interest if they stand to achieve personal gain (money or the equivalent) by failing to discharge professional obligations, either to protect the welfare of participants or to uphold the integrity of the scientific process.

Consent form: An easily understandable written document that allows the researcher to disclose complete information regarding participation in research and thereby allowing the participants to decide voluntarily.

Ethical guidelines: Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.

Epidemiology: Is defined as the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to control health problems.

Expedited review: Review of proposed research by the IERC chair or a designated voting member or group of voting members rather than by the entire IERC where the risk levels are low or minimal.

Informed consent: Is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subject to coercion, undue influence or inducement, or intimidation.

Device : "An instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar or related article, including a component, part or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man, which does not achieve any of its primary intended purposes/ uses, through chemical action within or on the body of man, or by being metabolized within the body."

Medical devices: A medical device is defined as an inert diagnostic or therapeutic article that does not achieve any of its principal intended purposes through chemical action, within or on the body.

Medicated devices: These are devices that contain pharmacologically active substances which are treated as drugs.

Multi-site research: A research conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.

Personal data: Data that relate to a living person and contain personally identifying information.

Principal investigator (PI): The main researcher overseeing or conducting the research process.

Privacy: The state or condition of being alone, undisturbed, or free from public attention, as a matter of choice or right; seclusion; freedom from interference or intrusion; absence or avoidance of publicity or display; secrecy, concealment, discretion; protection from public knowledge or availability.

Researcher: A person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Institutional Ethics Review Committee (IERC): Group of individuals who undertake the ethical review of research protocols applying agreed ethical principles.

Research involving human participants: Any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings:

i. Are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or
ii. Become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records.

Research protocol: A document that provides the background, rationale, and objective(s) of a research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol.

Risk: The probability that an event, favourable or adverse, will occur within a defined time interval. Although often contrasted to benefit (as in a "risk/benefit ratio"), the term "potential harm" is better for that context, leaving "risk" in its formal epidemiological sense to express the probability of a (typically adverse) event or outcome.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of research.

Standard of Care: This is a level at which the average, prudent provider in a given situation would manage the patient's care under the same or similar circumstances. With respect to research, the CIOMs guidelines stipulate that there should be no double standards and that it is unethical to exploit research participants. Every effort must be made to provide the best available standard of care to the research participants.

Voluntary participation: Performed or done of one's own free will, impulse, or choice; not constrained, prompted, or suggested by another; or free of coercion, duress, or undue inducement. Used in the health and disability care and research contexts to refer to a consumer's or participant's decision to receive health or disability care or to participate (or continue to participate) in a research activity.

Vulnerable research participants: Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

1.0 Background to Biomedical Research Ethics

Prior to 1947, there were no publicly available guidelines for research involving human participants except medical practice ethics. However, in 1947, the Nuremberg Code was developed. The code came into existence as a response to the atrocities the German physicians had carried out on the Jews, Russians and Poles with the help of their government during the Second World War (Nuremburg Code, 1947). These people were subjected to extremely inhuman experimentations that resulted in many deaths; and those who survived were left with severe scarring and other deformities. The objective of the Nuremberg Code was to ensure that such atrocities were not repeated anywhere in the world. The code underscored the importance of voluntary consent of the human participants before being involved in any medical research.

It also underscored the importance of doing experimentation in animals before using human participants in biomedical research. In the United States of America, the scandal such as Tuskegee and Willowbrook 1954-1972, gave rise to the development of the Belmont Report 1975, which was meant to provide broad principles that could be used to generate specific rules and regulations in the conduct of biomedical research involving human participants. It specifically focused on the use of informed consent, favourable risk-benefit ratio, and the need to ensure that vulnerable populations are not targeted for risky research. The Belmont Report (1979) also underscored the importance of honesty in experiments involving human participants.

In 1964, the World Medical Association developed the Declaration of Helsinki document. Its purpose was to provide guidance to physicians and other participants in medical research on ethical principles to be adhered to as they conduct biomedical research involving human participants. Since then the document has undergone multiple revisions in Tokyo, Japan, (1975); Venice, Italy, (1983); Hong Kong (1989); Somerset West, South Africa, in 1996; Edinburgh, Scotland (2000); Washington, USA (2002); Tokyo (2004) and latest in Seoul, Korea (2008), (WMA 2008). In 1982, the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS) published "Proposed International Guidelines for Biomedical Research Involving Human Participants".

The purpose of this document was to give guidance on how the Helsinki Declaration ethical principles could be effectively applied in developing countries, taking into consideration the culture, socio-economic conditions, national laws and executive administrative arrangements. These proposed guidelines were reviewed so as to take into account ethical issues that had arisen from the advent of HIV/AIDS pandemic, such as drug and vaccine trials in human participants. After this review, the 1982 proposed guidelines were superseded by publication in 1993 of "International Ethical Guidelines for Biomedical Research Involving Human Participants" (CIOMS 2016). However, this document has not yet received widespread utility in most African countries. To date, there are some African countries that conduct biomedical research involving human participants with either inadequately constituted ethical committees or in some cases with no ethical committees at all.

In Kenya, the legal framework for research came into existence in 1977 with the enactment of the Science and Technology Act (Cap 250). The Act established the National Council for Science and Technology and public research institutes. The National Council for Science and Technology was empowered by the Act to coordinate all research in Kenya and advise the government on all matters

related to research. This was achieved through the development of procedures and guidelines for research (NSCT 1984). Later, this act was repealed in 2013 as Science Technology and Innovation act No. 28 of 2013 that created National Commission for Science Technology and Innovation (NACOSTI) (Republic of Kenya, 2013). For research of a biomedical nature to be conducted on humans in Kenya, mandatory ethical clearance should be obtained from an accredited IERC. Emerging issues such as biobanking, stem cell research, biological material transfer and artificial Intelligence are posing new ethical challenges in research that must be addressed. This new edition of guidelines, in the spirit of Chapter Four of the Constitution of Kenya 2010 (Republic of Kenya 2010), provides a comprehensive framework for proper regulation of research involving human participants in Kenya.

2.0 Preamble to the Guidelines

Research is defined as any creative systematic activity undertaken to increase the stock of scientific and technical knowledge and to devise new applications. In the case of biomedical research, this means generation of knowledge that could lead to new preventive, prophylactic, therapeutic and diagnostic tools or improvements in current tools for the enhancement of health or well-being of human beings. Research investigations often begin with the construction of hypotheses which are then subjected to well designed and rigorous scientific methodologies and tested statistically under the direction of highly qualified personnel through pre-clinical and clinical phases.

Biomedical research involving human participants, even though they must be well and carefully designed, still may present some risks to the participants involved in research. However, with good research ethics infrastructure in place the potential benefits arising from biomedical research outcomes are valuable (Rugemalila and Kilama, 2001). For these reasons, these guidelines will be useful in managing the tradeoffs between risks and benefits in biomedical research in Kenya.

3.0 General Ethical Principles and other considerations

3.1. General Ethical Principles

All research involving human participants must be conducted in accordance with the following ethical principles.

3.1.1. Respect for persons

This broadly involves the following ethical considerations.

(a) Respect of autonomy, which requires that those capable of deliberating about their personal choices, should be treated with respect for being able to do so.
(b) Vulnerability, where those with diminished autonomy or vulnerable groups are protected against harm or abuse.
(c) Privacy and confidentiality, where the personal identity of the participants is protected, and that any information obtained should not be used or disclosed for purposes other than those for which it was collected or consented to.

3.1.2 Beneficence
This refers to the ethical obligation to maximize benefits and minimize harm or wrongs in all dimensions.

3.1.3. Justice
Treatment of people in accordance with what is morally right and proper. Let people have what is due to them. In a research situation, this means equitable distribution of the benefits and the burdens of the research.

3.2. Other considerations

3.2.1. Compensation of research participants for accident, injury or death
Research participants who suffer physical injury as a result of their participation in the research project have a right to compensation. They will be entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of adverse events, there should be proper assessment, evaluation and compensation.

3.2.2. Obligation of the sponsor regarding compensation
The sponsor whether a pharmaceutical company, a government, an institution, or an individual should agree before the research begins, to provide compensation for any injury that may occur, or agree to provide insurance coverage for an unforeseen injury whenever possible.

4.0: Requirements for conduct of biomedical research in Kenya
This section covers general and specific requirements for biomedical research in Kenya. It further gives in detail special requirements on the key elements of a protocol, informed consent, vulnerable populations, stem cell research, biobanking, secondary/stored data and principles and benchmarks for review of biomedical research.

4.1 General requirements for conduct of biomedical research
Biomedical research involving human participants must conform to national and international accepted scientific and ethical principles.

Before conducting any research involving human participants, the proposal must be approved by an IERC. All clinical trials must also be approved by the Pharmacy and Poisons Board (MOH, 2016).

a) Individuals and organizations who wish to engage in biomedical research involving humans, should affiliate themselves to institutions recognized in Kenya.

b) All biomedical research involving human participants in Kenya should only be conducted by scientifically qualified persons in collaboration with a clinically competent medical person. The safety of the human participants is the sole responsibility of the principal investigator. Biomedical research involving human participants must be preceded by a

careful assessment of risks in comparison with the anticipated benefits to the participants or others. The protection of the participants must always prevail over the interests of science and society.

c) It is mandatory to obtain voluntary and written informed consent for all biomedical research involving human participants.

d) Collaborative research projects should ensure that there is substantial participation by local researchers with clearly identified roles. There should be provision for capacity building, benefits sharing, and technology transfer factored into the proposal.

e) Research involving stem cells, cloning, bio-banks, archived local data, in vitro fertilization, organ transplant, HIV vaccine trials, genetics and any other emerging bio-technologies must adhere to relevant guidelines. This also applies to samples collected and stored in Kenya as well as foreign bio-banks.

f) Research involving vulnerable groups shall be carried out according to national and international guidelines.

g) All research involving human participants must comply with national laws and socio-cultural values.

h) No biological material shall be shipped out of the country without proper justification and authorization. In such a case, there must be a duly signed Material Transfer Agreement approved by the relevant institutions and deposited with NACOSTI. The same principle applies to biological research materials brought into the country. In the case of exportation of biological materials, a Kenyan investigator shall be included in the team to undertake the proposed investigations in the recipient country.

i) All biological samples and data collected during research belong to the local participating institutions and country.

j) Issues pertaining to authorship, publications and intellectual property rights should be addressed adequately to cover the interests of local researchers, institutions and the country during proposal development.

k) Dissemination and utilization of research findings for education and translation into policy, where appropriate, should be addressed during proposal development.

l) All IERCs should carry out regular monitoring of approved protocols involving human participants. In case of any adverse events, the IERC should report immediately to NBC in writing. National Bioethics Committee, upon due diligence process shall terminate at any stage research considered to be harmful to the research participant(s).

4.2. Specific requirements for conduct of biomedical research

4.2.1 Protocol

The following are the key elements of a protocol:

i. The title should adequately capture the essence of the study.

ii. The names, addresses, signatures and updated abridged curriculum vitae of the investigators should be provided.
iii. The Principal Investigator (PI) must provide evidence of prior training in Good Clinical Practice (GCP) (WHO, 1995) , where relevant.
iv. The names and addresses of the collaborating institutions and funding agencies must be provided.
v. A brief summary of the project
vi. Introduction, background and literature review
vii. Study rationale
viii. Study question(s)
ix. Hypothesis/hypotheses where relevant
x. Objectives
xi. Study site, design and methodology
xii. Ethical considerations:
    - Consent explanation- elements of consent explanations
    - Informed consent form with signature provisions for both participants and the principal investigators
    - Risks and benefits
    - Confidentiality
    - Recruitment of participants
    - Compensation
    - Undue inducement and coercion
    - Voluntariness
    - Alternative treatment(s) if available
    - Contacts of the PI/s
    - Contact of IERC
    - Storage of specimen
    - Material Transfer Agreement where applicable.
    - Data management and statistical analysis
xiii. Role of investigators
xiv. Time frame
xv. References
xvi. Budget

4.2.1 Informed consent

The purpose of informed consent is to ensure that individuals control their decisions whether or not they enroll in research and participate only when the research is consistent with their values, interests and preferences (Embleton at al , 2015; UNESCO 2008). Before requesting individuals to participate in research, the investigator must provide the individual with the following information in a language that is simple and comprehensible:

i. Invitation to participate in the research;
ii. Title of the project;
iii. Principal investigator(s) name(s);
iv. Institution where research will take place;

v. Purpose of the research study;
vi. Role of study participants and duration of participation;
vii. Procedures and investigations to be undertaken;
viii. Benefits of the research project;
ix. Unforeseen risks/discomfort;
x. Alternative procedures or treatment (if any);
xi. Confidentiality assurances especially on identifiable records;
xii. Investigators responsibility, if any, to provide medical services to the participant in case of injury;
xiii. Disclosure of alternatives: a statement on disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to participants when the research involves non-validated procedures, devices or therapies
xiv. Storage and exportation of biological samples;
xv. Storage and ownership of data;
xvi. Compensation, if any;
xvii. Non-coercive disclaimer /voluntariness to participate and to withdraw at any time with no loss of benefits;
xviii. Dissemination of findings ;
xix. Un-blinding where applicable;
xx. Consent to incomplete disclosure: In some cases, it is necessary to inform participants that some information is being withheld deliberately and the grounds supporting that decision, however, an offer to disclose the purpose at the conclusion of the study can be made
xxi. Contacts of the Principal Investigator and IERC;

Important notes: All consent for biomedical research must be written. In no case should collective community agreement or the consent of a community leader or other authority substitute for an individual informed consent. The consent form must include statement about the study, recruitment procedures, benefits, risks, compensation, voluntariness, confidentiality statement, researchers' and IERC contact information and signage page.

4.2.2 Vulnerable populations

The ethical issues that need to be considered in vulnerable populations include competence of the participant, disclosure of information by the participants, voluntariness, comprehension and compensation to the research participants (Embleton et al 2015; Gómez, 2016). Vulnerable populations covered under this section include: children, infants, neonates, fetus, embryos, zygotes, pregnant, lactating and breastfeeding women, prisoners, disciplined forces, terminally ill patients, homeless populations, communities in low resource settings, elderly/senior citizens, superior/sub-ordinate relations, persons with physical, mental or behavioural challenges. These individuals are open to exploitation whether physical, emotional or psychological. The context of vulnerability is well stipulated in (UNCST (2007), Children Act (Republic of Kenya, 2012a), and Gómez (2016).

4.2.2.1. Research involving children, infants, neonates, fetuses, embryos and zygotes

Before conducting research in children, the investigator must ensure that:

i. Children will not be involved in research that can equally be carried out in adults.
ii. The purpose of the research is to generate knowledge relevant to the health needs of children.
iii. A parent or legal guardian must give proxy consent. In children above the age of seven years and below the age of eighteen years where the parents or the legal guardian gives proxy consent, assent must be obtained from the child. However, if a child refuses to participate in the research, that refusal must be respected unless there's no other medical alternative from which the child could benefit.
iv. The risk presented by interventions not intended to benefit the child is low and commensurate with the importance of the knowledge to be gained.
v. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child as any available alternative.
vi. Potential parent(s) can make decisions on behalf of the foetus(es), embryo(s) and Zygote(s). Foetal, embryo and zygote(s) research should be limited to:
    a. Cases which present no harm or offer assistance to the life system of the participants.
    b. No procedures should be permitted which are likely to harm them.
    c. A foetus ex utero and alive, embryo and zygote should not be involved in research unless it is intended to enhance the life of that foetus, embryo and zygote or unless the research involves no risk to them.

4.2.2.2 Research involving persons with physical, mental or behavioural challenges

An investigator must ensure that before undertaking research in individuals with physical, mental or behavioural challenges and who are incapable of giving adequately informed consent, that the following conditions are fulfilled:

i. Such persons will not be participants of research that might equally be carried out on persons in full possession of their mental abilities.
ii. The knowledge gained would be relevant to the particular health needs of persons with physical, mental or behavioural challenges.
iii. The consent of the participant has been obtained to the extent of that participant capabilities and a prospective participant's refusal to participate in biomedical research is always respected.
iv. The degree of risk attached to the intervention not intended to benefit the individual participant is low and commensurate with the importance of knowledge to be gained.
v. In the case of incompetent individuals, informed consent shall be obtained from a legal guardian or other duly authorized person.
vi. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual participant as any alternative.

4.2.2.3 Research involving prisoners

There are opposing and persuasive arguments for and against doing research in prisons. Although no international declarations bar prisoners from participating in research, the opposing arguments preclude an internationally agreed recommendation. In many developing countries including

Kenya, prison conditions are very harsh, i.e., low quality or inadequate diet, poor linen and accommodation. The prisoners are always under fear of reprisals from the prison wardens if they do not comply with any instructions given to them. However, prisoners with serious illness or at risk of serious illness, e.g., HIV/AIDS, hepatitis, cancer and TB should not be denied access to investigational drugs, vaccines or other agents that show promise of therapeutic or preventive benefit. In a situation where an investigator wishes to conduct biomedical research in Kenya on prisoners, given the above conditions in Kenyan prisons, he must ensure that the prisoners actually give consent in conditions where there is no fear of reprisals from wardens if one chooses not to participate in the particular study. The IERC giving clearance must ensure that there will be independent monitoring of the research projects to assure the protection of rights and the dignity of the prisoners involved in the research.

4.2.2.4 Research involving pregnant, lactating and breastfeeding women

Vulnerability in pregnant, lactating and breastfeeding women is often associated with compromised long-term outcomes for the child. Below is the guideline for research involving such groups:

a) Pregnant, lactating or nursing women should in no circumstances be participants in clinical research unless the research carries no more than minimal risk to the foetuses or nursing infants.
b) As a general rule pregnant, lactating or nursing women should not be participants in clinical research except where such research are designed to protect or advance the health of the pregnant or nursing women, or foetuses or nursing infants and for which women who are not pregnant or nursing would not be suitable participants.
c) The justification for such research should be that participants must not be arbitrarily deprived of the opportunity to benefit from investigational drugs, vaccines or other agents that promise therapeutic or preventive benefits.

4.2.2.5 Research involving communities in low resource settings

Investigators conducting research in low resource settings must ensure that:

a) Persons in such settings should not be involved in research that could be carried out reasonably well in developed communities.
b) The research should be responsive to the health needs and priorities of the community in which it is to be carried out.
c) Undue inducement to participate in the research is avoided at all costs.

4.2.2.6 Research involving the homeless populations

Investigations involving street children and adults, internally displaced persons and refugees must ensure that:

i. They are protected from gross violation of human rights;
ii. There is strict adherence to ethical principles.

4.2.2.7 Research involving disciplined forces

Members of disciplined forces involved in research maybe vulnerable because of the conditions of their service and this may affect their ability to make voluntary decision regarding their participation in research. Research involving disciplined forces must ensure that:

i. They are protected from gross violation of human rights;
ii. There is strict adherence to ethical principles;
iii. At least one member of the IERC (co-opted) approving such research is an enlisted and authoritative member of disciplined forces.

4.2.2.8 Research involving terminally ill Patients

Terminally ill patients are those individuals who have an incurable medical condition. Their state may affect their ability to make voluntary decisions regarding their participation in research projects. Research involving terminally ill patients must fulfill the following requirements;

i. Such research can only be conducted in this group and that the objectives of the project(s) cannot achieved using another non-vulnerable group;
ii. There is strict adherence to ethical principles;
iii. The risk-benefit ratio should be favourable to the research participant.

4.2.2.9 Research involving elderly/senior citizens

A senior citizen or an elderly is defined in the Laws of Kenya as a person who has attained the age of sixty-five years. Their physical or mental state may affect their ability to make voluntary decisions regarding their participation in research projects according to CIOMs 2016 guidelines. Researching involving the elderly or senior citizen must fulfill the following requirements:

i. Strict adherence to ethical principles;
ii. The risk-benefit ratio should be favourable to the research participant;
iii. They must be protected from gross violation of human rights.

4.2.2.10 Research involving superior/sub-ordinates

These are researches that are involving data collection by superiors on their sub-ordinates such as employer-employee, teacher-students, supervisor-staff, sponsor-dependent and parent-children. This relationship impairs independent consent by the participants leading to complacency. Therefore, research involving the superior/sub-ordinate must fulfill the following requirements:

i. The superior/sub-ordinate must strictly follow ethical principles to avoid undue pressure;
ii. They must be protected from gross violation of human rights;
iii. As in all research with special and vulnerable populations, it must be borne in mind that their design must obey the need to know and improve the particular conditions of the subjects under study.

4.2.3 Stem cell research

Stem cell research in Kenya is an emerging area of scientific research. Stem cells have the remarkable potential to develop into many different cell types in the body during early life and growth (ICMR, 2007)Stem cells are distinguished from other cell types by the following important characteristics:

i. They are unspecialized cells capable of renewing themselves through cell division, sometimes after a long period of inactivity

ii. Under certain physiologic or experimental conditions, they can be induced to become tissue or organ specific cells with special functions.
iii. Stem cell research has been ongoing for a long time. Embryonic stem cells offer hope for new therapies but their use in research has raised a lot of controversies and ethical issues. Researchers are referred to specific national and international guidelines regarding research in this area.

Like any branch of science, stem cell research must be guided by a set of ethical principles (Lo and Parham, 2009). According to Lahiry et al, 2019 the health, safety, and rights of the donor are of the utmost importance under all circumstance. Scientific consideration must be sound with clarity on what basic and translational research is required including the levels of manipulation. Stem cell research may also require clear categorization of research with clear indication of what is permissible, restricted and prohibited and that consideration of banking, procurement and exchange must be handled correctly. Stem cell research in Kenya must fulfill the following requirements:

i. Adherence to national and international guidelines and ethical principles
ii. Must be conducted within the existing legal framework

4.2.4 Biobanking

A biobank is a collection of biological samples, which are stored for long periods of time, mainly for research purpose. Different types of samples can be collected and stored including whole organs, skin tissue, breast milk, hair, blood, saliva among other human biological material. From these samples, specific types of cells or genetic material can be derived for research, diagnostic and therapeutic purposes. Banking of biological samples involves risks concerning personal information that may be misused and this undermines autonomy, privacy and confidentiality. Bio banking guidelines set out applicable principles and best practices.

The creation of biobanks and their use in research should fulfill the following requirements:

i. Provide a resource for research that is valued by society and conducted within applicable local and international laws, regulations and ethical frameworks.
ii. Ensure the collection, storage and transfer, access, use and disposal of participants' samples and data are scientifically, legally and ethically appropriate.
iii. Secure the sustainability of the biobank, the protection of participants' privacy, the confidentiality of data and public trust.

4.2.5 Use of secondary data/Stored Samples

Use of personal data must conform with the legal requirement in accordance with the Data Protection Act No. 24 of 2012 (Republic of Kenya 2012e). The principle of informed consent demands that the person is adequately made aware of the use of the secondary data or stored biological material provided. There are, however, situations where opportunities to use already collected data or biological material for another research only appear later on. The secondary use of data requires approval by an accredited IERC. Since it is not practical for participants to give blanket consent, whenever possible, the researcher shall seek consent from the participants for the new study. For situations where this is not practicable, the relevant accredited IERC will give approval for waiver of individual consent following confirmation that the study participants had consented to storage of the biological samples/data which should be completely delinked from personal identifiers.

In cases where the sample is stored in a foreign institution, the collaborating national research ethics committee or an equivalent will deliberate and make appropriate decision regarding approval. Researchers sending samples abroad should ensure that consent for transfer of materials/ Material Transfer Agreement was obtained during collection of the samples and that the collaborating institutional ethics committee and other institutions charged with such mandate give approval accordingly.

4.2.6 Principles and benchmarks for review of biomedical research

Ethical requirements for clinical research aim to promote quality generation of knowledge while minimizing the possibility of participant exploitation by ensuring that they not used as subjects but are treated with respect. (ICMR 2006; CIOMS, 2016).

Below are the key principles and benchmarks for the review of biomedical research:

a) **Value**

The overall goal of clinical research is that it must be ethical and beneficial to the society. It further evaluates diagnostic or therapeutic interventions that could lead to improvements in health or well-being through etiological, patho-physiological, or epidemiological study.

There are two fundamental reasons why social, scientific, or clinical value should be an ethical requirement: responsible use of finite resources and avoidance of exploitation. Research resources are limited because of competing interests with social pursuits. Researchers should always avoid exposing human beings to potential harm.

b) **Scientific Validity**

Research must be conducted in a methodologically rigorous manner in conformity with the Singapore statement (Singapore Statement 2010). Even research asking socially valuable questions can be designed or conducted poorly and produce scientifically unreliable or invalid results. As the CIOMS guidelines (2016), succinctly state: Scientifically flawed research on human participants is unethical in that it may expose participants to risks or inconvenience to no purpose.

c) Fair participant Selection

The selection of participants must be fair. Participant selection encompasses decisions about who will be included both through the development of specific inclusion and exclusion criteria and strategy adopted for recruiting participants, such as which communities, which study sites and which potential groups will be approached. There are several facets to this requirement.

i. Participant selection requires that the scientific goals of the study, not vulnerability, privilege, or other factors unrelated to the purpose of the research, be the primary basis for determining the groups and individuals that will be recruited and enrolled

ii. Groups or individuals should not be excluded from the opportunity to participate in research without a good scientific reason or susceptibility to risk that justifies their exclusion. It is important that the results of research be generalizable to the populations that will use the intervention.

iii. Efficiency cannot override fairness in recruiting participants.

iv. Fairness requires that equitable selection of participants is considered in research, unless there is good reason, such as excessive risk, to exclude a particular group. Participants should be selected to minimize risks and enhance benefits to individual participants and society

v. Fair participant selection should be guided by the scientific aims of the research and is justified by the principles that equals should be treated similarly and that both the benefits and burdens generated by social cooperation and activities such as clinical research should be distributed fairly. This does not mean that individual participants and members of groups from which they are selected must directly benefit from each clinical research project or that people who are marginalized, stigmatized, powerless, or poor should never be included. Instead, the essence of fairness in research on human participants is that scientific goals, considered in dynamic interaction with the potential for distribution of risks and benefits, should guide the selection of participants.

d) Favourable Risk–Benefit Ratio

Favourable risk-benefit ratio should consider the following aspects:

1. Risk benefit ratio embodies the principles of beneficence and non-maleficence, long recognized as fundamental values of clinical research.
2. Clinical research involves drugs, devices and procedures about which there is limited knowledge.
3. Clinical research can be justified only if, consistent with the scientific aims of the study and relevant standards of clinical practice and fulfill the following conditions:
   i. The potential risks to individual participants are minimized,
   ii. The potential benefits to individual participants are enhanced,
   iii. The potential benefits to individual participants and society are proportionate to or outweigh the risks.
4. Assessment of the potential risks and benefits of clinical research by researchers and IERCs are thoroughly evaluated.
5. Risks are identified and, within the context of good clinical practice, minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
6. Potential benefits are delineated and enhanced. Assessment of the research plan should determine if changes could enhance the potential benefits for individual participants. However, extraneous benefits, such as payment, or adjunctive medical services, such as the possibility of receiving a hepatitis B vaccine not related to the research, cannot be considered in delineating the benefits compared with the risks, otherwise simply increasing payment or adding more unrelated services could make the benefits outweigh even the most risky research (Krugman, 1986). Furthermore, while

participants in clinical research may receive some health services and benefits the purpose of clinical research is not the provision of health services. Services directly related to clinical research are necessary to ensure scientific validity and to protect the well-being of the individual research participant.

7. Clinical research that presents no potential benefits to individual participants, such as phase 1 safety, pharmacokinetic, and even some epidemiology research, or when the risks outweigh the potential benefits to individual participants should be appropriately evaluated.
8. When research risks exceed potential benefits to individuals and or the benefit of useful knowledge to society, the clinical research is not justifiable.

e) **Independent Review**

1. Independent review by individuals unaffiliated with the clinical research helps minimize the potential impact of conflicts of interest. Whenever necessary, expertise can be outsourced where this is lacking in the accredited IERCs.
2. For some research with few or no risks, independent review may be expedited, but for much of clinical research, review should be done by a full committee of individuals with a range of expertise and have the authority to approve, amend or terminate a study.
3. Independent review of clinical research is also important for social accountability. Clinical research imposes risks on participants for the benefit of the society.
4. Review also assures people that if they enroll in clinical research, the trial is ethically designed, and the risk-benefit ratio is favourable.
5. In Kenya, evaluation of scientific research is done through accredited IERCs.

f) **Informed Consent**

Informed consent is the most important document to be reviewed by the IERCs. Each element of informed consent is necessary to ensure that individuals make rational and free determinations of whether the research is in consonance with their interests (see section on informed consent above). In emergency settings that preclude time for identifying and eliciting the consent of a proxy decision maker, research can proceed without either informed consent or permission of proxy decision makers when conducted under strict national and international guidelines. More importantly, there should be clinical equipoise, the absence of consensus regarding the comparative merits of the interventions to be tested. In such a case, the participant is not any worse off by enrolling.

g) **Respect for Potential and Enrolled Participants**

Ethical requirements for clinical research do not end when individuals either sign the consent form and are enrolled or refuse enrolment. Individuals must continue to be treated with respect from the time they are approached even if they refuse enrolment throughout their participation and even after their participation ends.

(i) Respecting potential and enrolled participants entail the following:

a. Privacy must be respected by managing the information in accordance with confidentiality rules.
b. Permitting participants to change their mind, to decide that the research does not match with their interests, and to withdraw without penalty.
c. New information gathered during the research must be provided to the study participants.
d. The welfare of participants should be carefully monitored throughout their research participation. If participants experience adverse reactions, untoward events, or changes in clinical status, they should be provided with appropriate treatment and, when necessary, removed from the study.
e. The research participants' contribution to clinical research should be recognized and there should be some mechanism to inform them of what was learned from the research.
f. It is imperative that the confidentiality of the research participants is maintained throughout and after the research project.

5.0 Principles for conducting clinical research

Studies designed to evaluate safety, effectiveness, or usefulness of an intervention includes research on therapeutic, diagnostic procedures and preventive measures including vaccines. It is essential to carry out research on human participants to discover better medical and therapeutic modalities. This type of research is associated with special clinical features and may have unique risks.

These guidelines address drug trials, vaccine trials, devices and other diagnostic materials, trials with herbal remedies, among others. Community representatives and researchers shall work together to make sure that research is conducted in the most appropriate way and the benefits shared (Emanuel et al 2008 & Beecher, 1966).

5.1 Multi-site research

A multisite trial is conducted simultaneously by several investigators at different centres following the same protocol. Ideally, these trials should be initiated at the same time at all the centres.

All the Investigators should give a written acceptance of the protocol provided by the sponsor which may be modified to suit the local requirements and should be followed for the trial duly approved by the ethics committee of the host institutes. Meetings should be organized at the initial and intermediary stages of the trial to ensure uniform procedures at all centres.

Training should be imparted to research staff at the participating centres to familiarize them with the uniform procedures. Standardization of methods for recruitment and evaluation/monitoring of laboratory procedures and conduct of trial should be carried out. There should be monitoring of adherence to protocol including measures to terminate the participation of some centres, if necessary.

Centralized data management and analysis should be planned as per the WHO's "Operational Guidelines for the Establishment and Functioning of Data and Safety Monitoring Boards".

Drafting of a common final report and publication procedure should be decided at the onset. No individual centre should publish any data till appropriate authorities accept the combined report.

5.2 Drug and Nutritional Product Development

Clinical trial of drugs and nutritional products are randomized single- or double-blind controlled study in human participants, designed to evaluate prospectively the safety and effectiveness of new drugs and new nutritional products formulations. The proposed trial should be carried out in accordance with the guidelines set out by the Pharmacy and Poisons Board (PPB) and Kenya Nutritionist and Dietician Institute (KNDI). The investigator should also get the approval from relevant IERCs before submitting the proposal to PPB and KNDI. All the guiding principles should be followed irrespective of whether the drug or nutrient has been developed in Kenya or abroad or whether clinical trials have been carried out elsewhere. PPB Act (Cap. 244) (Republic of Kenya 2012b) and NDA Act (Cap.253B) (Republic of Kenya, 2012c).

5.2.1 Phases of Clinical Trials

All phases require approval from relevant IERCs and government authorities.

Phase I refers to the first introduction of a drug into humans. Normal volunteer participants are usually studied to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness. Children are not involved at this stage of development.

Phase II investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients. Children may be involved if there is evidence from adult participants that the drug has therapeutic benefit to them.

Phase III trials are performed after a reasonable probability of effectiveness of a drug or nutritional product has been established and are intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug/nutrient-related adverse effects. This phase includes both controlled and uncontrolled studies.

Phase IV trials are conducted after the national drug registration authority and Republic of Kenya registration of food/dietary (info trade Kenya) has approved a drug for distribution or marketing. These trials may include research designed to explore a specific pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug or nutritional product. Phase IV trials may also be designed to evaluate a drug or nutritional product in a population not studied adequately in the pre-marketing phases (such as the vulnerable population) or to establish a new clinical indication for a drug or nutritional product.

5.2.2 Special Ethical Considerations in clinical trials

(a) Denial of any available treatment to the control (placebo) group in placebo-controlled trials is unethical.

(b) Throughout the drug or nutritional product trials, the distinction between therapy and research should be maintained.

(c) A physician /investigator who participates in research by administering the new drug or nutritional product to consenting participants should ensure that the participants understand that the drug or nutritional product is experimental.

(d) The criteria for termination of a trial must be clearly defined

5.3 Vaccine Development

Vaccines can be prophylactic and therapeutic in nature. While prophylactic vaccines are given to normal participants, therapeutic or curative vaccines may be given to patients suffering from particular disease. Many of the prophylactic vaccines are given to paediatric groups. The guidelines to conduct the clinical trial on investigational vaccines are similar to those governing a drug trial. Refer to guidelines for conduct of clinical trials in Kenya, PPB (2016) and ICH (2018). **Phase I** refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration and usually involves fewer than 100 volunteers. Children are never suitable candidates during this phase of vaccine development.

Phase II refers to the initial trials examining effectiveness in a limited number of volunteers (usually between 200 and 500); the focus of this phase is immunogenicity. Children are not suitable research participants. However, a phase II vaccine trial seeking evidence of immunogenicity in infants may be justified in the case of a vaccine that has shown evidence of preventing or slowing progression from asymptomatic HIV infection to disease in adults.

Phase III trials are intended for a more complete assessment of safety and effectiveness in the prevention of disease, involving a larger number of volunteers in a multi-centre adequately controlled study.

Phase IV Studies are done in the entire population or a sub-group to detect the rarer or unexpected events that may not be seen in smaller Phase II/ III studies. Post-licensure studies of large populations, in a more heterogeneous group of people, over longer periods of time are necessary to provide on-going assessment of vaccine safety and effectiveness. The pharmaco-dynamic studies provide information on the vaccines when other routes of administration are claimed. These are also done to conduct further research on age at vaccination, effect of simultaneous administration of other vaccines, efficacy and adverse events due to changes in vaccine strain, and interchangeability of vaccine. Bridging studies in vaccine trials are conducted to support clinical comparability of efficacy, safety and immunogenicity of new formulation when there is change in vaccine composition with regard to adjuvant, preservative, or a change in manufacturing process, site or scale. These are performed either before or after product licensure.

Special Ethical Considerations in vaccine development

1. Some vaccines that contain active or live - attenuated micro-organisms can possess a small risk of producing that particular infection. The participant to be vaccinated should be given adequate information about the adverse effects.
2. Should participants in the control group contract the disease for which a vaccine is being tested, free treatment should be provided.

3. The risks associated with vaccines produced by recombinant DNA techniques are not completely known. Therefore, guidelines issued by the Pharmacy and Poisons Board should be strictly followed.
4. Post-trial access to the vaccine should be available to the control group.

5.4 Clinical Trials using Surgical Procedures/Medical Devices

Biomedical devices used in diagnostic and therapeutic services require systematic and rigorous evaluation in order to establish and ensure their quality, safety and efficacy.

Special Ethical Considerations:

1. Data on safety in animal should be available prior to research in humans.
2. Study design of the intra-body devices such as dental, family planning, cornea and heart implants should have adequate protective safeguards.

5.5 Use of Radio -active Materials and X-rays

Different radiations, radiopaque contrast agents and radioactive materials are used for investigation and treatment purposes. The relative risks and benefits of the study utilizing radioactive materials or X-rays should be evaluated.

Use of such materials should be in accordance with the limits set by the relevant regulatory authorities in Kenya under the Radiation protection Act (Cap. 243) (Republic of Kenya , 2012d)..

Special Ethical Considerations:

1. For radioactive devices, information to be gained should be gathered using methods that do not expose participants to more radiation than acceptable limit levels.
2. Safety measures should be taken to protect research participants and others who may be exposed to radiation.
3. The protocol should make adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo.
4. Non-radioactive diagnostic agents are considered as drugs and the same guidelines should be followed when using them.

5.6 Clinical Evaluation of Traditional Remedies and Medicinal Plants

Complementary alternative medicine remains popular. Traditional remedies undergoing research should be subjected to the same scientific and ethical standards as other drugs.

When an ethno-medical product is ready for commercialization after it has been scientifically found to be effective, the legitimate rights of the community from which the knowledge was obtained should appropriately be considered while applying for the Intellectual Property Rights for the product.

6.0 Collaboration and partnerships in biomedical research

In collaborative research projects different levels of development in terms of infrastructure, expertise, social and cultural perceptions, and laws relating to intellectual property rights necessitate an ethical framework to guide collaboration.

Ethical Considerations:

1. The collaborating investigators, institutions and countries should function as equal partners by building appropriate safeguards.
2. There should be safeguards to avoid exploitation of local researchers and participants.
3. An external sponsoring agency should submit the research protocol to IERC according to the standards of the country of the sponsoring agency, additionally IERC clearance in Kenya where the research is to be conducted is mandatory.
4. Externally sponsored research designed to develop a therapeutic, diagnostic or preventive product must be responsive to the health needs of Kenya.
5. The sponsoring agency should agree in advance of the research that any product developed through the research will be made reasonably accessible to the community in which the research was conducted.
6. Consideration should be given to the sponsoring agency agreeing to maintain health services and faculties established for purposes of the study in Kenya after the research has been completed.
7. Such collaborative research should help to develop capacity for similar research in Kenya.
8. Such collaborative research must have a local/Kenyan peer Co-Principal Investigator
9. Sharing of benefits

7.0 Research regulation in Kenya

The ethical standards for Biomedical research must conform with the existing legal framework in addition to international normative practices such as those outlined by the World Health Organization (WHO, 2011; WHO 2000). This section contains information on research regulation, approving bodies, membership requirements, terms of appointment and conditions of appointment. It further gives details on offices for good functioning of IERCs, quorum requirements, independent consultants, education of IERC members and dispute resolution mechanism.

7.1 NACOSTI, NBC, IERCs

This section covers details on the functions of NACOSTI, NBC and IERCs.

NACOSTI

Institutions setting up ethics review committees should alongside this section familiarize themselves with the Accreditation Guidelines published by the NACOSTI.

NBC

National Bioethics Committee is set up by NACOSTI to advice it on matters of research ethics

IERCs

The purpose of an IERC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants. In their composition, procedures and decision making, IERCs need to have independence from political, institutional, professional and market influences. IERCs should be constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive and to ensure that their tasks can be executed free from bias and influence that could affect their independence.

IERCs should be multidisciplinary and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community and IERCs should be established in accordance with the applicable laws and regulations of Kenya and in accordance with the values and principles of the communities they serve.

IERCs should establish standard operating procedures that state the authority under which the committee is established, the functions and duties of the IERC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of secretariat, internal procedures, and the quorum requirements. IERCs should act in accordance with their written operating procedures.

Decisions on research protocols designated for review by the IERC are based on a thorough and inclusive process of discussion and deliberation. Protocols involving no more than minimal risk and burden to research participants may be reviewed on an expedited basis by one or more members (rather than the full committee), if the IERC has established written procedures permitting such a process IERCs should have elaborate written policies and procedures that specify the IERC's membership, committee governance, review procedures, decision-making, communications, follow-up, monitoring, documentation and archiving, training, quality assurance, and procedures for coordination with other IERCs.

IERCs should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the IERC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of secretariat, internal procedures, and the quorum requirements. IERCs should act in accordance with their written operating procedures**.**

IERC members have a need for initial and continued education regarding the ethics and science of biomedical research.

7.1.1 Membership Requirements for IERCs

Clear procedures for identifying or recruiting potential IERC members should be established. Membership requirements should be established that include the following:

1. the name or description of party responsible for making appointments;
2. the procedure for selecting members, including the method for appointing a member (e.g., by consensus, by majority vote, by direct appointment);
3. conflicts of interest should be avoided when making appointments, but where unavoidable there should be transparency with regard to such interests.

A rotation system for membership should be considered that allows for continuity, the development and maintenance of expertise within the IERC, and the regular input of fresh ideas and approaches.

7.1.2 Terms of appointment

Terms of appointment should be established that include the following:

i. The duration of an appointment,
ii. The policy for the renewal of an appointment,
iii. The disqualification procedure,
iv. The resignation procedure,
v. The replacement procedure.

7.1.3 Conditions of Appointment

A statement of the conditions of appointment should be drawn up that includes the following:

i. A member should be willing to publicize his/her full name, profession and affiliation;
ii. All reimbursement for work and expenses, if any, within or related to an IERC should be recorded and made available to the public upon request;

iii. A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters; in addition, all IERC administrative staff should sign a similar confidentiality agreement.

7.1.4 Offices

i. IERCs should establish clearly defined offices for the good functioning of ethical review. A statement is required of the officers within the IERC (e.g., chairperson, secretary), the requirements for holding each office, the terms and conditions of each office, and the duties and responsibilities of each office (e.g., agenda, minutes and notification of decisions). Clear procedures for selection or appointing officers should be established.

ii. In addition to the IERC officers, an IERC should have adequate support staff for carrying out its responsibilities.

7.1.5 Quorum Requirements

IERCs should establish specific quorum requirements for reviewing and deciding on applications. These requirements should include:

i. The minimum number of members required to compose a quorum (e.g., more than half the members);

ii. The professional qualifications requirements (e.g., physician, lawyer, statistician, paramedical, layperson) and the distribution of those requirements over the quorum; no quorum should consist entirely of members of one profession or one gender; a quorum should include at least one member whose primary area of expertise is in a non-scientific area, and at least one member who is independent of the institution/research site.

7.1.6 Independent Consultants

IERCs may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IERC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, participants, or special interest groups. Terms of reference for independent consultants should be established.

7.1.7 Education for IERC Members

IERC members have a need for initial and continued education regarding the ethics and science of biomedical research. The conditions of appointment should state the provisions available for IERC members to receive introductory training in the work of an IERC as well as on-going opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of IERC members. This education may be linked to co-operative arrangements with other IERCs in the area, the country, and the region, as well as other opportunities for the initial and continued training of IERC members.

7.1.8 Dispute Resolution

i. IERCs should have specific procedures and a clear mechanism for dispute resolution.

ii. Where an applicant is dissatisfied with the initial decision of an IERC, he/she should apply for review to the same IERC.

iii. A further appeal lies with the National Bioethics Committee (NBC).

iv. The NBC will deliberate and inform the aggrieved parties of its decision.

v. The NBC decision will be final.

7.2 Regulatory Agencies

The following list of agencies in Kenya:

i. Kenya Plant Health Inspectorate Services;
ii. Pharmacy and Poisons Board;
iii. Ministry of Health(MoH);
iv. Kenya Wildlife Services ;
v. Kenya Nutritionist and Dietician's Institute;
vi. National Biosafety Authority.

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