NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

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

2018

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Chairperson
National Commission for Science, Technology and Innovation

Foreword

Kenya has a fairly elaborate research system comprising of regulatory and executing institutions. The research system comprises the National Commission for Science, Technology and Innovation (NACOSTI); the Ministry responsible for research; public research institutes; commodity-based research institutes; institutions of higher learning; and private institutions and non-governmental organizations.

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

The Kenya Vision 2030 envisages significant growth in the knowledge production sector. It is expected that growth will result in more complexity in the management of scientific projects. Guidelines will establish a uniform approach to ethical issues that invariably arise whenever new methods are sought. Along with the improving legal framework, the guidelines will streamline ethical considerations both by researchers and reviewers.

In this document ethical guidelines have been developed using internationally recognized reference material. Adherence to these guidelines will ensure ethically sound research involving human participants in Kenya. The document also provides guidance on constitution of ethical committees.

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

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Overview of the Second Edition

The first edition of these guidelines was published in 2004, when the scale of research projects involving human participants was comparatively smaller than it is today. This revision was necessary to address developments that have since taken place. New ethical situations arise as more research projects are developed, because research by its nature involves developing and testing novel ideas. The research enterprise worldwide continues to create new ethical situations that require analysis and resolution. Several circumstances have made it especially important to revise the guidelines at this stage in the development of the national research enterprise.

Kenya adopted a new Constitution in 2010. Since then, there have been new developments in areas such as stem cell research, greater demand for collaborative studies supported by foreign funding agencies, increased participation of foreign researchers in the country, growing demand for trials in new populations, and more requests for shipment of tissues for experimentation and storage outside Kenya. At the same time, public awareness of rights and demand for information from research institutions have increased. These guidelines also take cognizance of global developments in research, human rights, bioethics, and the social context in which research takes place. Most importantly, the guidelines are anchored in principles endorsed by the Universal Declaration on Bioethics and Human Rights.

These developments have generated new ethical issues that must be addressed in updated guidelines. The National Bioethics Committee, which did not exist in 2004, has risen to this challenge by revising the earlier document. This revision forms part of ongoing efforts to streamline the conduct of research in line with Kenya's current needs. Like the first edition, these guidelines remain a living document and will be revised periodically based on experience gained from their application. It is my belief that this document will make a useful contribution to the research community in Kenya.

Amina Muhammed
Cabinet Secretary, Ministry of Education
March, 2018

Abbreviations

CIOMS	Council for International Organisations of Medical Sciences
DNA	Deoxyribonucleic Acid
EC	Ethics Committee
GCP	Good Clinical Practice
HIV/AIDS	Human Immunodeficiency Virus, Acquired Immunodeficiency Syndrome
IERC	Institutional Ethics Review Committee
KEMRI	Kenya Medical Research Institute
NBC	National Bioethics Committee
NCST	National Council for Science and Technology
NACOSTI	National Commission for Science, Technology and Innovation
PI	Principal Investigator
PPB	Pharmacy and Poisons Board

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.

Biobank: An organized collection of human biological materials and associated data stored for current or future research, diagnostic, therapeutic, or public health purposes under approved governance arrangements.

Biobanking: The process of collecting, processing, storing, managing, accessing, transferring, using, and disposing of biological samples and related data in accordance with scientific, legal, and ethical requirements.

Bioethics: A field of ethical enquiry that examines ethical issues and dilemmas arising from health, health care, and research involving humans.

Biomedical: Relating to the application of biological, medical, clinical, laboratory, behavioural, or public health sciences to the study, prevention, diagnosis, treatment, or control of disease and the promotion of human health.

Compensation: That which is given in recompense, as an equivalent rendered, or remuneration.

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 documents a potential participant's consent to be involved in research.

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.

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. Medical devices include diagnostic test kits, crutches, electrodes, pacemakers, etc.

Multi-site research: A clinical trial 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.

Quorum: A quorum is the minimum number of members that must be present to constitute a valid meeting where decisions can be taken concerning submissions put forward for ethical review. A meeting is properly constituted when there is quorum.

Reimburse: To repay (a sum of money which has been spent or lost).

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) (also known as Ethical Review Board [ERB], Research Ethics Committee [REC], Ethical Review Committee [ERC], Human Research Ethics Committee [HREC], Institutional Review Board [IRB]: Group of individuals who undertake the ethical review of research protocols involving humans, 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 biomedical 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.

Revision: Requirement by the research ethics committee to alter the protocol in some way prior to approval or additional review by the committee.

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:** The level at which an average, prudent provider in a given situation would manage a 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 research participants.

Voluntary: (1) Performed or done of one's own free will, impulse, or choice; not constrained, prompted, or suggested by another; (2) 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.

Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable.

Examples include members of groups with hierarchical structures, such as medical, pharmacy, dental, and nursing students; subordinate hospital and laboratory personnel; employees of the pharmaceutical industry; members of the armed forces; and persons in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished persons, patients in emergency situations, minority groups,

homeless persons, nomads, refugees, minors, and those incapable of giving consent. This list is not exhaustive, as there may be circumstances in which other groups are considered vulnerable.

1.0 Background to Biomedical Research Ethics

Before 1947, there were no widely available guidelines for research involving human participants beyond the ethics of medical practice. In 1947, the Nuremberg Code was developed in response to atrocities committed by German physicians during the Second World War. The Code emphasized the importance of voluntary consent before involving human participants in medical research and the need to conduct appropriate animal experimentation before research is undertaken in humans. In the United States of America, scandals such as the Tuskegee and Willowbrook studies contributed to the development of the Belmont Report in 1979, which set out broad principles to guide biomedical research involving human participants. These principles focused on informed consent, a favourable risk–benefit ratio, and the need to protect vulnerable populations from risky research.

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). 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." 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 was established in 1977 with the enactment of the Science and Technology Act. The Act established the National Council for Science and Technology and public research institutes. The Council was empowered to coordinate research in Kenya and advise the Government on matters related to research. For biomedical research involving human participants in Kenya, mandatory ethical clearance must be obtained from an accredited ethics review committee. Researchers who are not affiliated with institutions that have accredited IERCs are required to seek clearance from an accredited committee. These guidelines provide a framework for the proper regulation of research involving human participants in Kenya.

2.0 Preamble to the Guidelines

In general, research is defined as any creative, systematic activity undertaken to increase the stock of scientific and technical knowledge and to devise new applications. In biomedical research, this means generating knowledge that may lead to new preventive, prophylactic, therapeutic, and diagnostic tools, or improvements in existing tools, for the enhancement of human health and well-being. Research investigations often begin with hypotheses that are tested in laboratories and in experimental animals using rigorous scientific methodologies under the direction of qualified personnel. For findings to be clinically useful, studies may also need to be conducted with human participants to test their scientific validity.

Experiments in humans are often well and carefully designedbut still present some risks to the participants involved in the research. However, the risk can be justified since the individuals taking part in research may benefit. Furthermore, information generated may increase human knowledge in the relief of suffering and prolongation of life. During the conduct of research involving humans, the tendency for researchers to use vulnerable populations cannot be ruled out and therefore there is need for caution in involving them in research. These guidelines are for protection of human participants taking part in research in Kenya.

3.0 General Ethical Principles

All research involving human participants must be conducted in accordance with three basic ethical principles:

3.1. Respect for persons

This involves at least two 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) Those with diminished autonomy or vulnerable groups should be protected against harm or abuse.

3.2. Beneficence

This refers to the ethical obligation to maximize benefits and minimize harm or wrongs.

3.3. 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.

3.4. 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 death, their dependents are entitled to material compensation. The right to compensation may not be waived.

3.5 Obligation of the sponsor regarding compensation

The sponsor whether a pharmaceutical company, a government, or an institution, 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. An arbitration committee could be set up by the institution to decide on the issue of compensation on a case-by-case basis for larger trials where such a step is feasible. Alternately an institution can also establish such a committee to oversee these issues.

4.0 Guidelines for conduct of biomedical research in Kenya

a) Biomedical research involving human participants must conform to national and international accepted scientific and ethical principles.

b) 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.

c) Individuals and organizations who wish to engage in biomedical research involving humans, should affiliate themselves to institutions recognized in Kenya including Kenya Medical Research Institute (KEMRI), Kenyatta National Hospital, Moi Teaching and Referral Hospital, and Aga Khan University Hospital Nairobi (a comprehensive list is available at www.NACOSTI.go.ke)

d) 4) 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 medically qualified person. 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.

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

f) 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.

g) 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 in Kenya and stored in foreign bio-banks.

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

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

j) No biological material shall be shipped out of the country without proper justification and authorization.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.

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

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

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

n) Research involving human participants shall be terminated at any stage if it is considered to be harmful to the research participant(s).

4.0. Guidelines for conduct of biomedical research in Kenya

4.1 Protocol Development

The following are the elements of protocol development:

- The title should adequately capture the essence of the study.
- The names, addresses, signatures and updated abridged curriculum vitae of the investigators should be provided.
- The Principal Investigator (PI) must provide evidence of prior training in Good Clinical Practice (GCP) where relevant.
- The names and addresses of the collaborating institutions and funding agencies must be provided.
- A brief summary of the project
- Introduction, background and literature review
- Study rationale
- Study question(s)
- Hypothesis/hypotheses where relevant
- Objectives
- Study site,design and methodology
- Ethical considerations:
    - Consent explanation- elements of consent explanations
    - Consent form with signature page for the participants
    - 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
- Data management and statistical analysis
- Role of investigators
- Time frame
- References
- Budget

4.2 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. 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:

- Invitation to participate in the research
- Title of the project
- Principal investigators
- Institution where research will take place
- Purpose of the research study
- Role of study participants and duration of participation
- Procedures and investigations to be undertaken
- Benefits
- Unforeseen risks/discomfort
- Alternative procedures or treatment (if any)
- Confidentiality
- Investigators responsibility, if any, to provide medical services to the participant
- Storage and exportation of biological samples
- Storage and ownership of data
- Compensation
- Voluntariness with no loss of benefits
- Dissemination of findings
- Un-blinding where applicable
- Contacts of the Principal Investigator and IERC
- 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.

4.2.1 Informed consent for epidemiological studies

The objective of epidemiological research is to elucidate the characteristics in a population of the prevalence and incidence of a disease and or other health problems (Accidents, violence) and distribution of the problem (e.g. according to age sex, type of work, social conditions, place of residence, daily habits/behaviour). It might include a variety of modes of participation such as:

i. Use of already collected data
ii. Filling out of a written or electronic questionnaire
iii. Participating in an interview
iv. Providing biological samples

Consent should be based on the actual purpose of the epidemiological research project concerned. For several epidemiological researches, it is either impracticable or inadvisable to obtain individual consent. In such circumstances the relevant ethical review committee should determine whether it is ethically acceptable to proceed without the individual informed consent and whether the investigator has put in place mechanisms to protect the safety and to respect the privacy of the research participants, and to maintain the confidentiality of the data. Such studies would be for example, examination of medical records, or stored biological samples.

When the focus of the study is an entire community rather than individual human participants then the investigators should secure the agreement and cooperation of the local administrative authority. In some areas in the country, the permission of the community leaders may be sought where this is necessary. In addition to the above requirement, if the studies involve personal contact between the investigators and the individual participants, the general requirements of informed consent must apply.

Special consideration for the cultural characteristics of the communities that are being studied is essential to ensure that cultural sensitivities are not compromised because of the investigation. A particular concern is the fact that some population based data may also have implications on issues like national security and this need to be carefully considered in advance.

If an individual chooses not to participate in the study despite the agreement and cooperation given to the investigators by both the official leadership through local administration, the local informal leadership, and the public health leadership, that decision must be respected and there should be no penalties.

4.3 Vulnerable Groups

Vulnerable groups are persons or communities whose ability to protect their own interests or provide fully voluntary consent may be limited by age, illness, dependency, institutionalization,

poverty, displacement, limited resources, pregnancy, social marginalization, or unequal power relationships. Such groups include, but are not limited to, children, infants, foetuses, pregnant and breastfeeding women, persons with mental or behavioural disorders, prisoners, communities in low-resource settings, refugees, displaced persons, persons with serious or incurable illness, and persons who may be subject to undue influence or coercion.

4.3.1 Research involving children, infants and fetuses

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

- Children will not be involved in research that can equally be carried out in adults.
- The purpose of the research is to generate knowledge relevant to the health needs of children.
- 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.
- The risk presented by interventions not intended to benefit the child is low and commensurate with the importance of the knowledge to be gained.
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child as any available alternative.
- Potential parent(s) can make decisions on behalf of the foetus (es). Foetal research should be limited to:
- Cases which present no harm or offer assistance to the life system of the participants.
- No procedures should be permitted which are likely to harm the foetus.
- A foetus*ex utero* and alive should not be participant to research unless it is intended to enhance the life of that foetus or unless the research involves no risk to the foetus.

4.3.2 Research involving persons with mental or behavioural disorders

An investigator must ensure that before undertaking research in individuals with mental or behavioural disorders 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 faculties.
ii. The knowledge gained would be relevant to the particular health needs of persons with mental or behavioural disorders.
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 non-clinical research is always respected.

In the case of incompetent individuals, informed consent is obtained from a legal guardian or other duly authorized person.

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.

Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual participant as any alternative.

4.3.3 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 ethical committee 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.

4.3.4 Selection of pregnant and breastfeeding women as research participants

a) Pregnant 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) The object of the research is to obtain new knowledge about pregnancy or lactation.
c) As a general rule pregnant or nursing women should not be participants in clinical trials except where such trials 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.
d) The justification for such trials should be that they should not be arbitrarily deprived of the opportunity to benefit from investigational drugs, vaccines or other agents that promise therapeutic or preventive benefits.

4.3.5 Research involving communities in low resource setting

The investigator must ensure that:

a) Persons in underdeveloped communities 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.

4.4 Stem cell research

Stem cells have the remarkable potential to develop into many different cell types in the body during early life and growth. Stem cells are distinguished from other cell types by two 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 guidelines regarding research in this area.

4.5 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, blood and saliva. From these samples, specific types of cells 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 purpose of biobanks are to:

i. Provide a resource for research that is valued by society and conducted within applicable 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, ongoing public trust and involvement.
iv. Provide information for diagnostic and therapeutic purposes

Researchers are referred to Appendix X in the national guidelines.

4.6 Use of pre- existing data/Stored Samples

The principle of informed consent demands that the person is adequately made aware of the use of the data or 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 ethics committee. 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 ethics committee 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 institutional research ethics committee will deliberate and make appropriate decision regarding approval. Researchers sending samples abroad should ensure that consent for transfer of materials was obtained during collection of the samples and that the collaborating institutional ethics committee approves accordingly.

4.7 Principles and benchmarks for review of biomedical research

Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research participants are not merely used but are treated with respect while they contribute to the social good. There are seven requirements that provide for this framework.

These requirements are listed in chronological order from the conception of the research to its formulation and implementation. They are meant to guide the ethical development, implementation, and review of individual clinical protocols. These seven requirements are discussed in detail below.

a) ***Value***

To be ethical, clinical research must be valuable, meaning that it evaluates a diagnostic or therapeutic intervention that could lead to improvements in health or well-being; or a preliminary etiological, patho-physiological, or epidemiological study to develop such an intervention; or tests a hypothesis that can generate important knowledge about structure or function of human biological systems, even if that knowledge does not have immediate practical ramifications.

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. Even if major funding agencies could fund all applications for clinical research, doing so would divert resources from other worthy social pursuits. Beyond not wasting resources, researchers should not expose human beings to potential harm without some possible social or scientific benefit.

b) ***Scientific Validity***

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

For a clinical research protocol to be ethical, the methods must be valid and practically feasible: the research must have a clear scientific objective; be designed using accepted principles, methods, and reliable practices; have sufficient power to definitively test the objective; and offer a plausible data analysis plan. In addition, it must be possible to execute the proposed study. Research that uses biased samples, questions, or statistical evaluations, that is underpowered, that neglects critical end points, or that could not possibly enroll sufficient participants cannot generate valid scientific knowledge and is thus unethical. Careless research that produces un-interpretable data is not just a waste of time and resources, it is unethical.

Reviewers should not dismiss a proposal that uses inadequate methods without first considering whether adjustments could make the proposal scientifically valid.

The justification of validity as an ethical requirement relies on the same two principles that apply to value-limited resources and the avoidance of exploitation. Invalid research is unethical because it is a waste of resources. Without validity the research cannot generate the intended knowledge, cannot produce any benefit, and cannot justify exposing participants to burdens or risks.

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 women be included in the research, unless there is good reason, such as excessive risk, to exclude them. Participants should be selected to minimize risks and enhance benefits to individual participants and society

v. If a potential drug or procedure is likely to be prescribed for women or children if proven safe and effective, then these groups should be included in the study. Groups and individuals who bear the risks and burden of research should be in a position to enjoy its benefits, and those who may benefit should share some of the risks and burdens. Groups of participants who will predictably be excluded as beneficiaries of research results that are relevant to them typically should not assume the burden so that others can benefit. However, this does not preclude the inclusion of participants who are scientifically important for a study but for whom the potential products of the research may not be relevant, such as health control participants.

vi. 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

1. Risk benefit ratio embodies the principles of beneficence and non-malfeasance, 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, three conditions are fulfilled:
   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 review bodies typically involves multiple steps.
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. For example, consistent with the scientific objectives, tests and interventions should be arranged to increase benefit to the participants. However, extraneous benefits, such as payment, or adjunctive medical services, such as the possibility of receiving a hepatitis 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. 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.

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 ethics review committee.
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 enrol 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 ethical review committees in the relevant local institutions.

f) ***Informed Consent***

Informed consent is the most important document to be reviewed by the ethics committee. Each element of informed consent is necessary to ensure that individuals make rational and free determinations of whether the research trial is in consonance with their interests (see section on informed consent) 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 guidelines. Most 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***

(i) 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.

(ii) Respecting potential and enrolled participants entails the following:

(iii) Privacy must be respected by managing the information in accordance with confidentiality rules.

(iv) Permitting participants to change their mind, to decide that the research does not match with their interests, and to withdraw without penalty.

(v) New information gathered during the research must be provided to the study participants.

(vi) 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.

(vii) 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.

(viii) It is imperative that the privacy and confidentiality of the research participants is maintained throughout the research project.

(ix) Respect for potential and enrolled participants is justified by three ethical principles- autonomy, beneficence, and justice.

The eighth principle is collaborative partnership. Researchers, sponsors, host institutions, communities, and relevant authorities should work together in a manner that respects local priorities, strengthens local capacity, promotes shared decision-making, and ensures that the benefits of research are reasonably available to the community in which the research is conducted.

1. Collaborative partnership
2. Social Value
3. Scientific Validity
4. Fair Participant Selection
5. Favourable risk-benefit ratio
6. Independent review
7. Informed Consent
8. Respect for Participants

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.

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. Standardisation 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.

Centralised 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 outset. No individual centre should publish any data till appropriate authorities accept the combined report.

5.2 Drug Development

Clinical trial of drugs is a randomized single or double blind controlled study in human participants, designed to evaluate prospectively the safety and effectiveness of new drugs/ new formulations. The proposed trial should be carried out in accordance with the guidelines set out by the Pharmacy and Poisons Board (PPB). The investigator should also get the approval from relevant ethical authorities before submitting the proposal to PPB. All the guiding principles should be followed irrespective of whether the drug has been developed in Kenya or abroad or whether clinical trials have been carried out elsewhere.

5.2.1 Phases of Clinical Trials

All phases require approval from relevant ethical committees 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 has been established and are intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies.

Phase IV trials are conducted after the national drug registration authority 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. Phase IV trials may also be designed to evaluate a drug in a population not studied adequately in the pre-marketing phases (such as children or the elderly) or to establish a new clinical indication for a drug.

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 trials, the distinction between therapy and research should be maintained.

(c) A physician /investigator who participates in research by administering the new drug to consenting patients should ensure that the patients understand that the drug 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 available specific National Vaccine Trial Guidelines (Ministry of Health).
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 studies done in the entire population or a subgroup 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 ongoing 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 studyutilizing 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.

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 Concerns

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 ethical and scientific review according to the standards of the country of the sponsoring agency, additionally ethical 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 theresearch 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

7.0 Information on research regulation and approval in Kenya

7.1 NACOSTI, NBC, and IERCs

The purpose of an Ethics Committee (EC) in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants. Institutions setting up ethics review committees should alongside this section familiarize themselves with the Accreditation Guidelines published by the NACOSTI.

In their composition, procedures and decision making, ECs need to have independence from political, institutional, professional and market influences. ECs 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.

ECs 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 ECs 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.

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

Decisions on research protocols designated for review by the EC 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 EC has established written procedures permitting such a process ECs should have elaborate written policies and procedures that specify the EC's membership, committee governance, review procedures, decision-making, communications, follow-up, monitoring, documentation and archiving, training, quality assurance, and procedures for coordination with other ECs.

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

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

7.2 Membership Requirements

Clear procedures for identifying or recruiting potential EC 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 EC, and the regular input of fresh ideas and approaches.

7.3 Other Regulatory and Approval Bodies

Depending on the nature, location, and subject matter of a study, additional approvals may be required from relevant national or county authorities. These may include the Pharmacy and Poisons Board for clinical trials and investigational health products; the Directorate of Medical Services or Ministry responsible for health for health-sector matters; the Kenya Plant Health Inspectorate Service for plant-related research; the Kenya Wildlife Service for wildlife-related studies; relevant county governments and local administrative authorities for field-based work; and any other statutory body with jurisdiction over the proposed research activity. Researchers should identify all applicable approvals during protocol development and obtain them before commencing the study.

7.4 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.

7.5 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 EC 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 EC administrative staff should sign a similar confidentiality agreement.

7.6 Offices

i. ECs should establish clearly defined offices for the good functioning of ethical review. A statement is required of the officers within the EC (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 EC officers, an EC should have adequate support staff for carrying out its responsibilities.

7.7 Quorum Requirements

ECs 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.

7.8 Independent Consultants

ECs may call upon, or establish a standing list of, independent consultants who may provide special expertise to the EC 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, patients, or special interest groups. Terms of reference for independent consultants should be established.

7.9 Education for EC Members

EC 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 EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of EC members. This education may be linked to cooperative arrangements with other ECs in the area, the country, and the region, as well as other opportunities for the initial and continued training of EC members.

7.10 Dispute Resolution

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

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

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.

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