KENYATTA UNIVERSITY

ETHICS REVIEW COMMITTEE OPERATIONAL GUIDELINES FOR BIOMEDICAL RESEARCH

July 2009

FUNDAMENTAL STATEMENTS

1.1 The Vision Statement

The vision of Kenyatta University is *"to be a dynamic, all inclusive, globally competitive center of excellence in the provision of quality education, training and research for sustainable development."*

1.2 The Mission Statement

The mission of Kenyatta University is *"to provide quality education and training, through knowledge generation, research, innovation, creativity and community service"*

1.3 The Identity Statement

Kenyatta University is *"a community of scholars committed to the generation and dissemination of knowledge, and cultivation of wisdom for the welfare of society."*

1.4 The Philosophy Statement

Kenyatta University's philosophy is *"sensitivity and responsiveness to societal needs, and the right of every person to knowledge."*

2.0 PREAMBLE

Research dealing with human subjects is guided by international rules and regulations, the most important being the World Medical Association Declaration of Helsinki. This declaration quotes numerous other documents that deal with ethical handling of human subjects. World Health Organization (WHO) recommends the formation of Ethical Review Committees (ERCs) at the Regional, National and Institutional level and has provided operational guidelines for ERCs. It is in this context that Kenyatta University came up with these guidelines to provide guidance to the Kenyatta University Ethical Review Committee (hereinafter KU-ERC) to review and clear biomedical research proposals. For the purposes of these guidelines, biomedical research includes research on clinical aspects, pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records,

biological samples, as well as epidemiological, social, psychological and behavioural investigations. These guidelines in conformity with international and national guidelines require the ethical and scientific review of biomedical research proposals alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect the individual person and the communities who participate in research. Compliance with these guidelines ensures that the dignity, rights, safety and well-being of research participants are promoted and that the results of investigations are credible.

3.0 BACKGROUND

Research has produced substantial benefits. It has also generated challenging ethical issues. Reported and widespread abuses of human subjects during the Second World War triggered public outcry. As a result of the Nuremberg war crime trials, a Code (the Nuremberg Code 1947) was written as a set of standards for judging physicians and scientists who had conducted covert biomedical experiments on prisoners in concentration camps. This Code became the prototype of many later Codes intended to ensure that research involving human subjects would be carried out in an ethical manner. The World Medical Association developed the Declaration of Helsinki document in 1964. The document has undergone multiple revisions including Tokyo (1975), Venice (1983), Hong Kong (1989), Somerset West (1996), Edinburgh (2000) and Washington (2002). 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 Subjects". The purpose of this document was to give guidance on how the Helsinki Declaration ethical principles could effectively be applied in developing countries, taking into consideration the culture, socio-economic conditions, national laws and executive administrative arrangements. In addition, the Belmont Report of 1979 provides basic ethical principles and guidelines to be used in resolving ethical problems that surround the conduct of research with human subjects particularly the

vulnerable groups.

In Kenya, the legal framework for science and technology came into existence in 1979 under the Science and Technology Act. The Act established the National Council of Science and Technology (NCST) empowering it to coordinate all research in Kenya and advise the government on all matters related to research. The function of NCST entails the documentation of all research in the country and all the institutions in which biomedical research is being conducted. For research of biomedical nature to be conducted on humans in Kenya, ethical clearance is mandatory and this is done by ERCs in the respective institution.

The Ethical Review Committee in Kenyatta University is anchored in the Kenyatta University Research Policy and mandated to review ethics of proposals and projects in accordance with the University Research Policy. The guidelines herein are intended to facilitate the review and clearing of researches involving human subjects both locally and internationally.

4.0 RATIONALE

Kenyatta University has in the past undertaken research in diverse fields including those involving human subjects. Ethical clearance has previously been sought and obtained from collaborating partners and existing clearing institutions recognized by the NCST. Kenyatta University has also established several medical programmes which have generated more research on human subjects hence the need for ethical guidelines.

5.0 OBJECTIVES

The objectives of these Guidelines are to;

- contribute to quality and consistency in the ethical review of biomedical research conducted at and/or overseen by Kenyatta University.
- complement existing policies and regulations governing research at Kenyatta University and other networking partners.
- provide a basis for evaluation of the Standard Operating Procedures (SOPs) for biomedical research
- be used by structural units of Kenyatta University in developing, monitoring, evaluating and progressively refining SOPs

6.0 THE ROLE OF KU-ERC

The role of KU-ERC is to:

- review and clear proposed research before its commencement.
- provide independent, competent, and timely review of the ethics of proposed studies. In its procedures and decision-making, KU-ERC will be independent from political, institutional, professional, and market influences.
- review prospective and continuing research protocols so as to safeguard the dignity, rights, safety, and well-being of all actual or potential participants in biomedical research. This is in cognizance of the fact that the goals of research, should never be permitted to override the health, well-being, and care of research participants.
- take into consideration the principle of justice. This requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, cultural, political, religious, ideological, race and ethnic considerations.
- review the adequacy of the informed consent document, particularly as to its description of the risks and benefits.
- ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.
- evaluate reports for unanticipated problems, possible non-compliance, and other information and incidents that might affect approval of protocol or the subjects' willingness to continue to participate.

- act in the interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

7.1 SUBMITTING AN APPLICATION

The KU-ERC secretariat will receive biomedical research proposals for ethical review from applicants through the Division of Research, Innovation and Outreach in the manner and format prescribed in Annexure A.

7.2 Application

An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research.

7.3 Application Requirements

The requirements for the submission of a research project for ethical review will be clearly described in an application procedure as set out in Annexure A. These requirements will include the following:

a. the name(s) and address(es) of the ERC secretariat to whom the application material is to be submitted.
b. the documentation (see Annexure B for the checklist).
c. the language in which documents are to be submitted will be English. [Documents submitted in any other language should be translated into English by a competent and accredited interpreter at the expense of the applicant].

1. The deadline for submission of the application is 2 weeks prior to the next scheduled meeting.

2. Applications will be acknowledged and researchers shall be informed of the review date via shortest mode possible.

3. The acknowledgement of the application shall be communicated to the researchers within a week after receipt of the application.

4. In cases where the ERC requests supplementary information or changes to documents from the applicant, such information should be provided to ERC at least a week before the next meeting.

5. In cases where clarification is sought and researchers fail to respond within 3 months, ERC will send a reminder and allow a further 3 months period for response. Beyond these 6 months, the application file will be closed.

6. Researcher may be asked to present a case in an ERC meeting if required, including follow-up and end-report.

d. There shall be a fee for the review of every proposal which shall be determined from time to time by KU-ERC.

e. The application procedure for amendments to the protocol, the recruitment material, the potential research participant information, or the informed consent form.

8.1 REVIEW

All properly submitted applications will be reviewed in accordance with the procedure established by KU-ERC.

8.2 Meeting Requirements

Meetings shall be held by KU-ERC on the following terms:

- Meetings will be held every second Tuesday of the Month.
- In the event that it is not possible to hold the meeting on the scheduled Tuesday (e.g. due to a public holiday), the committee shall meet on the following Wednesday.
- Meetings will also be held at such other times as the Committee may determine such as when they need to handle expedited reviews.
- Documents to be discussed during the meeting will be circulated to the reviewers at least a week before every scheduled meeting
- Minutes will be taken in all scheduled meetings and the same approved by the office holders.

The applicant, sponsor, and/or investigator may be invited to present the proposal or elaborate on specific issues.

Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

8.3 Elements of the Review

The primary task of the KU-ERC is to review research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the sustainability and feasibility of the protocol. KU-ERC will take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations as outlined in Annexure C. The following should be considered, as applicable:

- Scientific design and conduct of the study
- Recruitment of research participants
- Care and protection of research participants
- Protection of research participants' confidentiality
- Informed consent process
- Community considerations

8.4 Approval Conditions

1. Approval shall be given for a specified period. If the project takes longer than the specified period to complete, a request for an extension of the ethics clearance shall be sought.

2. Approval shall be given on condition that any alterations proposed to the approved protocol are submitted to the Committee for approval prior to the alterations being effected.

3. Approval shall be given on condition that a copy of the research project final report will be submitted to the Ethics Committee for its information

4. Approval shall be given subject to researchers notifying the Ethics Committee if and when a project is curtailed, terminated or completed.

5. Approval shall be given for therapeutic trials subject to the Principal

Investigator notifying the Ethics Committee within seven (7) days of any adverse event or occurrence that takes place during that trial.

6. Research may be audited by KU-ERC during the research period to ensure compliance with guidelines.

ANNEXURE A - APPLICATION REQUIREMENTS

Application

The investigator responsible for the ethical and scientific conduct of the research should submit **a typed** application for review of the ethics of proposed biomedical research to the following address:

Through
The Deputy Vice-Chancellor (Research, Innovation and Outreach)

Chairman – Ethics Review Committee
Kenyatta University
P.O. Box 43884-00100
Nairobi, Kenya.

Application form

The application form together with supporting documents are to be submitted to the Chairman, Kenyatta University Ethics Review Board through the Deputy Vice-Chancellor, Research, Innovation and Outreach.

Documents for submission

All documentation required for a thorough and complete review of the ethics of proposed biomedical research should be submitted by the applicant.

These include, but not limited to,

1. Three hard copies of signed and dated KU-ERC application form (see annexure B) should be submitted. Application forms will be available online on www.ku.ac.ke

2. Ten hard copies and one soft copy of research protocol (clearly identified and dated), together with supporting documents and annexes. This should include description of the ethical considerations involved in the research

3. Questionnaire (if applicable) intended for research participants should be included

4. When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, a summary of the product's characteristics).

5. A description of the process to be used to obtain and document consent.

6. A statement of agreement to comply with ethical principles set out in relevant guidelines.

7. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.

8. CIOMS guideline "Research subjects who suffer physical injury as a result of their participation are 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 dependants are entitled to material compensation. The right to compensation may not be waived".

9. A description of the arrangements for insurance coverage for research participants, if applicable.

10. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ERCs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

ANNEXURE B - DOCUMENTATION CHECKLIST

- Duly signed and dated application forms;
- A dated protocol of the proposed research together with supporting documents and annexes;
- A synopsis of the protocol;
- A detailed description of the ethical considerations involved in the research;
- Research tools such as case report forms, diary cards, and other questionnaires intended for research participants;
- When the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of the product's characteristics);
- All investigators' updated curriculum vitae;
- Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
- Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
- A description of the arrangements for indemnity, if applicable;
- A description of the arrangements for insurance coverage for research participants, if applicable;
- A statement of agreement to comply with ethical principles set out in relevant guidelines;

- All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

ANNEXURE C - ELEMENTS OF REVIEW

1. Scientific design and conduct of the study. This includes:

a. The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.
b. The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
c. The justification for the use of controls.
d. Criteria for prematurely withdrawing research participants.
e. Criteria for suspending or terminating the research as a whole
f. The adequacy of provisions made for monitoring and auditing the conduct of the research. Where applicable, mechanisms for quality control should be indicated.
g. The adequacy of the site, including the supporting staff, available facilities, and emergency procedures.
h. The manner in which the results of the research will be disseminated.

2. Recruitment of research participant. This will take into account the following factors:

a. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity).
b. The means by which initial contact and recruitment is to be conducted.

c. The means by which full information is to be conveyed to potential research participants or their representatives.
d. Inclusion criteria for research participants.
e. Exclusion criteria for research participants.

3. Care and protection of research participants

a. The suitability of the investigator(s)'s qualifications and experience for the proposed study.
b. Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
c. The medical care to be provided to research participants during and after the course of the research.
d. The adequacy of medical supervision and psycho-social support for the research participants.
e. Steps to be taken if research participants voluntarily withdraw during the course of the research.
f. The criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
g. The arrangements, if appropriate, for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so.
h. The protection of the special groups in any research especially pregnant women and women of child bearing potential.
i. A description of any plans to make the study product available to the research participants following the research.
j. A description of any financial costs to research participants;
k. The rewards and compensations for research participants (including money, services, and/or gifts).
l. The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research.
m. The insurance and indemnity arrangements.

4. Protection of research participant confidentiality

a. A description of the person(s) who will have access to personal data of the research participants, including medical records and biological samples.
b. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

5. Informed consent process

a. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
b. The adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s).
c. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
d. Assurance that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being).
e. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

6. Community considerations

a. The steps taken to consult with the concerned communities during the course of designing the research.
b. The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
c. The influence of the community on the consent of individuals.
d. Proposed community consultation during the course of the research.

e. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
f. A description of the availability and affordability of any successful study product to the concerned communities following the research.
g. The manner in which the results of the research will be made available to the research participants and the concerned communities.