UNIVERSITY Of KIGALI

"Unequalled Education Excellence

RESEARCH ETHICS POLICY

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1. PREAMBLE

The University of Kigali as a teaching institution has an obligation to train academics, staff, students and research associates to carry out research ethically and ensure ethically sound research practices.

The University also as an institution of higher learning has an obligation to provide guidance to researchers to address the special ethical issues that arise as people conduct research.

The University of Kigali as an organisation with a culture and context of its own has a moral obligation to act as a gatekeeper for ensuring protection to research subjects and the environment

In pursuance of the above objectives the University of Kigali issues these 'research ethics guidelines' based on best practice, national and international standards.

2. RESEARCH ETHICS POLICY IMPLEMENTATION AND MANAGEMENT

The University of Kigali commits itself to the obligation to ensure ethical conduct of research with all research subjects, including human subjects, animals, flora, fauna, environment, business and technology.

The management framework and guidelines to ensure compliance with the University Research Ethics Policy is provided as under:

2.1 University Research Ethics Committee:

The University Research Ethics Committee shall manage research ethics affairs at the University level. The DVCR & PGS will provide strategic leadership on research ethics.

The Research Office will be responsible for the development of University vision, mission, policy and strategy for research ethics, implementation of research ethics strategy and strategic research ethics plan and coordination with key internal and external stakeholders namely; Faculties, Centers, Campuses, Government and other institutions. It shall undertake training and sensitization of research supervisors, students and research associates on research ethics.

The University Research Ethics Committee shall constitute of the following members:

DVCR & PGS	Chairperson
Faculty, Centre, Campus Coordinators	Members
Director Research	Member Secretary

The scope of functions and responsibility of the UREC shall include the following:

• The UREC shall meet regularly to address research ethics issues.

• The UREC shall accept research proposals from Researchers submitted through the Coordinators of the Faculties, Centers, Campus Research Ethics Committees for review.

• Establish, review guidelines for use in research and teaching with human subjects, animals, plants, environment, etc.

• Scrutinize procedures and protocols involving use of animals and plants for research and teaching.

• Maintain ethical standards in the handling of animals and plants for research and teaching.

• Ensure that the ethical standards for handling and use of animals and plants for research and teaching are in conformity with relevant national and international ethical standards for the management of animals and plants for research and teaching.

• Shall set guidelines to address animal euthanasia, tumour induction, use of analgesia, genetically modified animals, blood and tissue collection, animal monitoring, transportation and storage, animal breeding, and any other relevant procedure or technique dealing with animals for research and teaching.

• Stop or terminate the use of animal or plant research activities that deviate from approved proposals and protocols.

• Order euthanasia to be carried out if unbearable pain is brought on to an animal through research activities.

• Order the closure of any animal activity or plant facility that does not comply with ethical standards.

• Facilitate seminars and workshops dealing with ethical issues in the use of animals and plants for research and teaching;

• University Research Ethics Committee may constitute sub-committees for ethical review of research proposals involving Human subjects, Animals, Environment, Business Research and other specialised research. These committees shall be constituted of members having expertise in the specialised areas.

• The UREC shall draw up strategic, functional and implementation plans for every academic year.

• The UREC shall submit regular reports on its activities to the University authorities and the Senate.

Department, Faculty, Centre, Campus Level Research Ethics Committees

Each Department, Faculty, Centre and Campus shall have a Research Ethics Committee.

The Department, Faculty, Centre and Campus Research Ethics Committees shall have an active researcher and academic as its convener and chairperson.

The Faculty, Center, Campus Research Ethics Chairperson/Coordinator shall be member of the UREC.

The respective committees shall be responsible for the implementation of University Research Ethics Policy at their respective Departments, Faculties, Centers, Campus.

The activities of these bodies amongst others will include the following:

• The Heads of Departments and Deans of Faculties, Centers, Campus will be responsible for the implementation of the University Research Ethics Policy at their respective levels.

Degree and Masters level research proposals shall be reviewed as per the Research Ethics checklist in their respective Departments and Faculties, Centers or Campus at the outset.

• The Agenda and Minutes of the Department, Faculty, Centre or Campus RECs shall be documented and forwarded to the UREC together with the corresponding research proposals.

• The Coordinators of Committees shall submit regular reports of its activities to their respective Deans and University Research Office.

2.2 Research Ethics Sub Committees:

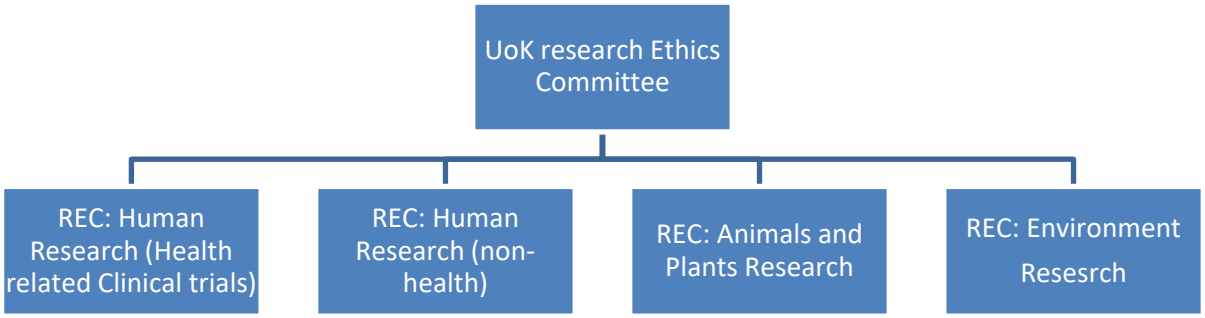
The University Research Ethics Committee will constitute the following Research Ethics sub committees.

Research Human Subjects (Health related Clinical Trials)

Research Human Subjects (Non-health)

Animals and Plant Research

Environmental Research



2.3 Qualifications for RECs Members:

REC members should have initial and continued education regarding ethical review and scientific research related with human subjects, animal subjects and environment.

The REC members should receive introductory training in ethical review work and also have an on-going opportunity for enhancing their capacity for ethical review of research.

2.4 Membership of RECs:

There shall be a minimum of five (5) members on each sub-committee. The composition of the Committees shall be multidisciplinary, balanced in age and gender distribution both. The members REC must have sufficient experience of their discipline as well as scientific research and requisite expertise to be able to make informed decisions.

The REC must include at least one person to represent the community/society. The REC may co-opt consultants in their discussions to meet the requirement of expertise or diversity. Conflict of interest should be avoided when making decisions. In cases where it is unavoidable, transparency should be maintained with regard to such interests.

Rotation system that allows for continuity, development and maintenance of expertise within the REC among the members and also regular infusion of fresh ideas and approaches should be considered.

A list of REC members and their qualifications should be maintained by the UREC.

Terms and Conditions of Appointment of Members:

The University of Kigali shall empower the Research Ethics Committees (RECs) to perform the following roles and responsibilities:

Review research proposals in relation to the required international and national ethical and scientific standards.

Determine whether informed consent is sufficient, and appropriate safeguards have been put in place for protecting the research subjects.

Assess the benefits and risks both from the research and make fair distribution of benefits and risks of research.

Complete the review process in time acting in accordance with the guidelines of the UREC.

Communicate the decisions on review to the UREC through appropriate authorities.

3. TYPES OF ETHICAL REVIEWS:

The ethical review depending upon the requirement in the case may be full review, executive review or expedited review.

3.1 Full Review:

A full review refers to review by full committee as constituted under the University guidelines.

All research involving human subjects, including vulnerable populations: children, institutionalized persons, aged, HIV positive persons and AIDS patients (not limited to the mentioned pollutions), sensitive questions or information about HIV/AIDS, experimental drugs or devices, invasive procedures should undergo full review

A full review will be also done in research involving animal and the environment

All Master's degree, Doctoral and Post-doctorate Research should be subjected to full review.

3.2 Executive review:

An executive review may be done by the Chairperson of the Research Ethics Sub Committee. A research can be cleared by the Chairperson of the relevant REC in cases when the research proposal for ethical clearance is accompanied by a letter of ethical approval from another recognized institution's REC/IRB. This may be applicable in the cases of collaborative research.

3.3 Expedited review:

Ethical clearance may be expedited when the research involves no more than a minimal risk to research subjects or in cases where the proposal is a replication of another proposal that had been approved by the REC previously. An expedited reviews involves approval by some members of the REC, who conduct detailed assessment of the research proposal and give a written approval on the research proposal.

3.4 Bachelors and Masters Degree Level Research Reviews:

Bachelors and Masters level research will be reviewed for ethical and scientific compliance by individual supervisors/lecturers of students at the outset. These reviews will be guided by a

uniform review checklist provided by the UREC and will be monitored by the relevant REC's within Departments and Faculties, Centers and Campus.

Such a review will be applicable when the research is part of a bachelor or master course, offered by the university and the research involves no more than minimum risk

4. ETHICAL REVIEW PROCESS:

All research proposals involving human subjects, animals and environment must be submitted for review of scientific merit and ethical compliance to appropriate REC. The Research Ethics Committees (REC's) shall review the research proposals independently as per the University guidelines.

The RECs will monitor the scientific and ethical compliance of approved research proposals.

In case there is any change in the study during the course of investigations, the researcher must notify the UREC of the change. The REC will review the change and communicate its decision to the researcher through the UREC.

4.1 Submission of Application for Ethical Clearance:

All applications for ethical clearance should be submitted according to the following procedure:

The application should be as per application form available on the UoK web site

Five hard copies of the completed application and documentation, as prescribed in the guidelines should be submitted to the Research Office (RO) 15 days prior to the scheduled date of meeting of the REC.

All applications should be in English.

All correctly completed applications received by the RO prior to the mentioned date will be presented at the meeting of the REC and considered by the REC.

The decision of the REC will be communicated electronically within one weeks of the REC meeting to the researchers submitting the applications.

In case the REC requires supplementary documentation from the applicants, this will be communicated to the applicant electronically. Additional information must be submitted before the meeting date to facilitate the review process.

In case the applicants are expected to clarify some issues in person this will be communicated electronically to the candidate. The applicant must present themselves before the committee on the meeting date to facilitate the review process.

Incomplete application will be referred back to the applicants and will be reviewed at the next scheduled meeting after correctly completed and documentation and information is received as required.

5. Documentation required for review:

The following documentation should be prepared and submitted for ethical clearance of research proposals.

Signed and dated application form and submission checklist

The proposal of the proposed research (clearly identified and dated), together with relevant documents and annexes;

A summary/abstract/synopsis of the proposal;

A description of the ethical considerations involved in the research;

Questionnaires, diary cards, and/or case report forms intended for research participants.

When the research involves a study of 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);

Investigator(s)'s updated, signed, and dated curriculum vitae (CV); materials to be used (including advertisements) for the recruitment of potential research participants;

A description of the process used to obtain and document consent; written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants.

Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants

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 to research participants, if applicable;

A description of the arrangements for insurance coverage for research participants;

A statement of agreement to comply with ethical principles set out in these Guidelines;

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

All properly submitted applications will be reviewed in timely fashion and in accordance with the established review procedure.

6. MEETINGS OF RECS:

The REC's shall meet from time to time, at least once a month on scheduled dates.

The REC members should be given the copies of the applications with relevant documentation a minimum of 7 days in advance of the review meeting for examination.

Proceedings at REC meeting shall be conducted as per the approval procedure and the decisions shall be minutes. The applicant may be invited to present the proposals or elaborate on specific issues. Independent advisors/consultants may be invited to the REC meetings to provide advice (subject to applicable confidentiality agreements). The quorum for the meetings shall be majority of members.

7. GUIDELINES FOR REVIEWS:

Guideline 1: Ethical justification and scientific validity of research involving human subjects:

The ethical justification of research involving human subjects is the prospect of discovering new ways of benefiting people's health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and care for the subjects of that research and are morally acceptable within the communities in which the research is carried out.

Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefits, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally-accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature and processes.

Guideline 2: Informed Consent:

For all research involving human subjects the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative, in accordance with applicable law.

The REC members should consider the following in relation to Informed Consent:

- Process.
- Language.
- Comprehension.
- Documentation of consent.
- Renewal of consent.
- Cultural considerations.
- Consent to use for research purposes biological materials (including genetic materials) from subjects in clinical trials.
- Use of medical records and biological specimens.
- Secondary use of research or biological specimens.
- Obligations of sponsors and investigators.
- Incentives to participate.

Guideline 3: Benefits and risks of participation in study:

For all research involving human subjects, the investigator must ensure that potential benefits and risks are reasonably balanced and risks are minimized.

Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual subject.

Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual must be justified in relation to the expected benefit to society (generalisable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

Guideline 4: Research in populations and communities with limited resources:

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

the research is responsive to health needs and priorities of the population or community in which it is to be carried out; and

any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

Guideline 5: Equitable distribution of burdens and benefits in the selection of groups of subjects in research:

Groups or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. The exclusion of groups or communities that might benefit from study participation must be justified.

Guideline 6: Research involving vulnerable persons:

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

Guideline 7: Research involving children:

Before undertaking research involving children, the investigator must ensure that:

the research might not equally well be carried out with adults;

the purpose of the research is to obtain knowledge relevant to the health needs of children;

a parent or legal representative of each child has given permission.

the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and,

a child's refusal to participate or continue in the research will be respected.

Guideline 8: Research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent:

Before undertaking research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent, the investigator must ensure that: such persons will not be subjects of research that might equally well be carried out on persons whose capacity to give adequately informed consent is not impaired; the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioral disorders; the consent of each subject has been obtained to the extent of that person's capabilities, and a prospective subject's refusal to participate in research is always respected, unless, in exceptional circumstances, there is no reasonable medical alternative and local law permits overriding the objectives; and, in cases where prospective subjects lack capacity to consent, permission is obtained from a responsible family member or a legally authorized representative is accordance with the applicable law.

Guideline 9: Women as research subjects:

Investigators, sponsors or UREC should not exclude women of reproductive age from biomedical research. The potential for becoming pregnant during a study should not, by itself, be used as a reason for precluding or limiting participation. However, a thorough discussion of risks to the pregnant woman and to her fetus is a prerequisite for the woman's ability to make a rational decision to enroll in a clinical study. In this discussion, if participation in the research might be hazardous to a fetus or a woman if she becomes pregnant, the sponsors/investigators should guarantee the prospective subject a pregnancy test and access to effective contraceptive methods before the research commences. Where such access is not possible, for legal or religious reasons, investigators should not recruit for such possible hazardous research women who might become pregnant.

Guideline 10: Pregnant women as research participants:

Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and UREC should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility. Research in this population should be performed only if it is relevant.

Guideline 11: Safeguarding confidentiality:

The investigator must establish secure safeguards of confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

Guideline 12: Right of injured subjects to treatment and compensation:

Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive this right to compensation.

Guideline 13: Strengthening capacity for ethical and scientific review and biomedical research:

Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions. In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively to national or local capacity to design and conduct biomedical research, and to provide scientific and ethical review and monitoring of such research.

Capacity-building may include, but is not limited to, the following activities:

Establishing and strengthening independent and competent ethical review processes/committees.

Strengthening research capacity.

Developing technologies appropriate to health-care and biomedical research.

Training of research and health-care staff.

Educating the community from which research subjects will be drawn.

Guideline 14: Research involving animals, plants and the environment:

Research activities that involve any type of animals (including domestic animals, pets, amphibians, reptiles, mammals, birds, fish and crustaceans, insects, anthropoids, amongst others) are of ethical concern.

The components of the environment which include different types of buildings, construction sites, mining sites, industrial settings, soils, water bodies (ponds, rivers, lakes, streams, oceans, sub-surface waters) and atmosphere are of ethical concern.

•Strict control shall be necessary to address the aspects of environmental monitoring and control, environmental pollution, waste management, etc in the conduct of research.

•The researcher must evaluate the potential impact of the research on animals, plants and environment, and declare that possible impact.

• Care must be taken to ensure that the research is carried out with necessary concern for the impact that it could have on physical, biological and spatial environment.

• All researchers undertaking research with bio-hazardous material that could potentially cause harm to humans, animals or the environment or the researcher and supporting staff must familiarize themselves with appropriate bio-safety and containment procedures.

• All research involving genetically modified organisms or research that poses a risk to the natural environment or the researcher and supporting staff, must be submitted to the University Research Ethics Committee (UREC).

• Ethical clearance is also required where animals are also used for teaching and exhibition.

Guideline 15: Research involving hazard to humans, animals, plants and the environment:

In the case of where research activities that involve hazardous biological, chemical, and geological materials are conducted in hazardous environments, safety considerations are of prime importance, especially when dealing with radiation materials. All such proposals must have ethical approval by the UREC including such materials used for teaching and exhibition.

• Ensure that staff and students engage in research activities dealing with hazardous, toxic and ionizing radioactive materials have understanding of ethical issues, guidelines, and good code of conduct in performing such research;

• Ensure that hazardous, toxic and ionizing radioactive materials are avoided as much as possible in the execution of research activities and only used where there is no suitable alternative;

• Ensure that research activities involving hazardous, toxic ionizing (x-rays, gamma rays, alpha and beta particles) and non-ionizing (microwaves, radio waves, ultra violet rays) radiations have very limited exposure to radiation materials to staff, students, the university community, and the biophysical environment;

• Ensure that staff and students engaged in research activities dealing with hazardous, toxic and ionizing radioactive materials have adequate knowledge of appropriate accident and emergency procedures.

Guideline 16: Choice of control in clinical trials:

As a general rule, research subjects in the control group of a trial of a diagnostic, therapeutic, or preventive intervention should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or "no treatment".

Placebo may be used:

When there is no established effective intervention.

When withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms.

When use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

Guideline 17: Collaborative research, financial interest and Conflict of interest:

Conflicts of interests can be effectively managed by disclosure and transparency. A researcher should be aware of, and where appropriate disclose, the following potential conflict of interest:

• Equity or stock holding in a sponsor company; • Propriety interests in product-patent holding, intellectual property rights, trademark, and licensing agreements;

• Grants paid speaking arrangement, retainers for ongoing consultations, sitting on 'Pharmaceutical Advisory Boards', etc.

• Travel and conference sponsorships;

• Recruitment fees or other personal payments that are linked to study outcome, in any way;

• Co-authorship of articles, where the co-authors' input has been minimal;

• Funding by sponsor for additional staff facilities, especially if not directly linked to the research project;

• Equipment for use in a study that will then belong to the department;

• Donation of equipment unrelated to study;

• Contribution to a departmental research budget, etc.

Guideline 18: Authorship:

Researchers are expected to make a reasonable effort to publish the results of their research in a peer reviewed journals. The following principles apply to authorship:

• Authorship credit should be based on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; and final approval of the version to be published.

• Acquisition of funding, collection of data, or general supervision of the research group alone, does not justify authorship;

• An administrative relationship to the investigation does not of itself qualify a person for co-authorship;

• The order of the names of in a publication is decided according to the quality of the contribution, the extend of the responsibility and accountability of the results, and the custom of the discipline;

• The authorship is not affected by where the researchers were paid for their contributions or by their employment status;

• In authorship for publications of research, where a student has done the bulk of the work, including the innovative and development of completed work he/she should be considered for first authorship.

• The author who submits a manuscript for publication accepts the responsibility of having included as co-authors all persons who are entitled to co-authorship, and none who are inappropriate;

• The corresponding author should send each co-author a draft copy of the manuscript and should make a reasonable attempt to obtain consent to authorship, including order of names; and –other

contributions should be indicated in a footnote of an 'Acknowledgements' section, in accordance with the standards of the discipline and the publisher

Guideline 19: Misconduct in Research:

The University undertakes to thoroughly investigate all allegations of research misconduct and act appropriately, according to the outcomes of such investigations .

• Complaints regarding the conduct of any researcher shall be referred to the Head of Department and/or the Faculty Dean for investigation by the Chairperson of the University Research Ethics Committee.

• The Chairperson of the University Research Ethics Committee shall take action on the recommendations of investigating authorities as deemed appropriate in the cases.

• Minor issues will be discussed and resolved at Department or Faculty Level.

• More serious matters will be referred to line management for further investigation and action. Standard University Disciplinary procedures will be followed in such cases.

• Any matter of alleged research misconduct, if the matter could potentially present any form of risk to the University shall be referred to the University administration.

8. CRITERIA FOR UREC APPROVAL:

In order to approve research, the UREC shall determine that all of the following requirements are satisfied:

Risks to subjects are minimized: by using procedure which are consistent with sound research design and which do not necessarily expose subjects to risk, and whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the UREC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The UREC should not consider possible long-term effects of applying knowledge gained in the research (e.g. the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable. In making this assessment the UREC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations,

such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Informed consent will be sought from each prospective subject or the subjects' legally authorized representative.

Informed consent will be appropriately documented.

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

9. Decisions at UREC/RECs:

In making decisions on applications for the ethical review of research involving humans, the UREC/RECs should take the following into consideration:

A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes;

A decision may only be taken when sufficient time has been allowed for review and discussion of an application;

Decisions should only be made at meetings where a quorum (as stipulated in the UREC/REC's written operating procedures) is present;

The documents required for a full review of the application should be complete and the relevant elements mentioned above;

Only members who participate in the review should participate in the decision;

There should be a predefined method for arriving at a decision (e.g., by consensus, by vote). It is recommended that decisions should be arrived at through consensus, where possible. When a consensus appears unlikely, it is recommended that the UREC/RECs decide by vote.

Advice that is non-binding may be appended to the decision;

In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-viewed should be specified;

A negative decision on an application should be supported by clearly stated reasons.

10. COMMUNICATION OF DECISION:

The decision should be communicated in writing to the applicant according to REC's procedures, preferably within one weeks' time of the meeting at which the decision was made. The communication of the decision should include, but not limited to, the following:

The exact title of the research proposal reviewed.

The clear identification of the proposal of the proposed research or amendment, date and version number (if applicable) on which the decision is based.

The names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including potential research participants information sheet/material and informed consent form.

The name and title of the applicant.

The name of the site(s).

The date and place of the decision.

The name of the REC taking the decision.

A clear statement of the decision reached.

Any advice by the REC.

In case of a conditional decision, any requirements by the REC, including suggestions for revision and the procedure for having the application re-reviewed.

In case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the REC; submission of progress report(s); the need to notify the REC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the REC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other REC's; the information the REC expects to receive in order to perform ongoing review; the final summary or final report.

The schedule/plan of ongoing review by the REC.

In case of a negative decision, clearly stated reason(s) for the negative decision.

Signature (dated) of the chairperson (or other authorized person) of the REC.

11. FOLLOW-UP:

The UREC/RECs should establish a follow-up procedure for follow up of progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The ongoing lines of communication between the UREC/REC and the applicant should be clearly specified. The follow-up procedure should take the following into consideration:

The quorum requirements, the review procedure, and the communication procedure for follow-up reviews, which may vary from the requirements and procedures for the initial decision on an application.

The follow-up review intervals should be determined by the nature and the events of research projects, though each proposal should undergo a follow-up review at least once a year;

The following instances or events require the follow-up review of a study;

Any proposal amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study.

Serious and unexpected adverse events related to the conduct of the study or study

product and response taken by investigators, sponsors, and regulatory agencies.

Any event or new information that may affect the benefit/risk ratio of the study.

A decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the REC's original decision or confirmation that the decision is still valid;

In the case of the premature suspension/termination of a study, the applicant should notify the REC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the REC;

The REC should receive notification from the applicant at the time of the completion of a study;

The REC should receive a copy of a final summary or final report of a study.

12. SUSPENSION OR TERMINATION OF UREC/REC APPROVAL OF RESEARCH:

The UREC/REC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the REC's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the REC's action and shall be reported promptly to the investigator, appropriate UREC authorities, including the relevant Dean and Head of Department.

12.1 EXEMPTIONS FROM UREC/REC APPROVAL:

All research activities involving human subjects must be reviewed and approved by the REC unless the UREC determines through due process that the research qualifies to be exempt from REC review and approval.

12.2 DOCUMENTATION AND ARCHIVING:

Proper records shall be maintained in respect of all applications and documents received for review of research proposals, minutes of the meetings of the RECs, decisions taken by the RECs, follow up action on the decisions, communications from time to time with the researchers by the UREC and all other relevant bodies of the University.

13. Annexures:

Annexure 1 – Application for ethical clearance of research proposal

Annexure 2 – Consent of Participant in research

Annexure 3 - Ethical Review Check List Master's degree level research

Annexure 4 – Ethical review check list Degree level research

Annexture 5 - Ethical Clearance Certificate

Annexure 1 : Application for ethical clearance of research proposal: Human subjects related research

Note: 1. Please complete all sections of the application form.

2. Please attach the research proposal and all relevant documentation to the application

Title and Name: …….
Academic Position: ……
Institution: …….
Contact details:
Telephone no: ……
Office: ……
Cell: ……
Email address: ……

Title of research project: …….

Place where this project will be carried out: …….. Country: …….. Region: ……..

1. Purpose of the research:

2. Objective of the research (Please list all objectives)

3. Nature and methodology of data collection of research

3.1 Please indicate the nature of the research by ticking appropriate box(s)

Collection of personal and social information directly from research participants	
Participants will undergo physical examinations/assessments	
Participants will undergo psychometric testing	
Identifiable information will be collected about persons from records	
Anonymous information will be collected from available records	
Literature, documents, archival sources will be collected on individuals/groups	

3.2 What information will you provide to participants regarding this study?

3.3 Did you attach the Informed consent form to this application?

YES	
NO	

If NO, Please motivate why informed consent form is not necessary

3.4 Please indicate your data collection method

Questionnaires	
Interviews	
Observations	
Experimentation	
Other frameworks : (please state)	

Note: Please attach to this application your data collection instrument. The application shall not be considered without this document.

4. Research Participants

4.1 State where human participants will be selected for this study

4.2 Please indicate the method of participants selection

Participant will be volunteer	
Participants will be selected	

4.3 Please describe how participant will be asked either to volunteer or how selection will be done for this study.

4.4 Please indicate whether research participants are subordinates to the researcher/s of this study

YES	
NO	

If, yes, please justify the selection of the subordinate participants

4.5 Please indicate if control group (participants) will be used in this study?

YES	
NO	

If, yes, please describe how control group will be selected

4.6 Please indicate the age range of participants in this study

4.7 If children are used in this study, please indicate whether parent/guardian consent will be obtained

YES	
NO	

If no, please explain why consent will not be obtained

4.8 Please indicate whether children assent for participation will be obtained

YES	
NO	

If no, please explain why assent will not be obtained

Note: Please attach both parent/guardian consent and child assent forms to this application.

4.9 Indicate if participation or non-participation to this study will be disadvantageous to the participants

YES	
NO	

If yes, please explain in what way

4.10 Indicate whether this study will benefit the participants in any direct way

YES	
NO	

If yes, please explain in what way

5. Research procedures/period and general issues

5.1 Indicate the level of risks participants may be subjected to in this study

No risk	
Discomfort	
Pain	
Possible complication	
Persecution	
Stigmatisation	
Negative labeling	
Other (please specify)	

Note: Please provide details of risks (other than no risk) indicated above

5.2 Please indicate when this study will commence

5.3 Please indicate over what period the research will be conducted

5.4 Have you obtained permission from other relevant authorities as needed

YES	
NO	

If yes, Please indicate the relevant authority that have authorized you

5.5 Please explain how confidentiality will be maintained in this study

5.6 Please indicate to whom and how research results will be disseminated after completion of this study

5.7 Please indicate how this study will be funded

Researcher	
Institution	
Sponsors	
Collaborations	
Others (please specify)	

Please explain all of the boxes marked above

5.8 Is there any conflict of interest relevant between researcher and sponsors/funders for this study?

YES	
NO	

If, yes, please provide details of the conflict of interest

5.9 Is there any possible property rights/ interest relevant to this study?

YES	
NO	

If yes, please provide complete details of the property rights/ interest

5.10 Please provide any other relevant information considered important for the UREC/REC in decision making

Date: **Signature Applicant:**

Annexure II: Consent from participant for participation in research

Title of the Study:……

(Explain to participant who the researcher(s) are and why this study is being done.)

1. Purpose of the study*:*
   (In more explicit, but understandable terms explain the purpose of the study as in the proposal)

2. Procedures:
   (Explain what the researcher will expect the participant to do)
   Potential risks and discomforts
   (Provide information on risk, discomforts or inconveniences of participation in the study)

   Potential benefits of the study
   (Explain benefits to participant, community and society as applicable)

3. Payment for participation
   (State whether or not participant can expect payment for involvement in the study.)

4. Confidentiality
   Explain how confidentiality will be maintained throughout the study)

5. Rights of the participant
   (Explain participant's right to voluntary participation and withdrawal from the study. Explain that no coercion or force will be exercised to answer questions and that refusal will not bear any negative consequences for participant)

6. Researcher information
   (Provide participants with contact details and invite participants to clarify issues as needed)

7. Declaration by participant

I, _____(*name of participant)* was informed fully and in (*mention language of communication)* of all the relevant aspects of the mentioned research and my voluntary participation in the study, by *(name of researcher).*

I was given opportunity to ask questions and these questions were answered fully and to my satisfaction.

_____ _____

Signature participant/parent guardian **Signature Child**

8. Declaration by Researcher

I, _____ *(name of researcher)* declare that *(name of participant)*received truthful and full information regarding the research and that I have answered all questions honestly and to the best of my knowledge. Information was given in *(language)* and *(name of interpreter)*/no interpreter was used to facilitate understanding.

_____

Signature researcher **Date**

Annexure III Check list for ethical review of research for Master's degree students

(To be completed for each student undertaking research separately)

Description of ethical review considerations	Supervisor
1. Has the student obtained consent from other relevant authorities for research	Yes No
2. Have the purpose & objectives of research been clearly stated	Yes No
3. Can the student motivate the method of data collection	Yes No
4. Can the student motivate the selection of research participants	Yes No

5. Can the student explain all the relevant information to be provided to participant to obtain informed consent	Yes No
6. Can the student describe the risks involved to participants in the project	Yes No
7. Can the student explain to the participants how identified risks will be minimized in the project	Yes No
8. Can the student describe the benefits of the research for participant/the community/society from their participation	Yes No
9. Can the student explain how confidentiality will be maintained during the project	Yes No
10. Can the student explain how research data will be protected	Yes No
11. Can the student describe how research data will be disseminated and to whom	Yes No

NB: Please tick mark Yes or No in the relevant column

Signatures Supervisor **Signatures Head**

Date **Date**

Annexure IV: Check list for ethical review of research for degree students

(To be completed for each student undertaking research separately)

Description of ethical review considerations	Supervisor
1. Has the student obtained consent from other relevant authorities for research _____	Yes No
2. Have the purpose & objectives of research been clearly stated	Yes No
3. Can the student motivate the method of data collection	Yes No
4. Can the student motivate the selection of research participants	Yes No
5. Can the student explain all the relevant information to be provided to participant to obtain informed consent	Yes No

6. Can the student describe the risks involved to participants in the project	Yes No
7. Can the student explain to the participants how identified risks will be minimized in the project	Yes No
8. Can the student describe the benefits of the research for participant/the community/society from their participation	Yes No
9. Can the student explain how confidentiality will be maintained during the project	Yes No
10. Can the student explain how research data will be protected	Yes No
11. Can the student describe how research data will be disseminated and to whom	Yes No

NB: Please tick mark Yes or No in the relevant column

Signatures Supervisor **Signatures Head**

Date **Date**

Annexure V: Ethical Clearance Certificate

Ethical clearance reference number …… Date …… This ethical clearance certificate is issued by the University Research Ethics Committee of the University of Kigali in respect of the research project outlined below on the recommendations of the Faculty/Centre/Campus Committee of ……..

Title of Research Project

…….…….

…….

Principal Researcher ……..,……..

Host Department and Faculty …….…….

Supervisor …….……..

The Clearance is given on the following conditions:

(a) Any significant changes in the conditions or undertaking or outline in the approved research proposal must be communicated to the UREC.

(b) Any breach of ethical undertaking or practices that have an impact on ethical conduct of research must be reported to the UREC.

(c) Principal researcher must report through his/her Supervisor and Department REC issues of ethical compliance at the end of the research project.

(d) The UREC retains the right to withdraw or amend the ethical clearance if any breach of ethical practices as outlined in the URE Policy and URE Guidelines is detected or suspected.

Chairperson **Date**

University Research Ethics Committee

……..University of Kigali, Kigali Rwanda