RONGO UNIVERSITY- INSTITUTIONAL REVIEW AND ETHICS COMMITEE

STANDARD OPERATING PROCEDURE

for

BEHAVIOURAL, BIOMEDICAL, ENVIRONMENTAL, HEALTH SCIECIES AND SOCIAL RESEARCH

September 2020 - August 2023

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ABBREVIATION ANS ACRONYMS

CBOs	Community Based Organizations
CITI	Collaborative Institutional Training Initiative
COI	Conflict of Interest
CO-PI	Co-Principal Investigator
CVs	Curriculum Vitae(s)
DVC- ASA	Deputy Vice Chancellor - Academics and Students Affairs
DVC-FP	Deputy Vice Chancellor- Finance and Planning
EOG	Ethics Operational Guidelines
ERC	Ethics Review Committee
IREC	Institutional Review and Ethics Committee
KEMRI	Kenya Medical Research Institute
MoH	Ministry of Health
M&E	Monitoring and Evaluation
NACOSTI	National Commission for Science, Technology and Innovation
NGO	Non- Governmental Organization
PI	Principal Investigator
QMS	Quality Management System
RU	Rongo University
SOP	Standard Operating Procedure
ST&I	Science Technology and Innovation
ToC	Table of Content
VC	Vice Chancellor

DEFINITION OF TERMS

Assent	means an affirmative agreement of a child (aged 12- 17 years) or an individual with impaired consent capacity to participate in research. Mere failure to object i.e. absence of affirmative agreement should not be construed as assent.
Confidentiality	Actual treatment of the personal information, that an individual has disclosed in a relationship of trust, with the expectation that this information will not be divulged to others without permission.
Conflict of interest	A conflict of interests arises when a member (or members) of the RU-IREC holds interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when an RU IRECmember has financial, material, institutional or social ties to the research.
Consent	An affirmative agreement by an adult research participant with legal capacity to participate in a research.
Falsification	manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
Investigator	A qualified scientist who undertakes scientific and ethical responsibility either on his/her own behalf or on behalf of an organization/ firm, for the ethical and scientific integrity of a research project at a specified site or group or sites. In some instances a coordinating or principal investigator may be appointed as the responsible leader of a team of co-investigators
Privacy	Having the control over the extent, timing of sharing oneself (physically, behaviorally or intellectually) or information about oneself with others.
Plagiarism	Appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Protocol	A document that provides the background, rationale, and objective(s) of a Biomedical, Social, Behavioral and Environmental research project and describes its designs, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol.
Scientific Misconduct	Improper and unprofessional behavior resulting from lack of integrity in executing a research misconduct

1.0 GENERAL OVERVIEW

The unreserved need of Rongo University to become a world-class University is the force that has been driving its rapid growth in the last six years. Today, the higher education sector is facing increasing demands from the society as pedestals to champion socio- economic transformation of societies and nations. There is a clear need to develop systems and processes that will enable the University to effectively respond to the emerging challenges and tap the opportunities in the operating environment.

Rongo University undertakes research in diverse fields including those involving human subjects and experimental researches impacting on the environment. Ethical clearance has previously been sought and obtained from collaborating partners and existing clearing institutions recognized by the NACOSTI. However, as students' enrollment in health-related program and Community Service Institutions continue to expand, there is need for RU to establish Institution Review Ethics Committee medical programs which have generated more research on human subjects hence the need for ethical guidelines.

1.1 Scope and responsibility of the IERC

The main responsibility of a **Rongo University -Institutional Review and Ethics Committee(RU -IREC)** is to protect potential participants in the **research**, but it must also take into account potential risks and benefits for the community in which the **research** will be carried out and where necessary, protect investigators from exploitation by authorities. Its ultimate goal is to promote high **ethical** standards in **research** for society health and overall well-being. This to be achieve through execution of specific objective as outlined below: -

1.2 Objectives of the committee

- To streamline research processes for timely execution and delivery of results to solve population challenge in a relevant manner
- Review the adequacy of the informed consent document, particularly as to its description of the care and protection of subjects, confidentiality, risks and benefits to individuals and communities.
- Assessing the procedures and methods used to ask for participants' informed consent
- 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
- Take into consideration the principle of justice. This is to say that all 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

- Ensuring that all the research activities are recorded properly and reported in a responsible, honest, and objective way.
- Recognizing any financial or personal interests that may affect the research

1.3 Institutions Served

Rongo University - Institution Review Ethics Committee (RU-IREC) seeks to provide ethics review to the County, Community Based Organizations (CBOs), Non- Governmental Organizations (NGOs) and any other institutions conducting evaluation and researches that impact on human and environment in general.

2.0 FORMATION AND FUNCTIONS OF THE COMMITTEE;

The constitution of the RU-IREC will adhere to the national and internationally set requirements so as:

a) To ensure that it is established in accordance with the policies of Rongo University and adherence to the values and principles of the communities they serve.

b) To be multi-disciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution and laypersons representing the interests and the concerns of the community.

c) To ensure that it establishes publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the ethics committee, membership requirements, the terms of appointment, the offices, the structure of the secretariat, internal procedures and the quorum requirements.

2.1 Membership requirements

The appointment of RU-IREC membership will be direct appointment by the Vice Chancellor of Rongo University. TheRU-IREC shall be 9 (Nine) to 15 (Fifteen) members of whom at least 40% shall be drawn from human health professions, taking into account the diversity of the disciplines in the University. The committee shall also include at least 40% of either gender.

Eligibility of membership shall be as follows:

1) A social and behavioral scientist (cultural anthropologist and medicalsociologist),physician, epidemiologists, basic scientists, Educationist,social and behavioral scientists, a lawyer, a statistician, a lay person, a religious representative, a community representative, a media person, Environmentalists, natural scientists,. 'This list is clearly indicative and not exhaustive'

2) A rotation system will be adopted for membership in order to maintain continuity, development and maintenance of expertise within the RU-IREC, and the regular input of fresh ideas and approaches.

2.1.1 Terms of membership

1) Members should be willing to make public their full names, profession, and institutional affiliation.

2) Members shall be expected to declare any conflicts of interest which may arise or exist during their tenure on the RU-IREC committee. Such conflict will be declared in writing before each meeting and documented in the minutes. Members will recuse themselves from any discussion of a protocol in which they have a conflict of interest (COI).
3) Members will sign a confidentiality agreement at the beginning of their appointment regarding meeting deliberations, RU-IREC committee applications, information on research participants, and related matters; in addition, all RU-IREC Secretariat staff shall sign a similar confidentiality agreement.
4) Each member shall serve for a period of three (3) years. The tenure may be renewed for one or more additional terms at the discretion of the Vice Chancellor and the University Board of Management.
5) The Vice Chancellor in consultation with the University Board of Management shall have authority to remove or replace a RU-IREC committee member.
6) The Vice Chancellor may terminate the services of or disqualify a member of the RU-IREC on grounds of:
    i. Misconduct.
    ii. Abuse of office.
    iii. Non-disclosure of competing interests.
    iv. Inappropriate behaviour.
    v. Unprofessional conduct.
    vi. Failure to abide by the terms of appointment.
    vii. Failure to attend more than 60% of the meetings in a year.
7) A member may resign from the RU-IREC on his/her own volition. The member shall be required to submit his/her resignation in writing at least two (02) months prior to his/her anticipated end date to allow time to fill the vacancy that will exist as a result of his/her resignation.
8) When a new member has been appointed to the RU-IREC, an appointment letter from the Vice Chancellor shall be sent to the new member. The chairperson of RU-IREC or a RU-IREC committee Secretary shall then arrange an orientation session with the new member. On completion of the induction, the new member may begin attending the RU-IREC meetings.
1) Members will be reimbursed for expenses incurred in attending the RU-IREC meetings and/or research site visits. The allowance shall be decided upon by the executive members of RU- IREC

Note: The Executive RU-IREC members is composed of the VC, DVC - ASA, RU-IREC chairperson and secretary and Dean, Research and post graduate studies.

2.1.2 Continuing Education for RU-IREC Members

1. All the RU-IREC committee members shall be asked to participate in workshops germane to the RU-IREC committee responsibilities.
2. Each RU-IREC committee member shall be given the opportunity to attend Bioethics and Scientific Conferences or Seminars whenever funds to support these activities are available.
3. All the RU-IREC members shall be required to undertake ethics training, e.g. The Collaborative Institutional Training Initiative (CITI) program or a similar curriculum, at least once every three (3) years.

2.2 Committee Members Roles and Responsibilities

2.2.1 The RU-IREC Committee Chairperson (s)

The RU-IREC Chairperson(s) must have an in-depth understanding of ethical issues in the conduct of Social and human research, the law and NACOSTI research guidelines.
The responsibilities of the RU-IREC Chairperson (s) shall be (but not limited to) the following:

1) To provide leadership in establishing and implementing guidelines and standard operating procedures for the RU-IREC.
2) To assess conflict of interest reported by other RU-IREC members.
3) To direct proceedings and discussions of the full RU-IREC committee meetings.
4) To serve as a reviewer for research proposals under expedited review and/or designate atleast three RU-IREC committee members to conduct expedited review depending on their expertise.
5) To represent the RU-IREC in defending or discussing RU-IREC decisions with investigators.
6) To confirm and sign the minutes for the appropriate RU-IREC committee meeting.
7) To represent the RU-IREC committees in discussions between RU and other institutions with research interest.
8) To write specific correspondence to an investigator or institution as agreed upon at a convened RU-IREC meeting.
9) To carry out other duties common to all the RU-IREC committee members.

2.2.2 The RU-IREC Committee Secretaries

The RU-IREC Committee Secretary shall be a Senior or Principal Research Analyst based at the RU-IREC Secretariat and shall also carry out duties of a RU-IREC committee member.In addition, other responsibilities of the RU-IREC Secretary shall include (but not be limited to) the following:

1) To coordinate routine functions of the RU-IREC and work closely with the appropriate RU-IREC Chairperson to provide for the efficient management of the RU-IREC operations.

2) To represent the RU-IREC in discussions with non- RU affiliated investigators.
3) To call for and coordinate RU-IREC meetings.
4) To coordinate and conduct educational activities designed to improve staff, and student knowledge of sound ethical research practices.
5) Any other duties as may be assigned by the RU-IREC Chairperson.

2.2.3 The RU-IREC Committee Members

The RU-IREC committee members shall be of diverse cultural backgrounds representative of the population in Kenya and the committee shall be gender balanced i.e. no more than sixty percent (60%) of either female or male.

The responsibilities of the RU-IREC committee members shall include (but not be limited to) the following:

1) To develop an understanding of ethical principles of research involving human participants set forth in the RU-IREC SOPs, national and international guidelines and in the Office of Dean Research and post graduate studies, Rongo University.
2) To evaluate all proposed and continuing submitted to the committee.
3) To ensure that all approved studies comply with the terms and conditions of approval for the duration of the research.
4) To review the RU-IREC committee documents and materials assigned to the member prior to the RU-IREC meeting and submit a written and typed report a day before each scheduled meeting.
5) To attend scheduled monthly meetings prepared to discuss proposals and items on the agenda within the member's area of expertise.
6) To identify and facilitate the resolution of any issues for a given proposal when appointed as a designated reviewer.
7) To participate in expedited reviews when called upon by the RU-IREC committee Chairperson(s) and provide written and typed review comments.
8) To participate in and conduct educational activities in research ethics.
9) To participate in monitoring or audit functions of the RU-IREC.

2.2.4 The RU-IREC Secretariat

The RU-IREC Secretariat Office (referred to hereafter as "the RU-IREC Office") staff shall be composed of: The head and secretary of RU-IREC, Researchers and Assistant Research Analysts, an Administrator and support staff.

The RU-IREC office shall be located within the Rongo university main campus. All staff of the RU-IREC Secretariat shall be employees of Rongo University.

The activities of the RU-IREC Secretariat shall include (but not be limited to) the following:

1) To provide support to the RU-IREC committee Chairpersons and Secretaries in the review process.
2) To serve as an interface for Investigators, regulatory authorities and any other stakeholders on matters of health and social research ethics.
3) To ensure that submitted research proposals or applications are reviewed.
4) To oversee the accurate and timely processing, tracking and filing of all applications.
5) To effectively communicate with investigators, RU-IREC committee members, and other interested groups in a timely manner.
6) To ensure that quorum is present and maintained during convened RU-IREC committee meetings.
7) To ensure that continuing review of research is conducted appropriately and in a timely manner.
8) To maintain accurate records of the RU-IREC committee actions.
9) To record minutes of the RU-IREC committee meetings.
10) To document communication with investigators and others involved in the conduct of research.
11) To maintain an accurate and comprehensive database of reviewed and approved research.
12) To maintain an accurate archiving system that allows for access to open and closed studies.
13) To update the RU-IREC on any new information or regulation and changes affecting the RU-IREC function or protection of research participants.

3.0 APPLICATION PROCEDURE AND BUSINESS CONDUCT

RU- IREC, has instituted systematic application and decision-making procedures; defined types of reviews; meetings confidentiality; review outcome notifications; code of conduct for RU-IREC members and investigators.

3.1 Procedure for proposal submission

All research proposals involving human participants need to be submitted by individual investigator to the RU-IREC Secretariat, using an online submission portal and 2 hardcopies to be delivered to RU-IREC secretariat.

Each proposal undergoes a preliminary screening by the Secretariat to confirm that all necessary documentation has been submitted i.e.

i. Duly filled and signed proposal submission forms;
ii. the study proposal accompanied withinformed consent forms, study instruments,
iii. Local ethics approval,

iv. Payment receipts etc.

Only when all required documentation has been duly submitted, will the Secretariat forward the study for review by the RU-IREC. A study will only receive final approval from the RU-IRECwhen all core documentation has been satisfactorily submitted, including local ethics approval.

3.2 Decision making and notification

Only when all required documentation has been duly submitted, will the Secretariat forward the study for review by the RU- IREC. A study will only receive final approval from the RU-IREC when all core documentation has been satisfactorily submitted, including local ethics approval.

3.3 Types of Reviews

Based on certain set of criteria, a proposal is submitted for one of the following types of review:

a) Full committee review of proposals

All research proposals that present more than minimal risk to human subjects are reviewed by two RU-IREC members who present the proposal to the RU -IREC for general discussion and a consensus decision. occasionally, the owners of the proposal under review are invited to respond to queries raised and to provide clarifications and/ or justifications.

b) Expedited review of proposals

A proposal is circulated for expedited review when the research procedures present no more than minimal harm to the research participants or communities. In this case, the proposal is sent to three RU-IRECmembers who are required to provide their feedback to the secretariat within 5 working days. As appropriate, the proposal is then either approved or returned to the investigator for further action.

c) Exemption from RU-IREC review

Proposals are exempt from RU-IREC review when there is no possibility of harm arising as a result of the conduct of the research project or when the information being collected is available from the public domain for example in systematic review.

d) Accelerated review

In the event of a public health emergency, such as the investigation of a disease outbreak or a disaster relief operation, a protocol may be submitted for accelerated review, the identified two reviewers will have a maximum five days to review and submit feedback to RU-IREC for discussion and consensus in ad hoc meeting.

e) Continuing review

Since ethics approvals are provided to studies for a limited time period, the RU-IREC reviews the progress of the study at periodic intervals(every six months). In order to renew the approval, the investigators should submit the necessary documentation to the RU-IREC prior to approval expiry.

3.4 Review Meetings

3.4.1 Each RU-IREC committee shall hold at least twelve (12) scheduled meetings in each calendar year for the purpose of scientific/ ethical review.

3.4.2 The meeting schedule shall be established in advance and a hard copy provided to the RU-IREC committee members at the beginning of each calendar year.

3.4.3 The schedule for the RU-IREC committee meetings shall set out the dates, times, venues of meetings, and the closing date for applications to each meeting.

3.4.4 The RU-IREC Chairperson(s) shall convene special ad hoc meetings, within three (3) to five (5) working days' notice, to provide expeditious review of research proposals or applications, address concerns regarding the rights and welfare of study participants, review unanticipated problems or non-compliance issues.

3.4.5 The RU-IREC members shall receive final notification of the meeting, the agenda and the RU-IREC meeting files at least six (6) to ten (10) working days in advance of the meeting.

3.4.6 The minutes of each meeting shall be recorded and confirmed at the next convened RU-IREC meeting, with the signature of the Chairperson appended on the last page of the document.

3.4.7 The RU-IREC Secretariat may invite a Principal Investigator to a RU-IREC meeting to present their proposal or to elaborate on specific issues or to offer clarifications.

3.4.8 The RU-IREC Secretariat may also invite independent consultants to a meeting or request them to provide written comments upon review of an application subject to prescribed confidentiality agreements (refer to Appendix VI: Confidentiality Agreement Form).

3.4.9 All the RU-IREC committee meetings shall be directed by the Chairperson; if the Chairperson is not available, the Vice Chairperson or alternate shall conduct the meeting. This arrangement shall be recorded in the minutes of the meeting.

3.4.10 All core RU-IREC members must be present at each meeting or must have provided their evaluation comments via the RU-IREC Secretariat prior to a scheduled RU-IREC committee meeting.

3.4.11 No RU-IREC meeting shall be held or proceed without a quorum constituting of fifty percent plus one (50% plus 1) of core RU-IREC members including one member from the RU-IREC Secretariat. A quorum shall consist of one member who is a health scientist one member who is a non-health scientist, two members with professional training in a non-scientific area, a non-affiliated member and a lay representative.

3.4.12 If quorum is lost during a meeting, the RU-IREC shall not make a decision on a research proposal or application until the quorum is restored. If quorum cannot be reestablished, the meeting shall be stopped and re-scheduled.

3.4.13 A RU-IREC committee member should attend at least sixty percent (60%) of the scheduled meetings each calendar year. Failure to attend the required minimum may lead to termination of the appointment to the committee.

3.5 Review verdict

A Committee decision on a research proposal shall be made by consensus. RU-IREC committee(s) will make one of the following decisions at the meeting:

1. Approve application as submitted if all of the following conditions are satisfied:
    - The risks to research participants are reasonable in relation to anticipated benefits.
    - The knowledge that is expected to result from the research of public health or clinical importance and/or of advancement of the field of research.
    - The risks to research participants are minimized.
    - The selection of research participants is equitable.
    - Informed consent/assent will be sought from each prospective research participants or their legally authorized representative and will be adequately documented, unless a waiver has been granted.
    - The research plan provides for monitoring of data collected.
    - There are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of research data.
    - There are adequate safeguards to protect the rights and welfare of research participants who are vulnerable to coercion or undue influence, where appropriate.
2. Where consensus cannot be reached the RU-IREC Committee will defer making a decision on the research proposal or application until the reasons for the deferment have been addressed or;
3. Defer making a decision until specialist advice or opinion has been sought and received, where applicable.
4. Not recommend ethical clearance if any of the following conditions apply:
    - The study design will mount excessive risks to research participants; or
    - The study design is flawed and will not yield generalizable knowledge of scientific merit; or

- The value of the study results will be negligible. Thus, even though the risks may be minimal and the potential benefit almost zero, the overall risk/benefit ratio would be considered unacceptable; or
- The study presents significant risk and asks a question that has been answered in earlier research; or
- There is insufficient safety data on a given investigational product or device to warrant testing in any living individual.

3.6 Communication to Principal Investigator

Whether a proposal has been submitted to a Full Committee or for an "expedited review", the outcome of the review will be communicated electronically to the investigator. additionally, hardcopies are made are made available at the RU-IREC offices.

The Secretariat will provide an RU-IREC Summary Review Form to the investigator outlining the concerns, if any, raised by the RU-IREC.

The RU-IREC recommends that the investigator should not contact individual RU-IREC members present at a meeting when their proposal was discussed. Any questions or concerns that a investigator might have with regard to his/her proposal should be referred directly to the Secretariat.

The review summary is sent electronically initially and is followed by the hard-copy only after the proposal is fully approved or if it is rejected.The RU may give any one of the following recommendations as feedback to be communicated to the investigator

a) Approved as submitted

The proposal is approved and no modifications are required. In this case, the secretariat will prepare the Ethical Review Approval letter/certificate..

b) Approved conditionally; requires amendments and/or clarifications

The proposal's approval is contingent upon an adequate response by the Principal Investigator to the satisfaction of the reviewers or the Chair on behalf of the RU-IREC.
If amendments are required, they should be included in the proposal and the amended proposal submitted to the RU-IREC Secretariat. The proposal will either be scrutinized by the Secretariat or by the Primary Reviewers as decided by the RU-IREC.

c) Not approved; requires additional information and/or rewriting

The proposal should be improved and the revised version of the proposal should be re-submitted as a new submission to the RU-IREC for re-review by the Committee.

d) Rejected

The proposal is ethically unacceptable and may not be approved by the RU-IREC. The Principal Investigator may submit a new proposal that takes into consideration the ethical issues raised by the Committee.

3.7 Confidentiality of RU-IREC Applications and Proceedings

3.7.1 RU-IREC shall have strict regard to confidentiality of records and of the decisions which are based on consensus of members of RU-IREC.

3.7.2 RU- IREC committee members and RU-IREC secretariat staff shall be required to sign a confidentiality agreement upon appointment (refer to Appendix VI: Confidentiality Agreement Form).

3.7.3 All RU-IREC documents shall be delivered to the respective RU-IREC committee members' offices by the RU-IREC Secretariat staff.

3.7.4 At the end of each RU-IREC meeting, all members shall be required to return their meeting files to the RU-IREC Secretariat and submit their evaluation reports to the Head /Secretary/ Assistant Secretary of RU-IREC. If a RU-IREC member chooses to retain any document for his/ her own interest, he/she may do so but shall assume full responsibility for maintaining its confidentiality and for its safe disposal.

3.7.5 The meeting documents shall be disposed within one (01) year of the respective RU-IREC meeting. The committee members who choose to retain documents must sign a document that indicates that they are retaining the RU-IREC document(s) and they understand that they are responsible for maintaining its confidentiality. Should they destroy the documents in their custody, they must notify RU-IREC in writing.

3.7.6 All the RU-IREC documents shall be disposed of in a confidential manner such as shredding and/or incinerating.

4.0 DOCUMENTATION RECORD KEEPING, ARCHIVING

All documentation and communication of theRU-IREC shall be dated, filed, and archived according to Rongo University Quality Management System (QMS) written procedures. Documents to be filed and archived include but not limited to:

a) The RU-IREC guidelines
b) Written standard operating procedures of theRU-IREC
c) Regular annual reports
d) The curriculum vitae of allRU-IREC members
e) A record of all income and expenses of the RU-IREC including allowances and reimbursements made to the secretariat and committee members
f) The published guidelines for submission established by RU-IREC
g) The agenda of RU-IREC meeting

h) The minutes of RU-IREC meetings

i) A copy of all materials submitted by an applicant

j) The correspondence by RU-IREC secretariat with applicants or concerned parties regarding application, decision and follow-up

k) A copy of the decision and any advice or requirements sent by an applicant

l) All written documentation received during follow-up

m) The notification of the completion, premature suspension or premature termination of a study

n) The final summary or final report of the student

5.0 RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR;

6.0 COMPLAINTS; HANDLING PROCEDURES, DISPUTE RESOLUTION, APPEALS AND REPORTS

1. The Head of RU-IREC shall handle all complaints regarding the conduct of a research study.
2. The position and contact information of the Head RU-IREC shall be included in all Informed Consent/Assent Documents for all studies.
3. Any individual with a complaint about the conduct of a study will be required to notify the Head RU-IREC for further action.
4. The RU-IREC committee(s) will document, in writing, the basis of the complaints.
5. The RU-IREC committee(s) shall review all claims of serious or continuing non-compliance with the RU-IREC requirements. Non-compliance involves conducting research in a manner that disregards or violates the RU-IRECs regulations and/or an approved protocol.
6. The RU-IREC committee(s) shall investigate the complaint or concern within thirty (30) working days from the date of the meeting where it was discussed.
7. Communication to the PI will be sent within six (6) working days from the date of the RU-IREC review. The PI shall be required to respond to the claim.
8. The appropriate RU-IREC committee shall review both the claim and response, upon which the committee may recommend:
    i. Dismissal of the claim as unjustified.
    ii. Referral of the matter to another more appropriate process or authority within the respective institutions or other relevant authority for resolution.
    iii. Resolution through corrective or educational measures where the violation is minor or inadvertent.

iv. The launch of a formal RU-IREC investigation where the allegation or complaint appears founded and is of a serious nature.

Note: Should the RU-IREC decide to launch a formal investigation, this shall be referred to the Quality Assurance and Monitoring Department. The PI under investigation shall be given an opportunity to submit written comments and to appear before the investigation committee on at least one occasion before the committee issues a report of its findings. The actions the committee may take with respect to the investigation include but are not limited to:

a) Dismissal of the complaint as unjustified.
b) Corrective or educational measures.
c) Frequent monitoring of research activities.
d) Recommend frequent reporting by the researcher of his/her research activities.
e) Recommend restrictions on research practice.
f) Suspension of approval of one or more of the investigator's studies.
g) Termination of approval of one or more of the investigator's studies.
h) Referral of the matter to other RU-IREC committees for possible further review and action by those bodies.

5. The RU-IREC may take such measures as necessary to protect the identity of person(s) making allegations and may liaise withUniversity administration to protect complainants or informants from any retaliatory actions. The complainants or informants shall be reassured of their protection to the extent permitted by law.

6. The Head, RU-IREC/Chairperson(s) will notify the PI and the complainant or informant, in writing, the results of the inquiry and reasons for such decision.

7. The committee(s) Chairperson/Head RU-IREC shall inform the study sponsor, the University Management and the Chair and Secretary of the National Bioethics committee (NACOSTI) and others relevant body of the termination or withdrawal of any ethical approval.

7.0 MONITORING OF APPROVED PROCEDURES

All proposals that receive a positive decision shall be monitored and evaluated periodically throughout the project life cycle. The follow-up procedure should take the following into consideration:

a) The M & E review will be carried out by a sub-committee constituted by the RU-IREC for the specific project. The quorum requirement, the review procedure, and the communication procedure for follow up reviews will be determined by the respective sub-committee.
b) The follow –up review intervals will be determined by the nature and the events of research projects but in the following instances or events, a follow-up review is mandatory:

c) Any protocol amendment likely to affect the rights,safety,and/orwell-being of there search participants or the conduct of the study

d) Serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors and regulatory agencies

e) Any event or new information that may affect the benefit/risk ratio of the study indicating modification, suspension, or termination of theRU-IRECs original decision or confirmation that the decision is still valid

f) A decision of a follow-up review shall be issued and communicated to the applicant, in the case of premature suspension/termination of a study, the applicant should notify theRU-IREC of the reasons for suspension/termination.

g) A summary of results obtained in a study prematurely suspended/terminated should be communicated to theRU-IREC by the researcher.

h) RU-IREC will receive notification from the applicant at the time of the completion of a study.

i) RU-IREC shall receive a copy of the final summary or final report of a study Linkages with other ethics review committees.

8.0 APPENDICES

a) Proposal Format

b) Checklist (Requirements for application)

c) Application form

d) Consents and Assent/Informed consent form F Informed assent for children

e) Waiver/exemption form

f) Confidentiality Agreement

g) Reviewers guidelines

h) Events report Form

Appendix I: Proposal Format

A s proposal should have the following basic sections:

1. Title
2. Investigators
3. Table of Content(TOC)
4. Abstract
5. Background
6. Rationale/justification of the study

7. Objectives
8. Significance of study
9. Literature Review
10. Methodology
11. Ethical Considerations
12. References
13. Informed Consent
14. Data Collection Tools
15. Time Frame
16. Budget
17. Any authorizations (if available)

Appendix II: Requirements for Ethical Approval

Part A: Requirements for Students

1) Download application forms for Ethics Operational Guidelines (EOG) for Research from the Rongo University Website - Fill three (3) copies.
2) Three (3) copies of Approval of Research Proposal from Graduate School.
3) Five (5) copies of your proposal duly stamped from Graduate school.
4) Attach your Curriculum Vitae at the back of each of the proposals.
5) If the supervisors are not from Rongo University, attach their Curriculum Vitae at the back of each of the proposal.
6) Ensure that your proposal has a work plan, budget and informed consent for participants.
7) Refer to the ethical review regulations and guidelines provided on the website for guidance on criteria for presentation of the proposal
8) Must attach Turn it in Report of the proposal from the department.

PART B: Requirements for projects

1) Download application forms from the Rongo University Website and Fill in three (3) copies(Triplicate.
2) Three (3) copies of Research Authorization to the National Commission for Science, Technology and Innovation or Affiliate Institution.
3) Five (5) copies of your proposal duly signed.
4) Attach the Curriculum Vitae of the PI and CO-PI at the back of each of the proposals
5) Ensure that your proposal has a work plan, budget and informed consent for participants.

6) Refer to the ethical review regulations and guidelines provided on the website for guidance on criteria for presentation of the proposal

PART C: Payments

Students

	RU Students		**Non-RU students**	
PhD	$55	Ksh. 5000	$ 60	Ksh.5500
Masters	$25	ksh. 2000	$ 30	Ksh. 2500
Under graduate	$ 15	Ksh. 1000	$ 20	Ksh. 1500

Projects

	RU Stuff		**Non-RU staff**	
Non-Funded	$ 55	Ksh. 5000	$ 110	ksh. 10000
Funded				
Up to 10 Million	$ 230	Ksh. 20,000	$ 500	Ksh.40,000
Over and above 10 million	$ 450	ksh. 40,000	$ 850	Ksh. 80,000

Appendix III: RU-IREC Application Form

Application Number

Submit one copy of this form with original inked signatures **incomplete forms** will not be accepted. All relevant appendices e.g. consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statements, advertisements, etc.) must be included at the back of the proposal.

I. Research Team : Provide the information requested below:

Name & Area of Specialization	**Institution**	**Academic Degrees**	**Contacts (*Cell Phone & E-mail*)**
Principal Investigator			
Co-Investigators			
Research Administrator (if any)			

Note: All correspondence shall be addressed to the Principal Investigator. Research Administrators may have delegated signatory authority only when listed as Co-investigators.

II PROJECT TITLE

_____

_____

_____

_____

_____

As the Principal Investigator in this research I declare that:

1) Any change to this protocol and/or procedure shall be notified to and effected only after approval by the RU-IREC.
2) I shall notify the RU-IREC of intended publication, or any other form of dissemination of results of this study and provide the draft contents.
3) Other members of the research team are bound by 1) and 2) above.

III **FUNDING INFORMATION**

Briefly describe current and pending grant and contract information

IV REQUIRED ATTACHMENTS

1. Letters of Study Approval from the Principal Investigator's Home Institution or approval letter from Dean, post graduate studies.
2. One copy of the Curriculum Vitae of each member in the research team describing their research qualifications and experience.
3. Research Personnel Information (Roles and responsibilities in the research project).
4. Abstract and consent forms

Principal investigator's Signature _____ Date_____

Appendix IV: Consents and Assent or Informed assent for children

A. Informed Consent (Sample)

My name is.....(name of organisation/I am a Ph.D/Master/Bachelor student from Rongo University). I am conducting a study titled "....." The information will be used (indicate the purpose of the study and significance).

Procedures to be followed

Participation in this study will require that I ask you some questions and I also examine you in order to screen you for ..... . Some specimen (indicate type of specimen, amount and from where) will be taken from you for further tests. I will record the information you provide in a questionnaire.

Voluntarism

You have the right to refuse participation in this study. You will get the same services and care whether you agree to join the study or not and your decision will not change the care you will receive. Please remember the participation in this study is voluntarily. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you receive here or any other organization now or in the future.

Discomforts and Risks

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you so choose. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait before you receive your routine services. During the removal of blood there will be some pain or discomfort but we will try our best to minimize this by being gentle.

Benefits

If you participate in this study you will help us to learn how to provide effective screening services that can improve ..... You will also benefit from being screened for ..... and if you are found to have a problem you will be advised on the treatment.

Reward

If you agree to participate in this study, lunch will be provided and transport expenses will be reimbursed at 200/- per visit.

Or there are no rewards or any payment to you if you participate.

Confidentiality

The interviews and examinations will be conducted in a private setting within the clinic. Your name will not be recorded on the questionnaire. The questionnaires will be kept in a locked cabinet for safe keeping at Rongo University. Everything will be kept private and only shared with the study team.

Contact Information

If you have questions about the study call the Dr... 07.....or .Supervisor...07...../ Investigators tel nos. to be inserted

However, if you have questions about your rights as a study participant: You may contact Rongo University Ethical Review Committee Secretariat on chairman.ruirec@rongovarsity ac.ke, secretar y.ruirec@rongovarsity.ac.ke

Participant's statement

The above information regarding my participation in the study is clear to me. The study has been explained to me and I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care that I will receive from the clinic today or that I will get from any other clinic at any other time.

Name of Participant.....

Signature or Thumbprint _____ Name of Representative/Witness

Investigators statement

Date _____

(where necessary) Relationship to Subject

I, the undersigned, have explained to the volunteer in a language s/he understands, the procedures to be followed in the study and the risks and benefits involved

Name of Interviewer ..... Signature Date

B. INFORMED ASSENT FOR CHILDREN

Rongo University Institutional Review and Ethics Committee

ProjectTitle: ..... Protocol Number:.....
Principal Investigator:.....
The investigators named above are doing a research study.

These are the things we want you to know about research studies:

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

What is the study about?
Explain the purpose of study and what it entails in simple language here
Why am I being asked to be in this research study?
You are being asked to be in the study because (detail you chose the participant What will happen during this study?
Indicate all the procedures and what the study expects from the participant.
If you agree to be in this study, you will.....
Will the study hurt/risks?

Some of the tests might hurt. The doctor will need some of your blood. The needle stick hurts for a little bit as the blood is taken. When _____, you may get dizzy or feel short of breath. Having a _____ sometimes makes people feel _____.

What else should I know about the study?

If you feel sick or afraid that something is wrong with you, tell an adult at once. You do not have to be in the study

Your Name (Printed) Age

Your Signature _____ Date

_____

Signature of Person Obtaining Consent_____Date_____

Signature of Witness _____
Date_____

Appendix V: Waiver/exemption form
EXEMPTION FROM ETHICAL REVIEW FORM

I. Research Team : Provide the information requested below:

Name & Area of Specialization	**Institution**	**Academic Degrees**	**Contacts (*Cell Phone & E-mail*)**
Principal Investigator			
Co-Investigators			
Research Administrator (if any)			

Note: All correspondence shall be addressed to the Principal Investigator. Research Administrators may have delegated signatory authority only when listed as Co-investigators.

2. PROJECT TITLE

_____

_____

_____

As the Principal Investigator in this research I declare that:

4) Any change to this protocol and/or procedure shall be notified to and effected only after approval by the RU-IREC.
5) I shall notify the RU-IREC of intended publication, or any other form of dissemination of results of this study and provide the draft contents.
6) Other members of the research team are bound by 1) and 2) above.

3. Project Details

PLEASE MARK the appropriate box as √

Type of study	Yes	No
a. Retrospective review of patient's charts		
b. Prospective data collection of patient's charts		
c. Analysis of laboratory/ radiology data		
d. Clinical audits		
e. Evaluation of practice guidelines		
f. Case reports		
g. Others; please specify		

4.. Period of data collection From: To: g. Starting date of study From: To :

5.. Summary of data to be collected	Yes	No
a. Demographics of the patients i.e name addresses, phone numbers, email addresses		
b. Clinical notes		
c. Photographs		
d. Laboratory / radiology data		
e. Management data		
f. Other; please specify		

6. Utilization of data collected; Will it be used for	Yes	No
a. Publication of papers in journals/ newspapers		
b. Oral/poster presentation in meetings/ conferences		
c. Students/resident's teaching		
d. Planning subsequent larger studies		

7. Summary of Objectives & Methods of study including selection and exclusion criteria of study subjects, sample size, analysis plan e.t.c

8.. Please answer the following questions and mark the appropriate box as✓

	Yes	No
a. Will any photographs be used/taken for publication?		
b. If yes,has written permission been obtained from study subject or guardian		
c. Has the study been reviewed by department research/ review committee		
d. Was any ethical concern raised by departmental committee		
e. If yes, what were the ethical issues?		
f. Were those ethical concerns resolved?		

Certificate of Review by the RongoUniversity Ethics Review Committee And Chair of the Department

The above study has been reviewed by the Institutional Review and EthicsCommittee (IREC). The Committee membersare satisfied that the study falls in the exemption category and has no ethical issue. The study is being submitted to RU-IREC for granting of an exemption letter.

Signature of Supervisor.....Date.....

_____

Appendix VI: Confidentiality Agreement

I, _____, agree to maintain full confidentiality in regards to any and all documentation received from researchers, Rongo University -Institutional Review and Ethics Committee(RU-IREC) Committee members "the Committee" and other entities in matters related to RU-IREC function.

Furthermore, I agree:

1. To adhere to the RU-IREC Office Management Procedures.
2. To ensure that all RU-IREC related documents are in a safe, secure location as long as they are in my possession.
3. To not make copies of any documents received at the RU-IREC Office unless specifically requested to do so by the principal investigator or his/her representative, the Committee and University Management.
4. To not to discuss, disclose, or reproduce any confidential information except when I carry out my functions as an RU-IREC Member.
5. To hold in strictest confidence the identification of any individual that may be reprimanded by the Committee.
6. To delete all electronic files containing RU-IREC-related documents from my computer hard drive and any backup devices when I leave the RU-IREC Office.

I am aware that I can be held legally liable for any breach of this confidentiality agreement and for any harm incurred by individuals as a result of the violation.

Name:(printed) _____
Signature:_____
Date: _____

Witnessed by the RU-IREC Committee Chairperson:

Name:(printed) _____
Signature:_____

Date:_____

Appendix VII Reviewers Guideline

This is a guide for reviewers to handle both scientific and ethical components of the proposal.

Background information

1. Is the rationale for the study clearly stated in the context of present knowledge? Yes 0 No 0 2. Is a review of literature with references included? Yes 0 No 0
3. Is the study setting described? Yes 0 No 0
Comments: ...

Goals and objectives

4. Are the objectives and/or hypothesis to be tested clearly stated? Yes 0 No 0 Comments: ...

Study Design

5. Does the protocol provide a clear description of the study design (e.g. whether it is basic science research, social science research, or epidemiological - observational or intervention - research) and the study participants, outcomes and intervention and control groups (if relevant)? Yes 0 No 0

Comments: ...

Methodology

6. Is an estimate of sample size provided, along with the assumptions on which it is based? Yes 0 No 0

Is this adequate? Yes 0 No 0
7. Are the inclusion and exclusion criteria clearly stated? Yes 0 No 0

8. Are the procedures for participant recruitment, admission, follow up and completion fully described and appropriate? Yes 0 No 0

9. Is protection of participants fully described and is it adequate? Yes 0 No 0
10. Are the drugs and/or devices to be used fully described? Yes 0 No 0 N/A 0

11. Are the clinical procedures to be carried out, fully described and appropriate? Yes 0 No 0 N/A 0

12. Are the laboratory tests and other diagnostic procedures fully described and appropriate?

Yes 0 No 0 N/A 0

13. Does the protocol include information on procedures that are experimental and part of the research, as opposed to those that are part of routine care? Yes 0 No 0 N/A 0

14. Does the protocol describe how the specimens and/or data will be coded/anonymised? Yes 0 No 0

15. If the study is an intervention study, including placebo controlled trials, is justification for the control group provided? Yes 0 No 0 N/A 0 Is the justification satisfactory? Yes 0 No 0 N/A 0

6. If the study is an intervention study, are the types and methods for subject allocation to

intervention and control group clearly explained and appropriate? Comments: ...

17. Population of study:

a) Children Yes 0 No 0 N/A 0

b) Pregnant Women Yes 0 No 0 N/A 0

c) Prisoners Yes 0 No 0 N/A 0

d) People with special needs Yes 0 No 0 N/A 0

18. Participant safety/protection

a) Have any risks to participating in the research been identified and does the protocol state how these will be minimized? Yes 0 No 0

b) If the study is an intervention study, is a plan for adverse event reporting included in the protocol? Yes 0 No 0 N/A 0

19. Does the protocol include a discussion of ethical issues? Yes 0 No 0 N/A 0

20. Is there a consent /assent form?Yes 0 No 0 N/A 0 b) Is it adequate? Yes 0 No 0 N/A 0

Comments: .....
.....

Data Management and Statistical Analysis

21. Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis? Yes 0 No 0

22. Is the plan for statistical analysis provided? Is the study appropriately powered to answer the research question? Yes 0 No 0

Comments: ...

Expected outcomes and dissemination of results/Community Consideration

23. Does the protocol indicate how the study will contribute to advancement of knowledge and how the results will be utilized? Yes 0 No 0

24. Does the protocol describe any community considerations? Yes 0 No 0

25. Does the protocol discuss how the research contributes to identifying and/or reducing inequities between women and men in health and health care or does not perpetuate gender imbalances? Yes 0 No 0

Comments: ...

Project Management/Study Instruments

26. Does the protocol state the expected duration of the project (Time frame)? Yes 0 No 0

27. Where questionnaires, diary cards and other materials are used, are these relevant to answer the research questions? Yes 0 No 0 N/A 0

28. Are they provided in the participant language /English? Yes 0 No 0 Comments: ...

Overall Comments

a) Approved:.....

b) Approval with advice.....

c) Conditional approval.....

d) Resubmission.....

e) Rejected.....

Protocol Title and Version/Date: _____

Reviewer Name and Title: _____

Reviewer Signature: _____ Date: _____

Appendix VIII: Events Report Form

Title of Proposal:

_____

Applicant/Investigator(s):

_____

IREC /Number:_____Date:_____

1. Type of Report: Initial or Follow-up (_____)

2. Study study/project participant/group information: Identification number, age, height, weight, etc

_____

_____

_____

3. Adverse event start date: Adverse event stop date: or Ongoing _____

_____ _____

4. State/Indicate location of the event, if applicable:

_____

5. Describe the adverse event: Describe the signs, symptoms, severity, time course, relevant medical history, and laboratory data. Include confirmatory results, if any. Indicate any medication required to treat the event and the outcome.

_____

_____

_____

_____

_____

_

6.Describe the investigational drug, medical treatment or procedure or device causing the event:

_____

_____

__

7.Describe circumstances of the event, where applicable: Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study/project participant/group requires medical or surgical intervention to prevent other outcomes.

_____

_____

8. Describe the action taken

_____

_____

9. Specify any simultaneous treatment.

_____

_____.

10.State relationship to drug/participation in a project: not-related, possibly, probably, definitely unlikely related to drug/participation and explain why. _____

_____

11.State if adverse event is described in current approved informed consent/assent document.

_____

12.State if event requires a change or changes in consent/assent documents and to the study/ project procedures.

_____ _____

_____

13.State whether or not enrolled study/project participants/groups shall be advised of the event. If yes, explain how this new information will be conveyed. If not, explain why.

_____

_____

_____

14.Describe any other information not included/ covered above

_____

_____

_____

_____

_____

Name and Signature of the Applicant/Investigator .....

Date.....

Address:.....

Telephone ..... Cell phone:.....