

**NDOLA COLLEGE OF BIOMEDICAL SCIENCES  
RESEARCH ETHICS COMMITTEE  
(NCBS-REC)**

**STANDARD OPERATING PROCEDURES  
[SOPs]**

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## Table of Content

Table of Content.....	2
<b>I. Introduction.....</b>	<b>2</b>
<b>Definition Of Research .....</b>	<b>2</b>
<b>II. Objectives of the REC.....</b>	<b>2</b>
<b>III. Role of the REC.....</b>	<b>4</b>
<b>IV. Process of Ethical Review.....</b>	<b>4</b>
<b>V. The REC Composition.....</b>	<b>4-5</b>
<b>VI. REC Membership Requirements .....</b>	<b>5</b>
<b>VII. Conditions of Appointment.....</b>	<b>5</b>
<b>A. Quorum Requirements.....</b>	<b>6</b>
<b>B. Offices .....</b>	<b>6</b>
<b>VIII. Training of REC members.....</b>	<b>6</b>
<b>IX. External reviewers and Consultants .....</b>	<b>6</b>
<b>X. Documentation-Application Procedures and Requirements.....</b>	<b>6-7</b>
<b>XI. Protocol Submission Procedure.....</b>	<b>7-8</b>
<b>XII. Review Procedure.....</b>	<b>8</b>
<b>XIII. Elements of Review .....</b>	<b>8</b>
<b>A. Design and conduct of the study.....</b>	<b>8-9</b>
<b>B. Recruitment of research human participants and/or animal subjects.....</b>	<b>9</b>
<b>C. Care for the research human participants and animal subjects.....</b>	<b>9</b>
<b>D. Confidentiality .....</b>	<b>9</b>
<b>E. Biological specimens.....</b>	<b>9-10</b>
<b>F. Informed consent process.....</b>	<b>10-11</b>
<b>G. Community considerations .....</b>	<b>11</b>
<b>H. Vulnerable populations.....</b>	<b>11</b>
<b>XIV. Expedited Review.....</b>	<b>11-12</b>
<b>XV. Decision Making.....</b>	<b>12-13</b>
<b>XVI. Communicating the Decision.....</b>	<b>13-15</b>
<b>XVII. Follow-up Procedures .....</b>	<b>15</b>
<b>XVIII. Record Keeping and Archiving.....</b>	<b>15-16</b>
<b>XIX. Updating REC members.....</b>	<b>16</b>
<b>XX. References.....</b>	<b>17</b>

## **I. Introduction**

The Ndola College of Biomedical Sciences Research Ethics Committee (NCBS-REC) is intended to allow research work involving human participants and animal subjects to be conducted in accordance with Internationally recognized principles such as the; Nuremberg Code of Human Rights (1947), World Medical Association's Declaration of Helsinki (1964-2000), Council for International Organizations of Medical Sciences (CIOMS), International Guidelines for Biomedical Research involving Human Subjects (2001), World Health Organization (WHO) and the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (1995), Belmont Report (1979), National Health Research Committee (2012) guidelines and Institutional Animal Care and Use Committee Guidebook.

These guidelines are a standard for the ethics review of any research involving human participants and ensure that research promotes and respects the dignity, rights, safety and well-being of research human participants and animal subjects. The NCBS-REC review process will comply with the Regulations and Guidelines on Clinical Investigator & IRB Responsibilities (2003) code of federal regulations. All research will be done in accordance with the requirements and needs of relevant International and local regulatory agencies and applicable laws.

### **Definition of Research**

Research is defined as any systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge. It may consist of:

- a. therapeutic procedures – interventions administered with the intent of providing direct benefit to the research participant;
- b. non-therapeutic procedures – interventions that are not administered with therapeutic intent and are only intended to answer the scientific question of the study.

For the purpose of these Guidelines, activities which meet this definition constitute research, whether they are conducted or supported under a programme which is considered research for other purposes. For example, some demonstration and service programmes may include research activities.

Health research that is conducted anywhere in Zambia must comply with all sections of these Guidelines.

## **II. Objectives of the REC**

The NCBS-REC Standard Operating Procedures (SOPs) aims to contribute to the effective functioning of the Committee, so that a quality and consistent ethical review mechanism for any health research is achieved, and followed for all proposals dealt with by the Committee to protect the rights, welfare and wellbeing of research participants and animal subjects.

### **III. Role of the REC**

The primary and ultimate role of this REC; is to protect and safe guard the health, dignity, and rights of all human participants and animals that will be serving as research populations. The committee will therefore review all types of research proposals to ensure that

they adhere to all international and local ethical principles involving human and animal research participants. This will assure participant beneficence, autonomy and justice. The REC will ensure that research goals, no matter how important, are never permitted to override the health, well-being and care of research participants. The REC will also provide ethical oversight of approved projects, give ethical support and advice to researchers, policy makers and any other stakeholders. The REC will also conduct community outreach activities when necessary so as to sensitize communities and individuals about health research and health research ethics.

The REC is mandated to comply with the National Health Research Authority through all its activities such as proposal reviews, study monitoring etc. Studies submitted to the NCBS-REC will only commence their studies after approval is granted.

### **IV. Process of Ethical Review**

All ethics committees reviewing Biomedical Research in Zambia shall be affiliated to the National Health Research Ethics Committee (NHREC). The NHREC members are appointed by the Ministry of Health and their main function is to regulate the conduct of research throughout the country.

NHREC has prescribed the types of research protocols that it can review and those that can be reviewed by local ethics committees. The NHREC can also request a local ethics committee such as NCBS-REC to review research proposals on its behalf and make the necessary recommendations.

### **V. The REC Composition**

The composition of the NCBS-REC shall be multidisciplinary and multi-sectorial. The NCBS-REC membership shall comprise of individuals with relevant scientific expertise, age and gender balance, and laypersons representation to safeguard the interests and concerns of the community. Members shall be appointed in their personal capacity based on their varying professional competencies and backgrounds to review various types of received protocols.

The following shall be the minimum composition of its members:

- The Chairperson
- The Vice Chairperson
- Legal representative
- Religious representative
- Community representative
- Nursing representative

- Laboratory medicine representative
- Medicine and Surgery (Medical and Veterinary) representative
- Social Science representative
- Biostatistics representative
- Epidemiology representative
- Pharmacology representative
- Secretariat to take care of all Administrative work (team)

## **VI. REC Membership Requirements**

All members of the REC will be official members upon appointment and will serve for a period of three years, at the end of which fifty percent (50%) of membership will be replaced through an official meeting called by the Head of Ndola College of Biomedical College. Membership eligibility will require certification by the NHRA or other relevant recognized organization or institution which will involve ethics training course.

Members of the REC will be replaced based on:

- Members who have served more than two consecutive terms
- Members who will be absent for more than four consecutive meetings without a justified reason.
- Death of a member
- Resignation
- Non-availability
- And for other reasons that will be determined by the committee in sitting

All REC members will be required to sign a confidentiality agreement regarding meeting deliberations, applications, verdicts and other information on research participants/animal subjects and related matters.

## **VII. Conditions of Appointment**

The following conditions shall apply when considering all potential members of the Committee:

- Must be willing to attend all the meetings.
- Accept an invitation from the appointing authority. Acceptance must be indicated by the member's dated signature in a meeting.
- Must be willing to publicize his/her full name, profession, and affiliation
- All reimbursement for work and expenses, if any, within or related to NCBS-REC affairs shall be recorded and made available to the people concerned upon request.

#### **A. Quorum Requirements**

- A minimum of 60% members shall constitute a quorum
- No quorum shall consist entirely of members of one profession or gender
- A quorum shall include at least one member who is a Non Scientific

#### **B. Offices**

The Chairperson will conduct all meetings of the NCBS-REC. In the absence of the Chairperson, the Vice-Chairperson or an alternate Chairperson elected from the members present will conduct the meeting. The Secretariat is responsible for, Coordinating REC activities, organizing the meetings, maintaining the records and communicating with all concerned. Secretariat will prepare the minutes of the meetings and get them approved by the Chairperson before communicating outcomes to the researchers and other relevant parties.

### **VIII. Training of REC members**

REC members will undergo trainings at the beginning of tenure of office and periodically as need arises. All REC members will have additional international online trainings such as the Collaborative Institutional Training Initiative (CITI) platform found at [www.cititprogram.org](http://www.cititprogram.org) when necessary.

REC members or selected members from the REC shall be required to attend research ethics trainings organized by the NHRA or other institution deemed fit by the REC.

### **IX. External Reviewers and Consultants**

The NCBS-REC may call upon external reviewers and independent consultants who may provide expertise to NCBS-REC on specific research protocols and other research matters. These external reviewers and consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups.

The external reviewers and consultants will be paid for reviewing protocols.

### **X. Documentation-Application Procedures and Requirements**

The following are the general requirements for an intensive and complete audit of the protocols submitted to the NCBS-REC;

- Three copies of the proposal including one soft copy, submitted to the NCBS-REC email
- Protocols should be submitted at least three weeks before the next review meeting. Any protocol submitted after this deadline shall be accepted but considered for the next scheduled meeting.
- All protocols to be submitted in English.
- Proof of payment for the review as determined by the Committee.
- A letter or relevant documentation of approval from the Head of the Institution, and a Scientific and Technical Committee number (where applicable).

- An application form as endorsed by NCBS-REC format clearly stating the name of the investigator with their designation, the date of application, name of sponsor (where applicable) and the title of the project.
- A 2-paged research summary with Research title, background and significance of the study, general and specific objectives, methods, data analysis plan of the study, in simple lay English language.
- Name of the foundation/hospital/field zone where the research will be conducted.
- The convention of the research protocols as indicated by the endorsed NCBS-REC format.
- A detailed budget and source of funding for the study.
- A statement indicating adherence to relevant or stipulated national/international guidelines, and fundamental ethical principles.
- Any potential ethical issues in the research and the plans to address these issues.
- A statement declaration of conflict of interest.
- The Informed consent process which should include; Subject's information sheet and informed consent structure in English and the local language where applicable. In the event of translation into the local language, a back-translation into English by an independent recognized body/person may be requested if the local language is not understood by any Committee member.
- Enclosed supporting documentation such as case report structures, questionnaires, a sample of advertisements, follow-up cards, and so forth.
- Inclusion of any pertinent decisions obtained from regulatory agencies and/or previous Ethical Review Committees in the event of amended protocols.
- The curriculum vitae of the investigator including publications in the previous 5 years where applicable. However, this does not apply with students in whose case, the supervisor submits a CV.
- A data sharing and/or material transfer agreement where applicable.
- All Principal Investigators must show proof of having experienced fundamental preparing in Research Ethics, and on account of clinical preliminaries, Good Clinical Practice (GCP) certification.
- A consent to report all conflicts/serious adverse events immediately to NCBS-REC.
- Any other data important to the study.

#### **XI. Submission Procedure**

- All the applications must include: A detailed protocol (outlining potential ethical issues and how they will be addressed, informed consent form where necessary, copies of questionnaire/s or data collection form/s or interview schedules) and signed application forms.
- All proposals shall be submitted in the prescribed application format, the details of which are given under submission guidelines.
- All relevant documents shall be enclosed with the application form.
- The Research Ethics Committee will only consider the protocol submitted

with the required number of copies along with the application forms and documents in the prescribed format which are signed by the Principal Investigator (PI).

- Where the Principal Investigator is not locally based, the Co-Principal Investigator must be locally based (resident).
- The prescribed fees shall be remitted along with the application.

## **XII. Review Procedure**

- Meetings will be held at the Ndola College of Biomedical Sciences on a quarterly basis. However, proposal review and ADHOC meetings may be called when necessary.
- The proposals will be reviewed by 3 reviewers who must give feedback within one week of receipt of the proposal.
  - External reviewers may be invited to offer their assessment on certain research topics if need arises.
  - Researchers may be invited if need be, to offer explanations.
  - All decisions on proposals will be made after a consensus, and if a consensus is not reached, voting will be done, and the majority vote will be adopted to make the final decision. However, the Chairperson can grant an ethical waiver to protocols without ethical issues and only those with ethical issues should require calling for the REC meeting.
  - All the meetings will be minuted and adequate time should be given to review minutes of the previous proceedings.
  - If revisions are made, the revised document should be submitted in the required number of copies as per committee's recommendation.

## **XIII. Elements of Review**

The Committee will pay special attention to the observance of key elements set in the NCBS-REC objectives with special attention to design and conduct of the study, documentation of information, care for participants, the feasibility of the study, and the informed consent process. The following specific items will be considered during the review process:

### **A. Design and conduct of the study**

- Adequate background information, literature review, a clear methodology including statistical methods, sample size calculations and approach to reaching comprehensive conclusions with the smallest number of participants.
- If justice and beneficence have been applied in the selection of participants.
- If potential risks and inconveniences are weighed against the probable benefits to the research participants and concerned societies.
- With a criteria for withdrawing participants from the research or suspension of the entire research is clearly stated.
- Whether there is adequate infrastructure, staff and emergency procedures at the investigational site.
- With an adequate investigational team and provisions for monitoring

and data audit, and where applicable, including the constitution of a Data and Safety Monitoring Board or Oversight Committee.

- With clearly stipulated modes of reporting and publicising research results.

**B. Recruitment of research participants**

- The selected site of investigation and method of recruitment and whether the safety of participants is assured.
- Qualifications and training provided for the site investigators.
- General characteristics of research participants to include gender, age, literacy levels, race, socio-economic status and religious or cultural beliefs.
- Preparations made to obtain consent and assent, where applicable.
- Criteria for inclusion and exclusion of research participants.

**C. Care for the research participants**

- The methods of communicating information to the research participants and/or their representatives.
- Standard of care to be provided to research participants, including medical and psychosocial care.
- Justifications for any plans to withhold or alter standard therapy for research.
- A statement to indicate any implications of withdrawing from the study by the research participants.
- A statement on treatment/indemnity arrangements in case of injury, disability or death of a research participants.
- Statement on the plans to make study products and other benefits available to the research participants after completion of the study.
- A statement on any financial cost to the research participants.
- Evaluation of rewards for research participants including money, gifts, and services.

**D. Confidentiality**

- Measures which are taken to ensure the confidentiality and security of personal information from study participants.
- Statement on who will have access to personal data, medical records, and biological samples of research participants.

**E. Biological specimens**

- A description of the type of biological specimens to be collected such as blood, body tissues, body fluids etc.
- A statement on the plans to obtain consent and clearance from NCBS-REC or any other relevant authority for long term storage, transfer (import/export) or intended future research on the samples providing

specific purpose for such.

- Permission to transfer samples will only be allowed if; they are proved to be safe and non-hazardous; they will be used for the intended purpose specified in the proposal, and if there is a clear material transfer agreement.
- Arrangement for disposal of samples.

#### **F. Informed consent process**

The informed consent process must strictly adhere to the following:

- The design of the consent process which should be appropriate for the type of research.
- A description of how consent will be obtained including the identity of those who will obtain the consent.
- Adequate information in a simple language (both oral and written) to be given to research participants or their sound representative(s) at an educational level no higher than 8 years of education in Zambia. Avoid unnecessary jargons and restrict the consent form to a maximum of four pages, to encourage retention of important information.
- Where participants are unable to provide written consent, researchers must indicate alternative means of proving consent such as thumb-printing or witnessed audio recording by an uninterested party.
- Detailed contact information, including a contact address, telephone/fax, email or any means of communication of the Principal investigator and the institutional review body.
- Clarity of the information on the study title, duration and expected involvement of study participants.
- Information is given to research participants that their participation is voluntary and that there is no penalty and they will continue to enjoy their rights and freedom in the event of refusal and withdrawal from participation.
- Clarity of justification for the intention for the inclusion of participants who cannot consent, and arrangements made to obtain consent and/or authority to participate.
- In the event of vulnerable populations, including children under the age of 16 years, researchers must provide evidence of criminal record clearance before consent is obtained.
- Clarity of information to potential participants that they will receive relevant information that is made available during the study without excluding their rights, safety and welfare.
- A description of possible risks and benefits and intervention modalities in the event of injury or any other adverse events.
- Information that the participants will receive information on any amendments of the protocol and any re-consenting process, where applicable, during the course of the study.

- Researchers must keep copies of the consent form and should make them available for examination by participants, review bodies, sponsors, institutions and/or any other relevant authorities. Participants are entitled to keep a copy of a consent form.
- Where applicable, researchers may be required to provide translations appropriate to the social and cultural characteristics of study populations.
- Information that provisions will be made for receiving and responding to questions and complaints from both the research participants and/ or their sound representative during or after the course of the research.

#### **G. Community considerations**

- Evaluation of the impact and relevance of the research on the local community.
- Community, wider concerned communities and environment from which the research participants are drawn.
- Proposals and actions taken with the concerned communities such as consultation with concerned communities and relevant authorities before and during the research.
- How the research will contribute to the capacity building e.g. infrastructure and staff development of health facilities.
- A description of the consideration of the accessibility and affordability of any successful study product to the communities involved in the study after completion of the study.
- The influence of the community and community leaders on the consent of individuals
- How research results will be communicated to both the research participants and the communities at large.

#### **H. Vulnerable populations**

- Information on how the researcher will protect the rights and well-being of the vulnerable population, i.e. mentally impaired, disabled, children, pregnant women, refugees, prisoners, elderly persons, orphans, etc.

### **XIV. Expedited Review**

- A researcher/applicant may request that an ethics application be considered under the Fast-track review process. This means that the application would receive an expedited review, and this may not require a meeting of the full REC. In case of the expedited review, the time from submission to REC decision may be approximately 14 working days, depending on time taken to resolve amendments and clarifications.
- The Chairman will assign a minimum of three reviewers from the REC

to each Fast-track application and notifies the reviewers of their assigned review as soon as possible.

- A response from the three committee reviewers should be provided within seven days if possible.
- Applicants will receive feedback from the Chairman within 14 working days from the time of protocol submission.
- Expedited review may also be applied in cases of nationally relevant proposals needing urgent review and in cases of outbreaks of disease.
- All REC members shall be informed at the next regular meeting of research proposals which have been reviewed under this procedure.

## **XV. Decision Making**

a. The committee have four decisions available:

- Approved
- Requires Revision (pending approval on condition of further information, clarification or revision)
- Rejected

- Referred to National Health Research Authority (NHRA) with or without advice.
- However, before arriving at any decision members will discuss various issues surrounding the protocol.
- A member shall withdraw from the meeting before the review process concerning an application where a conflict of interest exists, and this shall be communicated to the Chairperson prior to the review of the application and recorded in the minutes.
- Decisions will be made only in meetings where a quorum is constituted.
- Only members can make the decision. The independent consultants will only offer their opinions in writing; or they may be invited to a meeting but will not participate in the decision-making.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application resubmitted shall be specified.
- Applicants should submit the information requested by the date indicated in the notification of decision.
- If the additional information, clarification or revision is very straightforward and/or minor, the Chair or Vice-Chair will approve if it is satisfactory.
- In the case of substantial revision or major amendments the Chair will ask a subgroup of members to review the additional information to determine if the conditions for approval have been met.
- Amended protocols may be reviewed through an expedited review process by identified members or the Chairperson.
- Researchers can appeal against the decision to the Senior Medical Superintendent through the Head of the Ndola College of Biomedical Sciences.

#### **XVI. Communicating the Decision**

- A decision shall be communicated in writing to the applicant within two weeks of the meeting at which the decision was made. The communication of the decision shall include the following:
  - The name and title of the applicant;
  - The exact title of the research proposal reviewed;
  - A clear identification of the protocol of the proposed research or amendment, including the date and version number (if applicable) on which the decision has been made;
  - The names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;
  - The date and place of the decision;

- A clear statement of the decision reached;
- Any advice by NCBS-REC
- In the case of a conditional decision, any requirements by NCBS-REC including suggestions for revision and the procedure for having the application resubmitted;

- In the case of a positive decision, a statement of the responsibilities of the applicant: for example, confirmation (Researcher to sign that he/she will comply to the conditions) of acceptance of any requirements imposed by NCBS-REC
  1. submission of Progress Report(s), the need to notify NCBS-REC in cases of protocol amendments, the need to report serious 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 ethics committees;
- In the case of a negative decision, clearly stated reasons for the negative decision;
- Signature (dated) of the Chairperson (or other authorized person) of NCBS-REC;
- The Senior Medical Superintendent shall be informed about research proposals which have been Approved, rejected etc.;
- Study sites shall be monitored at any time/day by this Committee.

### **XVII. Follow-up Procedures**

- Progress Reports shall be submitted to NCBS-REC every six months and will be reviewed at the monthly meetings;
- The Final Report shall be submitted at the end of the study;
- All serious adverse events and the interventions undertaken shall be reported;
- Any protocol deviation, if any, shall be reported with adequate justifications;
- Any amendment to the protocol shall be submitted for approval before implementation;
- Premature termination of the study shall be notified with reasons, along with a summary of the data obtained so far;
- Any change of investigators/sites shall be reported to NCBS-REC;
- The decision of a follow-up review shall be issued and communicated to the applicant, including any modification, suspension, or termination of NCBS-REC's original decision or confirmation that the decision is still valid;
- The reports of Data and Safety Monitoring Boards and Oversight Committees, where applicable, shall be submitted to NCBS-REC regularly.

### **XVIII. Record Keeping and Archiving**

- The following documents shall be kept by the NCBS-REC secretariat:
- Written Standard Operating Procedures (SOPs) of NCBS-REC;
- The *Curriculum vitae* (CV) of all members of NCBS-REC;
- A record of all income and expenses of NCBS-REC, including allowances and reimbursements made to the Secretariat and NCBS-REC members;
- Copies of all study protocols with enclosed documents, progress reports, and adverse events reports;
- Minutes of all meetings duly signed by the Chairperson;
- Copies of all existing relevant national and international guidelines on research ethics and laws along with any amendments;
- Copies of all correspondence with members, researchers and others,

including national regulatory bodies.

- Final reports of completed approved projects;
- NCBS-REC shall compile and disseminate an annual report of its activities.
- All documents shall be archived for a minimum period of three years.

#### **XIX. Updating REC members**

As science is developing rapidly, members of the REC will receive all relevant information in tandem with ethics new developments and important communications.

## **XX. References**

1. Association of Research Ethics Committees (2013). A framework of policies and procedures for university research ethics committees. Association for Research Ethics. Available <http://s3.spanglefish.com/s/21217/documents/independent-membership/12-11-13-frameworkcomplete.pdf>
2. National Health Research Act of Zambia, 2013
3. WHO Operational Guidelines for Ethics Committees that review Biomedical Research. WHO, Geneva (2000).
4. Standard Operating Procedures of the Indian Medical Council (2003).
5. Council for International Organisations of Medical Sciences (2001) International Guidelines for Biomedical Research Involving Human subjects.
6. Code of Federal Regulations (2003) Regulations and Guidelines and Clinical Investigator and REC Responsibilities.
7. The Belmont Report (1979). Ethical Principles and Guidelines for Protection of Human subjects of Research. The National Commission for the protection of Human Subjects of Behavioral Research.
8. The Nuremburg Code of Human Rights (1947).
9. The WHO and ICH (1995) Guidelines for Good Clinical Practice.
10. The World Medical Association's Declaration of Helsinki (1964-2000). Recommendations guiding Medical Doctors in biomedical research involving human subjects.
11. Mulungushi School of Medicine and Health Sciences Ethics Review Committee SOPs
12. National Health Research Ethics Committee (2012) Guidelines for the ethical conduct of health research in Zambia