NCRHA RESEARCH ETHICS COMMITTEE (REC)

PROPOSED FUNCTIONS AND PROCESS OF REVIEW OF RESEARCH

EDUCATION FOR REC MEMBERS

- REC members have a need for initial and continued education regarding the ethics and science of biomedical research.
- All EC members must be conversant with guidelines for research involving human subjects.
- REC members will receive introductory training material in the work of an REC as well as ongoing opportunities for enhancing their capacity for ethics review.

PROCESS OF REVIEW

A qualified researcher responsible for the ethical and scientific conduct of the research should submit an application for review of the ethics of proposed biomedical research.

Documentation

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

- signed and dated application form
- the protocol of the proposed research clearly identified and dated, preferably together with supporting documents and annexure, a summary, synopsis, or diagrammatic representation ('flowchart') of the protocol
- a description of the ethical considerations involved in the research
- forms and other questionnaires intended for research participants
- when the research involves a study product such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological, pharmaceutical , and toxicological data available on the study product
- material to be used including advertisements for the recruitment of potential research participants, if any
- 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
- informed consent form clearly identified and dated
- budget allocation, if any
- a statement describing any compensation for study participation including expenses and access to medical care to be given to research participants
- a description of the arrangements for indemnity, if applicable
- a statement of agreement to comply with ethical principles set out in relevant guidelines
- all significant previous decisions (e.g., those leading to a negative decision or modified protocol by other RECs or regulatory authorities for the proposed study whether in the same location or elsewhere and an indication of modifications to the protocol made on that account. The reasons for previous negative decisions should be provided.

ELEMENTS OF THE REVIEW

The primary task of the REC lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. REC will take into account the opinion of coopted experts, as well as the requirements of applicable laws and regulations.
The following will be considered, as applicable:

Study design

1. the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants
2. the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities
3. the justification for the use of control arms
4. criteria for prematurely withdrawing research participants
5. criteria for suspending or terminating the research as a whole
6. the adequacy of provisions made for monitoring and auditing the conduct of the research
7. the adequacy of the site, including the supporting staff, available facilities, and emergency procedures
8. the manner in which the results of the research will be reported and published

Care and Protection of Research Participants

1. the suitability of the investigators' qualifications and experience for the proposed study
2. any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action
3. the medical care to be provided to research participants during and after the course of the research
4. the adequacy of medical supervision and psycho-social support for the research participants
5. steps to be taken if research participants voluntarily withdraw during the course of the research
6. the criteria for extended access to, the emergency use of, and/or the compassionate use of study products
7. the arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so
8. a description of any plans to make the study product available to the research participants following the research
9. a description of any financial costs to research participants; the rewards and compensations for research participants (including money, services, and/or gifts)
10. the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research
11. the insurance and indemnity arrangements

Protection of Research Participant Confidentiality

1. a description of the persons who will have access to personal data of the research participants, including medical records and biological samples
2. the measures taken to ensure the confidentiality and security of personal information concerning research participants

Informed Consent Process

1. a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent
2. the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s)
3. clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals
4. assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being
5. the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project
6. Community Considerations
7. the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
8. the steps taken to consult with the concerned communities during the course of designing the research
9. the influence of the community on the consent of individuals
10. proposed community consultation during the course of the research
11. the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs
12. a description of the availability and affordability of any successful study product to the concerned communities following the research
13. the manner in which the results of the research will be made available to the research participants and the concerned communities

Recruitment of Research Participants

1. inclusion and exclusion criteria for research participants
2. the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity)
3. the means by which initial contact and recruitment is to be conducted
4. the means by which full information is to be conveyed to potential research participants or their representatives

MEETING REQUIREMENTS

REC will meet at 10.00 am on the **SECOND Thursday of every month** unless otherwise specified.

The meeting requirements are:

- REC members will be given all the relevant documents at least one week in advance of the meeting for review
- Minutes of the meetings will be recorded and approved in the subsequent meeting
- The applicant, sponsor, and/or investigator may be invited to present the proposal or elaborate on specific issues
- Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements.

EXPEDITED REVIEW

An expedited review procedure consists of a review of research involving human subjects by the REC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the REC.

Research activities that

- present no more than minimal risk to human subjects, and
- involve only procedures listed in one or more of the categories, may be reviewed by the REC through the expedited review procedure

A brief summary and review decision of the protocol will be placed before the REC members in the next meeting.
The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
The expedited review procedure may not be used for classified research involving human subjects.
The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or convened, utilized by the REC.

DECISION-MAKING

In making decisions on applications for the review of biomedical research, the REC will take the following into consideration:

- A member will 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
- Decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of REC staff.
- Decisions will only be made at meetings where a quorum is present.
- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made.
- Only members who participate in the review will participate in the decision.
- Decisions will be arrived at through consensus, where possible; when a consensus is not possible, the REC will vote.
- Any advice that is non-binding will be appended to the decision.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.
- A negative decision on an application will be supported by clearly stated reasons.

COMMUNICATING A DECISION

REC's decision will be communicated in writing to the applicant, preferably within two weeks' time of the meeting at which the decision was made.

The communication of the decision will include, but is not limited to, the following:

1. the exact title of the research proposal reviewed and the clear identification of the protocol of the proposed research or amendment, date and version number (if applicable)
2. the names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form
3. the name and title of the applicant
4. the name of the site(s) where research is proposed to be undertaken
5. the date and place of the decision
6. in case of a conditional decision, any requirements by the REC, including suggestions for revision and the procedure for having the application re-reviewed
7. in the case of a positive decision, a statement of the responsibilities of the applicant; 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 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; the information the REC expects to receive in order to perform ongoing review; the final summary or final report
8. in the case of a negative decision, clearly stated reason(s) for the negative decision
9. signature (dated) of the chairperson (or other authorized person) of the REC

FOLLOW-UP

REC will follow-up 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 follow-up review intervals will be determined by the nature and the events of research projects, though each protocol will undergo a follow-up review at least once a year.
- REC will be undertake the follow up process
- A decision of a follow-up review will 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 must 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.
- REC should receive notification from the applicant at the time of the completion of a study
- REC should receive a copy of the final summary or final report of a study.

DOCUMENTATION AND ARCHIVING

All documentation and communication of REC will be dated, filed, and archived. Documents will be archived for a minimum period of 3 years following the completion of a study.

Documents that will be filed and archived include (but are not limited to):

- the constitution, written standard operating procedures of the REC, and regular (annual) reports;
- the curriculum vitae of all REC members
- the published guidelines for submission established by the REC
- the agenda and minutes of the REC meetings
- one copy of all materials submitted by an applicant
- the correspondence by REC members with applicants or concerned parties regarding application, decision, and follow-up
- a copy of the decision and any advice or requirements sent to an applicant
- all written documentation received during the follow-up
- the notification of the completion, premature suspension, or premature termination of a study
- the final summary or final report of the study