PU-ERC STANDARD OPERATION PROCEDURES (SOP)

PART IV

APPLICATION PROCEDURES

4.0 Submission of Application Packages to the ERC

1. The applicant must be the Principal Investigator (PI) or co-PI of the proposed research project.
2. The Proposal Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee.
3. Signed cover letter from the PI or co-PI and the Head of the Institution (which should include physical address, fax number, telephone number, mobile number and email address) must be submitted.
4. The applicant should submit hard and electronic copies of the full research proposal (number of copies to be determined by the ERC).
5. All materials to be used in 'advertising' the research project (e.g. campaign materials and brochures) should be submitted for ethical review.
6. Updated CVs of the PI and/or co-PI should be submitted.
7. Where the proposal is for an intervention study:
   a. For clinical trials Insurance certificate covering damages on participants and errors in the Proposal implementation should be submitted.
   b. A letter showing commitment to make the products readily available to the study community should be submitted to the ERC
8. Material Transfer Agreement (MTA) if applicable.
9. Data Sharing Agreement (DSA) if applicable.

4.1 Contents of Application Packages

1. The full proposal which should contain relevant sections from among the following: background/introduction; rationale; objectives (general and specific); clear-end points; methodology; recruitment strategy; laboratory investigations to be done; plans for analysis and publication; personnel budget and justification; timeframe of the project; dissemination plan; community sensitization.
2. The informed consent form and information leaflet, in both the official and when necessary the translation into the local vernacular language. Back translation into official language may be requested by the ERC.
3. Data collection tools such as questionnaires, interviews/discussion guides, checklists and case record forms.
4. All materials to be used (including advertisements) for the recruitment of actual research participants.
5. Where the proposed study is a clinical trial, the investigator's brochure which provides adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience of the study product to date (e.g. recent investigator's brochure, published data, summary of the product's characteristics etc).

4.2 Amendments to Research Proposal

1. Any intended modifications/changes or revisions from the approved proposal and/consent forms should be submitted to the ERC as Proposal Amendments for review before they can be implemented.
2. Investigators should use the relevant amendment form and submit the amended proposal with track changes and a covering letter which briefly explains and justifies the changes.
3. Proposal amendments should be reviewed by the full ERC unless it is urgent and it qualifies to undergo expedited review as per the ERC conditions and requirements specified in the relevant SoP.

4. The ERC should assess if the intended proposal amendments are scientifically and ethically justifiable and whether they compromise the safety and welfare of the participants and communities.
5. Change of investigators, that is addition or removal of some PI, co-PI or other researchers originally included in the proposal is an amendment that must be reviewed and approved by the ERC. In case of addition of a new PI/co-PI or other researchers, their full CV or should also be submitted.
6. Implications of any proposed amendment on the timeframe and budget of the research project should be scrutinized.

4.3 Principal Investigator (PI) and Participating Investigators

In most cases, research is conducted by a principal investigator who has entered an agreement with a sponsor. She/he is the person responsible for the conduct of research at the trial site/s. A clinical trial can however be conducted with or without a sponsor. If a sponsor is involved in the research, the implementation must be designed, conducted and reported in collaboration with both the sponsor and the principal investigator. If there is no sponsor, the principal investigator must clearly state in the proposal who takes on the role of the sponsor in the initiation, management and / or funding of the research.

4.3.1 Principal Investigator (PI)

1. Must be based in Kenya
2. Will ensure that approval(s) from the relevant approved local ethics committee have read and accepted the relevant information package developed by the sponsor for the research
3. Will have good knowledge of the project, related documents and the regulatory requirements of the regulatory authority(ies) and other relevant legislation
4. Will have read, understood and agreed to work according to the project
5. Will undertake to use the investigational and comparator product(s) only for the purposes of the study as described in the project
6. Will take responsibility for accountability of the investigational product(s)
7. Will document clearly the sequence of events to be followed in the conduct of the research, including time-frames, roles and responsibilities

8. Will ensure the availability of all necessary facilities, equipment, and finance to conduct the research
9. Will develop proper mechanisms to ethically obtain informed consent of participants
10. Will accept the involvement of monitors to review and verify the quality control procedures and conduct data verification
11. Will accept the possibility of audit and/or inspection by an independent auditor appointed by the sponsor, regulatory authority or ethics committee
12. Will obtain the right to publish; it is unethical for the sponsor to reserve to right to publish
13. Will generate the information package for the participant, and where applicable with the sponsor
14. Will ensure proper safety reporting procedures