NATIONAL INSTITUTE OF MEDICAL RESEARCH

STANDARD OPERATING PROCEDURES

FOR

THE NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

2nd Edition

2014

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Julius Massaga PhD
SECRETARY
NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

ABBREVIATIONS

CIOMS	Council for International Organization of Medical Sciences
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
ICH	International Conference on Harmonization
IRB	Institutional Review Board
IREC	Institutional Review Ethics Committee
MOHSW	Ministry of Health and Social Welfare
MRCC	Medical Research Coordinating Committee
NatHREC	National Health Research Ethics Committee
NIMR	National Institute for Medical Research
NSR	Non-Significant Risk Device
PI	Principal Investigator
RTI	Research Triangle Institute International
SAE	Serious Adverse Events
SOPs	Standard Operating Procedures
TANHER FORUM	Tanzania National Health Research Forum
TFDA	Tanzania Food and Drug Authority
UN	United Nations
WHO	World Health Organization

FOREWORD

It is with great pleasure that we have established the Standard Operating procedures (SOPs) for the National Health Research Ethics Committee (NatHREC), a Sub-Committee of the Medical Research Coordinating Committee of the National Institute for Medical Research (NIMR), Tanzania.

The SOPs, by definition are detailed written instructions to achieve uniformity and maintain standards in the performance of a specific function. In this particular case, these instructions have detailed procedures guiding the establishment of Institutional Health Research Review Committees or Boards (IRBs) and their basic functions. The document outlines procedures for structuring and administering IRBs, and reviewing as well as monitoring research during the phase of implementation.

NatHREC followed these SOPs since 2007 but with time it was realized that certain procedures outlined in the SOPs 2007 required modification to ensure their practical implementation. This, coupled with the fact that it was always envisaged the SOPs would be a dynamic document that would be reviewed when the need arises the NatHREC decided to review the SOP in 2014

As a dynamic and living document, the SOPs will be reviewed from time to time in the future and NIMR will endeavor to ensure the full participation of all stakeholders.

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Mwelecele Malecela, PhD

CHAIR, MEDICAL RESEARCH COORDINATING COMMITTEE

Chair, Medical Research Coordinating Committee

INTRODUCTION

Health research in Tanzania like in all developing countries and in particular Africa is increasing because of many discoveries that are being made in biomedical sciences and the new diagnostic procedures, drugs, vaccines and devices that need testing. However, much as this is a positive development, the high disease burden, ignorance, poverty, weak regulatory organs and ethical review frameworks expose people in these regions to abuse of human rights by researchers who may not be inclined to observing research ethics stipulated in the international guidelines. In addition, this also exposes the population in these areas to potential exploitation. The situation is compounded more by limited awareness and knowledge among local health research scientists about existence of international guidelines or even understanding them for those who have ever come across or heard about them.

The need for good basis, applied and clinical research practices is the basis for establishment of various health research guidelines that include: the Declaration of Helsinki, CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, WHO and ICH Guidelines for Good Clinical Practices and guideline on Ethics for Health Research in Tanzania 2nd Edition, 2009. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and wellbeing for research participants are promoted and that the results of the investigations are credible.

All international guidelines require ethical and scientific review of biomedical research alongside informed consent and the appropriate protection of those unable to consent as essential measures to protect the individual persons and communities who participate in biomedical research and related fields involving human participants. It is against this background that the National Health Research Ethics Review Committee (NatHREC) was established by the Medical Research Coordinating Committee (MRCC) of the National Institute for Medical Research (NIMR) which was mandated to carryout, control, coordinate, register, monitor,

evaluate and promote health research in Tanzania, or elsewhere on behalf of or for the benefit of the government of Tanzania (NIMR Act of Parliament in 1979).

The purpose of this document is to outline the process for reviewing, authorizing, archiving, and amending Standard Operating Procedures (SOPs) for the NatHREC and other health research ethics committees operating in the country. The Institutional health research ethics committees in Tanzania are expected to adapt these standard operating procedures.

The procedures shall be written in immediate future tense using active verbs and shall be written in simple language so that a reader unfamiliar with the procedures would be able to understand and apply the procedures accurately in proper time sequence by following the document.

Health research ethical review determination criteria

Health Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to new knowledge.

Activities which meet this definition constitute health research for purposes of this SOP document, whether or not they are conducted or supported under a program which is considered health research for other purposes. For example, some demonstration, use of secondary data, use of stored specimen, studies involving vectors for human diseases and service programs may include health research activities.

Health Research subject to regulation, encompass those research activities for which data is collected by any method for the purpose of generating knowledge or improving program or interventions in any area of public health in Tanzania mainland.

VISION, MISSION AND FUNCTIONS

The Vision and Mission statements for NatHREC together with the roles and functions are summarized herein:

Vision Statement

To have ethically and scientifically sound health research conducted in Tanzania.

Mission Statement

To ensure the scientific and ethical merits of health research and guarantee the rights, dignity, safety and protection of all health researchers, research participants and the entire community.

The role of the NatHREC in Tanzania

The National Health Research Ethics Review Committee (NatHREC) was established in 2002 with the major role of overseeing health research conducted in Tanzania and safeguarding the national interests, protecting research participants while taking into account the interests of the researcher and the research. Protection of research participants is based on five principles namely: Respect of autonomy, Beneficence, Justice, Community engagement and informed consent.

Functions of the NatHREC

- Provide national level ethical approval for health research in Tanzania.
- Review proposed research involving human subjects and ensure that all health research is scientifically sound and ethically conducted.
- Advise the MRCC on any relevant matters related to health research.
- Develop and establish mechanisms for monitoring of health research approved by the NatHREC.
- To receive, review, and document bi-annual reports of approved local health research by IRBs.

- To receive and document approved health research proposals by local IRBs on a quarterly basis.
- To sensitize and update researchers, the community and other stakeholders on health research related issues.
- Establishment of an internal quality improvement program.
- To accredit and monitor IRBs reviewing health research.

THE STANDARD OPERATING PROCEDURES

Under this part of the document the Standard Operating Procedures (SOPs) for health research ethics review have been articulated to give guidance to health research review committees in the protection and furtherance of the rights of research participants while taking cognizance of the key roles of relevant health research in improving the welfare of humankind.

SOP 01: CONSTITUTING THE HEALTH RESEARCH ETHICS REVIEW COMMITTEE

This SOP describes procedures for constituting the NatHREC, its composition, terms of reference and ethical basis. It also gives membership conditions of appointment, resignation or disqualification and replacement.

Composition

The Committee consists of up to 15 members who collectively have the relevant qualification and experience to review and evaluate the science, medical aspects, and ethics of health research proposals. It is composed of members with varying backgrounds to promote a complete and adequate review of health research proposals commonly received by NIMR. The NatHREC shall include the following category members:

- Medical scientists;
- Biomedical scientists;
- Social scientists;
- Legal representative
- Unaffiliated community representatives (Teacher/Nurse);
- Representatives of religious/Faith-Based Organizations.

Terms of reference

The Committee operates within specified Standard Operating Procedure (SOPs), which are detailed, written instructions presented in a format that describes all activities and actions to be undertaken by an organization for achieving uniformity of the performance of specific functions. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standard of performance. They facilitate and support ethical review by improving the standard and uniformity of the decision-making and assure and gain the confidence of the public in the working of NatHREC. The SOPs promote transparency and efficiency in communication and operations of NatHREC.

The following are terms of reference under which the Committee operates:

1. Review health research proposals submitted to it within a reasonable time and document its views in writing to the applicant(s), clearly identifying the study, the documents reviewed and the dates for the following:
    1.1 Approval for commencement of the study
    1.2 Modifications required prior to its approval
    1.3 Disapproval
    1.4 Termination/suspension of any prior approval

2. Safeguard the dignity, rights, safety and wellbeing of study participants and communities. Special attention shall be paid to studies that may include vulnerable participants.

3. The Committee may ask the Principal Investigator (s) to provide additional information on any aspect of the study, including physical presentation/personal communication regarding the research proposal to the full committee; however, the researcher/investigator shall not participate in the deliberations of the Committee or in the voting of the Committee on any issue.

4. Obtain the following documents from Principal Investigator(s):
   i. Application form
   ii. Summary of Proposal
   iii. Study proposal(s) and/or amendment(s)
   iv. Written Informed consent forms and consent form updates that the Principal Investigator(s) proposes for use in the study
   v. Participant recruitment procedures
   vi. Written information to be provided to participants
   vii. In case of a clinical trial, the investigator's brochure should be provided
   viii. For clinical trials there should be a document of intent of insurance from an insurance company
   ix. Institutional Review Board certificate of applicant's institution
   x. Institutional Review Board certificate of collaborating foreign institution where applicable
   xi. IRB certificate and/or commitment letter of collaborating local institutions
   xii. Research budget and its justification
   xiii. Curriculum vitae (CVs) and composition of the research team

5. Consider the suitability of the investigator(s) for the proposed study by considering relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation:
   a) May request more information than is given when additional information would assist NatHREC in taking a decision on the proposal or provide protection of the rights, safety and/or well-being of participants researchers.
   b) Review both the amount and type of benefit to participants to ensure that such benefits do not present problems of coercion or undue influence on the study participants.

c) Concerns itself strictly on the scientific and ethical merits of submitted proposals for approval; executing the tasks free from bias or influence and not involving itself in the day to day administration, policy and other Institutional issues.

d) Assists investigator(s) in the submission process. In this regard, the following items shall be made available to them by the Committee Secretariat:

i. Proposal submission forms and all relevant guidelines as stipulated in this Standard Operating Procedures (SOPs)

ii. Meeting Almanac

iii. Checklist

6. The Committee members and consultant reviewers shall be provided by the Committee Secretariat with all relevant SOPs to guide them in the review process of the proposals given to them.

Ethical review basis

1. The Committee recognizes that the proposals it approves may also be approved by institutional review committees/community committees prior to submission to this Committee or their implementation in specific localities.
2. In evaluating proposed health research, the Committee is aware of the diversity of laws, cultures and practices governing research and medical practices in various communities in Tanzania.
3. It attempts to inform itself where possible of requirements and conditions of the various localities where proposed health research is being considered.
4. The Committee seeks to be informed, as appropriate, by institutional review boards and researchers of the outcome of the research it has approved through progress reports.
5. The Committee is guided in its work by the ethical principles expressed in the *Declaration of Helsinki,* the *International Ethical Guidelines for Biomedical Research*

Involving Human Participants (CIOMS), the *Belmont Report*, and *European Convention on Human Rights and Biomedicine.*

6. The Committee has established its own SOPs based on *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO) and the ICH *Guidelines for Good Clinical Practices*.
7. The Committee seeks to fulfil the requirements for international assurances and is established and functions in accordance with the national laws.

Membership Appointments

1. The Director General of NIMR is to be responsible for making appointments of Committee members.
2. Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge, and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the Committee's work.
3. Membership will be reviewed every 4 years.

Condition of Appointment

1. Willingness to publicize their identity, name, profession and affiliation to the Committee.
2. Willingness to sign a confidentiality agreement at the start of the term and abide by the confidentiality agreement regarding meeting deliberations, applications, proposal submissions, information on research participants and related matters which they have had the privilege to have as a result of being members of the Committee. The confidentiality protects the privacy and confidentiality of all parties whose information may be disclosed to the Committee in the course of its work.
3. Willingness to disclose any conflict of interest– financial, professional, or otherwise – in a project or proposal under consideration.

4. Any member who has any vested interest in a proposal submitted to the Committee for review may provide the NatHREC with information about the proposal, but shall not participate in the deliberations on the proposal.

Resignation, Disqualification, Replacement of Members

1. Members may resign their position by submitting a letter of resignation to the Chairperson.
2. Members may also be disqualified from continuance should the appointing authority provide written reasons to the NatHREC members and there is unanimous agreement.
3. NatHREC shall request for a replacement of any member under the following circumstances:
    i. Protracted illness of a member, which does not permit him/her to participate in the deliberations of the Committee.
    ii. Persistent absenteeism of a member without reasonable cause
    iii. Voluntary withdrawal by a member.
    iv. Ethical misconduct (s)

SOP 02. CONFIDENTIALITY OF PROCEEDINGS

1. Members do not sit on the NatHREC meeting in any specific representative capacity (institutions, associations, departments) and must be able to discuss freely the applications submitted to them.
2. The NatHREC meetings must be completely confidential.
3. Any breaches of confidentiality by members will result in termination of their membership.

SOP 03: CONFLICT OF INTEREST AGREEMENT

The WHO Declaration of Interests for WHO Experts defines a conflict of interest as follows: "A conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported".

The purpose of this procedure is to provide a form of Conflict of Interest Agreement, who should read, keep in mind and sign it, when and where to sign and how the signed document be kept. This SOP covers the Agreement on both Confidentiality and Conflict of Interest, concerning activities and information of NatHREC.

It is the responsibility of all newly appointed Committee members and Consultant reviewers to read, understand, accept and sign the agreement stated on the Confidentiality/Conflict of Interest form (Form 01) before beginning their tasks on conducting activities with NatHREC to protect the rights of the participants.

Detailed instructions

1. Newly appointed members or consultant reviewers shall:
    i. Obtain two copies of the Agreement Form (Form 01) from the Secretariat.
    ii. Read through the context of the form very carefully and fill in their names and their address in the blanks.
    iii. Ask questions, if any and the Secretariat shall explain or clarify the context.
    iv. Sign and date both copies at the undersigned signature and give the forms back to a Secretariat.
    v. Keeps a copy as their records (Secretariat and Members).

The Secretariat shall keep a copy of the signed Agreement as the NatHREC's records in a Conflict of Interest Agreement file.

SOP 04: ADMINISTRATION AND FUNCTIONS OF THE COMMITTEE

The purpose of this SOP is to describe the administration, office bearers and their functions in the NatHREC. It therefore describes the Secretariat, functions of the Chairperson, Secretary, the Committee, Director General of NIMR, Consultant reviewer and dissolution of the Committee.

Secretariat and Officers

1. The officers of the Committee shall comprise of the Chairperson and Secretary.
2. The Chairperson is elected from among appointed members of the Committee and the Secretary shall always be an employee of NIMR.
3. The Chairperson shall be a respected person in the community, who has the qualifications of Health and Health related science is concerned about human rights and ethical issues and is well informed in regulations relevant to the use of human subjects in research. The Committee shall have a permanent secretariat at NIMR managed by the Committee Secretary and administrative supporting staff who are also employees of NIMR
4. NIMR shall also provide the necessary office space for the operations of the Committee.

Function of the Secretary:

1. The Secretary will be in charge of the day to day running on the Secretariat.
2. Undertake all administrative procedures in providing training and educational programs to new and continuing Committee members, and the scientific community in Tanzania on issue related to health research ethics. The training shall include programs about the basic principles of human subject protection, current literature and regulations and guidelines affecting the Committee and NIMR.
3. Assist the institution to recruit new Committee members
4. Prepare and submit annual Committee operational budget and plan to NIMR management in consultation with the Chair.

5. When appropriate, update the NatHREC about revisions to applicable regulations and guidelines.
6. Evaluate final reports and outcomes of NatHREC-approved research.
7. Be available for and attend any outside investigations or audits of the Committee.
8. Comply with requests during an investigation or audit.
9. Determine submissions that could be exempted from full review, and notify the Committee and the respective investigator of such exemptions.
10. Review and accept revisions that were made as per the Committee recommendation pending proposal approval.
11. Preparation of the Annual ALMANAC and Compilation of the quarterly and annual reports.

Functions of the Secretariat

1. Organizing an effective and efficient tracking procedure for each proposal received.
2. Prepare, maintain, and distribute proposals and meeting materials for review.
3. Organize Committee meetings according to the meeting almanac.
4. Prepare and maintenance of meeting agenda and minutes.
5. Maintain the Committee's documentation and archive.
6. Communicate with the Committee members and applicants.
7. Arrange for training for personnel and Committee members.
8. Organize the preparation, review, revision and distribution of SOPs and guidelines.
9. Provide the necessary administrative support for the Committee related activities to the Chairperson of the Committee e.g. communicating a decision to the applicant.
10. Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to Committee members.
11. Responsible for the oversight of Committee documents, records and archives.

12. Perform a pre-review of each submission of the Committee to ensure adherence to administrative submission requirements.
13. Design and disseminate templates for Committee submission documents, including research proposals, informed consent materials, agreements and periodic and final reports.
14. Design and maintain a system for collecting and filing all Committee documents, including meeting minutes, member qualifications, proposal submission versions, deviations from approved proposals, and periodic and final reports.
15. Accept, verify, duplicate and distribute all submitted items to the appropriate members for Committee review. Ensure that all required materials for submission are present and complete.
16. Create and distribute meeting agendas, and arrange meeting logistics.
17. Attend Committee meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
18. Communicate with all submitting researchers at all times throughout the submission and review process, while remaining independent of the researcher's proposal operations. Advise submitting investigators on preparing and submitting proposals for review according to relevant SOPs.
19. Maintain files of all correspondences.
20. Assist the Chairperson with the conduct of Committee meetings.
21. Nominate Consultant Reviewers.

Functions of the NatHREC Chairperson

1. To chair Committee meetings in accordance with all regulations.
2. With the assistance from the Secretariat, to identify expedited review proposals and facilitate the review of research that meets the expedited review criteria.
3. To approve and sign minutes of the committee meetings.

Functions of the NatHREC Vice-Chairperson

1. In the absence of the Chairperson, the Vice-Chairperson will take on the responsibilities of Chairperson.

Responsibilities of Members of the Committee

1. Review, discuss and consider research proposals submitted for evaluation.
2. Review progress reports and monitor on-going studies as appropriate.
3. Review reports on Serious Adverse Events (SAEs) and recommend appropriate actions.
4. Support the Secretariat in the discharge of their duties when called upon.
5. Maintain professional confidentiality of documents and deliberations of the Committee meetings.
6. Declare conflicts of interest when they exist.
7. Participate in continuing education activities in biomedical ethics and research.
8. Undertake duties assigned to them by the Chairperson.
9. Attend meetings regularly and participate actively during deliberations.
10. Participate in the review of SOPs.
11. Conduct site monitoring visits.

Responsibilities of the Director General of NIMR

1. Provide a statement of assurance when required by regulation, guidelines, or sponsor requirements.
2. Ensure the provision of the necessary logistics and financial support for the operations of the Committee.
3. Sign ethical clearance certificates.

Dissolving the Committee

1. At any point in time, should NIMR cease to exist, the Committee is automatically dissolved.
2. The Director General of NIMR, following written notification to each member, may also dissolve the Committee at any time.

SOP 05: COMMITTEE MEETING

This SOP describes procedure for scheduling meeting, distribution of agendas and meeting procedures. Except for unavoidable circumstances, the Committee shall meet once a month unless stated otherwise and in such a case, an alternate meeting time, date, and venue shall be provided by the Secretary.

Quorum requirements and meeting attendance

A quorum of at least half the number of Committee members, including at least one member whose primary concerns is in non-scientific areas and one medical scientist is required for the NatHREC to conduct business.

The Secretariat will keep a record of attendance, indicating which members were present for the discussion of each proposal application Review. The Chairperson shall lead the meeting. In the absence of the Chairperson, the Vice-Chairperson shall be directed by the Chairperson prior to his/her departure to lead the meeting. The Secretary shall notify all Committee members of an upcoming meeting at least two weeks in advance.

1. The notification shall include a meeting agenda, which shall outline all proposal and related research submissions for consideration in the meeting, and shall include all related materials, including copies of proposals, informed consent materials, continuing and final reviews, safety reports, etc.
2. The Secretariat shall notify all Committee members of any changes in meeting time, date or agenda as soon as possible.

Meeting Procedure

1. The meeting should be conducted according to the Almanac.
2. The Chairperson or a delegated member of the Committee shall call the meeting to order only when a quorum of members is realised. If a quorum is not realised, the meeting shall be rescheduled.

3. The Chairperson shall follow the agenda for the progress of the meeting. S/he may also choose to deviate from the agenda based on personal judgement. The meeting shall most likely follow the following order:
    i. Adoption of provisional agenda
    ii. Confirmation of minutes of the previous meeting
    iii. Discussion on research proposals
    iv. Review and acceptance of Serious Adverse Events (SAEs), periodic and annual reports, and final reports)
    v. Any Other Business (AOB)
4. If the meeting is to review a proposal which has specific issues the, Principal Investigator of that proposal may be invited when deliberating on the proposal to answer questions that shall be raised by the Committee but must leave when decisions are been made on the proposal.
5. Whenever possible the meeting should reach decisions by consensus. If a consensus is not achievable, a formal vote should be taken. All members have the right to vote including the Chairperson and the decision is by simple majority.

Meeting Minutes

1. During Committee meetings, all deliberations shall be recorded in written i.e. meeting minutes recorded electronically.
2. The minutes shall include a list of attendees, actions taken by the Committee, the decision, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial or controverted issues and their resolution.
3. The Secretary shall produce a hard copy of the minutes, sign and issue with a copy of the next meeting's agenda to all Committee members at least a week before the date of the subsequent meeting.
4. All Committee members shall confirm the minutes for accuracy and completeness of the previous meeting.
5. The Chairperson shall confirm the accuracy and completeness by signing the minutes.

6. The Secretariat shall archive the official minutes with the meeting's agenda and all relevant attachments.

SOP 06: SUBMISSION OF RESEARCH PROTOCOL

1. An application for ethical review of a research study should be made by the Principal Investigator (PI) for that study. Applications may not be submitted by the sponsor(s) on behalf of the Principal Investigator.

2. Dully filled NIMR application form for ethical approval has to be admitted with the research protocol.

3. Applications must be accompanied by a completed Checklist for Researchers, and contain the required number of copies of all documents as specified by NatHREC

4. Photocopying the required number of copies of documents is the responsibility of the investigator.

5. Upon receipt of the application, the NatHREC will check that the application meets the stated criteria. Applications that fail to meet the criteria will be returned to the Principal Investigator.

6. A letter/e-mail acknowledging receipt of the application will be sent to the Principal Investigator by NatHREC within five working days from the date of receipt.

7. Following receipt of a valid application, the Secretariat will enter it on the Research Ethics Database ("the database"), on the day of receipt wherever possible. A unique identifying number will be generated by the database.
8. The Secretariat will identify three Primary reviewers or Expert reviewers to review the protocol prior to full review by the NatHREC.

9. For Clinical Trials the Secretariat will identify primary reviewers or expert reviewers to review the protocol prior to full review by the Clinical Trial sub-committee of NatHREC.

10. Reviewer's comments should be forwarded to the PI within 30 days from the date of acceptance by the NatHREC. Failure of the PI to respond to committee comments within thirty days, NatHREC should remind the PI by a letter/e-mail.

11. Thirty days after the reminder the Secretariat should notify the PI about intention to remove proposal from the database. *Following this the PI must reapply up fresh for ethical clearance including application fee.*

12. For Clinical trials, reviewer's comments should be forwarded to the PI within 30 days from the date of acceptance by the NatHREC. After 60 days the Secretariat should remind the PI about resubmission, failure of the PI to respond within 30 days should be followed by a reminder letter to the PI. After these 30 days a letter to the PI should be written with intention to remove the proposal from the database. Following the above (item 11) the PI must reapply up fresh for ethical clearance including application fee. *Following this the PI must reapply up fresh for ethical clearance including application fee.*

SOP 07: PROPOSAL REVIEW PROCEDURES

In this SOP, submission of proposals and review procedures are described. It is the responsibility of the Principal Investigator (PI) of a research proposal to submit an application for ethical review following the procedures as outlined in this SOP by filling in an Application Form (Form 02). The Secretariat is responsible for receiving and processing new proposal submissions, and for ensuring that the Application Form is complete and all elements required for consideration of the proposal are present.

Detailed Instructions

1. The submitting Investigator shall submit a research proposal with the following required documents:
    i. Covering letter from the Head of affiliated institution where applicable
    ii. 15 copies of duly completed Application Form
    iii. 5 copies of full research proposal - including relevant appendices (e.g. enrolment, data collection tools, budget and justification, etc.).
    iv. Wherever applicable, the IRB approval from originating/affiliating institutions. Consent forms (including translations)
    v. Curriculum Vitae of investigators
    vi. For external researchers, letter of support from local collaborator(s)
    vii. For clinical trials, documentation of appropriate intent of insurance company.
2. Investigators must submit all documents at least three months prior to the commencement of the research study.
3. The Secretariat is responsible for determining whether a submitted proposal qualifies for expedited review (see SOP #09).
4. Depending on the decision of the Secretariat on a particular proposal, three primary reviewers would be appointed to review the proposal. These primary reviewers will be the lead reviewers in the Committee meeting discussions. All

other members in attendance will have received and read the full research proposal prior to the meeting.

SOP 08: PARTICIPATION OF PRINCIPAL INVESTIGATOR IN COMMITTEE MEETINGS

This SOP provides conditions for participation of a principal investigator in the Committee meetings when his/her proposals are being reviewed.

Detailed instructions

1. The Secretary shall notify all PIs of the meeting scheduled to consider their submissions at least two weeks before the meeting date. The Secretary shall also notify each respective PI the place and estimated time their proposal will be tabled for discussion.
2. The PI may be invited into the meeting room during consideration of his or her proposal. A Co-Investigator may attend on the PI's behalf if necessary.
3. The PI may be invited to make a 15-20 minute presentation on the proposal under consideration. After the presentation, the PI shall remain in the meeting to answer questions, concerns and receive suggestions from members.
4. After the question and answer period, the PI and any other attendees with a potential conflict of interest with the proposal or institution submitting shall leave the meeting during the decision period.
5. Each Committee member shall have a say for or against a proposal. An absentee member is allowed to send in his/her comments.
6. In order for a proposal to be approved, it shall receive the approval on members' consensus. The Committee may also decide to postpone decisions on a proposal if more information or consideration is required.
7. After the Committee has voted on a proposal, the PI may be invited into the meeting room for immediate notification. The Committee may also decide to

contact the PI by other means to communicate the decision on the relevant proposal made in the meeting.

8. If the Committee decides to disapprove a research proposal, it shall include in its written notification to the investigator a statement of the reasons for its decision, and shall give the investigator an opportunity to respond in person or in writing.
9. If the PI is not satisfied with the committee's decision, the arbitration mechanism shall involve the PI presenting an appeal to MRCC.

SOP 09: ASSESSMENT OF STUDY PROPOSALS

This SOP describes how the NatHREC reviews and assesses the proposal documents submitted for approval. The Research Proposal Guideline Form (Form 04) is designed to structure the proposal review process and to facilitate reporting recommendation and comments. Specific questions in the Research Proposal Assessment Form must be adequately addressed in the proposal itself and/or proposal-related documents under review. Relevant points made during discussion and deliberation about a specific proposal shall be recorded on the form. The decision reached by the committee and the reasons for its decision shall be recorded on the Assessment Form. The reviewers will use the Health Research Reviewer's Guides (Clinical Trials, Biomedical and Humanities) to conduct their review.

Where the Committee had sought expert's advice on a proposal received for assessment, the Consultant shall also use the Research Proposal Guideline (Form 04) in assessing the proposal.

1. Detailed instruction

The Proposal in the Application Form shall be summarized to include general information about the proposal such as title of the proposal, proposal number and date, principal investigators and co-investigators, funding agency and project status whether new/revised/rejected version. Other information to be included in the summary shall be type of review whether regular, expedited or emergency, principal reviewer(s) from the Committee, brief summary of the study and comment by the Principal reviewer(s).

2. Study Design

The study design shall be reviewed with a view of evaluating the need for human participants for study, adequacy in literature review, objectives of the study, appropriateness of the methodology proposed, inclusion/exclusion criteria, control arms (placebo, if any) and withdrawal or discontinuation criteria. The study sites shall also be examined for suitability of the study in terms of geographical distribution of the problem under study, facility and infrastructure accessibility and availability at study sites to accommodate the study.

3. Qualifications of investigators

Qualifications and experience of investigators shall be examined to see whether the proposed study and background of the participating investigators demonstrate sufficient capacity to conduct the study. Disclosure of potential conflicts of interest shall also be examined. In case of investigators from outside Tanzania, the proposal will be examined to ensure that it includes a local investigator who has sufficient capacity to carry out the study.

4. Study Participation

Under this item the assessment shall be done with a view of evaluating voluntary, non-coercive recruitment of participation. The following aspects shall be assessed to see if they have been adequately considered in the proposal:

i. Procedures for obtaining informed consent

ii. Contents of the patient information sheet
iii. Contents and language of the informed consent document
iv. Translation of the informed consent document to the local language
v. Language used is plain and easy to understand by the general public
vi. Contact persons with address and phone numbers
vii. Privacy and confidentiality
viii. Risks -physical/mental/social
ix. Benefits -to participants and to others
x. Compensation -reasonable/ unreasonable
xi. Involvement of vulnerable participants
xii. Provisions for medical/psychosocial support
xiii. Treatment for study related injuries
xiv. Use of biological materials
xv. Matters related to insurance of research participants and sponsor/researcher indemnity

5. Examination of Local Institutions and community Involvement

Ethical research conduct involving human participation requires community consultation and involvement of local researchers and institutions in the study design, analysis and publication of the results. It also requires contribution to development of local capacity for research and treatment and benefit to local communities and availability of study results. The proposal shall be examined to assess adequate consideration of these aspects.

6. Decision by the Committee members

The guidance, advice and decision reached by the Committee members shall be summarized in the Reviewers Guide. The summary shall include proposal title and date of review, checklist of documents reviewed, and decision reached by the Committee for example approved/approved with stipulation/recommended for resubmission after revision or rejected. Recommendations and/or suggestions, if

any including reasons for disapproving a study (if so) shall be part of the summary. The summary shall also include a list of members participating in a review meeting.

7. Appeal procedures

1. A PI who considers that a decision of the NatHREC is flawed, and where there are substantial and compelling reasons, may appeal that decision in writing to the NatHREC within 30 days of receipt of the decision, stating the precise issues upon which the appeal is based.

2. The NatHREC will respond to PIs in writing within 30 days or upon scrutiny of the complains, the NatHREC may invite the PI to present in person to the full committee within 30 days on receiving the written complaints.

SOP 10: REVIEW OF PROPOSAL AMENDMENTS

The purpose of this procedure is to describe how proposal amendments are managed and reviewed by the NatHREC. This SOP applies to previously approved study proposals but later being amended and submitted for approval from NatHREC.

Amendments made to proposals may not be implemented until reviewed and approved by the Committee. It is the responsibility of the Committee Secretariat to manage proposal amendments. Investigators may amend the contents of proposals from time to time. Proposal amendments must be submitted to the Committee for either expedited review (SOP # 11) or review by the convened NatHREC.

Types of Amendment

There are three types of amendment

1. **Minor**: of relatively little importance and therefore not considered as substantial
2. **Substantial**: the following changes should normally be regarded as substantial:
    i. Changes to the design or methodology of the study, or to background information affecting its scientific value
    ii. Changes to the procedures undertaken by participants
    iii. Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study
    iv. Changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to other clinicians/scientists, information sheets for relatives or caregivers
    v. Change in the use of biological samples
    vi. A change of sponsor(s) or sponsor's legal representative
    vii. Appointment of a new PI or key collaborator
    viii. A change to the responsibility and liability insurance coverage for the study

ix. Appointment of a new PI at a research site
x. A significant change to the definition of a research site
xi. A change to the definition of the end of the study
xii. Any other significant change to the protocol or the terms of the original application

3. **Major**: whatever procedural changes alter the risk which participants are exposed to, or the potential benefit, constitutes a major amendment. Examples include:
   i. A change in the primary purpose or objective of the research, such as introduction of additional genetic studies.
   ii. A substantial change in research methodology
   iii. Introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved)
   iv. Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups)

Detailed instruction

1. The PI shall prepare the amendment package and submit to the Secretariat.

2. Upon receipt of the amendment package, the Secretariat shall follow the receiving procedures in Submission of Research Protocol (SOP# 06) and Procedure for Maintaining Confidentiality of NatHREC Documents (SOP# 02).

3. A request for amendment of a previously approved proposal shall describe the requested amendment, provide the rationale for the amendment, and describe the impact, if any, of the amendment on the proposal's risk: benefit profile.

4. The Secretariat shall check the amendment submission for completeness, including an amended version of the proposal and related documents. Changes or modifications in the amended version shall be underlined or highlighted.

5. The Secretariat shall then:

   a. Inform the Chairperson of the committee verbally and in writing
   b. Keep "Sent" and "Received" mails related to the notification of the Chairperson in the proposal file under the correspondence section
   c. Send the request for amendment memorandum together with the proposal and related documents to the Chairperson within one working day of receipt of the Secretariat and include a recommendation for expedited or full review.

6. After review of the materials, the Chairperson shall determine whether the proposal requires expedited (SOP # 11) or full review (SOP # 06). Proposal amendments that may require full review are those which increase risk to study participants as judged by the Chairperson. Examples of such changes that may increase risk include, but are not limited to:

   i) Additional treatments or the deletion of treatments,
   ii) Any changes in inclusion/exclusion criteria,
   iii) Change in method of dosage formulation, such as, oral changes to intravenous,
   iv) Significant change in the number of subjects,
   v) A significant decrease in the number of subjects if the decrease in the number alters the fundamental characteristics of the study,
   vi) Significant decrease or increase in dosage amount.

7. If the Chairperson decides the proposal requires full Committee approval, the Secretariat shall:

   vii) Place the proposal amendment request on the agenda for the next convened meeting, and;
   viii) Distribute to each Committee member the amendment's revision documents to clearly identify each change and requested changes to the consent form, if applicable.

8. If an amendment is received just prior to the Committee meeting, the Secretariat may decide to review the amendment in full Committee, even though the amendment may be expedited.

9. The Reviewers' Guide shall be used to review amended proposals and proposal-related documents.

10. The Chairperson shall call for a vote on the proposed amendments.

11. Changes to the proposal and/or informed consent requested by Committee members shall be recorded in the minutes and communicated to the clinical trial office or Principal Investigator in writing.

12. If the Committee does not approve the proposal amendment, the notification to the investigator shall also state the reason for not approving the amendment.

13. If the NatHREC requires modifications to any of the documents, specific changes required shall also be communicated to the investigator instructing him/her to make the necessary changes and resubmit the documents to the Secretariat.

SOP 11: EXPEDITED REVIEW PROCESS

The SOP on expedited review is meant to give instructions on how this process shall be determined and done. The Secretariat in collaboration with the Chairperson shall determine which proposals may require expedited review. The following categories shall be qualified for an expedited review:

1. Research activities that present no more than minimal risk to human subjects.
2. Minor changes (modification or amendment) to a previously approved research proposal.
3. Studies that involve interviews of non-confidential nature and not likely to harm the status or interest or not likely to offend study participants.
4. Studies that involve collection of small amounts of biological specimens by non-invasive means (e.g. Body fluids, excreta, hair or nail in non-disfiguring or threatening manner) for local analysis and no transfer of specimens outside of Tanzania.
5. Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia or sedation), routinely employed in clinical practices and using medical devices which have been already approved for use. Examples of such procedures include application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements.
6. Research involving data, documents or specimens that have been already collected or shall be collected for on-going medical treatment or diagnosis.
7. Continuing review of research previously approved by NatHREC as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified (i.e. the study has not yet been initiated); or
    c. where the remaining research activities are limited to data analysis, or

d. Where the NatHREC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

8. Final study reports/close-outs.

Detailed instructions

1. Expedited review shall be conducted by the Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the Committee in accordance with the requirements (SOP # 11).
2. The expedited review shall include a review of the complete study proposal with all required attachments including an amended Application Form (Form 03). Results of the review process may be communicated to the PI before being reported to the Committee.
3. Expedited reviewers may exercise all of the authorities of the Committee except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure.
4. Once expedited approval has been granted, the proposal may be implemented as approved. The approval need not be ratified or otherwise approved by the convened NatHREC.
5. The Secretariat shall notify the NatHREC of all completed expedited reviews at the next scheduled meeting via a listing in the meeting agenda.

SOP 12: CONTINUING REVIEW

The purpose of continuing review is to review progress of the entire study, not just changes made so as to ensure continued protection of rights and welfare of research participants. The Chairperson and Committee members are responsible for determining whether the research is reviewed annually, or more frequently appropriate to the degree of risk. The Committee is also responsible for determining whether an independent data and safety monitoring board is required. The investigator of the research is responsible for keeping the Committee informed of significant findings that affect the risk/benefit ratio and thus the need for more frequent review. The investigator is also responsible for following the continuing review procedures and deadlines.

Determination of Frequency of Continuing Review

1. At a research activity's initial review, the Committee shall determine:
    i. How often it shall re-evaluate the research project. All research shall be reviewed at intervals appropriate to the degree of risk, but not less than once per year.
    ii. The factors to be considered in setting the frequency of review should include the nature of the study, the degree of risk involved, and the vulnerability of the study subject population.
    iii. Whether these studies need verification from sources other than the investigator that no material changes in the research have occurred.

2. The investigator shall utilize the Continuing Review Form (Form 05) to complete the review report and shall include all required elements, including the following:
    i. Number and demographics of participants enrolled
    ii. Changes in principal or Co-investigator(s)
    iii. A summary description of subject experiences

iv. Any serious adverse events experienced

v. Numbers of and reasons for withdrawals from the research

vi. The research results obtained thus far

vii. A current risk-benefit assessment based on study results and

viii. Any new information since the Committee's last review.

3. If the investigator/researcher cannot provide any of the required information, s/he shall provide justification for the delay in the report, and a timetable for provision of the information. The investigator/researcher shall also submit a copy of the consent documents and procedures currently in use. Studies that expire must be suspended until NatHREC approval is obtained.

4. The investigator/researcher shall submit hard copies of the continuing review report, with original signature. Five copies are sufficient for research that qualifies for expedited continuing review, and 15 copies of the continuing review application form for research that must be reviewed by the convened NatHREC. For clinical trials, 12 copies of the full amendment application should be submitted.

5. Upon receipt of the continuing review report, the Secretariat shall conduct a review to ensure all the required elements are present. The Secretariat shall work with the submitting investigator to ensure all elements are present before distribution of meeting items. The Secretary shall place the continuing review report on the next meeting's agenda.

6. Committee members shall consider and vote upon all continuing review reports in full meeting utilizing the proposal voting procedure. The criteria the Committee use to approve or disapprove continuation of research are the same as the criteria for approval of an initial research project.

7. The Committee shall review the consent process and documents to determine whether they are still accurate and complete, whether new information that may have been obtained during the course of the study needs to be added, and

whether documents being used by the investigator/researcher have current Committee approval. After reassessment, the Committee may require that the research be modified or halted. The Committee may also impose special precautions or relax special requirements it had previously imposed on the research proposal. They shall also determine whether there are any important new findings that might affect the willingness of participants to continue participating in the research. If so, they shall require the Investigator notify the participants of these findings.

Timing of Continuing Review

If the Committee has not reviewed and approved a research study by the study's current expiration date, Committee approval has expired and research activities should stop and the research team notified in writing. No new subjects may be enrolled in the study. However, if the investigator/researcher is actively pursuing renewal and the Committee believes that an over-riding safety concern or ethical issue is not involved, the Committee may permit the study to continue for the brief time required to complete the review process.

Bi-annual Progress Report

Six months after the initial approval or following the annual continuing review approval, the investigator must submit a progress report updating the status of enrolment, human subject's participation, and pending activities.

SOP 13: USE OF DATA AND SAFETY MONITORING BOARD (DSMB)

All clinical studies require safety monitoring throughout the duration of the research, but not all studies require monitoring by a Data and Safety Monitoring Board (DSMB). DSMB's may be critical for studies intended to save lives, prevent serious disease progression, or reduce the risk of a major adverse health outcome. DSMBs are particularly important in studies where interim data analysis is required to ensure the safety of research participants.

The primary responsibility of a DSMB is to safeguard human subjects by analysing accumulating data relevant to the risks and benefits on a regular basis. Especially in long-term trials, the DSMB reviews data periodically to assess effectiveness and toxicity, and to decide if and when the data are sufficiently favourable to one treatment that the study should be discontinued. The DSMB shall also decide whether adverse events are serious enough to warrant termination of the study.

NatHREC considers DSMBs to be relevant in the following kinds of studies:

i. Controlled studies with mortality and/or severe morbidity as a primary or secondary end-point.
ii. Randomized controlled studies focused on evaluating clinical efficacy and safety of a new intervention.
iii. Early studies of a high-risk intervention.
iv. Studies in the early phases of a novel intervention with very limited information on clinical safety.
v. Studies where the design or expected data accrual is complex, particularly studies that take long duration.
vi. Studies carried out in emergency situations.
vii. Studies which involve vulnerable populations.

For clinical trials conducted only in Tanzania, the DSMB must include representation from Tanzania. For multi-country clinical trials, the DSMB should include regional representation, preferably Tanzanian, on its roster.

For Studies with DSMBs, the most recent report from the DSMB should be submitted to the NatHREC as an information item.

SOP 14: INQUIRIES FROM RESEARCH PARTICIPANTS, COMMUNITY MEMBERS OR ANY PERSON INTERESTED IN THE STUDY

The NatHREC shall consider its prime responsibility by assuming the protection of the rights and welfare of human subjects in research approved by the Committee. This SOP applies to all requests concerning the rights and well-being of the participants in the studies approved by the NatHREC. This procedure shall provide guidelines for dealing with and accommodating requests by participants regarding their rights as participants in any approved clinical research studies. It is the responsibility of all Staff and Committee members acting on behalf of the Committee to facilitate subjects/patients' requests within the scope of their responsibilities.

Informed Consent documents reviewed by the Committee may routinely contain the statement, "Questions regarding the rights of a subject/patient" may be addressed to the Chairperson, address and/or phone number. On some occasions the first contact a subject/patient may have upon contacting Committee would be with an administrative staff member.

The Chair of the MRCC through the NatHREC is responsible for communicating with participants or others regarding issues related to the rights of study participants. Delegation to non-Committee members is not permitted.

Managing Inquiries

1. Upon receiving an inquiry from a study participant or others, the Secretariat of NatHREC shall do the following:
    i. Record the request and information on the Participant's Inquiry Form (Form 05)
    ii. Determine whether the inquiry should be managed by the Secretariat, the Chairperson, the convened NatHREC, or MRCC and refer the inquiry in writing as appropriate.
    iii. Determine and document whether any corrective actions are necessary.
    iv. Report the findings, as appropriate, to the Chairperson, the convened NatHREC, or MRCC.
    v. Document everything in the project file.

SOP 15: MONITORING AND EVALUATION OF SAFETY/ADVERSE EVENTS (SAE) REPORT

The purpose of this SOP is to provide instructions on the review and follow-up reports of adverse experience and unexpected events for any active study approved by the Committee. Unanticipated risks are sometimes discovered during the course of a study. Information that may impact on the risk/benefit ratio must be promptly reported to, and reviewed by, the Committee to ensure adequate protection of the welfare of the study participants. This SOP applies to the review of SAE and unexpected events reports submitted by investigators, DSMB, Local safety monitor, IRB and any other intended parties

The primary responsibility of the Ethics Committee is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints. In addition, the Committee is authorized to offer mediation under appropriate circumstances. The Committee shall also make sure that researchers are

aware of the policies and procedures concerning reporting and continuing review requirements. The Secretariat shall be responsible for the screening and assessment of the reports and seeing whether they require a review of the full Committee, the Chairperson, or other qualified Committee members or experts.

Detailed instruction

1. Before each Board Committee

The Secretariat shall review the reporter's assessment to determine whether the report requires review by full Committee, the Chairperson or other qualified Committee member(s). Criteria of the review shall be as follows:

i. If assessment of adverse experience is unknown or unlikely, the report shall be forwarded to the Chairperson for review and determination if full Committee should review the report at the following convened meeting.

ii. If assessment of adverse experience is possibly caused by, or probably caused by the investigational product or intervention, the report shall be added to the agenda of the next convened or ad hoc meeting depending upon the severity of the event.

iii. If an adverse experience/investigational new drug or product safety report that has previously been seen by the full Committee is being resubmitted by another investigator in the same study (as part of a multi- Centre study), this notification shall not require full Committee review. Rather, the Chairperson will determine the course of action.

2. During the Committee meeting

After reading and reviewing the report, the Chairperson or designee shall entertain discussion on the report and similar adverse experiences or advisories. If appropriate to the discussions, the Chairperson may call for a consensus on whether to:

i. Request an amendment to the proposal or consent

ii. Request further information

iii. Suspend or terminate the study

iv. Take no action at the present time

3. The Secretariat shall notify the investigator in writing of any required actions. The Committee's decision shall be noted in the minutes.

SOP 16: ALLEGATIONS OF NON–COMPLIANCE AND NON-AUTHORIZED RESEARCH

The purpose of this SOP is to provide instructions for maintaining records that identify investigators/institutes who fail to comply with National/International guidelines for the conduct of human research or who fail to correspond to the NatHREC requests. This SOP applies to all research projects approved by the NatHREC as well as non-authorized researches. The Secretariat is responsible for maintaining documentation of alleged non-compliance.

Detailed instruction

1. Whenever non-compliance or non-authorized research has been alleged, the NatHREC shall investigate the allegations within 30 days to determine if they can be substantiated.
2. When non-compliance has occurred, or non-authorized research has been identified, a report from the Secretariat shall be placed on the agenda of the next Committee meeting.
3. A file shall be maintained that identifies investigators who are found to be in non-compliance with the requirements of the NatHREC, NIMR policy, TFDA and other relevant regulations, and any applicable international guidelines.

4. Researchers or others who fail to respond to the Committee's requests will be notified in writing of the Committee's decisions, and the appropriate institutions and individuals informed.
5. The Committee may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions shall be recorded in the minutes.
6. The Secretariat shall notify the investigator of the Committee's action in writing.
7. Four copies of the notification letter shall be produced. The original shall be sent to the investigator, the second copy to the relevant National Authority (e.g. TFDA, COSTECH), the third to the sponsor or the sponsor's representative of the study and the fourth to the non-compliance file and stored on the shelf with an appropriate label.
8. The researcher must respond in writing with a description of any corrective actions that are to take place and a timeline for implementation.
9. The findings will be communicated to the MRCC for further action.

SOP 17: ABSENCE OF PI

From time to time, the PI may be absent due to annual leave, sick leave or for other reasons. For absences of up to one month, the PI is responsible for ensuring that his/her responsibilities as PI are carried out by a suitable temporary replacement and that that replacement is identified to the Secretariat.

In case the PI is absent for one month to six months, he/she should notify NatHREC in writing. If the PI is absent for six months or more the proposal should be amended to replace the PI.

SOP 18: REVIEW OF FINAL REPORTS AND CLOSURE OF A RESEARCH STUDY

The purpose of this SOP is to provide instructions for the review and follow-up, if appropriate, of final reports for any study previously approved by the NatHREC. This SOP applies to the review and follow-up the final report which is an obligatory review of each investigator's activities presented as a written report to the Committee after the last participant had completed all visits and all adverse experiences have been brought to appropriate resolution.

Final reports must be submitted to NatHREC via a Close-out Form (Form 08) and processed as an expedited review.

Detailed instruction

1. The Secretariat shall review all Continuing Review and Close-out Forms that indicate that the research is closing.
2. The expedited reviewer will request additional information from the researcher as needed.
3. Written documentation acknowledging the close-out will be provided to the investigator and a copy retained in the proposal file.

SOP 19: COMMUNICATION RECORDS

The purpose of this SOP is to ensure proper completion, distribution and filing of verbal and written communication and other study-related or process-related information with investigators, sponsors, volunteer participants, institutes and TFDA. This SOP applies to all communicating activities related to the studies under the approval of the NatHREC.

Detailed instruction

1. Individuals may utilize different communication recording mechanisms; that may be handwritten, typed or computer-generated.

2. The attending officer will fill out the communication form (Form 09) for keeping records.

3. Written record shall contain, but not limited to, the following: date of communication, study information (e.g. sponsor, proposal number, investigator), name of person contacted, contact address, telephone number, and e-mail, summary of the communication made, notation of any follow-up necessary and signature of individual making the record.

4. Upon completion of the record, the individual shall distribute copies as appropriate for filing.

SOP 20: SITE MONITORING VISITS

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored with regards to the implementation of the proposal as approved by the NatHREC. This SOP applies to any visits and/or monitoring of any study sites identified in the approved proposal as the place where the studies and/or laboratory tests are being carried out or performed. It is the responsibility of the NatHREC to perform or designate some qualified agents to perform on its behalf site monitoring of the research projects it has approved. The Secretariat in consultation with the Chairperson shall initiate site monitoring of a study site for cause or not-for-cause.

Detailed Instruction

1. Selection of study sites

The database files of the approved proposals shall be reviewed periodically. Study sites to be monitored may be selected based on the following criteria:

i. If the research project has never been approved by the NatHREC, a study visit should be planned within thirty days after the study starts.
ii. Reports of serious adverse events of concern
iii. Sites that are implementing numerous proposals
iv. Allegations of research misconduct or other complaints
v. Failure to submit progress report or final report
vi. New sites

2. Preparing the visit

The Secretariat shall notify the investigator within two weeks prior to conducting a site visit. In preparation, the visiting team shall make the appropriate travel

arrangements, review the Committee files for the study and site, make appropriate notes, or copies of relevant parts of the files for comparison with the site files.

3. Surprise/Unannounced monitoring visit

A surprise/unannounced monitoring visit may be conducted at random to research in the following categories:

3.1 Researchers who allow their approval to lapse or who repeatedly fail to submit continuing review reports in a timely manner.

3.2 Researchers who prolong completion of their research beyond the approved time frame.

3.3 Researches that are suspected to have implemented modifications to their research without prospective approval from the NatHREC.

3.4 In response to complaints from participants, collaborators, sponsors, regulatory authorities, or others.

4. During the visit

The visiting team shall:

i. Review the informed consent document to make sure that the site is using the most recent version.

ii. Review a representative sample of participant files to ensure that participants are signing the correct informed consent document,

iii. Observe the informed consent process, if possible, and

iv. Review the site study files to ensure that documentation is filed appropriately and that confidentiality is maintained.

v. Debrief the research team prior to departure.

5. After the visit

The team that made the visit shall:

i. Write a report using the Checklist for a Monitoring Visit (form # 09) within two weeks describing the findings during the audit and requesting a written response that describes any corrective actions and a timeline for implementing any corrective actions.

ii. Submit a copy of the report and the researcher's response to the NatHREC for review and action.

iii. The Secretariat sends a copy of the report with NatHREC recommendations to the site for action and archives the report.

6. Present monitoring findings to the NatHREC

A copy of the report and the researcher's response shall be scheduled presented to the full Committee at the next scheduled meeting.

SOP 21: SELECTION OF INDEPENDENT CONSULTANT

The Committee may further be supported in its reflections on specific proposals or requests for advice on specific ethical issues by independent advisors. The purpose of this SOP is to provide procedures for engaging the expertise of a professional as a consultant to the Committee. If the Chairperson or the Committee determines that a study involves procedures or information that is not within the area of expertise of the Committee members, then the Chairperson or the Committee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available on the Committee. It shall be the responsibility of the Secretariat to nominate the Consultant.

Detailed instruction

1. Selection of Independent consultants

The Secretariat shall propose an appropriate consultant to review study documents from a roster of consultants. The roster of consultants shall be maintained by the Secretariat. The Chairperson or the Committee selects the consultant based on criteria including the most current CV, availability, and independence. The

consultant shall sign a Confidentiality and Conflict of Interest Agreement (Form # 01). This document shall be maintained in a consultant file.

2. Consultation Services

The Secretariat shall provide proposal packages to appropriate consultants. The Consultant will be provided with the relevant guidelines for review of the assigned work. The consultant may either attend the meeting to participate in the review of the study as a non-voting member and/or may review the documents and prepare a consultant report to be reviewed by the Committee in their regular meetings or extraordinary meetings. The Consultant's report shall become a permanent part of the study file.

SOP 22: PROTOCOL DEVIATIONS AND VIOLATIONS

i. The sponsor or PI may make minor deviations from a protocol to deal with unforeseen circumstances and communicate to NatHREC later. However, for deviations that would meet the criteria for a "substantial amendment" as defined in SOP #14 such amendment should be sought from NatHREC.
ii. Failure to report to NatHREC (substantial amendment) will necessitate NatHREC to write a warning letter to PI with relevant instruction on the deviation.
iii. Flagrant protocol deviation particularly that increases the risk of participants of breeches scientific principles shall be terminated by NatHREC.

SOP 23: RESEARCH STUDY TERMINATION

This procedure describes how premature termination of NatHREC approved proposals is managed by the NatHREC. It is the responsibility of the NatHREC to terminate research studies in the interest of participants' health or welfare. Proposals may be terminated at the recommendation of the Chairperson of MRCC, the NatHREC or local IRB, DSMB, study sponsor or any other authorized body. The Secretariat is responsible for management of the termination process.

Detailed instruction

1. Upon receiving a notification of study termination the Secretariat shall verify the contents of the package for inclusion of the following:
   i. Close out Form (Form 08).
   ii. Indicate termination as recommended action on the Close Out form
   iii. A cover letter providing the rationale for early termination of the study, and a description of how the study closure will be managed, including procedures for the orderly withdrawal of participants.
   iv. Additional relevant information and documentation.

2. The Secretariat shall notify the Chairperson regarding the request for proposal termination by sending a copy of the termination package to the Chairperson within one working day upon receipt of the termination request. The Chairperson shall review the submission and convene an ad hoc meeting of the NatHREC, if warranted.

3. The Secretariat shall sign and date the Continuing Review Application Form in acknowledgement and approval of the termination and return the form back to the Secretariat within five working days of receipt of the package who shall then do the following:

i. Review, sign, and date the Continuing Review Application Form indicating that the termination process is complete.
ii. Make a copy of the completed Continuing Review "Application Form" and send it to the PI for their records within seven working days.
iii. Store and inactivate the proposal documents
iv. Keep the original version of the termination memorandum for termination and the original version of the Continuing Review Application Form in the Proposal file.
v. Send the file to archive and store the file indefinitely.
vi. Place the study file in the inactive proposal folder.

SOP 24: PREPARATION AND MAINTENANCE OF STUDY FILES

The purpose of this SOP is to provide instructions for the maintenance of the study files. This SOP applies to all active study files that are maintained in the NatHREC office. It is the responsibility of the Secretariat and staff to ensure that all study files are kept securely by a proper system, facilitating retrieval at any time and that they are stored at an appropriate place (free from dust and moisture) and for the specified period of time.

Detailed instruction

1. Study files

File folders shall clearly indicate the title of the study and the proposal number. Each study folder shall contain the following items:

i. Initial submission materials (e.g. application form, proposal, consent forms)
ii. Investigator's Brochure (investigational products)

iii. Approval notices
iv. Amendments
v. Advertisements
vi. Adverse Experiences reports
vii. Correspondences
viii. Continuing Review
ix. Reports from site monitoring visits

2. Maintenance of study files

All study files shall be kept throughout the course of the study with the most present documentation filed on top. All closed study files shall be sent to an off-site storage facility and stored for at least 15 years after the study closure. Archiving of files shall only be done when the NatHREC receives a final report of the study.

SOP 25: PROCEDURES FOR MAINTAINING CONFIDENTIALITY OF NatHREC DOCUMENTS

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents. This SOP applies to all kinds of handling, distribution and storage of submitted study proposals, Committee documents, and correspondence with experts as well as the IRB auditors. It shall be mandatory to maintain confidentiality of study Committee documents, and correspondences. It is the responsibility of all members of the Committee and staff of the Secretariat to enforce confidentiality.

Detailed instruction

1. Committee members

Committee members who have signed a confidentiality agreement with NIMR at the beginning of their term of service to the Committee (SOP # 01) shall have access to the confidential documents.

2. Confidential documents

Confidential documents shall include documents reviewed by Committee members (Proposals and related documents, case report forms, informed consent documents, diary forms, scientific documents, expert opinion or reviews). They shall also include NatHREC documents (meeting minutes, advice and decisions) and correspondences (experts, auditors). Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be taken out except when a document is needed for day-to-day operations.

3. Authorization of acquisition of copies

Only members of the NatHREC shall be allowed to ask for copies and only staff members of the Secretariat shall be allowed to make such copies.

4. Copies Issued to Non-Members of the Committee

If non-members of the Committee need copies of original documents, it shall be the responsibility of the Secretariat to provide the copies.

SOP 26: AUDITING AND INSPECTION OF THE NatHREC

The purpose of this procedure is to guide how to prepare for an audit or inspection of the IEC/IRB works. It is the responsibility of the Secretariat, members, Chairperson and administrative staff of the NatHREC for performing his/her task according to the SOPs and for being well prepared and available to answer questions during evaluation, audit or inspection visits of authorities and guests.

Detailed instruction

1. Upon receiving a notice of inspection visit, the Chairperson shall inform the Secretariat and alert every unit to prepare for the visit. The Secretariat shall prepare for the visit by going through all steps in a Checklist of Auditing and Inspection (Form 07). Specifically the following shall be made ready for inspection:
    i. Check if all documents are labelled and kept in the right order for easy and quick search.
    ii. Check for any missing or miss-organized records
    iii. Background and training records of NatHREC members and the Secretariat
    iv. Application Submission Records
    v. Proposal Assessment Records
    vi. Communication Records
    vii. Amendment Approvals
    viii. Meeting Agenda, Minutes, Action letters
    ix. Active files
    x. Continuing and Final reports
    xi. Reserve a meeting room and all necessary facilities.
    xii. Review the SOPs.
    xiii. Make sure that no omission or deviation exists.
    xiv. Make sure to have good reasons for any omission or deviation.

xv. Inform Committee members about the inspection date if they are able to attend the audit/inspection meeting.

xvi. Any other document needed by auditors

2. Upon arrival of the Auditor(s)/Inspector(s), the Director General of NIMR, Chairperson and the Secretary shall welcome and accompany the auditors/inspectors to the reserved meeting room. Members and some key staff shall also be present in the meeting room. The conversation shall start with the auditor(s)/inspector(s) stating the purpose of the visit and what kind of information and data they would need. The Chairperson/designated spokesperson of the Committee shall answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the points. All information and files shall be made available as requested by the auditors/inspectors.

3. After the auditor(s)/inspector(s) have left, the Chairperson shall call for correction of any mistakes pointed out by the audit(s) and internal follow-up shall be carried out. A report shall be written and get approval from the Chairperson. Appropriate time for correction and improvement process shall be allowed and an outcome of the audit process shall be evaluated. The record of the report on the audit/inspection meeting shall be kept in the audit/inspection file and record of findings from the internal follow-up audit in the internal audit file.

4. Internal auditing of NatHREC should be conducted by MRCC while the external IRB auditing to be done by the NatHREC.

SOP 27: ARCHIVING OF NatHREC DOCUMENTS

The purpose of this SOP is to provide instruments for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors. The files and documents are retained for at least fifteen years after completion of the research so that the records are accessible for auditors and inspectors. Copying files and documents for or by authorized representatives of the national authority when required is allowed.

Maintenance and retrieval of archived documents

1. After a study has been completed and the final report accepted, the Secretary shall do the following:
   i. Remove the contents of the entire study file from the active study filing.
   ii. Verify that all the documents are present in organized manner.
   iii. Provide an archive number from these documents and enter the number into the database and/or Archive Logbook.
   iv. Place the file in a storage container.
   v. Send it to the appropriate storage facility.
   vi. Maintain a log of materials that have been archived.

2. To archiving administrative documents, an administrative staff of the Secretariat shall perform inventories of miscellaneous administrative documents, place the documents in an appropriate storage container, and send it to the appropriate storage facility. In retrieving documents the Secretary shall maintain confidentiality as stipulated in (SOP# 5) (Procedure for Maintaining Confidentiality of Ethical Review Committee Documents).

3. Retrieval of documents shall be done following NIMR institutional procedures. The retrieved files shall be returned to the archive after completion of use.

SOP 28: DISTRIBUTION OF SOPs AND GUIDELINES

This standard operating procedure describes how to distribute and to control the distribution of the NatHREC approved SOPs and Guidelines. The NatHREC works according to internal rules as described in its written SOPs. In order to maintain a transparent relationship with the research community, the SOPs shall be made publicly available. The SOPs will be published in print and electronically, and made freely available.

SOP 29: REVISION OF SOPs

The purpose of this SOP is to address when and how SOPs shall be reviewed and, if necessary, revised. If the committee wishes to review and/or revise the SOP:

1. It shall request an electronic copy of the document from the Secretary or may request minor changes to be made directly by the Secretariat.
2. The SOP shall be reviewed for accuracy and timeliness every three years. SOPs may be revised more frequently when required.
3. The Secretary in consultation with the NatHREC shall ensure that the SOP reflects the actual procedures and all applicable regulatory requirements.

SOP 30: COORDINATION WITH INSTITUTIONAL REVIEW BOARDS

The purpose of this SOP is to address the relationship between the NatHREC and the local institutional review boards (IRBs) that may also review health research in Tanzania. It is acknowledged that not all human subject's research require review and approval at the national level. Consequently, ethics review at the institution conducting the research is important and complementary to the national-level review provided by the NatHREC.

Health researches that routinely require review by the NatHREC as well as the local IRB include clinical trials of investigational products or interventions and other health research with collaborators between local institutions as well as with foreign institutions.

In cases where research does not need to be reviewed at the national level, the local IRBs shall submit the IRB report (Form 10) to the NatHREC Secretariat, listing all studies which were approved by the local IRB in the preceding quarter.

The NatHREC Secretary may request any information related to approved research studies at the institutional level.

The NatHREC should communicate to institutional IRBs through the MRCC for issues of non-compliance.
Institutional Review Boards are also subject to audit by the MRCC and audit procedures will be guided by SOP 26.

SOP 31: INSURANCE REQUIREMENTS

The purpose of this SOP is to address issues of insurance for all clinical trials which are conducted in Tanzania mainland.

NatHREC encourages all researchers to provide health insurance to study participants for the duration of their participation in the research.

For clinical trials, insurance is required in accordance with section 5 (d) of the Tanzania Food, Drugs and Cosmetics Act of 2003 to ensure that clinical trials on drugs, medical devices and herbal drugs are conducted in accordance with prescribed standards. Section 67 (b) provides for insurance of participants taking part in the trial against any injury or risk of injury.

Intent of insurance coverage must be submitted to the NatHREC as part of the application for approval.

Should there be an amendment which NatHREC feels that there will be increased risk to the participants; the insurance premium must be reviewed.

SOP 32: FINAL REPORT AND CLEARANCE OF PUBLICATIONS

i. Final report:

The NatHREC should receive a final report within one year of the research terminating. The final report includes information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination of the research results including any feedback to participants.

ii. Permission to publication:

The purpose of this SOP is to describe the mechanism whereby the NatHREC approves publications resulting from approved health researches.

iii. Digital Object Identifier (DOI) on line publication:

Should the PI feel pressure to publish on line DOI, he/she inform the NatHREC in advance.

Details:

1. All principal investigators of researches approved by NatHREC should seek permission to publish from NatHREC. Manuscripts accompanied with a copy of clearance certificate and a cover letter should be sent to the NatHREC secretariat

2. The secretariat will review the manuscript and submit to the MRCC Chairperson for approval.

3. The Secretariat will communicate with the investigators regarding the outcome of the request.

APPENDIX I: GLOSSARY OF TERMS AND DEFINITIONS

Description of titles of the personnel

Titles	Description
Active Study Files	Supporting and approved documents, records containing communications, and reports that correspond to each active (current) study approved by the NatHREC.
Administrative Documents	These includes official minutes of the Committee meetings as described in SOP # 04 the SOPs, historical files and Master Files as described in SOP # 20, Distribution, Implementation and File Maintenance.
Administrative Staff	They are NatHREC staff that are responsible for the day-to-day administrative functions and duties, which support the activities and responsibilities of the Committee.
Adverse Event	Is any untoward and unintended response in a research participant which is related to any dose administered, medical devise or psychological disturbance.
Adverse Reaction	Is any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered to a research participant
Amendment	Any change to a NatHREC approved study. Amendments must be prospectively approved unless the change is required to package of the amended parts and related documents of the proposal, previously approved by the IEC/IRB, but later decided to make changes after the study had been carried for some time.
Appointing Authority	The body responsible for the establishment and support of NatHREC, in this case is the MRCC-NIMR
Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Chairperson	A member of the Committee presiding over a meeting.
Clients	As a national review Committee, NATREC considers investigators, investigational sites, sponsors or sponsor representatives as its clients or customers. Clients requesting the services of NATREC are asked to accept and abide by the procedures set forth in SOPs.
Committee Members	Individuals serving as regular and alternate members on the NatHREC's operations. This Committee is constituted in accordance with the NatHREC membership requirements set forth in SOP # 01.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of Committee information and documents
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest

	sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: (i) An individual's private interest differs from his or her professional obligations to the institute. (ii) Professional actions or decisions occur that an independent observer might reasonably question. (iii) A conflict depends upon situation and not on the character or actions of the individual. (iv) Potential conflicts of interest must be disclosed and managed as per policy.
Expedited review	A review process in which one or more experienced NatHREC members review and approve research on behalf of the NatHREC. Only activities that meet the criteria for expedited review (see SOP #11) may be reviewed using the expedited review procedures.
External researchers/ collaborators	These are non-Tanzanians that are participating in a research in the country.
Final Report	An obligatory review of study activities presented as a written report to the Committee after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.
Health	Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
Independent Consultant	An expert who gives advice, comments and suggestions to the NatHREC with no affiliation to the institutes or investigators proposing the research proposals.
Inspection	The act by a regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities.
Investigational New Drug	Investigational new drug means a new drug, antibiotic drug, or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part.
Investigator's Brochure	Is a document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects
Medical Device	A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kids, crutches, electrodes, prescribed beds, pacemakers, arterial

	grafts, intraocular lenses, and orthopaedic pins. Medical devices also include diagnostic aids such as reagents and test kids for in vitro diagnosis of disease and other conditions, for example, pregnancy.
Minutes	The official record of events, activities, and actions taken by the convened NatHREC.
Monitoring visit	Oversight visits to study sites by the NatHREC or its representatives to assess the conduct of NatHREC-approved research.
National Research Ethics Committee (NatHREC)	A national independent ethics review committee that is housed within the NIMR structure. The NatHREC is a subcommittee to the MRCC.
Nutrient Supplements	Substances, which may or may not be regulated that are necessary for the body's nutritional and metabolic processes.
Participants' rights	Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. It is essential that Human Rights should be protected by the rule of law.
Principal Investigator (PI)	The investigator/researcher with overall responsibility for the research. In a multi-site study, in a country, there should be one overall PI to be answerable, with other CO –PI's as the case may be.
Project Manager	Individual responsible for coordinating an investigational study. This person may also be referred to as a Site Coordinator. Serve as the primary point of contact for the NatHREC.
Proposal Deviation/ Violation	Any instance in which the NatHREC-approved proposal has not been followed.
Protocol	A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study.
Quorum	Attendance at any convened meeting of the board where at least half of the regular (or alternate) members, including at least one physician and one layperson, is maintained throughout the discussions and voting portions of the meeting.
Research	Research is a systematic process of steps used to collect and analyze information to increase understanding of a topic or issue". It consists of three steps: Pose a question, collect data to answer the question, and present an answer to the question.
Research Participant	Is a patient, service user, or any healthy person who is taking part in the study
Serious Adverse Event (SAE)	Is untoward occurrence that results in death, is life-threatening, and requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity or that maybe consistence with development of a congenital anomaly. The adverse event is SERIOUS and should be reported when the

	patient outcome is: **Death -** Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life- Threatening** - Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. *Examples: Pacemaker failure; gastrointestinal haemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.* **Hospitalization -** (initial or prolonged)-Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples. Anaphylaxis pseudomembranous colitis or bleeding causing or prolonging hospitalisation.* **Disability -** Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. *Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity, peripheral neuropathy.* **Congenital Anomaly -** Report if there is suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. *Examples: Vaginal cancer in female off spring from diethylstilbestrol during pregnancy, malformation in the offspring caused by thalidomide.* **Requires Intervention to Prevent Permanent Impairment or Damage-**Report if suspect that the use of a medical product may result in a condition, which required medical or surgical intervention to preclude permanent impairment or damage to a patient. *Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage burns from radiation equipment requiring drug therapy, breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.*
Standard Operating Procedures (SOPs)	Detailed, written instructions, in a certain format, describe activities and action undertaken by an organization to achieve uniformity of the performance of a specific function.
Study site	Is an organization, a unit that is responsible for carrying a research in a given locality.
Vulnerable Participants	A vulnerable category of participants includes children, prisoners, pregnant women, handicapped or mentally disabled persons, and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

APPENDIX II: FORMS/TOOLS

FORM 01:
CONFIDENTIALITY AND CONFLICT OF INTEREST DECLARATION FORM FOR MEMBERS OF THE NATIONAL HEALTH RESEARCH ETHICS REVIEW COMMITTEE

…… Meeting of National Health Research Ethics Review Committee/Clinical Trials Sub-committee

Confidentiality:

I ……..……agree to consider all discussions and / or statements made in this meeting as confidential information. I declare to safeguard confidentiality during and after the meeting. I also declare to consider any documents, materials or information provided to me in the course of the meeting, or in conducting activities of this committee after the meeting, as confidential materials, never to be divulged to any person without any prior written permission of the Chairperson of the committee.

Conflict of Interest

I declare that **I have no/I have** a conflict of interest in relation to the following/none of the proposals tabled for discussion in this meeting.

Conflict of Interest: (*Write down*)

……..

……..

Proposal for which I have a Conflict of Interest

Proposal title:

……..…

…….

PI:
Type of Conflict of Interest:

☐	Financial
☐	Proposal Development
☐	Other aspects of the proposal

Signature: ……

Date: …….....

FORM 01: CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT

CONFIDENTIALITY

In recognition of the fact that, member's name, and his/her affiliation herein after referred to as the "undersigned" and as a member of the National Ethics Review Committee has been asked and appointed to assess research studies involving human subjects, in order to ensure that the studies are conducted in a humane ethical manner, with highest standard of care according to the applied national local regulations, institutional policies and guidelines;

You have been appointed as a member of the National ethics review committee as an individual, not as an advocate or representative of your home province/territory/community or as the delegate of any organization or private interest. Your fundamental duty is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions you review.

The National Ethics Review Committee aims to meet the highest ethical standards in order to merit the trust and confidence of the communities' protection of rights and wellbeing of human subjects. As a member of the National Ethics Review Committee you are expected to meet the same high standards of ethical behaviour as you carry out your mandate.

This Agreement, encompasses any information deemed confidential or proprietary provided to the Undersigned in conjunction with duties as a member of the National Ethics Review Committee. Any written information provided to the undersigned that is of a confidential, proprietary or privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all confidential or proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes; shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained, and all confidential information (and any copies and notes thereof) shall remain the sole property of the National Ethics Review committee.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any confidential or proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

CONFLICT OF INTEREST

It is a policy of the National Ethics Review Committee that no member may participate in the review or approval for activities in which that member has a conflict of interest except to provide information as requested by the National Ethics Review Committee.

You shall immediately disclose to the Chairperson of the National Ethics Review Committee any actual or potential conflicts of interest that you may have in relation to any particular proposal submitted for review by the Committee and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an Ethics Review Committee member has a potential conflict, the investigator may request in writing or by telephone to the Chairperson that the member be excluded from the review of the protocol.

Members will notify the Chairman any conflict of interest that they may have with any application and if so will not participate in evaluation of the proposal of interest.

A member or members who may have a conflict of interest may not be counted toward a quorum and may not vote.
All members of the National Ethics Review Committee will sign a Confidentiality and Conflict of Interest declaration form at the beginning of every meeting that they will attend. The form will define elements of Conflict of Interest.

Confidentiality and non-disclosure

In the course of your activities as a member of the National Ethics Review Committee, you may be provided with confidential information and documentation (referred to as the "Confidential Information"). You agree to take reasonable measures to protect the Confidential Information: subject to applicable legislation,

including the Access to Information Act, not to disclose confidential information to any person; not to use confidential information for any purpose outside the committee, and for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to yourself or any third party, and to return all confidential information (including any minutes or notes you have made as part of your committee duties) to the Chairperson upon termination of your functions as a committee member.

Please sign and date this agreement, if the undersigned agrees with the terms and conditions set forth above. The original shall be kept in file in the custody of the regularly compliance office. A copy shall be provided for your records.

I (name) …… Address……...

……..

Have read and accept the aforementioned terms and conditions as explained in this agreement.

…… ……..

Undersigned Signature Date

…… …….

Compliance Officer Date

FORM 2: CHECKLIST ETHICAL CLEARANCE APPLICATION SUBMISSION

1. NEW PROPOSAL AND AMENDMENT

Required Documents: Five (5) hard copies of all documents	Attached with application?
1. National Health Research Ethics Committee (NatHREC) Application Form	□
2. Cover letter with Institution logo signed by PI or CO-PI	□
3. Commitment letter from affiliated institution and/or local government officials	□
4. Full study proposal (s) /or Amendment (s) with all relevant sections: Summary, Background and Rationale, Objectives, Methodology, Ethical considerations, Budget and Budget justification, References and Appendices, etc.	□
5. Informed Consent Forms/Assent Forms in English and Kiswahili with institution logo Local PI and NatHREC contacts	□
6. IRB approval certificate from affiliating institution (s) where applicable	□
7. Data collection tools in English and Kiswahili	□
8. Elaborated recruitment procedure	□
9. Written information to be provided to participants in English & Kiswahili	□
10. Curriculum Vitae (CVs) and composition of the research team	□
11. Evidence of application and registration fees payment (Bank slip)	□
12. Filled in Data Transfer Agreement (DTA) and/or Material Transfer Agreement (MTA) (where applicable)	□
For Clinical Trials: Additional documents must be submitted with application	
1. Investigator's Brochure and Case Report Forms	□
2. Proof of Insurance Coverage arrangement	□
3. List of DSMB members (with at least one Tanzanian)	□
NB: For Amendment proposals: attach copy of Initial Ethical Clearance Certificate	

2. RENEWAL OR EXTENSION

Required Documents: Two (2) hard copies of all documents	Attached with application?
1. Cover letter with Institution logo signed by PI or CO-PI	□
2. Progress report of study indicating what is to be covered in the renewal period	□
3. Copy of previous ethical clearance certificate	□
4. Evidence of payment (Bank slip)	□

3. PROGRESS REPORT

Required Documents: Two (2) hard copies of all documents	Attached with application?
1. Cover letter with Institution logo signed by PI or CO-PI	□
2. Progress report of study including status of: ➢ Activities that have been conducted ➢ Activities that remain to be conducted	□
3. Copy of previous ethical clearance certificate	□

FORM 3: APPLICATION FORM

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

APPLICATION FORM FOR ETHICS APPROVAL

MEDICAL RESEARCH COORDINATING COMMITTEE

Secretariat
National Health Research Ethics Review Committee
National Institute for Medical Research
2448 Ocean Road
P.O. Box 9653
Dar es Salaam, Tanzania
Tel: +255 22 2121400
Fax: 255 22 2121360
Website: www.nimr.or.tz

APPLICATION FORM FOR ETHICS APPROVAL

For use of Ethics Committee only	Application No.	
Name, date and signature of NatREC administrator receiving the application	Name:_____ Signature:_____ Date: ----------	

Instructions: All applications for ethics approval should be submitted using this form. The Principal Investigator is required to ensure the information provided is accurate and will sign on this form to indicate that he/she approves the content. Although it is required that the final protocol approved by the sponsor and other relevant documents are submitted for review together with this form, the information provided in this form is expected to be complete and adequate for reviewers to make a decision on the final disposition of the proposal.

First (initial) submission: YES/NO Revised/Amended submission: YES/NO

Protocol Version/Revision No…….Protocol Version Date……..,……..

Title of Project:	
Name of the Principal Investigator (PI) based in Tanzania	
Names of other investigators (PIs and Co-PIs)	
Qualifications of PI	
Position	
Institution and Department/Unit	
Other co-investigators at the PI institution	
Signature of the PI	
If Research student: Name, signature and approval of Supervisor (include letter from the student institution or university)	
Contact details for correspondence (include the name of contact if different from the PI)	
If this study involves more than one institution, name the overall study PI, institution and contact address	
Name of other institutions involved in the study if this study involves	

more than one institution	

Is this a randomized controlled trial?	YES/NO
Does this study involve the taking of blood and/or any other biological samples?	YES/NO
Does this study involve shipment of biological samples outside Tanzania?	YES/NO
Does this study going to involve data transfer outside Tanzania?	YES/NO
Provide details of all ethical clearances sought or obtained from other ethics committees? (This includes institutional ethics approval within Tanzania and in other countries if appropriate). Please attach approval certificates from other ethics committee(s).	
Provide the list of changes from the first (initial)/previous submission in case of revised/amended submission	

1.	Provide the scientific background, study design and objectives and hypotheses. *Max 400 words*
2.	State the intended value of the project or rationale. Why it is important to conduct this study in Tanzania? Provide relevant references as appropriate. *Max 300 words*
3.	State the total duration of the project, and where it will be undertaken in Tanzania (and also in other countries if appropriate).
4.	Provide evidence (such as commitment/endorsement letter) to show that local government officials in the region(s)/district(s) where the proposed research will be conducted have been informed about this study. IF THIS HAS NOT BEEN DONE, describe how you plan to achieve this BEFORE the study starts.
5.	Specify the number of the study participants, with scientific justification for sample size, age, gender.
6.	Specify recruitment methods, inclusion and exclusion criteria and study end points.

7.	Specify data collection procedures, including interviews and sample collection, involving human participants with brief details of actual methods. Attach copies of questionnaires and other data collection tools in English and Kiswahili. *Max 500 words*
8.	If applicable, describe procedures to be used to process, store and test biological samples (e.g. blood, genital swabs, urine, etc).
9.	If samples will be taken overseas, are there samples which will be left in Tanzania? Describe procedures to be used in their shipping, storage and when will be destroyed. Indicate which institution or laboratory samples will be analyzed. Please note that before samples are shipped outside Tanzania MTA clearance is required.
10	Is the technology required for analysis of samples available in Tanzania? YES/NO If YES, please describe why are samples being taken outside the country
11	Would local scientist(s)(Tanzanian) be involved in sample analysis? YES/NO If YES describe her/his involvement, and if NOT please explain what are the strategies for technology transfer
12	Specify data management procedures and methods to be used during data analysis.
13	If data will be taken overseas, please describe why are being taken outside the country Please note that before data are take outside Tanzania, clearance is required by completing a Data Transfer Management Agreement Form
14	Describe the potential risks, discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological). What precautions will be taken to reduce risks and ensure participants' safety?
15	Describe potential benefits for the participants and the population where they come from. Are there direct benefits for the people of Tanzania and/or other countries?
16	Specify how confidentiality of the study participants and data collected will be maintained.
17	State the manner in which consent will be obtained and documented in writing. Provide copies of the informed consent forms and other relevant documents in English and Kiswahili. Describe steps to be taken to minimize coercion/undue influence

	during the consent process.
18	Describe how you are going to assess comprehension of the information provided during the consent process.
19	Will payments be made to participants? (These should usually not be for more thantravelling expenses and/or loss of earnings and must not be coercive or represent an undue inducement to take part) NO. If YES give details and justification.
20	State theexperience of the PI and co-investigators in the study in the field concerned, and their role will be on the project.
21	Please describe how project staff (PI and other staff) will be trained on the protection of study participants in research. In case already trained attach certificate.
22	When applicable, state what medical supervision is available to the participants
23	Describe the facilities available to support the successful conduct of the proposed research study, i.e.; office space, equipped laboratories.
24	If this is a clinical/intervention trial of a medicine, device, biologic/vaccine, or any other form of treatment or intervention, please respond to the following questions:
a)	Does the trial comply with Good Clinical Practice (GCP)?
b)	Does this trial involve testing a new drug, vaccine or medical device which is not registered in Tanzania?
c)	If this trial involves testing a new drug, vaccine or medical device, please attach the investigator brochure? If there is no investigator brochure, please explain the reason.
d)	What will be offered to the control arm?
e)	Please confirm that TFDA approval will be processed before data collection begins.
f)	Is there a Data Monitoring & Safety Committee in place? YES/NO If NO, please explain reasons
g)	If the intervention to be tested is found to be effective, describe plans to make it available to the participants and other people after the end of the trial.
h)	Have you obtained a certificate insurance cover for study participants locally (a cover

	from insurance company based in Tanzania)? YES/NO If YES please attach If NO please describe how this will be obtained
25.	Is the study going to involve vulnerable population? YES/NO (Vulnerable population include: pregnant women, human foetuses, neonates, children, prisoners, hospitalized patients, mentally ill persons etc) If YES, describe steps which will be taken to ensure protection of human subjects
26.	Please give details of the funder.
27.	Please give details of research sponsor. This is not necessarily the funding body. The sponsor is responsible for the initiation and management of the study. All clinical trials should have an identified sponsor.

FORM 4: RESEARCH PROPOSAL ASSESSMENT FORM

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

Telephone 255 22 2 121400
Telex 41919 NIMR TZ
Telegrams MEDSEARCH
Telefax 255 22 2 12120020
Email: headquaters@nimr.or.tz

P.O. Box 9653
Dar es Salaam
Tanzania

[DATE]

Our Ref No. [####]
Your Ref. [####]

[Name of Reviewer]
[Address]

Dear [Name of Reviewer]

REQUEST TO ASSESS A HEALTH RESEARCH PROPOSAL

[SUMMARY OF REQUEST FOR REVIEW]

The attached **Proposal/Amendment** research proposal entitled: [TITLE OF PROPOSAL AND NAME OF PRINCIPAL INVESTIGATOR] has been submitted for both scientific and ethical clearance by the MRCC Secretariat. I should be most grateful for your help in evaluating it. In case you do not agree with the statement given check Comments to Principal Investigator (CPI).

1. SUMMARY	☐	Is clear, succinct, and has all element of the proposal.
	☐	See CPI
2. BACKGROUND	☐	Clearly, stated, and meets users' demands
	☐	See CPI
3. OBJECTIVES	☐	Relevant to the research problem
	☐	See CPI
4. RATIONALE	☐	Proposal well reasoned out
	☐	See CPI

5. METHODOLOGY Stated ☐ Proper, well designed and related to all objectives

☐ See CPI

6. PERSONNEL (CVs) ☐ Proposers are scientifically and technically capable

☐ See CPI

7. BUDGET AND JUSTIFICATION ☐ See CPI

8. ETHICAL CONSIDERATION: Have Ethical issues been well addressed in this proposal? Please Comment (Use an additional sheet of paper if necessary)

.....
.....
.....
.....

9. ANY OTHER COMMENTS: (Use an additional sheet of paper if necessary)

.....
.....
.....
.....

10. CONCLUSION: Do you recommend approval of this proposal?

☐ Yes, as presented

☐ Yes, with minor revisions shown under. "Any Other Comment"

☐ Yes, with major revisions shown under, "Any Other Comments

☐ No, I do not recommend it; see under, "Any Other Comments"

I am thanking you in advance for your early co-operation.

Yours sincerely,

Director General

Please use another sheet of paper for your precise comments to the proposer, please do not sign the comments sheet, as it may be sent to the proposer.

FORM 05: PARTICIPANT'S INQUIRY FORM

Date Received	
Requested from:	Telephone call:
	Fax: ...……..……. Of .....……..... Date: ……....
	Mailed letter Ref: ……. Of ……. Date: ……....
	Email of: ……..... Date: …….....
	Other methods (Specify):
Name of participant:	
Address:	
Title of the protocol being participated in	
Starting date of participation:	
What is requested:	
Action taken	
Outcome	

…… ……

Name of receiving officer **Signature**

FORM 06: ANNUAL CONTINUING REVIEW APPLICATION/ASSESSMENT

Protocol title:		
Certificate approval no.		
Principal Investigator:		
Action requested:	Review for new subject accrual to continue [ ] Review for enrolled participants follow-up only [ ] Review for termination of study [ ]	
Have there been any amendments since last review?	Yes [ ]	Comment:
	No [ ]	Comment:
Impaired participants	None [ ] Physically [ ] Mentally [ ] Both [ ] Others (Specify):	
Have there been any changes in the participant population, recruitment or selection criteria since the last review?	No [ ] Yes [ ] Explain:	
Have there been any changes in the informed consent process or documentation since the last review?	No [ ] Yes [ ] Explain:	
Has any information appeared in the literature or evolved from this or similar research that might affect the committee's evaluation of the risk/benefit analysis of human subjects involved in this protocol?	Yes [ ]	Comment:
	No [ ]	Comment:
Have any participants withdrawn for this study since the last approval?	No [ ] Yes [ ] Explain:	
Summary of protocol	Actual ceiling set by the NatHREC	

participants	New participants accrued since last review Total participants accrued since protocol began	
Have any unexpected complications or side effects been noted since last review?	Yes [ ]	Comment:
Investigational new drug/device	No [ ]	Comment:
Have any investigators been added or deleted since the last review?	No [ ] Yes [ ] Comment:	
Changes in medical advisory/investigation?	No [ ] Yes [ ] Comment:	
Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	No [ ] Yes [ ] (Append a statement of disclosure)	
Signature	 Principal Investigator ……..... Date …….....	
Committee Comment/decision		
Approvals	Chairperson, NatHREC…….…..... Date…….....	
Completion	Secretary, NatHREC ……..... Date …….....	

FORM 07: CHECKLIST FOR AUDITING AND INSPECTION

Type of Audit	Internal Audit [ ] External Audit [ ]		
The Date(s) which the audit/inspection has been agreed for:			
Shall an interpreter be required? If Yes what arrangement has been made?	Yes [ ] No [ ]		
Review the SOPs and note details of any omissions or deviations, with reasons			
Check the files for the presence of all signed documents: Note any that are missing and action taken			
Components	**Present**	**Missing**	**Action taken**
Background and training	[ ]	[ ]	
Application submission records	[ ]	[ ]	
Protocol Assessment Records	[ ]	[ ]	
Communication Records	[ ]	[ ]	
Amendment Approval	[ ]	[ ]	
Meeting Agenda, Minutes, Action letters	[ ]	[ ]	
Active files	[ ]	[ ]	
Continuing and Final reports	[ ]	[ ]	
Are any documents known to be missing from the study master file?			Yes [ ] No [ ]
Which personnel and members shall be available? Give details of times and dates.			
What arrangements are there in the event the auditor/inspector needs to make copies of documents?			
Checklist completed by: Name ……………………………………………...................... Signature ……………………………………………............. Auditor's Institution ……………………………..................			Date ……………………….…...

FORM 08: CLOSE-OUT FORM

Instructions for Closure of a Research Study

Send to the NatHREC:

1. This completed Close-out Form only.

Complete and submit this form before the expiration date for your study. If NatHREC approval is not granted by the expiration date, all study participants' activities will be suspended until approval is regained.

Date of this Submission: _____

Study Title:

_____
_____
_____
_____
_____
_____

Proposal Number: _____

Sponsor/Funding Agency: _____
_____
_____

Date of last Continuing Review Approval: _____

Section A. Study Status

1. Summary of research activities to date.

2. Number of subjects involved in the study **to date** (cumulative) either through direct contact or through use of their data. (complete all blanks)

   a. Number of people screened: _____

   b. Number of subjects enrolled (i.e., the number who consented/assented and took part in any part of the study intervention or data collection, for randomized trials list those who were randomized) in the study to date: _____

c. Projected number of enrolled subjects, as approved by the NatHREC in the proposal. Numbers must match the numbers listed in the initial approval for the study. If amendments have been submitted to increase sample size after initial approval, list both original approved sample size and note the approved amended sample size: _____

If (b) is greater than (c) above, please explain:

3. Since subject enrollment began, have any subjects withdrawn from the study (e.g. voluntarily withdrawn or lost to follow-up) or been withdrawn from the study by the investigator? (NOTE: Do not include refusals.)

☐ Yes – provide cumulative number and reasons for withdrawal

_____

_____

_____

☐ No

4. Did any unanticipated problems, protocol violations, adverse events (AEs), or serious adverse events (SAEs) occur since the initial review or last continuing renewal? (NOTE: If study has been renewed one or more times, please only list problems or events from the current approval period.)

☐ Yes – provide a list of these problems, protocols violations, AEs, and SAEs, and indicate which ones were previously reported to the NatHREC

_____

_____

_____

☐ No

5. Were any complaints received about the research since the initial review or last renewal by the NatHREC? (NOTE: If study has been renewed one or more times, please only list complaints from the current approval period.)

☐ Yes – provide a list of these complaints and indicate which ones were previously reported to the NatHREC

_____

_____

_____

☐ No

6. Were any amendments approved by the NatHREC for this study since the initial review or last renewal by the NatHREC? (NOTE: If study has been renewed one or more times, please only list amendments from the current approval period.)

☐ Yes – provide a list of amendments (including amendment #) by date of approval with the description of the amendment. For example: *Amendment 03: 5/2/09--Revised consent forms*

_____
_____
_____

☐ No

6a. Were any additional changes made to the study procedures or materials since the initial review or last renewal by the NatHREC that were <u>not</u> submitted for approval? (NOTE: If study has been renewed one or more times, please only list changes from the current approval period)

☐ Yes – provide a list of these changes

_____
_____

☐ No

7. Summary of any remaining activities.

8. Does your institution currently maintain any identifiable subject data or specimens from this study? (select one)

☐ Yes, still maintain identifiable data or specimens from this study
☐ No, no longer maintain any identifiable data or specimens from this study.

Specify the Material Transfer Agreements (MTAs):

Section B. REASON FOR CLOSING THE STUDY:

☐ Research completed and no identifiable data or specimens are maintained. Data analysis of de-identified data and report writing can continue.
NOTE: Documentation of informed consent of subjects - either signed informed consent forms or short forms and written

research summary - must be retained by the research team for at least 5 years after completion of the research (per regulations), unless NatHREC waived the requirement for informed consent or documentation of informed consent.

☐ Research was never done (lack of funding, etc.)

☐ Other reason to close the study, specify _____

……
Name of Principal Investigator

…… ……

Signature Date

FORM 09: COMMUNICATION RECORD FORM

Date	
Attention requested	
Requested by:	
Contact information	Institution _____ _____ _____ Postal address: _____ _____ _____ Telephone number: _____ Mobile number: _____ Email: _____
Action taken	

…… ……

Name of attending officer Signature

FORM 10: INSTITUTIONAL REVIEW BOARD (IRB) REPORT FORM

Name of Institution/Institutional Review Board: _____
_____

Date of Submission: _____ / _____ / _____
DD MM YYYY

Period: [_] Qtr 1 (Jan-Mar) [_] Q2 (Apr-Jun) [_] Q3 (Jul-Sep) [_] Q4 (Oct-Dec)

No.	Proposal	IRB approval number	Date approval issued	Source of funds	Principal Investigator (PI)	Contact information for PI	Type of study	Duration of study	Study area
1									
2									
3									

4									
5									

Comments:

References

1. Standard Operational Procedure (SOPs) for NatHREC, 2007 edition 1
2. ADD THE TANZANIAN GUIDELINES
3. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
4. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
5. 45 Code of Federal Regulations 46.115 IRB Records, .108.b IRB Functions and Operations.
6. The Belmont report
7. International Ethical Guidelines for Biomedical Research on Human Subjects, CIOMS, 2002
8. 21CFR56.115 IRB Records