

**ST. FRANCIS UNIVERSITY COLLEGE OF HEALTH
AND ALLIED SCIENCES (SFUCHAS)**

*(A constituent College of St. Augustine University of
Tanzania)*

**STANDARD OPERATING PROCEDURES FOR THE SFUCHAS ETHICAL
REVIEW COMMITTEE**

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ABBREVIATIONS

SFUCHAS	St. Francis University College of Health and Allied Sciences
SFUCHAS-REC	SFUCHAS Research Ethics Committee
TTCIH	Tanzanian Training Centre for International Health
TFDA	Tanzania Food and Drug Authority
SOPs	Standard Operating Procedures
WHO	World Health Organization
PI	Principal Investigator
DSMB	Data and Safety Monitoring Board
SAE	Serious Adverse Event
NIMR/NatHREC	National Institute for Medical Research/National Health Research Ethics Committee
MTA	Material Transfer Agreement
CIOMS	Council for International Organization for Medical Science
IPR	Intellectual Property Right
DSA	Data Sharing Agreement

INTRODUCTION

The Research Ethics Committee of the Saint Francis University College of Health and Allied Sciences (SFUCHAS) is to ensure that all research that utilises human subjects and/or informants is bound by research ethics guidelines. Therefore, research proposals should be subjected to prior ethical review by the Research Ethics Committee of the SFUCHAS (SFUCHAS-REC) will be responsible to ensure that the ethical principles and practices put forward in the guidelines will be followed in the proposed research. In addition, the SFUCHAS-REC has a monitoring function in respect of generally accepted scientific principles that underlie all research. The underlying rationale is to preserve and respect the rights, freedom and well-being of research participants and communities. SFUCHAS-REC therefore acts to protect the community from where the human research subjects have been selected.

The guidelines and procedures to protect research participants includes the Declaration of Helsinki, Council for International Organization for Medical Science (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects, WHO, International Conference on Harmonization (ICH) guidelines for Good Clinical Practices outline ethical and scientific standards for biomedical research and National Institute for Medical Research/National Health Research Ethics Committee (NatHREC). The SFUCHAS-REC will provide assurance that these guidelines are actually being followed to ensure that the dignity, rights, safety, and well-being for research participants are promoted.

1.1 Vision

To maintain highest possible ethical standards through providing ethical guidelines necessary in the conduct of health research studies involving human participants.

1.2 Mission

The mission of the SFUCHAS-REC is to ensure that all research involving human participants, personal data, or human tissue are conducted according to ethics guidelines that helps to promote the ethical conduct of research and enhances and protects the rights and well-being of research participants and communities. However important, the research goals, should never be allowed to override the health and well-being of the research subjects.

STANDARD OPERATING PROCEDURES FOR THE SFUCHAS ETHICAL REVIEW COMMITTEE

SOP # 01: CONSTITUTING THE RESEARCH ETHICS COMMITTEE

1. Composition of the St. Francis University College of Health and Allied Sciences (SFUCHAS) ethics committee

The SFUCHAS Ethics Review Committee (SFUCHAS-REC) consists of 16 members with diverse scientific expertise, age and gender balanced and who have the qualifications and experience necessary to comprehensive review and evaluate scientific and medical ethics aspects of the research protocol. The SFUCHAS-REC will also have at least one community representative to represent concerns of ordinary members of communities, one non health scientist (lawyer/social scientist).

The committee shall consist of:

1. Chairperson
2. Vice chairperson
3. Research and publication coordinator /Director
4. Quality assurance director
5. SFUCHAS,
6. TTCIH,
7. St.Francis Referral Hospital,
8. Ifakara Health Institute,
9. Edgar Maranta school of Nursing
10. Community representative Male
11. Community representative Female
12. Council Medical officer from the Ifakara town council
13. District Social welfare officer from the Ifakara town council
14. Representative from Christian religion
15. Representative from Muslim religion
16. Lawyer

2. Terms of Reference (TOR)

The SFUCHAS-REC operates within specified Standard Operating Procedure (SOPs) and the role of these SOPs and their accompanying checklists/forms is to contribute to the effective functioning of the Committee so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects.

The following are Terms of Reference under which the Committee operates:

1. Review health research protocols 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:
 - i. Approval for commencement of the study
 - i. Modifications required prior to its approval
 - ii. Disapproval
 - iii. Termination/suspension of any prior approval
2. Safeguard the dignity, rights, safety and well-being of all study participants and communities. Special attention shall be paid to studies that may involve vulnerable participants. SFUCHAS-REC will review all research projects involving human subjects to be conducted at the university, irrespective of the funding agency.
3. The SFUCHAS-REC will take care that all the cardinal principles of research ethics (Autonomy, Beneficence, Non - maleficence and Justice) are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.
4. It will review the proposals before the start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.
5. Assists investigator(s) in the submission process. The following items shall be made available to researchers by the Committee Secretariat and at the SFUCHAS website:
 - i. Protocol submission forms and all relevant guidelines as stipulated in this Standard Operating Procedures (SOPs)
 - ii. Meeting almanac
 - iii. Committee membership list
 - iv. The National Research Guidelines

3. Independence of the SFUCHAS-REC

- i. The FUCHAS-REC will be independent from the appointing authority, hosting institution, researchers, sponsors and any other stakeholders in its review and decision-making processes
- ii. If there is any conflict of interest on a particular proposal, the SFUCHAS-REC members must declare their conflict of interest and excluded themselves from the review process.

- iii. Conflict of interest must be declared at the time research proposals are submitted, and upon receiving the SFUCHAS-REC agenda prior to the meeting. Members who have conflict of interest related to any research protocol must refrain from participating in any discussion of the protocol or related matters and should not vote for those protocols or related matters.
- iv. The SFUCHAS-REC member or expert with conflict of interest will be required to leave the room for the final discussion and vote unless he/she is requested to provide the information to the SFUCHAS-REC.
- v. Members of the ethics committee should not share or give their personal opinions concerning the submitted proposals and the review decisions outside of the SFUCHAS-REC meetings.

4. Membership Appointments and Office Term

- i. The SFUCHAS Principal is to be responsible for making appointments of the SFUCHAS-REC members.
- ii. 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.
- iii. Members are appointed for a period of 3 years.
- iv. Membership may be renewed, however; at least one-third of the old members should be retained at every point in time. The maximum tenure of office of SFUCHAS-REC members is six (6) years.
- v. For continuity and smooth running of the SFUCHAS-REC office, SFUCHAS-REC Secretary should serve up to a maximum of 3 terms, which translates to a maximum of nine (9) years.
- vi. The SFUCHAS'S secretariat will advise the SFUCHAS'S Principal on appointments
- vii. Inclusion of religious representatives is a prerequisite.

5. Condition of the Appointment

- i. Willingness to publicize their full names, profession and institutional affiliation.
- ii. Willingness to declare any conflicts of interest which may arise or exist during their tenure on the SFUCHAS-REC. Members will recuse themselves from any discussion of a protocol in which they have a conflict of interest.

- iii. Willingness to sign a confidentiality agreement at the start of the term and abide by the confidential agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to have as a result of being members of the SFUCHAS-REC. The confidentiality protects the privacy and confidentiality of all parties whose information may be disclosed to the Committee in the course of its work.

6. Resignation, Disqualification, Replacement of Members

- i. Members may resign their position by submitting a letter of resignation to the Chairperson.
- ii. Members may also be disqualified from continuance should the appointing authority provide written arguments to the other members and there is unanimous agreement.
- iii. Membership should be terminated by the appointing authority upon advice by the SFUCHAS-REC if a member has been absent from three consecutive meetings without sending any apologies.
- iv. Membership should be terminated by the appointing authority on grounds of misconduct, abuse of office, non-disclosure of competing interests, inappropriate behaviour or unprofessional conduct.
- v. Membership should be terminated if a member is convicted by a court of law for a criminal offence
- vi. Membership should automatically terminate when a member is dead.
- vii. SFUCHAS-REC shall request for a replacement of any member under the following circumstances:
 - a) Protracted illness of a member for a period of more than 6 months, which does not permit him/her to participate in the deliberations of the Committee.
 - b) Persistent absenteeism of a member without reasonable cause for a period of six months.
 - c) Voluntary withdrawal by a member.

7. Orientation and Training of members

- i. New members should undergo an orientation exercise upon joining the SFUCHAS-REC in order for them to familiarize with the SOPs and train them on basic Health Research Ethics. Such training should be organized by the SFUCHAS-REC secretariat. In addition, the initial training of all members of a newly established SFUCHAS-REC will be conducted by National Health Research Ethics Committee (NIMR/NatHREC).

- ii. Continuous training of SFUCHAS-REC members on Health Research Ethics and other relevant areas such as Good Clinical Practice (GCP) and Experimental designs should be organized as frequently as possible or as is necessary.
- iii. Each SFUCHAS-REC members shall be given the opportunity to attend national and international training Bioethics and Scientific Conferences or Seminars whenever funds to support these activities are available ethics for maintaining quality in ethical review and be aware of the latest developments in this area.
- iv. All relevant new guidelines should be brought to the attention of the members.

8. Term of office

- i. Membership should be for a period of three (3) years.
- ii. Membership may be renewed, however; at least one-third of the old members should be retained at every point in time. The maximum tenure of office of SFUCHAS-REC members is six (6) years.
- iii. For continuity and smooth running of the SFUCHAS-REC office, SFUCHAS-REC Secretary should serve up to a maximum of 3 terms, which translates to a maximum of fifteen (9) years.

9. Dissolving the Committee

The SFUCHAS-REC shall be dissolved and shall cease to exist when the university at which it is based (SFUCHAS) ceases to exist.

SOP # 02: CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT

The purpose of this procedure is to provide a form of Confidentiality/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 SFUCHAS-REC.

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 SFUCHAS-REC 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 blank
 - iii. Ask questions, if any and the Secretariat officer shall explain or clarify the context
 - iv. Sign and date both copies at the undersigned signature and give the forms back to a Compliance Officer to sign and date
 - v. Keeps a copy as their records.
2. The Compliance Office shall keep a copy of the signed Agreement as the Institute's records in a Confidentiality/Conflict of Interest Agreement file and store in a secure cabinet with limited key holders.

SOP # 03: ADMINISTRATION AND FUNCTIONS OF THE COMMITTEE

The purpose of this SOP is to describe the administration, office bearers and their functions in the SFUCHAS-REC. It therefore describes the Secretariat, functions of the Chairperson, Vice Chairperson, Secretariat, the Committee, Head of SFUCHAS, Consultant reviewer and dissolution of the Committee.

Secretariat and Officers

1. The officers of the SFUCHAS-REC shall comprise of the Chairperson, Vice Chairperson and Secretary.
2. The Chairperson is elected among the appointed members of the Committee for each specific term and the Secretary shall always be an employee of SFUCHAS.
3. The Chairperson should have an in-depth knowledge of ethical and scientific issues in the conduct of research and is well informed in regulations relevant to the use of human subjects in research.
4. The chairperson should have authority to sign SFUCHAS-REC official documents such as the approval certificate.
5. Should the chairperson decide to step down as chairperson of the SFUCHAS-REC, he/she should inform the committee in writing at least one month in advance; and the secretariat is obliged to inform the appointing authority.

6. The Committee shall have a permanent secretariat at SFUCHAS manned by the Committee Secretary and administrative supporting staffs who are also employees of the SFUCHAS.
7. SFUCHAS shall also provide the necessary funding for the operations of the Committee.

Functions of the Secretariat

1. Organizing an effective and efficient tracking procedures for each proposal received.
2. Prepare, maintain, and distribute study files.
3. Organize Committee meetings regularly.
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. Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to Committee members.

Responsibilities of the Secretariat shall include but not limited to:

1. The Secretariat shall be responsible for the oversight of Committee documents, records and archives.
2. Perform a pre-review of each submission of the Committee to ensure adherence to administrative submission requirements.
3. 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 the SFUCHAS.
4. Support the Chair in preparing and providing a statement of assurance when required by the regulations guiding the establishment of the Committee.
5. Design and disseminate templates for Committee submission documents, including research protocols, informed consent materials, agreements and periodic and final reports.
6. Design and maintain a system for collecting and filing all Committee documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approved protocols, and periodic and final reports.

7. Assist the SFUCHAS-REC to recruit new Committee members.
8. Prepare and submit annual Committee operational budget and plan to SFUCHAS management in consultation with the Chairperson.
9. 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.
10. Create and distribute meeting agendas, and arrange meeting logistics.
11. Attend Committee meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
12. Correspond with all submitting researchers at all times throughout the submission and review process, while remaining independent of the researcher's protocol operations. Advise submitting investigators on preparing and submitting protocols for review according to relevant SOPs.
13. Properly distribute and keep files of all correspondences.
14. Assist the Chairperson to conduct Committee meetings. Continually study and update staff about Committee operational regulations.
15. Be available for and attend any outside investigations or audits of the Committee. 16. Comply with requests during an investigation or audit.

The responsibilities of the of the Chairperson

Shall be (but not limited to) the following:

1. Chair Committee meetings in accordance with all regulations.
2. Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the Committee.
3. Facilitate the provision of training and educational programs to new Committee and continuing Committee members and the health and social scientific community of the Tanzania. The training shall include programs about the basic principles of human subject protection, current literature, regulations and guidelines affecting the SFUCHAS-REC and the SFUCHAS.
4. Review and accept revisions that were made as per the committee recommendation pending protocol approval.
5. Determine submissions that could be exempted from review, and notify the Committee and the submitting investigator of such exemptions.

6. Perform expedited review of research that meets the expedited review criteria.
7. Assign responsibilities and duties to any other member in his or her absence and assign responsibilities to other members of the Committee.
8. Supervise the Secretary and ensure s/he is performing his/her task dutifully.

Vice Chairperson

1. The Vice chairperson should chair meetings and sign SFUCHAS-REC official documents when the chairperson is not available.
2. In the absence of both the chairperson and Vice chairperson, the SFUCHAS-REC members should select an acting chairperson to chair the current meeting provided a quorum is met.
3. The selected acting chairperson should sign minutes of previous meeting confirmed during his/her chairpersonship.
4. Acting chairperson should not have authority to sign SFUCHAS-REC official documents such as approval certificates except minutes confirmed during his/her chairpersonship.

Responsibilities of Members, and Mandates of the SFUCHAS-REC

1. To safeguard the dignity, rights, safety, and well-being of all actual or potential research participants and/or communities
2. To act in the full interest of actual or potential research participants and concerned communities, taking into account the interests and needs of researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws
3. Review, discuss and consider research protocols submitted for evaluation to safeguard the rights and well-being of study participants.
4. Review progress reports and monitor ongoing studies as appropriate.
5. Evaluate final reports and outcomes.
6. To ensure that only qualified investigators are allowed to conduct proposed studies (the investigators and study teams should be qualified by training and experience).
7. To provide ethical oversight through passive and active monitoring of approved projects.

8. To suspend, withdraw approval or stop health research projects that obtained SFUCHAS-REC approval but have been proven to be harming the participants to an extent that makes the risk/benefit ratio ethically unacceptable.
9. To ensure that research results have potential benefit to the participating individuals/communities and are disseminated to policy makers to enable translation into policy and/or interventions.
10. To provide initial review, continuing review and review of amendments of health research proposals as detailed in the relevant SOPs.
11. Support the executive in the discharge of their duties when called upon.
12. Maintain confidentiality of documents and deliberations of the Committee meetings.
13. Declare conflict of interest.
14. Participate in continuing education activities in biomedical ethics and research.
15. Undertake duties assigned to them by the Chairperson.
16. Attend meetings regularly and participate actively during deliberations.
17. To charge administrative fees for services rendered. The payments should be made within the financial institutional framework of the SFUCHAS but fully allocated to the activities of the SFUCHAS-REC.

Responsibility of the Principal of SFUCHAS

1. S/he shall prepare and provide a statement of assurance when required by the regulations guiding the establishment of the Committee.
2. S/he shall ensure the provision of the necessary logistic and financial support for the smooth operations of the Committee.
3. If s/he has an interest in a particular protocol, s/he shall not take part in the reviewing process of that protocol.
4. To provide necessary administrative support to the Committee

Dissolving the Committee

1. At any point in time, should SFUCHAS cease to exist, the Committee is automatically dissolved.

2. The Principal of SFUCHAS, following written notification to each member, may also dissolve the Committee at any time.

SOP # 04: COMMITTEE MEETINGS

This SOP describes procedure for scheduling the meetings, distribution of agendas and meeting procedures. The frequency of the scheduled SFUCHAS-REC meetings should depend on the workload in terms of volume of applications submitted to the SFUCHAS-REC as well as the availability of the SFUCHAS-REC members who may have other core duties at their places of employment. The calendar dates and time of scheduled SFUCHAS-REC meetings should be agreed and confirmed by the committee and made public.

1. A minimum of half the number of Committee members including at least one member (community member) whose primary concerns is in non-scientific areas and relevant expertise. If the protocol under review involves a target group of women, there must be a female member of the Committee present to form a quorum.
2. The Chair shall lead the meeting. In the absence of the Chairperson, the Vice Chairperson shall lead the meeting and shall be directed by the Chairperson prior to his/her.
3. The Secretariat shall notify all Committee members of an upcoming meeting at least two weeks in advance by at least one of the following means: electronic mail, fax or carrier mail/messenger delivery.
4. The notification shall include a meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting, and shall include all related materials, including copies of protocols, informed consent materials, continuing and final reviews, safety reports.
5. The secretariat should prepare and distribute a tentative agenda based on the applications received and matters arising from the previous meeting.
6. In the case where the Secretariat is unsuccessful in sending the materials to Committee members, the Secretary shall at least notify the member(s) of the non-occurrence of the meeting, and shall arrange for alternative means of distributing the materials. Whenever possible, the Secretariat shall distribute the materials electronically.
7. The Secretariat shall notify all Committee members of any changes in meeting time, date or agenda as soon as possible.
8. Committee members shall keep an archive of all copies of meeting agenda and all other documents.

Meeting Procedure

1. The Chairperson or a delegated member of the Committee shall call a meeting when a quorum is present. If a quorum is not met, the meeting shall be rescheduled.
2. 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 following agenda format shall be used:

- i. Attendance/Apologies.
 - ii. Declaration/ signing of Conflict of Interest.
 - iii. Confirmation of minutes of the previous meeting.
 - iv. Matters arising from the previous minutes.
 - v. Review of new proposals or applications.
 - vi. Review of amended protocols.
 - vii. Review of study status reports.
 - viii. Review of final study reports.
 - ix. Review of safety reports.
 - x. Protocol Deviation/ Protocol Violation notifications.
 - xi. Expedited review reports.
 - xii. Any other business.
 - xiii. Date of the next SFUCHAS-REC meeting
3. The agenda may also include reference to proposed discussion of the following where appropriate:
 - a) General ethical issues, for example arising from new guidelines or recent publications.
 - b) Matters relating to the establishment or membership of the SFUCHAS-REC.
 - c) Matters relating to SFUCHAS-REC procedures.
 - d) Training issues.
 - e) Workload and decision making data.
 4. If the meeting is to review a new submitted protocol, the principal investigator of that protocol may be invited when deliberating on the protocol to answer questions that shall be raised by the board but must go out when decisions are made on the protocol.

Meeting Minutes

1. During Committee meetings, all deliberations shall be recorded in written meeting minutes or recorded electronically.
2. The minutes shall include a list of attendees, actions taken by the Committee, the decision or vote on those actions, including the number of members voted for against and abstaining, the basis for requiring changes or disapproving research, and a written summary of the discussion of issues and their resolution.

3. The Secretary shall also include a summary of each considered protocol in the minutes.
4. 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.
5. All Committee members shall review the minutes for accuracy and completeness.
6. The Committee members shall make recommendations to the minutes at the next Committee meeting.
7. The Chairperson shall confirm the accuracy and completeness and sign the minutes during the next meeting.
8. The Secretary shall archive the official minutes with the meeting's agenda and all relevant attachments.

SOP # 05 REQUIREMENTS FOR SUBMITTING AN APPLICATION TO THE SFUCHAS-REC AND PROTOCOL REVIEW PROCEDURES

In this SOP, submission of protocols and review procedures are described. It is the responsibility of the Principal Investigator (PI) of a protocol to submit an application for assessment of a protocol following procedures as outlined in this SOP by filling in an Application Assessment Form (Form # 02) and Investigator's Check List Form (Form # 03). The Secretary is responsible for receiving and processing new protocol submissions, and for ensuring that the form # 02 is adequately filled in and all elements required for consideration of the protocol are present.

Detailed Instructions

1. The submitting Investigator shall submit a research protocol with the following required documents:
 - i. Covering letter from the investigator where applicable (should include physical address, fax number, telephone number, mobile number and email address).
 - ii. Summary of the protocol
 - iii. Wherever applicable, a full protocol pre-reviewed by a scientific committee from originating/affiliating institutions with the comments.
 - iv. Enrolment forms, Questionnaires, Consent forms (refer, Form # 04: Format and Content of an Informed Consent Document and Form # 05: Guidance on Research Participants' Rights).
 - v. Up-to-date Curriculum Vitae CVs of the Principle investigator (PI) and or all co-PI

vi. Budget

vii. If the proposal is for an intervention study:

- a) For clinical trials Insurance certificate covering damages on participants and errors in the protocol implementation should be submitted (Insurance Act of 1998).
- b) A letter showing commitment to make the products readily available to the study community should be submitted to the SFUCHAS-REC.
- c) It requires approvals from NIMR/NatHREC and TFDA if applicable.

viii. For all protocols which involve data sharing and Shipment of samples and biological materials outside of Tanzania, Data Sharing Agreement (DSA) and Material Transfer Agreement (MTA) will be sought from NIMR/NatHREC accordingly. Therefore, investigators will be requested to apply for DSA and MTA from NIMR/NatHREC.

2. Biological Investigators must submit all documents at least three months prior to the commencement of the research study.
3. The Chairperson is responsible for determining whether a submitted protocol qualifies for expedited review.
4. Depending on the decision of the Chairperson on a particular protocol, primary reviewers would be appointed to review the protocol.

Contents of a full protocol

1. Protocol contents should include summary of the study, background/introduction, rationale, objectives (general and specific), methodology, recruitment strategy, laboratory investigations to be done, plans for analysis and publication, personnel, budget and justification and timeframe of the project, dissemination plan and community sensitization.
2. The informed consent form and information leaflet, in both the official and Swahili language and when necessary into the local vernacular language. Back translation into official language may be requested by the SFUCHAS-REC.
3. Data collection tools such as questionnaires, interviews /discussion guides, checklists and case record forms must also be submitted.
4. All materials to be used (including advertisements) for the recruitment of actual research participants must be attached to the protocol.
5. If the proposed study is a clinical trial, the investigator's brochure which provides adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience of the

study product to date (e.g. recent investigator's brochure, published data, summary of the product's characteristics etc), must be submitted.

SOP # 06: STUDY PROTOCOLS REVIEW PROCEDURES

This SOP describes how the SFUCHAS-REC reviews and assesses the protocol submitted for approval of the study. The Application Assessment Form (Form # 02) is designed to structure the protocol review process and to facilitate reporting recommendation and comments. This SOP applies to the assessment of all protocols submitted for review. The specific questions in the Application Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant points made during discussion and deliberation about a specific protocol shall be recorded on the form. The decision reached by the Committee and the reasons for its decision shall be recorded on the Application Assessment Form.

It is the responsibility of the Secretariat/staff to record and file the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision on the Application Assessment Form. The Chairperson of the SFUCHAS-REC shall sign and date to approve the decision in the form.

The Protocol in the Application Assessment Form shall be summarized recording general information about the protocol in the form (Form # 02) such as title of the protocol, protocol 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).

1. Study Design

The study design shall be reviewed with a view of evaluating the need for human participants for study, objectives of the study, and adequacy in literature review, appropriateness of the methodology proposed, inclusion/exclusion criteria, control arms (placebo, if any) and withdrawal or discontinuation criteria. Information on where to report a participant with unexpected disease(s) and state clearly how the PI should handle that case.

2. Qualification of investigators and study sites

Qualification of investigators shall be examined to see whether study and training background of the participating investigators relate to the study. The study sites shall also be examined for suitability of the study in terms of geographical distribution of the problem of under study and facility and infrastructure accessibility and availability at study sites to accommodate the study. Disclosure of potential conflicts of interest shall also be examined.

3. Review 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 protocol:

- 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 be plain and easy to understand by the general public
- vi. Contact persons with physical address and phone numbers
- vii. Confidentiality, risks -physical/mental/social, benefits to participants and to others
- viii. Compensation -reasonable/ unreasonable
- ix. Provisions for medical/psychosocial support
- x. Treatment for study related injuries and use of biological materials
- xi. The issue of insurance of health research participants, indemnity
- xii. Potential risks already stated in the proposal and any other that may have been omitted but are deemed likely to occur should be assessed in light of potential benefits
- xiii. Criteria for withdrawal or discontinuation of participants should be assessed to ensure fairness and safety of participants
- xiv. If a placebo is to be used, there must be scientifically and ethically acceptable evidence-based justification that must be clearly explained in the protocol
- xv. The recruitment process should be suitable for the targeted prospective participants and their communities in terms of cultural, traditional, religious or socioeconomic factors.
- xvi. Health research should be conducted on or with vulnerable groups such as orphaned children, pregnant women, children, prisoners and mentally ill people only if the research questions cannot be answered when non-vulnerable groups are used.
- xvii. In the case of clinical trials, Data Safety and Monitoring Board (DSMB) should be set up and should provide names and contacts of members, one of whom should be a national of at least one of the host countries (to be discussed by the entire group, local DSMB members) to the SFUCHAS-REC.
- xviii. If the research project involves more than one institution and samples are to be shipped from one institution to another, a signed Material Transfer Agreement between the sample or data provider and the recipient must be submitted to the SFUCHAS-REC.

4. Examination of Community Involvement and Impact

Ethical research conduct involving human participation requires community consultation, involvement of local researchers and institutions in the protocol 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 protocol shall be examined to assess adequate consideration of these aspects.

During the evaluation of a research proposal or application, the SFUCHAS-REC shall consider the following issues:

- i. The potential impact and relevance of the research on the concerned communities from which the research participants are drawn.
- ii. The steps taken to consult with the concerned communities during the course of conducting the research and in disseminating research findings are transparent.
- iii. The measures taken to preclude the influence of the community on the consent of an individual.
- iv. The proposed community engagement process including permission from the community leaders/elder or persons acknowledged as community representatives.
- v. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare systems and the improved capability of the community to respond to their health needs.
- vi. The provision for making available of any successful trial product to the participating communities on completion of the research and sustainability of any intervention.
- vii. The manner in which the results of the research will be made available to the research participants and the concerned communities.
- viii. The consideration for cultural sensitivities and concerns.

Attendance of a Principal Investigator

The SFUCHAS-REC Secretariat shall invite a PI, in writing, to attend the meeting at which his/her application requires further clarification or discussion. The PI shall not be required to make any formal presentation of the study at the meeting, unless requested to do so ahead of the meeting. The purpose of invitation shall be to enable the PI respond directly to requests from the committee for further information, clarification or reassurance.

1. When the PI is unable to attend and is not available to participate, it is acceptable for another investigator or collaborator to attend instead, subject to agreement by the SFUCHAS-REC Chair. It is not acceptable for a representative of the sponsor to attend in place of the PI.
2. In the case of applications submitted by students, the SFUCHAS-REC shall consider inviting both the student and supervisor to attend a meeting.
3. The attendance of the PI shall not be prescriptive and consideration of the PI's application shall not be biased if he/she is unable to attend.
4. The costs incurred in attending an SFUCHAS-REC meeting shall be borne by the PI or applicant.

5. When further consideration needs to be given to an application after the attendance of the PI, his/her re-attendance shall be deemed useful in formulating a conclusive decision on his/her application.
6. The PI shall not be present during the confidential discussions and final assessment of their application by the committee and therefore must go out when decisions are made on his/her protocol.

SOP # 07: REVIEW OF THE PROTOCOL AMENDMENTS

This applies to previously approved study protocols but later being amended and submitted for approval from SFUCHAS-REC. Amendments may be minor or major. The SFUCHAS-REC must review and approve all amendments to protocols involving human participants before implementation.

Minor Amendments: A minor amendment is defined as a change that does not materially affect the balance of risks and benefits in a study or does not substantially change the specific aims or design of the study. Examples of minor amendments include:

- a) Administrative or informational amendments:
 - i. Changes in research staff.
 - ii. Changing the study title or telephone numbers.
 - iii. Addition or removal of qualified investigators, study sites.
 - iv. Revision of format of consent documents, recruitment materials or questionnaires.
 - v. Correction of typographical errors.
- b) Procedural amendments
 - i. Drawing slightly different amounts of blood.
 - ii. Changing frequency at which blood is drawn.
 - iii. An increase or decrease in proposed number of participants supported by a statistical justification.
 - iv. Narrowing the range of inclusion criteria.
 - v. Broadening the range of exclusion criteria.
 - vi. Changing the amount of compensation, within reasonable limits.
 - vii. Revisions to the informed consent documents to improve clarity, to include missing elements or to revise lay language.
 - viii. Decreasing drug dosage or frequency of administration.
 - ix. Decrease in number of study visits provided such a decrease does not affect collection of relevant safety-related data.

Major Amendments: Such amendments involve significantly increased risk to participants and often reflect changes in the direction of a study that may substantially change its purpose or goal. Changes that alter the overall purpose or objective of a study may require a new study submission.

- i. Examples of changes that may affect the balance of risks and benefits include:
- ii. Adding a new activity that may increase risk to participants.
- iii. Changing drugs or medications as well as dosages.

- iv. Changing levels of radiation exposure.
 - v. Adding a vulnerable population.
 - vi. Adding or changing invasive procedures.
 - vii. Adding a research arm to the study.
 - viii. Substantially extending the duration of exposure to the test material or intervention.
 - ix. A substantial change in research methodology.
 - x. Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups)
1. All principal investigators (PIs) shall be required to submit any proposed changes to a previously approved study to the SFUCHAS-REC for review prior to initiation. The PI shall prepare the amendment package and submit to the Secretariat of the SFUCHAS-REC. The PI shall be required to submit the amended protocol, a cover letter outlining the nature of the suggested changes, the justification for the change, the Amendment Submission Form (Form # 06) and must have made an evaluation of any ethical consequence arising from the proposed amendment.
 2. The Secretariat shall check the original Amendment Submission Form (Form # 06) for completeness, presence of appropriate signatures, amended version of the protocol and appendix related documents. Changes or modifications in the amended version shall be underlined or highlighted.
 3. Upon receipt of the amendment package, the Secretariat shall follow the receiving procedures in requirements for submitting an application to the SFUCHAS-REC and protocol review procedures (SOP# 06).
 4. The Secretariat shall then:
 - i. Inform the Chairperson of the Committee verbally and in writing.
 - ii. Keep “Sent” and “Received” mail related to the notification of the Chairperson in the protocol file under the Correspondence section.
 - iii. Send the request for amendment memorandum and the protocol and related documents to the Chairperson within one working day of receipt of the Secretariat.
 5. After review of the materials, the Chairperson shall determine whether the protocol requires expedited or full review. Protocol amendment which increase risk to study participants, as judged by the Chairperson, such as a change in study design, may include but is 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 (for example there would be a significant increase if there are <20 participants enrolled, a change of 5% is significant; if there are >20 participants enrolled, a change of 20% is significant.

Or there shall be a significant decrease if the decrease in the number alters the fundamental characteristics of the study)

- v. Significant decrease or increase in dosage amount.
6. Change of investigators, that is addition or removal of some PI, co-PI or other researchers originally included in the protocol is an amendment that must be reviewed and approved by the SFUCHAS-REC. In case of addition of a new PI/co-PI or other researchers, their full CV should also be submitted.
7. Implications of any proposed amendment on the timeframe and budget of the research project should also be scrutinized.
8. If the Chairperson decides the protocol requires full Committee approval, s/he shall indicate this decision on the Checklist, sign and date the form.
9. If an amendment is received just prior to the Committee meeting, the Chairperson may decide to review the amendment in full Committee, even though the amendment may be expedited.
10. Upon receiving the recommendation from the Chairperson, the Secretariat shall:
 - i. Place the protocol amendment request on the agenda for the next convened meeting and
 - ii. Distribute to each Committee member the amendment's revision documents to clearly identify each change and requested changes to the consent form, if applicable.
11. The process outlined in the Application Assessment Form (SOP # 02) shall be used to review amended protocols and protocol-related documents.
12. The Chairperson shall call for a vote on the proposed amendments
13. The Secretary shall note recommendations for changes to the protocol and/or informed consent requested by Committee members in the minutes and communicated the decision to the clinical trial office or investigator in writing.
14. The SFUCHAS-REC shall determine whether the amendment is approved as submitted or if further information, clarification or change is required for the evaluation of the suggested amendment and clearly articulate the basis for such a decision to the PI or applicant.
15. In principle, minor amendments can go through expedited review, while for major amendments require approval by the SFUCHAS-REC or a new application for ethical review.

16. If the Committee does not approve the protocol amendment, the notification to the investigator shall also state the reason for not approving the amendment.
17. If the SFUCHAS-REC votes to require modifications to any of the documents, the specific changes required shall also be communicated to the investigator instructing him/her to make the necessary changes and resubmit the documents to Committee.
18. The Chairperson shall complete a decision form after the Committee has reached the decision.
19. The SFUCHAS-REC Secretariat shall communicate to the PI, in writing, the outcome of the SFUCHAS-REC deliberations on the request within six (6) working days of the meeting at which the request for the amendment was considered.
20. The form and minutes of the meeting relevant to the discussion and decision reached shall be kept as an official record of the amendment review process

Verbal communication and preliminary written communication of the decision and Completion of the Amendment Submission Form

1. The Chairperson shall notify verbally the investigator about the decision reached as soon as possible after the review, but no later than seven working days following the review.
2. The Chairperson shall send an electronic version and send a copy of the Amendment Submission Form with his/her signature and date of approval to the Secretariat within one working day or whenever possible, but not later than three working days after the review has taken place.
3. The Chairperson must sign and date the original version of this form and return this to the Secretariat within three working days after the review.
4. The Secretariat shall assign a unique ID letter to the protocol number corresponding to the number of the amendments.
5. The Secretariat shall sign and date the original version of the form and send a signed and dated Amendment Submission Form to the Clinical Trials Office where applicable or the PI within seven working days.
6. The Clinical Trials shall then provide a “clean” copy (underlining and highlighting recommended/approved changes) of the protocol and protocol related documents to the Secretariat.
7. The Secretary shall place the original completed documents, the “clean” version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

SOP # 08: EXPEDITED REVIEW

Expedited review is when the process of review is speeded up so that an application does not wait for the normal scheduled committee meetings. Expedited review should be requested and justified by the investigator through a written application to the SFUCHAS-REC. The Chairperson in collaboration with the Secretariat shall determine which protocols may require expedited review. The following categories shall be qualified for an expedited review:

1. Research activities that present no risks to human subjects.
2. Minor changes in previously approved research protocol.
3. Modification/amendment of protocol.
4. Protocol involves interviewing of non-confidential nature and not likely to harm the status or interest or not likely to offend the sensibility of study participants.
5. Studies that involve collection of biological specimens by non-invasive means (e.g. Blood fluids, excreta, hair or nail in non-disfiguring or threatening manner)
6. 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.
7. Research involving data, documents or specimens that have been already collected or shall be collected for ongoing medical treatment or diagnosis.
8. Continuing review of a protocol previously approved with no modification to the original protocol and studies has taken place and no additional risk has been identified.
9. Research projects investigating issues that may potentially have serious negative impact at community, ethnic group or population level should not qualify for expedited review.
10. Research projects investigating sensitive social issues should not qualify for expedited review (Homosexuality, Commercial Sex Workers, drug abuse, child abuse, gender violence, Female Genital Mutilation, etc).

Instructions

1. Expedited review shall be conducted by one or more experienced reviewers designated by the Chairperson from among members of the Committee in accordance with the requirements. If the review involves a revised version, the selected members shall normally be those who reviewed the previous version of the protocol.
2. The expedited review shall be carried out on a complete study protocol with all required attachments as if it was being submitted for the first time (Form # 02). Results of the

review process may be communicated to the PI before being discussed at a Committee meeting and reported retrospectively to the Committee meeting.

3. Expedited review shall take not longer than 4 weeks and if any member of the Committee raises a concern about a protocol that was expedited reviewed the protocol shall undergo a regular review. In an expedited review, the 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. The Secretary shall inform all members about the outcome of an expedited review as soon as practicable.

SOP # 09: 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 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 but at least once before the end of the data collection stage.
 - 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 # 09) to complete the annual review report and shall include all required elements, including the following:
 - i. Number and demographics of participants enrolled
 - ii. Changes in principal and/or associate investigator(s)

- iii. A summary description of subject experiences
 - iv. All adverse events experienced and numbers of and reasons for withdrawals from the research
 - v. The research results obtained thus far
 - vi. A current risk-benefit assessment based on study results and
 - vii. 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.
 4. The investigator/researcher shall submit one hard copy of the continuing review report, with original signature. The investigator/researcher is also encouraged to submit an electronic copy of the review report via e-mail.
 5. Upon receipt of the continuing review report, the Secretary shall conduct a pre-committee review to ensure all the required elements are present. The Secretary 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. The Chairperson may elect to invite an independent or alternate reviewer to the meeting. Committee members shall consider and vote upon all continuing review reports in full meeting utilizing the protocol voting procedure. The risk/benefit ratio may change over time. The criteria the Committee uses 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.
 8. 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 protocol. 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. The Secretary shall archive continuing review reports and supporting materials with the relevant meeting minutes.

Timing of Continuing Review

1. 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. No

new subjects may be enrolled in the study. However, if the investigator/researcher is actively pursuing renewal with the Committee and the Committee believes that an overriding 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.

2. If the investigator/researcher cannot provide any of the required information, the investigator/researcher shall be reminded to justify 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.

SOP # 10: STUDY EXTENSION/ RENEWAL OF APPROVAL

SFUCHAS-REC Ethical approval is given for one (1) year initially, but may be renewed. The presumption is that approvals will continue to be renewed provided that the SFUCHAS-REC has adequate assurances of the continuing value of the resource and compliance with the terms and conditions of approval.

1. The PI should provide the latest annual progress report by the due date, together with an updated version of the original application form and supporting documentation taking into account changes during the intervening period - this documentation should be submitted to the SFUCHAS-REC secretariat.
2. The SFUCHAS-REC should issue a reminder about the need to submit the renewal documentation one (2) months prior to the due date - all documentation in respect of the renewal of approval will be managed under the original SFUCHAS-REC reference number.
3. If the documentation in (2) is not received by the due date, the SFUCHAS-REC secretariat should issue a further reminder and notify the PI that the approval will lapse if it is not received within a further month.
4. The renewal documentation should be reviewed at the next available full meeting of the SFUCHAS-REC and if approved, a renewal letter should be issued. The SFUCHAS-REC should aim to issue the renewal within 30 days of receipt of the renewal documentation, excluding time taken by the PI to respond to one request for information. An overall deadline of 60 days will apply to the renewal application.
5. Exceptionally, the SFUCHAS-REC may decide not to renew the approval where it has serious concern about one of the following:
 - i. Failure to comply with the terms and conditions of approval.
 - ii. Failure to use the resource to support research of public benefit.
6. Before terminating ethical approval, the SFUCHAS-REC should first write to the PI setting out its concerns and allowing opportunity for further representations to be made.

SOP # 11: 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 Committee (DSMC). DSMCs may be critical for studies intended to save lives, prevent serious disease progression, or reduce the risk of a major adverse health outcome. The primary responsibility of a DSMB is to safeguard human subjects by analyzing accumulating data relevant to the risks and benefits on a regular basis.

1. DSMCs are particularly important in studies where interim data analysis is required to ensure the safety of research participants. A DSMC is often considered 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 intended to reduce severe morbidity or mortality.
 - iii. Early studies of a high-risk intervention (risk of non-preventable, potentially life-threatening, complications; or risk of common, preventable adverse events of interest.
 - iv. Studies in the early phases of a novel intervention with very limited information on clinical safety or where prior information raises concern regarding potential serious adverse outcomes.
 - v. Studies where the design or expected data accrual is complex, or where there may be ongoing questions with regard to the impact of accrued data on the study design and participants' safety, particularly in studies with a long duration.
 - vi. Studies carried out in emergency situations.
 - vii. Studies which involve vulnerable populations.
2. The SFUCHAS-REC may also suggest to the sponsor that a DSMC be established for a particular study. Although the DSMC has no direct relationship with the SFUCHAS-REC, all protocol revisions approved by the SFUCHAS-REC should be submitted to the DSMC.
3. The SFUCHAS-REC may request the PI to provide the DSMC with a periodic report.
4. The composition of a DSMB must include:
 - i. Multidisciplinary representation, including physicians from relevant medical specialties and biostatisticians. This may include other experts such as bioethicists, epidemiologists and basic scientists.
 - ii. Members who are free of significant conflicts of interest (i.e., financial, intellectual, professional, or regulatory).

- iii. The appropriate size depending on the type of study and types of expertise needed.
5. Different trials might require the inclusion of different disciplines on a DSMB.

DECISION-MAKING PROCEDURE BY THE COMMITTEE MEMBERS

The guidance, advice and decision reached by the Committee members shall be summarized and recorded. The summary shall include protocol title and date of review, checklist of documents reviewed, and decision reached by the Committee. 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.

1. SFUCHAS-REC members can only make decisions if the quorum requirements as stipulated in the relevant SOP are satisfied.
2. Any member with conflict of interest regarding a particular proposal must not take part in the review of the proposal and subsequent decision making process. Members with conflict of interest must recuse themselves.
3. Non-members such as project PIs and independent experts may be consulted as part of the review process.
4. A decision should only be taken after there has been sufficient time to allow for review and discussion of an application in the absence of non-members from the meeting.
5. Only SFUCHAS-REC members who participated in the review process and deliberations should take part in the decision-making process.
6. SFUCHAS-REC member's decisions shall be either unanimous when all members are in agreement or by consensus when there is voting or the position voted for by the majority becomes the SFUCHAS-REC decision. In case there is a tie, other members who were absent should be consulted otherwise independent expert opinion should be sought.
7. SFUCHAS-REC decisions regarding applications shall be:
 - i. Approval- the project can go ahead with no changes
 - ii. Provisional approval in case of expedited review
 - iii. Conditional approval for proposal with minor changes required which can be verified by secretariat without submitting to SFUCHAS-REC meetings.
 - iv. Major changes necessitating resubmission of the application to SFUCHAS-REC meetings. The project cannot go ahead until required changes have been made
 - v. Deferment- pending a decision at a later date.

- vi. Disapproval- the project cannot proceed, for reasons that should be clearly specified by the reviewers.
8. For any decision made by the SFUCHAS-REC, clear reasons and justifications should be given and should be documented in the minutes and in the communication to the applicant.

COMMUNICATING SFUCHAS-REC DECISIONS TO THE APPLICANTS

1. Decisions regarding submitted protocols should be officially communicated, in writing, to the applicant within 10 working days of the meeting that made the decisions.
2. Communication of the SFUCHAS-REC decision shall include but not limited to the following:
 - i. The name, title and address of the applicant
 - ii. The title of the proposal reviewed
 - iii. The name of the site(s) or study area
 - iv. The names and identification numbers (versions numbers/dates) of the reviewed documents
 - v. A clear statement of the decision reached by the SFUCHAS-REC
 - vi. The date of the decision and signature of the Chairperson/Vice Chairperson
 - vii. In case of a conditional decision, any requirements by SFUCHAS-REC, including suggestion for revisions should be clearly explained in writing to the applicant
 - viii. In case of a positive decision, a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the SFUCHAS-REC.
 - ix. The validity period of the approval
 - x. The final approval certificate/letter shall be signed and dated by the Chairperson/Vice Chairperson of the SFUCHAS-REC.
3. The approval certificate/letter shall also bear the name and address of the NIMR/NatHREC and an electronic and hard copy of each certificate/letter shall be sent to NIMR/NatHREC.

SOP # 12: SELECTION OF INDEPENDENT CONSULTANTS/EXPERTS

The Committee may further be supported in its reflections on specific protocols 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 shall involve procedures or information that is not within the area of expertise of the Committee members. 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 name of the Consultant.

Detailed instructions

1. Selection of Independent consultants The Secretariat shall choose a consultant to give study documents to review from a created roster of Consultants based on areas of expertise. The creation of the roster of experts shall involve the Secretariat conducting a qualification review of prospective consultants and making decision based on expertise, availability and independence criteria. The consultant shall provide to the Secretariat their Curriculum Vitae and sign a Confidentiality/Conflict of Interest Agreement (Form # 01). The documents shall be kept in a consultant file.
2. The Secretariat shall provide protocol packages to appropriate consultants. 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.
3. Consultation services may be terminated by either the consultants themselves or the Committee. Upon termination of the consultant's services, the Secretariat shall ensure that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

SOP # 13: REVIEW OF FINAL REPORTS

The purpose of this SOP is to provide instructions on the review and follow-up, appropriate, of Final Reports for any study previously approved by the SFUCHAS-REC. 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. Although SFUCHAS-REC provides a Study Report Form (Form # 11) to the investigator, any mechanism (letter format, form provided by the sponsor) may be used, provided that the information submitted is sufficient. It is the responsibility of the Secretariat to review the report for completeness before making copies for the Committee meeting.

Detailed instructions

1. Before each Committee meeting the Secretariat shall be guided by SOP# 05 (Protocol Review Procedures) for receiving and checking the report packages. The Secretariat shall

read the submitted report and give a briefing to the Chairperson before making copies and distributing it to all Committee members.

2. During the Committee meeting each Committee member shall review a copy of the final report before deliberating on it. The designee shall entertain any discussion of the study. If appropriate to the discussions, a Committee member may call for consensus on whether to request further information or to take other action with the investigator before summarizing what action to be taken. The Secretary shall note the decision in the meeting minutes.
3. After the Committee meeting, the Secretariat shall notify the investigator of the decision taken. If no action is taken, file the final report and consider the study as closed. Get a copy of the final report signed by the Chairperson or the designee, send an acknowledged letter to the investigator and archive the entire study protocol and the report.

SOP# 14: HANDLING OF APPEALS/COMPLAINTS ARISING FROM SFUCHAS-REC DECISIONS

Any appeals arising from a SFUCHAS-REC decision should be filed by the PI. Any PI with a complaint regarding the Committee's decision on their proposed research study may refer the complaint for review to the Principal of the SFUCHAS in writing, detailing the basis of the complaint or may request the SFUCHAS-REC Chairperson to do so on his/her behalf.

1. The SFUCHAS-REC Chairperson shall provide the Principal with all the necessary information about the proposed research study which shall include:
 - i. The complaint.
 - ii. All documents pertaining to the proposed study that was reviewed by SFUCHAS-REC.
 - iii. The relevant section of the minutes detailing SFUCHAS-REC's deliberation on the research proposal.
 - iv. Further information on the research proposal where necessary.
2. The Principal in consultation with the relevant committees, shall review the documents provided by the SFUCHAS-REC Chairperson to determine if further investigation is warranted. The SFUCHAS-REC's decision shall be upheld if it is determined that there is no need for further investigation.
3. The Principal shall inform the SFUCHAS-REC and the PI, in writing, of the decision. If it is determined that the appeal deserves further investigation an Independent REC preferably NatHREC shall be consulted to review the petitioned documents. However, the costs incurred shall be borne by the PI or applicant.
4. In conducting its review, the NatHREC shall consider whether the SFUCHAS-REC acted in compliance with:

- i. Research guidelines for research clearance and conduct of research.
 - ii. SFUCHAS-REC Terms of Reference.
 - iii. The SFUCHAS-REC Standard Operating Procedures.
 - iv. The SFUCHAS-REC acted in an impartial or biased way.
5. The NatHREC will notify the Principal, in writing, the outcome of the investigation which may be:
- i. Dismissal of the appeal, in which case the decision the SFUCHAS-REC made will be final. The Principal shall communicate this determination to the SFUCHAS-REC and the PI.
 - ii. Referral back to the SFUCHAS-REC for re-consideration with new information obtained by the NatHREC. If the appeal file is referred back to the SFUCHAS-REC for further evaluation, the SFUCHAS-REC's decision on the matter shall be final.
 - iii. The final decision shall be communicated to the complainant within five (5) working days of the meeting at which a final decision on the matter was reached.

SOP # 15: HANDLING COMPLAINTS ON THE CONDUCT OF THE STUDY AND VOLUNTEERS REQUESTS REGARDING THEIR RIGHTS

The SFUCHAS-REC shall consider its prime responsibility by assuming the protection of the rights and welfare of human subjects in a clinical investigation 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 SFUCHAS-REC. 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 or any other complaint" 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 SFUCHAS-REC policy shall designate the Chairperson as the person responsible for communicating with participants regarding their rights as study participants. Delegation of this responsibility to another member is acceptable as long as delegation is documented in writing.

Handling a request

- 1. Upon receiving an inquiry from a study participant, the SFUCHAS-REC Staff shall do the following:
 - i. Record the request and information on the Request Record Form (Form # 12).

- ii. The SFUCHAS-REC shall review all claims of serious or continuing non-compliance with the SFUCHAS-REC requirements. Non-compliance involves conducting research in a manner that disregards or violates the SFUCHAS-REC regulations and/or an approved protocol.
 - iii. The SFUCHAS-REC shall investigate the complaint or concern within thirty (30) working days from the date of the meeting where it was discussed.
 - iv. Communication to the PI will be sent within six (6) working days from the date of the SFUCHAS-REC review. The PI shall be required to respond to the claim.
 - v. The appropriate SFUCHAS-REC committee shall review both the claim and response, upon which the committee may recommend:
 - a. Dismissal of the claim as unjustified.
 - b. Referral of the matter to another more appropriate process or authority within the respective institutions or other relevant authority for resolution.
 - c. Resolution through corrective or educational measures where the violation is minor or inadvertent.
 - d. The launch of a formal SFUCHAS-REC investigation where the allegation or complaint appears founded and is of a serious nature.
2. Should the SFUCHAS-REC decide to launch a formal investigation, the PI under investigation shall be given an opportunity to submit written comments and to appear before the investigation committee on at least one occasion before the committee issues a report of its findings.
 3. The actions the committee may take with respect to the investigation include but are not limited to:
 - i. Dismissal of the complaint as unjustified.
 - ii. Corrective or educational measures.
 - iii. Frequent monitoring of research activities.
 - iv. Recommend frequent reporting by the researcher of his/her research activities.
 - v. Recommend restrictions on research practice.
 - vi. Suspension of approval of one or more of the investigator's studies.
 - vii. Termination of approval of one or more of the investigator's studies.
 4. The SFUCHAS-REC Chairperson will notify the PI and the complainant or informant, in writing, the results of the inquiry and reasons for such decision.
 5. The Secretariat shall Record information and any actions or follow-up taken in the form (Form # 12) and the Chairperson should sign and date the form.

SOP # 16: MONITORING APPROVED STUDIES

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 its performance or to GCP. This SOP applies to any visits and/or monitoring of any study sites as stated in the SFUCHAS-REC approved as the

place where the studies and/or laboratory tests being carried out or performed. It is the responsibility of the SFUCHAS-REC to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved. The Secretariat in consultation with the Chairperson shall initiate an on- site evaluation of a study site for cause or for a routine audit.

Passive monitoring

1. For Serious Adverse Events reports, investigators and/or sponsors are obliged to report in writing (Form # 07) any serious adverse events (SAEs) to the SFUCHAS-REC within 24 hours.
2. Adverse Events should be recorded by the investigators and reported to the SFUCHAS-REC when progress reports are due.
3. PIs should submit progress reports at intervals stipulated by the SFUCHAS-REC as a condition for renewal of approval. Such progress reports enable the SFUCHAS-REC to assess if the research project is progressing as per the approved protocol and if there are no issues that may need to be addressed.
4. Material Transfer Agreement which states quantities, types and specific purpose of any samples to be moved from the institution where they are collected to another recipient institution within the same country or in another country should be signed by the provider and the recipient.
5. Reports from other relevant stakeholders such as Regulatory Authorities and Data Safety and Monitoring Boards (DSMB) that may be shared with SFUCHAS-REC to assess the way approved research projects are conducted.
6. Final reports which are supposed to be submitted when a research project has been completed help the SFUCHAS-REC to determine if the whole project was conducted as per the approved protocol.

Active monitoring

The SFUCHAS-REC members should physically visit the research projects in the field in order to assess if the projects are being conducted as per the approved protocols.

1. Every approved study should be actively monitored to ensure adherence of health research ethics.
2. In the event that there is a study being implemented without ethical approval, urgent site visit should be carried out and appropriate action taken.
3. The number of SFUCHAS-REC members to undertake the oversight visit should depend on the workload of the inspection activities that will be done. In order to

maximize objectivity in the oversight exercise, at least 3 members of the SFUCHAS-REC with relevant diverse expertise should make up the oversight team.

Types of oversight visits

- i. SFUCHAS-REC–initiated announced oversight visits: the SFUCHAS-REC informs the PI of the project to be visited in advance of the date of the visit. The Committee representatives shall notify the investigator within one week about plans of the visit. Meanwhile the visiting team shall make the appropriate travel arrangements, review the Committee files for the study and site, make appropriate notes, or copies some parts of the files for comparison with the site files.
 - ii. Surprise monitoring visit: A surprise-monitoring visit will be conducted at random to researches falling under following categories:
 - a) Researchers who do not submit progress reports as per regulations after two reminders.
 - b) Researchers who prolong completion of their research beyond the approved time frame.
 - c) Researches that are suspected to changed their objectives and conduct as approved.
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, review 25% of the participant files to ensure that participants are signing the correct randomly informed consent, observe the informed consent process, if possible, and review the Committee files for the study to ensure that documentation is filed appropriately and confidentiality.
 - ii. Make contact with research study participants and the surrounding community members to enquiry information about the study related issues.
5. After the visit, the Committee representative that made the visit shall
- i. Write a report using the Checklist for a Monitoring Visit (Form # 10) within two weeks describing the findings during the audit.
 - ii. Forward a copy of the site visit to the site-monitoring file for full Committee review.
 - iii. Send a copy of the report to the site for their files.
 - iv. Place the report in the correct site files.
 - v. Make debriefing before departure.
 - vi. Present the inspection results to the full Committee The presentation shall be scheduled in the meeting agenda and presented to the full Committee.

SOP # 17: MONITORING AND EVALUATION OF SAFETY/ADVERSE EVENTS (SAE) REPORT

The SFUCHAS-REC shall require the reporting of any adverse events noted during the conduct of a study. The SFUCHAS-REC shall consider an adverse event as any unfavourable sign, symptom or disease of whether or not it has a causal relationship. A serious adverse event is any untoward medical occurrence that:

- i. Results in death.
 - ii. Is life-threatening.
 - iii. Results in persistent or significant disability or incapacity.
 - iv. Requires inpatient hospitalization or prolongation of existing hospitalization.
 - v. Is a congenital abnormality or birth defect.
 - vi. Requires intervention to prevent permanent impairment.
 - vii. Is otherwise considered medically significant by the investigator
1. Any study-related unexpected or serious adverse event must be reported to the SFUCHAS-REC via email (sfuchas-rec@sfuchas.ac.tz) within forty eight (48) hours after the PI becomes aware of the event. The hard copies of the report must be forwarded to the SFUCHAS-REC Secretariat within five (5) working days of the initial notification. Follow-up reports should be submitted as soon as more information becomes available.
 2. Any study-related expected adverse event or adverse events not related to participation in the study must be reported by the PI, in writing, within ten (10) working days after the investigator becomes aware of the event (refer to Adverse Event Reporting Form i.e. REC Form-07). However, if the PI notices that the expected adverse events are occurring with greater frequency than anticipated or a higher level of severity than expected, then the reports must be submitted within three (3) working days.
 3. The written safety report should be addressed to the Chairperson of SFUCHAS-REC and submitted to the SFUCHAS-REC Secretariat office. The reporting should include the presumptive diagnosis and the PI's opinion on the relationship of the adverse event with participation in the study.
 4. The SFUCHAS-REC shall review the adverse event at its next scheduled meeting at which a determination shall be made on the appropriate course of action. The appropriate action may include:
 - i. Request for an amendment to the approved protocol.
 - ii. Request that additional information regarding risks be given to the research participants.
 - iii. Increased surveillance of the study.

- iv. Further investigation of the event by a SFUCHAS-REC member or external expert.
 - v. Suspension of ethical and scientific approval.
5. The PI shall be required to submit a follow-up report if the information received suggests that the severity of an event has increased, or suggests the event is more likely to be related to the study than initially thought, or seems to affect the rights and welfare of current study participants.
6. The SFUCHAS-REC shall also review external adverse events whenever reported by a local investigator. The external adverse events shall typically be reported by an external investigator and describes adverse experiences by study participants engaged in a multicentre or multi-country clinical trial in which SFUCHAS is one of the participating trial sites.
7. The SFUCHAS-REC shall communicate to the PI, in writing, its decision or its intention to take a particular action within five (5) working days of the date at which the decision was made.

SOP # 18: NON-COMPLIANCE/ MISCONDUCT OF HEALTH 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 SFUCHAS-REC requests. This SOP applies to all research projects involving human participants and approved by the SFUCHAS-REC. The Secretariat is responsible for collecting and recording on the Protocol Deviation or Violation Reporting Form (Form # 08).

Detailed instructions

1. Whenever non-compliance has been observed, it shall be ensured that the investigator information is placed on the agenda of each Committee meeting.
2. A file shall be maintained that identifies investigators who are found to be in non-compliance with TFDA regulations or who fail to respond to the Committee's requests.
3. Research Misconduct includes but is not limited to:
 - i. Conducting health research which involves human participants or potentially affects humans in the area it was conducted without first obtaining ethical approval.
 - ii. Collecting samples or information from human participants without first obtaining valid informed consent.

- iii. Sharing samples collected from human participants with other researchers or institutions without ethical approval to do so and without a signed Material Transfer Agreement.
 - iv. Sharing samples collected prospectively from human participants with other researchers or institutions without the informed consent of the sample donors to do so. The SFUCHAS-REC may waive the requirement for informed consent in the case of archived samples if the justifications are considered to be ethically and scientifically sound by the SFUCHAS-REC.
 - v. Failure to submit mandatory reports such as progress reports and final reports to the SFUCHAS-REC.
 - vi. Failure to uphold privacy and confidentiality of participants' information
 - vii. Failure to report deviations from the approved protocol or unjustifiable deviations.
 - viii. Fabricating falsifying , or knowingly plagiarizing data
 - ix. Misuse of project funds at the expense of the approved project activities
 - x. Forgery of SFUCHAS-REC documents –(alteration of approval letter/certificate; Material Transfer Agreement, etc)
4. The SFUCHAS-REC may receive reports of cases of misconduct via investigators, community members, research participants, or through its oversight activities. Upon receiving such reports the SFUCHAS-REC should confirm the validity of the alleged misconduct before deciding on an appropriate action to take. The actions that the SFUCHAS-REC may take after confirming the misconduct include:
- i. A warning letter will be written to the PI with instructions for the misconduct to be stopped and/or rectified; the head of the institution, partners, and sponsor should be copied.
 - ii. In the event that serious harm was caused to participants as a result of the misconduct, compensation for the harm caused should be demanded from the researchers. The compensation package should be determined by qualified and relevant authorities.
 - iii. Legal action in the case of criminal misconduct.
5. The Secretariat shall record the Committee's decision and draft a notification letter that shall be signed by the Chairperson and date the letter.
6. 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, 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.

7. The SFUCHAS-REC shall have the authority to terminate the approval of any research for which it has granted clearance when:
 - i. There is gross misconduct by a PI or any investigators on the study that is evidently confirmed.
 - ii. The research presents excessive risks to research participants i.e. the actual risk-benefit status of the study is not consonant with the predicted risk-benefit ratio prior to implementation of the study.
 - iii. A PI or study team members fail to comply with research regulations.
8. The Committee Chairperson shall request an immediate termination of further accrual of new study participants or of continued participation of previously enrolled study participants whenever any of the conditions outlined above.
9. The committee Chairperson shall convene a special meeting at the earliest convenience to review the termination report. The actions the SFUCHAS-REC may request for include (but are not limited to):
 - i. A summary of the study protocol and the accrued data.
 - ii. Submission of the study results at the time of termination.
 - iii. Establishment of a mechanism for an extended follow-up to monitor safety issues.
 - iv. Require the PI to debrief study participants of the termination and also notify those study participants who have completed study activities.
 - v. Compensation of study participants, where applicable.
 - vi. A requirement that the principal investigator and the study team members undertake health research ethics and GCP re-training.
 - vii. Perform an audit of other active studies of the principal investigator.
10. The SFUCHAS-REC committee shall give reasons for its action and advise the PI and study sponsor, in writing, of such termination and the measures needed.
11. The termination shall occur within six (5) working days of the date the SFUCHAS-REC committee makes the determination and no later than five (5) working days after the PI has received the notice of termination.
12. The PI shall not resume a terminated study.
13. The Committee Chairperson shall inform the study sponsor and the Chairperson of National Health Research Ethics Committee (NatHREC) of the termination or withdrawal of any ethical approval.

SOP # 19: COMPLETION OR EARLY TERMINATION/ABANDONMENT OF A RESEARCH PROJECT

Upon completion, early termination or abandonment of an approved research project, the PI must complete and submit a completion of the study/early termination report form (Form-13) to the SFUCHAS-REC.

The PI should notify the SFUCHAS-REC in writing that the study has ended within 90 days of the conclusion of the research. A final study report should be submitted and notice of closure must be issued on. The Committee should also be notified of the arrangements for publication or dissemination of the research including any feedback to participants.

If a study is abandoned prior to commencement, the PI should notify the SFUCHAS-REC by letter, giving reasons. If a study is abandoned and it is later proposed to start it afresh, a new application should be made.

SOP # 20: HANDLING REQUESTS FOR SECONDARY USE OF BIOLOGICAL SAMPLES OR SPECIMENS

The SFUCHAS-REC shall review all new applications requesting use of archived samples at its next available meeting provided the applications are received by the SFUCHAS-REC Secretariat on or before the deadline for submission.

Requirements

- i. A disclosure of the name of the PI for each of the studies from which the samples will be obtained.
- ii. A disclosure of the study or studies (give titles and any SFUCHAS-REC study identification numbers) from which the samples were derived.
- iii. The specific purpose for which the samples are to be used.
- iv. Evidence that scientific review of the proposed study has been done to ascertain the merit in conducting the study.
- v. The number and types of samples to be obtained from each study.
- vi. An assessment must have been made on the integrity of the archived samples to be used to ensure that the samples in question are suitable for use in the proposed study and will yield meaningful results.
- vii. An analysis must have been made on the limitation of the new study presented by the criteria for collecting the samples and the storage conditions and how it will be addressed.
- viii. A disclosure of whether the PI of the new study can link the specific samples to the individuals or the community from which the samples were obtained either directly or indirectly through an existing code, coding system or by a combination of variables that can result in identification of an individual or community or whether anonymized samples (i.e. stripped of all identifiers) will be used.
- ix. The arrangements for privacy protections where it is possible to identify the samples.
- x. The identification of the samples must be limited to the extent necessary to achieve the study objectives and a justification should be provided.
- xi. A detailed description of the agreements between the investigators on transfer and storage of the biological sample, ownership of data, findings or IPR/patents.
- xii. A copy of the previously approved consent document used for the initial collection of the biological specimen.

For samples collected and archived without notification of future potential uses, the FUCHAS-REC shall make a determination of the scientific merit in using the archived samples and shall provide surrogate consent for their use provided that the samples will be anonymized or

coded and the research is being conducted in line with the objectives of the initial study for which the samples were collected or a justified public health concern. If the study is likely to produce information relevant to the health or wellbeing of the person who gave the sample, the SFUCHAS-REC shall request that appropriate follow up be done where it is possible to re-contact the study participants.

The SFUCHAS-REC's discussions on the application shall be recorded in the minutes. The SFUCHAS-REC shall communicate to the PI, in writing, the decision of SFUCHAS-REC on the Application within six (6) working days of the meeting at which the decision was reached.

SOP # 21: PROCEDURES FOR MAINTAINING CONFIDENTIALITY OF THE SFUCHAS-REC 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. It applies to all kinds of handling, distribution and storage of submitted study protocols, Committee documents, and correspondence with experts and auditors general public. It shall be mandatory to maintain confidentiality of study Committee documents, and correspondence. It is the responsibility of all members of the Committee and staff of the Secretariat to enforce confidentiality.

Detailed instructions

1. Committee members

Committee members and the Secretary who have signed a confidentiality agreement with SFUCHAS-REC at the beginning of their term of service to the Committee (SOP # 02) shall have access to the confidential documents.

2. Confidential documents

Confidentiality documents shall include documents reviewed by Committee members (Protocol and there related documents, case report forms, informed consent documents, scientific documents, expert opinion or reviews). They shall also include SFUCHAS-REC documents (SOPs, meeting minutes, advice and decisions) and correspondence (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 SFUCHAS-REC shall be allowed to ask for copies and only staff members of the Secretariat shall be allowed to make such copies. The Secretary of the Committee may ask for help, but shall be responsible for maintaining confidentiality of all documents.

4. Copies Requested by Non-Members of the Committee

If non-members of the Committee (including the Secretary) need copies of original documents, it shall be the responsibility of one member of the Committee to request a copy and to maintain confidentiality of copied documents.

SOP # 22: DOCUMENTATION AND ARCHIVING

1. All documentation and communication done by the SFUCHAS-REC should be dated, filed, and archived
2. Documents should be archived for a minimum period of 5 years following the completion of a study
3. Documents that should be filed and archived include but are not limited to:
 - i. Written standard operating procedures of SFUCHAS-REC
 - ii. Updated lists of SFUCHAS-REC members
 - iii. CVs of the SFUCHAS-REC members
 - iv. Agenda of SFUCHAS-REC meetings
 - v. Minutes of SFUCHAS-REC meetings with names of members present, date of meeting, decisions made, and any other details
 - vi. One copy of all materials submitted by each and every applicant
 - vii. Correspondence between SFUCHAS-REC Secretariat and applicants or concerned parties regarding application, decision and follow up
 - viii. Copy of the decision and any advice or requirements sent to each and every applicant
 - ix. Progress reports received from researchers as per SFUCHAS-REC requirements
 - x. Serious Adverse Events reports submitted by researchers
 - xi. Final reports from researchers
 - xii. Oversight visit reports by SFUCHAS-REC members

SOP # 23: REVISION OF SOP

The purpose of this SOP is to address the when and how SOPs shall be reviewed. If the Committee wishes to revise or update 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 Secretary.
2. The SOP shall be evaluated for accuracy and timeliness in an annual review and the Secretary shall alert the Committee of an annual review requirement.

3. The Committee, Secretary or an assigned reviewer shall ensure that the SOP reflects the most current outline of procedures. If the document does not need revision, the author shall return the document to the Secretary for recording and filing.

REFERENCES AND GUIDELINES

1. Guidelines on Ethics for Health Research in Tanzania (2001)
2. Council for International Organization of Medical Sciences (CIOMS), Geneva 1993
3. Federal Register 2004. Department of Health and Human Services. 42 CFR Parts 50 and 93 Public Health Services Policies on Research Misconduct; Proposed Rule.
4. Protection of Human Subjects, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Oviedo 1979
5. World Medical Association, Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects. Finland, 1964
6. International Conference on Harmonization (ICH), 1996
7. World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research, Geneva, 20001.
8. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
9. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
10. Code of Federal Regulations 46.115 IRB Records, .108.b IRB Functions and Operations.
11. The Belmont report
12. Ethical Guidelines for Biomedical research



SFUCHAS-REC Form-01

APPENDICES

Conflict of Interest and Confidentiality Agreement for Review Committee Members, and External Reviewers (REC -Form-01)

Conflict of interest

A conflict of interest is a conflict between a person's duties and responsibilities with regard to the review process, and that person's private, professional or public interests. There may be a real, perceived or potential conflict of interest when the review committee member or external reviewer:

- i. Would receive professional or personal benefit resulting from the funding opportunity or proposal being reviewed.
- ii. Has a professional or personal relationship with a candidate or the applicant institution
- iii. Has a direct or indirect financial interest in a funding opportunity or proposal being reviewed.
- iv. Are a relative or close friend, or have a personal relationship with the candidates.
- v. Are in a position to gain or lose financially/materially from the funding of the proposal.
- vi. Have had long-standing scientific or personal differences with the candidates.
- vii. Feel for any reason unable to provide an impartial review of the proposal.

The SFUCHAS-REC reserves the right to resolve areas of uncertainty and to determine if a conflict exists.

Disclosure and compliance measures

Any review committee member or external reviewer who becomes aware of a conflict of interest must promptly disclose the conflict to SFUCHAS-REC. No review committee member or external reviewer may participate in the review process of a proposal with which he/she is in conflict of interest. Such disclosures and compliance measures shall be documented and retained for the record.

Confidentiality

Documentation submitted to the SFUCHAS-REC by the applicant will be provided to the review committee members and/ external reviewers. The documentation may contain personal information and confidential commercial information. Candidates have the right of access to the information provided by review committee members and external reviewers about their proposals. Review committee members' names can be released at the discretion of the SFUCHAS-REC.

Review committee members and external reviewers must ensure that:

- i. All documentation and information that the SFUCHAS-REC entrusts to review committee members and external reviewers is maintained in strict confidence at all times.



SFUCHAS-REC Form-01

It must be used only for the purpose for which it was originally collected—namely, to review proposals.

- ii. Review documentation is stored in a secure manner to prevent unauthorized access. It must be transmitted using secure techniques and when it is no longer required, it must be destroyed in a secure manner. Any loss or theft of the documentation must be reported to the SFUCHAS-REC.
- iii. All enquiries received by review committee members and/external reviewers about a proposal or its review must be referred to the SFUCHAS-REC. Review committee members, or external reviewers must not contact the candidates for additional information or disclose matters arising from the review process to the candidates.
- iv. Review deliberations are confidential. Comments made by review committee members during the review of proposals and the conclusions of the committee’s review must never be discussed or disclosed with individuals not involved in the review process unless required by legislation or the courts.
- v. The identity of successful candidates must remain confidential until a decision is made by the SFUCHAS-REC and officially announced to the candidates.

Confirmation

By signing this form, I certify that I have read and understood the Conflict of interest and confidentiality agreement. I agree to comply with the requirements of the Conflict of interest and confidentiality requirements of the SFUCHAS-REC. I understand that any breach of this agreement will result in a review of the matter, with the SFUCHAS-REC reserving the right to take appropriate action including, but not limited to, my removal from serving on current or future SFUCHAS-REC review committees or from serving as an external reviewer. The use of review documentation for any other purpose could result in a SFUCHAS-REC investigation and/or report to the relevant authorities.

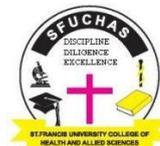
I agree to take personal responsibility for complying with these requirements.

Name:.....

Position:.....

Signature:.....

Date:



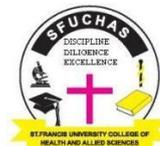
SFUCHAS-REC Form-02

Application Assessment Form (REC Form-02)

New protocols must be submitted to the SFUCHAS-REC at least two months before the study implementation, however, for studies which involve external collaborators, it should be three to four months. Any submission to SFUCHAS-REC must accompany with Application Assessment Form (REC Form-02). Must include copies of the following:

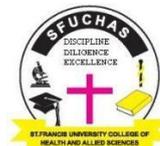
1. Filled SFUCHAS-REC Form-02
2. Signed cover letter from Investigator (should also include physical address, fax number telephone number preferred personal number and email address)
3. Protocol contents to include summary of the study, background, objectives, rationale, methodology, personnel, budget, justification, if applicable a statement of compensation for study participation (including expenses access to medical care) to be given to research participants and agreement statement to comply with ethical principles set out in relevant guidelines.
4. One hard copy and electronic form of the research protocol
5. Informed consent (in English and Swahili)
6. Instruments for data collection (e.g. questionnaires, topic guide etc)
7. Up to date CVs of PI and Co-Investigator (if applicable)
8. Investigator's brochure if it is a clinical trial
9. Importation approval by the Tanzania Food and Drug Authority if applicable (but may also be submitted at a later stage)
10. An adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, summary of the product's characteristics).
11. All materials to be used (including advertisements) for the recruitment of potential research participants must be attached to the protocol.
12. Budget

1.	Project title	
2.	Date of submission	
4.	Principal Investigator	Name:
		Email:
		Phone No.
		Fax No.
5.	Co-Investigator (s) (if applicable)	Name:



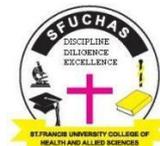
SFUCHAS-REC Form-02

		Email:
		Phone No.
		Fax No.
6	Types of Submission	<ul style="list-style-type: none"> a. New Protocol b. Feedback c. Amendment d. Extension e. Report
7.	Collaborating Institution (if applicable)	Name:
		Email:
		Phone No:
		Fax No:
8.	Has this protocol been approved by another Ethical Committee (EC)?	<i>(Circle appropriate)</i> <ul style="list-style-type: none"> a. Yes b. No If yes, name of the EC
9.	Has this protocol been previously disapproved by SFUCHAS-REC?	<i>(Circle appropriate)</i> <ul style="list-style-type: none"> a. Yes b. No If Yes, why?.....
10	Research Site/s	
11	Sponsor/funding agency	
12	Proposed population	<ul style="list-style-type: none"> a. Males/Females b. Adolescents (12-17yrs) of age



SFUCHAS-REC Form-02

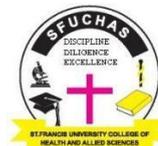
	(Circle all that apply)	<ul style="list-style-type: none"> c. Children d. Pregnant women e. Elderly f. Infants g. Other _____ (specify)
13	Is equipment available at this site to treat any life threatening adverse events? (Describe)	<p><i>(Circle appropriate)</i></p> <ul style="list-style-type: none"> c. Yes d. No <p>If no, what are the plans? </p>
14	Type of study (circle all that apply)	<p><i>(Circle appropriate)</i></p> <ul style="list-style-type: none"> a. Survey b. Case control c. Secondary data analysis d. Clinical trial e. Community based trial f. Longitudinal study g. Other _____ (Specify)
15	Informed Consent	<p><i>(Circle appropriate)</i></p> <ul style="list-style-type: none"> a. Written b. Oral c. English d. Local dialect e. Other
16	Do you consider this research	<p><i>(Circle appropriate)</i></p> <ul style="list-style-type: none"> a. Greater than minimal risk b. Minimal risk c. No risk <p>If (a) or (b) selected, indicate how are you going to manage</p>
18a	Type of study topic	<ul style="list-style-type: none"> a. Malaria b. HIV/AIDS c. Tuberculosis d. Reproductive Health e. Other
18b	If other topic, please specify.	



SFUCHAS-REC Form-02

20	Is the receipt of payment or invoice attached?	1. Yes 2.No
21	Did you undertake a short course in protecting human research participants (See a link below?) <i>(It is highly recommended to undertake a short course in protecting human research participants before submission http://phrp.nihtraining.com/users/login.php)</i>	1. Yes 2.No

¹Use additional A4 page where necessary

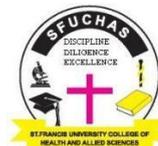


SFUCHAS-REC Form-03

Investigator's Check List Form (REC Form-03)

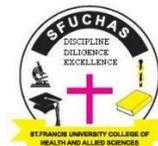
Review your submission according to Investigator Check List for Submitting Protocols so as to ensure your protocol submission is complete.

S/N	ITEM	DETAILS	YES	NO
1	Completely filled Application Assessment Form (REC -01)	The form should bear names and addresses of all PIs and investigators participating in the study (including Student investigators)		
		One PI has to be of Tanzanian nationality		
2	Cover Letter	Give brief explanation on aim of the study, study site, type of subjects to be recruited		
		Provide list of contents submitted with cover letter		
		Cover letter should be signed by PI		
3	Protocol	Should include summary of the study, background, objectives, rationale, methodology, personnel, budget, justification, if applicable a statement of compensation for study participants (including expenses access to medical care) to be given to research participants and agreement statement to comply with ethical principles set out in relevant guidelines		
		It has to include investigators brochure if it is a clinical trial		
		If applicable, an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure, published data, summary of the product's characteristics)		
		Study should recruit children or pregnant mothers or orphans only if the information researched can not be obtained from any other type of subject		
		If the study might impact any kind of emotional effect on subjects or others, PI has to state how that will be addressed		
		If applicable, importation approval by the Tanzania Food and Drug Authority (May be submitted at a later stage)		
		If applicable, all materials to be used (including		



SFUCHAS-REC Form-03

		advertisements) for the recruitment of potential research participants must be attached to the protocol		
		Briefly outline a plan for dissemination of results to the participants/community		
4	Informed Consent Form	Should be submitted in English and Kiswahili		
		Should bear logo of all institutions involved in the study		
		Should have title of study		
		Should contain information on aim of the study, type of participants needed and justification, as well as name/s of implementing institutions.		
		Should contain information about Risks to participants		
		Should contain information about Benefits to participants		
		Should contain information about role of participants		
		Should contain statement that participants may withdraw from study without any repercussions on the quality of health care subject was receiving		
		Should contain information on contact person incase of emergency (name, physical address and phone contact)		
		Space for participant signature		
		Space for participant thumb print (for participants who can read and write)		
		Space for participant witness (applicable for participants who make a thumb print)		
		Signature for person implementing the Informed Consent process		
		Should contain information of independent contact person from SFUCHAS-REC		
5	Instruments for Data Collection	Should be submitted in English and Kiswahili		
6	Material Transfer Agreement, MTA (if applicable)	If samples or data are going to be transferred to another institution, an MTA should be completed and signed (issued by NIMR)		



SFUCHAS-REC Form-03

7	Data Transfer Agreement (DTA)	If data are going to be transferred to another institution, DTA should be completed and signed (issued by NIMR)		
8	DSMB	If a study is a clinical trial DSMB should be signed and a copy of the charter should also be available; A local representation of DSMB members is mandatory. IEC/brochure materials should be part of the protocol		
9	Certificate of insurance	Clinical trial: A copy of insurance cover (including insurance policy) for participants should be submitted		
10	Budget	Budget should be reasonable and reflect activities in the protocol		
		Funding source should be named		
11	Amendments	All applications for changes should be submitted with a justification description		
12	CV	CVs of all participating investigators should be attached with the protocol submission		
13	Other ethical approvals	If there are any ethical approvals from elsewhere, copy of certificate should be attached		
15	Review fee	A copy of an invoice/receipt of payment should be attached		
16	It is highly recommended to undertake a short course in protecting human research participants before submission	http://phrp.nihtraining.com/users/login.php		

Submit your application to:

SFUCHAS-REC secretary

St. Francis University College of Health and Allied Sciences

P O Box 175, Ifakara

Email: sfuchas-rec@sfuchas.ac.tz



SFUCHAS-REC Form-04

Format and Content of an Informed Consent Document (REC Form-04)

The level of language and syntax used should be appropriate to the age, comprehension and reading level of the study population. The use of legalistic phrases, scientific and medical terminologies should be avoided. Volumes, weights as well as scientific measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls, or tablespoonfuls).

PROPOSED FORMAT OF A CONSENT FORM

Title of the Research Study:

Investigators: Provide the name and institutional affiliation of all investigators on the study.

Study location: Indicate where the study will be conducted:

Purpose of the Research: Briefly describe the purpose of the study.

Description of the Research:

The study you are about to participate in is (briefly describe the study). Should you agree to participate in the study, you will be asked to (summarize study procedures).

- i. Provide a brief description of the proposed research as it will be experienced by the research participants. Interventions or procedures that are part of standard care and those that are research must be distinguished.
- ii. If specific testing (e.g. HIV testing) will be done as part of the research, this must be explained.
- iii. If the study participant is receiving any therapy prior to enrollment in the study and this therapy will or may be altered or discontinued as a result of participation in the study, this must be explained.
- iv. If randomization or sequential assignment is planned, this must be explained.
- v. If blood will be drawn, the total volume (teaspoons and millilitre equivalents) must be indicated and a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection should be provided. If other specimens (e.g. urine, stool, saliva etc) will be collected, the study participants must be informed.
- vi. The frequency and duration of specific testing, as well as the duration of the entire study should be specified.
- vii. The study participants should be informed that any changes made to the study or should new information become available, he/she shall be so informed.



SFUCHAS-REC Form-04

- viii. Future use of the research data beyond the current study is anticipated, this should be clearly explained. If the research data/samples are to be destroyed after the study is complete, study participants must be informed of the plan.
- ix. If any tests will be done at other locations, the study participants must be informed of the location where the testing will be done and the purpose for the tests. This information must also be reflected in the body of the research protocol.
- x. If a questionnaire will be administered or interview conducted, a description of the questionnaire/interview, the length of time it will take to complete it must be provided; the participants must also be informed that they may choose not to answer any questions or withdraw at any time.
- xi. If data will be abstracted from medical records or from other confidential sources, this must be so described.
- xii. The study participants must be informed if a study involves videotaping, taking photographs or audio recordings.

Potential Harm, Injuries, Discomforts or Inconvenience, Risks:

- a. If there is no known or known harm/risk to the study participants, this should be clearly stated.
- b. If there is known or anticipated risk, this must be clearly enumerated.

Potential Benefits:

- a. If study participants will not benefit or might benefit directly from participation in the study, this should be stated and the potential benefits should be described.
- b. If the community in general or patients with a similar condition stands to benefit from the results of the study, this should also be explained.

Alternative Procedures or Treatments:

- a. If there is no treatment alternative, the alternative to participation in the study is non-treatment and this should be explained.
- b. If there is/are a treatment alternative(s), the alternative(s) should be identified and described.
- c. If the research is not about a treatment, this section may be omitted.

Confidentiality:

- a. No information that reveals the identity of any study participant should be released or published without consent.
- b. If access is required by a sponsor, SFUCHAS-REC or other health regulatory authorities for the purpose of monitoring the study, this must be explicitly stated.
- c. The plan for maintaining confidentiality of research records and materials must be clearly explained.

Reimbursement:



SFUCHAS-REC Form-04

- a. Study participants or their parents/guardians can be reimbursed for loss of wages, transportation expenses and for their time. Under no circumstances should payment be offered for harm or discomfort.
- b. Include specific information whenever study participants will receive an inducement.

Participation:

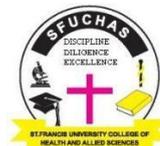
- a. If there are parts of the research study in which a study participant may choose not to participate, this should be clearly explained.
- b. Parents/guardians of study participants should be made aware that assent may be required from their child.
- c. All study participants must be given a copy of the signed and dated consent form to keep.
- d. The plan for referrals for further medical care or treatment should be explained, where applicable and clarify who will be responsible for the cost of such treatment.

Sponsorship:

In situations where a study may be terminated at the discretion of the investigator or the study sponsor even if the study participants are benefiting, there should be provision for discussing the next course of action with the study participants and/or procedures for orderly termination.

Contact:

For any questions or concerns about a study or in the event of a study-related injury, the contact person is the principal investigator and/or the principal investigator's representative who should provide his/her 24 -hour contact telephone number. The physical address must also be provided.

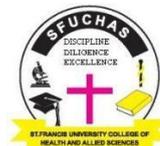


SFUCHAS-REC Form-05

Guidance on Research Participants' Rights (REC Form-05)

Each person who is asked to participate in a research study has a right to:

1. Be informed of the purpose of the research study.
2. Be informed of what will happen to them or their child during the course of a particular research study.
3. Be informed of any procedures, drugs or devices that are different from what would be used in standard clinical practice.
4. Be informed of the risks, side effects or discomforts of any procedure that will happen during the course of the research study.
5. Be told if they or their child can expect any benefit from participating, and if so, what the benefit might be.
6. Be told of the other choices available to them or their child and how the choice may be better or worse than what is currently being offered by the study.
7. Be allowed to ask any questions concerning the study both prior to agreeing to be involved in the research study and during the course of the research study.
8. Be told what sort of treatment is available should any complications arise during their participation in a study (clinical trial).
9. Be free from duress when considering whether the individual or their child wishes to participate in a research study.
10. Be free to refuse to participate at all in a research study or change their mind about their participation or their child's participation after the study has begun and that any decision made will not affect the care the individual or their child would receive if they were not in the research study.
11. Be given a copy of the signed and dated consent form to keep.



SFUCHAS-REC Form-06

Amendment Submission Form (REC Form-06)

Use this form to request approval for an amendment to an existing ethics approval provided by SFUCHAS-REC.

Note: Significant amendments to a project may require submission of a new Research Ethics Application.

SFUCHAS-REC reference no.			
Research title:			
Name			
Telephone		Email:	

Changes to Investigator List:

Additional researchers / co-investigators/students

Researcher	Title, given name, and family name	University/Institution	Email	Co-investigator/stud
1				
2				

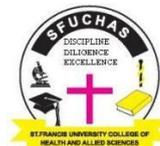
Researchers no longer work on this project

Researcher	Title, given name, and family name	University/Institution	Date no longer associated with projec
1			
2			

[Insert additional rows for additional investigators]

Summarize all changes to the research project:

Reasons for changes: Provide reasons why the changes are necessary.



SFUCHAS-REC Form-06

Impact on project documents: What changes will be required to existing project documents (e.g. information and consent forms, etc.)	
Potential impacts on participants: Indicate any potential inconveniences, discomforts, harms or risks to participants.	
Actions taken to manage risk: Indicate any additional actions or support that you need to provide as a result of the changes.	
Expected date of implementation:	

Please attach the following:

1. New or modified documents such as the Participant Information Form or Participant Consent Form.
2. Electronic copy of any other relevant documentation such as letter from governing authority.

Certification / signature

Principle Investigator or Supervisor of the Student:	<p>Declaration by the Principle Investigator</p> <p>I declare that the information in this form is accurate and complete.</p> <p>Signed: _____ Date: _____</p> <p>Name: _____</p>
---	---

Please note the following when submitting an amendment:

- Amendments that involve adding procedures that are not considered minimal risk must be referred to the Full Board for review and approval;
- Any changes to documents should be clearly explained and highlighted on the attached, revised document;
- Where the amendment is limited to an 'administrative change' (e.g. changes in granting status, staff personnel, contact person, etc.), please include an explicit statement to the effect that the research procedures (including recruitment, consent, etc.) have not been changed in any way; and
- Briefly explain the rationale behind any changes in the protocol.

Submit completed form & supporting documents to SFUCHAS-REC secretary:

SFUCHAS-REC secretary
 St. Francis University College of Health and Allied Sciences
 P O Box 175
 Ifakara
 Email: sfuchas-rec@sfuchas.ac.tz



SFUCHAS-REC Form-07

Adverse Event Reporting Form (REC Form-07)

Title of Proposal:

Principal Investigator(s)

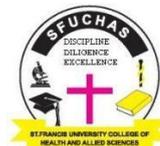
SFUCHAS-Ethical Approval Number:

1. PI's mailing address:
2. Date of Report:
3. Type of Report: Initial or Follow-up
4. Study participant information: Identification number, age, height, weight, etc.
5. Adverse event start date:
6. Adverse event stop date: or Ongoing
7. State the location of the event, if applicable:
8. Describe the adverse event: Describe the signs, symptoms, severity, time course, relevant medical history and laboratory data. Include results of confirmatory procedures, if any. Indicate any medication required to treat the event and the outcome.
9. Give a presumptive diagnosis.
10. Describe the investigational drug, medical treatment or procedure or device causing the event.
11. Describe the circumstances of the event, where applicable: Death (whether an autopsy was done), congenital abnormality, indicate whether it is life-threatening, if prolonged hospitalization is required, if persistent or significant disability occurred, if the study participant requires medical or surgical intervention to prevent other outcomes.
12. Describe the action taken:
13. Specify any simultaneous treatment.
14. State the relationship to the drug/participation in a project: not-related, possibly, probably, definitely, unlikely related to drug/participation and explain why.
15. State if the adverse event is described in the current approved informed consent/assent document.
16. State if the event requires a change or changes in the consent/assent documents and to the study procedures. State whether or not the enrolled study participants will be advised of the event. If yes, explain how this new information will be conveyed. If not, explain why.
17. Indicate whether the study sponsor and/or the DSMB have been notified.

Typed name

Signature of the PI

Date:



SFUCHAS-REC Form-08

Protocol Deviation or Violation Reporting Form (REC Form-08)

Title of Proposal:

Principal Investigator(s):

SFUCHAS-Ethical Approval Number:

1. Date of Deviation/Violation:
2. Study Participant number (where applicable):
3. Name of treating physician (where applicable):
4. Provide a description of the deviation/violation: State whether the study participants were adversely affected by the deviation/violation; whether the deviation/violation placed the Study participants at greater risk and whether the study participants were informed of the deviation/violation, where applicable.
5. Provide an explanation as to why the deviation/violation occurred.
6. Describe the measures taken to address the deviation/violation.
7. Describe the measures taken to preclude future recurrence of the deviation/violation.
8. Indicate whether the study sponsor has been notified.

Name

Signature of the PI

Date



SFUCHAS-REC Form-09

Evaluation Form for Continuing Approval/Review (REC Form-09)

Name of the Principal Investigator:

Title of proposal:

SFUCHAS-Ethical Approval Number:

1. Changes in principal and/or associate investigator(s)
2. Number and demographics of participants enrolled
3. Is there evidence of compliance with provisions of the approved research study? If yes, so state. If not, explain why.
4. Does the risk/benefit status of the research remain unaltered?
5. Does the consent document contain information that is up-to -date?
6. Achievements made in the reporting period:
 - a. Has significant progress been made? If yes, so state. If no, explain why
 - b. If research is completed, what is the outcome? Has the initial hypothesis or research question been substantiated by the findings?
7. Plans for the next twelve (12) months:
 - a. Are the proposed plans for the next twelve (12) months scientifically sound?
 - b. Are the proposed plans justified and achievable?
 - c. Is the proposed budget for the next twelve (12) months appropriate?
8. Suggestions, Comments or recommendations regarding the annual report or the proposed plan for the next study period:
9. Comments during meeting:



SFUCHAS-REC Form-10

Study Monitoring Visit Form (REC Form-10)

Checklist for a Study Monitoring Visit Form

Monitoring Visit DATE & TIME	PROTOCOL SFUCHAS-REC NO.	PI's Name
1	Subject Details:	
	Total Enrolled:	
	Nos. on-going:	
	Nos. completed:	
	Nos. dropout:	
2	Subject Interview (if planned):	
	Awareness of the study:	Y/N
	Awareness of the rights:	Y/N
	Satisfied with the process	Y/N
3	Appropriate Protocol facilities (as required by the protocol and regulations):	Y/N
4	Study protocol and related documents:	
	Use of recent (SFUCHAS-REC approved) version of protocol	Y/N
	Use of recent (SFUCHAS-REC approved) version of informed consent document	Y/N
	Informed consent process complete (including source documentation)	Y/N
	SAE reporting timely and complete (if any)	Y/N
5	Investigational product:	
	Logs up-to date	Y/N
	Safekeeping with controlled access and temperature maintenance	Y/N
6	Ethical concerns:	
	Grievance handling explained and the same documented	Y/N
	Subject/s remuneration done as due	Y/N



SFUCHAS-REC Form-10

7	Comments (if any):	
8	Corrective action by PI on the monitoring findings	Y/N

Report on Inspection of Clinical Trials by SFUCHAS-REC Members

Monitoring Visit DATE & TIME	PROTOCOL SFUCHAS- REC NO.	PI's Name

SUMMARY

Key Dates	Subject Enrollment Status	Latest Versions & Date	Key Team Members Name & Qualification, GCP training
Approval: Study Initiation: First-Subject Screened On:	Screened: Randomized: Withdrawn / Dropout: Ongoing:	Protocol: ICF:	Investigator: Sub-Investigator: Coordinator:

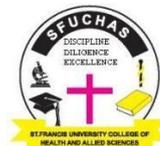
Documents Reviewed:

- Investigator's undertaking _____
- Signed Informed Consents: _____
- Source Documents: _____
- Monitoring/ auditing reports: _____
- Investigational Product use, storage & reconciliation records: _____
- Delegation of Responsibilities Log: _____
- Subject Enrolment Log (equitable distribution): _____
- Clinical trial Agreement, Indemnity & Insurance: _____
- Payments to Subjects: _____
- Investigator's File & Communications file: _____
- SFUCHAS-REC Protocol File: _____

II. FINDINGS:

III. SUGGESTIONS:

SFUCHAS-REC MEMBERS SIGNATURES:



SFUCHAS-REC Form-11

Annual/Study Report Form (REC Form-11)

Title of Proposal:

Principal Investigator(s):

SFUCHAS-Ethical Approval Number:

1. **Project start date:** **End date:**
2. **Project period covered:** Indicate the project period covered by the current report e.g. 28 February 2016 to 16 January 2017
3. **Research objectives:** Briefly describe the purpose of the study.
4. **Research progress summary:** Briefly describe the progress made during the reporting period, highlighting key findings and achievements during the period. Include the number of new study participants enrolled/recruited into the study, the number of study participants continuing participation and the number of new study participants expected to enroll or leave the study during this period and reasons for their departure. Summarize on-going activities.
5. **Amendments:** Indicate any amendment applications made to SFUCHAS-REC and approved during the reporting period e.g. changes in research site, increase in study sites, sample size, procedure, recruitment plan, investigators, start/end date, modification of informed consent documents, or any other deviation from the original, approved study or protocol violations etc.
6. **Adverse events reports:** If applicable, report any adverse events—expected or unexpected e.g. related to a drug or a product/procedure being tested that may have occurred during the reporting period, the proportion of the study participants involved, the severity and how the events were handled.
7. **Projects outputs:** State if there were any publications, abstracts, a product, patent applications, etc. during the reporting period, please list these and provide copies.
8. **Constraints:** State any constraints experienced during the reporting period, and whether or not they adversely affected project progress. Constraints may include lack of funding, transport, personnel, space etc.



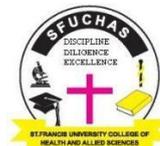
SFUCHAS-REC Form-11

9. If the research project is discontinued before the anticipated date of completion, researchers should inform the SFUCHAS-REC as soon as possible. They must also provide an explanation of the circumstances that led to the project being discontinued before the anticipated completion date.

10. **Any other relevant information:** Include any information that might be relevant to this report but not captured in the items listed e.g. if there has been new literature in the field that may or may not affect the conduct of the study or the risk/benefit status of the study. State whether or not a continuation approval is required for the project.

11. **Plans for the next project year:** State project activities planned for the coming year or continuing into the next year. Indicate if this is the last project year.

Attachment: Enclose one copy of the current approved study protocol and the current stamped and signed consent documents.



SFUCHAS-REC Form-12

Request or Complaint Record Form (REC Form-12)

Title of Proposal:

Principal Investigator(s):

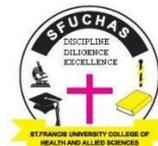
SFUCHAS-Ethical Approval Number:

1. Date of reporting:
2. Study Participant number (where applicable):
3. Provide a description of the request/complain:
4. Describe any or follow up taken to address the complaint after informing the PI:

Name

Signature of the Chairperson

Date



SFUCHAS-REC Form-13

Completion of the Study/Trial or Early Termination Report Form (REC Form 13)

Title of the Study/Project:

Principal Investigator(s):

SFUCHAS-REC Approval Number:

Tel:

Email:

Actual Start Date of Study (YYYY/MM/DD):

Expected Completion Date (YYYY/MM/DD):

Actual Completion Date (YYYY/MM/DD):

1	Did this study terminate prematurely?	Yes	No
2	Is a final report stating the research outcomes attached with this form?	Yes	No
	2a. If no, please specify when will this report be submitted?	DATE (YYYY/MM/DD):	
3	What is the reason for the early termination of the study?		
4	Are there any potential implications for research participants resulting from the termination? If yes, please describe the action planned to address these implications.		

Signature of Principal Investigator:

Date:



SFUCHAS-REC Form-13
