



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

(A Constituent College of St. Augustine University College of Tanzania)

GOVERNANCE STRUCTURE AND BY LAWS

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1. Governance and Administrative Structure

The SFUCHAS IRB is a standing committee instituted under the University's Directorate of Research, Partnerships and Community Services (DRPCS). Its establishment follows the National Institute for Medical Research (NIMR) requirement that institutions form their own research ethics committees. The IRB charter and bylaws are approved by SFUCHAS leadership (Provost/University Council), and the IRB reports administratively to the Provost through the DRPCS. An IRB Secretariat is maintained within the DRPCS office to provide logistical and clerical support. The IRB is empowered to make binding decisions on research ethics within SFUCHAS, subject to final institutional authority. The committee operates independently and free from undue influence, ensuring that it fulfills its mandate to protect research participants. SFUCHAS's annual reports note that "the SFUCHAS IRB, under the DRPC, reviewed over 574 research protocols in 2024/25," and that it holds regular (e.g. quarterly) meetings to discharge its duties.

2. Roles and Responsibilities of IRB Members

IRB members collectively safeguard the rights, safety and welfare of human research participants. Key responsibilities include:

2.1. Protocol Review

Thoroughly review submitted research protocols (including scientific merit, methodology and ethical issues) and consent materials to ensure compliance with ethical standards and regulatory requirements. Approve only those studies that meet the IRB's criteria; otherwise require modifications or disapprove protocols.

2.2 Informed Consent Oversight

Ensure informed consent processes meet national guidelines, protecting participant autonomy. IRB members verify that consent forms clearly describe the study, risks, benefits, confidentiality, voluntary nature, withdrawal rights, and contact persons for questions or injuries. The IRB may require investigators to assess participant understanding (e.g. comprehension checks).

2.3 Monitoring and Continuing Review

Oversee ongoing research. Members review progress reports, amendments and adverse event reports, and may conduct site visits to verify compliance. The IRB has the authority to suspend or terminate approved research if it is not conducted per IRB requirements or if serious harm occurs. All investigators must keep the IRB informed of protocol deviations or new information affecting participant welfare.

2.4 Documentation and Reporting

Maintain detailed minutes and records of all IRB activities. Ensure correspondence and decisions are communicated promptly to investigators (e.g. approval letters or reasons for disapproval are provided in writing within 14 days of review). Quarterly and annual IRB activity reports are submitted to NIMR.

2.5 Ethics Training and Education

Attend initial and ongoing training in research ethics. As per NIMR guidelines, each member must complete basic ethics training within one year of appointment and refresher training at least every two years. The IRB promotes research integrity campus-wide (e.g. by hosting seminars).

2.6 Leadership Roles

The IRB is led by a Chairperson (often a senior faculty member) who convenes meetings, sets agendas, and liaises with SFUCHAS administration. A Vice-Chair or Co-Chair may be appointed to assist. A Secretary or administrator (drawn from senior faculty/staff) manages the IRB's paperwork, meeting logistics and minutes. (SFUCHAS practice, for example, mirrors its research groups in having "a Chair and Secretary drawn from senior faculty" for the IRB.)

2.7 Professional Conduct

Members must act impartially and protect the confidentiality of protocols and deliberations. No member may exploit reviewed protocols for personal use or unduly burden investigators. The IRB collectively upholds the highest ethical principles (Respect for Persons, Beneficence, and Justice) in line with international norms.

3. Membership Criteria and Appointment Procedures

The IRB shall have a multidisciplinary membership meeting national standards. Composition includes:

3.1. Scientific/Technical Experts

Physicians, nurses, laboratory scientists, pharmacists or other health professionals with research expertise. At least one member should have substantive knowledge in clinical research and one in biomedical or social science. A statistician or epidemiologist may be included as needed.

3.2 Non-Scientific Members

Lawyers, ethicists, or other professionals to address legal and ethical dimensions. SFUCHAS may include faculty from law or theology if available.

3.3 Community/Lay Representatives

Individuals not employed by SFUCHAS (and not immediate family of employees) to represent community values and perspectives. At least one such external member is required. These members ensure lay concerns (cultural, moral) are considered.

3.5 Other Stakeholders

If research routinely involves vulnerable groups (e.g. children, prisoners, mentally impaired), the IRB will include or consult members with experience in those areas. External consultants with specific expertise may be co-opted on a case-by-case basis (non-voting).

3.6 Appointment Procedure

Members (including Chair) are appointed by the University principal. Appointment follows open calls or nominations, and is based on qualifications, experience and interest in research ethics. Each appointee serves a fixed term (three years), renewable once. Unexpired vacancies are filled by new appointments via the same process. SFUCHAS will maintain written bylaws detailing the composition, appointment, tenure and replacement process. Members should collectively represent diverse professional and community perspectives, as required in NIMR guidelines.

3.7 Terms of Membership

Terms are three years (renewable). To balance continuity and fresh insight, regular rotation is encouraged. Attendance is mandatory; the bylaws shall specify grounds for removal (e.g. absenteeism, conflict of interest, misconduct). Each new member must undergo orientation in SFUCHAS IRB procedures and Tanzanian ethics rules, and thereafter attend periodic ethics refresher sessions. The institution will ensure the IRB maintains a current roster of members, including their qualifications and affiliations.

3.8 Mandate and Authority

The IRB is authorized to:

- i. Review and approve research involving human participants
- ii. Require modifications before approval
- iii. Defer or disapprove protocols
- iv. Suspend or terminate ongoing research
- v. Monitor compliance
- vi. Report serious ethical breaches to University authorities and NIMR

3.2 Composition Requirements

The IRB shall:

- i. Consist of 7–15 voting members
- ii. Include at least:
 - One scientific member
 - One non-scientific member
 - One community (non-affiliated) member
- iii. Maintain gender balance
- iv. Include multidisciplinary expertise

External consultants may advise but do not vote.

4. Terms of Reference (Mandate, Scope, Meetings)

i. Mandate and Scope

The IRB's mandate is to review all research involving human subjects conducted by SFUCHAS faculty, students, or on SFUCHAS-sponsored projects. This includes biomedical, clinical, behavioral, educational, and public health studies. The IRB's scope covers initial review, continuing oversight, and final approval of study close-out. As per NIMR policy, the IRB's primary functions are to "maintain ethical standards of practice in research," "protect research participants...and preserve...rights and welfare," and "ensure adherence to the ethical conduct of approved research". All research protocols must receive IRB approval (or exemption) before any human contact or data collection begins.

ii. Meetings

The IRB meets at least quarterly (four times per year) and additionally as needed whenever sufficient protocols accumulate. The Chair, in consultation with the Secretary, sets the meeting calendar and agenda. Special meetings can be convened for urgent reviews. Per guidelines, the IRB "should hold meetings as frequently as possible" to ensure timely review.

iii. Quorum

A quorum consists of at least 50% of IRB members present, including at least one non-affiliated/lay member. If a quorum is not met, the meeting is rescheduled.

In very limited cases (e.g. minor matters or certain expedited reviews), a subcommittee or chair may act, but all decisions must be reported to the full IRB at the next convened meeting.

iv. Decision-Making

Decisions on research protocols are made by simple majority vote of members present. (For expedited reviews, the Chair or delegate may decide subject to confirmation later by the full IRB.) The IRB shall document decisions as "Approved," "Approved with Minor Modifications," "Requires Major Revisions," or "Disapproved." Any disapproval or requirement must be supported by written justification referencing ethical or scientific concerns. The IRB will issue written notice of its decision to the investigator within 14 days of the meeting, including any conditions or required changes.

v. Procedures

The IRB has the authority to review and approve protocols, require modifications, and monitor approved studies. It may invite attendance by the investigator or expert

consultants for clarification. The Chair has authority to act on certain low-risk protocols or minor amendments between meetings, provided all members receive the information and may challenge the decision at the next meeting. The IRB shall maintain and follow written Standard Operating Procedures (SOPs) for all review processes (see Annex I).

vi. Authority

In addition to approval decisions, the IRB may suspend or terminate the approval of research that deviates from the approved protocol or poses unforeseen serious risks. If a suspension/termination occurs, the IRB must document reasons and report the action promptly to the investigator, SFUCHAS officials, and the NIMR Director General. The IRB also has the power to investigate allegations of non-compliance or ethical misconduct in SFUCHAS research.

vii. Documentation

All IRB deliberations and records are maintained in the IRB office. This includes detailed SOPs, submitted protocols and amendments, consent forms, correspondence, and meeting minutes. Minutes summarize attendance, votes (for/against/abstain), decisions, and key discussion points. Records of continuing review and progress reports are retained. The institution ensures IRB records are stored securely and accessible to authorized representatives. All documents are archived for at least five years after study completion.

5. Reporting Structure and Accountability

5.1 Internal Reporting

The IRB is accountable to SFUCHAS leadership. The IRB Chair shall report regularly (at least annually) to the Principal and DRPCS on IRB activities, membership, and major decisions. Summaries of IRB activity (e.g. number of protocols reviewed, approvals granted, suspended studies) may be provided to the Academic Council or Research Committee. Any serious ethical issues (e.g. a finding of misconduct) are promptly reported to the University's Executive Committee.

5.2 External Reporting

The IRB submits quarterly and annual reports of its activities to the NIMR. These reports include statistics on protocols reviewed, approval outcomes, and any serious adverse events or suspensions. SFUCHAS's IRB operates under the oversight of the NIMR's National Health Research Ethics Committee (NatHREC).

5.3 External Permits and Approvals

The IRB ensures compliance with Tanzania’s research regulations. For studies involving foreign investigators or collaborators, the principal investigator must obtain a research permit from the Tanzania Commission for Science and Technology (COSTECH) **after** IRB approval. All clinical trials (drug or device studies) must be registered with and approved by the Tanzanian Medicines and Medical Devices Authority (TMDA) before commencement. The IRB will not approve research that lacks required national permits or regulatory clearances.

6. Conflict of Interest (COI) Policy

To preserve objectivity, all IRB members must avoid conflicts of interest.

A “conflict of interest” exists when a member has personal, financial, or professional interests that could affect impartiality on a protocol. Each member must complete the IRB Conflict of Interest Declaration Form annually and whenever a new interest arises. Members are required to disclose, for example, financial investments, employment, consultancies, or personal relationships related to SFUCHAS research activities. The IRB reviews disclosed interests and, if a potential conflict is identified, takes appropriate action to mitigate it.

Specifically, any member who has a conflict with respect to a research proposal must recuse themselves from the IRB’s initial and continuing review of that study. Such a member may not vote or influence the IRB’s decision on the protocol, except to answer questions if requested. The IRB’s COI policy (detailed in Annex II) ensures transparency and includes procedures for managing or eliminating conflicts. Receipt and review of COI disclosures are documented in the IRB records.

7. Ethical Review Process

7.1 Submission Requirements

Investigators submit a completed IRB application form with full study protocol, informed consent documents, and supporting materials. Submissions must address all elements required by NIMR (objectives, design, population, risk/benefit, consent process, investigator qualifications, data protection, etc.).

7.2 Initial Review

All proposals involving human subjects undergo ethical review before beginning research. The IRB uses two primary review pathways:

7.3 Full Board Review

Applied to studies with more than minimal risk or those not eligible for expedited review. The protocol is reviewed at a convened IRB meeting with full discussion. A face-to-face meeting of the IRB is held, minutes are taken, and a vote is taken on the study.

7.3 Expedited Review

For studies involving *no more than minimal risk* and fitting predefined categories (e.g. anonymous surveys, blood draws within minimal volumes, analysis of existing coded specimens, etc.), review may be expedited by the Chair or a designated subcommittee. The IRB will define its expedited criteria in SOPs, consistent with NIMR guidelines. Expedited decisions are reported at the next full meeting.

7.4 Accelerated (Fast-Track) Review

In special cases (e.g. certain drug trials), the IRB may conduct an accelerated review to expedite approval. This process allows designated reviewers to exercise full IRB authority, but the final decision still follows normal approval procedures. The IRB may, at its discretion, convert an accelerated review back to a full review if warranted by the protocol's complexity.

7.5 Exemptions

Some activities are exempt from full IRB review (though NOT exempt from ethical principles). Exemptions are narrowly defined and require IRB concurrence. For example, low-risk educational research or surveys of public officials in their official capacity may qualify for exemption. Investigators must request exemption, and the IRB will determine eligibility. All exempted studies are documented and reported

7.6 Continuing Review

Approved studies are subject to ongoing IRB oversight. At a minimum, the IRB re-evaluates each study at least annually (or more frequently for high-risk research). Investigators must submit periodic progress reports, including enrollment updates and safety data. The IRB reviews proposed amendments (changes in protocol or consent) and requires review/approval **before** implementation. Any new findings or safety

information are reviewed to determine their impact on the study's risk. The IRB has the authority to suspend the consent process or study conduct if necessary.

7.7 Decision Notification

After review, the IRB Chair (or Secretary) communicates the outcome to the investigator in writing. Approval letters specify any conditions or modifications. If the IRB disapproves a study, the written notice must include the reasons for disapproval. Investigators may appeal IRB decisions through the established university procedure.

7.8 Monitoring and Compliance

The IRB and SFUCHAS officials jointly ensure compliance. Investigators must report any protocol deviations, serious adverse events or unexpected problems to the IRB promptly. The IRB may perform audits or require monitoring visits for cause. Non-compliance or ethical violations are taken seriously: the IRB will recommend corrective actions or disciplinary measures, possibly in coordination with NIMR or TMDA.

9. SFUCHAS IRB-ORGANOGRAM

The SFUCHAS –IRB Organogram follows the following chain of command (Fig. 1).

The organogram shows a clear top-down administrative hierarchy. At the top is the Principal, followed by DP-ARC, then the Director-RPCS. Below them is the IRB Chairperson/Vice Chairperson, who oversees the IRB Secretariat, led by the IRB General Secretary. At the operational level, the structure branches into administrative, research scientists, other secretariat staff and voting members, indicating both management and decision-making functions within SFUCHAS- IRB system.

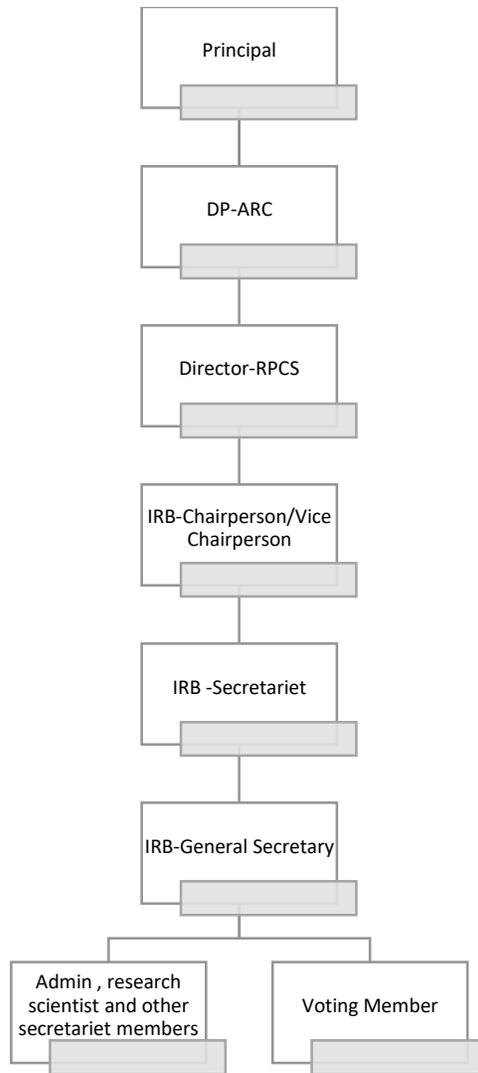


Figure 1. SFUCHAS IRB-Organogram

REFERENCE

- i. The National Institute for Medical Research Act, Cap 59 R.E. 2002
- ii. NIMR Guidelines on Ethics for Health Research in Tanzania, 3rd Edition (2023)
- iii. Medical Research Coordinating Committee (MRCC) Directives
- iv. The Personal Data Protection Act, 2022 (United Republic of Tanzania)
- v. Tanzania Health Research Regulations
- vi. Research Permit Requirements of the Tanzania Commission for Science and Technology (COSTECH)
- vii. Clinical trial regulatory requirements of the Tanzania Medicines and Medical Devices Authority (TMDA)
- viii. World Medical Association, Declaration of Helsinki
- ix. CIOMS International Ethical Guidelines for Health-Related Research Involving Humans ICH-GCP (E6 R2) Guidelines
- x. UNESCO Universal Declaration on Bioethics and Human Rights