

TMRCC's Ethical Guidelines

The Medical Research Coordinating Committee (MRCC)

As one of the Council Committees, the MRCC is a **National Regulatory Body** responsible for the supervision of health research in Tanzania. It is clearances body with different terms of reference amongst which are to review and evaluate the science, medical aspects and ethics of research proposals and hence recommend for clearance of research protocols.

The Committee:

1. Meets once every quarter
2. Examines research carried out within NIMR
3. Approves health research to be carried out in Tanzania
4. Follows up and monitors health research carried out in Tanzania
5. Monitors adherence by health researchers on standard operating procedures (SOPs)
6. Approves for material transfer agreement for research sample collectors
7. Receives and approves NIMR quarterly reports

Composition

1. Director General NIMR, Chairman
2. Director, Research Coordination and Promotion, NIMR, Secretary
3. Director General, COSTECH, Member
4. Medical Association of Tanzania Member
5. Muhimbili University College of Health Science, Member
6. Director, Preventive Services (MoHSW), Member
7. Head, Health Systems Research Unit (MoH) Member
8. University of Dar-es-salaam, Member

National Health Research Ethics Review Sub-Committee

This is an organ of MRCC, which meets every month. It operates within specified Standard Operating Procedures. It focuses more on ethical issues on the submitted research proposals.

Composition

1. National Institute for Medical Research (NIMR)
2. Commission for Science and Technology (COSTECH)
3. Muhimbili University College of Health Sciences (MUCHS)
4. Christian Social Services Commission (CSSC)
5. The Muslim Council of Tanzania (BAKWATA)
6. Economic and Social Research Foundation (ESRF)
7. Tanzania Gender Networking Programme (TGNP)
8. Legal and Human Rights Centre (LHRC)
9. University of Dar-es-salaam (UDSM)
10. Ministry of Health (MoH)
11. Ministry of Education (MoE)

Guidelines on the Research proposal format

The proposal should have the following:

1. Summary
2. Introduction and Literature review
3. Statement of the problem
4. Rationale
5. Objectives
6. Methodology, to include data collection instruments
7. Personnel, CVs
8. Budget and Budget justification
9. Ethical consideration: (Obtaining verbal/ written informed consent: Obligations of investigators and sponsors, benefits and risks of study participation, recruitment, cultural values, and confidentiality measures)
10. Limitations of the study
11. Dissemination of research results
12. Institutional ethical clearance, if any

Review Process

- Proposals are received and registered
- Each proposal is sent to three identified reviewers
- Status of the review process is communicated monthly to Sub Committee meetings
- Received comments are sent to Principal Investigators for revision of their proposals and to resubmitted within a month
- Resubmitted proposals are resent to reviewers for recommendations
- Approved proposals are recommended to MRCC for ethical clearance
- Investigators who do not respond within three months are removed from the register.

Key areas examined

- Scientific validity
- Ethical content
- Capability of the Investigators
- Data ownership and material transfer issues
- Budget issues and justification
- Local contact institution

Ethical Clearance Application Procedure

For each research proposal, an application should be sent with a covering letter.

The following are required

- Four copies of the research proposal
- Ethical clearance fee
 1. Foreign Researchers, USD 300 per proposal
 2. Researchers from Tanzania institutions or local collaborators USD 100 per proposal.
 3. Tanzanian students USD 100 per proposal.

Clearance Process

- Clearance certificates are issued signed by the Chairman of MRCC (Director General, NIMR) and the Chief Medical Officer, Ministry of Health.
- The whole process of receiving, reviewing and approving the proposals takes 4-6 weeks depending on the communication of responses from both the Principal Investigator and the and reviewers.

Clearance Certificates

The certificates state clearly roles and responsibilities of Principal Investigators, which have to strictly adhere to. Moreover, it is stipulated in the certificate that:

- PI's have to provide progress reports after each six months and final reports to NIMR and the Ministry of health, Regional and District Medical Officers where the study has been carried on.
- Get a permission to publish from NIMR and
- Copies of final publications are made available to NIMR and the Ministry of Health
- Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine.

Contacts for sending your proposal application (s)

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