NATIONAL INSTITUTE FOR MEDICAL RESEARCH

NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

THE ETHICS CLEARANCE PROCESS

CLIENT SERVICE CHARTER

APRIL 2023

DOCUMENT CONTROL

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TABLE OF CONTENT

ACRONYMS

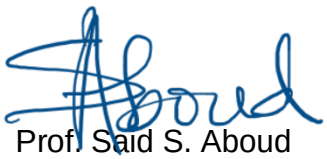
CDC	U.S. Centers for Disease Control and Prevention
COSTECH	The Tanzania Commission for Science and Technology
CSC	Client Service Charter
DSTAs	Data Sharing and Transfer Agreements
ICF	Informed Consent Form
IRBs	Institutional Review Boards
IREC	Institutional Research Ethics Committee
MRCC	Medical Research Coordinating Committee
MTA	Material Transfer Agreement
NatHREC	National Health Research Ethical Committee
NGOs	Non-Governmental Organizations
NIMR	National Institute for Medical Research
PI	Principal Investigator
REIMS	Research Ethics Information Management System
SAEs	Serious Adverse Events
SOPs	Standard Operating Procedures
SUSARS	Suspected Unexpected Serious Adverse Reaction
TZS	Tanzanian Shillings

PREFACE

The National Health Research Ethics Committee (NatHREC) was established in 2002 as a sub-Committee of the National Medical Research Coordinating Committee (MRCC). The main function of NatHREC is to oversee the ethics clearance process and to ensure ethical standards are met for the conduct of scientifically sound and ethically acceptable health research in Tanzania. As the technical arm and a sub-committee of the MRCC under the National Institute for Medical Research (NIMR), it is the clearinghouse of all health research protocols to be conducted in Tanzania.

NIMR envisions good research conduct and the importance of its research clients accessing the right and sufficient information needed for this to be achieved. On this basis, NIMR is pleased to serve its clients better to maximise their satisfaction as it may allow. Therefore, readers of the present document will likely find the most useful information they need. This document targets reviewers, applicants/investigators of the respective protocols and IRECs/IRBs. Besides its distinguished expertise at NatHREC, NIMR has put mechanisms to solicit and recruit expert reviewers from different disciplines in the field of health research.

NIMR wishes to unite its clients by allowing them to have common knowledge and understanding of what is needed or what should be done pursuant to undertaking appropriate and quality health research in Tanzania. NIMR greatly thanks all its partner institutions and stakeholders for their invaluable contributions and collaboration in developing this Client Service Charter. This document will be reviewed every five years but can be revised at any time should the need arise.



Prof. Said S. Aboud
DIRECTOR GENERAL

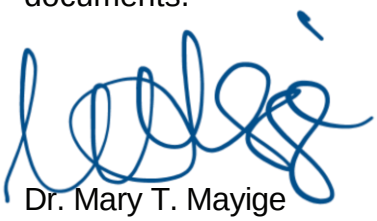
ACKNOWLEDGEMENTS

The Client Service Charter is aimed at shedding light to readers and users of all the guidelines and other documents prepared to inform individuals or teams wishing to undertake health research in Tanzania. It has been prepared in cognisance of all stakeholders' right to know the key elements and aspects needed to be considered while writing their research intentions/protocols before their submission to NatHREC and even after their protocols have been approved by the MRCC for actual implementation in the field.

The preparation of this Charter was done through the cooperation of representatives from different research and academic institutions as well as non-governmental organisations also dealing with health research. To mention but not all, inputs from NIMR, Muhimbili University of Health and Allied Sciences (MUHAS), Hubert Kairuki Memorial University (HKMU), Kilimanjaro Clinical Research Institute (KCRI), Catholic University of Health and Allied Sciences (CUHAS), Ifakara Health Institute (IHI), Management and Development for Health (MDH), Commission for Science and Technology (COSTECH), Christian Council of Tanzania (CCT), and Tanzania Muslims Council (BAKWATA) have been of a great value towards the development of this Charter.

NIMR is indebted to the scientific community and the general public members in Tanzania and beyond who have continuously been giving feedback through the existing communication channels.

Lastly, NIMR highly appreciates the financial support from the US Presidential Emergency Plan for AIDS Relief (PEPFAR) through the CDC. The support was timely received, contributing to the timely production of the present Charter and its associated documents.



Dr. Mary T. Mayige

DIRECTOR OF RESEARCH INFORMATION AND REGULATORY AFFAIRS

1. INTRODUCTION

The National Institute for Medical Research (NIMR), a parastatal organisation under the Ministry of Health (MoH), was established by Parliament Act No. 23 of 1979 (Cap. 59, R. E. 2002) and became operational in 1980. The Act gives NIMR dual mandates as a health research institution and national regulatory authority of health research undertaken within Tanzania.

NIMR fulfils its regulatory roles through two principal committees, namely, the Medical Research Coordinating Committee (MRCC) and the National Health Research Ethics Committee (NatHREC). The Medical Research Coordinating Committee (MRCC) is Tanzania's national health research coordinating and regulatory body for health research. The MRCC is a NIMR Council Committee.

Established in 2002 and under delegation by the Medical Research Coordinating Committee (MRCC) of NIMR, the National Health Research Ethics Committee (NatHREC) registers, reviews, recommends for approval and monitors all health research carried out in Tanzania on behalf of MRCC. NatHREC's role is to ensure that health research protocols are scientifically and ethically sound. Hence, protocols are reviewed to safeguard the dignity, rights, safety and well-being of research participants. The Committee oversees the research conducted through continued reviews and all health research data and material transfers issues. Institutional and Zonal Research Ethics Committees complement NatHREC's function of issuing institutional ethics clearance certificates and monitoring the approved research at their institutions. In addition, it is the responsibility of NatHREC to carry out research monitoring through active site visits in collaboration with district and regional medical authorities for approved ongoing and completed studies.

2. INSTITUTIONAL VISION AND MISSION

The Institute pursues the following Vision, Mission and Core values, which define its strategic direction:

i. Vision: To be a leading institution for advancement of high-quality health research and innovations.
ii. Mission: To conduct, regulate, coordinate, and promote health research that is responsive to the needs and well-being of Tanzanians.

iii. Core Values:

- Integrity: We uphold high ethical and moral standards in our conduct reflected by honesty, sincerity, truthfulness, and confidentiality in executing our duties.
- Inclusiveness: We embrace broad participation, teamwork and partnerships so as to harness multiple complementarities, skills and experiences in discharging our research work objectives.
- Excellence: We seek to execute our duties professionally, creatively, innovatively, and continuously striving to improve organisational performance.
- Accountability: We are collectively and individually accountable in discharging our responsibilities.
- Transparency: We conduct our activities with openness.

3. PURPOSE OF THE CHARTER

A client service charter is a document that outlines a service provider's commitment to its clients in terms of the quality and standard of service it offers. It typically includes information on the services offered, the expected level of service quality, and the procedures for making complaints and providing feedback. The Client Service Charter illustrates the commitment of the Institute to health research clients to promote and enhance the conduct of ethical health research by ensuring that health research conducted in Tanzania meets ethical principles and guidelines.

NIMR hosts the NatHREC Secretariat and coordinates the functions of the Committee. This document describes services that are offered by NIMR and its staff on behalf of NatHREC.

4. TYPES OF CLIENTS

Our client includes researchers, research institutions, and other stakeholders involved in health research in Tanzania. These include but are not limited to the following:

i. Researchers
ii. Academicians
iii. Government Regulatory Bodies and Agencies
iv. International and Local Non-Governmental Organizations (NGOs)
v. International and local Institutional Review Boards
vi. Research participants

vii. Local and international students
viii. Health facilities
ix. Business groups, including pharmaceutical industries
x. Health research stakeholders
xi. The community at large

5. SERVICES OFFERED

The overall service is to provide ethical review and clearance of health research protocols and monitor and evaluate research studies. The ethical clearance process follows a rigorous ethical clearance process, which involves the submission of research proposals, review by the NatHREC, and communicating the decision to the researcher. Services are further described as follows:

i. Receiving and registering all health research carried out in Tanzania;
ii. Ensuring that all health research protocols are thoroughly reviewed to safeguard the dignity, rights, safety and well-being of research participants;
iii. Advising researchers on the risks and responsibilities of conducting research;
iv. Recommending to the MRCC for ethics clearance approval, all health research protocols that have complied with the country's ethics regulations and guidelines;
v. Monitoring and coordinating all approved health research conducted in Tanzania;
vi. Advocating for and overseeing all issues pertaining to health research data and material sharing and/or transfer;
vii. Support health research institutions in Tanzania to establish Institutional Ethics Review Committees (IRECs) or Institutional Review Boards (IRBs); and,
viii. Accrediting Health Research Institutions' Research Ethics Committees/Institutional Review Boards (IRECs/IRBs).

6. SERVICE STANDARDS

NatHREC is committed to providing ethical review and clearance of health research protocols in a timely and efficient manner while maintaining high ethical standards. NIMR commits to providing quality services to clients, which will fulfil this by meeting the service standards as shown in the table below:

TABLE 1: SERVICES AND STANDARD OF DELIVERY

S/N	TYPE OF SERVICE	STANDARDS OF SERVICE DELIVERY
	TIMELINES FOR REVIEWING PROTOCOLS AND GRANTING ETHICS CLEARANCE	
1.	Ordinary review	Six (6) to eight (8) weeks from the date of receiving a complete application
2.	Expedited and accelerated review	Four (4) weeks from the date of receiving a complete application
	VALIDATION OF PROTOCOLS	
1.	Validation for new protocols	Maximum of two (2) working days
2.	Validation of protocol amendments	Maximum of two (2) working days
3.	Validation of protocols requesting extensions	One (1) working day
	REVIEW OF PROTOCOLS FOR ETHICS CLEARANCE	
1.	Assignment of reviewers	Two (2) working days after validation
2.	Ordinary review of protocol	Fourteen (14) working days from the date the protocol was sent to reviewers
3.	Expedited review of protocol and student protocols	Seven (7) working days from the date the protocol was sent to reviewers
4.	Accelerated review of clinical trials	Seven (7) working days from the date the protocol was sent to the reviewers
5.	Feedback to the applicants/PIs	Two (2) days after all reviewers have submitted review comments
6.	Notifications of the ethics review stage reached	Continuous, through the Research Ethics Information Management System (REIMS) until a final decision on the protocol is made
	ISSUANCE OF ETHICS CLEARANCE CERTIFICATES	
1.	Preparation of ethics clearance certificate	Five (5) working days after MRCC approval of the research protocol
2.	Rejected protocols	The PI is informed within three (3) working days after the meeting
3.	Research extension/renewal certificates	Ten (10) working days of receiving a complete application
	POST-APPROVAL PROCESSES	

1.	Permission to publish	Ten (10) working days of receiving complete request documents
2.	Material Transfer and Data Sharing and Transfer Agreements	i. Queries related to submitted MTAs and DSTAs will be communicated within two (2) working days after receipt of the application ii. Approvals for duly filled MTAs/DSTAs will be processed within fourteen (14) working days
	ACKNOWLEDGEMENT OF REPORTS AND NOTIFICATIONS	
1.	Acknowledgement of receipt of Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSARS)	i. Email acknowledgement within two (2) working days ii. Letters of acknowledgement will be sent within five (5) working days of receipt of the notification
2.	Notifications by email of safety reports, sponsor communication etc.	i. Email acknowledgement within two (2) working days ii. Letters of acknowledgement will be sent within five (5) working days of receipt of the notification
3.	Providing feedback after evaluation of SAE and SUSAR reports	Within thirty (30) days of receipt of the notification
4.	Progress reports	i. Acknowledgment of receipt is immediate through REIMS. ii. Any feedback will be given within thirty (30) days of receipt of the report.
	COMMUNICATION, COMPLAINTS AND FEEDBACK STANDARDS	
1.	Telephone	i. We are accessible by telephone from 8:00 am to 4.00 pm East African Time (EAT) during workdays. ii. Clients' calls are responded to within four (4) rings.
2.	In person	i. Clients are received from 8:00 am to 3.00 pm on workdays. ii. We attend to clients within ten (10) minutes.
3.	Correspondences (Email, Letters, e-mrejesho etc.)	i. We acknowledge and respond to e-mail and e-mrejesho inquiries within one (1) working day of receipt. ii. Letters are responded to within three (3) days of receipt.

4.	Whistleblowing, complaints, concerns or suggestions	i. Acknowledgement is two (2) days after receipt of information. ii. Immediate feedback is provided within five (5) days for complaints, concerns or suggestions. iii. Feedback to whistle-blowers is provided within twenty (20) days after receiving information.

7. INSTITUTIONAL RESPONSIBILITY TO CLIENTS

NIMR is committed to ensuring that all health research conducted in Tanzania meets ethical principles and guidelines and providing excellent service to its clients. We undertake to:

i. Monitor our performances against the standards set out in this Charter and publish the results in Annual Reports and other publications that are available upon request from our Office.
ii. Periodically provide information on our performance through the NIMR website.
iii. Being open to feedback on our performance. The suggestions for improvement from our clients and the public help us to adjust our programs and services, where necessary, based on the information received.
iv. Publish information showing levels of satisfaction with our services, including complaints received and the resolution of those complaints.
v. Provide explanations when our services do not meet acceptable standards of quality, timeliness or accuracy.
vi. Formally review the standards set out in this Charter once a year and make modifications where appropriate in light of clients' comments and in response to ongoing changes.
vii. Independently review our Charter at least every five years or as needed by inviting comments from clients, stakeholders and staff as part of the monitoring and review process.

8. CLIENT RIGHTS

NIMR strives to guarantee its clients of high-quality service by having a well-trained staff and a supportive Secretariat that maintains an open and accountable culture that is fair and reasonable in dealing with clients. In addition, quality services are guaranteed by:

i. Seeking to understand your needs and to identify what services are important to you.
ii. Recognizing that our clients have different needs and personalising our services and advice in ways that fit those needs.
iii. Treating our clients respectfully and courteously and maintaining confidentiality whenever required.
iv. Providing clean and comfortable areas for our clients.
v. Giving clear, accurate, timely and relevant information and/or guiding our clients to find it.
vi. Providing a solution to all troubleshooting issues encountered during the submission or review of protocols.
vii. Being clear and helpful in all dealings with clients, giving reasons for all decisions made.
viii. Respecting the confidentiality of personal information and using it only in accordance with the law.
ix. Acting with care and diligence when preparing a response and conducting ourselves honestly and integrity.
x. Presenting responses to inquiries or letters clearly and concisely, using formally acceptable language(s) in English or Kiswahili in understandable graphics or other means relevant to the community's needs.

9. RESPONSIBILITIES OF THE CLIENTS

Researchers can help NIMR and NatHREC by submitting complete and accurate research proposals, adhering to ethical guidelines, and providing timely responses to committee requests. The clients have the following responsibilities:

i. To treat NIMR staff and NatHREC members with courtesy.
ii. To attend scheduled appointments punctually.
iii. To respond to requests for information accurately, thoroughly and in a timely manner.
iv. To abide by any legal requirements and other obligations that clients are to meet in order to be eligible for the services sought.

v. To pay required ethical clearance fees timely and provide valid evidence of payment.
vi. To provide updates on changes in approved research promptly.
vii. PIs to provide progress reports of approved protocols every six (6) months.
viii. PIs to apply for a renewal/extension two (2) months before the end of the certificate validity for ordinary protocols and three (3) months for clinical trials.
ix. PIs to respond to comments timely and resubmit the protocol within shortest time possible. A maximum response time for ordinary protocols is within four (4) weeks and twelve (12) weeks for clinical trials; beyond the stated timelines, the protocol will be retracted from the system (REIMS) and the PI will need to re-apply Requests for an extension of a date for resubmission will be dealt with on a case-to-case basis.

10. CLIENTS' FEEDBACK ON SERVICE DELIVERY

NIMR welcomes views or comments which are vital for monitoring and improving the relevance and quality of the services delivered to meet its client's needs. Accordingly, the Institute requests our clients to:

i. To help us give you the best possible services, we welcome suggestions for improvement to address any difficulties you are experiencing.
ii. Anyone with a suggestion is free to contact us. We consider all suggestions fully and promptly in our planning for service improvement.
iii. Inform or alert us as soon as possible when your expectations are not met. We will investigate your complaints and tell you what we have done about it.
iv. To present complaints with clear details, carrying relevant facts, and identifying yourself and the dates when you make a complaint so that we serve precisely.

11. SUBMISSION AND HANDLING OF COMPLAINTS, CONCERNS AND WHISTLEBLOWING

The client service charter includes guidance on how client complaints will be handled. The complaints will be handled through an open and transparent system that prioritises client satisfaction. The following procedures are in place for reporting:

i. Complaints will be received and documented through various channels, including phone calls, suggestion boxes, email, and the government E-Mrejesho system at https://emrejesho.gov.go.tz/. E-Mrejesho is a centralised government web-based system for submission and processing complaints, suggestions,

inquiries and compliments. Within the E-Mrejesho system, click on the “Afya” tab, then click on “NIMR” to lodge your complaint.

ii. NIMR has a whistleblowing policy that is shared upon request and available on the NIMR website.

iii. At NIMR, after receiving a complaint, the client service team will acknowledge it and document the details. To ensure transparency, the client service team will document all complaints and resolutions in a complaint register. The team will investigate the complaint and take appropriate action to resolve the issue. The client will be informed of the progress and the outcome of the complaint.

iv. Complaints may be lodged directly through submission to the office, postal address, telephone, suggestion box, fax, or e-mail by contacting the following:

The Director General,
National Institute for Medical Research,
3 Barack Obama Drive,
P.O. Box 9653,
Dar es Salaam, Tanzania.
Telephone (Landline): (+255) 022 2121400 – Available 0800 -1600 hrs
Dar es Salaam. Fax :(+255) 022 2121360
Mobile: +255 754 301 692 (Chairman of MRCC)
E-mail: dg_office@nimr.or.tz, said.aboud@nimr.or.tz, ethics@nimr.or.tz

v. The client service team will continuously review the system in place and endeavour to apply best practices to the complaint-handling process.

12. BUSINESS HOURS

We are open from 0800hrs to 1600hrs East African Time (EAT) from Monday to Friday, except on public holidays.

13. MONITORING, EVALUATION AND REPORTING OF THE PERFORMANCE AGAINST STANDARDS

i. Monitoring and evaluation of the client service charter is crucial to ensure that the institute delivers the promised level of service to its clients. It helps to identify gaps in service delivery, track progress over time, and make data-driven decisions to improve the quality of service.

ii. Monitoring and evaluation of the client service charter is essential to ensure that the Institute is meeting the needs of its clients and delivering quality service. In addition, it helps to build trust and confidence in the Institute and improves client satisfaction.

iii. The monitoring and evaluation process will include the following:

a. Establish Key Performance Indicators (KPIs): KPIs should be developed to measure the Institute's performance against the standards set in the client service charter.

b. Data Collection: Data should be collected regularly to measure the KPIs. Data collection will be reliable and consistent to ensure accurate and valid data.

c. Data Analysis: The data collected will be analysed to identify trends, patterns, and areas of improvement. The analysis will also identify areas where the Institute is performing well and areas that need improvement.

d. Reporting: Regular reports will be produced to communicate the performance of the Institute against the client service charter. The reports should be easily accessible and transparent to clients.

e. Continuous Improvement: Based on the findings of the monitoring and evaluation process, the Institute will develop a continuous improvement plan to address gaps in service delivery and improve the overall quality of service.

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