National Health Research Ethics Committee

CLIENT SERVICE CHARTER
Aprill, 2014
### ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CSC</td>
<td>Client Service Charter</td>
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<tr>
<td>COSTECH</td>
<td>The Tanzania Commission for Science and Technology</td>
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<tr>
<td>DTAs</td>
<td>Data Transfer Agreements</td>
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<tr>
<td>ICF</td>
<td>Informed Consent Form</td>
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<td>IRBs</td>
<td>Institutional Review Boards</td>
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<tr>
<td>IREC</td>
<td>Institutional Ethics Review Committee</td>
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<td>MRCC</td>
<td>Medical Research Coordinating Committee</td>
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<td>MSH</td>
<td>Management Sciences for Health</td>
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<td>MTAs</td>
<td>Material Transfer Agreements</td>
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<td>NatHREC</td>
<td>National Health Research Ethical Committee</td>
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<td>NIMR</td>
<td>National Institute for Medical Research</td>
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<tr>
<td>NGOs</td>
<td>Non-Governmental Organizations</td>
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<tr>
<td>TZ-ICB</td>
<td>Tanzania Institutional Capacity Building Project</td>
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<tr>
<td>TZS</td>
<td>Tanzanian Shillings</td>
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<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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Ensuring and guaranteeing the rights, dignity, safety and protection of all individuals and communities participating in health research activities is the core function of the National Health Research Ethical Committee (NatHREC). The Committee, through the Medical Research Coordinating Committee (MRCC) is similarly committed to ensuring scientific merits of the health researches and protecting the rights of the researchers in order to conduct researches that will provide evidence-based information that is responsive to the needs of human wellbeing.

The Service Charter defines who we are, what we do and who our clients. It is an expression of our commitment to offer services of international standards to clients such that scientifically and ethically sound, and high quality health researchers are undertaken in Tanzania.

The Charter outlines the core values that guide our core functions. Most importantly, this milestone document stipulates our obligation to our clients and their rights to quality services, accountability and transparency. The Charter laydown approaches for ensuring clients satisfaction and feedback.

NatHREC is reviewing health research proposals from national and international researchers countrywide, we pledge to be guided by the standard of this Charter to ensure NatHREC performance to the valued clients is prime. This Charter serves as our benchmark toward attaining our mission.

Mwelecele N. Malecela, PhD

CHAIR, MEDICAL RESEARCH COORDINATING COMMITTEE
FOREWORD

Since establishment in 2002, the National Health Research Ethics Committee (NatHREC) has endeavored to raise the ethical standards of the conduct of health research in Tanzania. Being the right arm of the Medical Research Coordinating Committee (MRCC), as one of the three functional Council Committees’ of the National Institute for Medical Research (NIMR), NatHREC is the clearinghouse for all health research to be undertaken in Tanzania.

Having served for over 10 years, the Committee has set up Tanzania’s ethical guidelines and regulations, and has sensitized other health research institutions capable of hosting and conducting health research to establish institutional or zonal ethical review boards to complement the national committee’s efforts. The Country’s ethical review framework has the National Committee and Institutional Review boards (IRBs). NatHREC as a national has written and set the Standard Operating Procedures (SOPs) for these Institutional review boards to operate emulating the National Committee example.

Through the years, NatHREC has realized the importance of its clients and the information that is often needed in the conduct of health research that meets International ethical standards. It is with great pleasure and commitment to our clients, we are establishing the NatHREC’s Clients Charter. In the document you will find most information you need in order to get us serve you better. We have developed this document with keen interest and provided the details from our experience in the review process and the researchers requirements.

We want to thank our partner institutions and stakeholders for their valuable contributions and collaboration without which this charter would not have reached this far. We trust this is the first issue, and believes it will need to change from time to time. We welcome your input anytime, because in this noble service you are our valuable customer.

Julius J Massaga, PhD

SECRETARY, MEDICAL RESEARCH COORDINATING COMMITTEE
ACKNOWLEDGEMENT

Technical assistance for development of this client service charter was provided by the Tanzania Institutional Capacity Building (TZ-ICB) project. The TZ-ICB project is funded by the Centers for Disease Control and Prevention (CDC) and led by Management Sciences for Health (MSH).
INTRODUCTION

The Client Service Charter for the National Health Research Ethics Committee (NatHREC) of the Medical Research Coordinating Committee (MRCC) of the National Institute for Medical Research (NIMR) informs you about:

- Who we are
- Our vision
- Our mission
- Our values
- Our services
- Our clients
- Ethical Clearance Process
- Our service standards
- How we will be accountable
- Our commitment to you
- How you can help us
- Additional information about NatHREC
- How to contact us
Established in 2002 and working 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. MRCC is one of the three functional committees of NIMR Council, with the national mandate to coordinate health research, and has to ensure all health research follows country’s ethics regulations. NatHREC role is to ensure health research proposals are scientifically and ethically sound. Hence, proposals are reviewed to safeguard the dignity, rights, safety and wellbeing of research participants. It also looks at Informed Consent process in relation to the participant’s capacity and voluntariness to take part in the proposed research. The Sub Committee is responsible for overseeing the research conduct yearly through continued reviews, and all issues pertaining to health research data and material transfers. Over the years, the Sub Committee has supported a number of research institutions in Tanzania to establish their own Institutional Ethics Review Committees (IREC) or Institutional Review Boards (IRBs). These IRECs complement NatHREC’s function of issuing institutional ethical clearance and monitoring the approved research at their institutions. 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.

Members of the NatHREC include physicians, lawyers, biomedical scientists including medical doctors, bioethicists, molecular biologists, sociologist/anthropologists and representatives from faith-based organizations.

The Committee members are appointed by MRCC based on knowledge, qualification and interest on matters of health research and research ethics. The NatHREC chairperson is non-affiliated whereas the Secretary is affiliated to the National Institute for Medical Research.
The NatHREC has developed guidelines, regulations and standard operating procedures for ethics review, as well as evaluating, monitoring and controlling new, ongoing and approved health research.

OUR VISION

NatHREC’s vision envisages the NIMR’s vision that is: To be an outstanding institution for advancement of health research excellence in Tanzania and beyond

OUR MISSION

NatHREC mission is to ensure and guarantee the rights, dignity, safety and protection of all individuals and communities who participate in research activities. The committee is also committed to ensuring scientific merits of the research and protecting the rights of the researchers as well.

OUR CORE VALUES

NatHREC’s core values envisage the NIMR’s core values that are:

- Integrity
- Accountability
- Unity
- Innovation
- Quality
OUR SERVICES

- Receiving and registering all health researches carried out in Tanzania.
- Ensuring that all health research proposals are reviewed to safeguard the dignity, rights, safety and wellbeing of research participants.
- Advising researcher on risks and responsibilities of conducting research.
- Recommending for ethical approval all health research protocols that have complied with country’s ethical regulations (per the national guideline), and granting ethical clearance on behalf of MRCC.
- Monitoring and coordinating of all approved health research conducted in Tanzania.
- Advocating for and overseeing all issues pertaining to health research data and material transfers.
- Supporting research institutions in Tanzania to establish their own Institutional Ethics Review Committees (IREC) or Institutional Review Boards (IRBs).

_NathREC Secretariat member attending a client_
OUR CLIENTS

NatHREC deals with arrays of clients ranging from:

- International and National Researchers from Research and Training Institutions, International and Local NGOs
- International and local Institutional Review Boards
- Research participants
- Individuals (non-researchers and researchers)
- Local and international students
- Health facilities
- Government regulatory bodies and Agencies
- Business Groups including pharmaceutical industries
- The community at large
ETHICAL CLEARANCE PROCESS

Guided by the NatHREC’s Standard Operating Procedures (SOPs), ethical clearance process has four steps;

- Application for ethical clearance
- Ethical review of the Proposal by the committee
- Committee’s decision
  Authorization

Complete application

The checklist for application is available at the NIMR website or the link provided at the end of this charter.

The ethical clearance fees should be paid at the time of proposal submission.
**ETHICAL CLEARANCE FEES**

<table>
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<tr>
<th>PROPOSAL SUBJECT</th>
<th>REQUIRED FEE</th>
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<tbody>
<tr>
<td></td>
<td>RESEARCHERS</td>
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<tr>
<td></td>
<td>Tanzanians (TShs.)</td>
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<tr>
<td>Registration**</td>
<td>100,000</td>
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<tr>
<td><strong>Ethical Clearance Fees</strong></td>
<td></td>
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<tr>
<td>Ordinary Health Research Proposal</td>
<td>300,000</td>
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<tr>
<td>Clinical Trials Research Proposal</td>
<td>2,000,000</td>
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<tr>
<td>Renewal of Ethical Approval ordinary proposal</td>
<td>100,000</td>
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<tr>
<td>Renewal clinical trial research proposal</td>
<td>200,000</td>
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<tr>
<td>Expedited review on ordinary proposal</td>
<td>600,000</td>
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<tr>
<td>Expedited review on clinical trial proposal</td>
<td>3,000,000</td>
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<tr>
<td>Amendment on Clinical trial Health Research Proposal</td>
<td>500,000</td>
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<tr>
<td>Amendment on ordinary Health Research Proposal</td>
<td>200,000</td>
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* A collaborative research proposal with non-Tanzanian researchers
** Paid only on submission of new application
BANK DETAILS FOR FEE PAYMENT

Account Name: National Institute for Medical Research  
Bank: NBC Samora Branch  
Account Number: 012105009961 (USD Account)  
Account Number: 012103015635 (TZS Account)  
Swift Code: NLCBTZTX

Note: Payment should be made under PI or Co-PI’s name, and local investigator if applicable.

PROTOCOL REVIEW

MRCC format (criteria) used to evaluate proposal include:

- Summary
- Introduction and literature review
- Statement of the problem
- Rationale
- Objectives of the study
- Research Methodology & Data collection and analysis tools
- Budget and its justification
- Ethical considerations-social value of the study on the potential participant and community values/benefit, confidentiality measures, informed consent process, voluntary participation, and freedom to withdraw anytime, compensation for time and travel
- Dissemination of results to key stakeholders including the participating community
- Personnel’s, and CVs
- List of references
- Annexes:
  - I) Informed Consent forms (ICF) and or Assent forms in both English and Kiswahili,
  - Ii) Research tools,
  - Iii) Questionnaires,
iv) Tables,
v) Investigators brochures,
vi) Approval from foreign and/or local Institutional Review Boards,
vii) Letter of Intent of Insurance (clinical trials) and
viii) Any supporting documents.

Upon receiving the required documents, the review process will follow the service standards described in this charter. Proposals will also be received through electronic submission process.

APPROVAL DECISION

After review, the Committee’s decision is communicated to the PI. The approval decision is categorized as follows;

- As presented
- Minor Revision
- Major revision
- Not Recommended
- Outright Reject

As presented status means the proposal/protocol is scientifically sound and has met the ethical requirements; hence ethical clearance certificate will be issued.

Minor revision status means the proposal/protocol is missing some minor but important issues that need to be attended to. Ethical approval will be issued after the PI has resubmitted the proposal to fulfill these requirements.

Major Revision status means the proposal/protocol is not scientifically or/and ethically adequate. Ethical approval will be issued after resubmission by the PI to fulfill these requirements.

Not recommended status means the proposal/protocol is not scientifically or/and ethically complying with requirements and researchers have not addressed reviewers and committee’s comments, as instructed. The ethical approval will not be issued until the PI has complied.

Outright Reject means the proposal lacks scientific merit and/or ignores ethical principle.
OUR SERVICE STANDARDS

NatHREC Services and measures of Effectiveness

The service standards outline the performance standards upon receiving proposals, however the details of the ethical approval process are provided in the NIMR standard operating procedures.

<table>
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<tr>
<th>Service</th>
<th>Measure of Effectiveness</th>
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| Receiving and registration of research applications | o Checking for completeness of the research proposals by the NatHREC secretariat and forwarding to the Registry section for registering into NIMR Register.  
  o Registered proposals are brought to the NatHREC secretariat office again for registration, and step by step review process.  
  o Registering the proposal into NatHREC’s Register and Electronic database within a day of receiving the documents from NIMR Registry Section.  
  o Providing acknowledgment within 3 working days after receiving proposal documents from NIMR Registry Section. |
| Review of proposals for ethical approval | o Allocation and sending proposals to reviewers within 4 working days after receiving the proposal.  
  o Follow up on comments from the reviewers within 14 days of sending the proposals for review.  
  o Organize monthly ethical committee meeting to discuss and decide on reviewer’s comments.  
  o A schedule of meetings should be available in the document  
  o Provide committee’s decision to PIs within 3 working days after committee meeting.  
    - The PI is required to respond to comments and resubmit proposal (if necessary) within 4 weeks for ordinary proposals and within 12 weeks for clinical trials or may request extension for submission of comments  
    - After receiving responses from PIs, the Committee will make decision on ethical approval during the next/following (monthly) meeting.  
  o If rejected, PI will be informed of Committee’s decision within 3 working days after the (monthly) meeting. |
If approved, the certificate of ethical clearance will be prepared within 5 working days of committee’s approval of the research proposal. Three copies of certificate of clearance (for PIs, Regional Medical Officer and District Medical officer) will be issued. For external collaborative research, PIs shall submit a photocopy of certificate to COSTECH for Research Permit and Clearance process.

- The information about the certificates will be communicated on the website
- The timeline for the whole review process and ethical clearance shall take 6-8 weeks from the date of receiving a complete initial/revised submission.
- The expedited review process is completed in 4 weeks after receiving the complete applications.

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<thead>
<tr>
<th>Monitoring and coordinating research activities</th>
<th>Receiving progress reports for all ongoing approved health research activities in Tanzania every six months.</th>
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<tr>
<td></td>
<td>All ethical clearance certificates are valid for 12 months after which PIs are required to apply for renewal/extension. NatHREC will process research extension requests within a week of receiving complete application documents.</td>
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<tr>
<td></td>
<td>Researchers are required to apply for permission to publish. NatHREC will process permission to publish within 10 working days of receiving complete request documents.</td>
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<td>In collaboration with regional and district medical authorities and IRBs, conducts site visits to monitor research activities on quarterly basis.</td>
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<tr>
<th>Overseeing Material/Data Transfer</th>
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<td>Material/ Data Transfer Agreements (MTAs/DTAs) requests require that the source provider be a Tanzanian, signed and stamped by the source institution/authority, signed and stamped by recipient institution/authority and particulars of material/data to be transferred.</td>
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<tr>
<td>NatHREC will receive and review the complete material/data transfer requests and approve within 5 working days.</td>
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<tr>
<th>Support establishment and oversight of IRBs</th>
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<tr>
<td>Support at least one research institution in Tanzania to establish Institutional Ethics Review Committees (IERC) or Institutional Review Boards (IRBs) annually.</td>
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<td>Monitoring and quality check of these IRBs</td>
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## Communication, complaints and feedback standards

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<tr>
<th>Communication</th>
<th>Measures of Effectiveness</th>
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| **Telephone** | o Client’s calls will be answered promptly. We are accessible by landline telephone from 9:00am to 5.00pm East African Time during working days. We will respond to your calls within four (4) rings.  
o We will be courteous, professional and helpful. We will identify ourselves when answering the telephone and when we call. |
| **In Person** | o Clients are received from 10:00am to 3.00pm. We shall assist you promptly. We will attend you within 10 minutes if you have made appointment and 30 minutes if you do not have an appointment. We will advise you, in advance, about any unexpected delays in attending you.  
o Our offices will be clean and comfortable, have relevant information on display. |
| **E Mail, Fax & Letters** | o We will respond to your correspondence promptly using the most convenient method.  
o We will acknowledge and respond to E-mail inquiries within one working day of receipt.  
o We will record all of your correspondence on secretariat databases and filing systems. |
| **Publications** | o All approved protocols/proposals are posted to the NIMR website quarterly. |
| **Website** | o We will review and update information (including guidelines and other documents) on our website to ensure it is current and meets your needs and expectations. |
| **Complaints** | o Clients can lodge complaints at different levels using a convenient method (e-mail, fax, telephone calls, etc.). Depending on the nature and extent, we will respond to client complaints within a maximum of 5 working days. |
| **Suggestions** | o We will acknowledge client suggestions within one working day of receipt. |
HOW WE WILL BE ACCOUNTABLE

We undertake to:

- Monitor our performances against the standards set out in this Charter and publish the results in Annual Report and other publications, which will be available upon request from our Office.
- Performance information will also be provided on NIMR website.
- Be open to feedback on our performance, and suggestions for improvement from our clients and the public and make adjustments to our programs and services based on information received.
- Publish information showing levels of satisfaction with our services, including complaints received and the resolution of those complaints.
- Provide explanations when our services do not meet acceptable standards of quality, timeliness or accuracy.
- Formally review the standards set out in this Charter once a year and make modifications where appropriate in light of client’s comments and in response to ongoing changes.
- Independently review our Charter at least every three years by inviting comments from clients, stakeholders and staff as part of the monitoring and review process.

*Mrs. Joyce Ikingura, Deputy Secretary NatHREC*
RELATIONSHIP BETWEEN NatHREC AND IRECs

Institutional Research Ethics Committees (IRECs) are not allowed to approve researches of clinical trial nature and those with foreign collaborators.

OUR COMMITMENT TO YOU

NatHREC is committed to respect the rights of the client to:
- Timely receive the complete service package
- Revise and amend the proposal
- Lodge a complaint
- Appeal
- Privacy and confidentiality
- Communicate proactively in case there is a delay in clearance process

NatHREC fulfill client’s service guarantee by having well trained and supportive secretariat staff who maintains an open and accountable culture that is fair and reasonable in dealing with clients.

We will provide you with quality service by:
- Seeking to understand your needs and to identifying what service is important to you.
- Recognizing that NatHREC clients have different needs and personalizing our services and advice in ways that fit those needs.
- Treating you with respect and courtesy, maintaining confidentiality where required.
- Giving you clear, accurate, timely and relevant information or help you find it.
- Being clear and helpful in our dealings with you, giving reasons for our decisions.
- Respecting the confidentiality of personal information and using it only in accordance with the law.
- Acting with care and diligence as we prepare a response, conducting ourselves honestly and with integrity.
Presenting our responses to your inquiries or letters clearly and concisely, using plain English, understandable graphics, or other means relevant to your needs.

However, **the clients have the following responsibilities;**

- To treat NatHREC staff and committee members with courtesy
- To attend scheduled appointments punctually
- To respond to requests for information by NatHREC accurately, thoroughly and in a timely manner.
- To abide by any legal requirements and other obligations that clients are to meet in order to be eligible for services sought.
- To pay required ethical clearance fees timely and provide valid evidences of payment
- To provide NatHREC with updates on changes in approved research promptly.

**HOW YOU CAN HELP US**

NatHREC welcome your views and comments as vital in helping us to monitor and improve the relevance and quality of our services.

- To help us give you the best possible service, we welcome suggestions for improvement to address any difficulties you are experiencing.
- If you have a suggestion, feel free to contact us, we will consider all suggestions fully and promptly in our planning for service improvement.
- Let us know as soon as possible when we do not meet your expectations.
- We will investigate your complaint and tell you what we have done about it. You can help us by providing clear details of relevant facts, persons and dates when you make a complaint.
- Complaints should be made to the person you have been dealing with (or that person's supervisor) or sent to us using a convenient method.
ADDITIONAL INFORMATION ABOUT THE NatHREC

Additional NatHREC information can be found at [http://www.nimr.or.tz/ethical-guidelines/](http://www.nimr.or.tz/ethical-guidelines/) or through the Directorate of Research Coordination and Promotion at NIMR Office.

Links to important documents/Information

<table>
<thead>
<tr>
<th>Document/Information</th>
<th>Link</th>
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<tr>
<td>The National Institute for Medical Research</td>
<td><a href="http://www.nimr.or.tz">http://www.nimr.or.tz</a></td>
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<tr>
<td>Application Form for Ethics Approval</td>
<td><a href="http://www.nimr.or.tz/wp-content/uploads/2013/05/MRCC_Form.pdf">http://www.nimr.or.tz/wp-content/uploads/2013/05/MRCC_Form.pdf</a></td>
</tr>
<tr>
<td>MRCC’s Ethical Clearance Guidelines</td>
<td><a href="http://www.nimr.or.tz/wp-content/uploads/2013/05/Ethical-Clearance.pdf">http://www.nimr.or.tz/wp-content/uploads/2013/05/Ethical-Clearance.pdf</a></td>
</tr>
<tr>
<td>The Standard Operating Procedures (SOPs) for the National Health Research Ethics Committee</td>
<td><a href="http://www.nimr.or.tz/wp-content/uploads/2013/05/SOPs-_NIMR.pdf">http://www.nimr.or.tz/wp-content/uploads/2013/05/SOPs-_NIMR.pdf</a></td>
</tr>
</tbody>
</table>
HOW TO CONTACT US

General feedback should be sent to NatHREC by

1. **E-Mail**: ethics@nimr.or.tz

2. **Physical Address**
   NIMR Headquaters
   2448 Barack Obama Drive
   Ground Floor, NatHREC office

3. **Post Address**
   Chairperson, NatHREC
   National Institute for Medical Research
   P.O. Box 9653
   Dar es Salaam, Tanzania

4. **Telephone & Fax**
   Tel: +255 22 2121400
   Fax: 255 22 2121360
NATIONAL HEALTH RESEARCH ETHICS COMMITTEE

Physical Address
NIMR Headquarters: 2448 Barack Obama Drive
Ground Floor, NatHREC Office

Post Address
Chair, NatHREC
National Institute for Medical Research
P.O. Box 9653, Dar es Salaam, Tanzania
Telephone & Fax: Tel: +255 22 2121400, Fax: 255 22 2121360
E- Mail: ethics@nimr.or.tz
www.nimr.or.tz