National Institute for Medical Research

Accreditation Guide for
Institutional Research Ethics Committees in Tanzania

March 2023

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Definition of Terms

1. **Institutional Research Ethics Committee (IREC):** The Committee responsible for ethics review of research protocols at institutional level. It is also called Institutional Review Board (IRB).
2. **IREC Accreditation:** The granting approval or certification by a relevant authority representing the interest of both the Public and Researchers to an Institutional Research Ethics Committee on account of having a quality assurance system that ensures the conduct of ethics review for a particular period of time. The approval of IRECs in this context is granted to function for a specified mandate.
3. **Lay Member:** A member of an ethics Committee who is NOT:
    a) A health practitioner (for example a doctor, nurse, midwife, dentist or pharmacist);
    b) An officer of, or someone otherwise employed by, any health board, health authority, the Ministry of Health, or medical school;
    c) Involved in conducting health research or who is employed by a health research agency and is in a sector of that agency that undertakes health research; or
    d) Construed by virtue of their employment, profession or relationship to have a potential conflict or professional bias in a majority of protocols reviewed.

1. Introduction

The National Institute for Medical Research (NIMR) is a national health research institution in Tanzania, established by the Parliamentary Act no. 23 of 1979 (Cap 59 R.E. 2002) as a parastatal service organization under the Ministry of Health. The establishment of NIMR was in recognition by the Government of the need to generate scientific information required for the development of better methods and techniques for enhancing disease management, prevention and control in the country.

NIMR is mandated to register, carry out, promote, monitor, control and coordinate all medical research undertakings within the country or elsewhere on behalf of the Government of Tanzania and for the benefit of Tanzanians. Oversight of the health research coordination and regulation role is done by the Medical Research Coordinating Committee (MRCC) which is a NIMR Council Committee.

The MRCC is responsible for ensuring that all health research undertakings in the country comply with the national health ethics requirements and it ensures that scientific merits are observed. These are precursors for the conduct of research that provides quality evidence-based information to contribute to the well-being of the citizens and the entire society.

The MRCC has delegated the day-to-day functions of ethics clearance of research protocols to the National Health Research Ethics Committee (NatHREC) which was established in 2002. NatHREC functions to ensure that health research conducted in Tanzania is scientifically sound, and is performed in ways that safeguard and guarantee human participants in health research of their rights, dignity, safety and well-being. NatHREC is also responsible for overseeing all issues pertaining to health research data and material transfers and sharing.

In the NIMR Act, amendment of 1997 gazetted on 7th November, 1997 under the title “Coordination of Health Research in the United Republic of Tanzania” (ISSN 0856-

036-038)", NIMR has, according to sub-sections 5 and 7 the functions of registering institutions located within Tanzania that apply for being delegated with the mandate to review research protocols for institutional ethics clearance. The sections state "*institutions located in the United Republic of Tanzania and regularly hosting health-related research may apply to the National Institute for Medical Research to be mandated to review proposals for institutional ethics clearance. However, the mandate will only apply to the researches to be hosted by the institution*" and that "*The applications for authority to review proposals for institutional ethics clearance, shall list the names of the committee members, and show for each member, professional qualifications, research areas of interest, and publications in the last five years. Membership of the institutional ethics committee shall be reviewed every three years and the National Institute for Medical Research notified accordingly. Where feasible, the community served by the institution shall be represented on the committee by at least two enlightened and respected members conversant with national culture and laws".*

NIMR and NatHREC support health research institutions, universities of health sciences and tertiary hospitals in Tanzania to establish their own Institutional Research Ethics Committees (IRECs). These can be either Zonal or IRECs.

This guideline provides all IRECs and their hosting institutions with the essential requirements for accreditation. The IRECs recognized by this guideline are those concerned with health research involving human participants. The IRECs may either be in public or private organizations.

This guideline outlines the processes the respective Institutions and IRECs are expected to undertake in applying for accreditation and re-accreditation, respectively, as well as processes IRECs are expected to maintain for optimal function and thus provide a basis for standardization of ethics review in Tanzania and Compliance Monitoring.

Reporting and monitoring requirements have been introduced and are part of this guideline along with application timelines for the accreditation and subsequent renewals.

2. Objectives of Accreditation

Accreditation will focus on the following key elements:

a) Standardization of quality of ethics review in the country;
b) Development of public confidence and trust in national research systems;
c) Preservation of the right to autonomy of research participants;
d) Standardization of the constitution and operations of IRECs;
e) Facilitation of coordination and collaboration in ethics review endeavours;
f) Highlight areas of weakness and provide facilitatory support where necessary and feasible; and
g) Protection of staff working on research as investigators, data collectors or other duty categories from any possible risks in terms of either physical or mental/psychological harm or abuse and their exploitation.

3. Requirements for Accreditation

3.1 Application Requirements

Applicants will fill in form number 23: Application Form for Institutional Research Ethics Committees in *Appendix II* of this guideline.

Applicants are required and expected to submit documents listed below:

a) Application cover letter
b) List and curriculum vitae (CV) of the proposed Committee members and categorization of their membership (e.g., Chairperson, Layperson, Health professionals and others)
c) Proof of areas of expertise or experience of each member (e.g., ethics, law, theology, community involvement, medical practice, health research, statistics, economics, epidemiology, non-communicable diseases, etc.)

d) Gender of each appointed member to ensure gender balance
e) Letters from the institution stating date of appointment of each Committee member
f) Professional/institutional affiliation (if any) of each member
g) Description of the mechanism used to appoint members (e.g. by a recognized body/authority, professional body (state which), by the institution or any other);
h) IREC's standard operating procedures (SOPs) – see Section 4.1(viii) below
i) Copies of certificates of attendance to short courses (online or physical) on Protection of Human Subjects in Research (except for the lay member)

3.2 Membership Requirements for Ethics Committees

a) The Chairperson must have adequate experience in health research, leadership and have basic knowledge of bioethics;
b) A Committee must comprise at least five (5) members or more, the total must be an odd number;
c) At least one-third of the members of the Committee shall be of either gender;
d) At least one member should come from outside the institution;
e) At least two members should have research expertise and experience. one of these should be in the health field;
f) At least one member should represent a lay group;
g) For ethics committees reviewing clinical research, the committee should have representation from medicine, laboratory, pharmacy and nursing as needed. A clinician is mandatory. The clinician must be active in clinical practice (with a valid practising licence) or in clinical research;
h) At least one member of the Committee should possess knowledge and understanding of the Laws of Tanzania, preferably having been trained in Law;
i) Where a given Committee has been formed to serve more than one institution, the institution hosting the Secretariat is the one responsible for the functioning of the IREC in all aspects; and

j) Where multiple institutions are involved in one formed Committee, the appointing authority shall make the appointments in consultation with the relevant Heads of the respective institutions.

4. Criteria for Accrediting IREC

NatHREC has identified basic characteristics of quality required for all IRECs, which are referred to as “IRECs Accreditation Criteria”. These are statements of good practice that are expected in IRECs. The scope of each standard is described to facilitate its identification and compliance.

4.1 IREC Accreditation Assessment Criteria

Upon receipt of the application for accreditation from a registered academic and research institution or tertiary hospital, NIMR will appoint a team of experts to validate the submission and the physical verification. Thereafter, the exercise will be finalized by deliberating on the appropriate score that will be filled in the Inspection form for accreditation of IRECs (Form No -24), which will consider the following ten (10) areas:

i. Suitability of infrastructure and office space for IRECs activities
ii. Adequacy of equipment for support to ethics review management
iii. Adequacy of qualified IREC Secretariat staff (technical and support staff) to manage the ethics review procedures
iv. Appropriateness of IREC’s governance and structure
v. Plan for capacity building/training program for the IREC Secretariat, members and reviewers
vi. Plan for monitoring of research activities by the IREC
vii. Adequacy of Institutional support services
viii. Appropriateness of IREC’s SOPS: For accreditation review purposes ethics committees shall provide SOPs under which the ethics committee will operate. It is recommended that the SOPs should include but will not be limited to the following:

a) Scope and responsibility of the IREC; institution(s) served;
b) Objectives of the committee; streamlining research, safeguarding dignity and rights of research participants, facilitating correction and registration of research protocols;
c) Functions of the Committee;
d) Appointment and terms of appointment for members; appointing authority, responsibility to the authority;
e) Conduct of business procedures, decision making, notification, types of review, meetings, confidentiality, handling of conflicts of interest;
f) Documentation; record keeping, archiving;
g) Responsibility of the Principal Investigator;
h) Complaints handling procedures, dispute resolution, appeals and reports to NIMR;
i) Application procedures for ethics clearance;
j) Monitoring of approved procedures (at institutional level); and
k) Oversight of research projects that have received ethics clearance.

5. IREC Accreditation Assessment Team

NIMR will formulate an assessment team with clear terms of reference to conduct accreditation activities and monitor IRECs operations. This team will advise NatHREC, and NatHREC will recommend accreditation to the MRCC. The team will be constituted of members who have expertise and experience on institutional regulatory roles, and will be oriented on guidelines, and tools for conduct of the accreditation activities.

6. Mandate of IRECs

Registered and accredited IRECs support the NatHREC function of facilitating institutional ethical clearance and monitoring the approved research studies at the level of the institutions to which they belong or are affiliated. IRECs are not mandated to approve

research protocols of **clinical trial nature and those involving foreign collaborators**. These types of research are cleared at the national level only.

7. Benefits of Accreditation

a) **Benefits to Research Subjects**: Accreditation of the ethics committee results in high-quality care and human participants' safety. The rights and welfare of the human participants are respected and protected including confidentiality.

b) **Benefits to Institution (s)**: Accreditation of an ethics committee stimulates continuous improvement. It raises the community and gives research participants' confidence in health research. It also provides assurance to other stakeholders that all the procedures carried out at the site(s) are in compliance with regulatory guidelines and standards. It provides assurance and a sense of satisfaction to other external ethics committees/regulatory bodies that all the procedures and processes of carrying out research are in accordance with laid principles.

c) **Benefits to Staff and Investigators**: It provides an environment for continuous learning, and it improves the overall professional development of Investigators.

8. Accreditation Procedures

8.1 Application Procedure

After the applicant has successfully met the criteria or conditions set as the requirement for the application for accreditation (section 3 above), the accreditation body will conduct a physical visit to the Zonal or Institutional REC.

An IREC will be awarded one of three (3) categories depending on the score attained on physical verification and assessment, these are:

1. Preparatory: The IREC has not yet been allowed to operate. It is still at the preparatory stage.
2. Provisional Accreditation: an IREC on provisional accreditation will be allowed to operate for a period of one (1) year while working on areas of weakness to attain

full accreditation. If after a year they do not attain full accreditation, they will be required to reapply for accreditation

3. Full Accreditation: will be accredited to operate an IREC

NIMR will publish all accredited IRECs on its official website (www.nimr.or.tz)

8.2 Duration of Accreditation

The duration of accreditation shall be three (3) years from the date of notification (certification) by NIMR. That is, a certificate of accreditation will then be issued for a period of three (3) years based on the status of the accreditation reached. Accreditation shall not be retrospective.

8.3 Procedures for Renewal of Accreditation

Applications for renewal shall be made six (6) months before the expiry of the accreditation period. The documents submitted for renewal will mirror those submitted for initial (primaaccreditation. The decision will be communicated before the expiry date. The renewal of accreditation shall not be provided retrospectively.

8.4 Failure to Renew Accreditation

Failure to renew accreditation or failure to maintain the appropriate standards for continuity of accreditation will mean that the accreditation status of the ethics Committee will lapse at the end of the current accreditation period and the Committee shall cease to function henceforth.

8.5 Termination of Accreditation

Accreditation shall be terminated if in the opinion of NIMR in consultation with NatHREC satisfies itself that the accredited Committee has failed to maintain the required standards.

8.6 Appeal against Termination

If the applicant is not satisfied with the Committee's decision, the arbitration mechanism shall involve the applicant presenting an appeal (in the form of a letter) to the Arbitration Board, which in this case, is the MRCC and have it addressed to the MRCC Chairperson.

9. Reporting System to NIMR

a) The reporting calendar shall follow the financial calendar from 1st July – 30th June
b) All accredited IRECs shall submit their reports to NIMR on a quarterly and annual basis
c) Quarterly reports shall be received every 5th day after the end of the previous quarter
d) These reports shall be reviewed by NatHREC and the MRCC
e) Annual reporting should be received at MRCC every 5th July
f) The report shall comprise the following:
    i. A list of all protocols reviewed during the year, with the following information included:
        - Research title
        - Principal investigator and his/her qualifications
        - Co-investigators and their qualifications and institutional affiliations
        - Participating Institution(s)
        - Study site(s) - where the research is to be/has been undertaken
        - Date of protocol approval
        - Research category in terms of clinical trials vs non-clinical trials
        - Summary of protocols processed: initial submission; amendments; rejected, accepted (with and without corrections)

    ii. Additional Information that should be communicated includes:

- Any changes in the IREC membership, guidelines for operation, or other substantive changes which the Committee or its Chair should be noted (Members' statuses information)
- A summary of other activities of the Committee including training, active and passive monitoring and evaluation of approved research projects
- The SOPs are not required as part of the annual reporting process, unless they have been amended, but are required to be stated/included for the three-yearly re-accreditation review process. Any areas of review which caused difficulty for the Committee meetings in making a decision on any particular protocol(s), and any questions on policy or other matters which the Committee may wish to communicate to NatHREC.

10. Fees for Application and Renewal of Accreditation of IRECs

NIMR will charge fees during submission of the application form (Form Number 23) and on annual basis upon granting of accreditation. The initial application for accreditation will be charged a fee of TZS 1,000,000 (One million only). Renewal will be charged a fee of TZS 500,000 (Five hundred thousand only) annually. These fees shall be reviewed and /or revised periodically.

11. References

i. Royal College of Physicians. Guidelines on the practice of ethics committees in medical research with human participants. 4th edition. London: RCP, 2007.

ii. Standard Operating Procedures for the National Health Research Ethics Committee (2023). 3rd Edition. National Institute for Medical Research.

iii. NACOSTI, Guidelines for Accreditation of Institutional Ethics Review Committees in Kenya, Nairobi October 2017.

iv. Uganda National Council for Science and Technology (UNCST). 2016. National Guidelines for Research involving Humans as Research Participants. Kampala, Uganda: UNCST.

v. WHO, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011.

12. Appendices

Appendix I: Assessment Form for the Accreditation of IRECs

S/No.	Evaluation Criteria	Maximum Score	IREC Scores	
			1st Visit	2nd Visit (If applicable)
1	Suitability of infrastructure and office space for IRECs activities	7		
2	Adequacy of equipment for support to ethics review management.	6		
3	Adequacy of qualified IREC Secretariat staff (technical and support staff) to manage the ethics review procedures	4		
4	Appropriateness of IREC's Governance and structure	4		
5	Appropriateness of IREC's reviewers	4		
6	Appropriateness of IREC's SOPS	6		
7	Adequacy of level of funding and management of fees for ethics review	4		
8	Adequacy of capacity building/training program for staff at the IREC Secretariat, members and reviewers tailored for strengthening the ethics review process.	5		
9	Adequacy of plan for monitoring of research activities by the IREC	5		
10	Adequacy of Institutional support services and long-term plans	5		
	Total Scores	50		

S/No.	Evaluation Criteria	Maximum Score	IREC Scores	
			1st Visit	2nd Visit (If applicable)
	Average Score	5.0		
	Proposed for accreditation status: 0.0-3.4 Preparatory; 3.5 – 4.2 Provisional accreditation; 4.3 – 5.0 Full Accreditation			

Appendix II: Application Form for Accreditation of Institutional Research Ethics Committees

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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

FORM NUMBER 23: APPLICATION FORM FOR ACCREDITATION OF INSTITUTIONAL RESEARCH ETHICS COMMITTEES

Date(s) of Submission: Day: ….. Month: …….. Year: …….

Application Form for Institutional Research Ethics Committee Accreditation/Renewal of Accreditation

1. Name of Institution

2. Name of Institutional Research Ethics Committee (IREC)

3. Institutional Research Ethics Committee Address

Physical:
E-mail:
Website:

4. IREC Contact Officer

Name:
Position:

E-mail:
Phone:

5. IREC Chairperson

Name:
Position:
E-mail:
Phone:

6. IREC Secretary

Name:
Position:
E-mail:
Phone:

Scope of Accreditation (e.g., Social, Biomedical, environmental)

7. List the community or organizations served by the IREC

8. Please indicate how the membership of your proposed IREC is constituted

S/No.	Name	Gender	Category (e.g., Chair, lay)	Academic Qualifications	Membership to Professional body (Name)	Area of Specialization	Affiliation (Institution)	Ethics Training (Yes/No)

Gender Composition

Number of Males	Number of Females

9. Please indicate how the reviewers constituted for your proposed IREC

S/No.	Prefix (Prof./ Dr. /Ms./ Mr.)	First Name	Middle name	Surname	Gender	Email address	Phone number	Contact mailing address	Job title	Academic Qualifications	Membership to Professional body (Name)	Area of expertise for ethics review of proposals	Affiliation (Institution)	Ethics Training (Yes/ No)

10. Does the IREC have adequate staffing, facilities and infrastructure, and financial resources to allow it to carry out its responsibilities? Confirm availability of the following:

		Availability			
S/No	**Item**	**Exist**	**Does not exist**	**Copy Attached**	**Copy Not Attached**
1.	Permanent staff and Contract/temporary staff for the Secretariat support including their academic qualifications and experience				
2.	Adequate Infrastructure, office space(s), and equipment (computers, stationery, telephones, photocopying machines) for IRECs activities				
3.	Past, current and proposed budgets and financial statements				
4.	Documentation on any external foundation or other funding support				
5.	Certified audit, including management letter responding to audit queries (if any)				
6.	Does the IREC have adequate integrity to customers and are clearly displayed to clients to understand their rights and benefits from the services rendered by the IREC?				
7.	Policies regarding public information disclosure (transparency) addressing all matters listed including clients charter, newsletters, website etc				
8.	The policies that specify that high-level officials of the entity creating the IREC, or of any organization				

	that sponsors or conducts the research reviewed by the IREC (such as the director of an institution), do not serve as members of the IREC.				
9.	A mechanism for researchers, research participants, and other interested parties to lodge complaints about the IREC.				

11. Has the IREC developed Standard Operating Procedures?

Yes	No

12. (a) If yes to above, attach the Standard Operating Procedures

    (b) If no, explain

13. Has the IREC been registered or accredited by the MRCC in the past?

14. If yes in 13 above, indicate the date of notification and reference number from MRCC

15. Declaration (to be signed by the Appointing Authority of the institution referred to in 1 above)

I hereby declare that the information given in this form and any attachments are correct;

Name of IREC:

Name of Institution:

Name and Designation

Signature: _____ Date:_____

Official Stamp of Institution:

_____

For Official Use

Date Received: _____

Decision: _____

Notification Date: _____

Appendix III: Inspection Form for Accreditation of IRECs

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

FORM NUMBER 24: INSPECTION FORM FOR ACCREDITATION OF IRECs

Date(s) of Inspection: Day:… Month:…Year:…. **to** Day:…Month:….Year:……

Type of inspection: Announced visit [ ] Unannounced visit [ ]

Name(s) of monitoring team:

First name / middle / surname	Phone number / email address
1……/ ……/……	…….. / ……
2……/ ……/……	…….. / ……
3……/ ……/……	…….. / ……

PARTICULARS OF THE INSTITUTIONAL RESEARCH ETHICS COMMITTEES (IRECs)

i. Name of IREC:
ii. Name of host institution:
iii. Date established Name of IREC:
iv. Physical location and address:
v. Postal address:

Official Contact person and address: Chairperson/Secretary/Secretariat *(Circle appropriate)*

i. Postal address:
ii. Email:
iii. Phone No:
iv. Other contact details (personal) used if any;
    a. Email:
    b. Phone No:

Date that IREC was established: Day:… Month:…Year:……

- Operation: Day:… Month:…Year:….
- Launching (if applicable): Day:… Month:…Year:…….

Date of MRCC approval(s): Day:… Month:…Year:……..

Accreditation Criteria for IREC

Section I: Infrastructure and office space for IREC activities

1.1: Infrastructure verification

Sn.	type	Number provided	Number verified	Number functioning	Quality*			Remarks**
					Good	Average	Poor	
1.	**IREC Office:** *Is there an office space dedicated to accommodate IREC activities? Yes* [ ] No [ ] **If yes specify below**							
2.	Number of rooms:							
3.	Equipment and tools (computers, phone:)							
4.	Equipment and tools (LCD projector:)							
5.	Cabinets:							
6.	Office Furniture							
7.	Storage / Archive:							
8.	Is IT infrastructure (e-System) for submission of proposals available/ not available? - If available, explain the status of the online system of submission: …… …… ……							

- *** G** = Good**, A** = Average and **P** = Poor
- ****** explain if are adequate and up to date

1.2: Does the academic or research institution has a valid registration/accreditation certificate from the relevant authority? Yes [ ] No [ ]

1.3: Suitability of infrastructure listed in the Item 1.1 above for the support of IRECs activities.

1.	Available, adequate, conveniently located and in excellent condition	7	
2.	Available, adequate, conveniently located and in good condition	6	
3.	Available, conveniently located and in good condition but not adequate	5	
4.	Available, in good condition, adequate but not conveniently located	4	
5.	Available, in good condition, but not adequate and not conveniently located	3	
6.	Available, inadequate and in poor condition	2	
7.	Available, inadequate and in pathetic condition	1	
8.	Not available	0	

1.4: Comments, if any;

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Section II: Equipment

2.1: Adequacy of equipment for support to ethics review management.

1.	Available, sufficient and in excellent working condition.	6	
2.	Available, sufficient and in good working condition.	5	
3.	Available, in good working condition but not sufficient.	4	
4.	Available, insufficient and but in good working condition.	3	
5.	Available, insufficient and in poor working condition.	2	
6.	Available, insufficient and in pathetic condition	1	
7.	Not available	0	

2.2: Comments, if any;

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Section III: Secretariat staff for the IREC

3.1: Qualified IREC Secretariat staff (technical and support staff) to manage the ethics review procedures and processes

1.	Available, where 75% or more of them have appropriate qualifications and expertise as per approved SOPs by the MRCC.	4	
2.	Available, where less than 75% of them have appropriate qualifications and expertise as per approved SOPs by the MRCC.	3	
3.	Available, where less than 50% of them have appropriate qualifications and expertise as per approved SOPs by the MRCC.	1	
4.	The Institution has not allocated dedicated staff for the Secretariat functions as per approved SOPs by the MRCC.	0	

3.2: Comments, if any;

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Section IV: IREC's Governance and structure

4.1: The constitution of the IREC's membership and reporting structure is as recommended by the guideline and SOPs.

1.	The IREC has committee constituted by members where 75% or more of them have appropriate qualifications, affiliation and expertise as per approved SOPs by the MRCC	4	
2.	The IREC has committee constituted by members where less than 75% of them have appropriate qualifications, affiliation and expertise as per approved SOPs by the MRCC	3	
3.	The IREC has committee constituted by members where less than 50% of them have appropriate qualifications, affiliation and expertise as per approved SOPs by the MRCC	2	
4.	The Institution has not constituted a committee for the IREC as per approved SOPs by the MRCC	0	

4.2: Comments, if any;

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Section V: IREC's reviewers

5.1: The constituted list of reviewers for the IREC's has adequate qualifications, experience and expertise sufficient to manage the ethics review of proposals received by the IREC and have received recommended training/orientation for ethics reviews.

1.	The IREC has a list of reviewers constituted by experts where 75% or more of them have appropriate qualifications expertise, official appointment and have signed confidentiality agreement as per approved SOPs by the MRCC	4	
2.	The IREC has a list of reviewers constituted by experts where less than 75% of them have appropriate qualifications, expertise, official appointment and have signed confidentiality agreement as per approved SOPs by MRCC	3	
3.	The IREC has a list of reviewers constituted by experts where less than 50% of them have appropriate qualifications, expertise, official appointment and have signed confidentiality agreement as per approved SOPs by MRCC	2	
4.	The Institution has a list of reviewers dedicated for the IREC but have no official appointment and have not signed confidentiality agreement as per approved SOPs by the MRCC	1	
5.	The Institution has no list of reviewers dedicated for the IREC as per approved SOPs by the MRCC	0	

5.2: Comments, if any;

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Section VI: IREC's SOPS

6.1: The IREC developed SOPS that are in conformity with the NatHREC guideline and SOPs.

1.	SOPs are adequate and have been approved by the MRCC within five (5) years and the institution has implemented it for at least one year.	6	
2.	SOPs are adequate and have been approved by the MRCC within five (5) years and the institution has implemented not started implementing them.	5	
3.	SOPs are available, have standard format but not approved by the MRCC and the institution has implemented them for at least one (1) year.	3	
4.	SOPs are available, have no standard format and are not approved by the MRCC.	1	
5.	SOPs are not available.	0	

6.2: Comments, if any;

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Section VII: Level of funding and financial management of fees for ethics review (*ask if the fees are associated with the review procedures*)

7.1: The IREC has clear guideline on fees charged for ethics review of research protocols to investigators and guideline for payment of reviewers for the review process.

1.	The IREC charges fees to applicants and or pays reviewers fees as approved by the Institution's governing organ	4	
2.	The IREC charges fees to applicants and or pays reviewers fees but have no evidence of approval by the Institution's governing organ	1	
3.	The IREC charges fees to applicants and or pays reviewers fees but have not been approved by the Institution's governing organ	0	

7.2: Comments, if any;

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Section VIII: Capacity building/training

8.1: Adequacy of capacity building/training program for staff at the IREC Secretariat, members and reviewers tailored for strengthening the ethics review process.

1.	Training program available, and 75% or more of the reviewers, committee members and Secretariat have received appropriate training	5	
2.	Training program available, where less than 75% of the reviewers, committee members and Secretariat have received appropriate training	4	
3.	Training program available, where less than 50% of the reviewers, committee members and Secretariat have received appropriate training	3	
4.	Training program not available, but at least some of the reviewers, committee members and Secretariat have undergone appropriate training	2	
5.	Training program not available, and none of the reviewers, committee members and Secretariat have undergone appropriate training	0	

8.2: Comments, if any;

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Section IX: Plan for monitoring of research activities by the IREC

9.1: Adequacy of a plan for monitoring of research activities approved by the IREC.

1.	Monitoring plan available, synchronised in the IREC's almanac, reports are available and documented in the IREC's quarterly report to the MRCC	5	
2.	Monitoring plan available, synchronised in the IREC's almanac, reports are available although not documented in the IREC's quarterly report to the MRCC	4	
3.	Monitoring plan not available, no almanac but monitoring reports are available and documented in the IREC's quarterly report to the MRCC.	3	
4.	Monitoring plan available, no almanac, no reports and no documentation in the IREC's quarterly report to the MRCC.	2	
5.	Monitoring plan not available and no monitoring activities have been conducted.	0	

9.2: Comments, if any;

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Section X: Institutional support services and long-term plans

10.1: Are the institutional support services and long - term plans in favour of sustainability of the IREC?

1.	The institution strategic plan included IREC activities, a support system for receiving, recording and reporting of protocols submitted (manual/electronic) is available, financial support clearly documented and body of appeal for IREC activities defined	5	
2.	The institution strategic plan included IREC activities, a support system for receiving, recording and reporting of protocols submitted (manual/electronic) is available, body of appeal for IREC activities defined but financial support not clearly documented	4	
3.	The institution strategic plan included IREC activities, a support system for receiving, recording and reporting of protocols submitted (manual/electronic) is available, financial support not clearly documented and body of appeal for IREC activities not defined	3	
4.	The institution strategic plan included IREC activities, inadequate support system for receiving, recording and reporting of protocols submitted (manual/electronic), financial support not clearly documented and body of appeal for IREC activities not defined	2	
5.	The institution strategic plan does not clearly include IREC activities, inadequate support system for receiving, recording and reporting of protocols submitted (manual/electronic), financial support not clearly documented and body of appeal for IREC activities not defined	0	

10.2: Comments if any;

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Total score of the physical verification:

i.	Add the scores awarded in sections I - X above	50
ii.	Divide the total obtained in (i) by ten (10) to get the final average score ratings	5
iii.	The final average score is graded for decision by the MRCC	**Proposed score for accreditation status:** Scoring Scale: 0.0 – 3.4 Preparatory; 3.5 – 4.2 Provisional accreditation; 4.3 – 5.0 Full Accreditation
.		
iv.	Submit full technical report including all relevant attachments to justify what was observed during the visits, including: a. Achievements b. Challenges c. Pressing issues discussed d. Photographs	

Agreement among parties' full name(s) and signature(s):

IREC Team leader and secretary	**Monitoring Team leader and secretary**
_____	_____
Name and signature (Lead)	Name and signature (Lead)
_____	_____
Date	Date
_____	_____
Name and signature (Secretary)	Name and signature (Secretary)
_____	_____
Date	Date


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