Manual for Ethical Review Procedures **The Gambia Government / MRCG Joint Ethics Committee (EC)**		
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Abbreviations

ADR – Adverse Drug Reaction
AE – Adverse Event
CFR – Code of Federal Regulations
CIOMS – Council for International Organizations of Medical Sciences
CoI – Conflict of Interest
CV – Curriculum Vitae
DMC – Data Monitoring Board
DSA – Data Sharing Agreement
DSMB – Data and Safety Monitoring Board
EC – Gambia Government/MRCG Joint Ethics Committee
ESM – Ethics Committee Secretariat
FDA – Food and Drug Administration
FWA – Federal wide Assurance
GCP – Good Clinical Practice
GCLP Good Clinical laboratory Practices
GRP – Good Research Practice
ICRP – International Commission on Radiological Protection
ICD – Informed Consent Document
IMP – Investigational Medicinal Product
IRB – Institutional Review Board
LAR – Legally Authorised Representative
LSHTM – London School of Hygiene & Tropical Medicine
MCA – Medicines Control Agency
MRCG – Medical Research Council Unit The Gambia
MTA – Material Transfer Agreement
OHRP – Office for Human Research Protection
PACTR – Pan African Clinical Trials Registry
PI – Principal Investigator
REC – Research Ethics Committee
SAE – Serious Adverse Event
SAR – Serious Adverse Reaction
SCC – Scientific Coordinating Committee
SOP – Standard Operating Procedure
SUSAR – Suspected Unexpected Serious Adverse Reaction
WHO – World Health Organization

Table of Contents

1) Introduction

This ethical review manual outlines the procedures, standards, principles used by the Gambia Government/MRCG Joint Ethics Committee to review research proposals for their ethical acceptability, particularly the rights, safety, dignity, and well-being of research participants and the adherence to data protection laws.

The procedures for ethical review in this manual have been designed to assist in the application and assessment of ethical approval requests, implementation of good clinical research practice, and in the prevention of misconduct. This is to ensure that researchers conduct research of the highest quality.

Note: The Ethics Committee does not provide retrospective approvals

1.1) Purpose Of The Ethical Review Manual

This manual is developed to serve as a reference and guide for the overall operations of the ethical review process. It outlines the basic ethical principles and concepts to be adhered to in all research involving human participants, and the administrative procedures for applying for ethical approval and the actual review process. The main objective of this manual is to promote a consistent approach in the submission and administration of the ethical review process as well as the governance of research. It provides a platform for transparency in the review process.

1.2) Scope Of The Ethical Review Manual

This manual applies to the Ethics Secretariat ("Secretariat") staff, EC members, sponsors and all applying for ethical approval. The manual outlines the responsibilities of the Secretariat and the administrative processes involved in organizing and scheduling meetings for the review of various research project applications. These applications include new research projects, ancillary studies, changes to ongoing or future projects, requests for data or sample transfer outside of The Gambia, any other notifications related to research projects and quality improvement studies.

The EC's main responsibility is reviewing and overseeing research projects involving human participants to ensure their compliance with ethical principles for human subject research, and GCP and GCLP guidelines. Reviewers are to consider the potential risks and benefits to the community where the research will be conducted in addition to protecting the rights and safety of research participants.

The ultimate goal of the EC is to uphold high ethical standards in health research. To achieve this, the EC establishes appropriate guidelines based on recognised ethical principles and in alignment with the local ethics requirements and the values of the community it serves. The basic ethical principles governing all research involving human participants in The Gambia are:

1. **Respect for persons**: involves respecting human research participants irrespective of their attributes, background, circumstances or origins. It includes respect for autonomy through the informed consent process, voluntary non-coerced participation, protecting participants with diminished autonomy including provision of informed consent for children and adolescents, observing due diligence to participants' dignity and rights, their safety and wellbeing, and cultural differences. It also includes confidentiality and transparency through dissemination of informed consent processes and information in a manner understood by human participants and returning study results to participants.

2. **Beneficence:** encourages doing good. Research must have a positive impact on the participants and broader society, maximising benefits on participants' and communities' welfare.
3. **Non-maleficence:** requires minimising risks and avoiding harm such as physical, psychological, emotional and economic harms. Non-exploitation of research participants is a concept of non-maleficence. Risks must be comparable to background or standard risks where unavoidable. Risks must be identified and measures to mitigate them disclosed.
4. **Justice:** advantages, benefits, disadvantages and risks of research must be fairly distributed, upholding the concept of social justice.
5. **Confidentiality:** privacy protection.
6. **Honesty:** truthfulness in terms of the study.

Further ethical concepts to be considered in research involving human participants:

7. **Prudence and precaution**: a concept under non-maleficence to exercise the practice of caution where the risks are unknown including making carefully thought decisions without full knowledge of the scope of an action.
8. **Statistical considerations**: Sample-sizes must be determined for research involving research participants to obtain the minimal number of participants necessary to provide the statistical evidence for research, avoiding unnecessary exposure of humans to an intervention.
9. **Accountability**: Outline responsible parties for the full protection of human participants in research and optimisation of their safety, with a documentation of implementation and specific procedures.
10. **Inclusiveness of stakeholders**: All collaborators and parties involved in research must be documented with evidence of their competencies.

1.3) Objectives Of The Ethics Committee

1. Perform ethical reviews of research applications and oversee their conduct in The Gambia.
2. To conduct periodic reviews of ethical decisions to ensure compliance with the provided guidelines.
3. To formulate and publish ethical guidelines.
4. To ensure that these guidelines are understood and accepted by sponsors, researchers, investigators, applicants, and the wider community.
5. To provide a mechanism for consultation on major ethical problems.

1.4) Mission And Vision Of The Ethics Committee

Vision: To promote and safeguard the dignity, rights, safety and wellbeing of research participants by providing ethical guidelines, training in ethical principles, and the necessary resources to monitor and implement ethical decisions.

Mission: The EC will ensure that all research conducted complies with the fundamental principles of respect for persons, non-maleficence, beneficence, justice, confidentiality and honesty.

Composition: The committee is composed of multidisciplinary and multisectoral members with relevant scientific and legal expertise, as well as laypersons who can represent the concerns of the wider community.

1.5) Statement Of Compliance To Ethical Standards

The fundamental principles guiding research on humans and information related to them have been elaborated and refined in various international guidelines. The EC adheres to The Gambia regulatory authority, MCA Guideline for Clinical Trials in Humans, V4.0, 24 February 2025, The World Medical Association Declaration of Helsinki: The ethical principles for medical research involving human subjects (October 2024), taking into account the Council for International Organizations of Medical Sciences (CIOMS) - The International Ethical Guidelines for Health-related Research Involving Humans (2016), The Nuffield Council on Bioethics - The ethics of research related to healthcare in developing countries (2002), The Nuffield Council on Bioethics - Research in global health emergencies: ethical issues (2020), the Belmont Report – the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979), The International Council for Harmonisation (ICH) - Good Clinical Practice (GCP) E6(R3) (2025), The World Health Organization (WHO) - Guidance for best practices for clinical trials (2024). The UK Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, as well as other established standards in biomedical research as included in the list of references. Additionally, the EC complies with CFR, which includes a) Protection of Human Participants, also known as the Common Rule, (45 CFR Part 46), b) FDA Protection of Human Participants (21 CFR Part 50), and c) Institutional Review Boards (Part 56) and WHO GCP Guidelines and the respective WHO Handbooks.

The Ministry of Higher Education, Research, Science and Technology has validated the Draft National Research Bill, Research Excellence Assessment Framework (REAF), a comprehensive regulatory framework for the ethical governance of research in The Gambia and National Research Regulation on Wednesday, 23rd April 2025. The NaRDIC Bill 2025 established the National Research, Development and Innovation Council (NaRDIC) as the apex body to coordinate research and innovation, oversee ethical standards, and manage the National Research Fund. This bill will become effective when it passed at the National Assembly of the republic of The Gambia.

The Gambia Government/MRCG Joint Ethics Committee expects that projects (including student projects) are first judged scientifically sound by a recognised scientific committee or board.

MRCG at LSHTM is an institution that conducts research on human participants, and as the host of the Ethics Committee Secretariat, seeks approval of FWA for assurance of compliance from OHRP. The assurance of compliance is processed by the Secretariat to assure the HHS that the requirements set forth in the Code of Federal Regulations for the protection of human participants (45 CFR Part 46) will be complied with. The FWA is the only type of assurance of compliance accepted and approved by the OHRP. MRCG at LSHTM will also ensure that all research conducted under its auspices complies with its GRP Policy.

Organisation Ref: IORG0003305

FWA No: FWA00006873

IRB No: IRB00003943

The EC strives to ensure that all research projects meet the standards indicated above by reviewing projects against the six essential ethical principles: beneficence, non-maleficence, justice, respect for autonomy, confidentiality and honesty. Additionally, the research project must be based on good quality and valid science, risks must be minimised and should not exceed the background or standard risks and the potential benefits to the individual or community.

1.6) Research, Submission Process, And Exemptions

EC approval is required for most research to protect human rights and assess the scientific soundness of the research. For this, we first need to understand what research is. Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalisable knowledge" (Table 1). The SCC reviews the research projects before the EC review.

1.7) Type Of Research Studies And Approvals/Exemptions (Table 1).

Type of studies	Details about the need for approvals
Studies involving interaction or intervention	
1. Clinical Trials- pilot, all phases* and designs	A pilot study with an intention to contribute to general knowledge (fits the criteria for research). All phases of clinical trials require separate approvals.
2. All interventional studies	Even those using standard of care or non-pharmacologic interventions need approval.
3. Diagnostic tests and devices	Analysis of data and biologic specimens need approvals.
4. Medical records review	Those accessing and identifying private and personal identifying information need approvals.
5. Case reports	Case series need approvals as they are hypothesis testing.
6. Quality improvement and cost benefit analysis	Whenever it fits the definition of research, i.e., intent to generalise knowledge present.
7. Product evaluations	Whenever it fits the definition of research, i.e., intent to generalise knowledge present.
8. Public health surveillance	Those mandated by law, e.g., reporting of communicable diseases are exempt from EC review.
Studies not involving direct interaction or intervention	
1. Use of preexisting medical records or stored specimens	EC review required if identifying information is recorded.
2. Databases, registries, biobanks of biomedical specimens	EC review required for confidentiality purposes.

Type of studies	Details about the need for approvals
3. Surveys/Interviews	Collection of identifying or sensitive information requires EC approval.

*Phase refers to the stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4.

1.7) Risk Assessment

1. EC must be fully informed regarding the degree of risk and/or discomfort that participants will undergo.
2. EC must ensure that, where a research application involves greater than minimal risk or discomfort to participants, no feasible alternative exists that could provide the answer sought and that the investigator will take all possible steps to minimise such risk or discomfort.
3. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
4. EC must satisfy itself that there is an acceptable balance between the risk/discomfort that the participant is asked to undergo, and the benefit that is expected to result from the research.
5. EC must ensure that participants are not deprived of recognised benefits as a result of being included in a trial.
6. EC must be informed of the benefits that may be expected to result from the research, including:
    (i) potential benefits to participating participants;
    (ii) anticipated benefit to categories of individuals (e.g. sufferers from particular diseases);
    (iii) anticipated benefit to society and/or particular communities.
7. In evaluating risks and benefits, EC will consider only those risks and benefits that are directly related to participation in the research.
8. EC reviewers will identify any anticipated risks involved with the study and classify those risks as minimal or as greater than minimal risk. Reviewers then determine whether the anticipated risks to participants are reasonable in relation to the anticipated benefits to participants, and the importance of the knowledge that may reasonably be expected to result.
9. EC will then analyse level of risk, ensures risks are minimised, and ensures risks are reasonable relative to anticipated benefits, before approving the proposed research.
10. Investigators submitting research protocols for ethical review should understand that EC is responsible for assessing the possible risks vs. anticipated benefits, if any, of research as one of its primary functions.
11. In addition, once risks and benefits have been assessed, EC is responsible for ensuring that the risks of study participation are minimized to the greatest extent possible, while the benefits of study participation are maximised.
12. Furthermore, to approve research, the EC must determine that, where appropriate, the research plan makes adequate provisions for monitoring the data to ensure the safety of research participants.

1.8) Meetings Of The Ethics Committee

- Meetings are held on the last Thursday of every month.
- A special or additional meeting may be scheduled at any time to review emergency applications or clear a backlog of applications.
- The committee holds a minimum of 12 meetings per year.
- The annual meeting calendar is circulated every November.

2) Administration And Submission Procedures

This section describes the administrative and submission process and the duties involved in organising meetings of the Gambia Government/MRCG Joint Ethics Committee, including communications and documentation.

2.1) Scope

- This procedure applies to the Secretariat involved in the administration and operations of the EC.
- It also applies to applicants to the Ethics Committee.

2.2) Responsibilities

1. The Secretariat has the responsibility for the planning, coordinating and managing the ethics review process and its operations.
2. The Secretariat under the leadership and guidance of the Head of Governance and Research Support Services will ensure that all appropriate policies, procedures and guidelines are in place and implemented in the ethical review process.
3. The Secretariat is the focal point for all communications between the EC and applicants; and formally informs applicants about the EC's decisions in a timely manner.
4. The Secretariat publishes the annual meetings calendar for the EC.
5. The Secretariat is responsible for the renewal of the EC registration with the Gambia Ministry of Health, Ministry of Higher Education, Research, Science and Technology of Gambia, OHRP and reports changes in the membership in accordance with US Federal regulations.
6. The Secretariat provides advice and guidance to applicants on the ethics operational procedures.
7. The Secretariat assists the chairperson in the administrative matters of the committee.
8. The Secretariat ensures that the committee has all the required information, documentation and support to perform their review responsibilities and for the smooth running of meetings.
9. The ESM ensures that a quorum is reached and maintained throughout a meeting. The chairperson and scientific advisor are responsible for reviewing the draft minutes of the meeting and finalise the decisions with the ESM.
10. The Secretariat ensures that submissions received after the deadline are forwarded to the next committee meeting for review. The Secretariat conducts pre-review analysis and returns incomplete applications to applicant with comments for actions.

2.3) The Administrative Procedures (Table 2).

Description	Person(s) Responsible
Submissions to EC	
A calendar outlining submission deadlines and meeting dates is available on the website and intranet.	Secretariat
Submissions received after a deadline will be held over to the next EC meeting.	Secretariat
Applications approved by a recognised science committee in The Gambia can be submitted to EC from **here.** **See SCC Submission & Administration for more information**.	Secretariat
Information on EC Decision	
EC review outcome is usually communicated within 10 working days following the meeting. The letter communicates the decision of the EC and the reasons for the decision.	Secretariat
Full ethical approval must be received before research activities can start. All research applications involving animals must get AWERB approval before it can start its activities. Please refer to the **AWERB Committee for approval. Information on AWERB can be found here.**	PI
Full ethical approval must be received before substantial amendments can be initiated unless the change is necessary to eliminate immediate hazards to participants.	
All clinical trials must receive approval from the MCA in addition to the EC approval before starting any research activity and before initiating any substantial change to study procedures	
Meeting Governance	
The meetings of the EC are held on the last Thursday of every month, except otherwise stated. The deadline for submissions by applicants is at least 10 days before the actual meeting date.	Secretariat
Applications approved by SCC are automatically forwarded to EC for review.	Secretariat
Pre-review of submitted application is conducted prior to committee meetings to determine that a submission is complete, and thus the EC can review as per fulfilment of regulations and per committee requirements and policies.	Secretariat
Before the EC Meeting	

Ensure all applications submitted for ethics review are accompanied by an approval letter from a recognised scientific review committee.	Secretariat
Ensure submissions that are sent directly to the EC are eligible for ethical review.	Secretariat
Ensure applications have project IDs/Ethics reference numbers. Confirm that version numbers of support documents are correct and dated.	Secretariat
Ensure all applications are complete and distributed electronically at least 5 days before the meeting.	Secretariat
Prepare the agenda and the last meeting minutes.	Secretariat
Assign specific studies to EC members as primary and second reviewers and inform them of their assignments at least two days before a scheduled meeting.	Secretariat
After the EC Meeting	
Prepare minutes of meeting, review and finalise within 10 working days post meeting.	Secretariat/ Scientific Advisor/ Chairperson
Write to applicants informing them about the review outcome.	Secretariat
Respond to queries and submit response for final review where required.	PI
When applicable, review the PI response for consideration of a final ethical opinion.	Secretariat/ Scientific Advisor/Chairperson
Issue approval letter to applicant once final ethical opinion is granted.	Secretariat
Following finalisation of the minutes, file for approval at the next meeting	Secretariat
Electronic Documents Repository	
Applications are archived electronically by the LEO system.	Secretariat

3) Review Procedures

3.1) Purpose

The procedure describes the ethical review process of applications submitted to EC for review. The EC reviews and oversees research involving human participants with a purpose to safeguard their dignity, rights, safety and well-being.

3.2) Scope

The procedure applies to all members of the Gambia Government/MRCG Joint Ethics Committee members as well as the staff of the Ethics Secretariat.

3.3) Responsibilities

The EC is a national independent advisory body to researchers and relevant stakeholders.

The Scientific Advisor has the primary responsibility of reviewing the research protocols and their scientific soundness. The non-scientist member is crucial to safeguard human participants and practical issues of the research.

The Chairperson is responsible for ensuring the EC operates effectively and without bias, fostering a culture of ethical conduct and transparency. The Chairperson must encourage all members to participate in deliberations and decision-making processes. The chairperson will obtain declarations of potential conflicts of interest from all EC members at the start of meetings, as well as managing and documenting any disclosed COIs to determine appropriate handling. The Chairperson plays a crucial role in managing and addressing complaints filed against researchers or other EC members, which is a key aspect of maintaining the committee's integrity.

The ESM is the Ethics Committee Secretary and oversees the ethical review process ensuring strict compliance with policies and regulations. The ESM plays a vital role in the committee's functioning, serving as a central point of contact and managing the administrative operations of the Ethics Committee. This includes tasks like publishing annual meetings calendar, conducting pre-review analysis of submitted applications, ensuring quorum is reached and maintained throughout the meeting, attending meetings and taking minutes, managing pre and post meeting activities, handling documentation, defining and maintaining adherence to the manual, training EC members, assessing the need for expedited reviews/exemption from review, maintaining records, and facilitating communications between committee members, researchers, and other stakeholders.

The EC function is to review and approve research protocols, monitor ongoing research involving human participants with the aims of continual protection of human volunteers, advancement of research, and protecting the investigators' institute from litigation. Its main role is the protection of the human rights, autonomy, confidentiality, and welfare of the research participants especially vulnerable populations.

The EC evaluates research protocols by reviewing the submitted documents, paying special attention to the procedure and documentation of the consent process, the potential risks, safeguarding and benefits for research participants, the impact on the community and the ethical suitability and feasibility of the project. They ensure that a research project does not contradict any of the core ethical principles, GCP and MCA guidelines.

The EC takes the requirements of applicable national and international laws, by-laws, regulations, guidelines and best practices into account during the review process.

The EC is committed to an equitable clinical research enterprise that includes trials and studies that match the demographics of the disease burden under study, more diverse older adults, pregnant and lactating individuals and persons with disabilities who remain under-represented and even excluded from clinical trials and clinical research.

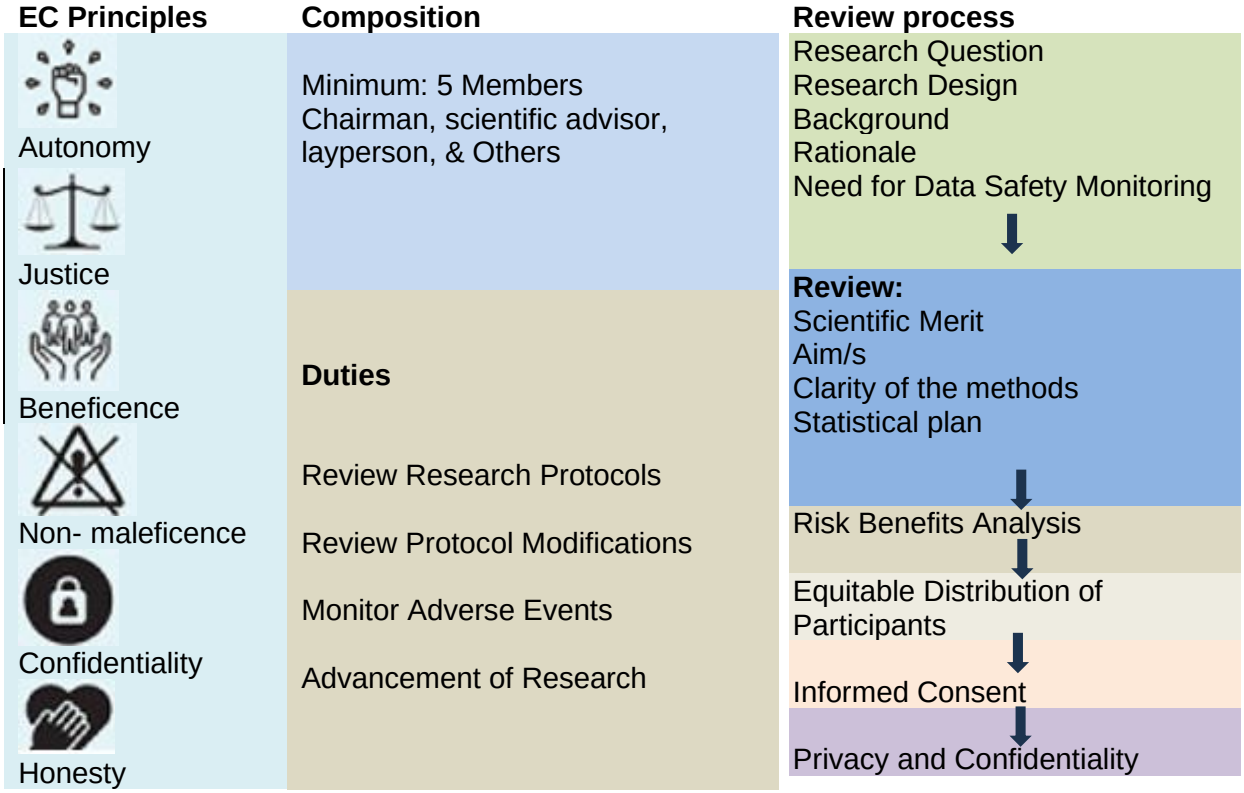
The EC will consider the:

1. scientific value (considering the scientific evaluation by a Scientific Committee)
2. application eligibility criteria
3. proposed recruitment activities
4. care and protection of research participants/communities
5. research participants' time spent in research and associated daily loss of earnings
6. protection of research participants' rights to privacy and confidentiality
7. protection of data and biological samples
8. consent document and assess the sensitivity of the information, the duration for which it will be held, the usefulness of the information, and the ability to protect it
9. measures taken by the research team to maintain the privacy of the research participants including the number of personnel with access to the information, data storage, and transfer for multicentre projects
10. community engagement and dissemination plan
11. community considerations (norms, cultural acceptance and safeguarding)
12. appropriateness of collaborators and partners listed in the research protocols
13. evidence of ethics and GCP training (GCP training is essential for investigators and staff working on clinical trials)
14. any presence of excessive barriers for participants to take part in research
15. adequacy of funding for the study
16. acceptability of the volumes of and frequency of human tissue collection

The Secretariat:

1. renews the EC registration with the Gambia Ministry of Health, Ministry of Higher Education, Research and Science and Technology of Gambia and OHRP and reports changes in the membership in accordance with US Federal Regulations.
2. keeps an up-to-date record of EC documentation, including the composition, manuals, policy, guidelines and procedures, constitution, training information, and make them available publicly.
3. reviews and processes ethics applications including the communication between the EC and applicants.

3.4) Ethics Committee: Structure And Roles (Figure 1).



3.5) Review Categories

3.5.1) Full Committee Review

Research protocols regardless of the risk level will require full committee review especially when the research involves human participants. Applications requiring full committee review are sent to the next calendared meeting once the application has received full scientific committee approval (such as SCC).

The ESM assigns submissions to a primary reviewer for presentation at the full committee meeting. At the conclusion of the verbal summary, the research protocol will be discussed and evaluated, and decision reached by consensus.

The review will be conducted by at least 5 members: chairperson, scientific advisor, 1 lay member and 2 other professional members. It is generally accepted that professional members of EC include scientists, health care professionals, lawyers, and persons with specific expertise in ethics. Other useful disciplines include epidemiology, clinical pharmacology, pharmacy, psychology, sociology, and biostatistics.

Lay members have no specific qualification with respect to biomedical research, medicine, or health care. They are expected to reflect the views of the public as well as those of participants.

3.5.2) Expedited Reviews

An application is circulated for expedited review when it falls under the following categories:

- **Secondary use of data**: For use of data collected as part of an already approved study, investigators must check if their proposed use is covered under the original approval including the existence of participant consent for use in further research beyond the initial project or study. If covered and with valid approvals, no further review is required. If not covered, a new application must be submitted.

- **Minor amendments** such as administrative changes to an ongoing study – the Chairperson and Scientific Advisor can review these applications and provide their feedback to the Secretariat within 10 working days. As appropriate, the research protocol is then either approved or returned to the PI for further action.

- **Research on interventions to control an outbreak of an infectious disease**
  This is done during an emergency response as a result of an outbreak. The Secretariat will conduct a pre-review analysis of the submission for validation as per the protocol submission criteria. Following this, the application will be forwarded to reviewers. The expedited review will be conducted as the Full Committee Review. The review (both SCC and EC) will be completed within two weeks from the date of validation by the Secretariat.

3.5.3) Exemptions From Review

Some studies may be exempt from review. For example, when publicly available data are analysed or the data for the study are generated by observation of public behaviour, and data that could identify individual persons or groups are anonymized or coded, the study may be exempt. Health systems research may be exempted from review if public officials are interviewed in their official capacity on issues that are in the public domain (CIOMS. 2016).

3.5.4) Quarterly Reports And Urgent Notifications

These are to be submitted to EC.

3.5.5) MTA/DSA

Applicants intending transfer research materials or data outside of The Gambia must complete an MTA and/or DSA at the time of the application.

3.6) Procedure For Review Of New Applications (Table 3).

DESCRIPTIONS	PERSON(s) RESPONSIBLE
Before the EC Meeting	
Conduct pre-review analysis for all applications submitted.	Secretariat
All applications submitted for initial review that have received approval by a recognised scientific committee and submitted in the appropriate format will be processed for EC review.	Secretariat
Prepare the meeting agenda and circulate the review package at least five (5) days before the EC meeting.	Secretariat
Allocate applications to primary and second reviewers for presentation during the meeting. **NB: Full research protocol (initial & resubmission) and major amendments will be assigned a primary and second reviewer.** **See appendix 03 (6.3.3) for changes that do not meet minor amendment criteria.**	Secretariat
Late submissions are not acceptable, but in extenuating circumstances, they **may be** considered at the discretion of the chairperson based on the type of application.	Secretariat
During the EC Meeting	
Confirm that quorum (5 members one of whom must be a lay member) is reached before the start of a meeting and ensure that it is maintained throughout the meeting. **NB: A lay member must be present for a quorum to be achieved.**	Secretariat
Request for declaration of Conflict of Interest by meeting attendees. **NB: Where a committee member is conflicted in an application under review, the said committee member recuse him/herself from the decision making. This is noted in the meeting minutes.**	Chairperson
Review and approval of minutes and actions from previous meeting.	EC
Review of applications	
Presentation of application to the committee by providing a verbal summary of potential issues of the research protocol. **NB: The Primary Reviewer is responsible for presenting the application.**	Primary Reviewer (supported by Second Reviewer)

The Primary Reviewer will ask the Second Reviewer for any supplementary information before opening the floor for discussion.	
The Primary Reviewer then welcomes comments and questions from the rest of the committee for discussion and decision.	EC
Comments are considered and fully discussed before a decision is reached. **NB: All ancillary studies, major amendments and request for further use of samples will be evaluated following the same principles as outlined above.**	EC
All other applications will be evaluated following the same principles as outlined above. **NB: A Second Reviewer is required for review of full project research protocol and major amendment only.**	EC
Decisions	
An application may receive one of the following **outcomes**: • approval; • provisional approval; • unfavourable opinion .	EC
An application may also require **resubmission for re-evaluation** based on a major omission or to address a major query from the committee.	EC
An application may be **rejected** for which the applicant will be **requested to resubmit** the application back to a recognised scientific committee e.g. SCC for re consideration of a fresh application.	EC
After the EC Meeting	
Prepare draft minutes within 5 working days following the meeting for review and finalisation.	Secretariat/EC Chairperson/ Scientific Advisor
Inform applicants about the decision of the committee in a letter from the Chairperson within: - 10 working days for non MRCG projects - 20 working days for MRCG projects – includes LSHTM review period.	
The letter will outline the issues raised by the EC with any outstanding action required from the applicant.	
Submit responses to queries raised for the consideration of chair's approval.	PI
Secretariat ensures that the required documentation is submitted for onward processing.	EC Chairperson/ Scientific Advisor
The Scientific Advisor will advise the chairperson on the decision as required.	
The chairperson is responsible for ensuring EC requirements are met before granting the approval.	
Review of minor amendments	

Minor amendments, those that do not adversely affect the risk/benefit ratio or the willingness of participants to enrol will undergo expedited review. **See Appendix 03 for more information.**	EC Chairperson/ Secretariat
Notifications to EC	
Safety reports, quarterly progress reports, deviations, safety reports, any reportable event or new information that may affect the benefit/risk ratio of the study and all notifications. **See Appendix 03 for more information.**	EC Chairperson/Designated person/Ethics Secretariat
The EC expects a quarterly progress report from all studies. **See Appendix 03(6.3.12) for more information.**	PI
A final report of all research projects must be submitted at the closure of a project containing all reportable events that have happened during the life of the study including any changes approved by the EC. **See Appendix 03(6.3.13) for more information.**	
End of study report should be submitted at least three months after the database is locked.	
A report is also required if a study is terminated prematurely. **See Appendix 03(6.3.13) for more information.**	
EC may request interim reports for studies the committee considered as high risk (studies involving vulnerable population, studies with sensitive topics, etc).	EC
The PI of a clinical trial is required to share DSMB/DMC reports with the EC.	PI
The EC requires that SAEs that occurred in a study conducted in The Gambia whether considered related or unrelated to the administration of any of the research procedures be reported. **See Appendix 03(6.3.10) for more information.**	PI
Research audits will be conducted on random selection for high-risk studies. **See Appendix 07 for more information.**	EC/Research Governance
Documentation of EC Decision	
Decisions made by the EC will be recorded • in the EC meeting minutes; and • in the reply letters provided by the Chairperson to the applicant.	Secretariat
All records (application forms and accompanying documents in support of an application, all correspondence between the Committee and applicants or concerned parties) are kept by the Secretariat for at least 10 years following the meeting	Secretariat

for non-intervention studies and 15 years for intervention studies or 5 years after marketing authorisation. The Ethics Committee's Constitution, CV and GCP/ethics training certificates of members are also kept for 15 years.	

3.7) Documents To Be Submitted For Review

1. Application Form
2. Scientific Committee Approval letter.
3. Research protocols and/or amendments
4. Investigator's Brochure or current scientific information, such as a basic product information brochure (e.g., Summary of Product Characteristics (SmPC), package leaflet or labelling), as appropriate, including their updates; if applicable.
5. Informed consent material(s), assent material(s), where applicable, and any updates, including the description of the process for how informed consent and assent is to be obtained; its translation into local languages and certificate of translation, where applicable (e.g. audio translation, video, adapted pictorial images for children, etc).
6. Other trial-related information to be provided to the trial participant(s), including a description of the media through which such information will be provided.
7. Advertisement for participant recruitment (if used) and information on the recruitment process.
8. Questionnaire (if applicable).
9. The following documents must be available for review of progress or safety by the EC as appropriate:
    i. Quarterly Report
    ii. Interim Report (if required)
    iii. End of Study Report (all studies)
    iv. Ongoing Update to Safety Information (if applicable)
10. A proof of registration with PACTR or an internationally recognised online registry
11. Proof of current training in Good Clinical Practice, research ethics training certificate not older than 3 years, signed and dated CVs with page numbers marked in the format, '1 of n'.
12. Any conditions, such as economic interests and institutional affiliations that might influence the impartiality of the investigators
13. In the case of trials involving human participants, proof of current, relevant and appropriate study insurance for all participants undertaken by the sponsor; or proof of sponsor or indemnification for investigators and trial sites; or professional indemnity insurance for investigators and other trial staff
14. Financial Declaration of the Trial
15. DSMB membership, CVs and signed charter (if applicable)
16. Certificate(s) of Analysis (if applicable)
17. PI protocol signature
18. Signed Declaration by Local Monitors (if applicable)
19. Qualifications of Local Monitor (if applicable) must be a scientist qualified by education, training and experience. Excellent knowledge in local regulatory requirements. Must have evidence of Good Clinical Practice training within the last 2 years.
20. Research protocols submitted for award of a degree must be accompanied by a letter of confirmation from the supervisor.
21. Requests for amendment or extension of study should include a copy of the previous approval letter.

22. An application must be accompanied by a non-refundable application fee as specified in the Investigator Guidelines. Otherwise, the review outcome will not be released.
23 Any other documents that the EC may need to fulfil its responsibilities.

4) Attachments

Attachment Numbers	**Titles** (as referenced on the attachment)
Attachment 01	Constitution
Attachment 02	EC guidelines for investigators
Attachment 03	MTA Template

5) References

1.	World Medical Association Declaration of Helsinki - the ethical principles for medical research involving human subjects. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association (accessed on 05 October 2025).
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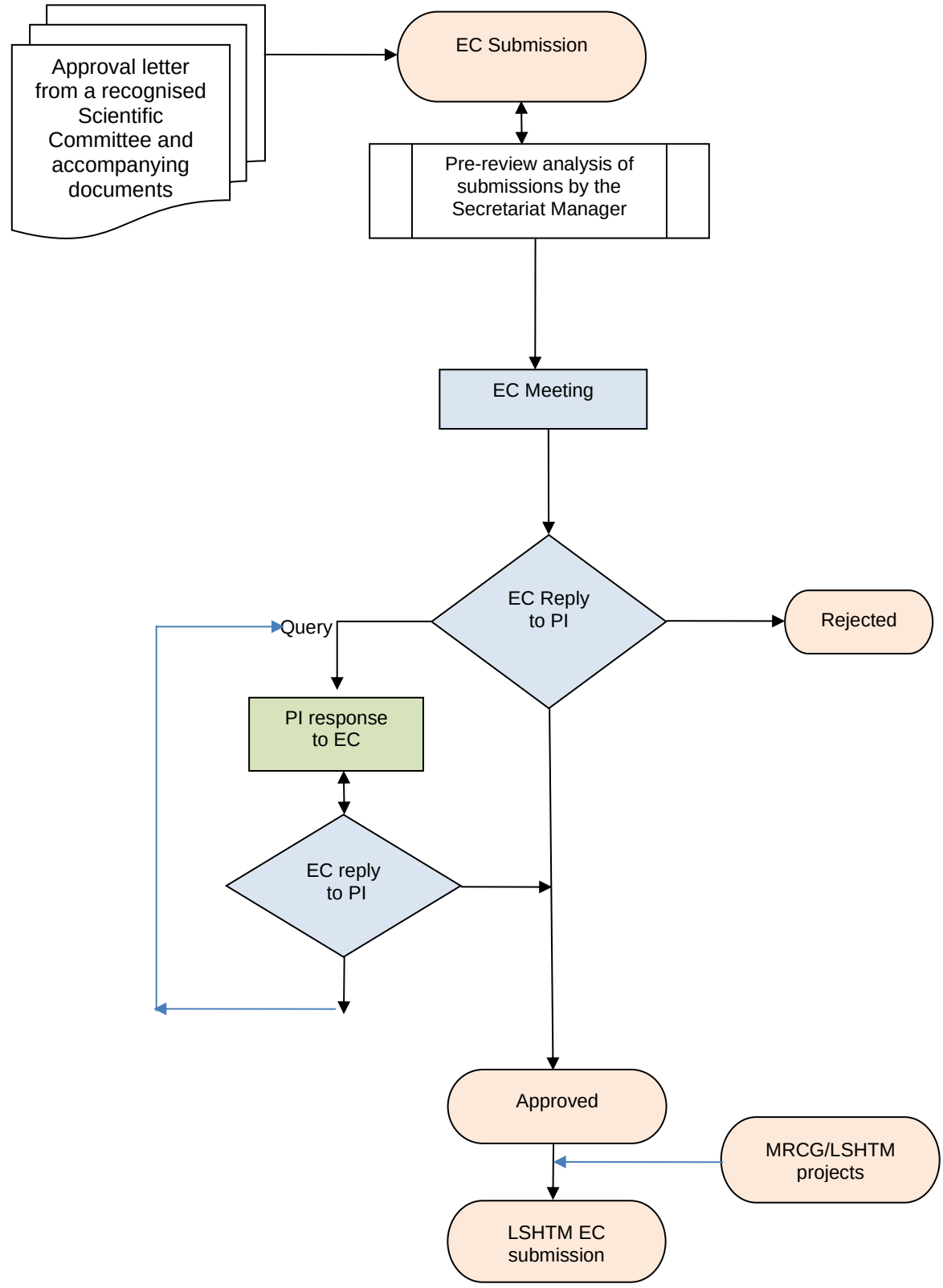
3.	Nuffield Council on Bioethics - The Ethics of Research Related to Healthcare in Developing Countries, 2002 [205pp; ISBN 0-952-2701-96; £3] The ethics of research related to healthcare in developing countries – Nuffield Council on Bioethics (accessed on 05 October 2025).
4.	Nuffield Council on Bioethics - Research in global health emergencies: ethical issues (2020) https://www.nuffieldbioethics.org/publication/research-in-global-health-emergencies-ethical-issues/ (accessed on 05 October 2025).
5.	Nuffield Council on Bioethics - Research in global health emergencies: ethical issues (2020). https://cdn.nuffieldbioethics.org/wp-content/uploads/RGHE_one_page_summary_-_ethics_committees1.pdf (accessed on 05 October 2025).
6.	Belmont report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979). The Belmont Report | HHS.gov (accessed on 05 October 2025).
7.	International Council for Harmonisation (ICH) - Good Clinical Practice (GCP) E6(R3) (2025). ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf (accessed on 05 October 2025).
8.	World Health Organization (WHO) - Guidance for best practices for clinical trials (2024). Guidance for best practices for clinical trials (accessed on 05 October 2025).
9.	US Federal Regulations: 45 CFR 46. Available from http://www.hhs.gov/ohrp/humanparticipants/guidance/45cfr46.htm (accessed July 2025)
10.	World Health Organisation (2011). Standards and operational guidance for ethics review of health-related research with human participants. https://www.who.int/publications/i/item/9789241502948 (accessed July 2025).
11.	ICRP. (2018). Ethical Foundations of the System of Radiological Protection. ICRP Publication 138. Ann. ICRP 47(1). ICRP (accessed 05 October 2025).
12	The UK Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (accessed on 05 October 2025).
13	The Gambia regulatory authority, Medicine Control Agency - Guideline for Clinical Trials in Humans (2025). MCA-GL-501_v3_Clinical-Trials_24Jan25.pdf (accessed on 05 October 2025).

6) Appendices

6.1) Appendix 01: Document History

Version number	Change history	Author(s)	Date
1.0	New document	Naffie Jobe & Farba Faye	23 January 2026

6.2) Appendix 02: Ethics Committee Flow Chart



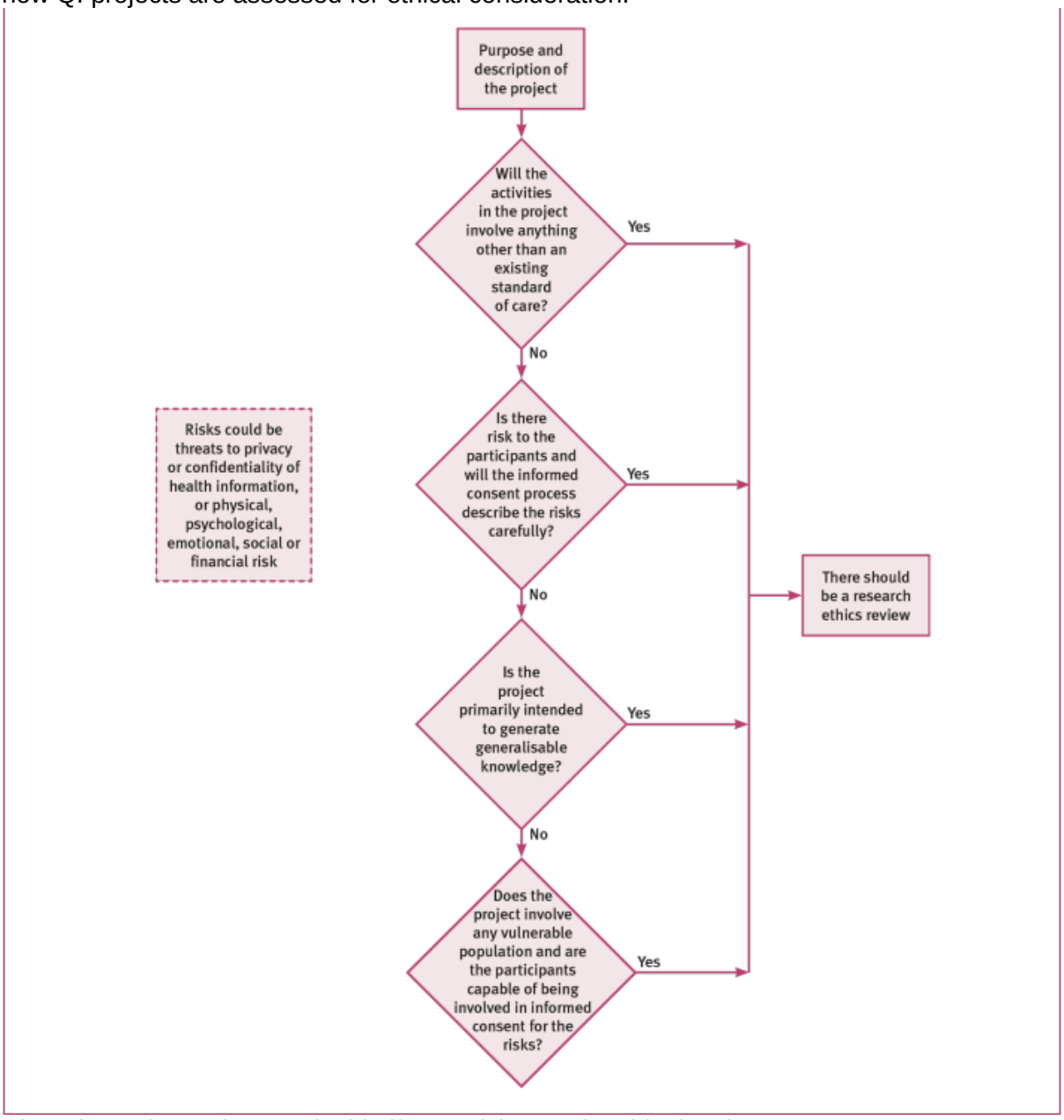
6.3) Appendix 03: Types Of Applications Submitted For Ethics Review

6.3.1) New Application

To undertake a research project that involves human participants.

6.3.2) Audit/Quality Improvement

This guide is intended to help the QI lead project who plans to perform a quality improvement work or publish QI findings when the work has already been done. The EC will review and develop arrangements for effective ethical oversight of QI and clinical audit and service evaluation activities, as required. All QI projects should be assessed for ethical consideration to decide if they need ethical review before a specific activity can commence. The flow chart below describes how QI projects are assessed for ethical consideration.



Flow chart of questions to decide if an activity needs ethical review

Questions to guide the decision on QI or clinical audit projects or service evaluations that should be screened for possible ethical issues are in the below questionnaire.

Does the proposed QI or clinical audit project or service evaluation have any of the following ethical issues that need consideration before starting the project?

Infringe on any patient's rights?
☐ Yes ☐ No

Risk breaching any patient's confidentiality or privacy?
☐ Yes ☐ No

Place a burden on a patient or carer or staff beyond those of the patient's routine care?
☐ Yes ☐ No

Involve any clinically significant departure from usual clinical care?
☐ Yes ☐ No

Involve a potential conflict of obligation to patients, for example, a trade-off between quality and cost?
☐ Yes ☐ No

Involve the use of any untested clinical or systems intervention, including an artificial intelligence (AI) system?
☐ Yes ☐ No

Allocate any interventions differently among groups of patients or staff?
☐ Yes ☐ No

Provide no direct benefit to patients or patient care?
☐ Yes ☐ No

Involve patients who are vulnerable, including homeless or deprived, having limited use of English language, or a disability?
☐ Yes ☐ No

If the answer to any of these questions is yes, the project should have ethical consideration

When the project has already been completed and or a draft manuscript is written, the project lead should write a letter to the chair of EC explaining that the work was done as a quality improvement project and hence ethical approval was not sought, send the letter with the manuscript to request a waiver.

Questions to guide the EC chairperson whether the findings of QI or clinical audit projects or service evaluations should be screened for possible ethical issues are in the below questionnaire.

Do the findings from a QI or clinical audit project or service evaluation represent any of the following ethical issues?

A serious risk for patients whose care was measured or for similar patients, for example, if care actually provided was inconsistent with evidence-based practice?
☐ Yes ☐ No

A patient for whom a life-threatening or quality-of-life threatening shortcoming in care happened, for example, if a patient with a diagnosis requiring specialist treatment was not referred for treatment?
☐ Yes ☐ No

Data that could be used to identify any patient included in the project by anyone not involved directly in the project?
☐ Yes ☐ No

Patients experience a clinically significant departure from usual and standard clinical care, for example, if patients require a follow-up assessment, but there is no evidence that the follow-up took place?
☐ Yes ☐ No

If the answer to any of these questions is yes, the implications for the patients involved should be assessed

6.3.3) Amendment/Modification

These are generally considered to be any change made to the study that impacts the reviewed and approved application, the protocol or any other supporting documentation. Any amendment/modification (this includes minor and significant changes) to the original research project must be submitted to the Ethics Committee for review. The proposed changes must not be implemented until a review takes place and approval granted.

The Secretariat will triage the application and refer significant amendments to the Committee for review.

Where the Secretariat deems the amendment to be minor based on a set criterion, this will be forwarded for expedited review by the Scientific Advisor and Chairperson, and their opinion will be confirmed in writing.

The ESM updates the committee on expedited reviews at each Committee meeting.

NB: No changes to the protocol and related documents should be implemented without prior written approval from the Ethics Committee, except when necessary to eliminate immediate hazards to the participants.

Amendment Definitions

6.3.4) Minor Amendments

1. Minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications.
2. Change of Principal Investigator or the Research Team.
3. Change of investigators at a particular trial site (other than appointment of a new Principal Investigator in a clinical trial).
4. Changes in funding arrangements.
5. Inclusion of new sites and investigators in studies other than clinical trials and interventional studies.
6. Extension of the study beyond the period specified in the application form.
7. Updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial).
8. Changes in contact details for the sponsor (or the sponsor's representative), chief investigator.

6.3.5) Substantial Amendments

1. Sample or data transfers.
2. Future use of human biological samples.
3. Changes to the design or methodology of the study, or to background information affecting its scientific value.
4. Changes to the procedures undertaken by participants.
5. Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study.
6. Significant changes to study documentation such as participant information sheets, consent forms, questionnaires, information sheets for relatives or carers.
7. A change of Sponsor.
8.
9. Temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt.
10. A change to the definition of the end of the study.

12 Any other significant change to the protocol or the terms of the previous ethics approval.

6.3.6) Protocol Deviation Or Violation Report

EC requires that changes in the conduct of an approved research study receive prior review and approval. When changes to the protocol are necessary to immediately eliminate or reduce an apparent hazard to the safety of research participants or others, those changes may be initiated without prior EC approval, but must be reported to EC within 10 working days of initiation for review at the next committee meeting.

6.3.6(i) What, When, and How to Report protocol deviation/violation /research related incidents to EC

Type of Incident	When to Report	Reviewer*
1. Important Deviation/Violation including, but not limited to incorrect intervention given, enrolment of ineligible participant, key safety procedure/lab not done or done outside window. 2. Key safety procedure/lab not done or done outside window	Within **10 days** of occurrence	Chairperson/Designated Person
Immediate protocol changes to protect participant safety	Within **10 days** of occurrence	Chairperson/Designated Person
Potential breach of confidentiality	Potential breaches of privacy or confidentiality**:** Within **48 hours** of occurrence	Chairperson/Designated Person
Important Incident including, but not limited to problem with consent or recruitment process, significant complaint or concern, lapse in study approval, loss of adequate resources	Other I**mportant** Incidents: Within **10 days** of occurrence	Chairperson/Designated Person

* These will be reported in the next full committee meeting.

Possible subsequent actions may include the following

1. **Acknowledge the incident** – if there are no queries.
2. **Request additional information** about the incident or other related information.
3. **Flag the report and monitor the study** for additional incident reports.
4. **Require a modification** to the protocol and/or informed consent document.
5. **Temporarily suspend** enrolment and/or study treatment.
6. **Permanently suspend or terminate approval** of research that has been associated with unexpected serious or continuing noncompliance.

6.3.7) Data Sharing

This is the practice of making research data available to others. The Secretariat will confirm that the approved protocol and ICD allow the sharing of individual data as proposed by the investigator. The following will be considered:

- If the sharing of participant data is not approved as part of an initial protocol review, a protocol amendment may be required later and EC will review whether the sharing of data is consistent with the scope of consent originally obtained from participants.
- Additional consent may be required if not originally addressed.
- Any investigator who plans to submit data into an open access database must be certain the informed consent document describes the plan to share data in an open access database.
- Any investigator who plans to share data with collaborators must be certain the ICD describes the plan to share data and must employ MTA/DSA.
- Any student investigator who plans to share data with university/supervisor must be certain the informed consent document describes the plan to share data and must employ an MTA where applicable.

6.3.8) Continual Review Of Research Following Favourable Opinion

Quarterly reports must be submitted to the EC to ensure they are continually informed of/involved in the progress of the research.

6.3.9) Waiver Of Documentation Of Informed Consent

EC may choose to waive the requirement to obtain written documentation of informed consent for:

i. research that presents no harm to participants;
ii. research that involves procedures or activities for which written consent is not normally required outside of the research context;
iii. the waiver or alteration will not adversely affect the rights and welfare of the participants;
iv. the research could not practicably be carried out without the waiver or alteration;
v. in cases in which the documentation requirement is waived, EC may require the PI to provide participants with a Letter of Information regarding the research.

Note: This provision can be used only for the waiver of documentation of consent.

6.3.10) AEs/Safety Information

Any unforeseen events or unfavourable medical occurrence including abnormal signs, symptoms or disease temporally associated with participant's participation in the research, whether considered related or unrelated to the participant's participation in the research must be reported to the EC. It is recommended to appoint a DSMB and medical safety monitor who will be reviewing SAEs and sharing reports with the PI and EC. The EC may also review SAEs and consult experts for causality assessment.

This applies primarily to regulated and interventional studies.

For non-interventional studies, the following applies:
Incidents in relation to the research participants resulting in significant negative outcomes (e.g., death, hospitalisation, disability, life-threatening) that can arise from study procedures, participant vulnerability (e.g., older adults, advanced illness) must be reported to the EC.

6.3.11) Reporting Format Or Frequency

The chart below describes which AEs/ and safety information need to be reported to EC.

6.3.11(i) What, When, and How to Report AEs/Safety Information To EC

Type of Event	When to Report*	How to Report/Review Timeline*
Adverse events/safety reporting timeline		
Minor/moderate unrelated	AEs that are unrelated to the research do not need to be reported to EC promptly. Unrelated AEs should be documented in the study records and may require notifying EC at quarterly as safety reports and must be submitted in a line listing format.	Complete the online application and attach the line listing format.
Serious but unrelated	Within 10 working days of event happening	Complete the online application and attach the SAE report template.
Definitely, probably or possibly related	Within 10 working days of event happening NB: In each safety report, the PI must identify all safety reports previously submitted to EC concerning a similar suspected adverse reaction and must analyse the significance of the suspected adverse reaction considering previous, similar reports or any other relevant information	Complete the online application and attach the SAE report template.
Other types of events/safety reporting timeline		
SUSAR/SAR Findings from other sites with the same IMP	Within 3 days of event happening SUSAR/SAR that occur at other clinical trial sites *must* be reported to EC, especially if they indicate a new risk, potentially leading to protocol changes or safety warnings across all sites. **NB:** Such a finding would result in a safety-related change in the protocol, IC, IB or other aspects of the overall conduct of the trial.	Complete the online application and attach the SAE report template. Submission of SUSAR/SAR report should be followed up with an email alert to ethics@mrc.gm
DSMB/DMC Report	As requested by EC (to aid the review of SUSAR/SAR)	PI to upload the report in LEO or email it to ethics@mrc.gm
Post Marketing ADR	Within 7 days of event happening (A detail account of the ADR must be provided to EC). **NB:** Such a finding would result in a safety-related change in the protocol, IC, IB or other aspects of the overall conduct of the trial.	

***** To be reviewed in full meeting

NB: If an adverse event not initially determined to be reportable is considered reportable, PI must report such event or reaction as a safety report as soon as possible, no later than 10 calendar days after the determination is made.

Possible subsequent actions may include the following:

i. **Acknowledge the report** — if there are no queries.
ii. **Request additional information** about the adverse event or other safety information.
iii. **Require a modification** to the study protocol, investigator brochure and/or informed consent document.
iv. **Flag the report and monitor the study** for additional AEs.
v. **Temporarily suspend** research activities.
vi. **Permanently suspend or terminate approval** of research that has been associated with unexpected serious harm to participants.

6.3.12) Quarterly Progress Report

The EC must be informed of the progress of studies by providing a quarterly progress report on the anniversary of the confirmation of favourable opinion. Quarterly progress reports should be submitted thereafter until the end of the study. This is to ensure that EC maintains appropriate ethical oversight of ongoing research.

1. MSc students who complete their projects within one year of receiving a favourable opinion are not expected to submit quarterly report but are required to submit end of study report to the EC.
2. AEs should also be reported as part of the quarterly progress report detailing the overall AEs.

6.3.13) End Of Project Report/Early Termination Of A Project

This must be submitted to update EC on the progress of the research. In the case of early termination, EC must be informed about the reason for the early termination of a research project.

6.4) Appendix 04: Obtaining Consent From Non-English Speakers

Informed consent must be obtained in language that is understandable to the participant (or the participant's LAR). EC requires that the informed consent meeting includes an independent witness when the prospective participant does not understand the language in which the ICD was written.

The appropriately translated consent documents should be submitted for review and approval prior to their use in enrolling participants including audios and/or videos.

EC may utilise expedited review procedures in approving such documents if the English language consent document has already been approved, and the investigator provides certificate(s) of translation.

6.5) Appendix 05: Re-consenting Of Research Participants

EC requires that informed consent be legally effective and properly documented. Re-consenting is as an action in which a participant (or representative) makes the decision to

participate in research once again. Situations that might warrant re-consenting are:

1. Failing to inform the participants about important risks related to the study.
2. Conducting the consent when the participant's decision-making capacity was compromised, or the participant was under duress.
3. Using an improper representative for a participant who is not capable of making an informed choice.
4. Significant changes in the research procedures, risks, potential benefits, or alternatives.
5. The participant's medical condition worsens or does not respond to treatment.
6. Research in which paediatric participants will reach adulthood while the study is still in progress, such as a longitudinal, prospective cohort study that follows children from birth through adulthood.
7. Re-consenting of participants who have completed their active participation in the study, or of participants who are still actively participating, when the proposed change will not affect their participation is **not necessary.**
8. However, when changes do occur in the conditions or the procedures of a study that would affect an individual participant, the investigator should once again seek informed consent from the participants.
9. EC does not require a participant re-consent at the time of the study continuation approval, unless there have been modifications to the consent form that would affect an individual participant.
10. Improperly documented consent such as:
    i. A participant did not sign the consent form.
    ii. An inappropriate legal representative signed for the participant.
    iii. The consent form was not translated into the participant's or representative's language and an independent witness wasn`t present.
    iv. The study's approval had expired during the time when the participant consented.
    v. The consent document contained some legally invalid language, such as a waiver of the participant's legal rights.
    vi. An outdated version of the consent form was used.

6.6) Appendix 06: Compensation And Evacuation Plan For Clinical Trial Participants

1. **Compensation for injury:** Where applicable, this must be clearly outlined in the informed consent document for EC to review and approve.
2. **Compensation for treatment for injury:** Where applicable, this must be clearly spelt out in the informed consent document for EC to review and approve.
3. **Evacuation plan:** Where applicable, this must be clearly spell out in the ICD for EC to review and approve,

6.7) Appendix 07: Research Audits/Inspections

As part of its functions to monitor continuing research, EC decides on the need to audit research studies based on the following criteria:

i. Reports of remarkable serious adverse events.
ii. Non-compliance or suspicious conduct.
iii. Not submitting information/reports on time.
iv. Insufficient recruitment.

Before the audit:

Members will decide on who will represent the committee, supported by the MRCG Research Governance Team.

During the audit:

The auditors will:

- ensure all research activities are conducted ethically and in accordance with relevant regulations and guidelines.
- transparency and integrity complied with in accordance with the terms and conditions of the ethical approval.
- review the informed consent document to make sure that the study is using the most recent approved version.
- Review randomly the participant files to ensure that participants are signing the correct informed consent.
- observe the informed consent process, if possible.
- collect views of the study participants, if possible.
- review any study document as deemed necessary.

After the visit:

- The auditors will provide a report within 2 weeks describing their findings.
- Submit the audit report to the Ethics Secretariat for full committee review.

Review audit report during EC meeting

- The Ethics Secretariat shall schedule the presentation of the audit report on the meeting agenda.
- A representative of the auditors shall present the results to the full committee.
- The full committee will discuss the findings and comments on the report.
- The Ethics Secretariat shall record the discussion and decision in the meeting minutes.

Notify the study audit

- The Ethics Secretariat shall notify the PI/study site of the Committee's decision and recommendation within 10 working of the meeting.

6.8) Appendix 08: Complaints Regarding Human Participant Research

- When the Secretariat receives a complaint, the ESM will share the information with EC Chairperson and Scientific Advisor in the first instance.
- EC will acknowledge receipt of the complaint by a letter while the investigation is ongoing.
- EC Chairperson, Scientific Advisor and ESM will meet to assess the need to investigate the complaint.
- When the complaint involves sensitive issues, the EC Chairperson will advise ESM to include it to the next committee meeting for discussion and recommendations prior to initiating any activity.
- Where the need arises, the EC Chairperson will nominate an investigation committee to investigate the allegations and report back the findings to EC.
- The findings of the investigation committee will be shared with the ESM for inclusion onto the next committee meeting agenda for discussion. A determination will be made by EC for any further actions that are to be taken.
- EC Chairperson will formally respond to the complainant about the findings of the investigation committee.

6.9) Appendix 09: Appeal Process

The PI may appeal the decisions of the EC in writing.

The PI should clearly stipulate the basis of the appeal and attach supporting documentation.
The Secretariat will receive the appeal and conduct an initial review of the appeal, and the appeal will be forwarded to the Chairperson for consideration of next actions.

The Chairperson may hold a closed session without the researcher to discuss the details of the research application and the appeal.

Alternatively, the PI may be invited to the meeting to discuss the details of the appeal.
If PI is a member of the committee, he/she will be recused during decision making.

After the review, EC may grant favourable ethical opinion of the research based on the appeal.
EC may also provide a provisional opinion requesting revisions or further information or they may uphold the original opinion.

Appeal findings will be provided to the PI in writing.
If the decision to disapprove the application is upheld – the decision of appeal is regarded as final.
The PI is allowed one appeal.

If applicant is still unsatisfactory, the matter can be escalated to the Director of Health Services at the MOH and Unit Director, MRCG who are ex-officio members and are responsible for the EC.
NB: Their intervention will not impact the decision of the EC.

Ethical Review Manual_23Jan2026

Final Audit Report 2026-01-22

Created:	2026-01-22
By:	Bai-Lamin Dondeh (bai-lamin.dondeh@lshtm.ac.uk)
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Signer chamk46@yahoo.co.uk entered name at signing as Mkcham

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Signing reason: Chairperson JEC

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