The Gambia Government/MRCG Joint
ETHICS COMMITTEE

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The Gambia Government/MRCG Joint Ethics Committee (EC) Guidelines for Investigators		
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Abbreviations

AE – Adverse Event
CV – Curriculum Vitae
DSMB/C – Data Safety Monitoring Board/Committee
DMC – Data Monitoring Committee
EC – Gambia Government/MRCG Joint Ethics Committee
FWA – Federal wide Assurance
GCLP – Good Clinical Laboratory Practice
GCP – Good Clinical Practice
GDPP – Gambia Data Protection and Privacy Policy
GLP – Good Laboratory Practice
GMP – Good Manufacturing Practice
ICD – Informed Consent Document
ICD – International Classification of Diseases
ICH-GCP – International Council on Harmonization of Good Clinical Practice
IDMC – Independent Data Monitoring Committee
IMP – Investigational Medicinal Product
IP – Investigational Product
IRB – Institutional Review Board
ISF – Investigator Site File
LEO – London Ethics Online
LSHTM – London of School of Hygiene and Tropical medicine
MCA – Medicines Control Agency
MDTA – Material & Data Transfer Agreement
MOHERST – Ministry of Higher Education, Research, Science and Technology
MRCG – Medical Research Council Unit The Gambia
MTA – Material Transfer Agreement
OHRP – Office for Human Research Protections
PACTR – Pan African Clinical Trials Registry
PI – Principal Investigator
RA – Regulatory Authority
SAE – Serious Adverse Event
SOP – Standard Operating Procedures
TMF – Trial Master File
TOR – Terms of Reference
WHO – World Health Organization

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1 General

These Guidelines are addressed to investigators, and sponsors of clinical research whether for academic purposes or for generation of data intended for inclusion in the regulatory submissions for medicinal products. These guidelines are developed in line with country and region-specific guidelines as well as guidelines from the Declaration of Helsinki (October 2024), ICH-GCP E6 R3 (23 July 2025), Part 46 of Title 45 of the Code of Federal Regulations, and The Gambia Medicines Control Agency (MCA) Guideline for Clinical Trials in Humans (26 February 2025) and WHO Guidance for best practices for clinical trials (2024). Any further changes to the national and international guidelines and recommendations will be considered and incorporated to the current guidelines accordingly.

The conduct of research in The Gambia is governed by a comprehensive set of national laws and policies designed to ensure ethical, inclusive, and responsible research practices. Key pieces of legislation include the Children's Act (2005), the Persons with Disabilities Act (2021), the Public Health Act, the National Health Policy (2012–2020), Gender Policy and GDPP. Additionally, the National Research Policy, under the Ministry of Higher Education, Research, Science and Technology (MOHERST), provides further guidance. These laws and policies ensure the protection of rights and well-being of research participants, safeguard sensitive data, and promote the advancement of knowledge.

Any research protocol needs first to be approved by a recognised Gambian scientific committee or board before submission to the Ethics Committee (EC). This should ensure that the science is sound before ethical judgements are made – see **appendix 1** for guidance.

New research protocols will be presented in an application form (e.g. the ethics application form or the SCC Application form) that allows detailed description of the research protocol. All EC applications are submitted via London Ethics Online (LEO) using http://leo.lshtm.ac.uk.

Applications to change an ongoing research protocol (amendments) or to conduct an ancillary study which is a continuation or modification of an ongoing approved research protocol or a pilot study for validation of techniques should be submitted as amendments. The amendment will describe any change that significantly affects the safety of participants, the scope of the investigation or the scientific quality of the study. Examples of changes that generally require formal amendment include, but are not limited to:

- changes in drug dosage or duration of exposure of participants to an investigational product beyond that described in the current protocol;
- significant increase in the number of participants under study or in the duration of the study;
- significant change in the study design, such as adding or dropping a study arm; and
- addition of a new test or procedure that is intended to improve monitoring for or reduce the risk of a side effect or adverse event, or the dropping of a test intended to monitor safety.

Requests for further use of stored biological samples or data collected as part of an already completed study, PI must verify if the proposed use is covered under the original approval, if covered and with valid approvals, no further review is required. If not covered, a new application must be submitted.

The Ethics Committee is registered with the US Office for Human Research Protections (OHRP) with an IRB #: IRB00003943 and Federalwide Assurance #: FWA00006873.

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2 Registration

Proof of registration of the trial with a Clinical Trial Registry shall
be submitted as part of a Clinical Trial application. The EC recommends the Pan African Clinical Trials Registry (PACTR).

3 Good Clinical Laboratory Practice Inspections

Inspection is the act by EC of conducting an official review of documents, facilities, records and any other resources that are deemed to be related to the clinical trial and that may be located at the site of the trial, at the facilities, or at other establishments deemed appropriate. Part VII, section 45 of the Medicines and Related Products Act, 2014 stipulates that the Agency (MCA) shall monitor a clinical trial from the beginning to the end in order to ensure that the specific and general conditions subject to which the trial was authorised are being strictly observed by the person conducting the trial and that the trial will achieve its aims and objectives.

The Medicines and Related Products Regulations, 2020 requires (in section 79) that the Agency shall inspect a clinical trial to ensure adequate protection of the general public is provided against the risks or adverse effects from the clinical trial of a medicine, and that the trial is conducted in accordance with the Act and the specific and general conditions of the Regulations.

The EC reserves the right to inspect and interrupt any trial for which authorisation has been given, as and when necessary. Periodic GCLP Inspections of the trial sites shall be conducted to verify compliance with the protocol, GCP, GLP, SOPs and applicable regulatory requirements.

Investigator site inspections of clinical trial sites will be planned based on a risk assessment. Critical elements such as, but not limited to, data quality of trial sites, enrolment rates, protocol deviations/violations, sites experience will be considered during site selection. A GCLP inspection can be undertaken before, during or after the conduct of clinical trials.
Note: Delays in reporting may lead to suspension or termination of the study.

4 Opinion from the Ethics Committee

Parallel clinical trial applications to the Ethics Committee and the MCA are encouraged to streamline or minimise the timelines for the clinical trial authorisation process in The Gambia. A favourable opinion from the Ethics Committee is required before the MCA can issue the clinical trial authorisation.

- The PI is required to submit the favourable opinion from the Ethics Committee when issued to the MCA.
- Sequential clinical trial application submission can also be done where the PI submits first to the Ethics Committee and when the favourable opinion is issued by the Ethics Committee the clinical trial application is submitted to the MCA for request of the clinical trial authorisation.

5 Insurance Cover

- All subjects must be satisfactorily insured against possible injuries that might arise during the conduct of the clinical research.
- For all Sponsor-initiated research, a valid insurance certificate for the duration of the study must be provided prior to study initiation.
- Sponsors and PIs shall ensure insurance cover for clinical research participants and shall submit as evidence a Certificate of insurance cover for participants. The certificate shall at least contain:
  - Insurance company
  - Policy number

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- Initial Date
- Expiry Date
- Insured (Policy Holder/Sponsor)
- Description of activity (purpose of the policy)

6 Financial Declaration

- The financial aspects of the trial should be documented in an agreement between the Sponsor and the PI.
- A declaration must be signed by both the Sponsor and the PI which states that there are sufficient funds available to complete the study.

7 Data Safety Monitoring Board/Committee (DSMB/C) or Independent Data-Monitoring Committee (IDMC) or Data Monitoring Committee (DMC)

- An independent data-monitoring committee (IDMC) should be established by the Sponsor to assess at intervals the progress of a clinical trial, data safety, and the critical efficacy endpoints, and to recommend to the Sponsor whether to continue, modify, or stop a trial.
- It is recommended that for trials conducted in The Gambia, at least one member of the IDMC must be a Gambian.
- The Sponsor shall include charter of work, membership and CVs of the IDMC members.
- All members of the DSMB/IDMC/DMC shall sign the charter.
- A DSMB/IDMC/DMC Charter shall include:
  - TOR
  - Membership and their CVs
  - Proof of Independence of the Committee
  - Scope of work for Members/responsibilities of the Committee which is to assess the progress of a clinical trial including safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial
  - Meetings schedule
  - SOPs of the Committee.

8 Investigational Medicinal Product

Investigational Product (IP) or Investigational Medicinal Product (IMP) is a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated and packaged) in a way different from the approved form, or when used to gain further information about an approved use (ICH E6 R3, 3.15 and EU Directive 2001/20/EC).

Study Drug is the overall term for IP and Additional Drug (drug specified in the protocol, other than the IP, supplied by the sponsor).

Good Manufacturing Practices (GMP) are guidelines concerning the manufacture of medicinal products including IMP.

The PI or delegate is responsible for ensuring that:

- The IPs are characterized as appropriate to the stage of development and manufactured in accordance with any applicable GMP or local requirements.
- The IMP is stable for the proposed period of use and that sufficient quantities are available to reconfirm specifications if necessary.
- Study drugs are packed and labelled according to the study protocol.

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- Study drugs are delivered on time and safely shipped to the study site (under the correct conditions).
- Safe and proper storage of study drugs after the study drugs have left the distribution site.
- Study drugs are never delivered to a clinical site before the required regulatory approvals have been received in writing.

9 Informed Consent

A process by which a participant or their legally acceptable representative voluntarily confirms their willingness to participate in research after having been informed and been provided with the opportunity to discuss all aspects of the research that are relevant to the participant's decision to participate.
Varied approaches to the provision of information and the discussion about the research can be used. This may include, for example, providing text in different formats, images and videos and using telephone or video conferencing with investigator site staff. Informed consent is administered and documented by means of a written (paper or electronic), signed and dated informed consent form. Obtaining consent remotely may be considered when appropriate (ICH GCP E6 R3) by using electronic methods, such as email, online forms, or digital signatures.

Informed consent documents (ICDs) should contain clear, preferably brief information, explaining the purpose of the project, the risks and discomfort involved and the benefits to the participant or society, the time and responsibilities for the participant involved and the kind of samples and amount of blood likely to be taken, if applicable, and how many participants will take part. It should contain a statement that participation is entirely voluntary and, that the participant can withdraw as desired at any time without any penalties for such action. It should also contain a statement about the confidentiality of the data. If specimens or information are to be stored, shared and possibly used for future research, in addition to the current project, this should be stated. The type and length of medical care that the participant is to receive, the kind and amount of compensation, if any, and the information he/she will receive as a result of the tests and the time this will take should also be clearly stated.

Consent for harmless procedures or procedures with minimal risk (such as a finger prick) can be given orally after an acceptable explanation by a field worker, nurse or doctor was provided. This must be documented. In these cases, the consent form will be wet or electronically signed by the investigator or designee (e.g. trained field worker), which denotes that he/she has delivered the explanation.

9.1 Assent

Consent for minors (age <18 years) should be obtained from a parent or guardian in studies involving minimal risk. In case of children aged between 12 and 17 years, assent should be obtained, preferably in writing, in addition to the consent from the parent/guardian. In the case of younger children (aged about 11 years and below) the willingness for participation should be considered. Emancipated minors who are married adolescents, can consent for themselves. Please see **appendix 2** for details on the ICDs review.

10 Reporting of Safety Issues

A safety issue arisen from any trial activity needs to be promptly evaluated and reported. Following identification of a safety related issue, the PI is obliged to inform the EC. The notification should be made as soon as the issue is discovered and no later than 10 days. Safety issues are defined as those that had or may to a significant extent affect safety, rights and integrity of clinical trial participants.
The following actions need to be taken within 48 hours (or sooner if deemed necessary) of EC knowledge of the event:

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- Suspension of the trial in case of urgent safety concern with potential immediate impact on clinical trial participants. One EC member maybe involved in the decision related to trial suspension to provide an independent quality assessment of the issue. In case of the need to remove immediate hazard to trial participants, the EC may suspend the clinical trial prior to the sponsor decision.
- Actions to be taken including containment actions and plans for future corrective/preventative actions.
- Any potential legal actions.

If an issue is confirmed as urgent safety measure for a given trial or requires reporting for a different reason, EC needs to be notified according to the relevant regulations

11 Reporting and Managing Adverse Events

The Sponsor of a clinical trial and PIs participating in a clinical trial are responsible for proper reporting of Serious Adverse Events (SAEs). The Sponsor should expedite the reporting of all adverse drug events (AEs) that are both serious and unexpected.

- Any SAE to the investigational product shall receive immediate medical attention and reported to EC within forty-eight (48) hours after receiving knowledge of the SAE.
- The SAE report form shall be completed and detailed information such as laboratory results submitted to enable causality assessment report by the Expert on drug safety and clinical trials of the EC.
- All fatal cases shall be accompanied by a formal autopsy report.
- In exceptional circumstances where a formal autopsy is not practicable, provision of a verbal autopsy report shall be approved by EC prior and shall be submitted with adequate reasons. Verbal autopsy shall be conducted in line with the World Health Organisation guideline for verbal autopsy. The cause of death shall be classified according to the current International Classification of Diseases (ICD) guideline.
- Any AE to the investigational product shall receive immediate medical attention and reported to the EC annually.

The PI is required to submit follow-up information as soon as it becomes available. Additional information may include copies of diagnostic test results, laboratory reports, or medical record progress notes. All additional information should be clearly marked as update information and should include the Protocol Number and Participant Number. All personal information should be masked.

12 Progress Report

- The EC should be informed in writing on the exact date of commencement of the study.
- Annual reports of the progress of clinical research starting from the date of issuance shall be submitted to EC.
- If the research is interrupted before its purpose is achieved, the reason shall be conveyed in writing to the EC within ten (10) working days. This shall include:
    - Justification for the premature ending or of the temporary halt of the research.
    - Number of participants/patients receiving IP/treatment at the time of the study termination.
    - Proposed management of participants/patients receiving IP/treatment at the time of halt or study termination.
    - Consequences of the evaluation of the results.

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13 Premature termination or suspension of a clinical study

The decision of premature termination or suspension of a study may be due to one of the following:

- Urgent safety issue (preclinical/toxicology or clinical).
- Non-compliance, misconduct or fraud.
- A decision by the EC Safety Reviewer and/or IDMC that the study must be terminated as it has met the completion criteria.
- Other concerns, e.g. shortfall or stock-out of study medication assessed as requiring temporary suspension/termination of the study.

If a decision of premature termination of the study is taken:

- The PI plans for appropriate therapy and follow-up for relevant study participants dependent on the individual situation and if not covered by the study protocol and/or local regulations.
- The PI ensures that EC is informed in writing of the decision to prematurely terminate the study and the reasons for this decision in accordance with required timelines.

In case of temporary suspension of the study:

- The PI ensures that all investigators are informed that the study is prematurely terminated, and the reasons for this decision. The sponsor should instruct the investigators to inform the local EC and all participating subjects of this decision and of any relevant therapy and follow-up which they will receive as per local regulations.
- The PI informs all partners that the study is prematurely terminated.

NOTE: In case EC suspends the approval of the study, the investigator will forward the EC letter concerning this decision to the sponsor who will then ensure that actions are taken accordingly, and all parties involved are informed.

14 Blood Collection

The collection and analysis of peripheral blood samples from both healthy participants (adults and children) and patients is a vital and widely accepted part of biomedical research. The collection of blood samples must be guided by both physiological considerations, to ensure that the volume collected cause no more than minimal risk to healthy participants and patients.

Also, by ethical principles, to ensure the distress and inconvenience of blood sampling is justified by the research question being addressed, by any other benefits to the participant or patient from taking part in the study and is minimized overall. These are distinct issues and must both be considered when designing or scientifically and ethically reviewing a study.

14.1 Points To Consider In Study Design Re Blood Volumes And Sampling Frequency

- Taking a blood sample will cause some pain and distress, particularly in children and those who are unable to consent/assent for themselves and must be justified by the research question. The volume and frequency of blood sampling that is acceptable will be influenced by the potential benefits of the study to the participant or patient. For example, the volume and frequency of blood sampling in patients who may gain significant benefit from taking part in a study, will generally be greater than for a healthy volunteer, particularly a child, who may gain little or nothing from taking part.
- Both the volume and frequency of blood sampling must always be minimized based on the needs of the research study. The blood volumes taken should allow for any

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limited repeat testing which may be needed (e.g., if an assay fails). Particularly in clinical research, when a participant is exposed to some risk associated with an investigational product, having inadequate samples to conduct the primary analysis may also be unethical. However, taking extra blood samples or excess blood volume without justification is not acceptable. This does not exclude taking samples to be stored in a biobank for future research when this is scientifically and ethically justified.

- In general, the acceptable sampling frequency in infants and children and in others who cannot consent/assent for themselves will be lower than that of adults who can consent for themselves.
- The volume and frequency of blood sampling must be justified thoroughly in the research protocol/application.
- The guidance applies to studies in healthy volunteers and to most studies in patients with underlying health conditions. In patients in whom there is a specific clinical risk of significant underlying anaemia (including pregnant women), particularly when serial blood samples or high blood volumes are needed, a baseline haemoglobin or hematocrit measurement may be warranted. However, this is not generally required, if it is a clinical decision which is the responsibility of the principal investigator (or clinically qualified senior delegate if applicable) to make and should not be routine unless for other reasons.
- In patients, in whom blood samples for clinical care will also be needed, these must be subtracted from the volume taken for research purposes only, so the total volume does not exceed the below recommendations.
- These guidelines must not be used to guide blood sampling for clinical care alone. In this case, the physician in charge of the patient's care should assess the need for a particular blood sample based on their own risk-benefit analysis (as per normal medical practice). If a significant number of extra blood samples are needed for clinical care (which may not have been accounted for in the study design) these must always take priority.
- The size of the blood samples that are acceptable are specified in millilitres/kilogramme (mL/kg) body weight. The volumes must be calculated based on a conservative (low) estimate of the expected participants weights and generally should be specified in the protocol in mL rather than mL/kg, so errors are avoided.
- The use of the same mL/kg limits across all age groups is generally, appropriately more conservative for newborns, infants and young children as the total blood volume in mL/kg is generally higher in progressively younger age groups (hence the percentage of the total blood volume taken with a sample will be lower).
- Dried blood spots (and point of care tests requiring only a drop of capillary blood) may be an option for some assays and offer significant practical advantages, particularly for large scale field surveys, if the scientific questions allow.
- No more than 3 attempts to obtain a peripheral blood sample should be made on any one visit. The third of these attempts should generally be made by a different person and the most skilled person available. This should be stated in the protocol/application.
- Peripheral and central arterial, and central venous stabs (e.g., at the femoral vein) are not acceptable to obtain blood samples for research alone. If arterial blood specifically is needed (for example in the context of a study of high dependency or intensive care or cardiorespiratory disease) this must be explained in detail.
- For repeated sampling over a short period (e.g., for pharmacokinetic studies) an indwelling peripheral cannula may be considered if the scientific question allows. If

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a central venous catheter is in place for clinical care this may be used for blood sampling if the protocol allows.

- Blood is viewed with considerable sensitivity by many in Gambian society including as being something which is not replaced/finite. There are also several long-standing sensitivities related to blood sampling for research. These issues have the potential to impact on the feasibility of a study, the rate of recruitment and the rate of retention which must be taken seriously. Anyone without knowledge or experience of this issue is strongly encouraged to discuss with someone with appropriate local knowledge and experience and to take the advice given seriously.

14.2 Summary Of Maximum Acceptable Blood Volumes And Sampling Frequencies

The below **table 1** indicates the **maximum** amounts of blood that can safely be taken on a single occasion (or within a single 24-hour period) and within an 8-week period without significant risk.

At a single blood draw (and within a single 24-hour period)	2 mL/kg up to a maximum of 140 mL
Within a single 8-week period	5 mL/kg up to a maximum of 350 mL

If toward the maximum allowable limits, the volumes must be calculated based on reasonable conservative estimates of the weights of the population to be recruited. Basing estimates on global averages is not acceptable as this will not generally reflect the population to be sampled.

No specific maximum number of samples over a given period/sampling frequency is specified if the total volume remains within these limits. For some studies (e.g. pharmacokinetic studies) quite a number of samples may be needed within a single 24-hour period with other long-term studies, samples will be much more widely spaced. However, as described in the points for consideration, the volumes and frequencies must be both kept to a minimum needed, to answer the research question and thoroughly justified. It is very unlikely that volumes above. Those specified in the table will be considered.

15 Reimbursement Of Study Participants

15.1 Applicability And Scope

This policy applies to medical research projects involving human participants, in which participants are invited to a study site and incur incidental expenses or loss of earnings (or lost wages) due to their study participation.

This policy also applies to other research including social science studies in which individuals are selected for participation within their communities or at a clinical/hospital setting for data collection activities, and where data collection is likely to take time away from their routine daily tasks and/or add time to their healthcare-seeking within the facility. This would include survey questionnaires, qualitative interviews, group discussions, and participatory action research.

Reimbursement does not apply to hospital-based studies in which persons seeking care are approached within their in-hospital patient flow for questionnaire/sample collection or administration of study intervention without altering this hospital flow or requiring study-related invasive procedures (excluding routine sample collection).

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15.2 Definitions

A Healthy Volunteer as a participant is an individual with no known significant health problems who participates in research to test a new drug, device, or intervention.
It is also recognised that participants can be selected for observational or intervention studies due to a particular health condition or experience they have had, e.g., pregnant women, individuals with hypertension, etc., for a better understanding of their perceptions and lived experiences of the condition and/or available treatments.

An Invasive Procedure is one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, including, but not limited to, endoscopes, catheters, scalpels, scissors, devices and tubes. In this policy, the term 'invasive procedure' excludes routine sample collections, such as phlebotomy, nasal, pharyngeal, or rectal swabs.

15.3 Responsibilities

It is the responsibility of the PI of a study to reimburse participants for their expenses and loss of earnings/lost wages as applicable.

The PI should state the manner and amount of reimbursement in the informed consent document (ICD), which will need to be reviewed and granted a favourable opinion by The Gambian Government/MRCG Joint Ethics Committee.

The PI is also responsible for:

- Including the anticipated costs for reimbursement in the research budget
- Stating the manner and amount of reimbursement in the ICD

The PI delegates a staff in the study team to be responsible for:

- Reimbursing participants at the rates outlined in this policy. Please see details in table 2.
- Documenting the reimbursement of participants.

15.4 Policy Statement (s)

For the studies within the scope of this policy, 3 categories of study participants are distinguished:

- **Category 1:** Healthy volunteers and other participants of observational and non-clinical intervention studies, phase 2, phase 3 and phase 4 trials, trials with nutritional supplements or trials with already licensed or repurposed drugs.
- **Category 2:** Healthy volunteers and participants of studies with invasive procedures (**excluding** minimally invasive procedures such as phlebotomy for sample collection, capillary blood collection, and nasopharyngeal or rectal swabs).
- **Category 3:** Healthy volunteers and other participants of observational and non-clinical intervention studies who are invited for **short (under 2.5 hours)** individual interviews or group-based discussions that take place in the home or nearby in the community. Research activities over 2.5 hours will fall into Category 1.
- Trial or study participants of all categories should be reimbursed for their:
    - anticipated loss of earnings/lost wages while participating in a study, dependent

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on the time taken by the research activities.
- incidental costs such as transport to attend study visits.
- refreshments can be provided during the research activities.

- Reimbursement is not applicable for home visits for the purpose of follow-up clinical visits.
- Reimbursement for lost wages is not applicable for unscheduled study visits initiated by the participants (usually for adverse events). Only transport costs should be covered at a standardised rate for these visits.
- When the participants are transported by MRCG at LSHTM vehicle from their homes to the study centre and back to their homes at the end of the visit, only anticipated loss of wages should be reimbursed.
- For logistic reasons, the following flat rates, rather than individual costing, will be provided to the participants at the end of each scheduled study visit (Attachment 1 provides the standardised transport costs).

16 The Standardised Transport Costs

Table 2

Group	Category 1 participants	Category 2 participants	Category 3 participants
Participants transported by research team	D300	D800	D200
Participants NOT transported by the research team	D300 + transport cost	D800 + transport cost	D200 + transport cost
Participants coming for Unscheduled visits	Transport costs only	Transport costs only	N/A

- Reimbursements are made for each study visit after it has occurred. They can be made in cash, cheque, mobile money transfer, gift etc., whichever is convenient for the participant and the study, and they must be documented appropriately.

- Reimbursement is done directly to the study participants, to their legal guardian or their caregiver as applicable and documented in a reimbursement log.

- The reimbursement must be made at the end of the visit.

- A thank-you gift may be given at the end of study participation.

- The Head of Governance and the MRCG ethics committee are responsible for ensuring that PIs and their team comply with this policy.

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17 Documents Management And Archiving

- The PI shall keep an ISF and the sponsor a TMF both can be electronic or paper, containing the essential documents relating to the clinical research as indicated in the ICH GCP E6 R3 section 4.2.7 guideline, which allow verification of the conduct of the clinical research and the quality of the data generated, taking into account all characteristics of the research. The files shall be readily available, and directly accessible upon request, for instance during an audit or inspection.
- The files shall be readily available, and directly accessible upon request, to the EC, MCA or any other RA.
- The sponsor and the PI shall archive the contents of the TMF and ISF, respectively, for at least 10 years for marketed products and 25 years for unauthorised IPs after the end of the clinical trial.

18 Review Fees

Applicants will need to pay an application fee at the point of application. Research application fees vary depending on the type of submission and the research project sponsor/funding type. The applicants won`t receive approval letters if they haven`t paid the application fees. Definitions are provided in the table 3 below.

Table 3.

Category	Initial Review (GBP)	Major Amendment (s) (GBP)
Observation Studies (All)	200	50
Clinical Trials (Academic)	350	50
Clinical Trials (Commercial Sponsored)	1500	200
PhD	100	25

19 Safeguarding

Safeguarding is the process of taking reasonable steps to protect people from harm. The ethical responsibility for safeguarding is to ensure that the rights and wellbeing of research participants are safeguarded during their participation in research. A key principle of research ethics that apply to safeguarding is voluntary participation based on valid inform consent.

It is the responsibility of the researcher to assure that all research participants agreed to join the study voluntarily based on the information that they have been provided with during consenting. Research information should be provided to the study participant in a format and language that the participant understands. Research information can be provided verbally or in a documented form.

Consenting is a continuing process, and for each visit by the research participant, the research team should check that the study participant still understands their commitment to join a study and their wish to continue to participate. Care must be taken during the consent process to ensure that participants are not being coerced to join the study due to fear of harm.

Research participants must also be made to understand that consent can be withdrawn without fear of any negative impact on self or community. All safeguarding issues or concerns highlighted during consenting should be addressed regardless of the participant joins the study or not.

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PIs should ensure appropriate oversight and upward reporting to ensure safeguarding issues and all incidents are captured and timely actions are put in place to address them. PI should identify a safeguarding focal point to support safeguarding activities.

20 Research Integrity

The EC will ensure an environment that promotes integrity, objectivity, and the highest ethical and quality standards in all research areas, including the biomedical, behavioural, and social science fields. All research team members have an obligation to report observed, suspected, or apparent research misconduct to the EC.

An allegation can be made in either oral or written format to the EC. The complainant may choose to be anonymous. Concerns reported to the EC can be done anonymously on-line or by phone, or confidentially by email. An allegation containing the following information is most useful:

- Name of the individual making the allegation;
- Name of the individual who is alleged to have committed the scientific misconduct;
- Name(s) of any witness(es) (if known);
- Description of the misconduct;
- Approximate date and time when the misconduct occurred;
- Supporting documentation; and
- Study title and number (if known).

If the circumstances described by the individual do not meet the definition of research misconduct, the EC will refer the individual or allegation to the research team lead with responsibility for resolving the problem. At any time, an individual may have confidential discussions and consultations about concerns of possible misconduct with the EC members and will be counselled about appropriate procedures for reporting allegations.

Any individual making an allegation not in good faith may be subject to disciplinary action. All individuals involved in the allegation (complainant, respondent, EC, and others involved in the inquiry or investigation of the allegation) should maintain confidentiality of the proceedings and the individuals involved.
Throughout the initial research misconduct proceeding, the EC will review the situation to determine if there is any threat of harm to study participants, staff, funds, and equipment, or the integrity of the research process. In the event of such a threat, the EC will, in consultation and collaboration with the PI, sponsor and/or, MOH, take appropriate interim action to protect against any such threat. Interim action may include:

- Audit of the research process and the handling of funds and equipment;
- Retraining of personnel involved;
- Adding additional quality checks or processes to study procedures and data collection
- Reassignment of personnel, or of the responsibility for the handling of funds and equipment;
- Additional review of research data and results; or
- Delaying publication.

All proven allegations will be notified to various parties, including but not limited to, the sponsor, professional membership organisations, and regulators. If no fraud or misconduct is found, no actions will be taken against the complainant(s), if the allegations have been made in good faith. If it can be demonstrated that the complaint was not made in good faith and the charges were unsupported, then the EC will decide if disciplinary action against the complainant(s) should be applied.

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The EC recommends open-access policies to ensure that research findings are freely available to the public and relevant stakeholders.

21 Research Involving The Sharing of Human Materials / Data with Commercial Industrial Entity

Genomic and immunogenic data from Africans, especially those with associated phenotype and health-relevant data, are scarce, extremely valuable, and highly desirable. Analysing both types of data together is crucial in fields like infectious disease to understand how genetic variations influence the immune system's response, predict treatment effectiveness, and develop novel vaccines and therapies.

This emphasises that the research institution has the duty to the communities and research participants, as custodians of their data, to remain mindful of the need to carefully consider the nature of potential benefit. On a practical level, this could mean at least setting the scene for equitable and affordable access to translational science that makes it into a clinical setting.

The Gambia Government/Medical Research Council Unit The Gambia Joint Ethics Committee (GG/MRCG-JEC) has decided that applicants submitting proposals for the purposes of research that involve the sharing of human materials/data with commercial or industrial interests shall be required to comply with the following guidelines:

i. That the researcher is advised to reconsent all participants who were involved in the original study research (in all cases where there is) need to engage a commercial or industrial entity for further research or use of data/samples.

ii. That a scientific justification for collaborating with the commercial or industrial entity must be provided to the Gambia Government/Medical Research Council Unit The Gambia Joint Ethics Committee (GG/MRCG-JEC) for approval, and NOT merely a case to meet the interest of the commercial or industrial company.

iii. That the Information Sheet should indicate the aim and objective(s) of sharing the original research data and/or samples with the industrial or commercial entity.

iv. That the Ethics applications should include an explanation of any risk to the study population and how the populations' data will be protected.

v. That a binding agreement between the researcher and the commercial entity should be submitted to the GG/MRCG-JEC which should include:

(1) Material and Data Transfer Agreement (MDTA);
(2) consistent and regular notification of the progress and outcome of the commercial research/innovation;
(3) proposal(s) on potential benefit sharing with the study population.

vi. That the commercial entity should not share data/samples with a third party, without prior consent of the primary provider or researcher.

vii. That the informed re-consent document should outline the intended sharing of data/samples with an organisation that works for marketable products of value in health-care landscape.

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viii. That a blanket consenting statement (such as "genetic or other samples we obtain from you can be used and shared in future for any form of research") is not acceptable when it comes to collaboration with commercial and Industrial entity.

ix. The GG/MRCG JEC therefore recommends the inclusion of the following statement in the re-consenting document:
"We would like you to provide permission that we can share your samples/data with a specific company called---------- who are seeking to develop drugs, or reagents (laboratory work materials) or vaccines.

This company is interested in its research to get an outcome from such samples/data of a final product that may be put into the market for sale if they are successful in the research with your sample.

We cannot at this stage commit any future benefit for you or the community because these kinds of research are not simple and straightforward. It may fail and may take a long time to know if there will be a beneficial outcome.

This sample/data may also be passed to a third party during the research process. However, you are assured that your sample/data will be anonymised and protected."

Do you have any concerns or questions?"

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22 References

1. Peplow C, Assfalg R, Beyerlein A, Hasford J, Bonifacio E, Ziegler AG. Blood draws up to 3% of blood volume in clinical researchs are safe in children. Acta Paediatr 2019;108(5):940-944. (In eng). DOI: 10.1111/apa.14607
2. Howie SR. Blood sample volumes in child health research: review of safe limits. Bull World Health Organ 2011;89(1):46-53. DOI: 10.2471/BLT.10.080010.
3. Duke University Health System, Human Research Protection Program, Drawing Blood for Human Participant Research (9/28/2021): https://irb.duhs.duke.edu/sites/default/files/2022-04/blood_collect_policy_9-28-2021.pdf
4. Children's Hospital Los Angeles, human participant protection program, investigator guidance, February 18 2020, Acceptable Blood Volumes drawn for children in research studies: https://www.chla.org/sites/default/files/atoms/files/Acceptable%20Blood%20Draw%20Volumes%20for%20Children%20in%20Research%2002-28-2020.pdf
5. Dana-Farber/Harvard Cancer Center. Guidance on Maximum Blood Draw for Research Purposes (March 2021) https://www.dfhcc.harvard.edu/crs-resources/ODQ_Documents/09_Investigator_Resources/DFHCC_Guidance_-_Maximum_Blood_Draw_for_Research_Purposes.pdf
6. Feinstein Institute for Medical Research Northwell Health, Human Research Protection Program Guidance Document (24/11/2014) https://feinstein.northwell.edu/sites/northwell.edu/files/2019-07/International-Human-Participant-Research-Activity.pdf
7. Hospital for Sick Children Toronto, Research Ethics Board Blood Sampling Guidelines: https://www.sickkids.ca/siteassets/research/reb/research-ethics-guidelines/sickkids-reb-blood-volume-guidelines-2020-2021.pdf
8. Medicines and Related Products Act, 2014
9. Medicines and Related Products Regulations, 2020
10. International Council for Harmonisation (ICH), Guideline for Good Clinical Practice E6(R3), 06 January 2025. ("ICH-GCP-Guideline")
11. WHO. Guidance for best practices for clinical trials in 2024.
12. African Vaccine Regulatory Forum (AVAREF). Guide for the Inspection of Clinical Trials. September 2019
13. EMA. Classification and analysis of the GCP inspection findings of GCP inspections conducted at the request of the CHMP (INS/GCP/46309/2012). 01 December 2014. https://www.ema.europa.eu/en/documents/other/classification-analysis-good-clinical-practice-gcp-inspection-findings-gcp-inspections-conducted_en.pdf (Accessed June 2025)
14. WMA: Declaration of Helsinki (2024) https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-participants/(accessed July 2025).
15. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
16. CIOMS:https://cioms.ch/publications/product/clinical-research-in-low-resource-settings/(accessed July 2025)
17. Consolidated ICH Harmonised Tripartite Guideline for Good Clinical Practice (2025) ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf (accessed 2025).
18. US Federal Regulations: 45 CFR 46. Available from http://www.hhs.gov/ohrp/humanparticipants/guidance/45cfr46.htm (accessed July 2025)
19. Guideline for GCP Inspections of Clinical Trials. 26 June 2025, MCA-GL-503, version 1 - 2025 MCA Technical Working Group

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23 Appendices

23.1 Appendix 1: Scientific Merit Review Checklist

Policy: All research protocols involving human participants undergo scientific merit review prior to submission to the EC. The information below provides a framework of the areas that a scientific reviewer should consider when reviewing new research protocols.

Background And Rationale

1	Is there an adequate description of the research leading up to this protocol?	Yes	No	NA
2	Do the scientific questions addressed in this protocol have sufficient merit or import to justify the required resources or possible risks to research participants?			

Study Objectives

3	Are the specific aims and objectives of this study clearly stated?	Yes	No	NA

Study design

4	Are the specific aims and objectives of this study measurable? If so, are the terms of measurement clear?	Yes	No	NA
5	Is there an analysis plan for each of the study objectives?			
6	Is the type of design appropriate to answering the research question?			
7	If randomization is used, is the method of randomization and randomization ratio clearly described?			
8	If blinding is involved, is the procedure to unblind (break the code described?			
9	Are the methods of data collection appropriate to answering the research question(s) and minimising bias?			
10	If appropriate, are prior human, animal or in vitro studies adequate to support this study?			

Research Populations

11	Are all study populations clearly identified?	Yes	No	NA
12	Are the inclusion and exclusion criteria for each population clearly stated?			
13	Are participants appropriately excluded, e.g., those who will not help answer the research question or those who are at too high risk?			
14	Are any participants being unnecessarily excluded?			
15	If vulnerable populations (e.g., People with diminished mental capacity, People in dependent relationships etc.) are included, could the research be done without including them?			

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Sampling

16	Is the sampling process designed to minimize bias?	Yes	No	NA
17	Has an appropriate power analysis been done to ensure a sample size adequate to meet the study objectives?			
18	Does the sample size calculation take into consideration screening failures, refusals to participate, and withdrawal of participants?			

Study Procedures

19	Is there a clear description of all study procedures and a reasonable timeline for carrying them out?	Yes	No	NA
20	Are the mechanisms for withdrawal or removal of participants once the study is underway clearly stated?			
21	Is there a clear description for biological sample collection and handling (if applicable)? Are all samples collected, or tests run on them necessary to answer the research questions?			
22	Is there a clear description of products being used (if applicable), including their registration and use in the countries where the research will take place. Is there a clear description of compliance with, or exclusion from, regulations of the U.S. Food and Drug Administration and/or regulatory body of the country where the research will be conducted?			
23	Are the data collection forms appropriately designed to capture relevant information?			
24	Do the data collection forms collect any information unrelated to addressing the stated primary and secondary study objectives?			

Staff, Training, Facilities

25	Do the principal investigator and research staff have the appropriate skills to carry out the research?	Yes	No	NA
26	Is any necessary staff training planned and described?			
27	Are the proposed facilities adequate to carry out the research?			
28	Is there provision for any specialized equipment that is required for the research?			

Risks And Benefits

29	Are the anticipated risks to participants (physical, social, emotional, financial) complete and clearly stated?	Yes	No	NA
30	Is there a good description of the procedures that are planned to minimize risks to study participants?			
31	Is there an adequate plan to deal with anticipated risks should they occur?			
32	Is there an adequate plan to deal with unanticipated adverse events, which includes assessment of intensity and causality, reporting, documentation, and follow-up?			

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33	Is there an adequate plan to monitor the safety and welfare of participants that is appropriate to the research?			
34	If this is a clinical research and if appropriate, is there a plan to create a data and safety monitoring board (DSMB)? If yes, is there a DSMB description (charter) that includes membership and a detailed scope of work, including set intervals for review, stopping rules, and other relevant information?			
35	Are the benefits to the individual participant, to the participant's family, to the community, and/or to society clearly described?			

Recruitment And Consent

36	Is there a recruitment and consent plan that describes under what conditions, by whom, and where recruitment and consent will take place?	Yes	No	NA
37	Is the recruitment and consent plan reasonable, given the proposed timeline, number of sites, and anticipated number of participants who meet the inclusion/exclusion requirements?			

Confidentiality And Data Management

38	Are the plans for the protecting the confidentiality of research participants and their data clearly described?	Yes	No	NA
39	Are the plans for the entry, labelling, cleaning, and secure storage of data including samples clearly described?			
40	Is there a plan to de-identify or to destroy data at the completion of data analysis? If not, are sufficient protections in place such that data including samples stored for future use is done with participant consent?			

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23.2 Appendix 2: Standard Format Of The ICF:

No.	Specific Elements required by ICH GCP	Yes	No	NA
A	All pages of the informed consent form are identified by protocol number			
B	There is a placeholder for the investigator's name in the header or footer			
C	The version date is clearly stated on all pages			
D	The page numbers are marked in the format, 1 of n, 2 of n etc…			
E	The format, presentation and text are clear, relevant and understandable to a layperson [ICH GCP E6 R3, 2.8.1b]			
F	The text does not contain language that causes the participant or legally acceptable representative to waive or to appear to waive any legal rights, or that releases the investigator, institution, sponsor or agents from liability for negligence [ICH GCP E6 R3 2.8.4]			
G	A statement that the participant or legally acceptable representative has read and understood the information			
H	A statement that the participant or legally acceptable representative will receive a copy of the ICF [ICH GCP E6 R3 2.8.11]			
I	A statement that the impartial witness agrees that the information in the consent form was explained to, and apparently understood by the participant and/or legally acceptable representative, and that consent was freely given by the participant and/or legally acceptable representative			
J	statement that, with the participant's permission, the investigator will notify the participant's usual medical practitioner of the participant's participation in the research [ICH GCP 4.3.3]. There should be reference made to the fact that (when the investigator is not the participant's GP) that the investigator may contact the GP to obtain medical records.			
K	The written information and the agreement form must be separate documents.			
L	The potential use of technology to inform participants (or their legally acceptable representatives) and obtain informed consent.			
M	Contact details of the ethics committee added to the form as required			

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The Following Are Required Elements Of The ICF:

1	Research identification			
2	The study involves research [ICH GCP E6 R3, 2.8.10 b]			
3	The purpose of the research [ICH GCPE6 R3, 2.8.10 a]			
4	A description of the research treatment(s) and the probability for random assignment to each treatment [ICH GCP E6 R3, 2.8.10 c]			
5	An explanation of "double-blind" and that the identity of the treatment is available immediately in case of emergency			
6	The research procedures, including all invasive procedures [ICH GCP E6 R3, 2.8.10 d]			
7	The participant's responsibilities [ICH GCPE6 R3, 2.8.10 e] (includes the participant's duty to report possible side effects, other health changes and/or changes to medical treatments)			
8	Those aspects of the research that are experimental or are outside normal clinical practice [ICH GCP E6 R3, 2.8.10 f]			
9	The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, foetus, or nursing infant [ICH GCP E6 R3,.2.8.10 f]			
10	The reasonably expected benefits. When there is no intended or expected benefit, the participant should be made aware of this [ICH GCP E6 R3, 2.8.10 g]			
11	The alternative procedure(s) or course(s) of treatment that may be available, and their important potential benefits and risks [ICH GCP E6 R3, 2.8.10 h]			
12	The risk/benefit information is consistent with the Reference Safety Information (e.g. Investigator Brochure) for concurrent research with this compound			
13	Statement about drug not packaged in child-resistant packaging, if applicable.			
14	The compensation and/or treatment available to the participant in the event of research-related injury [ICH GCP E6 R3, 2.8.10 j] and the existence of insurance to compensate for research-related injury.			
15	The anticipated prorated payment, if any, to the participant for participating in the research [ICH GCP E6 R3, 2.8.10 j]			
16	The anticipated expenses, if any, to the participant for participating in the research [ICH GCP 4.8.10 k]			
17	That participation in the research is voluntary and that the participant may refuse to participate, or withdraw from the research, at any time, without penalty or loss of benefits to which the participant is otherwise entitled [ICH GCP E6 R3, 2.8.10 l]			
18	The monitor(s), auditor(s), IRB/IEC, regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical research procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulation,			

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	And, that by signing a written informed consent form, the participant or legally acceptable representative is authorising such access [ICH GCP E6 R3, 2.8.10 o]			
19	That the records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the research are published, the participant's identity will remain confidential [ICH GCP E6 R3, 2.8.10 p]			
20	That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the research [ICH GCP E6 R3, 2.8.10 q]			
21	The site personnel to contact for further information regarding the research and the rights of research participants, and whom to contact in the event of research-related injury [ICH GCP E6 R3, 2.8.10 r]			
22	The foreseeable circumstances and/or reasons under which the participant's participation in the research may be terminated [ICH GCP E6 R3,2.8.10 s]			
23	The expected duration of the participant's participation in the research [ICH GCP E6 R3, 2.8.10 t]			
24	The approximate number of participant's involved in the research [ICH GCP E6 R3, 2.8.10 u]			
25	The sources of funding and any other financial or other ties to the sponsor, any possible conflicts of interest, and institutional affiliations of the researcher [Declaration of Helsinki]			
26	Name and address of the Sponsor [SAGCP]			
27	That the research has the IRB/IEC's positive opinion [EU Clinical Trials Directive]			
28	Arrangements for taking care of the participant after their participation in the research has ended, where there is additional care necessary because of the participant's participation in the research and where it differs from that normally expected according to the medical condition [EU Clinical Trials Directive]			
29	The participant's right to privacy and the means that have been taken to ensure protection of personal data, such as: • procedures for coding • the arrangement with the participant identification code-keys (Participant Identification Register): the name of the person responsible for keeping the key, who will have access, and where and for how long it is kept; • in case of retention of participant samples and information: ✓ to whom the data and samples are accessible; ✓ the location and duration of retention;			

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	✓ name of the person responsible for keeping the samples and results; • procedure for handling any retained identifiable samples; • plans to anonymise or destroy samples after analysis [EU Clinical Trials Directive]			
30	If the research involves photographing, videotaping or audiotaping of the participant, then there must be a section that allows the participant to explicitly consent to the procedures, or to participate in the research without the procedures, provided that the photographing, videotaping or audiotaping are not integral to research participation. If the photographing, videotaping or audiotaping is mandatory for research participation, then the Master ICF must include a statement to that effect. [21CFR 50.27 a]			

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23.3 Appendix 3: Recommendations

The first and second reviewers will assess the research protocol will independently assess the protocol to ensure its quality, clarity, and adherence to established guidelines. This process helps to identify potential weaknesses or areas for improvement before the research is approved for conduct.

Project ID/Ethics Ref #: .....

Study Title: .....

.....

Name of Reviewer: .....

Recommendations

Favourable opinion ☐

Favourable opinion with condition ☐

Modification required (chairperson's approval) ☐

Modification required (resubmission required) ☐

Unfavourable opinion (new application required) ☐

Comments:

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23.4 Appendix 4: Ethics Committee Composition

Name	Profession/Occupation	Affiliation/Institution
Dr. Mohammadou Kabir Cham (Chairperson)	Physician/Registrar	Medical and Dental Council, The Gambia
Rev. Engr. Gabriel Leonard Allen (Deputy Chairperson/Lay Member)	Reverend/Consultant Engineer	New Gambia Industrialist
Dr. Momodou T. Nyassi (Ex Officio)	Acting Director of Health Services	Ministry of Health
Prof. Umberto D'Alessandro (Ex Officio)	Physician/Clinical Epidemiologist/MRCG Unit Director	MRCG at LSHTM
Prof. Effua Usuf (Primary Member/Scientific Advisor)	Clinical Epidemiologist	MRCG at LSHTM
Prof. Ed Clarke (Primary Member)	Consultant Paediatrician/Clinical Researcher	MRCG at LSHTM
Dr. Karen Forrest (Primary Member)	Head of Clinical Services	MRCG at LSHTM
Dr. Pamela Esangbedo (Primary Member)	Dental/Oral Surgeon Specialist/ Assistant Coordinator, Dental Program	University of The Gambia
Mr. Momodou Y.M. Sallah (Primary/Lay Member)	Public Administrator/Chartered Accountant/Lawyer	Retiree
Dr. Jainaba Sey-Sawo (Primary Member)	Lecturer, Nursing & Reproductive Health	University of The Gambia
Dr. Charles A.P. Roberts (Primary Member)	Senior Consultant General Surgeon	Edward Francis Small Teaching Hospital, Ministry of Health
Mr. Bakary Sanneh (Deputy Member)	Laboratory Scientist	National Public Health Laboratory, Ministry of Health
Dr. Ramatoulie Janha (Deputy Member)	Epidemiologist	MRCG at LSHTM
(in attendance) Dr Farba Faye	Head of Governance & Research Support	MRCG at LSHTM
Ms Naffie Jobe	Research Ethics Secretariat Manager/EC Secretary	MRCG at LSHTM

Additional Information

Version number	Change history	Author	Date
1.0	New document	Farba Faye/ Naffie Jobe	23 January 2026