The Gambia Government / MRCG Joint

ETHICS COMMITTEE

THE GAMBIA GOVERNMENT/MRCG
JOINT ETHICS COMMITTEE CONSTITUTION

Preamble

The fundamental principles underpinning research on human beings and information relating to them have been elaborated and refined in various international guidelines. The Gambia Government/Medical Research Council Unit The Gambia (MRCG) Joint Ethics Committee follows the Declaration of Helsinki in its current version, taking into account the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016), the ethics of research related to healthcare in developing countries (Nuffield Council on Bioethics, 2002), and the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report, 1979), as well as other established standards in biomedical research as included in the list of references.

In addition, the Committee complies with the US Code of Federal Regulations (CFR), a) Protection of Human Subjects, also known as the Common Rule, (45 CFR Part 46), b) Food and Drug Administration (FDA) Protection of Human Subjects (21 CFR Part 50) and c) Institutional Review Boards (Part 56). Interventional clinical studies follow the requirements of ICH Harmonised Guideline for Good Clinical Practice (E6 (R2), 2016) and World Health Organization (WHO) Guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical products, 1995.

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 ("body"). The Committee reviews human research supported by the US Health and Human Services (HHS). MRCG at LSHTM hosts the Ethics Committee Secretariat and serve as a meeting venue for the Committee.

MRCG at LSHTM is an institution that carries out research on human subjects and in its capacity as host of the Ethics Committee submits a written assurance of compliance to the Office for Human Research Protection (OHRP). This assurance is submitted by the Secretariat to assure the HHS that the MRCG at LSHTM will comply with the requirements set forth in the Code of Federal Regulations for the protection of human subjects (45 CFR Part 46). The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP.

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FWA: FWA00006873

IRB: IRB00003943

The Committee endeavours to ensure that all research projects meet the standards indicated above by reviewing projects against the four essential ethical principles: beneficence, non-maleficence, justice and autonomy. In addition, the research project must be based on good quality, valid science, risks must be minimised and not exceed the potential benefits to the individual or community.

Article 1: Committee Responsibilities

The Gambia Government/MRCG Joint Ethics Committee is an independent body primarily responsible for acting in the interest of research participants and their communities in The Gambia. The Committee is also responsible to the Ministry of Health ("MoH") represented by the Director of Health Services, and MRCG at LSHTM ("Unit") represented by the Unit Director.

The Committee oversees the review of all ethical aspects of research projects on human subjects and focus on reviewing applications for new projects (observational, interventional studies) including rapid responses to outbreaks and student projects (PhD and MSc projects). The Committee reviews all submitted research projects against recognised international ethics standards as well as projects involving primary data collection.

Article 2: Functions Of The Committee And Frequency Of Meetings

The Committee shall review ethical aspects of research projects involving human participants and oversee ongoing research projects in The Gambia. In addition, the Committee reviews requests for further use of biological samples within The Gambia and/or the transfer of data or biological samples outside The Gambia.

Committee meetings shall be held monthly on the last Thursday of the month.

Expedited Review is available for emergency studies (research on interventions to control an outbreak of an infectious disease) and review of changes to existing studies. Further information on what qualifies for fast-track review is stipulated in the Committee's Standard Operating Procedures (**SOP-EC-01)**.

Article 3: Membership

The composition of the Committee is in compliance with the standards outlined in the ICH GCP Guideline and the requirements of the FWA as stipulated by OHRP and conforms to the FDA requirements as detailed in 21 CFR 56.107. It also meets the 'membership requirements' as stipulated in the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research.

3.1 Composition Of The Committee

The Committee shall consist of thirteen (13) primary members:

a. Chairperson.
b. Director of Health Services (MoH)
c. Unit Director (MRCG at LSHTM)
d. A minimum of eight (8) primary members to be nominated by the Directors. Each Director will nominate four (4) members, one of whom must be a lay member. Nominations should be mutually agreed by both Directors. An individual is considered as lay if his/her primary personal or professional interest is not in a research area and s/he is not a health or social care professional who has previously been involved in carrying out research involving human participants, their tissue or data.
e. Two (2) Representatives of Ministry of Higher Education (one of whom is a Representative of UTG nominated by the Vice Chancellor).

NB: Ad Hoc member(s) or Independent Consultant(s) (External Experts) may be invited to attend meetings whenever the need arises to provide specific advice or information where the Committee lacks the expertise. These Experts are not members of the Committee and cannot count toward a quorum or vote. The same is applicable to observers such as future Committee members on training.

3.2 Appointments And Renewal Process

The Chairperson is appointed jointly by the Directors and shall be independent of MoH and MRCG at LSHTM. The Secretariat will issue appointment letters signed by Directors for mutually agreed appointments.

Each Director will appoint deputy members from their own institutions who will attend meetings in the event of unavoidable absence of a primary member of the Committee. The Directors and the Chairperson will appoint from the appointed members a Scientific Advisor and a Deputy to the Chairperson.

3.3 Period Of Tenure

Members shall serve for an initial period of four years, which may be renewed once for a further four-year period. In exceptional circumstances, a member may serve for a longer period. The need for the extension must be agreed by both Directors and the reason must be stated in the renewal of appointment letter.
Members may resign in writing to the Directors before they have completed their period of tenure.

3.4 Initial and Continuing Training

Members will complete initial training on research ethics (the course can be accessed here: https://open.lshtm.ac.uk/course/view.php?id=39), and shadow review meetings before their first official meeting. Members will also be required to attend trainings organised by the Secretariat as part of the continuing education programme to keep abreast with changes in international regulations and ethics policies. More information on the prerequisite trainings is available in the **EC members training guide**.

Article 4: Member Responsibility

All members (including Deputies) must undergo appropriate training for their role as a member of the Committee. The Secretariat Manager will retain certificates of training for each member, as well as the list of training provided that meets the minimum requirement for membership, as per the Committee training guide. A member will not review a project until proof of completion of trainings (certificates) is submitted to the Secretariat. Members will be required to update their training every two years.

A new member on training can attend a meeting and participate but cannot count to a quorum.

4.1 Chairperson

a. Promote and protect the interests of participants and the public in research.
b. Agree procedures for ethics review in line with international standards and regulations.
c. Chair Committee meetings.
d. Maintain the Committee's reputation for being fair and impartial, immune from pressure either by the institution's administration, the investigators whose proposals are brought before it, or other professional and non-professional source.
e. Review applications and list any ethical concerns for the research project.
f. Make a final decision, considering the Committee's views (i.e. favourable, unfavourable or provisional opinion/request for clarification).
g. For expedited reviews or Chairperson's action, review submission and Scientific Advisor's comments and make final decision for the research project.
h. Act as point of contact for appeals or disputes from applicants as per the appeals procedure described below in Article 15.
i. Promote the effective working of the Committee as a cohesive group.
j. Monitor the standard and application of research ethics via discussions at the meetings.
k. Review potential conflicts of interest.
l. Ensure compliance with Committee policies and procedures as written by the Secretariat.
m. Provide advice to the researchers on all aspects of welfare and safety of research participants and the ethics of their projects.
n. Maintain confidentiality of documents obtained and discussions held during the review process.
o. Be familiar with and keep up to date with applicable ethical guidelines and regulations, as required.

4.2 Deputy Chairperson

a. The Deputy Chairperson will act as Chairperson in the latter's absence and cover the above responsibilities.

4.3 Scientific Advisor

a. Facilitate decision-making of the Committee by providing technical expertise to the Committee on the scientific merit of proposals under review.
b. Finalise the decision of the Committee by reviewing the minutes of the meeting before letters notifying applicants of outcome are being prepared for signoff by the Chairperson.
c. Assign applications to members as lead reviewers to present the proposal at the meeting.

4.4 Members

Each member is responsible for the competent review of all applications and listing any ethical concerns for the research project. Specifically:

a. provide independent review free from bias and influence.
b. maintain the Committee's reputation for being fair and impartial, immune from pressure either by the institution's administration, the investigators whose proposals are brought before it, or other professional and non-professional source.
c. provide advice to the researchers on all aspects of welfare and safety of research participants.
d. maintain confidentiality of documents obtained and discussions held during the review process.
e. develop the necessary skills to understand the ethical issues for each project.
f. assess the social value of the research and identify any possible harm that may occur to vulnerable participants.
g. allocate appropriate time for reviewing proposals.
h. declare any conflict of interest.
i. monitor the standard and application of research ethics submitted for review.
j. promote and protect the interests of participants and the public in research conducted in The Gambia.
k. comply with Chairperson's overall views as a consolidated view from the collective review of the Committee, incorporating individual responses.
l. comply with the policies and procedures for the Committee.
m. commit to review projects each month, endeavouring to attend at least 6 of the 12 months' meeting. Absenteeism due to unavoidable reasons (e.g. ill-health, duty travel, annual leave or other disruptions to normal work schedule) is acceptable. A member who is absent for three consecutive meetings without notifying the Secretariat and has not done any review (or send their comments for those meetings) will be asked to resign from the Committee. Apologies for absence should be sent to the Secretariat before the meeting for the records.
n. have full knowledge of the applicable ethical guidelines and regulation, as required.

4.5 Lay Members

In addition to the above, lay members are expected to provide input:

a. Regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
b. On areas relevant to their knowledge, expertise, and experience, professional and otherwise.
c. Check and ensure that all information given to the research participants is clear and easy for them to understand, honest and does not have a negative impact on the participant's autonomy as required by ethical standards and regulations.
d. A lay member must be present at every meeting for the purpose of meeting quorum requirement. Without a lay member, the meeting cannot proceed, even if enough members are present.

Article 5: Responsibilities Of The Secretariat

The Secretariat is responsible for providing all administrative support services for the Committee. The Secretariat Manager functions as the Secretary to the Committee, and handles the administration of applications, write appointment letters on behalf of the Directors. In addition, the Secretariat Manager will:

a. handle all communications on behalf of the Committee (e.g. nominations, appointment, trainings, inductions, meetings, etc.).
b. manage Committee operations, including meeting management, pre- and post-meeting activities, maintain comprehensive tracking throughout the course of the review.
c. maintain appropriate documentation and reporting of review, project status, and members' activities.
d. retain and update all relevant records (e.g. the constitution, membership lists, submitted documents, minutes of meetings and correspondence).
e. ensure that applications submitted are reviewed and validated in a timely fashion.
f. ensure that members receive applications within the set timelines and organise committee meetings accordingly.
g. ensure quorate for each meeting is reached and maintained throughout. Whenever the need arises, invite an External Expert to join for the review session.
h. ensure that Committee replies are sent to applicants in a timely fashion.
i. maintain CVs and training folder of members and a register of interests.
j. ensure all administrative regulatory and policy criteria are met.

Other duties undertaken by the Secretariat include:

k. assure compliance to the Good Research Practice Policy, as applicable.
l. provide researchers with an easy to use framework to consistently review the ethics of their projects.

m. monitor compliance of adherence to the Committee's conditions of decisions on research project.
n. promote best practices, measure and maintain performance and make adjustments to improve efficiency and effectiveness.
o. provide oversight for the ongoing work of the Committee in conducting human subject protection reviews.
p. utilise reporting tools to provide strategic insight into opportunities for quality and process improvement.
q. develop KPIs to measure the performance of the Committee.
r. oversee provision of training and advice on research ethics to members and to the applicants.
s. oversee the procedures for the Committee to ensure compliance with the assorted applicable regulations, as required.
t. monitor the standard of research ethics and develop training programmes for reviewers.
u. organise and coordinate project site visits on behalf of the Committee with research project field teams.
v. compile a single report on ethics reviews to be submitted to the Committee.
w. the Secretariat may help applicants prior to submission, and comment on legal/research governance aspects of the projects to be submitted.

Article 6: Quorum

The quorum for a meeting shall comprise the Chairperson or his/her deputy, seven (7) primary members or their deputies, one of whom must be a lay member and one Representative of the Directors (Health Services (MoH) and MRCG at LSHTM). The Directors of Health Services (MoH) and MRCG at LSHTM shall be *ex-officio* members of the Committee and shall not have voting rights on any project under consideration by the Committee.

Article 7: Conflict Of Interest And Recusals

Committee members and External Experts must declare to the Chairperson any conflict of interest including financial or personal interest in a project or a project funder. Members with a conflict of interest can provide information relevant to the specific proposal and recused from participating in the discussions that lead to the opinion of the Committee related to projects they are involved in. The Chairperson will decide whether the interest disqualifies the member from taking part in the discussion that will lead to the opinion of the Committee on the particular project. A conflicted investigator who is a member of the Committee can only present his/her proposal, provide information and must recuse from discussion of a proposal, cannot count toward a quorum and cannot vote. The information on the recusal of a member shall be captured in the minutes of the meeting.
The Secretariat Manager must ensure that the quorum will be maintained without the relevant member(s) involved in the projects throughout the meeting.

Article 8: Review Of Applications

a. All applications submitted for review must be prospective, i.e. the project or activity should not have started in any fashion.
b. The Committee will not review projects or activities after they have started, i.e. retrospectively. Deadlines for review will be strictly adhered to.
c. The review process will be documented.
d. External advice may be sought for specific applications.
e. The review process is undertaken either face-to-face or virtually. Members to choose the most suitable option i.e. attend face-to-face or join remotely.

Article 9: Review Procedure

The Committee reviews and oversees the ethical aspects of research projects and focus on reviewing applications for new projects (all human subject research and studentship projects). The Committee also reviews changes to existing projects, requests for use of data or biological samples, reports, protocol deviations and continuing review. The Committee must be informed about the end of a project or any early termination of a project. The details for amendments, serious adverse events and safety reporting for clinical trials, annual progress reports and end of project/early termination of project reports are laid down in **SOP-EC-01**.

Article 10: Committee Response

Research projects will receive one of the following responses from the Committee:

a. **Favourable Opinion.** The Committee is content for the research project to commence, contingent on all other appropriate approvals being received (e.g. Medicines Control Agency approval for Clinical Trials, and other regulatory approvals as required). The authorisation for the project is granted on the basis that the project progresses as stated in the submission. Any changes to the project following a favourable opinion must be submitted via the amendment application.
b. **Request For Clarification/Insufficient Information.** The Committee requests additional information or for amendments to the research project before issuing their final verdict.
c. **Unfavourable Opinion.** The Committee does not approve the project. The applicant may re-submit and the process starts from scratch.

The Committee may also revoke approval if dissatisfied with the conduct of the research. The reasons for the Committee's decisions/opinions will be provided. Should an applicant wish to appeal the decision made by the Committee there is an appeal process which can be followed as described in Article 14.

Article 11: Review Timelines

The Committee will review applications that have received scientific approval from a scientific review body before submission to the Committee meeting for that particular month. The submission deadline is approximately 14 days before the meeting date which is published in its calendar.

Although late submissions are not acceptable, however in extenuating circumstances late submissions **may be** considered at the discretion of the Chairperson based on the type of application.

Reviewers receive the documents 7 days before the meeting. The meeting outcome is communicated to applicants within 10 working days after the meeting.

Article 12: Confidentiality Agreement

Committee members and External Experts must complete confidentiality agreement prior to attending their first meeting.

All members and Secretariat staff should treat any information provided to the Committee as confidential. Any External Expert(s) invited to give an opinion to the Committee about a specific research proposal shall likewise keep the information confidential.

Article 13: Approval Or Rejection

A favourable opinion (approval) shall be based on consensus. A project shall be deemed approved or conditionally approved when it has received the support from the majority. Where there is no consensus, the submission may be rejected or recommended for resubmission.

Article 14: Right Of Appeal

An applicant whose project has been rejected will have the right to appear before the Committee in person with a view to appealing against the decision.

References

i. **Operational Guidelines for Ethics Committees That Review Biomedical Research**
https://www.who.int/tdr/publications/documents/ethics.pdf

ii. **ICH Harmonised Guideline for Good Clinical Practice E6(R2) (2016):**
www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

iii. **Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The Belmont Report (1979):**
www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

iv. **CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016):**
http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf

v. **WMA Declaration of Helsinki (2013):**
www.wma.net/en/30publications/10policies/b3/index.html

vi. **The ethics of research related to healthcare in developing countries, Nuffield Council on Bioethics (2002),**
https://www.nuffieldbioethics.org/assets/pdfs/Ethics-of-research-related-to-healthcare-in-developing-countries.pdf

vii. **Ethics Committee Standard Operating Procedure (SOP-EC-01):**
Ethics Committee Review SOP

viii. **Code of Federal Regulations (CFR), Title 21 Part 56:**
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

ix. **Code of Federal Regulations (CFR), Title 45 46:**
www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

x. **Code of Federal Regulations (CFR), Title 21 Part 50:**
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50

xi. **OHRP: https://www.hhs.gov/ohrp/**
Prevent: www.gov.uk/government/publications/prevent-duty-guidance