

## Statement of Compliance

The fundamental principles guiding research on human beings and information related to them have been elaborated and refined in various international guidelines. The EC adheres to the current version of the Declaration of Helsinki, 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.

Additionally, the EC complies with the CFR, which includes a) Protection of Human Subjects, also known as the Common Rule, (45 CFR Part 46), b) FDA Protection of Human Subjects (21 CFR Part 50), and c) Institutional Review Boards (Part 56).

Interventional clinical studies follow the requirements of ICH-GCP (E6 (R2), 2016) and WHO guidelines for 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 recognized scientific committee or board. The Committee reviews human research supported by the US HHS.

MRCG at LSHTM is an institution that conducts research on human subjects, 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 subjects (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.

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**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 four essential ethical principles: beneficence, non-maleficence, justice, and autonomy. Additionally, the research project must be based on good quality, valid science, risks must be minimized, and should not exceed the potential benefits to the individual or community.

Ethics meetings:

- 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 backlog of applications.
- The committee holds a minimum of 12 meetings per year.
- The annual meeting calendar is circulated in November.