Guidelines for application for ethical review on Biomedical Research involving human subjects in a healthcare setting

The main function of the NEC, amongst others is to review proposals for human research projects to determine whether they meet all relevant ethical standards prior to granting ethical clearance.

Applicants are requested to submit their project proposals for the consideration of the National Ethics Committee as per below guidelines:

1. Title of the study;
2. A summary of the proposed research in lay non-technical language;
3. A clear statement of the justification for the study, its significance in development and in meeting the needs of the country/population in which the research is carried out;
4. A concise report of all previous studies on the topic, including unpublished studies known to the investigators and sponsors and information on previously published research on the topic;
5. The objectives of the trial or study, its hypotheses on research questions, its assumptions and its variables;
6. A brief description of the design of the trial or study;
7. The number of research subjects needed to achieve the study objectives and how this was statistically determined for each objective;
8. The criteria for inclusion or exclusion of potential subjects and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons **(state how participants will be recruited)**;
9. No Objection from treating doctor is needed for clinical tests to be carried out;
10. No Objection from Director, Central Health Laboratory is needed for laboratory tests and to disclose source of funds or sponsors;
11. The potential benefits of the research to subjects and to others;
12. The expected benefits of the research to the population including new findings that the study might generate and how the findings would help in formulation of policy decisions;
13. How the participants/Responsible Party would be informed about the results of the study in relation to their specific case and in relation to the group tested;
14. A list of the references cited in the protocol;
15. The timeframe for completion of the study;
16. In case of sponsorships, an account of the sponsor's financial commitments (including past commitments if applicable) to the research institution, the investigators, the research subjects, and when relevant the community;
17. **No Objection from Consultant/Specialist/Treating Doctor and to have clinician as Supervisor/Co-Supervisor when study takes place in a healthcare setting;**
18. **No Objection from Regional Health Director/Head of Unit/Medical Superintendent when the study takes place in a healthcare setting;**

19. **Covering letter from academic Supervisor and CV of supervisor as well as CV of applicant should also be submitted (CV should be up-to-date within past 12 months);**

20. **Being given that your research topic is of relevance to the Ministry, you are requested to share your findings and recommendations and the final copy of your project proposal to our Ministry; and**

21. **Approval to be sought from the Ministry prior to publication (if applicable).**

Note:
-Kindly submit the following:
(i) soft copy of the project proposal (as zip folder via email) and
(ii) one hard copy of the project.

Application to be sent to:

Dr V. T Mohabeer,
Director Health Services
Chairperson
National Ethics Committee
Ministry of Health & Wellness
4th Floor, Nexsky Building
Ebene

Tel No: **52533809/4904085**
Email add: **training2.local@govmu.org**