Guide for the completion of the Leo form for Review of Project by SCC and Ethics Committees

The MRCG Scientific Coordinating Committee (SCC) reviews the scientific content of a research project to be undertaken in The Gambia for the purpose:

I. To judge that the project is scientifically feasible, has well-reasoned methodological process in answering the research questions

II. To potentially advice improvement on approaches in the study to maximise the outcome and impact of the study

III. To judge that the study environment is adequate and will facilitate timely recruitment of study patients and sample processes

IV. To advice on potential ethical issues to address before the project is passed on to the MRCG/Gambia Government Ethics Committee.

(Note that the Ethics Committee will not review any project if it is not approved by the SCC)

1. All research projects to be reviewed must be adequately explained in the Leo form following the systematic instructions in the form. (*It has been observed that some important sections are incompletely described, making it difficult for the SCC to review the project*). All sections are important, but we pick some important sections to help guide external applicants (Scientists and students outside the MRCG and LSHTM set up) to meet the description expectations.

2. Under Project Type, external applicants are not required to indicate any of the MRCG themes options (instead choose "other")

3. Section 12: (scientific outline of the Project). You are required to give the details of the proposal that includes Scientific background (global and local situation), brief rationale or importance of the proposal (What is unique about your study) different from what is known. Then explain your study environment that will support your study.

4. Do NOT repeat what you wrote under 12 in the following 12b. Rather make a simple summary of your project proposal in a layman's language (non-scientific explanation of what your proposal is about).

This can be a paragraph or two that will avoid all scientific terms, attempting to explain your proposal to a lay person.

5. If your study has detailed protocols such as in Clinical trials (mandatory) or a full MSc or PhD proposal (optional), you can upload it as suggested in section 12b.

6. Section 13 & 13a require you to detail the importance of the study and this expands the brief rationale you mentioned in section 12.

7. Section 18 is the Method section and requires the detailed explanation of the procedures and study tools you would use to answer the objectives. This is an important section that should be systematically answered. One should first explain the various methods and tools you would use to generate data, study population, inclusion and exclusion criteria, measures of your primary outcomes and secondary outcomes (if applicable), and your data analyses plan.

8. The method section is followed section 20 and 20a to detail your sample size.

9. It is expected that supervisors of MSc and PhD students review the student's input in the form and assist in correcting the details, making sure student do not complete the forms sloppily. Supervisors are also expected to sign the form before submission. It may be helpful if supervisors for MSc can attend the SCC presentation to witness the student presentation and his scientific understanding of the project.

10. Apart from the Leo form, an accompanying Information sheet for research consent from study participants are usually completed incorrectly, particularly for two areas:

    a) Under the section (**Why is this study being done?).** Imagine you are explaining to an uneducated participant you are recruiting and avoid any scientific explanation. Simply explain the importance of the study e.g., what the health condition is about and why you are interested to recruit him/her to help address your investigation and how this will help society at large

    b) The section (**What does this study involve?).** You state in simple terms for the understanding of the

uneducated participant, how he/she is participating in the study (e.g., answering questions for how long? how these questions will be recorded and what will be done with them; Or providing samples and how much? What the tools are employed to get data from samples etc, where they will be processed and who are involved in the processing and data analyses, what happens to results that affects them etc. The position here is to ensure that participants understand why they are participating in your study.