# **Guidelines for INVESTIGATORS**

***General:***

Any biomedical research project 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.

New research projects (proposals) will be presented in an application form (e.g. the ethics application form or the SCC Application form) that allows detailed description of the proposal. In addition, a clinical study protocol will be provided for interventional clinical studies (‘clinical trials’).

Applications to change an ongoing project (amendments) or to conduct an ancillary study which is a continuation or modification of an ongoing approved project or a pilot study for validation of techniques will be presented in a letter stating the reasons, references to the main project, summary of the main project, as applicable, and a brief description.

Requests for further use of stored biological samples or data will also be submitted in a letter as above, accompanied by the respective informed consent form to verify the ethical rightfulness of the request.

Investigators not known to the EC have to provide their curriculum vitae (CV). This is to ensure that the researcher involved is qualified to undertake the project.

In case of interventional studies on investigational medicinal products (IMPs) an Investigator’s brochure (IB) or equivalent product information will be submitted.

If interviews with participants will be conducted, the questionnaire(s) will be provided.

***Informed Consent:***

Informed consent forms (ICFs) should contain clear, preferably brief information, explaining the purpose of the project, the risks and discomfort involved and the benefits for 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 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.

In the case of older children (aged about 7 years) an acceptable explanation should also be delivered to the participant or, in interventional studies, a corresponding information sheet provided.

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 signed by the investigator or designee (e.g. trained field worker), which denotes that he/she has delivered the explanation.

Signed or thumb-printed informed consent by the participant is requested, if the procedure involves more than minimal risk (including venepuncture) or when interventions are administered, even if it is in the direct interest of the participant. Some overseas funding agencies demand signed informed consent for any procedure as a stipulation of the grant.

Consent for minors (age <16 years) should be obtained from a parent or guardian in studies involving minimal risk, and from minors (age <18 years) in studies involving more than minimal risk or interventional studies. In the case of older children (aged about 7 years) the willingness for participation should be taken into account. In case of children aged about 12 years and above, assent should be obtained, preferably in writing, in addition to the consent from the parent/guardian. Consent for clinical or other photographs should also be obtained.

***Blood:***

Capillary blood collected by a finger prick up to a volume of 800-1000 μl can be obtained from adults and children by a trained field worker. Blood obtained by venepuncture in children under the age of 5 years is to be obtained by a trained nurse, phlebotomist or physician. In the case of children older than 5 years or adults, venepuncture can be done by a nurse, or by a specially trained field worker, if this is approved by the responsible physician. No more than three attempts should be made to obtain capillary or venous blood at any time.

There are general guidelines about the volume of blood, which should not exceed 2ml/kg as stipulated by a number of institutions, including the Institute of Child Health, Great Ormond Street, London. In practice, as many persons in The Gambia do not regard blood as a renewable resource, the volumes for research purposes are limited to the following:

< 5 years of age 5 ml
5-9 years of age 5-10ml
10-14 years of age 10-15 ml
> 15 years of age 20-30 ml

In VERY severe anaemia that needs medical care, blood draw might be limited to lower amounts or restricted at all.

Sequential bleeds are permissible in projects such as vaccine studies or other projects where changes are being monitored over time. Volunteers are usually only asked to give blood at 3-monthly intervals in the amounts stated above. Exceptionally, this might be needed more frequently, which must be justified by the investigator.

It is usual to show the participant the size of the syringe involved and to explain the amount of blood in numbers of teaspoons (1 teaspoon = 5 ml). Anaemia, unless it is very severe, is not a bar to blood sampling. If possible, the participant should receive some benefit from the blood sampling (eg if a haemoglobin check is done or, if febrile, a check for malaria parasites is undertaken). Haematinics or vitamins can be administered thereafter, if the study design allows such substitution.

***Other Specimen:***

Other specimen like urine, nasopharyngeal swabs, sputum, etc can be collected by trained field workers or nurses under the supervision of a physician.

***HIV testing:***

Participants, or in the case of children, their parent or guardian, should be counselled before the test is undertaken, they should consent to the test and be informed that the results of the test will be available to them. Clear instructions should be given as to when and whom to approach for these results. As in the case of other sexual transmittable diseases (STDs) contact tracing and testing of the index case is only done with their consent as well.

At times, especially if specimens are to be sent overseas, requests are made that samples already collected should be tested for HIV. In these cases, in order to preserve anonymity, samples are pooled in lots of 5 or 10 and if a pool is positive these samples are rejected. In the case of prevalence studies anonymised samples may be used.

***Participation in multiple projects:***

It should be avoided that a participant takes part in more than one project unless the second project is a non-invasive observational study and limited to a brief questionnaire or anthropometric measurements.

***Payment****:*

Monetary or other rewards for participation are greatly discouraged, but the costs for transport involved in the project will be reimbursed. Exceptionally, adult healthy volunteers in interventional studies without any potential benefit for themselves or their population in the society and who spend much time on the project may get compensated for participation stating in writing the amount and the purpose and duration of their participation.