**Guide to Informed Consent Documents**

*The numbers in brackets {0} refer to the respective numbers in the Ethics Committee’s Checklist for participant information sheets*

**PARTICIPANT INFORMATION SHEET**

Version [include the version (e.g. 1.0, 2.0, etc) and date with day, month and year] **{18}**

Study Title [provide the full title],

SCC [Number], Protocol [Number, if different from SCC] {19}

Sponsor: [Name] **{13}**

Participant Identification: \_\_\_\_\_\_\_\_\_\_\_\_\_

* Insert the identification number allocated to the participant at screening or enrolment, as appropriate

What is consent?

* **Note:** Use the text as provided in the template

Why is this study being done?

* Describe the disease/ infection under study including prevention **{2}**

Example

[Disease] is a common disease worldwide. In the world as [Number] people, this is as many people as living in the Gambia, are getting sick or dying from it every year; most of them in Sub-Saharan Africa including The Gambia.

[Disease] is caused by a germ (parasite, bacterium, virus) called [Name] that affects mainly [organ(s)].

* **Note:** Inform about information to the community by using the text as provided in the template **{20}**

What is the new vaccine/drug?

* Explain the purpose and nature of the project **{1}**

What does this study involve?

* State the duration and numbers of participants **{3}**
* Describe the treatment and procedure
**Note:** For medical care at screening use the text as provided in the template **{3}**
* Explain the participant’s responsibilities **{3}**
* Explain the probability for random assignment and blinding, as applicable **{3}**
* State the foreseeable circumstances under which the participation may be terminated, if applicable **{11}**
**Note:** For the case of study termination use the text as provided in the template

What will happen to the samples taken in this study?

* Describe the procedures
* If applicable, give a statement that part of the sample(s) will be stored for future research within the scope of the Unit’s mandate
* If applicable, give a statement that genetic testing will be done.
* If applicable give a statement that sample(s) might be sent out of The Gambia **{14}**

Example

Part of the samples we will be sent outside of The Gambia for measurements that cannot be done here.

We want to store part of the samples for further research within the scope of the Unit’s mandate, but no genetic testing will be performed on your samples. If you do not agree to this, you can still continue to participate in the study.

OR

We want to store part of the samples for further research within the scope of the Unit’s mandate which will include genetic testing. If you do not agree to this, you can still continue to participate in the study.

What harm or discomfort can you expect in the study?

* Describe the reasonable foreseeable risks of harm and discomforts that might result in participation {4}

Example:

Collection of this amount of blood is safe and will not cause any harm to you, but might cause a little temporary discomfort.

The study medicine/vaccine was tested in [Population] in [Country] and found to be well tolerated.

Although very rare, serious unwanted effects can be seen with the medicine such as [list SARs].

What benefits can you expect in the study?

* Describe the possible benefits to the participants and/or to society {5}

Example:

As this is a research study there might be no direct benefits to you. The study will help health professionals to know more about [Disease] and how to control it so that it may help people suffering from [Disease] in the future to have better treatment.

Will you be compensated for participating in the study?

* **Note:** Use the text as provided in the template **{8}**

Are there other products or treatment?

* State alternative procedures to participating in the study, if applicable {17}

What happens if you refuse to participate in the study or change your mind later?

* **Note:** Use the text as provided in the template **{6}&{12}**

If you are injured in the study what compensation will be available?

* **Note:** Use the text as provided in the template **{9}**
* Provide the contact details of the study clinician

How will personal records remain confidential and who will have access to it?

* **Note:** Use the text as provided in the template **{7}**
* Information of findings to subject after completion of study

Example

After the research is completed and results are available, the doctors will analyse all the information and the study team will hold meetings in your or a nearby village to inform you, your family and the community about the results.

Who should you contact if you have questions?

* **Note:** Use the text as provided in the template and include the contact details **{10}&{16}**

Who has reviewed this study?

* **Note:** Inform about the Ethics Committee by using the text as
provided in the template **{15}**

**consent form**

Please note that there are two different templates for clinical trials consent forms:

2i: For adults in a clinical trial

2ii: For children in a clinical trial

* Use whichever applies to your project; include the SCC Number and study identifying title in the header and enter the Participant ID number where required.