[YOUR INSTITUTIONAL LETTERHEAD]
Please do not submit consent forms on the WHO letter head

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written.

Explanation
Example

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are. and explain that you are inviting them to have their child participate in research which you are doing.

Explanation
Example

Purpose

Explain the problem/research question in lay terms which will clarify rather than confuse.

Explanation
Example

Type of Research Intervention

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

Example

Participant selection

State clearly why you have chosen their child to participate in this study.

Explanation
Example

Voluntary Participation

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate.

Explanation
Example

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

Example 

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given.

It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

Example 

2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

Example 

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use.

Explanation 

Example 

B. Description of the Process

Describe the process on a step-by-step basis.

Example 

In case of a clinical research:
Explain that there are standards/guidelines that must be followed.

Explanation
Example 

For any clinical study (if relevant):
If blood samples are to be taken explain how many times and how much in a language that the person understands.

Explanation 

Duration
Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

Example 

Side Effects
Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Example 

Risks
A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks.

Explanation
Example 

Discomforts
Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Example 

Benefits
Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

Explanation
Example 

Incentives
State clearly what you will provide the participants with as a result of their participation.

Explanation
Example 

Confidentiality
Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team.

Explanation
Example 

Sharing of the results
Your plan for sharing the information with the participants and their parents should be provided.

Explanation
Example

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

Example

Alternatives to participating
Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

Example

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

Example

PART II: Certificate of Consent

Certificate of Consent
This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent.

Explanation
Example

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study and understand that I have the right to withdraw my child from the study at any time without in any way affecting either my child's or my own medical care.

Print Name of Participant_____

Print Name of Parent or Guardian_____

Signature of Parent or Guardian _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of parent

Signature of witness _____

Date _____
Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the parent or guardian of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Researcher_____

Signature of Researcher _____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____(initialled by researcher/assistant)

An Informed Assent Form will_____ OR will not _____ be completed.