INFORMED CONSENT FORM TEMPLATE

Notes to Researchers:

1. Please note that this is a template developed by the NBC-Pakistan (adapted with modification from Informed consent template forms of WHO ERC and IOWA state University) to assist the Principal Investigators in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: Part I (information sheet) and Part II (consent certificate).

3. Principal Investigator must ensure that the language used throughout the consent form is simple and easily comprehendible to potential research participants, same may be translated into local languages if potential participants are expected to NOT understand English language.

5. In this template:

* Square brackets indicate where specific information is to be inserted. Green text in the form may be replaced with the specific information.
* bold lettering indicates sections or wording which should be included in ICFs

**Consent Form**

**PART I [INFORMATION SHEET]**

*Note for Investigator: Information in this document MUST be sufficiently detailed, organized, and presented in a manner that facilitates comprehension and informed decision making.*

**Invitation to be Part of a Research Study**

You are invited to participate in a research study entitled [Title of the study] as a research participant. The purpose of this information sheet (Part I of consent form) is to provide you with sufficient information regarding the study that you may decide whether or not you would like to participate. If you have any question regarding the study or this form you are welcome to ask the project team. Please note you will only be included in the study if you consent to participate and sign the consent certificate (Part II of consent form).

**Who is conducting this Research?**

This study is being conducted by [List all key investigator(s) from all collaborating institutes along with their affiliations]

This study is funded by [name of funding agency].

**What is the purpose of this study?**

The purpose of this study is to [Explain WHAT do you want to study with little background on why is it important to study using layperson’s terminology keeping in mind your research participants]

**Why am I selected/invited to participate in this study?**

You have been invited to participate in the study as you meet the eligibility criteria *i.e* [using layperson’s language define participant’s inclusion criteria].

However, you should not participate in this study if [Describe key exclusion criteria using layperson’s language].

*If study involves some screening tests or procdures for eligibility mention that ;* Your eligibility will further be assessed by[mention screening process and procedures if any].

**What will I have to do as a research participant?**

If you consent to participate in the study, you will be asked to [Step wise explain **ALL** information or procedures that participants will be asked to provide or take part in during the research].

**How long will I be the part of study?**

Your participation in this study will last for total [mention time in suitable unit e.g. mins/days/months etc. also mention number of follow up visits and estimated time for each visit when required]

**Does the study involve any EXPERIMENTAL drug or procedure?**

An experimental drug/procedure is the one which is still under testing and is yet not approved by relevant authorities for routine use due to inadequate scientific knowledge regarding safety and efficacy of the drug/procedure.

This study [involves following/does not involve any] experimental drug or procedure. [If study involves an experimental drug mention the details [name of drug/procedure, manufacturer etc.]. Also mention phase of study along with previously reported experiences in terms of safety and efficacy in a simple language understandable to potential research participants]

**What are the possible harms, risks or discomforts I may experience during the study?**

While participating in this study you may experience the following risks or discomforts: [List all reasonably foreseeable physical, informational, emotional, psychological, legal, pain, inconvenience, and privacy concerns. Side effects of any drugs, supplements or other items must be noted.]

*Where applicable consider adding*: There may be risks or discomforts that are currently unforeseeable at this time.

*When applicable*, also add: If you are or become pregnant during this study, there may be risks to the embryo or fetus that are currently unforeseeable.

**How will I be managed if I experience any harm due to the study?**

In case you experience any harm/discomfort we will provide you with[List all the measures in place to manage harms/risks/discomfort experienced by any research participant]

**What are the benefits of my participation in the study?**

The results of this study will benefit society by [describe how the results of study will be useful to society etc.]

You [mention any direct benefits (diagnostic/therapeutic/other) to participants OR state that you are not expected to directly benefit from participation in the study].

We may learn information about your health as part of the research. We [will/will not] share this information with you [describe how, or why not].

# Is there any cost associated with my participation in the study and will I be compensated?

You [will/will not] have to bear any costs as a research participant [If participant needs to pay for anything please mention the cost here and whether or not they will be compensated]

**Who will have access to my information collected during the study?**

Your identity in this study will be treated as confidential. However, it is possible that other people and offices [enlist all other applicable groups including the funding agency, IRB, Drug regulatory authority etc.] responsible for making sure research is done safely and responsibly will see your information.

To protect confidentiality of the study records and data, the following measures will be taken: [describe any measures to ensure restricted access and enonymization e.g. coding, passwords etc.]

**Will my information or my bio-specimens be used for anything other than the current study?**

Information about you, including your biospecimens will not be used for any purpose other than as described above

OR

*Describe any known plans to share data with others, such as in a data repository or with collaborators. Also share plan for use of biospecimen for developing any commercial products and whether participants will or will not benefit from such use.*

**What if I do not wish to participate in the research?**

There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate.

**What are my rights as a research participant?**

You are free to choose whether or not to participate in this study.

You may withdraw to participate in the study for any reason by [Mention the procedure for requesting withdrawal]. Also you will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study. ,

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances [Describe possible reasons for termination]

**Whom should I contact for any query regarding the study?**

You are encouraged to ask questions at any time during this study. For further information ***about the study,*** contact [principal investigator’s name and contact information including phone number and any other emergency contact **MUST** be included].

**Consent Form**

**PART II [CERTIFICATE OF CONSENT]**

I *certify that th*e information provided in the Consent Form Part I [Information Sheet] of the study entitled [insert title of the study] has been read [by/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 to participate as a participant in this research.

Participant’s Name (printed)

Participant’s Signature Date

**CERTIFICATE BY WITNESS**

*In case where the research participant is 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).*

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 participant

Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the provided information.

I also confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

 A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_