**Annex 1a**

**Prime IRB Adult Consent Form Template**

[This template is drafted to help as you develop an informed consent document. Please provide all information clearly and in lay language. Generally, a sixth class/grade language level is recommended. Consent documents should be written in second person (you). All sections of the document must be included. All italicized text may be used as such in the final document.] **(Delete the bracketed text in the final document)**

***This is an adult informed consent form for your participation in a research study.***

***Your participation is voluntary.***

***Please consider all the information below and feel free to discuss the study with study organizers before making decision regarding your participation in the study.***

**1. Study Title:**

The study’s title should match the title provided on the IRB application.

**2. Researcher:**

Provide the name of the Principal Investigator (PI) and Primary Co-Investigator (PCI).

**3. Sponsor or funding agency (if any):**

If applicable, provide the name of the sponsor funding the research study.

**4. Explanation of the study**:

Using non-technical language, give a brief description about the purpose of the research (for instance, replace 7% prevalence with 7 out of 100). Explain why the subject is being asked to participate in the study (for instance, *you are being requested to participate in this study because..*). Clearly mention that the study results will be published.

**5. Number of participants:**

Mention how many total participants are there in this study.

**6. Study procedures**:

In plain language, describe the study process if the participant takes part in the study. What will the participant be expected to do? Indicate if transport will be provided to the participant. Additionally, give an overall process of the study.

**7. Duration of participation**:

Mention the expected duration of participation. Provide the number of contacts and expected duration of each contact with the participant over the course of the study.

**8. Study withdrawal:**

Clearly indicate that the participant reserves the right to discontinue his/her participation without any penalty. You may mention that any data collected up to the time of the participant’s withdrawal will not be removed from the study data and may be reviewed by the researchers applying confidentiality protocols of the study.

**9. Description of the risks:**

Indicate any reasonable risks and/or discomforts related to participation in the study. Describe the potential seriousness of any physical, social, economic, psychological, and legal harms related to the study participation. Indicate any precautionary measures in place to mitigate and minimize any risks.

**10. Description of the benefits:**

Describe any direct (information about their health status, free services etc.) or indirect benefits to the study participants. Mention any reasonable benefits from the research to the society or the body of science. Avoid exaggerating the benefits. If there are no direct benefits to the study participants, it may be stated, *you will not benefit directly from participating in the study*.

Monetary benefits should be indicated in the incentives section (see below).

**11. Confidentiality of records:**

Indicate the confidentiality protocols in the study related to any information that can be used to identify participants. Describe the fate of the participants’ records once the study is completed.

**12. Additional costs to participants:**

Indicate if there will be any additional costs related to participation. For instance, any costs related to participants’ travel for research related activities or any medical procedure costs that the participants may have to bear. If there are no additional costs involved, the following statement may be used: *There will be no additional costs to participate in the study.*

**13. Description of the incentives provided:**

Mention any payments or other incentives for study participation along with the amount, frequency, and procedure of payments. Any compensation should not be linked with study completion; instead it should be dependent on participation. Indicate if payments will be pre-taxed or otherwise. In case of no payments, it may be stated, “*you will not be paid to participate in the study”*.

**14. Compensation or medical treatments for injury:**

Describe any study protocol about compensation or medical treatments available to participants, if there is a study related injury.

**15. Participants’ rights**

The consent form should state the following: *the participation in the study is voluntary and refusal to participate will not involve penalty or loss of benefits to which the participant is entitled otherwise. The study subject may discontinue participation at any time without penalty or loss of benefits as per entitlement till that time.*

**16. Contact information**

The contact information for the principle investigator and/or research staff may be provided for any research study related concerns, or queries.

**17. Signing the consent form:**

*I have read (or someone has read to me) this informed consent form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.*

*I am not giving up any legal rights by signing this form. I will be given a copy of this form.*

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|  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_AM/PM**  **Date and time** |

**Investigator/Research Staff**

*I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.*

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| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Printed name of person obtaining consent** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of person obtaining consent** |
|  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_AM/PM**  **Date and time** |

**Witness(es)**: - May be left blank if not required by the IRB

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| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Printed name of witness** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of witness** |
|  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_AM/PM**  **Date and time** |

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| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Printed name of witness** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of witness** |
|  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_AM/PM**  **Date and time** |

Note: This template may also be used for the physically handicapped adult. For mentally handicapped adult, use the child consent form to obtain the guardian’s consent.