

ANNEX 1B



NMC ERB Child 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 a parental informed consent form for your child's participation in a research study.

Your child's participation is voluntary.

Please consider all the information below and feel free to discuss the study with your friends, family, and study organizers before making decision regarding your child's participation in the study.

1. Study Title:

The study's title should match the title provided on the ERB 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 child's participation is being asked for the study (for instance, *your child's participation in this study is important 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 child takes part in the study. What will the participants are 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 child over the course of the study.

8. Study withdrawal:

Clearly indicate that their child reserves the right to withdraw from the study at any time (*your child may leave the study at any time*). Also if the child or the parent chooses to leave the study, there will be no penalty and such a decision will not affect their relationship with NMC/QHAMC. Mention that any data collected up to the time of the child's withdrawal will not be removed from the study data and may be reviewed by the researchers applying the confidentiality protocols of the study.

9. Description of the risks:

Indicate any reasonable risks and/or discomforts related to child's participation in the study. Describe the potential seriousness of any physical, social, economic, psychological, and legal harm 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 the child's 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, "*Your child 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 the child or the parent. Describe the fate of the child's records once the study is completed. State that *efforts will be made to keep your child's study related information confidential*.

12. 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 be not 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.*

13. Compensation or medical treatments for injury:

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

14. 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. The Institutional Review Board responsible for human subjects research ensuring the protection of rights and welfare of research participants at the Prime Foundation reviewed this research project and found it to be acceptable.*

15. Contact information:

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

16. Signing the parental permission form:

I have read (or someone has read to me) this informed consent form and I am aware that I am being asked to provide permission for my child 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 permit my child 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.

Printed name of subject

**Printed name of person authorized to provide
permission for subject**

**Signature or right thumb impression of person
authorized to provide permission for subject**

Relationship to the subject

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.

Printed name of person obtaining consent

Signature of person obtaining consent

_____AM/PM

Date and time

Note: This form template may also be used for the mentally handicapped adult to obtain the guardian's consent.