

ASSENT FORM

Title of the protocol with version and date

Investigator details

Part 1:

1. Introduction

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/legal guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain).

2. Purpose of the study: Why are you doing this research?

3. Choice of participants: Why are you asking me?

4. Participation is voluntary: Do I have to do this?

5. Procedures: What is going to happen to me?

6. Risks: Is this bad or dangerous for me?

7. Discomforts: Will it hurt?

8. Benefits: Is there anything good that happens to me?

9. Reimbursements: Do I get anything for being in the research?

10. Confidentiality: Is everybody going to know about this?

11. Compensation details: What happens if I get hurt?

12. Sharing the Findings: Will you tell me the results?

13. Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

14. Who to Contact: Who can I talk to or ask questions to?

PART 2: Certificate of Assent

I / my parent or legal guardian has read the previous page(s) of the consent form and the investigator has explained the details of the study.

I/my parent or legal guardian understands that I am free to ask additional questions.

I/my parent or guardian understands that participation in this study entitled [insert name of study] is voluntary

I/my parent or legal guardian may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I/my parent or legal guardian, acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I agree to participate in the study and have been given a copy of this form.

Only if child assents:

Print name of child _____

Signature of child: _____

Date:_____

If illiterate:

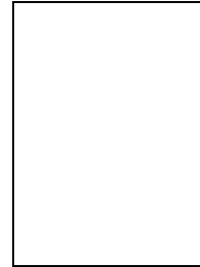
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

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

Print name of witness (not a parent)_____ AND Thumb print of participant

Signature of witness _____

Date _____



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

Print name of researcher_____

Signature of researcher_____

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 child understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her 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 assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____