

[YOUR INSTITUTIONAL LETTER HEAD]

Please do not submit assent forms on the WHO letter head

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is ***in addition to*** the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for _____]

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

Explanation 

Example 

[Name of Principle Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

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

Part I: Information Sheet

Introduction

This is a brief introduction to ensure the child knows who you are and that this is a research study.

Explanation 

Example 

Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

Example 

Choice of participants: Why are you asking me?

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

Example 

Participation is voluntary: Do I have to do this?

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

Example 

I have checked with the child and they understand that participation is voluntary __ (initial)

Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?

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

- 1) give the phase of the trial and explain what that means. Explain to the participant 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: What is going to happen to me?

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

Example



I have checked with the child and they understand the procedures _____ (initial)

Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

Example



Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

Example



I have checked with the child and they understand the risks and discomforts ____ (initial)

Benefits: Is there anything good that happens to me?

Describe any benefits to the child.

Example



I have checked with the child and they understand the benefits _____ (initial)

Incentives: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided.

Explanation

Example



Confidentiality: Is everybody going to know about this?

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

Example



Compensation: What happens if I get hurt?

Describe to the ability of the child to understand and explain that parents have been given more information.

Example 

Sharing the Findings: Will you tell me the results?

Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential.

Explanation 
Example 

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

You may want to re-emphasize that participation is voluntary and any limits to this.

Example 

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

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

Example 

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

PART 2: Certificate of Assent

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 identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead . A researcher or the person going over the informed assent with the child must sign all assents.

Example 

I know that I can choose to be in the research study or choose not to be in the research study [include any limits to child's assent]. I know that I can stop whenever I want.

I have read this information (or had the information read to me) and I understand it.

I have had my questions answered and know that I can ask questions later if I have them.

I understand any changes to this will be discussed with me.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have not signed the assent below. _____(initialled by child/minor)

Only if child assents:

Print name of child _____

Signature of child: _____

Date: _____
day/month/year

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). Children who are illiterate should include their thumb print as well.

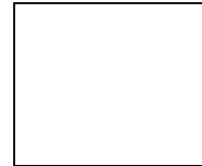
I have witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of witness (not a parent) _____ **AND**

Thumb print of child/ minor

Signature of witness _____

Date _____
Day/month/year



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 _____
Day/month/year

Copy provided to the participant _____ **(initialed by researcher/assistant)**

Parent/Guardian has signed an informed consent ___Yes ___No ___ (initialed by researcher/assistant)