**INFORMED ASSENT FORM TEMPLATE FOR MINORS OR CHILDREN**

**(12 TO UNDER 15 YEARS OLD)**

Adapted fromthe WHO Assent Template

([http://www.who.int/rpc/research\_ethics/informed\_consent/en/)](http://www.who.int/rpc/research_ethics/informed_consent/en/%29)

*(Language should be at a level appropriate to the child's age and development. This template is written for a pre-adolescent or young adolescent.)*

**Informed Assent Form for [Description of Group of Children Involved]**

**Name of Principle Investigator:**

**Name of Organization:**

**Name of Sponsor:**

**Name of Project and Version:**

**PART I: INFORMATION SHEET**

**INTRODUCTION**

*Introduce the researcher and provide a brief description of the study. Clearly state that you are doing research. Inform the child that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.*

**PURPOSE**

*Explain the purpose of the research in clear simple terms.*

**CHOICE OF PARTICIPANTS**

*Explain 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.*

**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.*

**INFORMATION ON THE TRIAL DRUG [Name of Drug]:**

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

**[Name of Drug]: What is this drug and what do you know about it?**

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 and toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial.

**PROCEDURES**

*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.*

**RISKS**

*Explain any risks using simple, clear language. Describe what have been found as cause for worry previously and how the researchers will do their best to ensure that this will not happen and if it does, he or she will be attended to promptly. Include the importance of complying with the scheduled visits in order to address concerns and issues about the study.*

**DISCOMFORTS**

*If there will be any discomforts (e.g., hurt from injection, reddening and swelling) state these clearly and simply. Address what may be some of the child's worries, for example, missing school or extra expense to parents.*

**BENEFITS**

*Describe any benefits to the child (and to others).*

**REIMBURSEMENTS**

*Mention any reimbursements (e.g., travel expenses and reimbursement for time lost) or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating.*

**CONFIDENTIALITY**

*Explain what confidentiality means in simple terms (for example: We will not tell other people that you are in this research and we will not share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.) State any limits to confidentiality. Indicate what their parents will or will not be told.*

**COMPENSATION**

*Describe how the research study group will take care of the child if he or she gets sick or hurt because of participation in the study. Describe the arrangement in accordance with the ability of the child to understand and explain that parents have been given more information.*

**SHARING THE FINDINGS**

*Explain that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly (i.e., in a book, journal, conferences, etc.).*

**RIGHT TO REFUSE OR WITHDRAW**

*Re-emphasize that participation is voluntary and describe any limits to this. He or she can think about it and decide later. It will also be ok to say “yes” now and change his or her mind later.*

**WHO TO CONTACT**

*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 he or she and parents can also talk to anyone they want to about this (e.g., their own doctor, a family friend, a teacher).*

**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. The researcher or the person going over the informed assent with the child must sign all assents. *(Example: I understand the research is about testing a new vaccine for malaria and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a finger prick.)*

**I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.**

**I agree to take part in the research.**

**Print name of child:**

**Signature of child:**

**Date: [DD/MM/YYYY]**

 ***(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: [DD/MM/YYYY]**

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: [DD/MM/YYYY]**

**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 or 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.**

 ***(Signature over printed name)***

**Name of Researcher/ Person taking the Consent**

**Date: [MM/DD/YYYY]**

Copy provided to the participant \_\_\_\_\_\_\_\_ (initialled by researcher/assistant)

Parent/Guardian has signed an informed consent

 \_\_\_\_\_\_Yes \_\_\_\_\_\_No (initialled by researcher/assistant)

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