AX5-V6.1/SOP 03/V6.1

Child Information Sheet and Assent Form

Understanding Assent in Minors

Definition of Assent: Assent is defined as a child's affirmative agreement to participate in research.

- The assent form chosen should be appropriate for the child's age and reading ability and in accordance with the developmental level and understanding capacity of the child.
- For example, a child aged 8 years should be told what exactly she/he is going to undergo, although they may not understand the abstract concept of research such as randomization.
- In older children however, the assent process should be similar to the informed consent process and should be commensurate with their cognitive development.
- If the study is of a longer duration, the researchers may have to repeat the assent process with more information, as the child grows older.
- For children between 7 (84 months and above) and 11 years of age, oral assent must be obtained in the presence of parent/LAR.
- For children between 12 and 18 years of age, written assent must be obtained. If a child becomes 12 years old during the course of the study, then written assent must be obtained in addition to parent/LAR consent.
- In cases of verbal assent, the parent /LAR's countersignature must be obtained confirming that the child's verbal assent has been taken.
- Re-assent must be taken in all the same situations as re-consent as mentioned above. For children less than 7 years of age, parental consent is sufficient.
- 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.

Please note that a mere failure of the child to object should not be interpreted as assent.

- Cultural and social factors and the child's general level of independence and autonomy play an important role in their ability to provide assent.
- Children with chronic illness may have been challenged to develop increased capacity to make independent judgments based on previous experiences.
- This is a joint decision-making process between the child and the concerned adult.
- As assent is part of the informed consent process, the regulations as per the CDSCO guidelines for regulatory hospital trials apply for assent as well!

When is assent not required?

Waiver of assent may be provided by the ethics committees in the following situations:

1) If the research has the potential of directly benefiting the child and this benefit is available only in the research context. In such situations, the child's dissent may be overruled.

2) Waiver of assent may also be considered if the research involves children with mental retardation and other developmental disabilities, where the children may not have the developmental level and intellectual capability of giving assent.

3) Assent may also be waived under the same conditions in which adult's informed consent maybe waived. **Dissent or refusal of a child to participate must always be respected.** Explanation must be given to ensure that the child understands that she/he may withdraw her/his assent at any time during the study.

Instructions to devise the Assent form:

- The informed consent form has 2 parts. The information sheet and the assent form.
- The template appears long only because it contains instructions/guidance to investigators on drafting the assent.
- In certain sections, key questions have been included as test of understanding, after information has been provided to the participants. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

Elements of Assent:

Mention the study title [Study

Title] [Name of Principle

Investigator] [Name of

Organization]

[Name of Sponsor], if applicable]

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)**

Part I: Information Sheet

1) Introduction

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you doand clearly state that you are doing research. Inform the child that you have spoken to their parents and 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.

(Example: My name is ___and my job is to do research and test _ to see which work best to stop _____ (state type of cancer) before it makes someone sick. We want to know if this new _ will stop children from getting sick and we think this research could help tell us that.

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)/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 any time and I will take time to explain.

2) What is research or a study

Research is when we look for information about something that we want to know more about. It's kind of like going on a treasure hunt to find out new things or solve a jigsaw puzzle or riddle, researchers look for information about different things.

3) Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

We want to find better ways to prevent cancer (study team to specify the type of cancer as per the study) before it makes children sick. We have a new drug (or specify the intervention as per the study) to prevent this illness which we are hoping might be better than the one that is currently being used. In order to find out if it is better, we have to test it.

4) 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.

We are testing this new drug (or specify the intervention as per the study) on children who are your age - between 12 and 18years old - who have [state the cancer type], just like you.

5) 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.

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes. This is still your hospital, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it's still okay.

If applicable:If anything changes and we want you to stay in the research study even if you want to stop, we will talk to you first.)

6) Information on the Study intervention or 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 hospital 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:The ____ [state the intervention] we are testing in this research is called ABX. It has been tested before with healthy adults who do not have the disease. We now want to test the _____[state the drug/intervention] in young children/adolescents who have this cancer. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. It has certain side effects. It can make you feel __ (state all side effects associated in simple language instead of using medical terminology). Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used treat this cancer. (state the risk and side effects of the standard treatment briefly).

7) 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: We are going to test the drug ABX by giving some of the children in the research study the new drugand the others are going to get the drug that is already being used to prevent _____[state cancer name]. Neither you nor the researchers will know which drug you were given until after the study is over. By doing the research like this, we can compare which of the drugs is better without

being influenced by what we think or hope the research will show.

If you decide that you want to do this, this is what will happen (in simple steps explain the procedures like blood draw/scans/ Chemo/radiation etc. with the time points) (For example, see below)

1. You will come to the hospital with your parents and you will undergo_.

2. At the hospital we will also give you a _____

3. Once a month for six months after that, (This is only an example, please input follow up period, if applicable as per the study protocol] you will come to the hospital and the nurse will take your temperature. She will also take a little bit of your blood, about three or four drops, from your finger with a finger prick. This might hurt a little but the hurt will go away before very long (This only an example and needs to be customized as per protocol)

Altogether you will come to the hospital ___times over ____months. At the end of ___months, the research will be finished. (To be customized as per protocol)

I have a picture here to show you what will happen. You can ask me to stop and explain again at any time and I will explain more about the process). (This is not mandatory, but helpful in complex trials and may or may not be retained as per your requirement/ complexity of study procedures etc)

8) Risks and Discomforts: Is this bad or dangerous for me? Will it hurt?

Explain any risks using simple, clear language. 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:There are a few other things that I want you to know. This drug ABX is known to cause __. If anything, unusual happens to you, however, we need to know and you should feel free you to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the hospital every month for a check-up. If you get sick or have concerns or questions in-between the scheduled visits to hospital, you should let me or the staff nurse know. You don't have to wait for a scheduled visit.)

Sometimes you may not want to come to the hospital to get your blood checked or have your temperature taken. It's important that you try to come. It won't take very long. You will miss a little bit of school - about an hour every month - and we will tell your teacher about that so that she knows its okay. (To be customized as per protocol)

9) Benefits: Is there anything good that happens to me?

Describe any benefits to the child.

(Example: Nothing really good might happen to you. The drug (study intervention) may not cure the cancer. But this research might help us to find a drug now or later that could help other children. There are a couple of good things if you do decide that you want to do this. You do get regular check-ups with the nurse so that if you are sick, we will know very soon and this can be important.) (To be customized as per protocol)

10) Reimbursements: Do I get anything for being in the research?

Mention any reimbursements 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. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined by the PI.

(Example:Because you live quite far from the hospital, we will give your parents enough money to pay for the trip here and (whatever other expense is reasonable).

11) 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: We will not tell other people that you are in this research and we won't 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 treatment /drugs you received and the results.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your hospitalian, IEC/ Regulatory bodies etc].)

12) 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:If you become sick during the research, we will look after you. We have given your parents information about what to do if you are hurt or get sick during the research.)

13) 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. 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.

(Example: When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.)

14) 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: You do not have to be in this research. No one will be mad or disappointed with you if you say no. Its your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.)

15) 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 etc).

(Example: You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.)

[Name of Principal Investigator]

[Contact details such as telephone number, email and address]

The details of the institutional ethics committee and its role also need to be informed to the child.

I would also like you to know that our hospital has a body called the Institutional Ethics Committee (IEC), that takes care of your safety and well being and safeguard your rights, if you decide to take part in this study.

In case you have any complaints or concerns as a participant in the study, you may contact the IEC through the contact details give below:

Chairperson/Member Secretary

Institutional Ethics Committee-

I/II/III

***Contact number IEC I**-022-24177262, **IEC- II**- 02224177000-4268, **IEC-III**-+91-22-27405154//27405126*

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.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Assent Form

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.**

1. *I understand the research is about testing a new _____[drug/device/other intervention] for _____cancer and that I might get either the new [drug/device/other intervention] which is being tested or the standard treatment which is currently being used.*
2. *I know that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any study related injury, which may be related to the study drug/ procedure/ device.*
3. *I am also aware of my right to not be part of the trial, at any time, without having to give reasons for doing so.*

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.

OR

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

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____

Date:_____

day/month/year

Name and Signature/ Thumb impression of Legally Acceptable Representative

Date

If illiterate:

A literate impartial 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 thumbprint 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 impartial witness (not a parent)_____ AND Thumb print of participant

Signature of impartial 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

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 _____

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)

Test of Understanding to specific sections given in the Child Information Sheet:

Section 5. Participation is voluntary

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

I have checked with the child and they understand that participation is voluntary _(initial) **Section 7. Procedures: What is going to happen to me?**

- ***Examples of question to elucidate understanding:****Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? How many times extra will you have to come if you decide to take part in the research study? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Section 8. Risks and Discomforts:

Examples of question to elucidate understanding: *Do you understand that, while the research study is on- going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

I have checked with the child and they understand the risks and discomforts

_____(initia

l) Section 9. Benefits

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

Section 10. Reimbursements

Examples of question to elucidate understanding: *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Section 11. Confidentiality

Example of question to elucidate understanding:*Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Section 15. Who to Contact

Example of question to elucidate understanding: Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.