INSTITUTIONAL ETHICS COMMITTEE (IEC)
Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 9

AX 09/SOP 05-A/V7.1

Sample Format of an Assent to be a Participant in a Research Study

(This template should be customized according to the requirement of individual research project)

(For Children between 7-18 years old) in English

Date:

Version:

1. **What do we wish to tell you?**

   I am Dr. …… We want to tell you about something we are doing called research study. A research study is when doctors collect a lot of information to learn more about something related to health and disease.

   After we tell / explain you about it, we will ask if you'd like to be in this study or not.

2. **Why are we doing this study?**

   We want to find out

   So we are getting information from …… boys and girls of your age.

3. **What will happen to you if you are in this study?**

   Only if you agree, two things will happen:

   (as applicable to research study)

   i. A small amount of your blood will be drawn. That means it will be taken by a needle in your arm. This will happen …... times. [If some or all of blood draws would be done anyway as part of child's clinical care, emphasize here what will be done extra for the study.]
   ii. The doctors will do some tests on ……..
   iii. You will need to answer some questions about ……...
   iv. You will be given a medicine …… (explain as applicable)

4. **Is this bad or dangerous for you to get involved in this research? Will this study hurt? (explain risks involved as applicable)**

   The stick from the needle to draw your blood will hurt, but it will soon disappear.

5. **How will this research study be useful to you?**

   No, this study won't make you feel better or get well. But the doctors might find out something that will help other children like you later.

6. **Will everybody come to know about your condition? (Confidentiality)**

   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.

7. **Do you get anything for being in the research?**

   [Mention any reimbursements or small gifts/incentives]

8. **Will you tell me the results?**

   [Include details if relevant. Also inform about possibility of publication and keeping confidentiality in publication]

9. **Do you have any questions?**

   You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

10. **Do you have to be in this study?**

    No, you don't. No one will be force you if you don't want to do this. If you don't want to be in this study, just tell us. And remember, you can say yes now and change your mind later. It's up to you. This will not affect in any way your future treatment in this hospital.

11. **Who can you talk to or ask questions to?**

    [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).]

12. **Signature of Person Conducting Assent Discussion**

    I have explained the study to …… (print name of child here) in language he/she can understand, and the child has agreed to be in the study.

    ……

    Signature of Person Conducting Assent Discussion Date

    ……

    Name of Person Conducting Assent Discussion (print)

    Assent Statement

    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.

    Name of child …….. Signature of child ……..

    Date …….

    OR

    I do not wish to take part in the research and I have not signed the assent below……

    (initialed by child/minor)

    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. [in case of illiterate child]

    Name of witness (not a parent) …… and

    Thumb print of participant

    Signature of Witness ……

    Date …….. Name of Investigator …….

    Signature of Investigator …… Date ……

(Copies of the Child information sheet and duly filled and signed ICFs of child and parent shall be handed over to the participant or his/her attendant)