**SOP 03-V 4 / ANX 08-V 2.1**

**Institutional Human Ethics Committee**

**PSG Institute of Medical Sciences and Research, Coimbatore**

**Assent to be in a Research Study**

**For children between 13-18 years old**

**Why are we meeting with you?**

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something related to health and disease. Dr. ….……………. and some other doctors are doing a study to learn more about…………………………. After we tell you about it, we will ask if you’d like to be in this study or not.

**Why are we doing this study?**

 We want to find out ………………………………

 So we are getting information from lots of boys and girls like you.

 In the whole study, there will be about …………… children.

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

Only if you agree, two things will happen:

1. 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.]*

1. The doctors will do some tests on…….
2. You will need to answer some questions about ……..

## Will this study hurt?

The stick from the needle to draw your blood will hurt, but the hurt will go away after awhile.

**Will you get better if you are in this study?**

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.

**Will everybody come to know about my 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

**Is this bad or dangerous for me? (Risks involved)**

**Reimbursement or compensation for the inconvenience: Yes/No**

If yes describe the plan

**Emergency Medical Treatment:** If applicable, add here along with available medical treatment in case of complications.

**Compensation for protocol Related Injury: Yes /No**

If yes describe the details of compensation or insurance for protocol related injury to the study participant. Explain who will bear the cost in case of trial related injury?

**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]

**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.]

## 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.

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

No, you don’t. No one will be mad at you if you don’t want to do this. If you don’t want to be in this study, just tell us. Or if you do want to be in the study, tell us that. 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.*

**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).

*If you don’t want to be in this study, just tell us. If you want to be in this study, just tell us. This will not affect in any way your future treatment in this hospital.*

*The doctor will give you a copy of this form to keep.*

**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*)

**Part 2: Certificate of Assent**

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 not signed the assent below.\_\_\_\_\_\_\_\_\_\_\_ (initialed 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). 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\*Modified from the Informed Assent form template for children/minors –World Health organization*