**AX5-V6/SOP 03/V6**

**Child Information Sheet and Assent Form**

Study title: “……………………………………………………………………”

**Introduction- Background and Rationale would be more appropriate**

We want to tell you about a study we are doing. This study is a “research” study. It is a special way to find out about something. We are trying to find out more about **[purpose of study in simple language].** You are being asked to join the study because **[insert the name of medical condition or other reasons for inclusion].** The reason why we are doing this need to do this is because [gap in knowledge in simple words]. This might help other children like you in future……………………………

We invite you to participate in this study.

**What will you have to do?**

You are being asked to be part of this project. The project is about [insert general statement about study]. Your [parents or legal guardian, if applicable] have already been told about the project. Your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form Please read this form and ask the researcher any questions you have. You can decide whether or not to take part in the study. You can say no as well. It is your choice to be part of the project or not.

The assent form describes the research study and states that you have been explained the purpose and the nature of the study to your satisfaction by the attending doctor and you are ready to follow the study procedures.

List all study procedures. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, non-technical & direct language.

**Risks, discomforts & Side effects**

If you experience any of these side effects you can contact your doctor immediately. The doctor will treat you

**Dr. Phone:**

(Describe in simple language provisions for treatment/hospitalization for side effects/injury)

We want to tell you about some things that might hurt or upset you if you are in this study. **[Describe risks – e.g., painful procedures, other discomforts, things that take a long time. For example: The needle we use to take the blood may hurt. You might get a bruise on your arm.]**

You and your parents will not bear the expenses regarding the therapy. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the study doctor who is treating you will be responsible for paying for the medical expenses for the treatment of that injury.

**Costs:**

Describe the cost for participating in the study to the subject/participant. The information must be written in clear terms regarding the cost which will be borne by sponsors/Principal Investigator/s of the project, and study participant.

**Reimbursement for Participation**

Describe plan for reimbursement or amount for expenses incurred, time spent and any inconvenience. State clearly the details for travel reimbursement for trial participants &/or attendant.

**Emergency Medical Treatment**

(If applicable, add here)

In case of the physical injury to the participant during the course of research please state the name and contact details of the PI.

Describe available medical treatment in case of complications.

**Benefits**

If you are in the study it may or may not help you to get better or benefit you. But we hope to learn something that will help other children like you some day.

**Confidentiality**

The information collected about you during this study will be kept safely locked up. Data will be stored securely for a period of \_\_\_\_\_\_\_\_\_\_ years. Nobody will know it except the doctor doing the research. The doctor will not tell your friends or anyone else.

The information will only be accessed by the doctor the Ethics Committee and the Regulatory authority

The study information about you will be given to your father/mother/guardian if required.

**Right to refuse or withdraw**

You do not have to be in this study, if you do not want to be. If you do not want to be in this study, we will tell you what other kinds of treatments there are for you. If you decide that you don’t want to be in the study after we begin, that’s OK too. Nobody will be angry or upset. We are discussing the study with your parents and you should talk to them about it too.

**Whom to contact**

You can ask questions if do you do not understand any part of the study. If you have questions later that you don’t think of now, you can call the doctor

<Name of PI > **Phone:** <Contact No.>

If you have any queries regarding your rights you may contact,

<Name of Member Secretary of IEC >

**Phone:** <022-24177262 /4268(IEC-I/II) 022-27405154 (IEC-III)>

**Your responsibilities**

It is the responsibility of your parent / guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or do not continue to receive treatment/care as per the study. It is also your responsibility and your parent / guardian to report any side effects that you may experience while on the study.

It is also your responsibility and that of your parent / guardian to inform the doctor if you consume any other medication apart from the study treatment.

We expect your co-operation throughout the study.

**Child Assent Form**

I\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to participate in the study. “………………………………………………………………………………”

I have been informed, to my satisfaction, by the attending physician, about the study. 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.

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

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

Name and Signature/Thumb impression of the study participant Date:

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

Name and Signature/ Thumb impression of Legally Acceptable Representative Date:

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

Name and Signature of Impartial Witness Date:

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

Name and Signature of the attending Physician Date: