

AX9-V6.1/SOP 03/V6.1 Assent for prospective audit study

Child Information: (Should be concise and simple)

To state the purpose of the study (What the study is about and why the study is being done)

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.

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.

Assent for Participation in the study

I understand that a study "Titled _" conducted by "Dr."_ (name, phone no.) involves the analysis of my medical data that has been collected as part of my routine medical care.

I understand that there will not be any additional medical procedures over and above those which I would encounter during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, Tata Memorial Centre and does not pose any additional risk to me beyond that which I would encounter while undergoing routine physical or psychological examinations or tests and/or which I would encounter in routine daily life activities. I further understand that confidentiality with regard to my medical data will be ensured, and that the results published will not in any

way be linked to me. I understand that the Principal Investigator (name) would be willing to provide me with any additional information that I would want to know regarding the study. I understand that if I have any queries regarding rights I may contact,
<Name of Secretary of IEC >**Phone:**<022-24177262/4268 (IEC-I/II) 022-27405154 (IEC-III)>

I understand that if I decline to participate in this study or withdraw my consent at any stage of the study my medical treatment will not be affected.

I am willing to allow the use of my data for the study.

Name and Sign / Thumb impression of the minor

Date

Name and Sign of the Guardian/Parent /LAR

Date

Name and Signature of Impartial Witness

Date

Name and Sign of the Principal Investigator

Date

Note: Copy of the Child Information Sheet and duly filled in Assent Document should be handed over to the participant or his/her attendant

A copy of the participant feedback form also needs to be provided along with the copy of the signed informed consent form.