

AX8-V6.1/SOP 03/V6.1

Consent for prospective audit study (for parents)

Parental/LAR consent

Parent Information: (Should be concise and simple)

Introduction:

Your child is invited to participate in a study/research/experiment. This document gives you a description of the study/trial in which you are being asked to participate. Your participation in

this study is voluntary, and you can enquire about all details before giving your written consent to participate in the study.

Purpose:

The purpose of this study is to

Consent

I understand that a study “Titled _” conducted by “Dr.”_ (name, phone no.) involves the analysis of my ward’s medical data that has been collected as part of his/her routine medical care.

I understand that there will not be any additional medical procedures over and above those which my ward 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 my ward beyond that which he/she would encounter while undergoing routine physical or psychological examinations or tests and/or which he/she would encounter in routine daily life activities. I understand that the Principal Investigator (name) would be willing to provide me/my ward with any additional information that I/my ward would want to know regarding the study.

I understand that if I have any queries regarding my ward’s rights I may contact,
<Name of Secretary of IEC >**Phone:**<022-24177262/4268 (IEC-I/II) 022-27405154 (IEC-III)>

I further understand that confidentiality with regard to my ward’s medical data will be ensured, that his/her privacy would be maintained and that the results published will not in any way be linked to him/her.

I am willing to allow the use of my ward’s data for this study.

I understand that my ward’s participation in the study is voluntary and that I am free to withdraw consent for my ward’s participation at any time, without giving any reason, without my ward’s medical care or legal rights being affected.

Name and Sign/ Thumb impression 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 Parent Information Sheet and duly filled in Informed Consent 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.