AX7-V6.1/SOP 03/V6.1
Consent for prospective audit study
Participant Consent for Participation in the study

Introduction:

You are 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.

This research study is approved by the Institutional Ethics Committee of Tata Memorial Centre. A copy of the ICF will be given to you for your record

Purpose:

The purpose of this study is to

……

Statement that the study involves research and explanation of the purpose of the research

Clearly state

1. The Aim/ objectives of the study to be mentioned
2. Statement of type of cancer patients/healthy volunteers enrolled

…… …… …… …… ……

Consent

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.

Purpose of the study-

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 my data will be stored for___years, 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 my rights I may contact,

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

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

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

Name and Sign/Thumb impression of the participant

Date

Name and Signature/ Thumb impression of Legally Acceptable Representative

Date:

Name and Signature of Impartial Witness

Date:

Name and Sign of the Principal Investigator

Date

Note: Copy of the Participant 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.