

Form No:28

Oral Assent Form Template

[oral assent: 07 to <12 yrs. and written consent: 12 to <18 yrs.]

Ihave read /have had read the participant information sheet version no.dated.....bearing page numbers of the research study entitled The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities'/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my assent willingly to participate in this research study.

For Limited or non-readers: (Illiterate participants) I have witnessed the assent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Signature Of Impartial Witness/LAR	Signature/Thumb Impression Of Representative & Date
Name of the witness	Name of the study participant
Signature/thumb impression of mother/father	Signature of the person administering the assent & date
Signature of principal investigator	Signature of person administering the consent