

INFORMED CONSENT DOCUMENT (ICD) PART-2

INFORMED CONSENT FORM

Title of the project:

Participant's name:

Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my routine medical care in this hospital being affected. I understand that confidentiality of my identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my information when required.

I have been given a copy of information sheet giving details of the study. I volunteer to participate in the above mentioned study.

(I also consent/ do not consent to use of my stored biological samples or related data for future scientific purposes, if applicable)

(I also consent / do not consent to be contacted over telephone for study purposes/ knowing the results — if applicable)

Name and Signature/thumb impression of the participant: _____ Date: _____

Signature of the witness with date: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator with date: _____ Date: _____

CONSENT FORM (for participants less than 18 years of age and for patients who cannot consent)

Parent/Legally authorized/acceptable representative (LAR)

Title of the project:

Participant's name:

Address:

Parent/LAR's name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my child's/ward's participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, and without my child's/ward's routine medical care in this hospital being affected. I understand that confidentiality of my child's/ward's identity will be maintained during the research period, after its completion as well as during publication of the results. Only investigator, ethics committee, institutional or regulatory authorities may have access to my child's/ward's information when required.

I have been given a copy of information sheet giving details of the study. I volunteer my child/ward to participate in the above mentioned study.

Verbal assent taken for children 7-12 year of age: Yes/No

(I also consent/ do not consent to use of my child's/ward's stored biological samples or related data for future scientific purposes, if applicable)

(I also consent / do not consent to be contacted over telephone for study purposes/ knowing the results — if applicable)

Name and Signature/thumb impression of the parent/LAR:

Date:

Signature of the witness with date:

Date:

Name and address of the witness for illiterate participants:

Signature of the investigator with date:

Date: