

PART II: Certificate of Informed Consent (must be translated into Hindi or the local language as well)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I voluntarily consent to participate in this research.

willingly, under no pressure from the researcher-

- (i) agree to take part in this research, and agree to participate in ALL INVESTIGATIONS which will help acquire knowledge for the benefit of mankind,
- (ii) agree to donate my or my children's samples, such as (5 ml of blood, Sputum, or any other biological sample)

My consent explicitly does not include the disclosure of any personal information. For disclosing any such personal information obtained from the investigations/ conducted on my samples, further consent should be obtained.

I have been informed that the researchers (PI and/or her/his colleagues and Research Scholar:.....) will take my prior consent before they draw benefits from research based on participation/ my samples/my child/children's samples.

Print Name of Participant _____

Signature of Participant _____

Date _____

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ AND Thumb print of participant

Signature of witness _____

Date _____

(In case of a minor participant, kindly take consent from the parents/legal guardian in front of two witnesses)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability, made sure that the participant understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the participant was given the opportunity to ask questions about the study, and that all questions asked have been answered correctly, to the best of my ability. I confirm that the individual has not been coerced into giving consent, and that the consent was given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Details of Research Scholar:

Name:

Contact Details

Mobile Number

E-mail:

NB: Three copies should be made, one each for (1) Patient, (2) Researcher, and (3) Institution.

(Investigators are advised to prepare the translation in simple, understandable Hindi or the local language on their own.

MINOR'S ASSENT TO PARTICIPATE IN THIS STUDY

(For ages >14 – <19 yrs): Minor should read or have the following read to him/her before signing.)

You are invited to participate in this study on: (title of study).

If you decide to participate, you will: (briefly describe what the child will do).

Your participation in this study is voluntary, and you may withdraw at any time without any penalty. If we use these results in any articles or presentations, we will not use your real name, so your identity will be protected. Please read this information and decide whether or not you want to participate in our study. Thank you so much for your help!

Name of Participant

Signature of Participant

Date

Assent obtained by:

Name:

Signature with Date