



INFORMED CONSENT DOCUMENT (ICD) PART-1

PATIENT / PARTICIPANT INFORMATION SHEET (PIS)

Title of the project:

Name of Investigators, Department:

1. Purpose of this project/study
2. Procedure/methods of the study
3. Expected duration of the subject participation
4. The benefits to be expected from the research to the participant or to others and the post-trial responsibilities of the investigator
5. Any risks expected from the study to the participant
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Reimbursement for participating in the study
9. Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.
10. Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
11. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
12. Possible current and future uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, this should be mentioned
13. Contact details of the Principal investigator (PI):

14. For other queries/ complaints, contact

*Member Secretary, Room No. 106, IEC (Human studies), Dean Research Office,
First floor, Administrative Block, JIPMER. Ph: 0413-2296106*

Place:

Name and Signature of the participant with Date:

Signature of the investigator with date:



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(Institute of National Importance under Govt. of India)

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: _____



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CONSENT FORM FOR PARENT/ LEGALLY ACCEPTABLE REPRESENTATIVE (LAR)

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

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 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: _____



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ASSENT FORM TO PARTICIPATE IN A CLINICAL RESEARCH

(for children above 12 years and below 18 years of age)

Child Participant's name:

Date of birth/Age:

Parent/LAR's name:

Address:

Title of the project:

We are doing a research study about(purpose in simple language). In this study we will be (description of the study - Procedures, Drugs to be used, risks, discomfort, in simple language).

The possible benefits from this study might be
(details of possible benefits of participation)

If you do not want to be in this research study, we will tell you other options. (for research projects that offer treatment or intervention.) When we are complete the study, we will write a report about what was learned. This report will not include your name or that you were in the study.

You can be in this study if you want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too. If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

Signature of the child participant :
(If child knows to sign/Thumb impression)

Date:

Signature of the parent or guardian :

Date:

Name and address of the witness :

Signature of the witness :

Date:

Signature of the Investigator :

Date: