**Institutional Ethics Committee (IEC)**

**RIMS, Ranchi**

 **(Performa of the Subject Information Sheet)**

Title of the project:

Site of the investigation:

Name and address of the Principal Investigator:

Contact number of Principal Investigator:

1. Aims and methods of the research (A brief introduction about the investigation along with purpose of the study and procedure of investigation involving human subjects in simplified manner (10-15 lines).
2. Expected duration of the subject participation.

The benefits to be expected from the research to the Participants or to others.

1. Alternative treatment/procedure options.
2. Right to prevent use of biological samples (DNA, cell line etc.) at any time during the research.
3. Any risk to the subject associated with the study.
4. Maintenance of confidentiality of records.
5. Provision of free treatment for research related injury.
6. Compensation of subjects for disability or death resulting from such injury.
7. Freedom of individual to participate or to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
8. Amount of clinical sample in quantity, to be taken should be mentioned.
9. Source of funding for the Investigation.
10. In case of drug trials:
11. The chemical name of drug, date of its manufacturing and batch number must be mentioned.
12. Initial bio equivalent study of the drug/references should be provided
13. Foreseeable extent for information on possible current and future usage of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.
14. Risk of discovery of biologically sensitive information.
15. Publication, if any, including photographs and pedigree charts.
16. Responsibility of Investigators.

**Informed Consent**

Title of the project:

Site of the investigation:

Name and address of the Principal Investigator:

Contact number of Principal Investigator:

1. I agree voluntarily to take part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I am free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that I will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if I am harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.

I willingly agree to take part in the above study.

Signature of the participant/guardian Date:

Name:

Age:

Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

*Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.*

**Signature page for research involving children ages birth to 6 years of age or unable to provide assent for other reasons**

Title of the project:

Site of the investigation:

Name and address of the Principal Investigator:

Contact number of Principal Investigator:

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child’s medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Allow Do not allow

Signature of the parent/guardian Date:

Name:

Age:

Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

**Waiver of assent**

The assent of ----------------------------- (name of child/minor) was waived because of:

Age:

Maturity:

Psychological state of the child:

Signature of the Parent/Legally authorized representative: Date:

*Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.*

**Signature page for research involving children ages 7 through 17 years of age and able to provide assent**

Title of the project:

Site of the investigation:

Name and address of the Principal Investigator:

Contact number of Principal Investigator:

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child’s medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.

I willingly agree that my child will take part in the above study.

Signature of the parent/guardian Date:

Assent of child

------------------------ (name of child/minor) has agreed to participate in above study

Signature of the child Date:

Name:

Age:

Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

*Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.*