**Informed Consent Document Template**

*Title of the study*

*Name of the research participant*

*Date of Birth/Age:*

*Address of the subject:*

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation. Please give your consent to participate in this study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant. Your participation in this study is voluntary.

**PURPOSE OF THE STUDY**

*Briefly state the background and rationale for undertaking this study in layman friendly language.*

* **EXPECTED DURATION OF THE STUDY AND NUMBER OF RESEARCH PARTICIPANT**

*You will be one of the approximately XXX people who will participate in this study. (If multicentric study – mention that the study is also being carried out at XXX other centres across the country/ state.*

**STUDY PROCEDURES**

*Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organize this section.*

*Do not use scientific / technical terms. Use language appropriate to the population.*

*If applicable, specify the subject's assignment to study groups, length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done.*

*Describe any invasive procedures or biological sampling.*

If you volunteer to participate in this study, you will:

1. Be asked about previous medical problems, your current health and your medications;
2. Have a brief physical examination for XXXX
3. Need to undergo routine investigation such as XXXX

**POTENTIAL RISK AND DISCOMFORT**

*In addition to physiological risks/discomforts, describe any reasonably foreseeable psychological, social, legal, or financial risks or harms that might result from participating in the research.*

**POTENTIAL BENEFIT**

*Describe benefits to subjects expected from the research. If the subject will not benefit directly from participation, clearly state this fact.*

*State the potential benefits, if any, to science or society expected from the research.*

*Note: Payment or other compensation for participation (e.g., a gift certificate, extra credit) is* ***not*** *a benefit and is not to be discussed in this section.*

**COMPENSATION FOR PARTICIPATION**

You will not be compensated for participating in this study. However, in the event of any injury during the study, due care will be taken care of by the investigators.

**CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of *describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.*.

*The results of the study will be published in the journals, however, your identity will not be revealed.*

**PARTICIPATION AND WITHDRAWAL**

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. Your decision will not affect your further treatment at this institute.

**CONTACT FOR FURTHER INFORMATION**

Thank you for your time to read (or have read to you) the information about this study. We undertake to maintain complete confidentiality regarding the information obtained from you during the study. The information obtained from you will be used for research only. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during and after the study.

If you have any questions about the study, or wish to report any medical problem related to study, please contact the study investigator XXX, designation, department XX, telephone number.

If you have any questions or concerns about your rights as a research participant, or complaints regarding the research study, you may call Dr. Devasena Anantharaman who is the Member Secretary of the Institutional Human Ethics Committee, Rajiv Gandhi Centre for Biotechnology on telephone 0471 2529590 (Monday to Friday – 9am to 05.30pm)

**Informed Consent Form**

1. I have read or have had read to me the information given in the informed consent document for the study entitled “XXXX”.
2. I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of the information sheet.
3. I understand that my participation in the study is voluntary and that I may withdraw from the study at any time, without any loss of benefits to which otherwise entitled.
4. I understand and accept that my biological samples may be used for future research.

Yes  No

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Name of research participant

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Signature/ thumb impression of participant Date

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Signature of Impartial witness Date