Sri MANAKULA VINAYAGAR Medical College and Hospital

*Annexure 9: AX 02/SOP 06/V2.2*

**Template for Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)**

**Informed Consent Document: Part I – Participant Information Sheet (PIS)**

[Instructions – This information sheet should address the participant of this study. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While preparing the PIS, the investigator must ensure that the information provided is in a simple and unambiguous language (avoid medical jargons) which can be understood by the participant. Please avoid copying & pasting from other study protocol.]

**Study title: .....**

Dear Participant**,**

You are invited to take part in a research study. Before you participate in this study, it is important for you to understand why this is being carried out. If you have any doubts regarding the procedure and purpose of the study or if you want more information, you are free to ask the contact person mentioned below.

**1. What is the purpose of the study?**

**2. Why have you been chosen?**

**3. Do you have to take part?**

**4. What will happen to you if you take part?**

**5. What is the duration of the study and the expected number of participants?**

**6. What do you have to do?**

**7. What is the procedure or drug that is being tested? (Mention the probability of random assignment for randomized trials)**

**8. What are the alternatives for diagnosis or treatment?**

**9. What are the possible benefits of taking part?**

**10. What are the possible disadvantages or risks of taking part? Mention what measures will be taken to minimize the risk, if any.**

**11. What are the provisions for treatment of research related injury?**

**12. Will compensation be provided to you in case of research related injury?**

**13. What are the possible current and future uses of the biological material collected or data to be generated from the research?**

**14. What if new information becomes available?**

**15. Will your taking part in the study be kept confidential?**

**16. What will happen to the results of the study?**

**17. Who is organizing the research study?**

**18. Who has reviewed the study?**

**19. Contact details of investigator for further information:**

| |
|---|
| CONTACT PERSON**:** |
| Name of the Principal Investigator |
| Designation |
| Name of the Institute |
| (Phone and email ID of the Investigator) |
| Ph.: xxxxxxxx, Email-xxxxxxxxxxxxxxx |

**20. Contact details of Institutional Ethics Committee (for appeal against violation of your rights):**

| |
|---|
| SMVMCH Ethics Committee |
| Sri Manakula Vinayagar Medical College and Hospital |
| Kalitheerthalkuppam, Madagadipet, |
| Puducherry - 605 107 |

I wish to thank you for taking your time to participate in the study.

**Date:** **Place:**

**Signature of investigator** **Signature/Thumb impression of participant**

**Signature of witness**

**Informed Consent Document: Part II – Informed Consent Form (ICF)**

**Participant's Name**

**Address:**

**Title of the study:**

The details of the study have been provided to me in writing and explained to me in my own mother tongue. I confirm that I have understood the purpose and procedure of the above study and that I 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 from the study at any time, without giving any reason whatsoever, and without my routine medical care in this hospital being affected. I was assured that the result of the study will be used only for scientific purpose(s) and I will not restrict the use of the results. I have also received a copy of the consent form giving the "Information for participants of the study".

I fully consent for my participation in the above mentioned study.

(I also consent/ do not consent to the 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)

Signature/Left thumb impression of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator: _____Date: _____