**SRI BALAJI VIDYAPEETH**

(Deemed University)

Accredited by NAAC with ‘A’ Grade

Pillaiyarkuppam, Puducherry – 607 402

**Patient/Participant Information Sheet (PIS)**

**Information for Participants of the Study**

**Instructions** – *This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant. (This need to be deleted after reading)*

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we are ready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

1. **What is the title of the Research Project?**
2. **Who /where this study is being conducted?**

This study is being conducted by ---------------------------------- a Post graduate medical student belonging to ……………………………………………… Department under the guidance of …………………

1. **What is the purpose of the study?**
2. **Procedure/Methods of the study (in brief, simple terms)**

Note: Do not copy paste from the protocol

1. **How long you are expected to participate in this study?**
2. **Why I am being considered as one of the participant?**

Describe in simple understandable terms.

1. **Should I definitely have to take part in this study?**

No. If you do not wish to participate you will not be included in this study. Also you will continue to get the medical treatment without any prejudice.

1. **If I am participating in this study, what are my responsibilities?**

 You may have to follow some simple rules. These are: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Are there any benefits for me/Public?**

Yes………….The benefits to be expected from the research to the participant or to others and the post-trial responsibilities of the investigator.

1. **Will there be any discomfort / risks to me?**

No risks. But some discomforts may be there like giving few ml of blood for investigation, undergoing some medical examinations or any other risks expected from the study to the participant.

1. **Will my participating in this study, my personal details will be kept confidentially?**

Your participation in the study and the study records relating to you will be kept confidential throughout the study and thereafter. Your personal identity will not be revealed in case of publication in any journal or analysis of your results, nor will it be shared with anyone. The study records relating to you will be preserved for a period of three/ five years for analysis and follow up.

1. **Will I be paid for the Study?**

 Provision of free treatment for research related injury.

1. **Can I withdraw from this study at any time during the study period?**

Your participation in the study is purely voluntary. You are free to withdraw from the study at any time without assigning any reason. Your withdrawal from the study would in no way affect the medical care or other benefits which you are otherwise entitled to receive from the Institute

1. **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, for which we seek your permission prior to the study inclusion?**

The biological materials collected from you may be utilized for further analysis, if needed. All the data and biological materials obtained from you will be used only for research purposes. It will not be used for any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

1. **Possible current and futures 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, for which we seek your permission prior to the study inclusion?**

The data collected from you may be utilized for further analysis, if needed. All the data obtained from you will be used only for research purposes. It will not be used for any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

1. **Will I be informed of this study’s results and the findings?**

Yes, on your request for the results of the study and its findings.

1. **Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:**
2. **Address and telephone number of the IHEC office, MGMCRI**

Office of Institutional Human Ethics Committee, 1st floor college block (Adjacent to dept. of Pathology), MGMCRI, Puducherry 607 402. Phone No.: 0413- 2616700 (Extn No.: 754)

Signature of the Participant Signature of the Investigators