**Participant Information Sheet (PIS)**

1. **Invitation paragraph**

You are invited to participate in the study titled ‘………………….……….. ‘.

The purpose of this document is to provide you with information about this study. Please read this document carefully and ask your doctor questions or seek clarification if anything is not clear to you. When all your questions have been answered to your satisfaction and if you are willing to participate in the study, you will be required to sign the consent form. You will be provided with a copy of this information sheet for your reference.

1. **Information about the study (introduction)**

*(Briefly explain in lay terms the background of the problem, the need & purpose of the study, Use simple explanatory language / words that can be understood by an averagely literate individual such as non-matriculate)*

1. **Why am I being requested to participate in this study?**

You are requested to participate in this study as you are suffering from………

1. **What are the benefits of my participation?**

*State possible benefits of the study if any or print your participation may or may not benefit you directly, however the information obtained from the study will be of benefit in the treatment of future patients*

1. **What will the study involve?**

*(Explain how long the patient will be required to be in the research. How often will he / she will require to visit a clinic if applicable)*.Provide details of the study procedure e.g. examination, intervention (drugs, surgery) tests, radiology etc. Explain *(allotment to a study group)* if it is a blinded study.

1. **What are the risks involved?**

\*For non-intervention studies state none as NO extra investigations or new therapy is involved.\* For intervention studies or where extra investigations are involved- list possible side effects *(common & uncommon)*

1. **What will be the cost of participation?**

All costs of the treatment or diagnostics, over & above those involved in standard diagnosis & treatment will be borne by the hospital. Costs as involved in routine care will be borne by the patient

1. **Will my results be informed to me?**

*(print as applicable)*

1. **What are my responsibilities?**

Explain are there any lifestyle restrictions, dietary restrictions, advise to follow all study related instructions, keep follow up dates, report any adverse reactions etc.

1. **Is my participation compulsory?**

No, your participation is voluntary and non-participation will not in any way affect your treatment at the hospital.

1. **Can I withdraw from the study?**

You are free to withdraw from the study at any time without giving any explanation. This will not affect your care at the hospital. No further test(s) etc. will be done. However, data already collected may be used for analysis of results.

1. **If something goes wrong what happens? Who treats & bears the cost?**

Any study related complication (diagnostic procedures & therapy) will be treated by the hospital. The hospital will bear the costs of any conditions arising out of study participation.

Mention availability of insurance, if any.*(State if no additional or new intervention is done the patient will bear the cost for such events.)*

1. **Do I get any compensation in case of research related injury?**

Research related injury is an injury that occurs to the subject as a result of research participation. Injuries may range from relatively minor harms (such as bruises or infected wounds) to major injuries (such as organ damage or temporary disability) to catastrophic injuries (such as permanent disability or death).An injury may require only acute or emergency care, or it may require continuing care. Injuries can be physical or psychological/emotional. In case of research related injury, the study subject shall be entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines. In case of death of the subject, his /her nominees are entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines. The financial compensation shall be over and above any expense incurred on the treatment of the subject. The decision for compensation shall be taken during the IEC meeting and adequately decided as per the provisions of rule 122DAB of The Drugs and Cosmetics Rules, 1945, and other guidelines provided by CDSCO.

1. **What about the confidentiality of my data?**

All the information obtained in this study will be kept strictly confidential and used for scientific purposes only. Data taken from this study may be published or presented in scientific meetings. However, your name and other identifying information will be kept confidential and will not be made publicly available. Investigators, study team members, ethics committee members & regulatory authorities (if required by law) may review your personal and medical records.

1. **Is the study approved by ethics committee or review board?**

Yes.

The study has been reviewed & approved by the Institutional Ethics Committee of Padmashree Dr D Y Patil Medical College, Hospital and Research Center, Navi Mumbai.

1. **Whom can I contact for more information?**

For any study related information:

PI / Research fellow and 24 hours contact details (refer first page)

For your rights contact the following:

**Dr Vaishali Thakare**

**Member Secretary**

Institutional Ethics Committee for Biomedical & Health Research (IECBH)

D Y Patil School of Medicine & Hospital and Research Center

Sector-5, Nerul, Navi Mumbai

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