

Format for PARTICIPANT INFORMATION SHEET (PIS)

[PIS is an information sheet to address the participant of the study in a simple non-medical layman's version in English and the Local Language understood by the participant ; PIS written in a single paragraph shall be containing the following information:

1. Title of the project, 2.Name of the investigator(s), 3.Purpose of this study, 4.Procedure/methods of the study, 5.Expected duration of the subject 's participation,6.The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator,7. Any risks expected from the study to the participant.8.Maintenance of confidentiality of records.9.Freedom to refuse to participate or withdraw from the study at any time during the study period without the loss of benefits like medical care ,etc. that the participant would otherwise be entitled.10. Possible current and future uses 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, this should be mentioned.11. Contact Address and telephone number of the investigator (s).12. The patient information sheet must be duly signed by the investigator.

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