



**अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360006**  
**All India Institute of Medical Sciences, Rajkot, Gujarat 360006**  
Institute of National Importance under PMSSY, MoHFW  
Government of India [www.aiimsrajkot.edu.in](http://www.aiimsrajkot.edu.in)

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**Participant Information Sheet (PIS)**

STUDY TITLE:

PROTOCOL NO:

SPONSOR:

PRINCIPAL INVESTIGATOR:

Name of Participant:

- 1. You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.**
- 2. What is your expected duration of the participation?**
- 3. What procedures will be followed during this study?**
- 4. What are the risks and discomforts to you?**
- 5. What benefits are expected from this research?**
- 6. What are the alternatives available to you?**
- 7. Are the data/records of the participant kept confidential?**
- 8. What will be the treatment schedule(s)?**
- 9. What compensation and/or treatment(s) are available to the Participant in the event of a trial-related injury?**
- 10. Whom to contact for trial related queries and what are the rights of Participant's in the event of any injury?**
- 11. Are the participants paid to take part in this study?**
- 12. What are your responsibilities during participation in the study?**
- 13. Statement that participation is voluntary, that the Participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Participant is otherwise entitled.**
- 14. Participant or Participant's representative will be notified in a timely manner if**



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**significant new findings develop during the course of the research which may affect the Participant's willingness to continue participation will be provided.**

- 15. Statement of foreseeable circumstances under which the Participant's participation may be terminated by the Investigator without the Participant's consent.**
- 16. Additional costs to the Participant that may result from participation in the study.**
- 17. The consequences of a Participant's decision to withdraw from the research and procedures for orderly termination of participation by Participant.**
- 18. A statement that the particular treatment or procedure may involve risks to the Participant (or to the embryo or fetus, if the Participant is or may become pregnant), which are currently unforeseeable**
- 19. Approximate number of Participants enrolled in the study:**
- 20. Any other pertinent information**

**Contact persons:**

For further information / questions, you can contact:

Principal Investigator:

You are also free to contact: The Head of Department of....., AIIMS Rajkot.

In case of conflicts, you can contact Institutional Ethics Committee at the following address:

The, Institutional Ethics Committee, AIIMS Rajkot