32. Participant Information Sheet (must be translated into Hindi or in the local language as well)

(for the subject/ patient recruited for the Biomedical study)

Jawaharlal Nehru University

School of ……

PATIENT/PARTICIPANT INFORMATION SHEET

This information sheet should contain all relevant information in simple, non-technical terms, easily understandable by a layperson, regarding your study. The information must be provided under the following headings and in the following sequence.

PART-I:

1. Title of the study.

2. Invitation to take part in the study.

Before going into the details of the study, express in a few lines regarding their freedom in participating in the study. An example is given below;

"We welcome you to take part in the study. You have the right to decide to take part or not to take part in the study. This document contains all relevant information regarding this study. It also mentions the benefits, discomfort, or possible risks involved in this study. We help you in the decision-making process by providing all relevant information about this study. Therefore, take adequate time to read what is given in this sheet, and you are free to discuss this with your friends, colleagues, family members, or your treating physicians. We are also ready to clarify any doubts in your minds regarding this study".

3. What is the purpose of the study? _____

4. Why have I been invited to participate? _____

List out the criteria used to select the subjects for this particular study.

5. Do I have to take part? _____

Tell them that taking part in the study is entirely their voluntary decision. It can be stated as follows;

"Decision to or not to take part in the study is entirely your own choice. If you choose to be part of the study, then a copy of this sheet will be given to you for your reference and you need to sign a consent form. Even after agreeing to take part in the study, you can withdraw from the study at any point in time, without giving any reason for your decision. Doing so will not affect the standard of treatment/care you receive."

6. What will happen to me if I take part? _____

Explain to them that they will be called for a basic physical examination / to fill out the questionnaire/ intervention/ newer treatment, or for follow-up. State how often and how long they need to come. Assure them that no injury will be inflicted on them.

7. What do I have to do?

Tell them whether they need to follow a certain type of lifestyle (lifestyle modification), change in their routine daily activities, or if they can continue to take their regular medication.

8. What is the drug or procedure that is being tested?

Give full information regarding the drug, viz., type, dosage, route, and frequency of administration, possible side effects, before or after food. The same way provides complete information on the procedure, viz., name, invasive or non-invasive, whether blood is withdrawn, possible side effects, and safety measures.

9. What are the alternatives to the diagnosis or treatment?

They should be informed about alternative options to the proposed diagnosis or treatment. That gives them the freedom to decide to join the research or refrain from it.

10. What are the side effects of taking part in the study?

List all the possible side effects of the drug or procedure in simple terms without using medical jargons so that the subject understands what is written. For example, instead of using terms like anemia or polycythemia, use simple terms like decreased or increased red blood cells. Some side effects may be unknown or new for that particular drug or procedure.
Therefore, advise them to contact you or any other persons involved in the research in case they notice the known side effects or any unusual manifestations. For this, they must have your address and the addresses of other investigators, along with their contact numbers.

11. What are the possible disadvantages or risks of taking part in the study?

These are for example purposes.

Pregnancy may pose a disadvantage or risk for participating in any study. So, give a clear warning as follows:

"The drug or the procedure may affect your unborn baby. Therefore, do not take part in this study if you are pregnant or planning to become pregnant during the course of the study. In case you become pregnant during the study period, inform the PI or other Investigators, who will relieve you from the study."

Screen women subjects for pregnancy before the start of the study. Advise them to use effective contraceptive methods if they are in the reproductive age group.

The same concern should be given to male subjects. The study should not affect their sperm or sexual life.

12. What are the possible benefits of taking part in the study?

The subjects should not be lured into the study by giving exaggerated information regarding the benefits of the drug or procedure. They should not also be coerced into the study by threatening them with exaggerated disadvantages if they do not take part in the study.

Therefore, it is advisable to state that the benefits of the drug or procedure are not known at present, but this study may benefit future patients.

13. What if new information becomes available?

Any new information that becomes available during the course of study should be shared with the subject. State it as follows:

"During the course of the research, if we get any new information, it will be shared with you. Based on the new information, you can decide by yourself whether to continue the research or not. If you like to withdraw from the study, we will make all necessary arrangements to continue your medical care that have been getting from us. Withdrawing from the study will

not affect the medical care given by us. If you like to continue, then you need to sign a new updated consent form."

14. What happens when research stops?

When the research stops due to some reason, exact reason must be told to the subject. If the sponsoring company stops sponsoring, the subject must be informed about other alternative drug/procedure.

15. What if something goes wrong?

The participants must know that there is a process/procedure in place to handle the complaints from them. Assure them that measures will be taken to rectify their grievances. If some serious events happen, the study must be stopped.

16. Will my taking part in the study be kept confidential?

Permission must be sought from the participants to get access to their medical records for necessary vital information. The information (of the subjects) that will be available during the course of the research should be strictly maintained confidentially. Though the data will be shared with other people, the identity of the subjects will not be revealed.

17. What will happen to the results of the research?

Inform them that the results of the research will be used for publishing the article in scientific journals and presentation at conferences.

18. Who is organizing and funding the research/trial?

Provide information whether the researcher is getting any financial aid from Govt., NGOs, pharmaceutical companies, organization or institution. If funded, state for what purpose the money being used viz., equipment, lab tests/ reagents, drug, procedure, etc.,

19. Did the study receive approval from the Institutional Ethics Board?

Mention that the IERB, JNU, has reviewed and approved the study. However, don't mention the individual names of the EC members who reviewed and approved the study.

20. Contact for further information:

Provide the PI's & Co-PIs' complete contact details, including mobile number/s, to the participant.

Name of the PI:	Name of the Co-PI's:
Designation:	Designation:
Contact Details:	Contact Details:
Mobile Number:	Mobile Number:
e-mail:	e-mail:

Place:

Signature of PI

Signature of PI

Details of Research Scholar:

Name:
Contact Details

Mobile Number

E-mail:

Signature of Research Scholar