GUIDELINES FOR PARTICIPANT INFORMATION SHEET

Principal Investigator: _____
(Insert your name, designation)

_____
(Department and Institute)

Contact Details: Phone no. _____ / Email Id. _____

Study / Project Title: _____
(Insert the title of the project)

INTRODUCTION FOR PARTICIPANTS

You are invited to take part in the research study. You can choose whether to take part or not to take part in the study. You can opt not to take part in the study without giving a reason and it won't affect the care you receive. You can withdraw from the study at any time. Your refusal to take part in the study will not involve any kind of penalty or loss of benefits to which you are otherwise entitled to.

This Participant Information Sheet will give you details of the study and help you decide whether to participate in the study or not. It sets out **why we are doing the study**, **what your participation would involve**, **what the benefits and risks to you might be**, and **what would happen after the study ends**. We will go through this information with you and answer any questions you may have. You do not have to decide now whether or not to participate in this study. Feel free to discuss with the research team if you have any doubts.

If you agree to take part in this study, you will be asked to sign the Consent Form which records your consent to take part in the study. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

GUIDELINES FOR PROJECT PIs

I. General information to be provided to the participants about the project:

1. **Description:** Provide a brief background of the proposed study (short description in few sentences, no more than a paragraph).
2. **Purpose of the study:** Provide in brief, what the study is all about and the need for it.
3. **Study Design & Participants:** Indicate how the study is going to be conducted (ie., the process) and from whom the data will be collected and how many participants will be involved.
4. **Use of Data:** Explain how the data will be used and presented (e.g. thesis, publications, possible future research, etc.) including, if appropriate, how the results will be shared with participants.

5. **Project Funding:** If relevant, indicate that the project has received specific funding and name the funding body. The reason for this section is that funding sources may create a potential for conflict of interest, and these should always be declared.

II. Participant Involvement:

(What would the participant wish to know before deciding whether or not to participate in a research project?)

6. What will participation in the study involve?

- Why has the person been chosen to participate?
- What will be done in the study, including how participation in it will differ from not being in the study
- The time involved in participation (e.g. the number and duration of any visits to the research centre, and the expected finishing date of the study) and follow up if relevant
- The purpose and expected number of tests or questionnaires to be performed during the study (explain the procedures that will be followed on a step-by-step basis).
- Will health information be collected (either directly from the participant via questionnaires or indirectly by accessing medical records). Inform the participants if the study involves questions which may be sensitive.

7. What are the possible benefits and risks of this study?

- Foreseeable risks, side-effects and discomforts of study participation, including any risks to the health of a participant's family member(s). Describe how these will be managed
- What are the possible direct benefits of this study? If no benefit is expected, the subject should be made aware of this
- The extent of the investigator's responsibility to ensure that care is provided to participants during the study
- A statement describing financial compensation and medical management in case of injuries during the participation

8. Who pays for the study?

- Participant will not incur any costs
- What payments or other forms of reimbursement, if any, will be provided in recognition of participation

9. What are the participants' rights?

Voluntary Participation & Withdrawal:

- Inform the intended participants that participation in the project is **voluntary** and that they may, without negative consequences, decline to take part or withdraw from the research without providing an explanation at any time.
- Inform the participants they can refuse to answer a question. Advise them that if they do withdraw, what will happen to their data.

- In the case of data drawn from individuals, it is usual that data from withdrawn participants will be destroyed and not used. You can give participants the option of allowing you to continue to use their data, but this should be opt-in.
- You should describe what you will ask participants to do in enough detail that they are able to form *informed* consent to participate. So, for example, if the interview will involve sensitive questions, you should tell participants that this will be the case, and briefly explain the nature of these questions, so they can choose to be involved or not.
- What provision will be made for the privacy and confidentiality of individuals.

10. Confidentiality:

- Describe the process briefly but in sufficient detail for the participants to understand how their data will be kept confidential during **both** the collection phase and in the publication of results.
- With regard to publication of results, indicate how participant information will be attributed – e.g. full name, pseudonym or no attribution within published materials.
- Indicate whether anyone but the nominated researchers will have access to the material provided by the participants and how the confidentiality of the participants' data is to be preserved.
- In the case of an agency handling the direct interactions with the participants the agency members will be trained to follow Ethical normatives in all interactions with the participants.
- Participants may in the participant information sheet record whether they would like the resulting publication/verbal sharing of conclusions to be provided to them.

III. Queries and Concerns:

Contact Details for more information:

- Include information on the method by which participants can raise queries on the project.
- For further requests for information or queries regarding the study, participants should be directed to the Primary Investigator.
- Provide name contact details (phone no. and email).