

## Participant Information sheet

Study title/Project Title:

Principal investigator:

Contact phone number:

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You are invited to take part in a study on [x]. 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 pull out of 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. Before you decide you may want to talk about the study with other people, such as family, whanau, friends, or healthcare providers. Feel free to do this.

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.

### 1. What is the purpose of the study?

- the purpose of the study, including its expected contribution to knowledge and its benefits to communities
- how the study meets the best intervention and equipoise standards?
- the purpose and practical significance of the use of randomisation, blinding or placebo
- the nature and sources for funding for the study, the institutional affiliations of the investigator(s), and who can be contacted to answer questions and how to contact them
- the study's status, with a current approval from an ethics committee.

### 2. What will my 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 (eg, 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 or cause embarrassment.

**3. 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
- discuss need for contraception if necessary,
- 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.

**4. 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

**5. What are my rights?**

- the voluntary nature of participation, including that they are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage
- that participants have the right to access information about them collected as part of the study
- that participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on their health
- what provision will be made for the privacy and confidentiality of individuals

**6. What happens after the study or if I change my mind?**

- whether any study intervention will be available to participants after the study and, if so, under what conditions (including any cost to them)

- how study data will be stored and for how long, whether the data will be retained for possible future use, who will be responsible for their secure storage and how they will be destroyed
- whether any biological specimens collected during the research will be destroyed at its conclusion and, if not, details of their storage and possible future use
- how the study findings will be communicated on completion of the study, including to participants, and in what expected timeframe.