Clinical Research Informed Consent

Participant information and consent. Participation is voluntary.

Study

STUDY TITLE

PROTOCOL NO.

CTRI REGISTRATION NO.

SPONSOR

ETHICS COMMITTEE

EC APPROVAL DATE

PRINCIPAL INVESTIGATOR

PI PHONE

PURPOSE, PROCEDURES AND DURATION

FORESEEABLE RISKS AND DISCOMFORTS

Your rights

- Taking part is voluntary. You may refuse or withdraw at any time without giving a reason and without losing any care you are otherwise entitled to.
- Your identity will be kept confidential. The sponsor, ethics committee and regulators may see your records to check the study, but you will not be named in any publication.
- If you are injured because of the study, you will receive free medical management and compensation as required by law.
- You will be told of any new information that may affect your willingness to continue.
- The consent process may be audio-video recorded where the rules require it.

Participant

FULL NAME

PARTICIPANT ID

DATE OF BIRTH

PHONE

LANGUAGE EXPLAINED IN

- [ ] I have read (or had read to me) the information about this study and had my questions answered.
- [ ] I agree to take part in this study.

☐ I agree that my samples and data may be stored and used for future research approved by an ethics committee.

An impartial witness signs if the participant cannot read; the participant then gives a thumb impression or mark on their signature line.

Participant

SIGNATURE

PRINTED NAME

DATE

Investigator

SIGNATURE

PRINTED NAME

DATE

Witness 1

SIGNATURE

PRINTED NAME

DATE