

INFORMED CONSENT

Protocol number:

1. Dr.
2. Dr.
3. Dr.
- 4.

Phone:

1. I have read (or have had read out) and understood the contents of the participant information sheet for the above mentioned study on (date)____ and I have been explained these details in my native tongue.
2. I have had ample opportunity and time to ask questions and clarify doubts from the research team whose contact details have been provided to me in the participant information sheet, in case of any further need.
3. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights as a patient, being affected. I hereby state that my decision to participate in this study is free from coercion or undue inducements.
4. I have been explained the purpose of the study and my responsibility in it. I have understood the possible risks and the benefits that might arise due to my enrolment.
5. I have been assured that my privacy will be respected and the data collected from me or my tissues will be kept confidentially secure.

6. I have also understood that the researchers might want to present the findings from the study or publish them in a scientific periodical or submit reports to the concerned authorities. I have been assured that in such situations my privacy and confidentiality will not be compromised.
7. I have also been informed that if my photographs are taken for the purpose of research, all efforts will be made to keep my identity confidential.
8. I understand that the sponsor/funding agency, others working on the sponsors' behalf, IEC- AIMS Chittoor auditors/inspectors and representatives of the regulatory authorities will, at times, need to access my records collected for the purpose of this research and I hereby consent to the same. No one else shall be privy to my details without my explicit, prior permission.
9. I understand that as per the existing laws, the audio/audio-visual recording of my informed consent process will be done and I consent to the same.
10. I understand that my tissues and my data generated from this research study, will not be shared with any other researchers or be used in any other research study without my prior, explicit permission.

11. I have understood that my tissues and the data arising from this research will be securely stored for a period of 5 years (in case of clinical trial)/3 years (in case of other studies) and when disposed, will be done as per the biomedical waste disposal management policy of the institution.
12. I have been given to understand that none of the research team members have any conflict of interest arising out of this research study.
13. I have also understood that one copy of the informed consent document and one copy of the participant information sheet (in my native language) can be kept by me for future reference.

Participant's Signature, Name
With date

PI's or trained research team member's
Signature, Name With date

PI's or the trained research team member's contact details:
Mobile number and/or email id

Participant's thumb impression (in case illiterate)

Independent witness signature, name with date