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| *Dear Principal Investigator,**To help you process your research protocol faster, we are providing some elements that we recommend should be there in the informed consent document. Before you submit the protocol for ethical clearance we strongly urge you to build a comprehensive informed consent document.* *A well-constructed informed consent document will ensure that:* *a. The participant will be provided enough information (including study title & PI name)**b. This will be provided in a language that he/she understands and using simple words that even a student of eighth standard of a non-English medium school**c. The participant will be given adequate time to understand the implications of consenting**d. Opportunity will be given to ask questions from the PI or a member of the study team**e. Some method of assessing the comprehension of the participant will be undertaken**f. Participant’s consent is voluntary and free of coercion**g. Option to refuse is offered, without comprising patient rights* *h. Option to voluntarily withdraw at any stage of the research, after initially agreeing without compromising rights**i. Participant will get to retain one copy of the consent form AND one copy of the participant information sheet* *j. Maintaining privacy of the participant and confidentiality of the data**k. Permission to publish the data while protecting privacy and confidentiality**l. The PI or a study team member will be available for clarification with adequate contact details**m. There is a place on the form for signature, name and date for the participant and/or legally authorized representative and a study team member**n. There is a place on the form for name, date and signature of an independent witness, in case the participant is illiterate or unable to sign* *o. Sample of the informed consent document is provided in a local language**PLEASE FIND BELOW A SAMPLE OF AN INFORMED CONSENT TEMPLATE AND PROCESS FOR YOUR READY USE* |

**SAMPLE FOR INFORMED CONSENT**

**Study title:**

**Protocol number:**

**Names of all the research team members (in the same order as in the approved protocol)**

**Participant name:**

**Age:**

**Address:**

**Contact details (to be collected only if required for the research purpose; not to be obtained by coercion)**

 **Email:**

 **Phone:**

**Name and address of the nominees and relation to participant (only for compensation purpose):**

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, Yenepoya Ethics Committee-1, 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 PI’s or trained research team member’s

With date 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

**Steps in the Informed Consent process:**

1. Identify a prospective participant (maybe in the OPD, ward or community)
2. Assess their willingness to participate in your study
3. If they seem willing, ask them for 15-20 minutes of their time
4. Take them (the prospective participant and their accompanying person and only 1-2 members of the research team) to a room or a not-crowded area. If your study is a clinical trial involving certain vulnerable populations then take permission to record the informed consent process
5. In case your prospective participant is an illiterate person, then an independent witness should be present to view the entire informed consent process and sign the document.
6. Make them feel comfortable, be respectful, speak their language, maintain appropriate eye contact, keep open body gestures, do not speak authoritatively
7. Ask them if they would like to read the participant information sheet on their own or would like to have it read out to them
8. Take them step-by-step through the information in the PIS. Repeatedly enquire if they have understood or would like more clarity
9. Encourage them to ask questions
10. Stress more on the following points: That this is research and not therapy; explain the risks truthfully; describe the benefits practically; describe in detail what you plan to do; describe clearly what you expect from the participant if they enrol.
11. Encourage them to not agree or disagree in a hurry. Encourage them to take the PIS home and discuss with family, well-wishers or lawyers
12. Ask them to return when they are ready to sign the informed consent document and enrol. Specify a date, time and place.
13. Both, the research team member and the prospective participant should sign the document at the same time.
14. In case your prospective participant is a child in the age range of 0-7 years then take parental consent (any one parent; no other person).
15. In case your prospective participant is in the age range of 7-12 years, then along with parental consent take oral assent from the child and document this in the informed consent form
16. In case your prospective participant is in the age range of 13-18 years, then along with parental consent take written, signed assent from the minor and store these two documents together
17. Hand over one copy of the signed ICF to the participant and keep one copy in your records
18. Take re-consent wherever appropriate
19. Store these documents securely for a period of 3 or 5 years, as the case maybe