|  |
| --- |
| *Dear Principal Investigator/Postgraduate student,**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**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 OR 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 FOR YOUR READY USE* |

**SAMPLE FOR INFORMED CONSENT**

**Study title:**

**Protocol number:**

**Participant initials:**

**Age:**

**Address:**

**Qualification:**

**Occupation**

**Annual income**

**Name and address of the nominees and relation to participant:**

1. I have read and understood the participant information sheet on (date)\_\_\_\_ and I have been explained these details in my native tongue.
2. I have had the opportunity to ask questions and clarify doubts from the research team whose contact details have been provided to me in case any further need.
3. I have been given adequate time and opportunity to decide on my enrolment 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 being affected. I hereby state that my decision to participate in this study is free from coercion or undue inducements.
4. I understand that the sponsor of the clinical trial, others working on the sponsors’ behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health records collected for the purpose of this research
5. I have understood the possible risks and the benefits that might arise due to my enrolment.
6. I have been assured me that my privacy will be respected and the data collected from me or my tissues will be kept confidential and will be shared only by members of the research team, ethics committee and regulatory authorities. No one else shall be privy to my details.
7. 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.
8. 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.
9. 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 PG/PI’s Signature, Name

With date With date

 PG/PI’s contact details

 Mobile number and/or email id

Participant’s thumb impression (in case illiterate)

Independent witness signature, name with date