YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

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GUIDELINES FOR WRITING INFORMED CONSENT

Guidelines for writing Informed Consent for a research protocol

Dear Principal Investigator/Postgraduate student,

To help you process your research protocol faster, we are providing some elements that are universally recommended to be a part of 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

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SAMPLE FOR INFORMED CONSENT

I,_____, age_____, resident of_____, have been explained the details of this study titled "_____" being conducted by Dr. (name of the principal investigator or postgraduate student) (if postgraduate student then add under the guidance of Dr. *guide name here*). I have been explained these details in my native tongue. I have understood the possible risks and the benefits that might arise due to my enrolment. I have been given adequate time to decide on my enrolment and have been given time and opportunity to ask clarifications from Dr._____. Dr._____has provided me his contact details and I understand that I can contact him/her any time for further clarifications about the protocol. I hereby state that my decision to participate in this study is free from coercion or undue inducements.

This study involves (describe what is going to be done in the study, what is the role of the participant; what are the risks and benefits to the participants and/or society. This should be at least 3-4 paragraphs) You are being selected for this research project because (state reasons why this participant is being selected). We encourage you to read the attached participant

I have also been explained that if I refuse right from the beginning, my healthcare rights will not be affected in anyway. I also understand that I have the right to withdraw at any point of time before study completion, without this decision compromising my rights as a patient of Yenepoya Medical College Hospital.

Dr._____(name of the PI or PG) has 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 privacy to my details.

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. I have also been informed that my photographs will be taken. I hereby give consent for my photographs to be taken for the purpose of this study only, and with the assurance that all efforts will be made to keep my identity confidential.

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

PG/PI's Signature, Name
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