Please provide a running title for the study, version number and date. Each time there is a revision, advance the version number and change the date. Always refer to the latest version

Dear Researcher,

This document is in pdf format and contains instructions (in blue) that will help you fill out the protocol proposal/synopsis (attached as a Word document) for submitting your research work for Scientific Review Board and Institutional Ethics Committee approvals.

Do not attempt to fill this form out. Fill the Word document using this template for instructions.

This form has been approved by the University and is applicable to all its constituent units (colleges), departments and centres.

For feedback and further assistance please contact ethcom@yenepoya.edu.in

Happy ETHICAL researching!!!

YENEPOYA _____ COLLEGE

Please add the name of the college/centre

YENEPOYA (deemed to be UNIVERSITY)

MANGALORE, KARNATAKA

(The blue and italicized words are instructions for researchers to fill the form. The researchers must ensure that all the blue and italicized words are deleted before submitting the protocol to SRB or EC)

YENEPOYA
DEEMED TO BE
UNIVERSITY
Recognized under Sec 3(A) of the UGC Act 1956
ACCREDITED BY NAAC WITH GRADE A+

PROFORMA FOR REGISTRATION OF ACADEMIC CLINICAL TRIAL/FACULTY RESEARCH/PhD THESIS/ PG DISSERTATION/SHORT STUDY

(Write the appropriate study type. Please delete what is not applicable and retain what is applicable

Please prepare the synopsis using Times New Roman/Arial font, font size 12, 1.5 spacing, all margins 1 inch)

PART A: PERSONAL DETAILS

1 Name of the Principal Investigator:	
2 PI's Designation and Name of the Department and College/Centre	Designation: Department: College/Centre: Employee code/Campus id:
3 Name of the Course (in case the PI is a student/scholar) *Delete if not applicable (eg. for Faculty studies)*	
4 Date of admission to course (in case PI is a student/scholar) *Delete if not applicable (eg. for Faculty studies)*	
5 Contact details of the PI	Valid mobile number: Active email id:
6 Name(s) of the PG Guide/Co-guides/Co-investigators /Research team members (with designation, affiliation, phone numbers and email ids) *Add names of all the co-investigators including research coordinators with designation and affiliation of each*	

PART B: PROJECT DETAILS

1. **TITLE OF THE RESEARCH TOPIC:**
   Provide title in PICO format and study design (Prospective/retrospective/clinical trial/observational/survey/interventional/etc)

2. **EXECUTIVE SUMMARY:**
   Please write a half to one page summary of the main points of your protocol

3. **INTRODUCTION & BACKGROUND:**

   Briefly introduce the topic and its various aspects

4. **NEED FOR THE STUDY:**

   Briefly describe the lacunae in literature and need for the study

5. **RESEARCH QUESTION:**

   a. **RESEARCH QUESTION OR HYPOTHESIS (ALTERNATE/NULL)**
      Please do not write NA for the research question or hypothesis

   b. **AIM**

      Please describe the broad aim of the study

   c. **OBJECTIVES**
      Objectives should be SMART: Specific/Measurable/Achievable/ Relevant/Time-bound. Avoid vague terms like understand, appreciate, etc

6. **REVIEW OF LITERATURE (Please follow Vancouver style of referencing and in-text citation):**
   Narrative style, not bulleted, not table form. At least 5-10 articles depending on the complexity of the study. Balance the review to include articles, both for and against. Each article review should (at least) include objective, method, participants/samples, their results and their conclusions. In clinical trials, provide details of drug approval (drug name, dosage, indication, route, combination). In devices, provide details of class of device

7. **METHODOLOGY:**
   Methodology should be descriptive and include all relevant details. Should not be bulleted and not in PowerPoint style

a. STUDY DETAILS:

i. STUDY DESIGN:

This should include the following:

1. *Prospective/retrospective/ambispective. If prospective then whether cross sectional/Longitudinal*
2. *Observational/Interventional. If observational, nature of the observation: cohort, case-control study. If interventional, nature of intervention (drug, device, implant, diagnostic tool, surgical technique, educational or psychometric tool)*
3. *Sponsored clinical trial/Academic clinical trial*
4. *Clinical and/or biomedical and/or sociodemographic*
5. *Add any other specific relevant details (genomics/stem cell/radiation)*

ii. STUDY SITE:

Name of the hospital from where the participants will be selected, or the community centre, or the community, laboratory, schools, etc

iii. FUNDING DETAILS:

Include name of the sponsor (pharma, funding agency, university seed grant or self-funded), amount of funding and period of funding. If applied but award awaited please include details; or if planning to apply but not yet applied, please include details

iv. **STUDY DURATION:**

Provide a planned start date and a planned end date. Keep in mind that the data collection can begin only after EC approval and other necessary permissions and approval (CTRI, DCGI, Stem Cell Committee, etc)

b. PARTICIPANT DETAILS:

i. SOURCE OF DATA:

Indicate from where the samples/participants will be drawn: Hospital, community, Medical records, Laboratories, hostels, schools, etc

ii. **SAMPLE SIZE:**

Indicate the total number of participants to be included in the study. If there are groups/arms/case controls, then specify how many in each group. Provide a scientific justification for the sample size using calculation. Provide a reference article and the details based on which sample size was calculated. Account for loss of follow-up, response rate, etc and provide the final number. This number should be written as a specific number and not approximate. eg.

sample size of 46 and not minimum sample of 46 or at least 46, etc. Even if the researcher is doing complete enumeration, a sample size calculated by the statistician is mandatory. If there are multiple sites, provide sample size from each site and the total.

iii. METHOD OF SAMPLING (SAMPLING TECHNIQUE):
Simple random (envelope/coin), systematic sampling, stratified, cluster, convenience, purposive, snowball sampling

iv. RANDOMIZATION AND BLINDING (IF ANY):
Wherever applicable, add the method of randomization, number of arms/groups
Whether blinding is applicable, who will be blinded, etc

v. INCLUSION CRITERIA:
All the demographic and scientific parameters required to include in the study. Must be specific characteristics (eg instead of children in general, include age group, instead of broad terms like comorbidities; specify which one- diabetes)

vi. EXCLUSION CRITERIA
Please do not write the reverse of the inclusion criteria as exclusion criteria
Please do not write participant not willing to sign informed consent or participant lost to follow up, as exclusion criterion
Please ensure that the exclusion criteria assessment parameters are captured in the data collection form

vii. WITHDRAWAL CRITERIA
Please state that the participant has the right to withdraw from the study at any time. Please state whether, on withdrawal, the samples/data already collected will be used for analysis

viii. DISCONTINUATION CRITERIA
Please state here why the researcher wishes to not continue the participant in the study any more (eg. participant develops a condition listed in the exclusion criteria after the study has started or does not complete follow up, etc)

c. STUDY TOOL:

i. DESCRIPTION (QUESTIONNAIRE; INTERVIEW SCHEDULE; SCALES; SCORES; DATA COLLECTION FORM; PROFORMA; ETC)
Detailed description of the tool must be provided

Eg. Questionnaire

What are the domains, types of questions (open ended, close ended, hybrid), number of questions, nature of responses, scales used, how will the scoring if any be done, how will it be administered? Self or PI administered

Online or face to face

Translations in local languages

Any sensitive questions?

Eg. Data collection form

Anonymous/coded/with personal identifiers

Main components which will include only that data which is required for analysis to meet the objectives of the study. Do not include the hospital case sheet with broad headings (personal history, family history, CVS examination, CNS examination.. etc)

Scales and scores: source, permissions must be mentioned and attached

ii. VALIDATION

If the tool is already validated and approved- then provide reference if available in the public domain or provide permission to use from the journal/author who hold the copyright

If the tool is prepared by the researcher, details of and evidence of validation of the tool, who validated, how many of them validated and certificate of validation. This should be done before submission to the Ethics Committee

iii. PRETESTING

This should be done ideally on 10% of the sample size on possible participants. These responses should not be included in the results of the study. The individuals should not be included in the participants of the study. Pretesting must be done to assess clarity, meaning and language of questions and to avoid ambiguity

d. METHOD:

i. DETAILS OF THE METHODOLOGY INCLUDING DETAILS OF SAMPLE COLLECTION:

Please provide as many details as the researcher can envisage, including the smallest details. Describe methodology phase-wise if applicable, Clinical/ laboratory/community- all separately in detail)

Who will be recruited, how and where will the informed consent process happen, what screening tests will be applied, how will the intervention be

applied, is the intervention approved by DCGI (in case of drugs), will placebo be given, what outcomes will be measured, what adverse effects are expected, how will they be managed, how will bias be managed, will the research results be shared with the participants, will photographs be taken, how many follow ups will happen, what will happen in each follow up, are the intervention and tests part of the routine healthcare, etc.
If tissue samples are collected, please describe in detail, how much sample will be drawn, how many times, who will draw it, how and where will the samples be stored, disposal of samples, purpose of storage, reuse in future, sharing with third parties, etc

ii. DETAILS OF ANALYSIS: (Including statistical tests)

For quantitative data: Include all the statistical tests here.

For qualitative data: Include the methods of analysis

8. **WORK PLAN:**

Provide a Gantt chart or its equivalent. Keep in mind that this will need to be updated from time to time.

9. **BUDGET:**

Provide details on who will bear the costs of the observations (tests or investigations), the intervention, the adverse events and their management, and compensation (in case of injury or death)

10. ETHICAL ISSUES:

A. Ethical guidelines followed:

(For all studies directly/indirectly involving human participants, the ICMR National Ethical Guidelines for biomedical and health research involving human participants 2017 to be followed. For all clinical trials, Good Clinical Practices guidelines to be following in addition)

B. Ethical approval:

Please state that the study will start (informed consent process, participant recruitment and data collection) only after ethical approval from the institutional ethics committee. Approved version of the protocol and protocol-related documents will be followed. Also state that any subsequent protocol amendments will be implemented only after prospective approval from the ethics committee. EC communications and reporting will be done as per the EC approval letter.

C. Informed consent:

Please state who will take the informed consent, when, where, and in what language

Please state that all participants will be included after a prior written voluntary informed consent process. Participation will be voluntary and no force or coercion will be used for recruiting participants.
For children 12-18 years; Parental written consent and child's written assent will be taken. (provide separate forms)
For children 7-12 years, parental written consent and documented child's oral assent will be taken (provide separate forms)
For children <7 years, parental written consent will be taken (provide separate form)
For participants who cannot give consent (mentally challenged, unconscious) surrogate consent will be taken (provide separate forms)
For studies involving communities- community consent in addition to individual consent
The researcher may request waiver of consent in certain situations (refer the website)

D. Vulnerable population:

Please state if the study is including vulnerable populations.

a. *Children (0-18 years)*
b. *Pregnant and lactating mothers*
c. *Mentally challenged individuals*
d. *Illiterate/socioeconomically poor*
e. *Tribal communities*
f. *Students/employees of the institution*
g. *Any other*

Please justify why the researchers are including vulnerable populations, or conversely, why the researchers are excluding vulnerable populations.
Please fill up the vulnerability checklist (available in the website), in case the researchers are recruiting vulnerable populations.
Simultaneously, in the harms and benefits section below, please provide what additional safeguards will be taken by the researchers to mitigate the harms and maximize the benefits.

E. Standard of care:

Please state if the intervention/observation/investigation is part of routine diagnosis/therapy/healthcare or is done for the purpose of research.
Please state whether standard of care for the participants will continue or be delayed or denied or modified for the purpose of this research.

F. Harms:

List the possible harms/adverse effects (common and serious) of the intervention/ observation/questionnaire (include physical/psychological/financial/social or any other harm)
Provide a plan to minimize the harm
Provide a plan to manage the adverse effects if they occur (who will bear the extra cost of the treatment of the adverse event)

In the case of a drug intervention trial or a new surgical procedure trial, please provide a letter from the Medical Superintendent that free medical care will be provided to the research participant in the event of the occurrence of an adverse event occurring as a consequence of the research intervention.

G. Benefits:

List if there are direct benefits to the participants (financial or non-financial) because of participation in research
List if there are indirect benefits to the community or scientific advancements

H. Risk-benefit ratio:

Please mention whether the risk: benefit ratio is favorable

I. Privacy:

Please mention what measures will be taken to assure privacy of the participants while collecting data/ examination/ sensitive information/ etc

J. Confidentiality:

Please mention how data will be kept safe and secure
For hard copies/samples- state details of secure provision/cabinet with lock and key accessible only the research team
For soft copies/data- secure folder/ secure computer with password protection accessible only the research team

K. Requisite permissions/approvals/agreements/MoU/MTA:

For clinical trials: Register the study with the Clinical Trial Registry of India and provide the registration number
For new drugs/interventions: Get approval from DCGI and provide the communication details
For approved drugs- attach a copy of DCGI approval for the drug/ indication/ dosage/route of administration/combination
For Sending samples/tissues to another lab outside Yenepoya- MoU and material transfer agreement wherever applicable
For collecting data from sites outside Yenepoya- permissions from authorities
For academic clinical trials- letter from HOD/MS to approve that any adverse events occurring due to the clinical trial will be treated free of cost

11. **BIOSAFETY ISSUES:**

Along with any biosafety issues envisaged by the researchers, please provide details on how the biological samples will be collected, transported, stored, used, reused, shared and destroyed.

12. **UTILIZATION OF RESULTS OF RESEARCH AND SPECIFIC DELIVERABLES:**

Please add how the results will be utilized for the benefit of the community

i. Improved healthcare

ii. Increased visibility to the institution through presentations in conferences, etc

iii. Increased credibility of the institution through scientific publications

13. **REFERENCES (in Vancouver Style)**

14. **LIST OF ANNEXURES:**

Please include data collection form, questionnaire, interview schedules, tools/scales, PIS, ICF, PIS translations, ICF translations, ***each one should be a separate document starting with page 1, with version number and short title in the header/footer with page numbers*** *(Do not continue the same page numbers as the main protocol.*
Also add permission letters, approvals, CTRI registrations, etc, as separate annexures. Number the annexures and list them in the covering letter.
Also add CVs of all investigators, conflict of interest declaration forms, vulnerability checklist

15. **DATA COLLECTION FORM (**aka Case Record Form, Performa or questionnaire, if any)

Please attach the data collection form as a separate annexure, and not within the main protocol.
Please provide the same running title, version number and date as in the case of the protocol.
Ensure that the data collection form is anonymous. Please avoid collecting personal information or identifiers unless absolutely necessary to answer the research question/ objectives.
Please refrain from capturing more data in the form than is necessary to answer the research question.
Please do not submit the department's clinical case sheet (which is used for academic purposes).
Please also provide a snapshot/screenshot of the Excel spreadsheet, where the data will be transferred from the Data Collection Form.

16. **PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM**

Please provide PIS and ICF as separate annexures and not within the main protocol text.
Please provide the same running title, version number and date, as in the main protocol
Please use the template for PIS and ICF available on the YEC-1 website.
For research studies enrolling minors, please change the title of the participant informed consent form to parental informed consent form. Please also add assent form wherever necessary.
Please keep the language of the English PIS so simple that a student of 8th standard from a non-English medium school will find it easy to understand.
Please do not use the word "patient". Use the word "participant". Please avoid the use of technical and scientific terms. Where it is unavoidable, please provide a simple language explanation in brackets.

Please provide translation in local languages

17. CURRICULUM VITAE OF PG/PI, CO-GUIDE (IF ANY) AND GUIDE

The CVs of all the research team members is mandatory with highlights on research experience.
The CVs should be up to date (not older than 6 months)
The CVs should be signed and dated.
Please provide proof of GCP training/ certificate (not older than 3 years)

18. STATEMENT BY RESEARCHERS ON RESEARCH INTEGRITY

We do hereby declare that this study titled "_____"will be carried out by me/us upholding the principles enshrined in the Declaration of Helsinki, and simultaneously abiding by the ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017). (For academic clinical trials please replace the ICMR guidelines with the New Drugs and Clinical Trials Rules, 2019 and Indian GCP Guidelines)

Date: Signature & Name of the PI

Place:

Date: Signature & Name of the Co-PI (guide/co-guide)

Place:

PART C: RECOMMENDATIONS AND SIGNATURES

Part C to be filled in only if the PI is a student or PhD scholar

Name of the PI	
Signature of the PI	
Remarks/recommendations of the co-guide (if any)	
Name & Designation of the Co-Guide (if any)	
Signature of the Co-Guide (if any)	
Remarks/recommendations of the Guide (if any)	
Name & Designation of the Guide	
Signature of the Guide	
Signature (with seal) of the Head of the Department	
Signature (with seal) of the Head of the Institution	

FORMAT FOR COVERING LETTER:

From,

To,

The Member-Secretary

Yenepoya Ethics Committee - 1/2 (strike of whichever is not applicable)

Yenepoya (deemed to be University)

Deralakatte Mangalore 575018 Karnataka India

Through proper channel

Subject: Request for ethics committee approval for Student Synopsis/PhD thesis proposal/Research Protocol

---

Respected Sir/Madam,

I _____ am conducting a study on **"**_____**"** from the Department of _____, _____ College.

I am attaching a copy of my synopsis/protocol along with this letter. I request you to kindly grant me approval for this study.

Thanking You,

Yours Sincerely

PI Sign

Date:

Place: Mangalore

Building a Research Participant Information Sheet

Instructions for writing a Participant information sheet for a research protocol

1. Ensure that the participant information sheet is addressed to the prospective participants of research and is therefore addressed as "you are invited, you will undergo.., you may experience.., you will receive compensation.." etc
2. Write in simple language which is easily understood by the participants (assume that the participant is an VIII standard student of a non-English medium school reading this document prepared in English)
3. Translate into regional language with the help of a translator and not an unverified free online translation.
4. Invite the prospective participant to enroll in the study and begin by clarifying that the study is research and not part of healthcare
5. Provide clear and complete information about the research including the following
    a. The title of the study
    b. The details of the investigators: Name, designation, department
    c. The total number of participants and the total study sites
    d. The purpose of the study in simple terms
    e. Reason why the participant is being included in the study. Example:
        i. If the study is on patients with malaria, state that he/she is included in the study because he/she is diagnosed of malaria
        ii. If the study is a case control study on smokers and non-smokers, then state that the person is included in the study because he is a smoker or non-smoker
    f. Details on the screening procedure and the eligibility
    g. Duration of the study and the duration for which the participant has to be involved in the study: Example
        i. If the study is going to be carried out for 2 years and the patient has to visit the hospital once for research and subsequently 6 monthly visits, then you may describe as "The duration of study is 2 years and you will be required to come once every month for six months"
        ii. If the study is going to be carried out for 2 years and the patient has to visit the hospital only once, then this may be described as "the duration of the study is 2 years and you will be required to visit only once.
    h. The participants' responsibility and cooperation
        i. Number of visits to the hospital with details
        ii. Total number of blood draws, total volume of blood, number X-rays, etc

iii. Need for hospitalization
iv. Any specific regime/restrictions to be followed
v. Maintenance of a diary
vi. Reporting of any symptoms or events to the PI

i. Ensure voluntariness in the enrollment process by providing following details:
    i. The choice that the subject has
    ii. The voluntary nature of the enrolment
        1. He/she can refuse to participate
        2. He/she can accept/agree/consent to participate
        3. He/she can withdraw from the study
        4. Any such decision will not affect
            a. The treatment
            b. The care
            c. The legal rights
    iii. That there is no force or influence to participate
    iv. That he/she can take enough time to decide whether or not to participate
    v. That he/she can ask any doubts to the PI at any point of time

j. Provide details on how the PI will assess the comprehension and understanding of the participant (whether the PI will use any formal comprehension assessment such as a multiple choice question constructed from the content of the PIS).

k. Details of the intervention/observation: Describe in detail the methodology of the intervention or observation or investigations or collection of samples or responding to questionnaire in simple language
    i. **Terminology:** Do not use medical terminology or jargon. Instead, use simple English words to describe the same. Example
        1. If the study requires Contrast CT: use the term “CT scan with an injection’
        2. If the study requires PCR for tuberculosis: use the phrase “ a blood test for detection of TB, which is called PCR”
        3. If the study requires an intervention like appendicectomy: use the phrase ‘operation on the abdomen (stomach) to remove a part of the intestine called appendix’
        4. If the study involves a medical regimen like HAART: use the phrase ‘ a group of drugs used in the treatment of HIV infection’
    ii. **Procedures:** Describe the procedures
        1. Eg. Ultrasound/X-Ray- who will do it, where, privacy, result sharing, precautions, possible complications, cost bearing, time needed, repeat testing, etc

2. Eg. Surgical procedure- explain in simple terms, anesthesia, what will be done, possible complication, post-operative care
3. Eg. Clinical tests: explain in simple terms, how the test will be done, time taken, any possible discomfort, etc,
4. Eg. Reports of investigations- histopathology report, X ray report from medical records

iii. **Biological samples:** If the study requires collection of biological samples for the purpose of research- Provide details on

1. Whether collected as a part of research or treatment
2. If collected as a part of research- what laboratory tests will be done for the purpose of this research
3. How much, method of collection including number of times
4. How long the biological fluid/tissue/sample will be stored
5. Any prospects of use of blood/tissue samples in future research
6. Whether the samples will be shared with other researchers,
7. When and how the samples will be disposed.
8. Provide details on what will happen to the data associated with the sample.

iv. Questionnaire-

1. Provide details on what information will be collected, and that personal identifiers will not be collected, and that if there are sensitive questions, how they will be delivered and details of any other information,
2. Provide details on the time required to respond
3. Option to refuse to answer sensitive questions
4. How privacy and confidentiality will be maintained

l. The benefits of the study: Example

i. To the participant
ii. To the society
iii. Scientific advancement

m. The harms of being involved in the study: Example

i. If the study involves taking a sample of blood, then state that 5 ml of blood will be taken from your arm just like a routine blood test and this is not associated with any risk or complications, except that you will experience some pain during the procedure and for a few minutes after that. No treatment is required for the same
ii. If the study involves taking an X-ray, then state that an X-ray will be taken which is usually not associated with any complications

iii. If the study requires intake of some medications, then state the common side effects of the drugs, their frequency and severity and whether they require to be treated

n. Provide details on whether compensation (reimbursement) will be offered or not:
   i. For the time/wages lost
   ii. For the tests/treatment

o. Please provide details on whether compensation will be made or not, for any harms/adverse events related to the research:
   i. Management plan for adverse event
   ii. Details on who will bear the cost
   iii. Compensation for serious adverse event
   iv. Details of the nominee in case of payment of compensation

p. Protection of the participant's privacy and the data confidentiality
   i. That the privacy of the participant will be ensured during the study
   ii. That the data/ findings of the study will be kept confidential and will be accessible only to the research team members and will not be shared with third parties except authorized persons like auditors, Sponsors, EC members.
   iii. That the data will be anonymized
   iv. That photographs taken (if any), will be masked so as to protect the privacy of the participant
   v. That the results of the study may be presented in conference or published in scientific journals, and if so, will be done anonymously.

q. Contact persons:
   i. Details of a responsible person from the research team who will clarify the doubts of the participant. Details of the person to contact in case of adverse events/ problems
   ii. Details of a responsible member of the ethics committee (preferably Member-Secretary) who will address the concerns on the rights of the research participant, in case he/she is not satisfied by the responses from the PI (phone number, email and contact address)

r. Provide details on whether or not there is any conflict of interest for any of the members of the research team.

s. A statement that one copy of the PIS and a signed copy of the ICF will be provided to the participant.

SAMPLE FOR INFORMED CONSENT (ADULT)

(For surrogate informed consent and written assent refer to the website of YEC-1)
www.ethics.edu.in/eth-com.html

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 enrollment.
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 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

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 enroll.
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 enroll. Specify a date, time and place.
13. Both the researcher and the 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. If your prospective participant is in the age range of 7-12 years, then with parental consent take oral assent from the child and document this in informed consent form
16. If your prospective participant is in the age range of 13-18 years, then with parental consent take written, signed assent from minor and store documents together
17. If your study runs over a period of time, and the child moves from one category to another, please take re-consent (as appropriate).
18. Hand over a copy of signed ICF to the participant and keep a copy in your records
19. Take re-consent wherever appropriate
20. Store these documents securely for a period of 3 or 5 years.