

Sethu Institute of Technology Kariapatti 626115

Format for submission of Research proposal to Institutional Ethical Committee (IEC) *

Serial No (IEC Cell):
IEC/2026/

Date of submission:

1. Title of the research project:
2. Brief Biodata of the principal investigator and co-investigator/s

A. Principal Investigator

Name	Designation	Department	Educational Qualification	Research experience	Address & Tel.no. Email/ Fax

B. Co-investigator/s (If any)

Name	Designation	Department	Educational Qualification	Research experience	Address & Tel.no. Email/ Fax

3. Department/s involved:
4. Expected duration of the project:

5. **Attach typed copy of Research Protocol** under following headings: (This protocol , which need not exceed 5 pages, must clearly define your role in your project and must have sufficient detail to permit review to the research committee) – **Please also submit a soft copy of the Research Protocol**

- **Title of the Research Project:**
- **Objectives:** (please enumerate)
- **Review of Literature (with references)** pertaining to the project (in less than 100 words)
- **Rationale of the study** (in less than 100 words)
- **Research design & methodology** (This will be the most detailed portion of the proposal.) Please include number of subjects, describe the study design, research methods and/or procedures that will be used for estimation and procedures to be employed for statistical analysis. Attach all relevant enclosures like proforma, case report form, questionnaires etc. Informed consent process, including patient information sheet and informed consent form in local language, if applicable. For any drug / device trial, mention all relevant pre-clinical animal data and clinical trial data from other centres within the country /other countries, if available- If applicable
- **Name and signature of Principal Investigator and co-investigator/s** on research protocol with date.

6. Checklist for attached documents:

1. Project proposal – 10 Copies
2. Curriculum Vitae of Investigators
3. Brief description of proposal
4. Patient information sheet
5. Informed Consent form
6. Investigator's brochure for recruiting subject
7. Copy of advertisements/Information brochures
8. Copy of questionnaire / data collection sheet

Place: _____ Signature & Designation of PI/Co-PI/Collaborator

Date: _____

7. HOD's remark with Name & Signature: _____

(Research proposal can be submitted in the office of Secretary, IEC, Sethu Institute of Technology)

Informed Consent form

“Title: _____”

Name of the participant:.....

Name of the Principal investigator:

Name of the Institution:.....

Documentation of the informed consent:

I,..... was explained in my language about the project in detail, which I have understood. I was free to ask any questions and they have been answered. I am over 18 years of age and exercising my free power of choice, hereby give my consent to be included as a participant in this study,“

.....”

- 1) I have read and understood this consent form and the information provided to me
- 2) I have had the consent document explained to me
- 3) I have been explained about the nature of the study
- 4) My rights and responsibilities have been explained to me by the investigator
- 5) I have been advised about the risks associated with my participation in the study
- 6) I agree to cooperate with the investigator and I will inform him immediately if I suffer unusual symptoms
- 7) I have not participated in any research study within the past ...12. Months
- 8) I am aware of the fact that I can opt out of the study at any time without giving any reason.
- 9) I am also aware that the investigators may terminate my participation in the study at any time for any reason without my consent.
- 10) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the ethics committee.
- 11) My identity will be kept confidential if my data are publicly presented.
- 12) I have had my questions answered to my satisfaction
- 13) I have decided to be in the research study

I am aware, that if I have any questions during this study, I should contact any one of the addresses listed. By signing this consent form, I attest that the information given in this document has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Participant’s initial.....

(Translated in vernacular language may be used whenever applicable)

Protocol No : **Information to participants**

Investigator.....{PI} **complete address with contact No.**

.....{Co- investigator}

Title : “.....”

You are invited to take part in this research study .The information on this document is meant to help you decide whether you want to participate or not. Please feel free to ask if you have any queries or concerns.

You are asked to participate in this study that is to be conducted in Sethu Institute of Technology because you satisfy our eligibility criteria:

1.
2.
3.
4.
5.
6.

What is the purpose of research?

The study design

Study procedures

Possible risks to you

Possible benefits to you

Possible benefits to other people

The Alternatives you have

What should you do in case of injury or a medical problem during this research study?

Confidentiality of the information obtained from you

How will your decision not to participate in the study affect you?

Can you decide to stop participating in the study once you start?

Can the investigator take you off the study?

Right to new information

Participant’s initial.....

(Explanation under each above said title in easy language should be made and a copy in English and local language should be included)