Title: Management of Submission of Protocol and Protocol-Related Documents

SOP Code: SOP06/v1

Effective Date: 20/02/2025

Prepared by:

Dr Akshatha K Member, YEC-3 SOP Subcommittee	Signature with date

Reviewed by

Mr Asir John Samuel Convenor, YEC-3 SOP Subcommittee	Signature with date

Approved by:

Dr. Haripriya S, Chairperson, YEC-3	Signature with date

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date

Table of Contents:

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepoya Ethics Committee - 3 (YEC-3) manages initial submissions of research protocols and protocol-related documents for ethical approval.

2. **Scope:** This SOP provides guidance on the initial handling of research-related documents and includes:

   2.1. Submission of research protocols and related documents for initial review

   2.2. For all other submissions, procedures are as per respective SOPs:

      2.2.1. Resubmission of protocols: SOP9A/v1

      2.2.2. Submission of amended protocols: SOP9B/v1

      2.2.3. Continuing review of approved protocols: SOP10/v1

      2.2.4. Protocol deviations/violations: SOP11/v1

      2.2.5. Serious adverse events initial report/follow up/final report: SOP12/v1

      2.2.6. Protocol completion: SOP13/v1

      2.2.7. Premature termination/suspension: SOP14/v1

3. **Definitions:**

   3.1. **Protocol (aka Synopsis):** The protocol (synopsis) refers to a document that contains the detailed components of the proposed study and for the purpose of this SOP will mean to include the components listed in 5.5 below and provided in template form in Ann05/SOP06/v1.

   3.2. **Protocol-related documents:** Protocol-related documents refers to the set of documents without which the protocol package will be treated as incomplete and for the purpose of this SOP will mean to include the items listed in 5.6 below.

   3.3. **Protocol package:** The protocol package refers to the set of documents that contain the detailed components of the proposed study and for the purpose of this SOP will mean to include the following

      3.3.1. The protocol (Point No. 3.1)
      3.3.2. Protocol-related documents (Point No. 3.2)

   3.4. **Complete protocol submission:**

      3.4.1. Covering letter addressed to YEC-3 Member-Secretary (Ann05/SOP06/v1)
      3.4.2. Initial application form and log delegation form (Ann01/SOP06/v1)
      3.4.3. The protocol package
      3.4.4. Relevant checklists (eg. vulnerability, consent waiver form, etc)
      3.4.5. Any other, as required for the study or by the YEC-3

4. **Responsibility:**

   4.1. **The Secretariat will:**

      4.1.1. Ensure that the initial submission of protocol package is complete in all aspects (documents, content, signatures, dates, permissions, versions, page numbers, etc)

4.1.2. Ensure that the covering letter and appropriate forms are duly filled, signed, and dated at the time of submission.

4.1.3. Ensure that the protocol has been cleared by the Scientific Review Board of the respective Institution/Department/Centre and the approval letter is attached.

4.1.4. Ensure that one hard copy and soft copy (by email) of the protocol is submitted which are not dissimilar in any aspect.

4.1.5. Ensure that the application forms are duly filled, singed, dated and submitted (Ann01SOP06/v1)

4.1.6. Return the protocol package to the PI on account of incompleteness.

4.1.7. Accept the protocol package, if complete in all aspects, and record the date of receipt

4.1.8. Communicate the receipt of the complete protocol package to the PI (and all the research team members) (Ann02/SOP06/v1)

4.1.9. Assign the YEC-3 protocol number, only after ensuring 4.1.1 to 4.1.5 are met

4.1.10. Forward the filed and numbered protocol package to the Member-Secretary only after all the documents are submitted completely

4.1.11. Record the details of protocol submission in the YEC-3 database.

4.2. **The Member-Secretary will:**

4.2.1. Initiate the process of categorization and review as per SOP07/v1

4.2.2. Oversee the return of any incomplete protocol submissions, if any, to the PI stating that the review process cannot be initiated.

5. **Detailed instructions:**

5.1. **Check for Complete protocol submission:**

5.1.1. The Secretariat will check that the submission is complete in all aspects

5.1.2. If the protocol submission is incomplete, the PI is informed about the deficiencies and requested to submit the deficient documents within 15 calendar days

5.1.3. If the initial protocol submission process is not completed within 15 calendar days, all the documents submitted to YEC-3 will be returned back to the PI. In which case, if the PI so wishes, the protocol can be submitted fresh.

5.2. **Verification of content of the submitted documents:**

5.2.1. The Secretariat will verify whether

5.2.1.1. Application form is submitted

5.2.1.2. All documents ticked as attached in the application form/covering letter are present in the submission

5.2.1.3. All requisite documents are signed and dated by all the research team members

5.2.1.4. All protocol documents bear a version number and page numbers

5.2.1.5. All required permission letters/SRB clearance letters and others as required for the study are attached

5.2.1.6. Receipt of the YEC-3 sitting fees (wherever applicable)

5.2.1.7. The signed pages of the protocol packages must be scanned and attached to the soft copies

5.3. **Covering letter** (Ann05/SOP06/v1)**:**

5.3.1. Should be addressed to the Member-Secretary, YEC-3

5.3.2. Should be forwarded to YEC-3 through the Head of the Department(s) and the Head of the Institution/ Centre.

5.3.3. Must be dated and signed by the Principal Investigator

5.3.4. Must contain the title of the study and the names of the investigators

5.3.5. Must contain a list of annexures

5.4. **Application form**:

5.4.1. The application form for all protocols is provided as a template (Ann01/SOP06/v1) .

5.4.2. Incomplete forms will be returned to the PI and considered as incomplete submissions

5.4.3. The forms must be submitted to YEC-3 office as hard copies and emailed

5.4.4. The information provided in the application form and the protocol package should not be discordant.

5.5. **The Protocol:** The protocol must contain the following headings (Ann05/SOP06/v1):

5.5.1. **Title:**

5.5.1.1. The title must be comprehensive and clear (and preferably constructed in the PICO format)

5.5.1.2. The title must ideally indicate the nature of the study

5.5.2. **Details of the research team:**

5.5.2.1. Name, designation, affiliation of the Principal Investigator

5.5.2.2. Names, designations, and affiliations of all the co-investigators including the Guide/ Co-guide including on-site/ off-site investigators

5.5.2.3. Updated and signed curriculum vitae of all the members of the research team

5.5.2.4. Training Certificates in Research Ethics/ Research methodology

5.5.2.5. ICH-GCP training certificate for Clinical trials of the Principal investigator and other research team members (within the last 3 years)

5.5.2.6. List of on-going research projects undertaken by the Principal Investigator (incorporated in the CV)

5.5.3. **Executive summary**

5.5.3.1. Not exceeding 250 words

5.5.4. **Background and introduction:**

5.5.4.1. The background should include a brief description of the condition/drug/device/other to be studied

5.5.5. **Need for the study**

5.5.6. **Research question, Aims and Objectives:**

5.5.6.1. Research question should preferably be in PICO format

5.5.6.2. Objectives to be listed in the S.M.A.R.T. format

5.5.7. **Review of literature (Investigator brochure in case of clinical trials)**

5.5.7.1. Should be in narrative form and orderly structure

5.5.7.2. Should be recent and written in Vancouver style

5.5.8. **Methodology in detail:** The methodology must include

5.5.8.1. Study design

5.5.8.2. Study intervention and its approval status

5.5.8.3. Study site

5.5.8.4. Study population

5.5.8.5. Sample size

5.5.8.6. Recruitment procedures including advertisements, notices, letters to doctors, etc

5.5.8.7. Inclusion and exclusion criteria

5.5.8.8. Withdrawal and discontinuation criteria

5.5.8.9. Details of intervention

5.5.8.10. Standard of care

5.5.8.11. Details of placebo/ if applicable

5.5.8.12. Data/ sample collection method and evaluation

5.5.8.13. Data collection form/ Case record form/ Participant diary/etc

5.5.8.14. Data/ sample management (use, storage, disposal, transport, sharing, reuse)

5.5.8.15. Data analysis and statistical methods

5.5.8.16. Maintenance of privacy and confidentiality \

5.5.8.17. Risk management

5.5.8.18. Benefits of study

5.5.8.19. Vulnerable populations and justification

5.5.8.20. Social and community involvement and impact

5.5.8.21. Consent process

5.5.9. **Study tool:**

5.5.9.1. Description

5.5.9.2. Validation, if applicable

5.5.9.3. Pre-testing, if applicable

5.5.9.4. Permissions, if applicable

5.5.10. **Informed consent document**

5.5.10.1. Participant information sheet (WHO informed consent' form templates)[1]

5.5.10.2. Informed consent form (WHO informed consent' form templates)[1]

5.5.10.3. Translation of PIS and ICF (certificate – not mandatory)

5.5.10.4. Waiver of consent, if applicable

5.5.10.5. Details of audio-visual recording of consent

5.5.10.6. Electronic consent, if applicable

5.5.10.7. Written assent form and translations, if applicable

5.5.10.8. Details of oral assent

5.5.10.9. Parental/ Surrogate informed consent

[1]https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms (Accessed on 13th Feb 2025)

5.5.11. **Statistical methods** (certificate – not mandatory)

5.5.11.1. Sample size calculations

5.5.11.2. Statistical tests

5.5.11.3. Significance values

5.5.12. **Drug/device/Intervention brochure**:

5.5.12.1. Details

5.5.12.2. Approval status

5.5.12.3. Adverse events

5.5.13. **Budget and funding details**

5.5.13.1. Source of funding and application status

5.5.13.2. Amount of funding

5.5.13.3. Duration of funding

5.5.13.4. Funding approval

5.5.13.5. Budget allocation

5.5.14. **Insurance policy**

5.5.14.1. Policy details of the participants indicating conditions of risk coverage, data of commencement and expiry of risk coverage.

5.5.14.2. Indemnity policy with details.

5.5.15. **Utilization of the results**

5.5.15.1. Deliverables to the society

5.5.15.2. Publication

5.5.15.3. Scientific presentations

5.5.15.4. Marketing potential

5.5.15.5. Patent development

5.5.16. **References**

5.5.16.1. References to be written in Vancouver style

5.5.16.2. In-text citation should be written in Vancouver style

5.5.17. **Any other (as suggested by YEC-3)**

5.6. **Protocol-related documents:**

5.6.1. **Scientific Review Board (SRB) approval letter:** A soft copy and hard copy of the relevant SRB to be submitted. The project title and name of the PI should be the same across all documents.

5.6.2. **Curriculum vitae:** All researchers have to submit a signed, updated, focused curriculum vitae as per the CV Template (< 3 months) Ann04/SOP06/v1.

5.6.3. **Training certificates:** Certificate of GCP and other related training (ICMR national ethical guidelines, specific trainings, research methodology) of the investigator(s) and guides (< 3 years)

5.6.4. **Conflict of interest:** COI declaration of the investigator(s) and all research team members

5.6.5. **Regulatory permission letters:** DCGI communications (or approval), ICSCR (for stem cell research), GEAC (for genetic engineering studies, BARC (for radiation studies), and any other as applicable.

5.6.6. **Other permissions:**

5.6.6.1. For investigator-initiated, interventional studies within the University, the PI will have to submit a letter from the Medical

Superintendent of the relevant hospital stating support for, and free treatment for research-related injuries.

5.6.6.2. For studies involving institutionalized participants (eg. college students, etc) permission letter from the head of the institution

5.6.6.3. For community-based studies, a copy of the signed approval of the appropriate gatekeepers must be attached.

5.6.6.4. Permission from the concerned authorities for access to stored data/ samples/use of dead body for research, wherever applicable

5.6.7. **Clinical Trial Registry of India (CTRI) registration:** Wherever applicable, the PI has to demonstrate provisional registration (this is possible even without EC approval). Once the PI gets YEC-3 approval, they have to upload to CTRI, obtain final registration and communicate a copy to YEC-3

5.6.8. **Clinical trial agreement (CTA):** For YEC-3 approval, a copy of the final, official, signed (by all parties) agreement - whenever applicable - is mandatory.

5.6.9. **Memorandum of Understanding (MoU):** Wherever the project is with collaborating institutions, a signed copy of the agreement/MoU is to be submitted.

5.6.10. **Material Transfer Agreement (MTA):** In line with the ICMR guidelines (2017), YEC-3 considers a material transfer agreement as necessary, wherever human samples, tissues or other biological materials are to be transferred/ transported to another organization for the purpose of research

5.6.11. **Insurance certificate and policy:** Whenever applicable, valid insurance documents showing evidence of third party assurance of management of research-related injury costs.

5.6.12. **Indemnity certificate**: Wherever applicable

5.6.13. **Supporting documents for funding**

5.6.14. **Details of Data Safety Monitoring Board (DSMB)**: Wherever applicable

5.6.15. **Ethics Committee approvals of other centers:** Wherever applicable

5.6.16. **Institutional Animal Ethics Committee approval:** Wherever applicable

5.6.17. **Any other:** As required for the study or by the YEC-3

5.7. **Complete the submission process:**

5.7.1. Once the complete protocol submission is received and verified the Secretariat will stamp the receiving date on the first page of the covering letter and initial it.

5.7.2. The Secretariat will make a file for the new protocol with the complete protocol submission

5.7.3. Each verified protocol file will be given a unique protocol number: YEC-3/ YEAR/ NUMBER and this will be displayed prominently on the file. The

number refers to the sequential number of the protocol received in YEC-3. (Eg. YEC-3/2023/200 refers to the protocol submitted to YEC-3 for review in the year 2023 and is the 200th protocol received by the YEC-3 in the year.) which is used and quoted for all future communications concerning the protocol from the time of categorization to shredding of the protocol.

5.7.4. Incomplete submissions will not be given a unique protocol number.

5.8. **Initiation of the review process:**

5.8.1. Once filed and given the unique protocol number, the file is forwarded to the Member-Secretary for categorization as in SOP07/v1

5.9. **Fees for YEC-3 review**:

5.9.1. The sitting fees for reviewing various categories of research study proposals in Indian Rupees (INR) are non-refundable and are notified by the University from time to time, as per the template in the annexure (Ann03/SOP06/v1: Sitting fees of YEC-3).

5.9.2. The sitting fees are paid to the University official account provided in the notification and a copy of the receipt should be submitted along with the protocol at the time of submission.

6. **References:**

6.1.1. SOP7A/v1: Full Review of Research Protocols

6.1.2. SOP09/v1: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol.

6.1.3. SOP15/v1: Request for Waiver of Consent

7. **Annexures:**

7.1.1. Ann01/SOP06/v1: Application form for initial review of protocols (Regulatory, Non-Regulatory Clinical Trial, observational, basic science or other protocols)

7.1.2. Ann02/SOP06/v1: Application form for Qualitative Research

7.1.3. Ann03/SOP06/v1: Receipt for submitted protocol

7.1.4. Ann04/SOP06/v1: Sitting fees of YEC-3

7.1.5. Ann05/SOP06/v1: Template for curriculum vitae of investigators

7.1.6. Ann06/SOP06/v1: Synopsis template for postgraduate dissertation/student projects/faculty projects/ Phd thesis

Ann01/SOP 06/v1: Application form for initial review for all protocols

Application Form for Initial Review

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

General Instructions : a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1] :

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/ student/fellow (Academic research) / Principal Investigator/ Guide (Sponsored research)			
Co-investigator/ Guide (Academic research) / Co-investigator/ student/fellow (Sponsored research)			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission ..... ii) Co-Investigator at time of submission: .....

(k) Duration of the study: .....

[1]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2]*Include telephone/mobile numbers and email id*

Version 1.0 *01*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

(a) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/	☐	Case Control	☐
Prospective	☐	Public Health		Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/ Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

.....

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site..... In India..... Globally .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .....

.....

.....

.....

.....

.....

[3]*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

Version 1.0 *02*

(b) Is there an external laboratory/outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs	☐	Pregnant or lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally ill (stigmatized or rare diseases)	☐		
Any other *(Specify)*:	☐	.....	

iii. Provide justification for inclusion/exclusion .....

.....

.....

iv. Are there any additional safeguards to protect research participants?.....

.....

.....

[4]*If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU*

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

.....

.....

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(a) Version number and date of Participant Information Sheet (PIS):.....(Annexure: WHO's ICF)

Version number and date of Informed Consent Form (ICF):..... (Annexure: WHO's ICF)

(b) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐ Audio-Video (AV) consent ☐

Consent from LAR ☐ (If so, specify from whom) ..... For children<7 yrs parental/LAR consent ☐ Verbal assent from minor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Other ☐

(specify) .....

(c) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* .....

Any tools to be used .....

(d) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done .....

If translation has not been done, please justify .....

.....

(e) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

(f) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Simple language	☐	Data/ Sample sharing	☐	Compensation for study related injury	☐
Risks and discomforts	☐	Need to recontact	☐	Statement that consent is voluntary	☐
Alternatives to participation	☐	Confidentiality	☐	Commercialization/ Benefit sharing	☐
Right to withdraw	☐	Storage of samples	☐	Statement that study involves research	☐
Benefits	☐	Return of research results	☐	Use of photographs/ Identifying data	☐
Purpose and procedure	☐	Payment for participation	☐	Contact information of PI and Member Secretary of EC	☐
Others (Specify)	☐				

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ N/A ☐

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

[7]*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes ☐ No ☐ NA ☐

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

.....

.....

.....

.....

(b) Who will be maintaining the data pertaining to the study? .....

(c) Where will the data be analyzed[8] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

.....

.....

.....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

.....

.....

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

.....

.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

.....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

.....

.....

.....

.....

[8] *For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: ....

Signature: ..... dd mm yy

Name of Guide and Co-guide: ....

Signature (s): ..... dd mm yy

Name of HOD/ Principal: ....

Signature: ..... dd mm yy

Version 1.0 *07*

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[9]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28		☐	☐	☐		
29		☐	☐	☐		

**For multicentre research.*
MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre
[9] Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

Version 1.0 *08*

Ann02/SOP06/v1: Application form for Qualitative Research

Application Form for Qualitative Research

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Data collection method used in the study

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/Oral history/Case studies	☐
Others *(Specify)*	☐				

.....

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

.....

.....

.....

2. Type of informed consent used in the study.

Individual consent	☐	Gate-keeper consent	☐	Community consent	☐
Others	☐	*(specify)*.....			

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

.....

.....

.....

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

.....

.....

.....

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

.....

.....

.....

Version 1.0

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

.....

.....

.....

.....

.....

.....

.....

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

.....

.....

.....

.....

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

.....

.....

.....

III. Describe how do societal benefits outweigh individual harm.

.....

.....

.....

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

.....

.....

.....

.....

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Version 1.0

Ann03/SOP06/v1:

Receipt for submitted protocol

Dear Dr
Thank you for the protocol submission for EC approval. Your research proposal is under review. We will get back to you.
The protocol details are as follows:

Protocol No.	
Protocol title	
Principal Investigator	
Co-Investigators (all names)	
Designation and Affiliation	
Date of receipt of complete protocol package	

Please note your protocol number is YEC-3/------ For a faster and quicker response, we request you to include the protocol number in the subject line of all your email communications with YEC-3.

For protocols kept for full review, add:

The submission has been categorized as "Full review" as per the SOP of the YEC-3 and will be reviewed and discussed in the YEC- 1 meeting scheduled on ----------. We will get back to you with comments/recommendations / approval within a week after the meeting.

Ann04/SOP06/v1:

YEC- sitting fees

SrNo	Category of review	International Funded research – Non-RCT (pharma/industry/ Government/ NGO; single or multi centre)	Indian funded research – Non-RCT (pharma/industry/ Government/ NGO; single or multi centre)	Govt sponsored/ NGO Research	Academic includes RCT or Investigator initiated Research
1.	New study protocol				
2.	Continuing review (per review)				
3.	Protocol Amendment (per amendment review) (if applicable)				
4	Reissue of YEC-3 Approval letter				

Effective from ; Add GST 18% Account details for payment of the fees:

Ann05/SOP06/v1: Template for Curriculum Vitae of Investigators

Format for Curriculum Vitae for Investigators

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*
Projects undertaken in the last 5 years:

Version 1.0

Relevant research training/experience in the area [1] :	
Relevant publications *(Give references to all relevant publications in the last five years):*	
Signature	Date:

[1] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

Version 1.0

Ann06/SOP06/v1

Synopsis template for postgraduate dissertation/student projects/faculty projects/ Phd thesis

YENEPOYA _____ COLLEGE

YENEPOYA (deemed to be UNIVERSITY)

MANGALORE, KARNATAKA

YU Logo

ACCREDITED BY NAAC WITH GRADE A+

PROFORMA FOR REGISTRATION OF

ACADEMIC CLINICAL TRIAL/FACULTY RESEARCH/PhD THESIS/

PG DISSERTATION/SHORT STUDYPART 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)	
4.	Date of admission to course (in case PI is a student/scholar)	
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)	

PART B: PROJECT DETAILS

1. **TITLE OF THE RESEARCH TOPIC:**
2. **EXECUTIVE SUMMARY:**
3. **INTRODUCTION & BACKGROUND:**
4. **NEED FOR THE STUDY:**
5. **RESEARCH QUESTION:**
    1. RESEARCH QUESTION OR HYPOTHESIS (ALTERNATE/NULL)
    2. AIM
    3. OBJECTIVES (S.M.A.R.T)
6. **REVIEW OF LITERATURE** (Follow Vancouver style of referencing and in-text citation)**:**
7. **METHODOLOGY:**
    1. **STUDY DETAILS:**
        1. STUDY DESIGN:
        2. STUDY SITE:
        3. FUNDING DETAILS:

4. STUDY DURATION:

2. **PARTICIPANT DETAILS:**
    1. SOURCE OF DATA:
    2. SAMPLE SIZE:
    3. METHOD OF SAMPLING (SAMPLING TECHNIQUE):
    4. RANDOMIZATION AND BLINDING (IF ANY):
    5. INCLUSION CRITERIA:
    6. EXCLUSION CRITERIA
    7. WITHDRAWAL CRITERIA
    8. DISCONTINUATION CRITERIA
3. **STUDY TOOL:**
    1. DESCRIPTION (QUESTIONNAIRE; INTERVIEW SCHEDULE; SCALES; SCORES; DATA COLLECTION FORM; PROFORMA; ETC)
    2. VALIDATION / PRETESTING
4. **METHOD:**
    1. DETAILS OF THE METHODOLOGY INCLUDING DETAILS OF SAMPLE COLLECTION:
    2. DETAILS OF ANALYSIS: (Including statistical tests)

8. **WORK PLAN** (Timeline or Gantt Chart)**:**
9. **BUDGET:**
10. **REFERENCES** (in Vancouver Style)
11. **LIST OF ANNEXURES:**
12. **DATA COLLECTION FORM (**Case Record Form, Performa or questionnaire, if any)

PARTICIPANT INFORMATION SHEET/INFORMED CONSENT FORM[1]
([1]https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms (Accessed on 13th Feb 2025)

13. **CURRICULUM VITAE OF PG/PI, CO-GUIDE (IF ANY) AND GUIDE (< 3 months)**
14. **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)/New Drugs and Clinical Trials Rules, 2019 and Indian GCP (in case of academic clinical trials)

Date: Signature & Name of the PI

Place:

Date: Signatures & Names of all the Co-investigators (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 (or student)	

Signature of the PI (or student)	
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 Head of Institution	

FORMAT FOR COVERING LETTER:

To,

The Member-Secretary

Yenepoya Ethics Committee – 3,

Yenepoya (deemed to be University),

Seminar Room-3, 6th floor, YPC, YPCRC Building,

Naringana, Mangalore 575018 Karnataka India

Through proper channel

Subject: Request for ethics committee approval for faculty study/student synopsis/PhD thesis proposal

—----------

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 Signature

Date: Place: Mangalore

8. **Glossary:**

BARC: Bhabha Atomic Research Centre

CoI: Conflict of Interest

CTA: Clinical Trial Agreement

CTRI: Clinical Trial Registry of India

DCGI: Drugs Controller General of India

DSMB: Data Safety Monitoring Board

GEAC: Genetic Engineering Advisory Committee

IAEC: Institutional Animal Ethics Committee

IB: Investigator's Brochure

ICF: Informed Consent Form

ICH-GCP: International Committee for Harmonization - Good Clinical Practice

Indian GCP: Indian Good Clinical Practice guidelines

ICSCR: Institutional Committee for Stem Cell Research

MoU: Memorandum of Understanding

MTA: Material Transfer Agreement

NAC-SCRT: National Apex Committee for Stem Cell Research and Therapy

PIS: Participant Information Sheet

Protocol: Set of documents that contain the detailed components of proposed study

SRB: Scientific Review Board