Title: Management of research study protocol and study related documents

SOP Code: YEC2/SOP06/v2

Prepared by:

Dr. K. Leena Pramod Convenor, YEC2 SOP committee	Signature with date 25/02/23

Reviewed by:

Dr. Rashmi Jain Member, YEC2 SOP committee	Signature with Date 25/2/23

Approved by:

Dr. Prasanna Keshava B Chairperson , YEC2	Signature with Date 25/02/23.

Notified by:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date Registrar YENEPOYA (Deemed to be University)

Table of Contents:

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Yenepoya Ethics Committee 2 (YEC 2) manages submissions of study protocols and other study related documents.

2. Scope:

The scope of this SOP includes:

- Submission of study protocol and related documents for initial review of the protocol
- Resubmission of protocols
- Submission of protocol amendments
- Submission of written communications related to
- Continuing review of approved protocols
- Protocol completion or termination or status
- Protocol deviations/violation
- Serious adverse events initial report/follow up/final report

3. Definitions:

Protocol: The protocol refers to a 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:

Title

- The title must be comprehensive and clear
- 2. The title must ideally indicate the nature of the study.
- Title should be in PICO format.

Details of the research team *(vide infra)*

- Name, designation, affiliation of the Principal investigator
- Names, designations, and affiliations of all the co-investigators including the Guide/ Co-guide including on-site/ off-site investigators
- Updated and signed Curriculum vitae of all the members of the research team

- Training Certificates in Research Ethics/ Research methodology
- ICH-GCP training certificate for Clinical trials of the Principal investigator and other research team members (within the last 2 years)
- List of on-going research projects undertaken by the Principal Investigator

Background and need for the study *(vide infra)*

- The background should include a brief description of the condition/drug/device/other to be studied
- A detailed review of literature to inform about the current status of the condition/intervention including results of animal studies and Phase 1 or 2 or 3 or 4 studies

Objectives

- Specific objectives to be listed

Methodology in detail *(vide infra)*

- Study design
- Study intervention and its approval status
- . Study site
- Study population
- . Sample size
- Recruitment procedures including advertisements, notices, letters to doctors, etc
- Inclusion and exclusion criteria
- Withdrawal and discontinuation criteria
- Details of intervention
- Standard of care
- Details of placebo/ if applicable
- Data/ sample collection and evaluation
- Data collection form/ Case record form
- Data/ sample management (use, storage, disposal, transport, sharing, reuse)

- Data analysis and statistical methods
- . Maintenance of privacy and confidentiality
- Risk management
- Benefits of study
- Vulnerability
- Social and community involvement and impact 21. Consent process

Sample/data collection details including case record form/ patient diary *(vide infra)*

Study tool *(vide infra)*

- Description
- Validation
- Permission

Informed consent document *(vide infra)*

- Participant information sheet
- Informed consent form
- Translation of PIS and ICF
- Translation Certificate
- Back translation of PIS and ICF
- Back Translation Certificate
- Waiver of consent, if applicable
- Audio-visual recording of consent
- Electronic consent, if applicable
- Written assent form
- Oral assent
- Parental/ Surrogate informed consent

Statistical tests

- Sample size calculations
- Statistical tests
- Significance

Budget and funding details *(vide infra)*

- Source of funding
- Amount of funding
- Duration of funding
- Funding approval
- Budget allocation
- Insurance policy (policy details) of the participants indicating conditions of risk coverage, data of commencement and expiry of risk coverage. (C)
- Indemnity policy with details. (C)

Utilisation of the results *(vide infra)*

- Publication
- Scientific presentations
- Marketing potential
- Patent development

Device/Drug brochure

- Details
- 2. Approval status
- 3. Adverse events

Any other, as required for the study or by the YEC2

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 following as applicable

Scientific Review Board (SRB) approval letter

Curriculum vitae of the investigators

Regulatory permission letters (DCGI, ICSCR, GEAC, BARC)

Other permission letters, as applicable

Clinical trial registry of India (CTRI) information

Clinical trial agreement

Insurance certificate and policy

Indemnity certificate, wherever applicable

Details of Data Safety Monitoring Board (DSMB), if applicable

Any other, as required for the study or by the YEC2

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 meanto include the following

The protocol

Protocol related documents

Complete protocol submission:

Covering letter addressed to YEC2 Member-Secretary with a list of all attachments

Appropriated application form

The protocol package

Any other, as required for the study or by the YEC2

Responsibility:

YEC 2 Secretariat:

The YEC 2 Secretariat will be responsible for receiving the protocols and related documents submitted to the YEC 2.

At the time of submission, the secretariat will check the protocols for completeness as per the standard checklist (YEC2/Ann2A/SOP06/v2) before accepting it.

The Secretariat will record the important details of submission in the entrylog book which includes name, department and institution of the Principal Investigator, date of application, date of clearance from the Scientific Review Board (if applicable) and the date of submission to YEC 2.

The YEC 2 Secretariat will ask the Principal Investigator to submit the softcopy by email (after making modifications as advised by the scientific review board) to **yec2@yenepoya.edu.in**

The YEC 2 Secretariat will present the protocols to the YEC 2 Member-Secretary for categorization for initial review and allocation of reviewers.

YEC 2 Secretariat will distribute the protocols to the reviewers as identifiedby the Member-Secretary by email

YEC 2 Secretariat will receive the reviewers' response and act according tothe report as follows:

- If the reviewer suggests modifications in the protocol, the secretariat will, in consultation with the Member-Secretary, communicate the same with the investigator via email.
- If the reviewer approves the protocol, the same will be communicated to the Member-Secretary.

YEC 2 Secretariat will enter the details of the protocol in the database of theYEC 2 Secretariat computer and update the details as the process of review is happening.

If the reviewer does not respond with the review report within 7 working days after sending the proposal for review, the Secretariat will send them areminder.

The Member-Secretary

Upon receiving the protocol for initial review, the Member-Secretary/ will allocate the primary and if necessary, the secondary reviewer based on the subject of research and the expertise of the reviewers

Upon receiving other protocols or related documents for review the Member-Secretary/Joint Secretary will be responsible for managing the reviews as per various SOP and the timeframes.

The Member-Secretary/Joint Secretary will be responsible for assigning the reviewers for each protocol

4. Detailed instructions:

Decision making and timing: When the Principal Investigator (PI) submits a researchproposal to the YEC 2 Secretariat for review, the decision under any of the following sections will be taken within the specified time period:

New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols (and related documents):

- In the case of regulated clinical trials, the protocol, complete in all documentation, *submitted at least four weeks* prior to the forthcoming YEC 2 meeting, will be reviewed and included for discussion under the category of full review. In the case of all other protocols classified for "full review" or "expedited review" or "exempt from review", completed documentation should be submitted at least 2 weeks prior to the date of the forthcoming YEC 2 meeting. The meeting dates for the calendar year will be put up on the website of the University (www.yenepoya.edu.in)
- **Submission of SAE (On-Site):** The SAEs will be reviewed and forwarded to the SAE subcommittee on an urgent basis as per the timelines stated in YEC2/SOP09/v2 for initial and detailed reporting of SAE.
- **Resubmissions for full review:** Resubmission documents which are for consideration at the full review of the YEC 2 meeting must be submitted to YEC 2 Secretariat, *at least 7 working days* prior to the date of the forthcoming meeting.
- **Other documents:** All other communications to the YEC 2 that need to be tabled in the agenda should reach YEC 2 Secretariat, *at least 3 working days* prior to the date of the forthcoming meeting.

Initial review application:

- **Check for submission items:** The Secretariat will check the hard and soft copies of the following items:
  - One hard copy set of the research protocol (after making all the necessary changes as suggested by the respective scientific review boards) to be submitted to the YEC 2 secretariat.

- The soft copy of the research protocol (after making all the necessary changes as suggested by the respective scientific review boards) to be sent by email to **yec2@yenepoya.edu.in** from the email id of the principal investigator.
- A completely filled YEC 2 Project Submission Application Form for Initial Review (YEC2/Ann1A/SOP06/v2 for regulated clinical trials or Ann1B/SOP06/v2 for non-regulated academic trials)
- The marked checklist (YEC2/Ann2A/SOP06/v2in case of regulated clinical trials and YEC2/Ann2B/SOP06/v2 in case of non-regulated academic trials)
- Duty Delegation Log of the Study team (YEC2/Ann03/SOP06/v2)

- **Verify contents of the submitted documents:**

  The secretariat will use the checklist (YEC2/Ann2A or 2B/SOP06/v2) to confirm whether all the ticked documents are present in the application. The Secretariat will ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the YEC 2 to review). All the following documents must be in the file before it is sent out to the reviewers for ethical review:

- Covering letter to Member Secretary
- Project submission application form for initial review
- Protocol
- Informed consent document: In English and Kannada/Malayalam (if applicable), along with back translations in English (in case of regulated clinical trials). (A)
- Patient information sheet in English and Kannada/Malayalam (if applicable) along with back translations (in case of regulated clinical trials). (A)
- Case record form
- Recruitment procedures including advertisement, notices, letters to doctors, permission letters from hospital (if and whichever applicable)
- Regulatory permissions (DCGI Approval, etc; whenever applicable) (C)
- Undertaking to DCGI (If applicable)

- Administrative sanctions from the Head of the institution or MoU in case of studies involving collaborative work or in case of sending samples to laboratories of other centres or institutions
- Ministry of External Affairs permission to send samples out of country (if applicable)
- Curriculum vitae of all investigators
- Training certificates
- GCP training certificate of the PI (within last 3 years)
- Certification in Research Methodology of the PI
- Drug/device brochure
- Details of funding and fund allocation (if applicable)]
- Clinical trial agreement with sponsors, investigators, and head of the institution (C)
- Insurance policy (policy details) of the participants indicating conditions of risk coverage, data of commencement and expiry of risk coverage. (C)
- Indemnity policy with details. (C)
- Ethics Committee clearance of other centers (if applicable) [C, A (if applicable)]
- Institutional Stem cell Research Committee approval (if applicable)
- Documentation of clinical trial registration (if available)
- Processing fee payment receipt (*See Guidelines for investigators)*
- The secretariat will check the submission checklist for completion
- Stamp the receiving date on the first page/last page of the covering letter and initial it.
- Make a photocopy of the completed document receipt form YEC2/Ann04/SOP06/v2andreturn the original copy of the YEC2/Ann04/SOP06/v2 to the applicants for their records.
- Keep the copies of the submitted documents with original signatures in the protocol “Submission” files.

- Number the project file as YEC2/YEAR/NUMBER (for example :YEC2/2023/001 This number is quoted for all future communications concerning the protocol.
- The total number protocol received by YEC2 show in the excel sheet as well as highlight in the YEC2 notice board.

- **Dispatch and store received documents**:
  - The Secretariat will make photocopies of the protocols only if the reviewers assigned request for hard copies. Otherwise all the document communications will be done through the official email of YEC 2 , **yec2@yenepoya.edu.in**
  - The Secretariat will ensure the protocol attaches the checklist YEC2/Ann2A/SOP 06/v2 or YEC2/Ann2B/SOP06/v2.
  - The secretariat will file all assessment forms as determined by the type of submission and type of review.
  - The documents will be despatched for review to the reviewers by email within 2 days of receiving the submission.
  - The secretariat will follow the colour code for files for various types of research protocols
  - Yellow for dissertations and thesis of YMC,YDC,YPC,YNC,YPRPC,YSAHS,
    - One blue line for Dissertation of YDC
    - Two blue line for Short study of YDC
    - One Green line for YPC Dissertation
    - Two green line for YPC Short study
    - One red line for YNC dissertation
    - Two red line for YNC short study
    - Violet for Ph.D., study
    - One Orange line for Dissertation of YMC
    - Two Orange line for Short study of YMC
    - One White line for Dissertation of YSAHS

- Two White line for Short study of YSAHS

❖ Blue for faculty projects
❖ Pink for Academic clinical trial
❖ Green for funded projects

Resubmission of protocol with corrections and amendment of protocols:

- All resubmissions will be made as hard copy submitted to the YEC 2 Secretariat along with a covering letter and a soft copy which is emailed to **vec2@yenepoya.edu.in**
- The Secretariat will verify the completeness of the documents.
- In case of minor changes/amendments, the same version is submitted with changes highlighted.
- In case of major changes or amendments, the resubmission is numbered as version 2 (written as v2 in the header).
- The protocol related documents which do contain changes/amendments which are already submitted and approved by the YEC 2 are not required to be submitted again.
- The secretariat will submit the documents to the Member-Secretary.
- The Member-Secretary will decide the review process under which the resubmissions and amended protocols will be categorised.
- The protocol management will follow the relevant SOPs depending on the type of review process
  - Full review: YEC2/SOP7A/v2
  - Expedited review: YEC2/SOP7B/v2

Annual continuing review of approved protocols, amended protocols and related documents/ study completion documents/termination reports, SAE reports, protocol deviation:

- The YEC 2 will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

Processing Fees for YEC 2 review

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

Sl. No	Category of review	Pharma industry sponsored Research	Govt sponsored/ NGO Research	Academic or Investigator initiated Research
1.	New study protocol	Rs. 25,000 /-	Rs. 20,000 /-	Nil
2.	Continuing review (per review)	Rs. 15,000 /-	Rs.10,000 /-	Nil
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. 15,000 /-	Rs. 10,000 /-	Nil

5. Issue of Duplicate EC:

If the PI will lost the Original EC certificate, PI should pay 5000 rupees for Duplicate EC

6. Collect the EC certificate

6.1 . The PI needs to collect the EC clearance of his/her study within 7 days of receiving email YEC2 office .

If they fail to collect within the said time the YEC2 secretariat sent reminder mail tothem to collect the certificate within 3 days or else they cannot start the data collection.

If the PI fails to collect the EC certificate within 1 month from the date of issue the ECcertificate will be cancelled. In event of cancellation the PI needs to resubmit the protocol

Data collected before this period will be treated as violation of the protocol

7. Reference to other applicable SOPs

YEC2/SOP06/v2: Management of Research Study Protocol and Study Related

DocumentsSubmitted for Ethics Review

YEC2/SOP7A/v2: Full-Board Review of Research Study Protocols

YEC2/SOP09/v2: Review of Amended Protocol, Protocol-related Documents andResubmitted protocol

YEC2/SOP15/v2: Request for Waiver of Written Informed Consent and Waiver of Consent

8. Annexures:

YEC2/Ann1A/SOP06/v2: Project submission application form for initial review for drugtrials and other regulatory studies (Industry and Government sponsored studies).

YEC2/Ann1B/SOP06/v2: Project submission application form for initial review foracademic (non-regulatory) studies.

YEC2/Ann2A/SOP06/v2: Checklist protocol submission for initial review of regulatedclinical trials

YEC2/Ann2B/SOP06/v2: Checklist protocol submission for initial review of academic(non-regulated) studies

YEC2/Ann2C/SOP06/v2: Checklist for PI to tick

YEC2/Ann03/SOP06/v2: Duty Delegation Log of Study team

YEC2/Ann04/SOP06/v2: Document Receipt Form

YEC2/Ann1A/SOP 06/v2

Project Submission Application Form for Initial Review for Drug Trials and Other Regulatory Studies (Industry and Government sponsored studies)

- Please fill in the details in legible hand writing
- Tick √ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

YEC 2 Protocol No.:

Title of the protocol:

	Name	**Designation and qualification**	**Department and Institution**	**Roles and responsibility***	**Signature**
PI					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-Investigator					
Co-ordinator					
Co-ordinator					

* Roles and responsibilities of investigators :choose the appropriate codes (A to T) below and write them against their name in the appropriate column above.

A.	Concept	**L.**	Examination of patients on follow-up
B.	Design	**M.**	Data collection and monitoring of data
C.	Screening of patients	**N.**	Interpretation of data

D.	Selection and recruitment of study participants	**O.**	Statistical analysis & Interpretation
E.	Informed consent	**P.**	Maintaining patients file and master file of project
F.	Selection & Recruitment of patients	**Q.**	Drafting final report
G.	Laboratory investigations	**R.**	Submission of final report to funding agency and YEC 2
H.	Laboratory report interpretation	**S.**	Publication
I.	Treatment decision	**T.**	Any other, please specify
J.	Patient evaluation		
K.	SAE evaluation and reporting		

(If additional collaborators attach details and letter of Consent by collaborator(s) on a separate page)

Please attach brief curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator)

Attached □

Non-sponsored (Investigator Initiated) study

Sponsored study

Sponsor Information :

1	**Indian**	State Govt.	Central Govt.	Private
2	**International**	Govt.	Private	UN Agency
3	**Industry**	National	Multinational	
4	**Contact address**			
5	**Indian contact address (For international sponsors)**			

Budget information

1	**Total Budget: Rs.**
2	**Please give details of allocation of budget in an attachment.**

	Attached		
3	**Research Fund will be deposited in: If other, please specify**		
Details of the study			
Type of study	Epidemiological	Animal study	
	Basic Science	Any other: Specify:	
Number of centres	Single centre	Multicentre:	
If multi-centric:	Number of centres In India Global:	Names and countries of centres:	
Clinical Trials:			
1	**Nature of trial**	Medicine	Devices
		Vaccine	Indian system of Medicine
		Any other: Specify:	Not applicable
2	**Approved**	Yes	No
		If Approved:	
		In India	UK/Europe
		USA	NA
		Other countries: Specify:	
3	**Route**	Does it involve change in route of administration	Yes # No Not applicable
		If Yes #, Whether DCGI/other regulatory authority's permission obtained	Yes * No ** Not applicable
		If yes * Date of Permission	
		If No **, Whether applied of permission	Yes/No Not applicable
4	**New investigational drug**	Yes No Not applicable	If yes, IND No.

		a) Investigator's Brochure submitted	Yes No NA
		b) *In vitro* studies data	Yes No NA
		c) Preclinical Studies done	Yes No NA
		Clinical Study Phase	I II III IV
		To submit package insert in case test drug is already marketed in India	Attached Not attached
		Are you aware if this study/similar study is being done elsewhere? **If yes give details**	Yes: No
		Whether DCGI's permission for testing IND obtained? If yes, Date of permission	Yes No
		Whether DCGI's permission for testing IND is applied for?	Yes No
		For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to the company submitted?	Yes No Not applicable
	Protocol of proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Submit as attachment)		

5	**Research participants** **Sample Size :** Number of research participants at this centre : Number of research participants at other sites in India : Total number of research participants at all sites (globally):

	Duration of study No. of visits :			
	Will research participants from both genders be recruited	Yes	No	NA
	Inclusion / exclusion criteria given	Yes	No	NA
	Type of research participants:			
	Volunteers	Yes	No	NA
	Patients	Yes	No	NA
	Vulnerable participants	Yes	No	NA
	Pregnant women	Yes	No	NA
	Elderly	Yes	No	NA
	Mentally challenged	Yes	No	NA
	Fetus	Yes	No	NA
	Illiterate	Yes	No	NA
	Handicapped	Yes	No	NA
	Children	Yes	No	NA
	Captives	Yes	No	NA
	Terminally ill	Yes	No	NA
	Seriously ill	Yes	No	NA
	Economically or socially backward	Yes	No	NA
	Dependent staff	Yes	No	NA
	Institutionalized students	Yes	No	NA
	Employees	Yes	No	NA
	HIV	Yes	No	NA
	Any other	Yes	No	NA

6	**Privacy and confidentiality**			
	Direct identifiers	Yes	No	NA
	Indirect identifiers (coded)	Yes	No	NA
	Completely anonymized (delinked)	Yes	No	NA
7	**Use of biological/hazardous materials**			

	Fetal tissue or abortus	Yes	No	NA
	Human organs or body fluids	Yes	No	NA
	Recombinant /gene therapy If yes: DBT approval obtained	Yes	No	NA
	Pre-existing/stored/left over samples	Yes	No	NA
	Collection of banking/future research	Yes	No	NA
	Collection for banking/future research	Yes	No	NA
	Use of ionizing radiation/radioisotopes If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	Yes Yes	No No	NA NA
	Use of Infectious/ bio hazardous specimens	Yes	No	NA
	Proper disposal of material	Yes	No	NA
8	**Will any sample collected from the patients be sent abroad?**	Yes	No	NA
	If yes Sample will be sent abroad because (Tick appropriate option): Facility not available in India Facility in India inaccessible Facility available but not being accessed If so, reasons…….. Lab. Address:			
	If no, Test on samples will be carried out (tick appropriate option): In institution Outside institution If outside institution, Address: ____ Specify with details of collaborators			
9.	Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)	Yes	No	NA
10	In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for? If yes, details:	Yes	No	NA
	Memorandum of Understanding: If yes, details	Yes	No	NA
	Material Transfer Agreement If yes, details	Yes	No	NA
11	**Consent form & participation information sheet**	Yes	No	NA
	Tick which elements are included: Simple language			

	Alternatives to participation Statement that study involves research Confidentiality of records Sponsor of study Contact information Purpose and procedures Statement that consent is voluntary Risks & Discomforts Right to withdraw Benefits Compensation for study related injuries Compensation for participation Benefits, if any, on future commercialization Consent for future use of biological material If written consent will not be obtained, give reasons: Whether applied for waiver of Consent:			
	Who will obtain consent? PI/Co-PI Nurse/Counsellor Research staff Any other, specify			
12	**Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)**	Yes	No	NA
13	**Risks & Benefits**:			
	Is the risk reasonable compared to the anticipated benefits to research participants / community / country?	Yes	No	NA
	Is there physical / social / psychological risk / discomfort? If Yes, • Minimal or no risk • More than minimum risk • High risk	Yes	No	NA
	Is there a benefit To the research participants? • Direct • Indirect	Yes	No	NA
	Benefit to the society	Yes	No	NA
14	**Data Monitoring**			
	Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No	NA
	Is there a plan for reporting of adverse events?	Yes	No	NA
	If Yes, reporting is done to : Sponsor YEC 2	Yes	No	NA

	DSMB			
	Is there a plan for interim analysis of data?	Yes	No	NA
	Are there plans for storage and maintenance of all trial database? If Yes, for how long?	Yes	No	NA
15	Is there compensation for participation If Yes, (tick appropriate) Monetary In kind Specify amount and type:	Yes	No	NA
16	Is there compensation for injury? If Yes, (tick appropriate) by Sponsor by Investigator by insurance by any other company	Yes	No	NA
17	Do you have any conflict of interest in the present study? (financial/non financial) If Yes, specify	Yes	No	NA
18	Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC and carried out by the Principal Investigator. (Information to be given: whether study is initiated, no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly	Yes	No	NA
19	Current Brief Curriculum Vitae (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator (Information required: age, designation and department, educational qualification, previous research experience in last five years) (Information about GCP training of PI and co investigator)	Yes	No	NA
20	**Training certificates** of principal investigator and coordinators (mandatory only for drug and device trials not for observational studies**)**	Yes	No	NA
21	**Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India(CTRI)/ any other WHO platform registry** **Registration number:** **If not registered, state the reason**	Yes	No	NA

Statement of Compliance:
We hereby declare that the information given above is true and that we will comply with the

guidelines mentioned in the Schedule Y [Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013, 8th February 2013 and any other recent notification/s from CDSCO (January 2017)], Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (E 6 GCP R 1 - July 1996 ~ R 2 - June 2015) while conducting the research study.
We also ensure that PI/ Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

Signature of PI with date:
Signature/s of Co-investigators with date:
1.
2.
3.
4.
5.
Signature of co - ordinator:
1.
2.
Forwarded by Heads of Department(s)
Signature/s with date of Heads of Department(s):
Stamp/Seal of the Department(s)

YEC2/Ann1B/SOP06/v2

Project Submission Application Form for Initial Review for Academic (non- regulatory) Studies

Please fill in the details in legible hand writing. Incomplete forms are likely to be rejected.
Tick √ in the box for the appropriate answer/ Write NA if question is not applicable

YEC 2 Protocol No. (to be filled by YEC 2 Secretariat at time of submission)			
Protocol title:			
Details of research study team	Name	Designation	Affiliation
PI			
Co-Investigator			
Co-Investigator			
Co-Investigator			
If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page			
Study is sponsored: Yes / No			
If sponsored Total Budget: Rs._____ From where is the study being funded a) Research fund is being utilized from in-house funding authority b) External funding agency (specify):			
Type of study: (tick whichever is applicable) a) Prospective / Retrospective / Cross-sectional b) Observational / Interventional If interventional, does the study involve Testing of a new drug? Yes / No Any deviation from routine/standard of care practices? Yes / No If yes to any of above questions, please provide details			
2. What is the type of intervention being researched? (tick whichever is applicable) a. Drug b. Alternative medicine c. Medical device d. New technique (surgical, OT, PT, etc)			

e, New diagnostic kit/method
f. Other (please specify):

g. Is the test/drug/device marketed in India? Yes / No
If yes to any of the above questions please provide relevant regulatory authority permissions (wherever applicable). Also please attach a copy of the package/product insert.

3. Subject selection:
a. Number of subjects to be selected at this centre:
If multicentre: Total no. of centres:
Total no. of subjects from all centres:
b. Vulnerable subjects: Yes / No (tick whichever is applicable)
c. Pregnant women / Illiterate / Seriously/terminally ill / Children / Neonates / Mentally challenged / Elderly / Physically challenged / Economic/social backwardness / Institutional employees / Students / Others (please specify)

4. Does the study involve use of:
a. Fetal tissue or abortus Yes / No
b. Organs or body fluids Yes / No
c. Gene therapy/genomics/proteomics Yes / No
If yes for gene therapy, then please attach copy of permission from Genetic Engineering Advisory Committee (GEAC)
d. Ionizing radiation / Radioisotopes Yes / No
If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission.
e. Infectious / bio hazardous specimens Yes / No
f. Will pre-existing / stored / left over samples be used Yes / No
g. Will samples be kept for banking / future research purpose Yes / No
h. Will any sample be sent abroad Yes / No
If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission
i. Is there any collaboration with an external institution,
laboratory or clinic (either domestic or foreign) Yes / No
a. If yes, please attach copy of MoU between YU and that organization.
b. If yes for foreign collaboration, please submit a copy of Health Ministry Screening Committee (HMSC) approval *or any other funding agency requirements (as applicable).*

5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc)
If yes, kindly attach a copy for YEC 2 review

6. Is there compensation for participation (travelling allowance)?
If yes, then Monetary / Kind
If monetary, then specify amount:
If kind, then provide details:

9. Are there any arrangements for compensation / treatment of trial related injury?

If yes, then who will provide: Sponsor / Insurance company / Investigator / Others Please provide relevant copies
10. Do you (or your PG guide) have any conflict of interest in the present study? (financial / non – financial/ any other) Yes / No If yes, specify
11. Is any other department involved in participant recruitment / investigation, but not co-investigators or collaborators? Yes / No If yes, give details: Attach relevant copy of other department with HOD signature

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of PI
Signatures of Guide/Co- investigators:

Signatures (with seals) of forwarding authorities (as predetermined by YU):

YEC2/Ann2A/SOP06/v2

Check List for Protocol Submission to Yenepoya Ethics Committee 2 for initial review of regulated clinical trials

Check List of Documents for Protocol Submission to the Yenepoya (Deemed to be University) Ethics Committee to be filled in by the study team

(Tick accordingly; Items marked * are compulsory documents and have to be submitted)

Sl No	Document	Yes	No	If pending, likely date of submission	NA
1.	*Project submission application form duly filled				
	a. Covering Letter				
	b. Project proposal – 3 hard copy				
	c. Project proposal – soft copy sent by e-mail to **yec2@yenepoya.edu.in**				
	d. CV of ALL Investigators				
	e. Fee for review				
2	Approval of Scientific Review Board (SRB)				
3	*Letter to Member Secretary requesting ethical clearance				
4	*Summary of protocol (in not more than 500 words)				
5	*Protocol				
6	*Informed consent document in English				
7	*Informed consent documents in Regional languages (Total No:-)				
8	Back translation of Informed Consent Documents (if available)				
9	Translation and Back translation certificates (if available)				
10	*Case Record Form				
11	*Research participants recruitment procedures: advertisement, notices (If applicable)				
12	*Patient instruction card, identity card, diary etc.				
13	a. *Research participants Questionnaire/s (If applicable)				

	b. Research participants confidentiality statement				
14	*Investigator brochure				
15	*Insurance certificate and policy				
16	*Investigator's undertaking to DCG(I)				
17	DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the YEC 2]				
18	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding / Copy of clinical trial protocol Material Transfer Agreement (MTA), as applicable, for collaborator & Govt sponsored trials (draft if final not ready)				
19	FDA marketing/manufacturing license for herbal formulations/ nutraceutics				
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations				
21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy				
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) Or Memorandum of Understanding (as applicable)				
	b) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or Material Transfer Agreement (as applicable)				
23	*Budget Sheet for the Proposed Study (Format for budget sheet stated below)@				
24	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-ordinator) (one copy only)				
25	*Ethics Committee clearance of other centres (Total No_____)				
26	*Log of delegation of responsibility of the study team members - Sample Format Enclosed)				

27	*Document Receipt Form (one copy only)				
28	*Current Status of Ongoing Studies approved by IEC and IEC conducted by PI(information may be submitted separately)				
29	Documentation of clinical trial registration (in Clinical Trial Registry of India) / any other WHO platform registry (whenever applicable)				
30	*GCP training certificates of principal investigator, co investigator/s, study co-ordinator/s for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only)				
31	Any other Documents submitted				

Budget:

1	Title of the Project:	
2	Name of PI(PI)	
3	Designation and address of the PI	
4	Names of Co-investigators with department/ institution:	
5	Source of funding (tick whichever is applicable) a. Government: b. In-house c. Private Foundation: d. Non profit agency/trust funded e. Pharma./ industry sponsored f. Other: g. No funding required	
6	Address, phone, fax. E-mail of sponsor with the name of the contact person	
7	Total Budget for the entire project in Rs.	
8	Duration of the Project in months	
9	Proposed date of starting the project	

10	Direct payments to investigators, if any	
11	Other benefits to investigator/department/institution	
12	Conflict of Interests, if any	

Name of the PI with signature and date:

YEC2/Ann2B/SOP06/v2

Checklist for Protocol Submission to Yenepoya Ethics Committee 2 ethical clearance for clearance

Instructions to fill:

- *Please fill out the soft copy of this form, print and take signatures, wherever applicable*
- *Incomplete files will not be accepted*
- *Tick √ in the box for the appropriate answer*
- *Write Not Applicable (NA) if question is not applicable for this study*
- *Do not leave any questions unanswered*
- ***Strictly do not edit/delete the content or formatting of this form***
- *Write annexure numbers whenever documents are referred to in the application form*

No	**Document**					Date of submission	Page no
1	Letter to Member Secretary	Guide signature	Head of the department (HOD) signature	PI signature			
2	Project &Proposal hard copy	**Header of the protocol**	Y/N	**Footer of the protocol**	Y/N		
		Version number		Page no For example (1 of 30)			
		Title					
		Date of submit the protocol					

<table>
<tr><td rowspan="4">3</td><td rowspan="4">Project &Proposal Soft copy

E-mail to yec2@yenepoya.edu.in (Please note that there should be no discrepancy between the hard copy and the soft copy submitted)</td><td>Header of the protocol</td><td>Y/N</td><td>Footer of the protocol</td><td>Y/N</td><td colspan="2" rowspan="4"></td></tr>
<tr><td>Version number</td><td></td><td rowspan="3">Page no

For example (1 of 30)</td><td rowspan="3"></td></tr>
<tr><td>Title</td><td></td></tr>
<tr><td>Date of submit the protocol</td><td></td></tr>
<tr><td>4.</td><td>Approval from SRB</td><td>Date of submit to SRB</td><td>Date of approval from SRB with SRB no</td><td>SRB corrections incorporated YES/NO
If yes, please mention page number and highlight.</td><td colspan="2"></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>5</td><td colspan="4">Detailed protocol</td><td colspan="2">Page no</td><td>Date of submission</td></tr>
<tr><td>a.</td><td>Title (write the title in the box)</td><td colspan="3"></td><td colspan="2"></td><td></td></tr>
<tr><td>b.</td><td>Study site</td><td colspan="3">Permission letter (If required)
Y/N</td><td colspan="2"></td><td></td></tr>
<tr><td>c.</td><td>Source of data</td><td colspan="3"></td><td colspan="2"></td><td></td></tr>
</table>

d.	Sponsor (Write the details of the sponsor if applicable)							
e.	Duration of the study	3 months	6 months	1yr	2yr	More than 2 yr		
f.	Type of study 1. **Qualitative study** • Experimental, • Quasi experimental study, • Survey study , • Correlation study 2. **Quantitative study** • Ethnography • Case study • Historical study 3. Descriptive study 4. Cross Sectional 5. Prospective study 6. Retrospective 7. Observation study 8. Genetic study 9. Document based study 10. Intervention 11. Epidemiological Any other specify,---------- (**Please write in the box**)							

g)	Description of the study (write here whatever applicable to your study)	Y/ N	If any other (write here)	Page no	Date of submission
	Randomized				
	Open-labelled				
	Questionnaire-based				
	Double blinded				
	Placebo controlled				
	Treatment controlled				

	Cross-over Parallel Interim Analysis Use of Tissue samples Use of Blood samples Use of genetic material				
h	Detailed methodology	YES	NO	Page No	Date of submission
	i. Materials/Tools				
	ii. Study design				
i	Ethical Issues	YES	NO		
	a) Recruitment of participants will start only after the ethical clearance				
	b) Have you attached PIS				
	English /Kannada /Malayalam				
	c) Have you attached ICF				
	English /Kannada/Malayalam				
	d) In PIS and ICF how will you assess the comprehension to the participants (				
	e)Permission to use photographs /Samples				
	f)How the sample will be discarded				
	g) Risk/Benefit Analysis **Risk ,** (mentioned 2points in each) If Yes, How the risk will be addressed and by whom? **Benefit** (mentioned 2points in each)				
	h) How will ensure privacy of the participants				
	i) Maintenance of confidentiality of				

	data							
	j) Sharing of samples/data							
	k) Compensation to participants							
	l) Ensuring standard of care to participant							
J	Budget			If applicable (Write the details		Not applicable		
k	Gantt Chart			Yes		No		
l	Questionnaire	Yes	No	No of Questions	Time	Validation YES/ NO If yes(Attach validation certificate		
m	Sample size	No of sample		Reference article		Statistician approval letter		

N	Inclusion criteria (Please tick which applicable)	General population	Vulnerable population (Pregnant women/ Children below 18 years/elderly/ Terminal Illness • Annexure for research involving pregnant women available in website		

DECLARATION BY THE PG STUDENT AND THE GUIDE /PRINCIPAL INVESTIGATOR

We hereby declare that the information given above is true and that we will comply with the all the stipulations/recommendations mentioned in the New Drugs and Clinical Trials Rules 2019, the current ICMR guidelines, any other recent notification/s from CDSCO (updated as applicable), the Indian GCP Guidelines and the Declaration of Helsinki, while conducting the research study.

We hereby declare that neither the PI, nor the Co-PI, nor any other members of the research team are concurrently involved as research team members in a similar study or another study using the same set of participants, as this one.

We also ensure that the Principal Investigator/Institution (for non-funded studies) will pay for the expenses for the treatment and/or compensation of research-related injury, as deemed necessary by Yenepoya Ethics Committee 2

Signature/s of Principal investigator and Co-investigators with date:
1.

2.

3.

4.

5.
Forwarded by Heads of Department(s)

Signature/s with date of Heads of Department(s):

Stamp/Seal of the Department(s)

YEC2/Ann2C/SOP06/v2
Checklist for PI to tick

- *Tick √ in the box for the appropriate answer*
- *Write Not Applicable (NA) if question is not applicable for this study*

Sl.No	Document		YES		NO
1	Letter to Member Secretary				
2	Principal investigator Details				
	Name	Designation and qualification	Department and Institution	Email id and phone number	
	Principal Investigator				
	Co-Investigator				
	Co-Investigator				
	Co-Investigator				
	Co-ordinator				
	(Add additional rows for any category if required)				
3	Brief signed copy of Curriculum Vitae (CV) of ALL Investigators (including PI, Co-PI, Guide) not more than two pages focusing on research activities and research training				
4	Fee for review (For external proposals				
5	Detailed Protocol				
6	Participant information sheet				
7	Informed consent				

Signature of Principal Investigator with date:

Signature/s of Investigator /Co-investigators with date:

Signature of Principal Investigator with date:

Signature/s of Investigator /Co-investigators with date:
1.

2.

3.

4.

5.

Signature of coordinator:
1.

2.

YEC2/Ann03/SOP06/v2
Delegation of Responsibilities of Study team

YEC 2 Protocol No.		
Study title:		
Name	**Role**	**No.**
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6
	Study co-ordinator *	7
	Study co-ordinator *	8

	Laboratory Technician	9
Please fill if more members		
on team		

(Please place tick marks against assigned duties for each member in the following table)

Code	**Tasks**	**Role played by each study team member**									
		1	2	3	4	5	6	7	8	9	10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug**,** document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination & supervision										

YEC2/Ann04/SOP065/v2
Receipt for Submitted protocol

Protocol No.		
Received date:		
Submitted date:		
Protocol title		
PI Name, Designation and Affiliation		
Communication with YEC 2	e-mail address: Phone: Fax:	
For office use only		
Documents submitted (tick whichever is applicable)	Complete / Incomplete / Will submit on ……	
Late documents submitted	Name of the document	Recd date
	Final signed clinical trial agreement	
	Informed consent form (English + local language)	
	Study budget	
	DCGI	
	CTRI	
	GCP training certificate	
	Other sites EC permission (if available)	
	Other documents (if any)	
Received by: (Name and signature)		
Date on which documents received:		

Note: Please bring this receipt with you when you visit the YEC 2 Secretariat

Guidelines to be following for PG/UG/Ph.D.,/Faculty study protocol being submitted to YEC2

For soft copy submission the documents must be in following order.

1. Signed and scanned covering Letter
2. Scanned copy of filled and signed checklist for protocol submission to YEC 2 (Available from website)
3. SRB approval letter
4. Statistician approval letter (If applicable)
5. PART- A of the protocol (number as 1 of ..)
6. PART- B of the protocol (number as 1 of ..)
7. PART- C of the protocol
8. Annexures
   a. English - Informed consent document - Participant information sheet, Informed consent form
   b. Regional language 1 - Informed consent document - Participant information sheet, Informed consent form
   c. Regional language 2 - Informed consent document - Participant information sheet, Informed consent form
   d. Data collection form
   e. Permission letter(If applicable),
   f. Validation certificate (If applicable),
   g. Reference for using standardised Questionnaire (If applicable).
9. Signed and dated CV of the Principal Investigator & Co-PI and Guide (not more than 4 pages)

Kindly note:

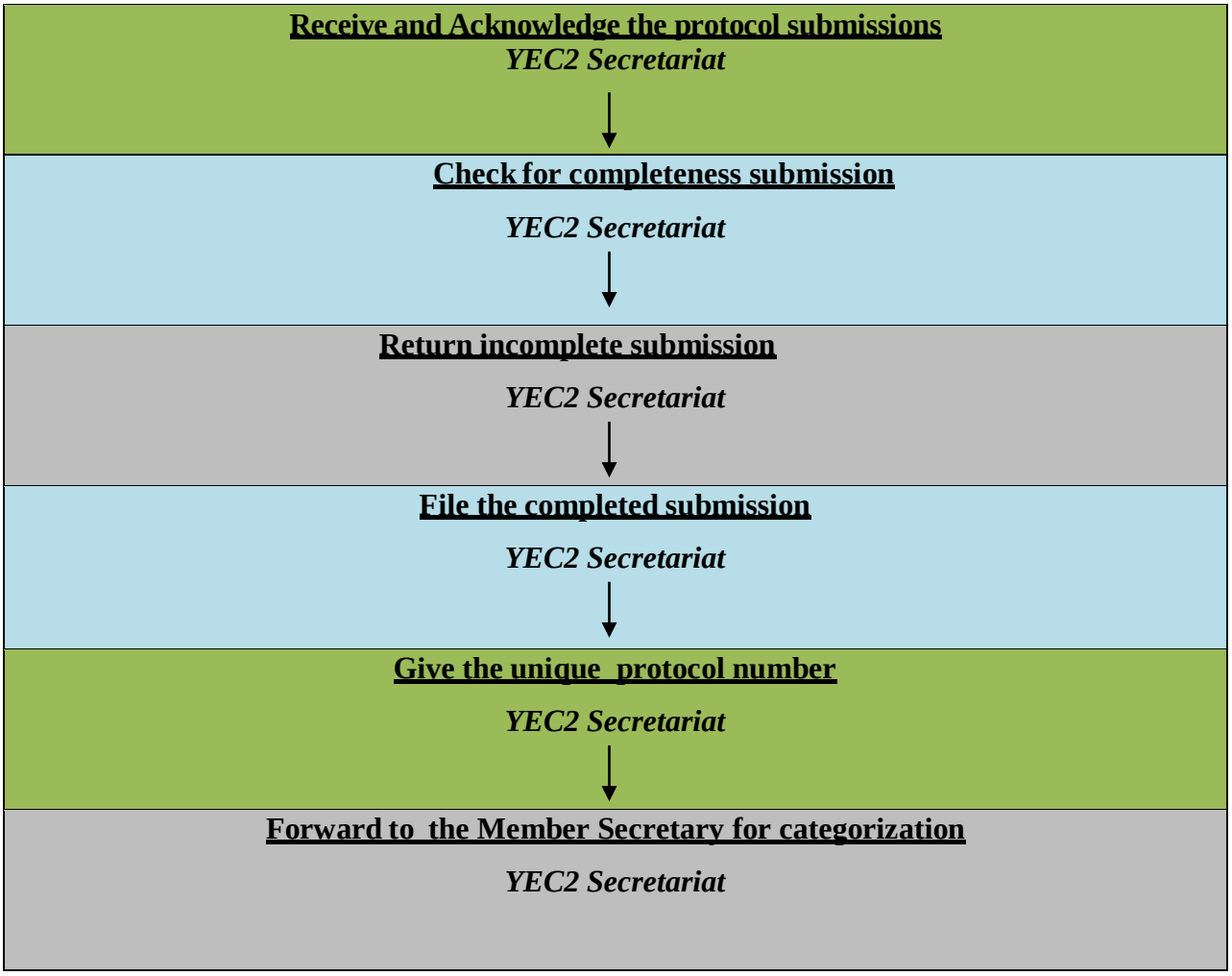
- Submit one hard copy and 2 Soft copy(1 PDF document, 1 word document) to Yenepoya ethics committee 2 office, Yenepoya Dental college.
- Email the soft copies to yec2@yenepoya.edu.in
- Only the signed copies should be scanned.
- While putting the page number note that PART-A, PART-B, PART-C and Annexure is different. All should start from fresh page number

Thanking you

Dr. K. Leena Pramod
Member Secretary
Yenepoya Ethics Committee 2

Member Secretary
Yenepoya Ethics Committee 2
Yenepoya (Deemed to be University)

6 Flow Chart



7. References

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6 th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf