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

SOP Code: SOP06/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date 1/6/2023

Reviewed by

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date 1/6/23

Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date 6/6/23

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date 7/6/23

Details of superseded SOP06

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP06/v4

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Glossary section added in the SOP 2. CV, training certificates and CoI included for all co-investigators 3. Fees for YEC-1 review updated 4. Researcher submission deadlines added

Table of Contents:

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepoya Ethics Committee - 1 (YEC-1) 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/v4

      2.2.2. Submission of amended protocols: SOP9B/v4

      2.2.3. Continuing review of approved protocols: SOP10/v4

      2.2.4. Protocol deviations/violations: SOP11/v4

      2.2.5. Serious adverse events initial report/follow up/final report: SOP12/v4

      2.2.6. Protocol completion: SOP13/v4

      2.2.7. Premature termination/suspension: SOP14/v4

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/v4.

   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-1 Member-Secretary (Ann05/SOP06/v4)
      3.4.2. Initial application form and log delegation form (Ann01/SOP06/v4)
      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-1

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/v4)

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/v4)

4.1.9. Assign the YEC-1 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-1 database.

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

4.2.1. Initiate the process of categorization and review as per SOP07/v4

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 30 calendar days

5.1.3. If the initial protocol submission process is not completed within 30 calendar days, all the documents submitted to YEC-1 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-1 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/v4)**:**

5.3.1. Should be addressed to the Member-Secretary, YEC-1

5.3.2. Should be forwarded to YEC-1 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/v4) .

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-1 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/v4):

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

5.5.10.2. Informed consent form

5.5.10.3. Translation of PIS and ICF

5.5.10.4. Translation Certificate (for regulatory clinical trials)

5.5.10.5. Back translation of PIS and ICF (for regulatory clinical trials)

5.5.10.6. Back Translation Certificate (for regulatory clinical trials)

5.5.10.7. Waiver of consent, if applicable

5.5.10.8. Details of audio-visual recording of consent

5.5.10.9. Electronic consent, if applicable

5.5.10.10. Written assent form and translations, if applicable

5.5.10.11. Details of oral assent

5.5.10.12. Parental/ Surrogate informed consent

5.5.11. **Statistical methods**

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-1)**

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 Ann04/SOP06/v4.

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

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-1 approval, they have to upload to CTRI, obtain final registration and communicate a copy to YEC-1

5.6.8. **Clinical trial agreement (CTA):** For YEC-1 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-1 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-1

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-1/ YEAR/ NUMBER and this will be displayed prominently on the file. The

number refers to the sequential number of the protocol received in YEC-1. (Eg. YEC-1/2023/200 refers to the protocol submitted to YEC-1 for review in the year 2023 and is the 200th protocol received by the YEC-1 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/v4

5.9. **Fees for YEC-1 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/v4: Sitting fees of YEC-1).

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/v4: Full Review of Research Protocols

6.1.2. SOP09/v4: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol.

6.1.3. SOP15/v4: Request for Waiver of Consent

7. **Annexures:**

7.1.1. Ann01/SOP06/v4: Application form for initial review of protocols (Regulatory, Non-Regulatory Clinical Trial, observational, basic science or other protocols)

7.1.2. Ann02/SOP06/v4: Receipt for submitted protocol

7.1.3. Ann03/SOP06/v4: Sitting fees of YEC-1

7.1.4. Ann04/SOP06/v4: Template for curriculum vitae of investigators

7.1.5. Ann05/SOP06/v4: Synopsis template for postgraduate dissertation/student projects/faculty projects/ Phd thesis

Ann01/SOP 06/v4:

Application form for initial review for all protocols

(Regulatory, Non-Regulatory Clinical Trials, Observational and Basic Science Studies)

Instructions to fill:
Please fill in the details in the soft copy, 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 this study
Do not leave any questions unanswered
Write the annexure numbers whenever documents are referred to in the Application form

PART A: INVESTIGATOR DETAILS

YEC-1 Protocol No.:
(to be filled in by the Secretariat when a protocol number is assigned)

Title of the protocol:

Researcher code	Research team member	Name	Qualification Designation and Department; Institution	Phone number Email ID
1.	**Principal Investigator**			
2.	Co-Investigator			
3.	Co-Investigator			
4.	Co-ordinator			

Add additional rows above to add details of more investigators

Activity log of research team members

No.	Activity *Marking for all rows is mandatory. Any row unmarked will be considered as incomplete protocol package and returned to PI*	Researcher code (Add more columns, if needed for additional researchers) and tick against the appropriate cell					
		1	2	3	4	5	6
1.	Study conceptualization						
2.	Design of the study						
3.	Participant recruitment (flyers, advertisement, medical records, etc)						
4.	Participant screening (selection based on inclusion/ exclusion criteria)						
5.	Informed consent process						
6.	Collection of biological samples (as applicable)						
7.	Laboratory investigations and interpretation						
8.	Storage and disposal of samples/tissues						
9.	Storage and log maintenance of study intervention						
10.	Administering the study intervention/ tool						
11.	Purchase, procurement, inventory in-charge						
12.	Ensuring standard of care						
13.	SAE reporting, evaluation and management						
14.	Participant follow-up visits						
15.	Collection,monitoring and storage of data						

16.	Data analysis & interpretation						
17.	Maintaining participant file and master file of project						
18.	Drafting interim and final report						
19.	Reviewing interim and final report						
20.	Authorship placements (for publication) (write 1 for first author, 2 for second author, …)						
21.	Communications with YEC-1						
22.	Any other activity						

Activity No.	**Submission of requirements**	**Researcher code (Add more columns, if needed for additional researchers) and write Yes/No against the appropriate cell**					
		1	**2**	**3**	**4**	**5**	**6**
1.	Updated CV attached						
2.	CoI declaration attached						
3.	Training certificates attached						

PART B: SPONSOR DETAILS:

(Type Not applicable and move to Part C if non-sponsored/non-funded study)

A. Name of the Sponsor/funding agency:	
B. Contact details:	
C. Status of funding approval (Applied/approved/under process)	
D. Amount	
E. Budget details (Attached/Annexure number)	
F. Nature of the sponsor	**Tick as applicable**
1. Indian Governmental	
2. Indian Private (Industry)	
3. International Governmental	
4. International Private (Industry)	

5. UN Agency	
6. Yenepoya (deemed to be University)	

PART C: STUDY DETAILS

S. No.	Type of study (Please make sure the information provided here	Tick whichever applicable
I.	**Prospective studies involving human participants**	
	A. Interventional study	
	1. Regulatory clinical trial	
	2. Investigator-initiated/Academic clinical trial	
	3. Surgical intervention trial	
	4. Device study	
	5. Vaccine trial	
	6. Other intervention (Specify)	
	B. Observational study	
	1. Clinical	
	2. Epidemiological	
	3. Questionnaire-based	
	4. Qualitative study	
	5. Genomic/ genetic study	
	6. Proteomic/ metabolomic/ biomarker	
	7. Biochemical	
	8. Histopathological	
	9. Any other (Specify)	
II.	**Retrospective study involving human participants**	
	1. Medical record based	

S. No.	Type of study (Please make sure the information provided here	Tick whichever applicable
	2. Imaging	
	3. Left-over biological samples	
	4. Any other (Specify)	
III.	Studies with no direct involvement of human participants	
	A. Data in public domain	
	B. In vitro studies on anonymous samples/ cell cultures	
IV.	Any other: Please specify	

Study sites

S. No.	Study sites	Number and details of the site
I.	Multi-centric Global 1. Number of sites globally 2. Number of sites in India	
II.	Multi-centric Indian	
III.	Single site (Provide specific details of the sites): Name of the hospital, laboratory, department, Centre, community setting, and other (Please note that YEC-1 will provide EC approval only for those studies which are conducting with 50 Km of its radius)	

PART D: CLINICAL TRIAL DETAILS

Provide details, if it is a Clinical Trials:			
1	**Nature of trial**	Medicine	Devices
		Vaccine	Indian system of Medicine
		Any other (specify):	Not applicable
2	**Approved (Provide reference of approvals)**	Yes	No
		If Approved:	
		In India	In UK/Europe
		In 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
	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 Not applicable

PART E: PROTOCOL DETAILS

Protocol of proposal: (Submit as attachment)

PI to note that all the protocol and related documents must bear the title of the document, version number, page number, date and signatures wherever applicable

1. Title
2. Background and need for the study
3. Objectives
4. Methodology (The methodology must be in great detail):
5. Sample/data collection details
6. Study tool
7. Statistical tests
8. Budget and funding details
9. Utilisation of the results **whether it is of national significance with rationale**

PART F: PARTICIPANT DETAILS

Provide details about 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 for the purpose of screening and research :			
Will research participants from both genders be recruited	Yes	No	NA
Inclusion / exclusion criteria given	Yes	No	NA
Type of research participants: (*If vulnerable population is included, PI must submit the appropriate checklist for involvement of vulnerable population in research available in SOP19/v4 and provide attachment number)			
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
Will any advertising be done for recruitment of research participants? (posters, flyers, brochures, websites, notices, letters – if so kindly attach a copy)	Yes	No	NA
Is there compensation plan for participation If Yes, (tick appropriate) Monetary In kind Specify amount and type:	Yes	No	NA
Is there a compensation plan for injury? If Yes, (tick appropriate) by Sponsor by Investigator by insurance by any other company	Yes	No	NA

PART G: PRIVACY AND CONFIDENTIALITY

Privacy and confidentiality			
Direct identifiers (Name, address, phone numbers, photographs, videographs)	Yes	No	NA
Indirect identifiers (coded)	Yes	No	NA
Completely anonymized (delinked)	Yes	No	NA

PART H: USE OF BIOLOGICAL/ HAZARDOUS MATERIAL

Use of biological/hazardous materials (Tick)			
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 from banking/future research	Yes	No	NA
Collection for banking/future researcH	Yes	No	NA
Use of ionizing radiation/radioisotopes If yes, has 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

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 (give 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			
Is 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
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

PART I: INFORMED CONSENT PROCESS

Consent form & participation information sheet	**Yes**	**No**	**NA**
Tick which elements are included:			
Simple language			
Regional language understood by the participant			
Alternatives to participation			
Statement that this consent is for research and not therapy			
Sponsor of study			
Contact information			
Purpose and procedures in detail			
Risks & Discomforts			
Benefits			
Statement that consent is voluntary			
Right to withdraw			
Confidentiality of records			
Compensation for study related injuries			
Compensation for participation			
Benefits, if any, on future commercialization			
Consent for future use of biological material			
Consent for photographs, if applicable			
Consent for publication/ conference presentation			

Who will obtain consent? PI/Co-PI Nurse/Counselor trained in ICH-GCP guidelines Research team member Any other, specify			
Where will the consent be taken? Specify the room			
Whether audio-visual recording of consent will be done?			
Whether audio recording of consent will be done?			
Whether surrogate consent will be obtained?			
Whether written or oral assent will be obtained?			
Whether electronic consents will be obtained?			
If written consent will not be obtained, give reasons:			
Whether applied for waiver of Consent:			

PART J: RISK AND BENEFIT

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

PART K: DATA SAFETY

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-1 DSMB	Yes	No	NA
	Is there a plan for interim analysis of data?	Yes	No	NA
	Are there plans for storage and maintenance of all trial databases? If Yes, for how long?	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 New Drugs and Clinical Trials Rules 2019 and the current ICMR guidelines and any other recent notification/s from CDSCO (updated as applicable)], and the Indian GCP Guidelines while conducting the research study.

We also ensure that the Principal Investigator / Institution will pay for the expenses for the treatment and / or compensation if research related injury.

Signature of Principal Investigator with date:

Signature/s of Co-investigators with date:

Signature of coordinator(s):

Forwarded by Heads of Department(s)

Signature/s with date Stamp/Seal of the Department(s)

Ann02/SOP06/v4:

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-1/------ 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-1.

For protocols kept for full review, add:

The submission has been categorized as "Full review" as per the SOP of the YEC-1 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.

Ann03/SOP06/v4:

YEC- sitting fees

SrNo	Category of review	International Funded research (pharma, industry, Government, NGO; single or multi centre)	Indian funded research (pharma, industry, Government, NGO; single or multi centre)	Govt sponsored/ NGO Research	Academic 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-1 Approval letter				

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

Ann04/SOP06/v4

Template for Curriculum Vitae of Investigators

1. Name (should match across all submitted documents)
2. Present affiliation (job title, department and institution/centre/organization)
3. Address (full work address)
4. Contact details (current mobile number; valid email address)
5. Qualifications (in chronological order - oldest to newest)
6. Professional registration (wherever applicable) (name of the registering body; registration number and date)
7. Research projects undertaken in the last 5 years

Sl. No.	Official project title	Role in the project (PI, Co-investigator, any other)	Status (ongoing/ completed)	EC approval status (and number)

8. Relevant research training/experience (research methodology/research ethics/Good clinical practice guidelines/other)

Sl No	Name of the training program	Organized by	Dates

9. Relevant (selected) publications of the last 5 years
10. Signature and date

Ann05/SOP06/v4

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
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. **ETHICAL ISSUES:**
    - **A.** Ethical guidelines followed:
    - B. Ethical approval:
    - C. Informed consent:
    - D. Vulnerable population:
    - E. Standard of care:
    - F. Harms:
    - G. Benefits:
    - H. Risk-benefit ratio:
    - I. Privacy:
    - J. Confidentiality:
    - K. Requisite permissions/approvals/agreements/MoU/MTA:
11. **BIOSAFETY ISSUES:**
12. **UTILIZATION OF RESULTS OF RESEARCH & SPECIFIC DELIVERABLES:**
13. **REFERENCES** (in Vancouver Style)
14. **LIST OF ANNEXURES:**
15. **DATA COLLECTION FORM (**Case Record Form, Performa or questionnaire, if any)
16. **PARTICIPANT INFORMATION SHEET/INFORMED CONSENT FORM**
17. **CURRICULUM VITAE OF PG/PI, CO-GUIDE (IF ANY) AND GUIDE**
18. **STATEMENT BY RESEARCHERS ON RESEARCH INTEGRITY**

We do hereby declare that this study titled "_____"will be carried out by me/us upholding the principles enshrined in the Declaration of Helsinki, and simultaneously abiding by the ICMR's National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017)/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 - 1/2 (strike off whichever is not applicable)

Yenepoya (deemed to be University), Deralakatte Mangalore 575018 Karnataka India

Through proper channel

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

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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.

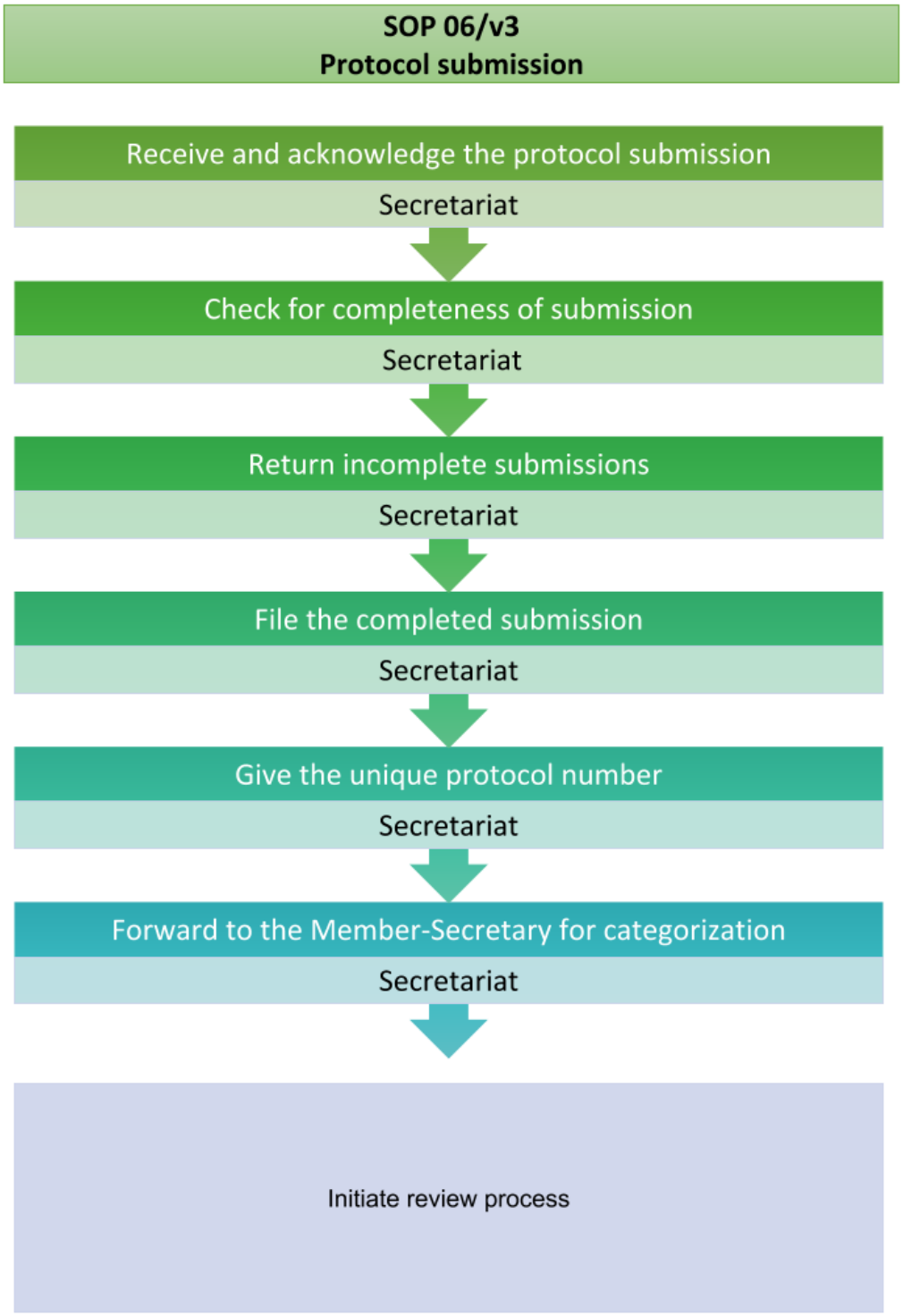
Thanking You,

Yours Sincerely

PI Signature

Date: Place: Mangalore

8. **Flowchart**:


SOP 06/v3
Protocol submission
Receive and acknowledge the protocol submission
Secretariat
Check for completeness of submission
Secretariat
Return incomplete submissions
Secretariat
File the completed submission
Secretariat
Give the unique protocol number
Secretariat
Forward to the Member-Secretary for categorization
Secretariat
Initiate review process

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