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

SOP Code: SOP06/v3

Effective Date: 03/10/2019

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date 3/10/2019

Reviewed by

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date 30 OCT 19

Approved by:

Dr. Vikram Shetty Chairperson, YEC-1	Signature with date 3/10/19

Notified by:

Registrar, Yenepoya deemed to be University	Signature with date 3/10

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:
    1. Submission of research protocols and related documents for initial review
    2. For all other submissions, procedures are as per respective SOPs:
        1. Resubmission of protocols: SOP9A/v3
        2. Submission of amended protocols: SOP9B/v3
        3. Continuing review of approved protocols: SOP10/v3
        4. Protocol completion: SOP13/v3
        5. Termination or status: SOP14/v3
        6. Protocol deviations/violations: SOP11/v3
        7. Serious adverse events initial report/follow up/final report: SOP12/v3
3. **Definitions:**
    1. **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:
        1. Title
        2. Details of the research team *(vide infra)*
        3. Background and need for the study *(vide infra)*
        4. Objectives
        5. Methodology in detail *(vide infra)*
        6. Sample/data collection details including case record form/ patient diary *(vide infra)*
        7. Study tool *(vide infra)*
        8. Informed consent document *(vide infra)*
        9. Statistical tests
        10. Budget and funding details *(vide infra)*
        11. Utilisation of the results *(vide infra)*
        12. Investigator brochure
        13. Any other, as required for the study or by the YEC-1

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 following as applicable
    1. Scientific Review Board (SRB) approval letter
    2. Curriculum vitae of the investigators
    3. Regulatory permission letters (DCGI, ICSCR, GEAC, BARC)
    4. Other permission letters, as applicable
    5. Clinical trial registry of India (CRTI) information
    6. Clinical trial agreement
    7. Insurance certificate and policy
    8. Indemnity certificate, wherever applicable
    9. Details of Data Safety Monitoring Board (DSMB), if applicable
    10. Any other, as required for the study or by the YEC-1
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
    1. The protocol
    2. Protocol related documents
4. **Complete protocol submission:**
    1. Covering letter addressed to YEC-1 Member-Secretary with a list of all attachments
    2. Appropriated application form
    3. The protocol package
    4. Any other, as required for the study or by the YEC-1

4. Responsibility:

1. **The Secretariat will:**
    1. Ensure that the initial submission of protocol package is complete in all aspects (documents, content, signatures, dates, permissions, versions, page numbers, etc)
    2. Ensure that the covering letter and appropriate forms are duly filled, signed, dated and submitted

3. Ensure that the protocol has been cleared by the Scientific Review Board of the respective Institution/Department/Centre and the approval attached.
4. Ensure that one hard copy and soft copy of the protocol is submitted which are not dissimilar in any aspect.
5. Ensure that the application forms are duly filled, singed, dated and submitted (Ann 1 and 2 / SOP06/v3)
6. Accept the protocol package and record the date of receipt
7. Assign the YEC-1 protocol number
8. Forward the protocol package to the Member-Secretary only after all the documents are submitted completely
9. Record the details of protocol submission in the YEC-1 database.

2. **The Member-Secretary will:**
    1. Initiate the process of categorization and review as per SOP07/v3
    2. Return any incomplete protocol submissions, if any, to the PI stating that review process cannot be initiated.

5. Detailed instructions:

1. **Check for Complete protocol submission:**
    1. The Secretariat will check that the submission is complete in all aspects
    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
    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.
2. **Covering letter:**
    1. Should be submitted in the name of the Member-Secretary, Yenepoya Ethics Committee-1

2. Should be forwarded to YEC-1 through the Head of the Department(s) and the Head of the Institution/ Centre.
3. Must be dated and signed by the Principal Investigator
4. Must contain the title of the study and the names of the investigators
5. Must contain a list of annexures.
6. Must be submitted as a hard copy, signed and dated by the PI and co-PI

3. **Application form**:
    1. The application forms for protocols are provided as templates.
    2. For Regulatory Clinical Trials Ann01/SOP06/v3 (All sections from Part A to K) must be submitted
    3. For Non-Regulatory Clinical Trials, Observational and other studies Ann01/SOP06/v3 (all applicable sections Part A to K)) must be submitted
    4. For all studies, Duty Delegation Log must be submitted (Ann02/SOP06/v3)
    5. All appropriately selected forms must be completely filled and signed by the PI
    6. Incomplete forms will be returned to the PI and considered as incomplete submissions
    7. The forms must be submitted to YEC-1 office as hard copies
    8. The information provided in the application form and the protocol package should not be discordant.

4. **Verification of content of the submitted documents:**
    1. The Secretariat will verify whether
        1. Appropriately selected application form is submitted
        2. All documents ticked as attached in the application form/covering letter are present in the submission
        3. All documents are signed and dated wherever applicable
        4. All protocol documents bear a version number and page numbers
        5. All required permission letters/ SRB clearance letters and others as required for the study are attached

6. Forwarding letter/acknowledgment from concerned scientific review board - A
7. Receipt of the YEC-1 review fees

5. **The Protocol:** The protocol must contain the following headings:

1. **Title:**
    1. The title must be comprehensive and clear
    2. The title must ideally indicate the nature of the study
2. **Details of the research team:**
    1. Name, designation, affiliation of the Principal investigator
    2. Names, designations, and affiliations of all the co-investigators including the Guide/ Co-guide including on-site/ off-site investigators
    3. Updated and signed Curriculum vitae of all the members of the research team
    4. Training Certificates in Research Ethics/ Research methodology
    5. ICH-GCP training certificate for Clinical trials of the Principal investigator and other research team members (within the last 2 years)
    6. List of on-going research projects undertaken by the Principal Investigator
3. **Background and need for the study**
    1. The background should include a brief description of the condition/drug/device/other to be studied
    2. 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
4. **Objectives:**
    1. Specific objectives to be listed
5. **Methodology in detail:** The methodology must include
    1. Study design
    2. Study intervention and its approval status
    3. Study site
    4. Study population
    5. Sample size

6. Recruitment procedures including advertisements, notices, letters to doctors, etc
7. Inclusion and exclusion criteria
8. Withdrawal and discontinuation criteria
9. Details of intervention
10. Standard of care
11. Details of placebo/ if applicable
12. Data/ sample collection and evaluation
13. Data collection form/ Case record form
14. Data/ sample management (use, storage, disposal, transport, sharing, reuse)
15. Data analysis and statistical methods
16. Maintenance of privacy and confidentiality
17. Risk management
18. Benefits of study
19. Vulnerability
20. Social and community involvement and impact
21. Consent process

6. Study tool:

1. Description
2. Validation
3. Permissions

7. Informed consent document

1. Participant information sheet
2. Informed consent form
3. Translation of PIS and ICF
4. Translation Certificate
5. Back translation of PIS and ICF
6. Back Translation Certificate
7. Waiver of consent, if applicable
8. Audio-visual recording of consent
9. Electronic consent, if applicable

10. Written assent form
11. Oral assent
12. Parental/ Surrogate informed consent

8. **Statistical methods**
    1. Sample size calculations
    2. Statistical tests
    3. Significance values
9. **Drug/device brochure**:
    1. Details
    2. Approval status
    3. Adverse events
10. **Budget and funding details**
    1. Source of funding
    2. Amount of funding
    3. Duration of funding
    4. Funding approval
    5. Budget allocation
    6. Insurance policy (policy details) of the participants indicating conditions of risk coverage, data of commencement and expiry of risk coverage. (C)
    7. Indemnity policy with details. (C)
11. **Utilisation of the results**
    1. Publication
    2. Scientific presentations
    3. Marketing potential
    4. Patent development
12. **Approval/ Permissions/Agreement letters**
    1. DCGI approval for Regulatory clinical trials
    2. CTRI registration
    3. Clinical trial agreement with sponsors, investigators, and head of the institution

4. Permissions from the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) wherever applicable
5. Institutional Committee for Stem Cell Research wherever applicable
6. Animal Research Ethics Committee wherever applicable
7. Permission from the concerned authorities for access to data/ samples/participants wherever applicable
8. Administrative sanctions from Head of the institution/Centre/ Laboratory or MoU in studies involving collaborative work or in case of sending samples to laboratories of other centres or institutions
9. Ministry of External Affairs permission to send samples out of country/ Material Transfer Agreement or other permissions for transport of samples, if applicable
10. Ethics Committee clearance of other centers (if applicable)
11. Any other permissions as and when required by the Regulatory authorities, University or Ethics Committee.
12. Any other, as required for the study or by the YEC-1

6. **Complete the submission process:**

1. Once the complete protocol submission is received and verified the Secretariat will stamp the receiving date on the first page/last page of the covering letter and initial it.
2. The Secretariat will make a file for the new protocol with the complete protocol submission
3. Each protocol file will be given a unique protocol number:
    1. YEC-1/ YEAR/ NUMBER. The number refers to the sequential number of the protocol received in YEC-1. (Eg. YEC-1/2019/200 refers to the protocol submitted to YEC-1 for review in the year 2019 and is the 200th protocol received by the YEC-1 in the year.)
    2. which is used and quoted for all future communications concerning the protocol from the time of categorization to shredding of the protocol.
    3. Incomplete submissions will not be given a unique protocol number.

7. **Initiation of the review process**

1. Once filed and given the unique protocol number, the file is forwarded to the Member-Secretary for categorization as in SOP07/v3

6. **Fees for YEC-1 review**:

1. The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table (liable to change from time to time, as approved by the University):

SrNo	Category of review	Pharma industry sponsored Research	Govt sponsored/ NGO Research	Academic or Investigator initiated Research
1.	New study protocol	INR 50,000 /-	INR 25,000 /-	Nil
2.	Continuing review (per review)	INR. 10,000 /-	INR 15,000 /-	Nil
3.	Protocol Amendment (per amendment review) (if applicable)	INR. 15,000 /-	Rs. 10,000 /-	Nil
4	Reissue of YEC-1 Approval letter	INR. 5000	INR. 5000	INR. 5000

6. Reference to other applicable SOPs:

1. SOP7A/v3: Full Review of Research Protocols
2. SOP09/v3: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol
3. SOP15/v3: Request for Waiver of Written Informed Consent and Waiver of Consent

7. Annexures:

1. Ann01/SOP06/v3: Application form for initial review of protocols (Regulatory, Non-Regulatory Clinical Trial, observational, basic science or other protocols)
2. Ann02/SOP06/v3: Delegation of Responsibilities of Study team
3. Ann03/SOP06/v3: Receipt for submitted protocol

Ann01/SOP 06/v3:
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:					
	Name	**Designation and qualification**	**Department and Institution**	**Roles and responsibility***	**Signature**
Principal Investigator	`				
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 B. Design C. Screening of patients D. Selection and recruitment of study participants E. Informed consent F. Selection & Recruitment of patients G. Laboratory investigations H. Laboratory report interpretation I. Treatment decision J. Patient evaluation K. SAE evaluation and reporting	L Examination of patients on follow-up M Data collection and monitoring of data N Interpretation of data O Statistical analysis & Interpretation P Maintaining patients file and master file of project Q Drafting final report R Submission of final report to funding agency and

(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			
Does any research team member have any **conflict of interest** in the present study? (financial/non financial) If Yes, specify	Yes	No	NA
Whether the PI is handling other research protocols at present. If yes, Number of ongoing protocols handled by the PI at present studies approved by YEC-1 or YEC-2 Describe briefly the details of the status of the protocols	Yes	No	NA
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
Training certificates of principal investigator and coordinators (mandatory for drug and device trials not for observational studies**)**	Yes	No	NA

PART B: SPONSOR DETAILS:

Sponsor Information:				
1	**Indian**	State Govt.	Central Govt.	Private
2	**International**	Govt.	Private	UN Agency

3	**Industry**	National	Multinational	
4	**Yenepoya deemed to be University**	Seed Grant	Institutional support	
5	**Contact address**			
6	**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**			

PART C: STUDY DETAILS

Details of the study (Tick whichever applicable)		
Type of study	Epidemiological survey/ study	Observational study
	Basic science (Proteomic/ metobolic/ biomarker/ / biochemical/ histopathological)	Genetic/ genomic study
	Clinical trial	Interventional study
	Surgical intervention	Interview/ Questionnaire based study
	Medical device	Retrospective study

	In vitro studies	Data in public domain
	Any other: Specify	
Number of centres	Single centre	Multicentre:
If multi-centric:	Number of centres In India Global:	Names and countries of centres:

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	InUK/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, the PI must submit the appropriate checklist for involvement of vulnerable population in research available in SOP19/v3 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 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
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			
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
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 database? 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:

1. 2. 3. 4. 5. Signature of coordinator: 1. 2.
Forwarded by Heads of Department(s) Signature/s with date of Heads of Department(s): Stamp/Seal of the Department(s)

Ann02/SOP06/v3:

Delegation of Responsibilities of Study team

YEC-1 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 coordinator*	7
	Study coordinator*	8
	LaboratoryTechnician	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										

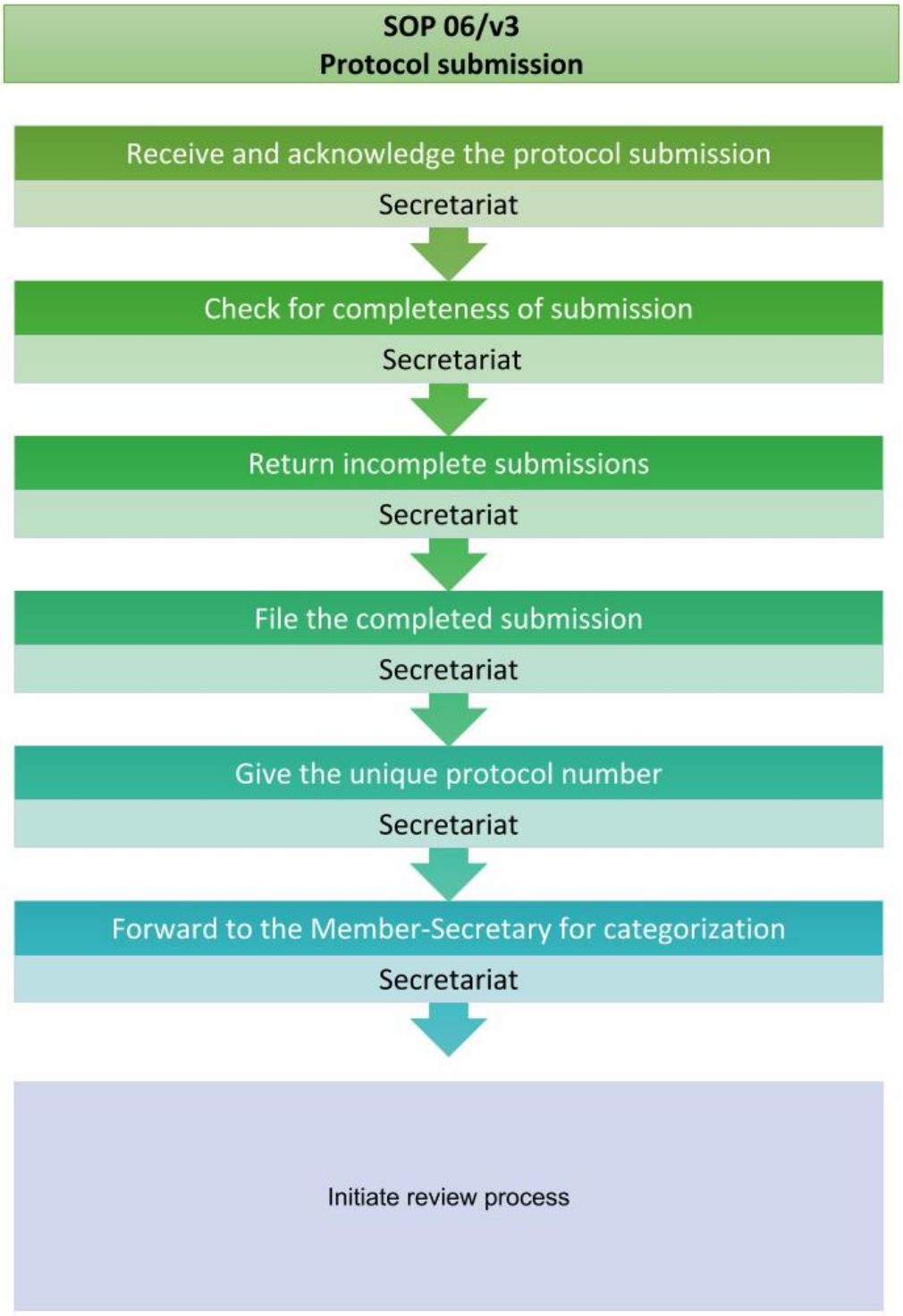
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing 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										

Ann03/SOP06/v3:
Receipt for submitted protocol

Protocol No.		
Received date:		
Submitted date:		
Protocol title		
Principal Investigator Name, Designation and Affiliation		
Communication with YEC-1	e-mail address: Phone: Fax:	
For office use only		
Protocol submission is complete:	Date:	
The following documents have not been submitted by the PI	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:		

Please note that the review process for your protocol will be initiated only when the complete protocol submission is received.

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