Title: Full Review of Protocols

SOP Code: SOP7A/v3

Effective date: 03/10/2019

Prepared by:

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Approved by

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

Notified by:

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Table of Contents:

1. **Purpose:** The purpose of this SOP is to describe the method of 'full review' of a research protocol submitted to the YEC-1 for ethical review and approval.

2. **Scope**: This SOP applies to the review of all research protocols submitted to the YEC-1 for ethical clearance categorized under "full review" as per the current guidelines fulfilling the criteria for "full review" as per SOP07/v3, and/or as per the discretion of the Member-Secretary, and/or as per the discretion of the primary reviewer.

3. **Responsibility:**

3.1. The YEC-1 Chairperson will

3.1.1. Oversee the timely review submissions

3.1.2. Oversee the discussions in the YEC-1 meeting

3.1.3. Encourage all members to take part in the deliberation during YEC-1 meetings

3.1.4. Ensure that each member reviews the protocol from his/her role in the YEC-1, as has been defined in the terms of reference

3.2. The YEC-1 Member-Secretary will

3.2.1. Assign reviewers and lead discussants and send the protocol package to them for full review.

3.2.2. Send the protocol package as soft copy (by email) to all the other YEC-1 members along with the agenda for the meeting where the protocol is scheduled for discussion.

3.2.3. Reassign reviewers and lead discussants if any of the reviewers either declare a conflict of interest or declare inability to review the protocol on time, or fail to review the protocol in the assigned time

3.2.4. Refer the protocol to an independent consultant, if deemed necessary or if requested by the reviewer during the review process as per SOP03/v3

3.2.5. Include the full review protocols in the agenda of the YEC-1 meeting as per SOP08/v3 (including protocols that have been deliberated in the YEC-1 meeting and resolved as resubmission for full review).

3.2.6. Ensure that the revised protocol documents go back to the lead discussants for assessment on the resubmission form (if recorded in the minutes of YEC-1 meeting)

3.2.7. Ensure that the relevant files and documents pertaining to the protocol in the discussion are available for ready reference of the members

3.3. The YEC-1 Secretariat will

3.3.1. Send the protocol and protocol related documents to the "lead-discussant" reviewers along with the assessment forms, clearly indicating whether the study is for full review, and by what date the reviewer's comments are expected back.

3.3.2. Inform the Member-Secretary, if any of the reviewers has declared a conflict of interest, or inability to review the protocol or has requested for review by an independent expert

3.3.3. Distribute the soft copies of the completed protocol submission to the reviewers assigned by the Member-Secretary via the email id of YEC-1 ethcom@yenepoya.edu.in

3.3.4. Only in case, the reviewer has a problem accessing email and requests for a hard copy, the reviewers are requested to visit the YEC-1 office and access the protocol for review.

3.4. The YEC-1 Members will

3.4.1. Declare any conflict of interest for the protocol within 2 calendar days after receiving the protocol for review.

3.4.2. Declare inability to do the initial review process, within 2 calendar days of receiving the protocol for review, if that is the case.

3.4.3. Complete the review as per the assessment form within the timelines laid down in this SOP (Ann01/SOP7A/v3)

3.4.4. Record their observations and comments in detail on the assessment forms and provide the provisional decision.

3.4.5. Return the completed and duly signed assessment form to YEC-1

4. Definitions

4.1. Lead discussant: A member who is primarily a reviewer and is also assigned to take a lead in summarizing the methodology in the protocol - in simple language - for the benefit of the members, and presenting the review assessment in the YEC-1 meeting

4.2. Reviewer: For full review protocols, all the members of YEC-1 who are not discussants

5. Detailed instructions:

5.1. Assignment of reviewers:

5.1.1. The Member-Secretary will assign two lead discussants for protocols categorized for full review based on based on the type of study/research area and expertise of the members in reviewing such studies.

5.1.2. The Member-Secretary will also assign reviewers for different aspects of the protocol which require review by specific members of YEC-1 as defined by their roles in YEC-1

5.1.2.1. Informed consent and the translation thereof by the layperson/ social scientist

5.1.2.2. MoUs, agreements, Insurance documents, indemnity, etc by the legal expert

5.1.3. If necessary, the Member-Secretary will assign one or two additional discussants depending on the complexity and merit of each protocol, however, every YEC-1 member will be encouraged to review all the full review protocols.

5.1.4. If necessary, the Member-Secretary will assign one or more independent consultants, depending on the merit and complexity of each protocol, or if specifically requested for by the discussant(s) as per SOP04/v3.

5.1.5. If necessary, the Member-Secretary will invite a community representative, depending on the merit and complexity of issues in the protocol, or if specifically requested for by the discussant(s) as per SOP04/v3.

5.1.6. The Secretariat will record the names of the reviewers for each protocol in the assessment forms and also in the database.

5.2. Reassignment of reviewers:

5.2.1. The lead discussants/ reviewers will inform YEC-1 of their inability to review the protocol in the given timeframe as follows (Part B of Ann01/SOP7A/v3)

5.2.1.1. Conflict of interest: within 2 calendar days

5.2.1.2. Inability to review within the given timeframe: within 2 calendar days

5.2.1.3. Inability to be available for the YEC-1 meeting within 2 calendar days

5.2.2. The Secretariat will inform the Member-Secretary of any communication from lead discussants/ reviewers about inability to review the protocol.

5.2.3. The Member-Secretary will reassign the lead-discussants/ reviewers in case of any of the following situations:

5.2.3.1. The assigned lead discussants/reviewers communicate their inability to complete the review process in time

5.2.3.2. The assigned lead discussant/reviewers declare a conflict of interest

5.2.3.3. The assigned lead discussant is unable to attend the YEC-1 meeting in which the protocol is tabled for discussion.

5.2.3.4. The initially assigned lead discussant fails to review the protocol in the given time.

5.3. Sending the protocol and protocol-related documents to the lead discussants/reviewers:

5.3.1. The Secretariat will send the soft copies of the documents by email to the reviewers and ICs.

5.3.2. The Secretariat will send the following documents to all the lead discussants/ reviewers:

5.3.2.1. The complete protocol package

5.3.2.2. The review request form

5.3.2.3. Conflict of interest declaration form

5.3.2.4. The review assessment form

5.3.3. The Secretariat will send the documents to the Independent consultants as per SOP04/v3

5.4. Review process:

5.4.1. The lead discussants and the reviewers will review the full review protocols within the stipulated time as per the current ethical guidelines and regulations

5.4.2. The YEC-1 members will review issues related to the protocol documents based on their role in the YEC-1

5.4.2.1. Scientific members: Scientific and ethical issues (Part A of Ann02/SOP7A/v3)

5.4.2.2. Social scientist/ theologist/ bioethicist: social/ religious and ethical issues (Part A of Ann02/SOP7A/v3)

5.4.2.3. Layperson: informed consent documents and ethical issues (Part B of Ann02/SOP7A/v3

5.4.2.4. Legal person: Legal documents and ethical issues (Part C of Ann02/SOP7A/v3)

5.4.3. Each reviewer will review the protocol and make comments/suggestions and recommendations in the assessment form

5.4.4. The reviewers will return the completed, duly filled and signed review forms to the YEC-1.

5.4.5. The other YEC-1 members who are not designated as the lead discussants will also review the protocol and are encouraged to send the assessment forms to YEC-1

5.4.6. The layperson who is assigned to review the informed consent will do so in the informed consent review form and send the completed review forms to YEC-1(Part B of Ann02/SOP7A/v3).

5.4.7. The legal person who is assigned to review the specific documents will do so in the form given as annexure (Part C of Ann02/SOP7A/v3) and send the completed review forms to YEC-1.

5.4.8. The social scientist/ theologist/ bioethicist will review the social and ethical issues in the protocol and protocol related documents (Part A of Ann02/SOP7A/v3) and send the completed review forms to YEC-1.

5.5. **Guidelines for review of protocols:**

5.5.1. **Scientific issues will be reviewed with emphasis on the following**

5.5.1.1. Scientific validity and justification (including review of literature)

5.5.1.2. Sample size and statistical tests

5.5.1.3. Study design (including pilot study)

5.5.1.4. Methodology (including details of clinical and lab data collection)

5.5.1.5. Details of the intervention (including medical device, IND, surgical, or genetic/stem cell)

5.5.1.6. Inclusion and exclusion criteria

5.5.1.7. Discontinuation criteria

5.5.1.8. Risk to participants

5.5.1.9. Benefits to the participants

5.5.1.10. Validation of the tool

5.5.1.11. Qualification, training and expertise of the research team

5.5.1.12. Infrastructure

5.5.1.13. Plans for medical management for study related injury

5.5.2. **Ethical issues will be reviewed with emphasis on the following**

5.5.2.1. Risk: benefit analysis (including harm to third party)

5.5.2.2. Fair selection of participants

5.5.2.3. Inclusion and exclusion criteria

5.5.2.4. Withdrawal criteria

5.5.2.5. Inclusion, justification and protection of vulnerable populations

5.5.2.6. Inducements, financial benefits and compensation

5.5.2.7. Protection of privacy of the participants

5.5.2.8. Methods of ensuring confidentiality of the data especially in case of genetic studies

5.5.2.9. Deception, if any

5.5.2.10. Disposal/storage/sharing/reuse of samples/data

5.5.2.11. Disclosure of potential conflicts of interest from members of the research study team

5.5.2.12. Informed consent process including who, where and how

5.5.3. **Social, religious and cultural issues will be reviewed with emphasis on the following:**

5.5.3.1. Social value

5.5.3.2. Community considerations/permissions

5.5.3.3. Cultural issues, if any

5.5.3.4. Religious issues, if any

5.5.4. **Legal issues will be reviewed with emphasis on the following:**

5.5.4.1. Clinical trial agreement

5.5.4.2. Insurance policy and certificate

5.5.4.3. Indemnity

5.5.4.4. Compensation plan

5.5.4.5. Permissions for transport of samples (Material Transfer Agreement)

5.5.4.6. Regulatory approvals

5.5.4.7. Budget

5.5.5. **Informed consent document including Participant Information Sheet (PIS) and Informed Consent Form (ICF):**

5.5.5.1. Invitation to participate in research,

5.5.5.2. Language and clarity of content in a layperson's language (PIS and ICF)

5.5.5.3. Avoidance of scientific jargon

5.5.5.4. Information about the methodology, risks, benefits associated with the research (PIS).

5.5.5.5. Provision of medical management, psychosocial support and compensation in case of study related injuries (PIS)

5.5.5.6. Use of biological material, its storage, future use, sharing, and disposal (PIS)

5.5.5.7. Use of data derived from samples, its storage, sharing, future use and disposal especially when the data is genomic or sensitive (PIS)

5.5.5.8. Provision for audio-visual recording of consent in case of clinical trials (ICF, PIS)

5.5.5.9. Statement about voluntariness including statement confirming free choice to participate or not, free from coercion or inducements or without affecting the rights (PIS and ICF).

5.5.5.10. Statement of comprehension of the information provided and opportunity for clarification of doubts from the Principal Investigator (ICF, PIS)

5.5.5.11. Statement assuring maintenance of participant privacy (ICF, PIS)

5.5.5.12. Statement assuring participant data confidentiality (ICF, PIS)

5.5.5.13. Compensation for participation, whether there is a chance of undue inducement (PIS)

5.5.5.14. Details of the contact person(s) from the study team and their phone numbers (PIS)

5.5.5.15. Details of the Ethics committee Chairperson / Member-Secretary and their contact details

5.5.5.16. Provision of signatures of participants, investigators or the person conducting the informed consent process, the independent witness with dates (ICF)

5.5.5.17. Translations, completeness and accuracy of translation into local language (PIS and ICF)

5.5.5.18. Back translation to English (in case of regulatory clinical trials) (PIS and ICF)

5.5.5.19. Translation and back-translation certificates (in case of regulatory clinical trials) (PIS and ICF)

5.6. **Delay in the review process:**

5.6.1. If the reviewer does not return the assessment form within 21 calendar days of sending the protocol for review for clinical trials and 15 calendar days for other protocols, it will be considered as delay in the review process

5.6.2. In case of delay in the review process, the YEC-1 Secretariat will send the first reminder to the reviewer by mail 10 calendar days before and and second reminder 7 calendar days before the YEC-1 meeting for regulatory clinical trial protocols and 7 calendar days and 4 calendar days before the meeting YEC-1 for other protocols.

5.6.3. If the reviewers do not return the assessment forms even before 7 calendar days from the YEC-1 meeting, the Member-Secretary will reassign the lead discussants and reviewers with a request to review the protocol on a priority basis.

5.7. Preparation for the full review meeting

5.7.1. The Secretariat will list the 'full review' protocols in the agenda for the next YEC-1 meeting, if the protocol is received at least 21 calendar days prior to the date of the meeting in case of regulatory clinical trials and at least 15 calendar days prior to the date of the meeting in case of other protocols to ensure adequate review time. If the protocol package is submitted later, then the Member-Secretary will keep the same in the agenda of the YEC-1 meeting after the next. (SOP06/v3)

5.7.2. The Secretariat will file all the assessment forms received from the lead discussants and reviewers in the protocol file and keep it ready for perusal during the YEC-1 meeting. (SOP08/v3)

5.7.3. Whenever deemed necessary, an invitation is sent to the community representative inviting them to the YEC-1 meeting and informing them about the meeting, date, time, venue and information about the protocol, in advance. (SOP05/v3)

5.7.4. Whenever deemed necessary, an invitation is sent to the Independent Consultant to attend the meeting and informing him/her about the meeting, date, time, venue, in advance. (SOP04/v3)

5.7.5. If deemed necessary by the Chairperson/ Member-Secretary, permission is granted to the Principal Investigator to attend the meeting and clarify the doubts of YEC-1 members, (SOP05/v3)

5.8. Full review meeting:

5.8.1. The lead discussants will present a summary of the protocol to all the YEC-1 members

5.8.2. The lead discussants will read out and discuss the scientific and ethical issues in the protocol from the assessment forms

5.8.3. The other reviewers will also deliberate on these and other issues in the protocol based on their roles in the YEC-1

5.8.4. Whenever sought, the observations and the recommendations of the Independent Consultants are read out and deliberated in the YEC-1 meeting. If necessary, the Independent Consultants is invited to the meeting, by the Member-Secretary in advance (SOP06/v3)

5.8.5. If necessary, a community representative can be invited to the meeting, by the Member-Secretary/Jt Secretary, in advance (SOP)

5.8.6. If necessary, clarifications may be sought by inviting the principal investigator of the protocol.

5.8.7. The Member-Secretary/Jt Secretary assisted by another YEC-1 member or the YEC-1 Secretariat will minute the proceedings of the discussions of each protocol

5.8.8. The final decision is made by voting by YEC-1 members as per SOP08/v3 present in the meeting, except the subject expert, community representative, if any as in the SOP08v3.

5.8.9. The decision is made by the majority, which is defined as >50% of the members present

5.8.10. In case of a tied vote among the members, the Chairperson has a casting vote to make the final decision.

5.8.11. If any member has a vote against the majority, his/her **dissent** is recorded in the minutes of the meeting.

5.8.12. The Secretariat will communicate the recommendations of the YEC-1 after masking the name of the reviewer to the principal investigator thorough an email within 7 calendar days with a request to respond within 15 calendar days

5.9. **Final decision:** The final decision in the YEC-1 meeting for full review protocols will be recorded as

5.9.1. **Approved**

5.9.2. **Resubmission for expedited review**

5.9.3. **Resubmission for full review**

5.9.4. **Not approved**

5.10. **Additional decisions:** The final decision in the YEC-1 meeting for full review protocols will be supplemented with the following additional decisions:

5.10.1. **In case of approved protocols,** decision about frequency and schedule for:

5.10.1.1. Continuing review

5.10.1.2. Audit/site monitoring

5.10.1.3. Period of validity of the EC clearance will be for a period of one year or for the duration of the study whichever is earlier.

5.10.2. **In case of resubmission for expedited review:** Decision about who will review the resubmission is taken in the YEC-1 meeting:

5.10.2.1. Member-Secretary

5.10.2.2. Initial Reviewers

5.11. **Communication with the Principal Investigator:**

5.11.1. **In case of approved protocols:**

5.11.1.1. The approval letter is issued as per the format Ann05/SOP7A/v3

5.11.1.2. The approval letter is issued within 7 calendar days of the YEC-1 meeting

5.11.2. **In case of resubmission of protocols:**

5.11.2.1. The letter asking for resubmission is sent to the PI as per the format in Ann01/9A/v3.

5.11.2.2. The communication is sent within 7 calendar days of the YEC-1 meeting

5.11.2.3. The PI is informed to resubmit at least 10 calendar days before the next YEC-1 meeting, so as to be included in the agenda for the next YEC-1 meeting, failing which, it will be considered for the subsequent YEC-1 meeting

5.11.2.4. The Member-Secretary will inform the PI to respond to resubmit the protocol within 180 calendar days, failing which the protocol will be considered as cancelled.

5.11.2.5. If the PI resubmits after 180 calendar days, then the PI is requested to submit a fresh protocol

5.11.3. **In case of Non-approval of protocols:**

5.11.3.1. If a protocol is 'Not-approved' during the YEC-1 meeting, the same is communicated to the PI

5.11.3.2. The reasons for the same must be listed with justification

5.11.3.3. The letter is communicated to the PI within 7 calendar days of the meeting.

5.12. Elements of the approval letter: The approval letter is given as a hard copy on a letterhead for initial full review protocols will contain the following information: **(**Ann04/SOP7A/v3)

5.12.1. YEC-1 protocol number

5.12.2. Title of the study

5.12.3. Name, designation and roles of the Principal investigator and co-investigators

5.12.4. Names of the YEC-1 members present in the meeting

5.12.5. Names of the YEC-1 members who declared a conflict of interest for the protocol

5.12.6. Names of the YEC-1 members who dissented the decision, if any

5.12.7. List of documents approved with the version number and date

5.12.8. Validity of YEC-1 approval letter

5.12.9. Responsibility of the PI to adhere to the current guidelines and regulations

5.12.10. Responsibility of the PI to adhere to the approved version of the protocol

5.12.11. Responsibility of the PI report to the YEC-1 in case of SAE, protocol amendments, protocol deviations/violations.

5.12.12. Responsibility of the PI to communicate to the YEC-1 the continuing review, pilot study, interim report and others

5.12.13. YEC-1's planned schedule for continuing review, and audit/site monitoring

5.12.14. Registration details of the YEC-1

5.12.15. Signature of the Member-Secretary/Chairperson with date

5.13. **Issue of the Approval letter: (**Ann05/SOP7A/v3)

5.13.1. The Member-Secretary will sign the approval letter within 10 calendar days of the meeting for regulatory clinical trials and other protocols

5.13.2. The Secretariat will inform the Principal investigator by email within 2 calendar days of signing of the approval letter

5.13.3. The principal investigator is requested to collect the Approval letter within 15 calendar days from the date of information.

5.13.4. The principal investigator is requested to read the approval letter in detail, clarify doubts, look for typo errors or factual errors in the approval letter at the time of receiving the approval letter

5.13.5. The Secretariat will keep a scanned copy of the Approval letter ready on which the principal investigator will sign stating "Read and Received"

5.13.6. The signed copy with the acknowledgement of receipt is filed in the respective protocol file

5.14. **Filing of documents:** The Secretariat will file the documents in the respective files

5.14.1. Conflict of interest for each protocol in the respective Protocol File

5.14.2. Extract of the minutes of the meeting in the respective Protocol File

5.14.3. For approved protocols, a copy of the approval letter of the Protocol in the respective Protocol File

5.14.4. The assessment forms, decision forms, and all communications will be filed in the respective Protocol files

5.14.5. The YEC-1 Secretariat will store the file in the designated cupboard in the YEC-1.

6. Reference to other SOPs

6.1. SOP06/v3: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review

6.2. SOP07/v3: Categorization of Submitted Protocols for Ethics Review

6.3. SOP7B/v3: Expedited Review of Research Study Protocols

6.4. SOP7C/v3: Exemption from Ethics Review of Research Study Protocols

6.5. SOP08/v3: Agenda Preparation, Meeting Procedures and Recording of Minutes

6.6. SOP09/v3: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

7. Annexures

7.1. Ann01/SOP7A/v3: Request letter for initial review

7.1.1. Part A: Request letter for initial review of protocols

7.1.2. Part B: Return of protocol and related documents due to inability to review the protocol

7.2. Ann02/SOP7A/v3: Assessment form for full review protocols

7.2.1. Part A: Scientific issues

7.2.2. Part B: Ethical issues including risk: benefit analysis; vulnerability; privacy; confidentiality; compensation; future use of samples

7.2.3. Part C: Social, cultural, religious and any other issues

7.2.4. Part D: Legal aspects

7.2.5. Part E: Informed consent and Participant information sheet

7.3. Ann03/SOP7A/v3: Checklist to review placebo justification

7.4. Ann04/SOP7A/v3: Full Decision form for full review protocols

7.5. Ann05/SOP7A/v3: Format for YEC-1 approval letter for protocols

Ann01/SOP7A/v3: Request letter for initial review of protocols

PART A

To

Dear Dr/Mr/Ms *Name of the Reviewer*,

The attached protocol has been categorized as full review. You have been assigned to review the protocol as:

1. Lead discussant
2. Reviewer.

You are requested to:

1	Review the protocol and related documents as per the guidelines and our SOPs. (please refer SOP7A/v3 http://www.ethics.edu.in/eth-com.html)	
2	Inform the YEC-1 if you have a conflict of interest (CoI) for the protocol on or before…. In case of doubt regarding CoI please refer SOP3A/v3 http://www.ethics.edu.in/eth-com.html	
3	Inform the YEC-1 if you are unable to review the protocol within the given time on or before...	
4	Inform the YEC-1 if any of the protocol or related documents are incorrect/ missing on or before...	
5	Fill and sign the assessment form and return the same to YEC-1 on or before...	
6	If you are the lead discussant be prepared with a brief summary of the protocol in simple language for presentation in the YEC-1 meeting to be held on...	
7	If you are the lead discussant, inform the YEC-1 your availability on the day of the meeting	

Details of the protocols for initial full review

1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-PI (All names)	
5	Department:	
6	Date of receipt of protocol	
7	Date of YEC-1 meeting	

Signature of the Member-Secretary

Date:

Part B:

Return of protocol and related documents due to inability to review the protocol

I hereby declare that I will not be able to review the protocol for the following reasons:

(Please tick the applicable reason)

	I have a conflict of interest	
	I am unable to review the protocol within the time given	
	I am unable to attend the YEC-1 meeting	

Signature of the YEC-1 member
Date

Ann02/SOP7A/v3: Assessment form for full review protocols

Protocol details

Protocol Number:	
Title:	
Name of the PI	
Names of the Co-PIs	
Department	
Type of study:	**Regulatory Clinical Trial:** **PhD studies:** **Seed grant:** **Funded studies:** **Faculty studies:** **Manuscript for review:** **Any other (after approval by the YEC-1):**
Number of Sites:	
Sample size at this site:	
SRB approval	
Name of the reviewer:	

Part A: Scientific issues

S.No	Scientific issues	Yes/ No	Remarks
1	Background information is sufficient		
2	Need for the study is sufficient		
3	Objectives are clear and well defined		
4	Study design is appropriate		
5	Sample size is adequate and justified		
6	Statistical tests are		

	described		
7	Inclusion criteria are appropriate		
8	Exclusion criteria are appropriate		
9	Discontinuation criteria are appropriate		
10	Benefits to the participants		
11	Research tool is validated		
12	Qualification and expertise of the researcher team is adequate for the study		
13	Infrastructure is adequate		
14	Plan for medical management for study related injury is adequate		

Part B: Ethical issues including risk: benefit analysis; vulnerability; privacy; confidentiality; compensation; future use of samples

S.No	Ethical issues	Yes/ No	Remarks
1	Method of sampling is fair		
2	Inclusion of vulnerable population is justified		
3	If yes, Whether checklist for inclusion of vulnerable population attached		
4	Exclusion criteria is justified		
5	Withdrawal criteria is clear		
6	Voluntary, non-coercive participation of participants		

	is ensured		
7	Standard of care extended to the intervention group		
8	Standard of care extended to the control group		
9	Justification for placebo, if applicable		
10	Inducements, financial benefits and compensation to the participants		
11	Protection of privacy of participants		
12	Maintenance of confidentiality of the data/samples/ genomic data		
13	Disposal, storing, sharing, reuse of samples/ data		
14	Declaration of conflict of interest by one or more members of research team		
15	Compensation for AEs and SAEs		

Risk Assessment Matrix

Likelihood of harm	**Unlikely**				
	Seldom				
	Likely				
	Very likely				
Risk assessment Matrix		**Insignificant**	**Mild**	**Moderate**	**Serious**

	Magnitude of harm

Part C: Social, cultural, religious and any other issues

S.No	Ethical issues	Yes/ No	Remarks
1	Social value		
2	Community involvement		
3	Cultural issues, if any		
4	Religious issues, if any		
5	Any other		

Part D: Legal aspects

S.No	Legal issues	Yes/ No	Remarks
1	Clinical trial agreement		
2	Compensation plan		
3	Permission letters for transport of samples (MTA)		
4	Insurance policies		
5	Insurance certificate		
6	Indemnity		
7	Regulatory approval		
8	Budget		

Part E: Informed consent form (ICF) and participant information sheet (PIS)

Does the informed consent form address or state the following elements:

S.No	Element	Yes/No	Remark
1	The participant will be provided enough information (including study title & name of the principal investigator)		
2	Is the Informed Consent form in a language that the local communities are conversant with		
3	Adequate time to understand the implications of consenting		
4	Opportunity to ask questions from the PI or a member of the study team, and contact details		
5	Assessment of the comprehension of the participant		
6	Voluntary nature of the informed consent process that is free of coercion		
7	Option to refuse without compromising patient rights `		
8	Option to voluntarily withdraw at any stage of the research without compromising patient rights		
9	Option for the participant to retain one copy of the consent form		
10	Assurance of maintenance of privacy of the		

	participant and confidentiality of the data		
11	Consent to publish the data anonymously		
12	Consent to take photographs to publish while protecting privacy and confidentiality		
13	Provision for signatures of participant and researcher. Provision for thumb impression in case participant is illiterate.		
14	English version of ICF (with version number)		
15	Local language translation and back-translation of ICF (with version number)		
16	Respective certificates of translation and back-translation		
17	Description (in the methodology) of the details of the informed consent process (who will do it, where will it be done, how long will it take, will privacy be provided, etc)		
18	Provision for informed assent (along with parental/LAR consent) written in case the participant is a minor between 12 and 18 years and oral assent in case the participant is between 7 and 12 years		
19	Provision for audio-visual consent process in case of vulnerable populations being recruited		
20	Provision for audio recording of the informed consent process in case the vulnerable		

	population is HIV or leprosy		
21	Provision for online/telephonic/oral consent in relevant situations (with justification for the same)		

Does the participant information sheet address or state the following elements

S.No	Element	Yes/No	Remark
1	PIS written in simple language without use of jargon, such that a student of standard VIII would be able to understand		
2	The title of the study, name(s) of principal investigator(s) total number of expected participants and number of trial sites, exactly as it is in the main protocol		
3	Information that this is research and not therapy		
4	Statement on why the participant is being recruited		
5	Details of eligibility during screening		
6	Details of how long the study will run and what are the expected responsibilities of the participant		
7	Voluntary nature of the enrolment; right to refuse; right to withdraw without prejudice		
8	Details of the intervention that is in simple,		

	clear language and not misleading		
9	Benefits to the participant (direct) or to the community (indirect)		
10	What laboratory tests will be done; how long will the blood samples be stored; will the samples be shared with other researchers; how will the samples be disposed		
11	Details of how the PI assures privacy of the participant and confidentiality of the data		
12	Sharing of the research results with the participant		
13	Risks of adverse events from the intervention or procedure (PI should include a list of commonly occurring adverse events - if known)		
14	Details of how will the PI handle research-related injuries		
15	Details on reimbursement for time spent and trouble taken		
16	Details on compensation in case of serious adverse events (including death)		
17	Details on the nominee in case of payment of compensation		
18	Statement on protection of anonymity and privacy in case of conference presentation,		

	publication or taking of photographs		
19	Adequacy of time provided for comprehension; details on assessment of comprehension; liberty to ask questions		
20	Contact details of responsible member of the research team who is trained in biomedical research and good clinical practices		
21	Details on PI's or research team members' conflict of interest or receipt of funds for carrying out this study		
22	Contact details of a responsible person from the Ethics Committee who will address queries related to the rights of the participant in case the participant is not satisfied with the answers provided by the PI		
23	One copy of the PIS and ICF provided to the participant		

Ann03/SOP7A/v3: Checklist to review placebo justification

A	Protocol No.		
B	Title of the protocol		
C	Name of the PI		
D	Name of the reviewer:		
		To be filled by the PI Yes/ No (Please justify either answer with detailed explanation. Do not simply write yes/no)	For reviewer use only Explanation adequate/ inadequate (If inadequate justify with details)
1.	Is there a standard treatment for the condition under study?		
2.	Is the standard treatment available locally?		
3.	Please provide evidence of the standard treatment in either national, international or society guidelines or in a standard reference textbook ?	Yes/No Details annexed: Yes/No	
4.	Are all newly diagnosed patients with this condition put in standard treatment		
5.	What is the treatment rationale ?		

	a. Pathophysiologic b. Symptomatic	 Yes/No Yes/No	
6.	Are most (more than 85%) of the patients with this condition responsive to standard treatment alternatives?		
7.	Are the side effects of the standard treatment severe?	Yes/No (Explain in detail)	
8.	Does standard treatment have many undesirable side effects?		
9.	Does standard treatment have contraindications that prevent some research participants from being treated?		
10.	Is there substantial (< 25%) placebo response in this disease or symptom?		
11.	Is the risk of using placebo instead of treatment life threatening?		
12.	Is the use of placebo instead of treatment likely to lead to permanent damage?		
13.	Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?		
14.	Can the use of placebo instead of treatment lead to an acute emergency		

15.	Can the risk of using placebo instead of treatment cause the persistence of distressing symptoms?		
16.	Can the risk of using placebo instead of treatment cause severe physical discomfort or pain?		
17.	Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?		
18.	Is there benefit in the overall management of the research participants?		
19.	Are research participants at high risk for the use of placebo excluded?		
20.	Is the duration of the study the minimum necessary in relation to the action of the drug?		
21.	Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?		
22.	Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences? *Not applicable/Yes/No.:*		
23.	Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression?		

24.	If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available? *Not applicable/ Yes/ No.:*		
25.	If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed? *Not applicable/ Yes/ No:*		
26.	If the risk of placebo is severely physical discomfort or pain, is there rescue medication? *Not applicable/ Yes/ No:*		
27.	Are the risks of getting placebo instead of active treatment fully disclosed in the Participant information sheet/ Informed consent form?		
28.	Are the risks of the test drug disclosed?		
29.	Are the advantages of alternative treatments explained?		

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Note: The use of placebo is ethically acceptable when

i. The participants are not exposed to severe or permanent harm by the use of placebo.

ii. The participants under placebo will benefit from the overall treatment of the disease.

iii. The risks of the use of placebo are minimized.

iv. The risks are adequately disclosed in the consent form.

Assessment key for reviewers (confidential)

Items 1 to 6: If the answers are "yes", placebo is not recommended. If any one or more answers are "no", placebo may be possible.

Items 7 to 10: If the answers are "no", placebo is not recommended. If any one or more answers are "yes", placebo may be possible Items 11 to 17: If the answer to any is "yes", placebo is not acceptable. Items 18 to 26: If answers are "yes", consider placebo. If no, placebo not recommended Items 27 to 29: If answers are 'yes', consider placebo **Provisional Decision of the reviewer:** • Placebo acceptable • Placebo not acceptable • Discussion in the YEC-1 Meeting: Name and signature of the reviewer Date:
Final decision of YEC-1 • Placebo acceptable • Placebo not acceptable • Recommendation to the PI: Signature of the Member-Secretary/ Chairperson Date:

Reviewer's signature with date:

Ann04/SOP7A/v3: Decision Form for Full Review protocols

Date of YEC-1 meeting:
Protocol number:
Title:
Principal investigator:
Department:
Final decision at the YEC-1 meeting:
1. Approved:
2. Resubmission for expedited review
3. Resubmission for full review
4. Not approved
If approved: Frequency of periodic review
1. 3 monthly
2. 6 monthly
3. Annual
4. Any other
Site monitoring schedule:
1. Dates:
If resubmission for expedited review:
1. Review by initial reviewer(s)

2. Review by Member-Secretary

If not approved: State reasons for non-approval:

Names of members and decision

S.No.	Members present	Approved	Resubmission for expedited review	Resubmission for full review	Not approved	Signature and date
1						
2						
3						
4						
5						
6						
7						
8						
9						

Comments:	
No. of members voting 'FOR' the decision:	
No. of members voting 'AGAINST' the decision:	
No. of members abstaining from voting:	

Signature of the Member-Secretary/Chairperson Date:

Ann05/SOP7A/v3: Protocol approval letter format

Subject: YEC-1 Approval Letter

Ref: Protocol no. YEC-1/ titled, " "

Names of all research team members *(including Guides)*

No	Name	Role in the research team	Designation/ Affiliation
		Principal investigator	
		Guide/ Co-PI	

(Insert rows to add more names)

(The following section with red font applies only to approvals for full review protocols)

The_____*(meeting number)* meeting of Yenepoya Ethics Committee - 1 (YEC-1) was held on_____ (DD/MM/YY) at _____ *(time)*

The YEC-1 members who attended the meeting are as follows:

No	Name	Position in YEC-1	Designation

(Insert rows to add more names)

It is hereby confirmed that neither the PI nor any of the research team members have participated in the decision making procedures of YEC-1.

The quorum was met as per the current regulations. The following YEC-1 member(s) declared a conflict of interest for the protocol and recused themselves.

No	Name	Position in YEC-1	Designation

(Write "None" if no members declare CoI; insert rows to add more names)

The YEC-1 reviewed the protocol and related documents as listed below:

No	Document name	Version	Date

(Insert rows to add more documents)

YEC-1 hereby approves the protocol no. YEC-1/_____/20___ and the related documents as listed above and this approval valid from _____ to _____.

Any data collected before or beyond the validity period shall be considered as protocol deviation and liable to action.

It is the responsibility of the Principal Investigator to:

1. Provide correct, updated contact details and respond to YEC-1 communications without delay.
2. Adhere to the current regulatory guidelines
3. Adhere to the undertaking signed by the PI.
4. Adhere to the approved version of the protocol (and related documents)
5. Adhere to the compensation plan as per the approved protocol
6. Restrict recruitment to the approved sample size of _____*(approved sample size)*
7. Inform the YEC-1 at the time of recruitment of the first participant.

8. Obtain written approval of YEC-1 before any proposed change in the protocol (amendment) is implemented in the prescribed format **(Ann01/SOP9B/v3)**
9. Report to YEC-1 any deviation from the guidelines/approved version of the protocol without delay (including change in research team members) in the prescribed format **(Ann01/SOP11/v3** - Initial report and **Ann02/SOP11/v3 -** Detailed report**)**
10. As per the current regulatory guidelines, report to YEC-1 all serious adverse events in the prescribed format **(Ann01/SOP12 v3** - Onsite SAE and **Ann02/SOP12/v3** - Offsite SAE**)** and their follow-up actions.
11. Submit the periodic review as specified by YEC-1 in the prescribed format **(Ann04/SOP10/v3)**
12. Submit continuing review form one month before the end of validity of this approval **(Ann04/SOP10/v3)**
13. Report to YEC-1 an adverse event/change in risk to participants (excluding SAEs) that may occur during the study in the periodic review
14. Submit a completion report to YEC-1 when the data/sample collection is completed in the prescribed format **(Ann01/SOP13/v3)**
15. Submit a summary of the study when the data analysis is completed.
16. Maintain the privacy of the participants/ samples and confidentiality of data.
17. Securely retain the original of YEC-1 approval letter, as issuing duplicate approval letter is liable to a fee
18. Respond to any communication from YEC-1 pertaining to the study/ auditing/ site monitoring/ others.

All communications with YEC-1 should be by email to ethcom@yenepoya.edu.in

YEC-1 functions in accordance with *(insert names of the current regulations and guidelines).*

YEC-1 is registered with *(insert names of the currently approved regulatory authorities, letter number and validity)* and recognized by *(insert names of the recognizing bodies with validity)*.

Member-Secretary/Jt Secretary/Chairperson, YEC-1 Date:

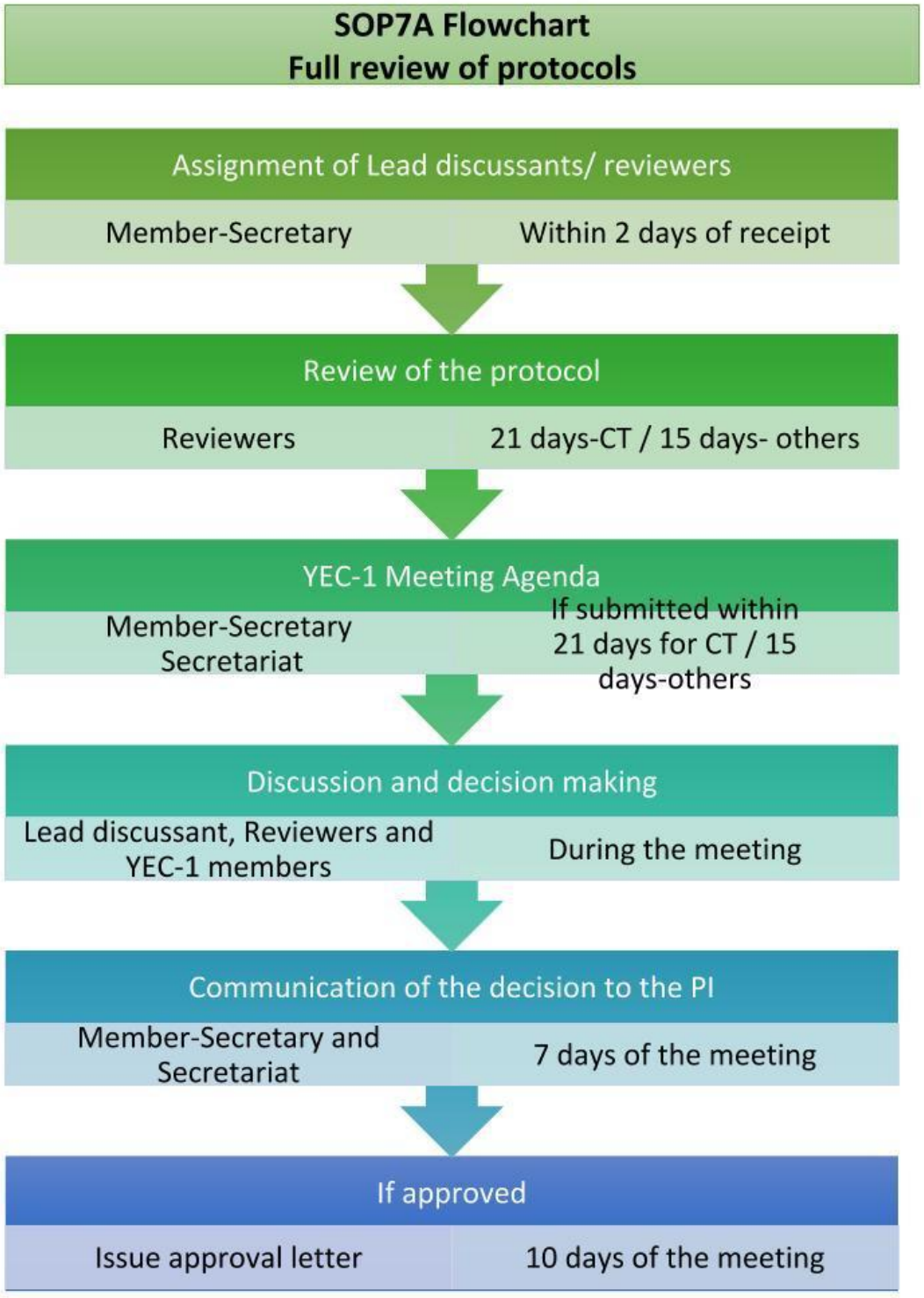
Important Dates:

Date of YEC-1 approval: *XX/XX/20XX*

Date of expiry of the validity of YEC-1 approval: *YY/YY/20YY*

Date for initiation of continuing review (if needed): *(write date a month prior to YY/YY/20YY)*

Flow chart:


SOP7A Flowchart
Full review of protocols
Assignment of Lead discussants/ reviewers
Member-Secretary
Within 2 days of receipt
Review of the protocol
Reviewers
21 days-CT / 15 days- others
YEC-1 Meeting Agenda
Member-Secretary
Secretariat
If submitted within 21 days for CT / 15 days-others
Discussion and decision making
Lead discussant, Reviewers and YEC-1 members
During the meeting
Communication of the decision to the PI
Member-Secretary and Secretariat
7 days of the meeting
If approved
Issue approval letter
10 days of the meeting