Title: Full Review of Protocols

SOP Code: SOP7A/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Details of superseded SOP7A:

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 SOP7A/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. Harmonized terms referring to reviewers and removed the term lead discussants 3. Timeline for full review protocols specified 4. Terms for categorization of risk aligned with ICMR guidelines 5. More items on review of vulnerability issues added to the review assessment form 6. More items on risk assessment added to review assessment form 7. Terms used in final decision revised

Table of Contents:

1. **Purpose:** The purpose of this SOP is to describe the method of 'full review' of a research protocol submitted to YEC-1 for approval.
2. **Scope:** This SOP applies to the review of all research protocols submitted (or resubmitted) to YEC-1 for approval categorized under "full review" as per the current guidelines fulfilling the criteria for "full review" as per SOP07/v4, and/or as per the discretion of the Member-Secretary/ primary reviewer, based on risk assessment.
3. **Definitions:**
    - 3.1. **Primary reviewer:** A reviewer who is also assigned to take a lead in summarizing the protocol - in simple language - for the benefit of the non-scientific members, and presenting the review assessment in YEC-1 meeting
    - 3.2. **Secondary Reviewer:** For full review protocols, all the members of YEC-1 who are not primary reviewers.
4. **Responsibility:**
    - 4.1. **YEC-1 Chairperson will:**
        - 4.1.1. Oversee the timely review of submissions
        - 4.1.2. Ensure that each member reviews the protocol from his/her role in YEC-1, as has been defined in the terms of reference
    - 4.2. **YEC-1 Member-Secretary will**:
        - 4.2.1. Assign primary reviewers (including legal expert and layperson, wherever applicable) and send the protocol package to each.
        - 4.2.2. Send the protocol package by email to the secondary reviewers (all the other YEC-1 members) along with the meeting agenda where the protocol is scheduled for discussion.
        - 4.2.3. Reassign primary reviewers (including legal expert and layperson) if any of them either declare a conflict of interest, declare inability to review the protocol on time, or fail to review the protocol in the assigned time.
        - 4.2.4. Ensure that timely reminders are sent to the reviewers
        - 4.2.5. Refer an independent consultant, if necessary or if requested by the primary reviewer during the review process (as per SOP03/v4)
        - 4.2.6. Include the full review protocols in the agenda of YEC-1 meeting as per SOP08/v4 (including protocols that have been deliberated in YEC-1 meeting and resolved as resubmission for full review).
        - 4.2.7. Ensure that the resubmitted protocol goes back to the appropriate reviewers for assessment on the resubmission form (as per the meeting minutes)
        - 4.2.8. Ensure that the relevant files and documents pertaining to the protocol in the discussion are available for ready reference of the members.
    - 4.3. **YEC-1 Secretariat will:**
        - 4.3.1. Send soft copies of the protocol, protocol related documents to the primary reviewers/ reviewers along with the assessment & request forms, clearly indicating whether the study is for full review, and by what date the primary reviewer's comments are expected back.

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

4.3.3. Send soft copies of the completed protocol submission to all members within 7 days of the forthcoming meeting, along with the agenda.

4.3.4. Provide hard copies of the protocol, if the primary reviewer has a problem accessing email and requests for the same.

4.3.5. Send email reminders to the primary reviewers, 10 days and again 7 days before the meeting date, requesting them to send the duly filled reviewer assessment form.

4.4. **YEC-1 Members will:**

4.4.1. Complete the review as per the assessment form within the timelines laid down in this SOP (Ann01/SOP7A/v4)

4.4.2. Return the protocol package within 2 calendar days from the date of receipt (in case of conflict of interest; or inability to review; or absence from the relevant meeting)

4.4.3. Record their observations and comments in detail on the assessment forms and provide the provisional decision. Members will be encouraged to express their observations on the ethical aspects, the assessment of risk and type of harm, and the risk-benefit analysis.

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

4.4.5. Recommend for referring the protocol to an independent consultant, wherever applicable.

5. **Detailed instructions:**

5.1. **Assignment of primary reviewers:**

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

5.1.2. For regulatory clinical trials and any other study so determined, the Member-Secretary will also assign primary 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, indemnities, etc by the legal expert

5.1.3. If necessary, the Member-Secretary may assign one or two additional primary reviewers depending on the complexity and merit of each protocol, however, every secondary reviewer will be encouraged to review all the full review protocols and participate in the deliberations.

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 primary reviewer(s) as per SOP04/v4.

5.1.5. If necessary, the Member-Secretary, after due approval from the Chairperson, will invite a community representative, depending on the merit and complexity of issues in the protocol, or if specifically requested for by the primary reviewer(s) as per SOP05/v4.

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

5.2. **Reassignment of primary reviewers:**

5.2.1. The primary reviewers will inform YEC-1 of their inability to review the protocol in the given timeframe as follows (Part B of Ann01/SOP7A/v4)

5.2.1.1. Conflict of interest: within 2 days

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

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

5.2.2. The Member-Secretary will reassign the primary reviewers in case of any of the following situations:

5.2.2.1. The assigned primary reviewers have communicated (within 2 days) their inability to complete the review process within 15 days

5.2.2.2. The assigned primary reviewers have declared conflict of interest

5.2.2.3. The assigned primary reviewer is unable to attend YEC-1 meeting in which the protocol is tabled for discussion.

5.2.2.4. The initially assigned primary reviewer has failed to review the protocol in the given time.

5.3. **Sending the protocol and protocol-related documents to the primary reviewers/reviewers:**

5.3.1. The Secretariat will send soft copies of the documents by email to the primary reviewers, reviewers and ICs (if recommended).

5.3.2. The Secretariat will send the following documents to all the primary reviewers (including legal expert and layperson)/ 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 IC (if recommended) as per SOP04/v4

5.4. **Review process:**

5.4.1. The primary reviewers will be encouraged to review the full review protocols within the stipulated time of 15 days so that the review comments are available ahead of the meeting.

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

5.4.2.1. Scientific members: Scientific and ethical issues (Part A of Ann02/SOP7A/v4)

5.4.2.2. Social scientist/ theologist/ bioethicist: social/ religious and ethical issues (Part A of Ann02/SOP7A/v4)

5.4.2.3. Layperson: informed consent documents and ethical issues (Part B of Ann02/SOP7A/v4

5.4.2.4. Legal person: Legal documents and ethical issues (Part C of Ann02/SOP7A/v4)

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

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

5.4.5. The secondary reviewers will also review the protocol and will be 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 section and send the completed review forms to YEC-1 (Part B of Ann02/SOP7A/v4).

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/v4) 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/v4) 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. Compensation plan

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

5.5.4.5. Regulatory approvals

5.5.4.6. 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) and who can have access

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)

5.5.5.20. For the benefit of the end users, a template of the PIS and ICF will be available on the website http://www.ethics.edu.in/eth-com.html

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

5.6.1. If the primary reviewer/reviewer does not return the assessment form within 15 calendar days of sending the protocol for review, it will be considered as delay in the review process

5.6.2. YEC-1 Secretariat will send the first reminder to the primary reviewer/reviewer by mail 10 days before and and second reminder 7 days

before YEC-1 meeting for regulatory clinical trial protocols and 7 days and 4 days before the meeting YEC-1 for other full review protocols.

5.6.3. If the primary reviewers/secondary reviewers do not return the assessment forms, 5 days from YEC-1 meeting, the Member-Secretary will reassign the primary reviewers and reviewers with a request to review the protocol on a priority basis.

5.7. **Preparation for the full review discussions in the 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 days prior to the date of the meeting in case of regulatory clinical trials and at least 15 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 YEC-1 meeting after the next. (SOP06/v4)

5.7.2. The Secretariat will file all the assessment forms received from the primary reviewers and reviewers in the protocol file and keep it ready for perusal during YEC-1 meeting. (SOP08/v4)

5.7.3. Whenever deemed necessary, an invitation is sent to the community representative inviting them to YEC-1 meeting and informing them about the meeting, date, time, venue and information about the protocol, in advance. (SOP05/v4)

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/v4)

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/v4)

5.8. **Full review meeting:**

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

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

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

5.8.4. Whenever sought, the observations and the recommendations of the Independent Consultants are read out and deliberated in YEC-1 meeting. If necessary, the Independent Consultant may be invited to the meeting, by the Member-Secretary in advance (SOP06/v4)

5.8.5. If necessary, a community representative may be invited to the meeting, by the Member-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/Joint Secretary assisted by YEC-1 Secretariat will minute the proceedings of the discussions of each protocol

5.8.8. The final decision is made by voting using Google form by YEC-1 members (as per SOP08/v4) present in the meeting, except the subject expert, community representative (if any) and guest/observer/invitee as in SOP08/v4.

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 voted against the majority, their dissent may be recorded in the minutes of the meeting, if they so express it.

5.8.12. The Secretariat will communicate the recommendations of YEC-1 without detailing the name of the reviewer to the principal investigator through an email with a request to respond within 10 days.

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

5.9.1. Approve

5.9.2. Minor modifications (Resubmit for expedited review)

5.9.3. Major modifications (Resubmit for full review)

5.9.4. Disapprove

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

5.10.1. Whether Chairperson's casting vote was utilized or not

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

5.10.2.1. Continuing review

5.10.2.2. Audit / site monitoring

5.10.3. In case of minor modifications and resubmission for expedited review, decision about who will review the resubmission is taken in YEC-1 meeting:

5.10.3.1. Member-Secretary

5.10.3.2. Initial primary reviewers/Reviewers

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

5.11.1. In case of approved protocols:

5.11.1.1. Approval letter will be issued as per format Ann03/SOP7A/v4

5.11.1.2. Approval letter will be issued within 7 calendar days of the meeting

5.11.2. In case of resubmission of protocols:

5.11.2.1. The letter asking for resubmission will be sent to the PI as per the format in Ann01/SOP9A/v4.

5.11.2.2. Communication will be sent within 7 working days of YEC-1 meeting

5.11.2.3. PI will be informed to resubmit within 10 days or at least 7 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 that if the resubmission response is not submitted within 180 days, the protocol will be considered as cancelled.

5.11.2.5. If the PI resubmits after 180 days, then the PI will be required 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 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 days of the meeting.

5.12. **Elements of the approval letter:** The approval letter on YEC-1 letterhead (given as a hard copy) for initial full review protocols will contain the following information: (Ann04/SOP7A/v4)

5.12.1. YEC-1 protocol number

5.12.2. Title of the study

5.12.3. Name of the Principal Investigator and other investigators

5.12.4. Details of the meeting

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

5.12.6. Names of YEC-1 members who declared a conflict of interest for the protocol. A statement affirming no conflict of interest from either the investigators or the ethics committee members.

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

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

5.12.9. Validity of YEC-1 approval letter

5.12.10. Restriction of data collection within the stipulated approval period

5.12.11. Responsibility to inform YEC-1 before recruiting first participant

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

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

5.12.14. Responsibility of the PI to report to YEC-1 in case of SAE/AE (change in risk), protocol amendments (including change in research team members), protocol deviations/violations.

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

5.12.16. YEC-1's planned schedule for periodic review, approval extension request and audit / site monitoring

5.12.17. Responsibility to submit completion report once the data collection is over (along with a summary of findings)

5.12.18. Responsibility to respond to communications from YEC-1 in a timely manner

5.12.19. Registration and accreditation details of YEC-1

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

5.12.21. A box highlighting the important dates

5.13. **Issue of the Approval letter:** (Ann04/SOP7A/v4)

5.13.1. The Member-Secretary will sign the approval letter within 15 days of the meeting for regulatory clinical trials and within 10 days after the meeting in case of other protocols

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

5.13.3. The principal investigator will be requested to collect the approval letter within 15 days from the date of information.

5.13.4. The principal investigator will be 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 will be 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. YEC-1 Secretariat will store the file in the designated cupboard in YEC-1.

6. **Reference to other SOPs:**

6.1. SOP06/v4: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review

6.2. SOP07/v4: Categorization of Submitted Protocols for Ethics Review

6.3. SOP7B/v4: Expedited Review of Research Study Protocols

6.4. SOP7C/v4: Exemption from Ethics Review of Research Study Protocols

6.5. SOP08/v4: Agenda Preparation, Meeting Procedures and Recording of Minutes

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

7. **Annexures:**

7.1. Ann01/SOP7A/v4: Request letter for initial review

7.1.1. Part A: Request letter for initial review

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

7.2. Ann02/SOP7A/v4: Assessment form for full review protocols

7.2.1. Part A: Scientific issues

7.2.2. Part B: Ethical issues including risk: benefit analysis;

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/v4: Checklist to review placebo justification

7.4. Ann04/SOP7A/v4: Full Decision form for full review protocols

7.5. Ann05/SOP7A/v4: Format for the approval letter for full review protocol

Ann01/SOP7A/v4

Ann01/SOP7A/v4: Request letter for initial review of protocols

PART A

To

Name of the primary reviewer/Reviewer:

Dear Sir/Madam,

You have been assigned to review (and lead the discussion on) the given FULL REVIEW protocol as:

1. Primary reviewer
2. Secondary Reviewer.

You are requested to:

1	Review the protocol and related documents as per the guidelines and our SOPs.	Please refer: www.ethics.edu.in
2	Inform YEC-1 if you have a Conflict of interest for the protocol on or before	
3	Inform YEC-1 if you are unable to review the protocol within the given time on or before	
4	Inform 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 primary reviewer be prepared with a brief summary of the protocol in simple language for presentation in YEC-1 meeting to be held on:	
7	If you are the primary reviewer, inform 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-I (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	
	Unable to review the protocol within the time given	
	I am unable to attend YEC-1 meeting	

Signature of YEC-1 member

Date:

Ann02/SOP7A/v4:

Reviewer assessment form for full review protocols

Protocol details:

Protocol Number:	
Title:	
Name of the PI:	

Names of the Co-I's:			
Department:			
Type of study:	Regulatory Clinical Trial:		Yes / No
	PhD study		Yes / No
	Seed grant:		Yes / No
	Funded studies:		Yes / No
	Faculty studies:		Yes / No
	Manuscript for review:		Yes / No
	Any other (after approval by YEC-1):		Yes / No
Number of sites:			
Sample size planned at this site:		Total sample size planned:	
SRB approval:			
Names of the primary reviewers:			

Plain language summary (by primary reviewer) for the benefit of non-medical members

Type of study; department; study design: Introduction to the topic: Sample size; inclusion and exclusion criteria: Details of the intervention: Any other remarks:

Part A: Scientific issues

S.No	Scientific issues	Yes/ No	Remarks (please make specific observations)
1.	Background and need for the study are sufficient		
2.	Aims and objectives are clear and well defined		
3.	Study design is appropriate		
4.	Sample size is adequate and justified		
5.	Statistical tests are described		
6.	Inclusion criteria are appropriate		
7.	Exclusion criteria are appropriate		
8.	Discontinuation criteria are appropriate		
9.	Research tool is validated		
10.	Qualification and expertise of the research team is adequate		
11.	Infrastructure is adequate		

12.	Plan for medical management for study related injury is adequate		
13.	Methodology for the intervention is adequately described		
14.	Methodology for data collection is provided		
15.	Data collection form is appropriate		
16.	Informed consent (IC) process: Details on the IC process (who will do it, where will it be done, how long will it take, will privacy be provided, etc)		

Part B: Ethical issues including risk: benefit analysis

S.No	Ethical issues	Yes/ No	Remarks
1.	Method of sampling is fair		
2.	Is there inclusion of vulnerable populations? If yes, please answer the following (a to k)		
	a. Is there adequate justification for involvement of vulnerable populations in the research?		
	b. If yes, Whether checklist for inclusion of vulnerable population attached		
	c. If yes, whether there are adequate safeguards for protection of the vulnerable population		
	d. Can the research be performed in any other non-vulnerable participants?		
	e. Are there additional safeguards for the protection of the vulnerable participants from harm?		
	f. Are there direct benefits to the individual or population under study?		
	g. Do the benefits justify the risks?		
	h. Are the participants selected equitably?		
	i. Have measures to protect the autonomy of the vulnerable population been described?		
	j. Has the IC been appropriately described?		
	k. Have issues about audio-visual recording of informed consent been adequately addressed?		
3.	Exclusion criteria is justified		
4.	Discontinuation criteria is justified		
5.	Withdrawal criteria is clear		
6.	Voluntary, non-coercive participation 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 the research team		
15.	Compensation for AE/SAE		
16	Advertisement/flyer/notice for recruitment are appropriately worded to ensure equitable selection of participants and no inducement		

Risk: benefit analysis

		Probability of harm		
Risk of harm (As per ICMR guidelines)		Not likely	Some what likely	Very likely
Magnitude of harm	Negligible			
	Small			
	Significant			
	Serious			

Risk of harm (As per ICMR guideline)	Less than minimal risk	Minimal risk	Minor increase over minimal risk	Major increase over minimal risk

Type of harm: a. Physical harm b. Psychological harm c. Information harm d. Social harm e. Financial harm f. Legal harm g. Genetic info harm	Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No Yes / No	Details:
Potential benefit:	Direct Indirect	
Risk: benefit analysis	Favorable Not favorable	
Recommendations to the PI to decrease risk & increase benefit		

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

S.No	Ethical issues	Yes/ No	Remarks
1.	Is there a social value?		
2.	Should the community be involved from the start?		
3.	Do you see any cultural issues?		
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.	Regulatory approval		
7.	Budget		
8.	Any other		

Part E: Participant Information Sheet (PIS) and Informed consent form (ICF)

Does the participant information sheet address or state the following elements:

S.No	Element	Yes/No	Remark
1.	Is the PIS written in simple language without use of jargon, such that a student of standard VIII (non-English medium) would be able to understand the English version?		
2.	Title of the study, name(s) of 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 on eligibility during screening		
6.	Details on duration of the study and participant's expected responsibilities		
7.	Voluntary nature of the enrolment; right to refuse; right to withdraw without prejudice		
8.	Details on the intervention in simple, clear language and not misleading		
9.	Benefits to the participant (direct) or to the community (indirect)		
10.	Details on laboratory tests that will be done; storage of tissues/samples; sharing with other researchers; disposal of samples/tissues		
11.	Details on assurance of participant privacy and data confidentiality		
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 on how will the PI handle research-related injuries		
15.	Details on reimbursement for time spent and trouble taken		
16.	Details on cost and compensation in case of SAE (including death)		
17.	Details on the nominee in case of payment of compensation		

18.	Statement on protection of privacy in 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 all research team members' conflict of interest or receipt of funds for carrying out this study		
22.	Contact details of the Member-Secretary, Yenepoya Ethics Committee-1 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.	Statement that a copy each (PIS and ICF) will be given to the participant		

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.	ICF written in a language that the local communities are conversant with		
3.	Adequate time to understand the implications of consenting		
4.	Opportunity to ask questions to PI or study team member (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 and who can have access		
11.	Consent to publish the data anonymously		
12.	Consent to take photographs while protecting privacy and confidentiality		
13.	Provision for signatures of the participant and researcher. Provision for thumb impression in case the participant is illiterate.		
14.	English version of ICF (with version number)		
15.	Local language translation and back-translation (with version number)		
16.	Respective certificates of translation and back-translation		

17.	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		
18.	Provision for audio-visual consent process in case of vulnerable populations being recruited		
19.	Provision for audio recording of the informed consent process in case the vulnerable population is HIV or leprosy		
20.	Provision for online/telephonic/oral consent in relevant situations		

Ann03/SOP7A/v4

Checklist to review placebo justification (Source SOP7A/v4)

A	Protocol No.		
B	Title of the protocol		
C	Name of the PI		
D	Name of the primary 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 adequ inadequate (If inadequate justify details)
1.	Is there a standard treatment for 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 Evidence annexed: Yes/No	
4.	In healthcare setting, would newly diagnosed patients with this condition be put on this 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?		
7.	Are the side effects of the standard treatment severe?	Yes/No (Explain in detail)	
8.	Does standard treatment have undesirable side effects?		
9.	Does standard treatment have contraindications that prevent some participants from being treated?		

10.	Is there substantial (at least 25%) placebo response in this disease treatment?		
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 disability?		
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 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.	In this study, are research participants at high risk for the use of placebo excluded?		
20.	Is the study duration the minimum necessary in relation to action of the drug?		
21.	Are there clearly defined rules to withdraw the participant in case of no improvement?		
22.	Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?		
23.	Are there defined rules to withdraw the participants before the advent of severe disease progression?		
24.	If the risk of placebo is an acute emergency, are rescue medication/emergency treatment available?		
25.	If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?		
26.	If the risk of placebo is severe physical discomfort or pain, is there rescue medication?		
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 advantages of alternative treatments explained?		
30.	Is there some kind of assessment of comprehension of the participant to document that he/she has understood the implication of the use of placebo?		

Note: The use of placebo is ethically acceptable when

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

ii. The research 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 primary reviewers/reviewers (confidential) Items 1 to 6: If the answers are "yes", placebo is not recommended. If one or more answers are "no", placebo may be possible. Items 7 to 10: If the answers are "no", placebo is not recommended. If 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 30: If answers are 'yes', consider placebo Provisional Decision of the primary reviewer/reviewer: • Placebo acceptable • Placebo not acceptable • Discussion in 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:

Primary /Reviewer's signature with date:

Ann04/SOP7A/v4

Decision Form for Full Review protocols

Date of YEC-1 meeting:
Protocol number:
Title:
Principal Investigator:
Department:

Final decision at YEC-1 meeting:
1. Approved:
2. Minor modifications (resubmit for expedited review)
3. Major modifications (resubmit 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 required: Yes/No
If yes: 3 months / 6 months / Annual
If resubmission for expedited review:
1. Review by initial reviewer(s)
2. Review by Member-Secretary
If disapproved: State reasons for disapproval:
Names of members and decision

S. No.	Members present	Approved	Minor modifications (resubmit for expedited review)	Major modifications (resubmit for full review)	Not approved	Signature and date
1.						
2.						
3.						
Comments:						
No. of members voting 'FOR' the decision:						
No. of members voting 'AGAINST' the decision:						
No. of members abstaining from voting:						
Dissent:						
Signature of the Member-Secretary/Chairperson					Date:	

Ann05/SOP7A/v4

Approval letter format for full review protocols

Ref: The study protocol no. YEC-1/ titled, " ".
Names of all the research team members, role in the research team, designation/affiliation
Dear Dr./Mr./Ms.,
The meeting of Yenepoya Ethics Committee - 1 (YEC-1) was held on at , in the . Dr. chaired the meeting.

The list of members who attended the meeting is as follows.

No	Name	Position in YEC-1	Designation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee. It is also hereby confirmed that none of the YEC-1 members who deliberated and decided on the protocol had any conflict of interest, and the ones who did have a conflict of interest recused themselves.

No	**Name**	**Position in YEC-1**	**Designation**
	Nil		

YEC-1 reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

No	**Document Name**	**Version**	**Date**
1			

YEC-1 hereby approves the proposal No. titled, "_____".

Your protocol and related documents mentioned above have been approved and this approval is valid from _____to _____.

Any data collected before or beyond the validity period shall not be considered for the study.

It is the responsibility of the Principal Investigator to:

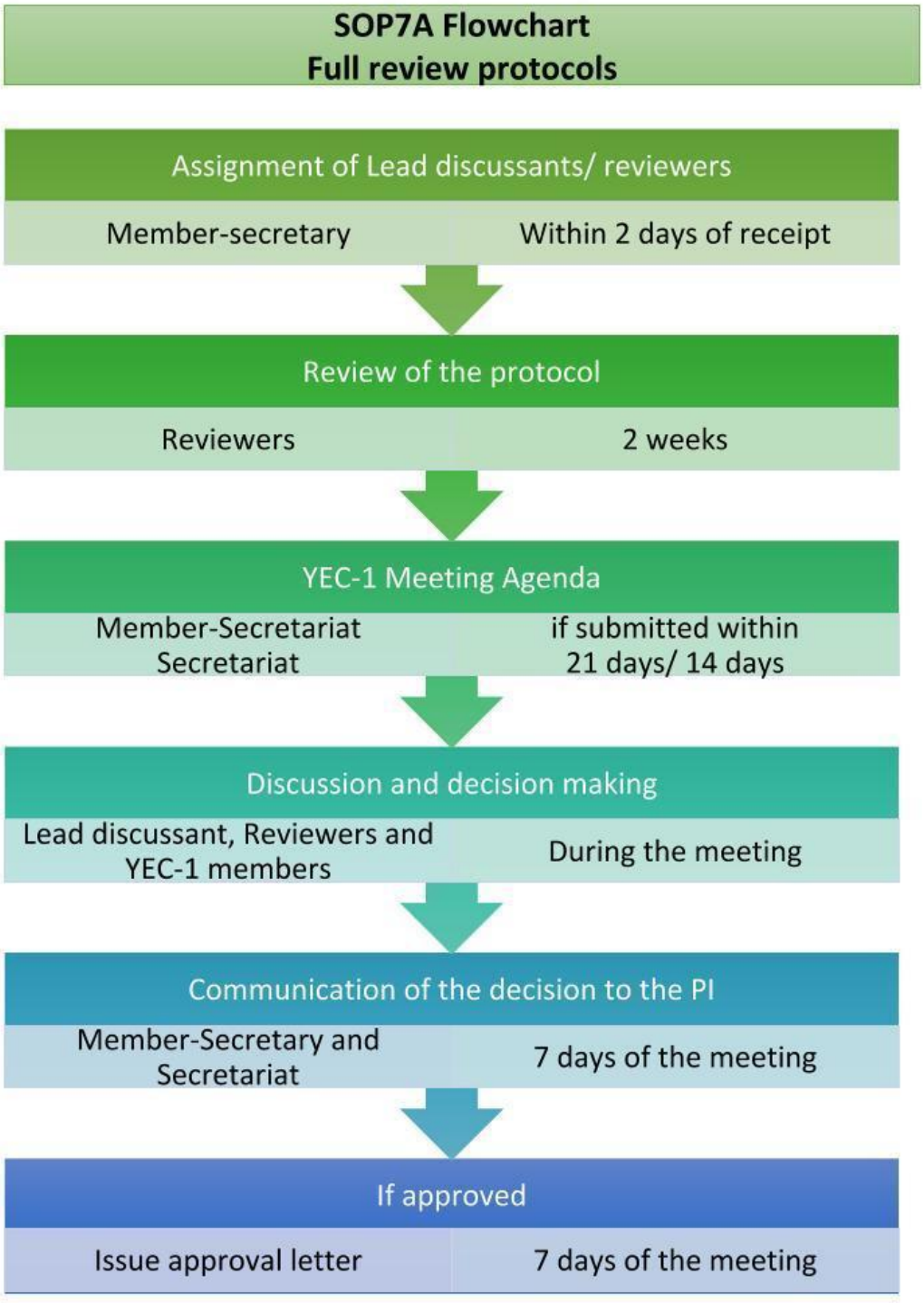
1. Provide correct, updated contact details
2. Start participant recruitment/data collection only after receipt of the YEC-1 approval letter (hard copy)
3. Adhere to the current regulatory guidelines
4. Adhere to the undertaking signed by the PI.
5. Adhere to the approved version of the protocol (and related documents)
6. Submit a periodic report to YEC-1 annually.
7. Adhere to the compensation plan as per the approved protocol (wherever applicable)

8. Restrict recruitment to the approved sample size of
9. Inform the YEC-1 at the time of recruitment of the first participant.
10. Submit the report of the pilot study to YEC-1 for review (wherever applicable)
11. Obtain written approval of YEC-1 **before** any proposed change in the protocol (amendment) is implemented, in the prescribed format **(Ann01/SOP9B/v4)**
12. 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/v4** - Initial report and **Ann02/SOP11/v4 -** Detailed report**)**
13. Submit the periodic review as specified by YEC-1 in the prescribed format **(Ann04/SOP10/v4)**
14. Submit continuing review form one month before the end of validity of this approval **(Ann04/SOP10/v4)**
15. Report to YEC-1 an adverse event/change in risk to participants (excluding SAEs) that may occur during the study in the periodic review
16. Submit a completion report to YEC-1 when the data/sample collection is completed in the prescribed format **(Ann01/SOP13/v4)**
17. Submit a summary of the study when the data analysis is completed.
18. Maintain the privacy of the participants/samples and confidentiality of data.
19. Securely retain the original of YEC-1 approval letter, as issuing duplicate approval letter is liable to a fee
20. 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 Declaration of Helsinki (2013), National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) and New Drugs and Clinical Trials Rules (2019).
YEC-1 is re-registered with the Office of the Drugs Controller General of India with Re-Registration no. ECR/521/Inst/KA/2014/RR-20 valid from 04/09/2020 to 03/09/2025 and re-recognized by Forum for Ethical Review Committees for Asia and the Western Pacific Region (FERCAP) for a period of 3 years from 30 November 2022 and re-accredited by National Accreditation Board for Hospitals and Healthcare providers (NABH) for a period of 3 years from 09 December 2022.

Member-Secretary/Chairperson, YEC-1 Date:

8. **Flow chart:**


SOP7A Flowchart
Full review protocols
Assignment of Lead discussants/ reviewers
Member-secretary
Within 2 days of receipt
Review of the protocol
Reviewers
2 weeks
YEC-1 Meeting Agenda
Member-Secretariat
Secretariat
if submitted within
21 days/ 14 days
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
7 days of the meeting

9. Glossary:

CDSCO: Central Drugs Standard and Control Organisation

CoI: Conflict of interest

DCGI: Drugs Controller General of India

DSMB: Data Safety Monitoring Board

GCP: Good Clinical Practice

GEAC: Genetic Engineering Advisory Committee

IC: Independent Consultant

ICF: Informed Consent Form

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

ICMR: Indian Council of Medical Research

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

NDCTR-19 New Drugs and Clinical Trials Rules 2019

PI: Principal Investigator

PIS: Participant Information Sheet

Protocol: Protocol refers to a set of documents that contain the detailed components of the proposed study

SAE: Serious Adverse Event

SRB: Scientific Review Board