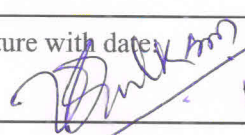


Title: Expedited Review of Protocols

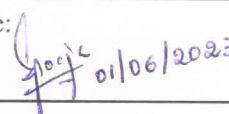
SOP Code: SOP7B/v4

Effective Date: 01/07/2023

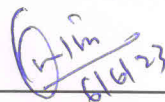
Prepared by:

Dr. Uma Kulkarni Convenor, SOP Subcommittee, YEC-1	Signature with date:  11/6/2023
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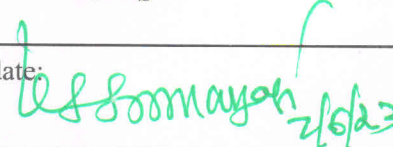
Reviewed by:

Dr. Pooja Harish Member, SOP Subcommittee, YEC-1	Signature with date:  01/06/2023
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Approved by:

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

Registrar, Yenepoya (deemed to be University)	Signature with date:  2/6/23
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Details of superseded SOP7B

Name of the subcommittee convenor	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 SOP7B/v4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	<ol style="list-style-type: none"> Glossary section added in the SOP Harmonized terms referring to reviewers The timeline for review of expedited review protocols specified Terms used in final decision revised



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1. **Purpose:** The purpose of this SOP is to describe the method of expedited review of a research protocol submitted to YEC-1 for review and approval.
2. **Scope:** This SOP applies to the review of all research protocols submitted to the YEC-1 for ethical clearance categorized as expedited review and will include
 - 2.1. Protocols submitted for initial review that have subsequently been voted as expedited
 - 2.2. Resubmitted protocols for expedited review (which were initially also expedited)
 - 2.3. Amended protocols (where risk change is minimal)
 - 2.4. Periodic review of protocols
3. **Responsibility:**
 - 3.1. **The YEC-1 Chairperson will**
 - 3.1.1. Oversee the timely review submissions
 - 3.1.2. 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 based on their expertise
 - 3.2.2. Reassign reviewers, 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
 - 3.2.3. Refer the protocol to an independent consultant, if deemed necessary or if requested by the reviewer during the review process as per SOP03/v4
 - 3.2.4. Include the approved expedited review protocols in the agenda of the YEC-1 meeting as per SOP08/v4 for ratification
 - 3.3. **The YEC-1 Secretariat will**
 - 3.3.1. Send the protocol and protocol-related documents to the assigned reviewers along with the assessment forms by email, clearly indicating whether the study is for expedited 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 expressed inability to review the protocol or has requested for review by an independent expert
 - 3.3.3. Provide the hard copies of the protocol and protocol-related documents to the assigned reviewers in the YEC-1 office in case such a request is made.
 - 3.4. **The YEC-1 Members will**
 - 3.4.1. Declare conflict of interest, if any, for the protocol, within 2 calendar days after receiving the protocol for review.
 - 3.4.2. Express inability to do the initial review process within the expected timeline, within 2 calendar days of receiving the protocol for review

- 3.4.3. Complete the review as per the assessment form within 15 calendar days
- 3.4.4. Record their observations and comments in detail on the assessment forms and provide the provisional decision.
- 3.4.5. Request Member-Secretary to assign an independent consultant (wherever deemed necessary)
- 3.4.6. Return the completed and duly signed assessment form to YEC-1

4. Detailed instructions:

4.1. Assignment of reviewers:

- 4.1.1. The Member-Secretary will assign reviewers for protocols categorized for expedited review based on the type of study/research area and expertise of the members in reviewing such studies.
 - 4.1.1.1. For initial review: two reviewers
 - 4.1.1.2. For amendment review: one reviewer/Member-secretary
 - 4.1.1.3. For periodic review: one reviewer/Member-secretary
 - 4.1.1.4. For resubmission: depending on the prior decision of review by initial reviewers or Member-Secretary
- 4.1.2. In addition, if deemed necessary, the Member-Secretary will also assign additional reviewers for different aspects of the protocol which require specific review by specific members as defined by their roles in YEC-1
 - 4.1.2.1. Informed consent and the translation thereof by the layperson
 - 4.1.2.2. MoUs, agreements, Insurance documents, indemnities, etc by the legal expert
 - 4.1.2.3. Adverse events reported in the periodic review by the clinician
 - 4.1.2.4. Social, religious, cultural issues by the social scientist/theologist
 - 4.1.2.5. If necessary, Member-Secretary will assign one or two additional reviewers depending on the complexity and merit of the protocol
- 4.1.3. In addition, if deemed necessary, 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 reviewers as per SOP04/v4.
- 4.1.4. The Secretariat will record the names of the assigned reviewers for each protocol in the assessment forms and also in the database.

4.2. Reassignment of reviewers:

- 4.2.1. The reviewers will inform YEC-1 of their inability to review the protocol in the given timeframe as follows (Part B of Ann01/SOP7A/v4)
 - 4.2.1.1. Conflict of interest (within 2 calendar days)
 - 4.2.1.2. Inability to review within the given timeframe (2 calendar days)

- 4.2.2. The Secretariat will inform the Member-Secretary of any communication from the reviewers about inability to review the protocol.
- 4.2.3. The Member-Secretary will reassign the reviewers in case of any of the following situations:
 - 4.2.3.1. The assigned reviewers communicate their inability to complete the review process in the given timeframe
 - 4.2.3.2. The assigned reviewers declare a CoI for the protocol
 - 4.2.3.3. The initially assigned reviewer fails to review the protocol in the given time, despite reminders.
- 4.3. **Sending the protocol and protocol-related documents to the reviewers:**
 - 4.3.1. The Secretariat will send the soft copies of the documents by email to the assigned reviewers and ICs.
 - 4.3.2. The Secretariat will send the following documents to all the reviewers:
 - 4.3.2.1. The complete protocol package
 - 4.3.2.2. The review request form
 - 4.3.2.3. Conflict of interest declaration form
 - 4.3.2.4. The review assessment form
 - 4.3.3. The Secretariat will send the documents to the IC as per SOP04/v4
- 4.4. **Review process:**
 - 4.4.1. The reviewers will review the protocols within the stipulated time of 15 days and as per the current ethical guidelines and regulations
 - 4.4.2. The YEC-1 members will review the protocol and specifically address issues related to the protocol based on their designation/role in the YEC-1
 - 4.4.2.1. Scientific members: Scientific and ethical issues
 - 4.4.2.2. Social scientist/theologist/bioethicist: social/religious and ethical issues
 - 4.4.2.3. Legal person: Legal documents and ethical issues
 - 4.4.2.4. Layperson: Informed consent documents and ethical issues
 - 4.4.3. Each reviewer will review the protocol and make comments/suggestions and recommendations in the assessment form
 - 4.4.4. The reviewers will return the completed, duly filled and signed review forms to the YEC-1 by email.
- 4.5. **Guidelines for review of protocols:**
 - 4.5.1. Scientific issues will be reviewed with emphasis on scientific issues as listed in the review assessment form Part A: Scientific issues of Ann02/SOP7A/v4

- 4.5.2. Protocols will be reviewed with emphasis on ethical issues as listed in the in the review assessment form Part B: Ethical issues of Annexure 02/SOP7A/v4
- 4.5.3. Social, religious and cultural issues will be reviewed as listed in the review assessment form Part C: Social, religious and cultural issues of Ann02/SOP7A
- 4.5.4. Legal issues will be reviewed (if required for an expedited review) as listed in the review assessment form Part D: Legal issues of Annexure 02/SOP7A/v4
- 4.5.5. Informed consent document including Participant Information Sheet (PIS), Informed Consent Form (ICF), assent and translations will be reviewed as listed in the review assessment form Part E: PIS/ICF of Ann02/SOP7A/v4
- 4.6. **Delay in the review process:**
 - 4.6.1. If the reviewer does not return assessment form in 10 calendar days of sending the protocol for review, it will be considered as delay in the review process
 - 4.6.2. In case of delay in the review process, the YEC-1 Secretariat will send the first reminder to the reviewer by mail/telephonic call after 10 calendar days of review assignment and a second reminder after 15 calendar days.
 - 4.6.3. If the reviewers do not return the assessment forms even after 15 calendar days of review assignment, the Member-Secretary will reassign the reviewers with a request to review the protocol on a priority basis.
- 4.7. **Use of standard assessment forms (Ann02/SOP7A/v4)**
 - 4.7.1. The standard assessment form (common to both full and expedited review) is designed to ensure a standard review process by each reviewer
 - 4.7.2. The assessment form will help in ensuring that all the elements of research protocol are reviewed and documented
 - 4.7.3. Each reviewer will go through the protocol and make comments/ suggestions and recommendations in the assessment form
 - 4.7.4. The duly filled, signed and dated assessment forms are returned to the secretariat along with the complete protocol submission
- 4.8. **Provisional decision by the Reviewers (Ann2A/SOP7B/v4):**
 - 4.8.1. The reviewers will record one of the decisions in the assessment forms:
 - 4.8.1.1. Approved
 - 4.8.1.2. Resubmission (see 4.8.2 and 4.8.3 below)
 - 4.8.1.3. Decision in YEC-1 meeting (see 4.8.4 below)
 - 4.8.2. In case of resubmission, the reviewers will also list the clarifications to be sought, suggestions and recommendations in the assessment form in details
 - 4.8.3. In case of resubmission, the reviewers will indicate whether the resubmission should be reviewed by the initial reviewer or the Member-Secretary
 - 4.8.4. In case of referring the decision to the YEC-1 meeting, the reviewer must write the reasons for the same in the assessment form.

4.9. Compilation of the assessment reports:

- 4.9.1. The YEC-1 secretariat will collect the assessment forms from each of the reviewers and file the copies in the respective file
- 4.9.2. The Member-Secretary will compile the comments and recommendations and provisional decisions of the reviewers

4.10. The final decision by the Member-Secretary (Ann2B/SO7B/v4):

- 4.10.1. Approved: (if both reviewers have approved)
- 4.10.2. Resubmission: (if one/both reviewers have asked for resubmissions)
- 4.10.3. Decision in the YEC-1 meeting: (if one/both reviewers have asked for this)

4.11. Communication with the Principal Investigator:

- 4.11.1. In case of approved protocols:
 - 4.11.1.1. The approval letter is issued as per the format Ann05/SOP7A/v4
 - 4.11.1.2. Approval letter is issued within 7 calendar days of YEC-1 meeting
- 4.11.2. In case of resubmission of protocols:
 - 4.11.2.1. Member-Secretary will compile the suggestions, clarifications and recommendations of reviewers and communicate with the PI.
 - 4.11.2.2. The resubmission is managed as per SOP9A/v4. The letter asking for resubmission is sent to the PI as per the format in Ann01/9A/v4.
 - 4.11.2.3. The communication is sent within 7 calendar days of the decision
 - 4.11.2.4. 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.
 - 4.11.2.5. If the PI resubmits after 180 calendar days, then the PI is requested to submit a fresh protocol

4.12. Additional decisions made

- 4.12.1. In case of approved protocols, decision about frequency and schedule is also taken and mentioned in the decision form:
 - 4.12.1.1. Continuing review
 - 4.12.1.2. Audit / site monitoring
 - 4.12.1.3. 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.

4.13. Approval letter:

- 4.13.1. The approval letter is drafted as per the template Ann05/SOP7A/v4.
- 4.13.2. The Member-Secretary will sign the approval letter within 7 calendar days of approval decision

- 4.13.3. The Secretariat will inform the principal investigator by email within 2 calendar days of signing of the approval letter
- 4.13.4. The principal investigator is requested to collect the approval letter within 15 calendar days from the date of information.
- 4.13.5. 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
- 4.13.6. The Secretariat will keep a scanned copy of the Approval letter ready on which the principal investigator will sign stating “Read and Received”
- 4.13.7. The signed copy with the acknowledgement of receipt is filed in the respective protocol file
- 4.14. **YEC-1 meeting:**
 - 4.14.1. Approved protocols:
 - 4.14.1.1. Once approved, the protocol is listed under the ‘expedited review’ category in the agenda of the next YEC-1 meeting. for ratification.
 - 4.14.1.2. If any member has any queries regarding any of the protocols, the concerned file containing the complete submission, the assessment forms and the ethical clearance letter issued, is opened for discussion.
 - 4.14.1.3. The primary reviewer/member secretary will brief the members, the summary of the study and read out the comments and recommendations from the assessment forms.
 - 4.14.1.4. If any change in the recommendation is felt necessary by the members, then the protocol is reviewed again and discussed as per full review in the next YEC-1 meeting as in SOP08/v4.
 - 4.14.2. For protocols where the decision is “Decision in the YEC-1 Meeting” the same is included in the agenda of the next meeting as per SOP08/v4 and managed as per SOP7A/v4
- 4.15. **The approval letter, printed on the approved letterhead, will contain the following matter:**
 - 4.15.1. Study reference number
 - 4.15.2. Study title
 - 4.15.3. A list of the versions of the protocol documents approved
 - 4.15.4. Validity of the approval
 - 4.15.5. Sample size approved
 - 4.15.6. Summary of the guidance, advice and decision that the YEC-1 members have reached in the meeting

- 4.15.7. Site monitoring, its frequency and tentative dates.
- 4.15.8. Other expectations from the principal investigator, if any
- 4.15.9. Need for submission of periodic review, continuing review and closure of the study and the timelines.
- 4.15.10. A box highlighting the important dates (for the researcher)
- 4.15.11. Signature of the YEC-1 member secretary with date
- 4.16. **Storage of documents:**
 - 4.16.1. The Secretariat will maintain all documents related to the protocol review (assessment forms by both reviewers, statements of the subject expert, decision form, and copy of the approval letter/resubmission request and all other communications in the study file in a sequential manner.
 - 4.16.2. The Secretariat will store the file on an appropriate shelf in the designated cabinet.
5. **References:**
 - 5.1.1. SOP 06/v4: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review
 - 5.1.2. SOP 07/v4: Categorization of Submitted Protocols for Ethics Review
 - 5.1.3. SOP 7A/v4: Full Review Protocols
 - 5.1.4. SOP 08/v4: Agenda Preparation, Meeting Procedures and Recording of Minutes
 - 5.1.5. SOP 9A/v4: Review of Resubmissions of protocols
 - 5.1.6. SOP9B/v4: Review of Amended Protocol and related documents
 - 5.1.7. ICMR's National Ethical Guidelines 2017
6. **Annexures:**
 - 6.1. Ann01/SOP7B/v4: Request letter for review of protocol
 - 6.2. Ann2A/SOP7B/v4: Decision form for expedited review (Initial reviewer)
 - 6.3. Ann2B/SOP7B/v4: Decision form for expedited review (Member-Secretary)
7. **Other related annexures**
 - 7.1. Ann02/SOP7A/v4- Study assessment form for primary reviewer
 - 7.2. Ann05/SOP7A/v4- Format of study approval letter

Ann01/SOP7B/v4

Request letter for review of protocol

PART A

To

Name of the Reviewer:

Dear Sir/Madam,

You have been assigned to assess the given EXPEDITED REVIEW protocol as a 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 the YEC-1 if you have a Conflict of interest for the protocol on or before	
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	

Details of the protocols for Expedited 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	

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 reason:

(Please tick the applicable reason)

1	I have a conflict of interest	
2	I am unable to review the protocol within the time given	

Signature of the YEC-1 member

Date

Signature of Member-Secretary/Chairperson with date

Ann2A/SOP7B/v4

Reviewer's Decision form for expedited review

For initial reviews/resubmissions/amendments

Protocol number:		
Title:		
Principal investigator:		
Department:		
Date of review assignment:		
Date of review completion:		
Reviewer decision:	Approved	
	Resubmission	Review by Member-Secretary
		Review by the Reviewer
	For full review	
If approved/resubmission review by Member-Secretary: Frequency of periodic review		
1. 3 monthly		
2. 6 monthly		
3. Annual		
4. Any other		
If decision referred to YEC-1 meeting: State reasons:		

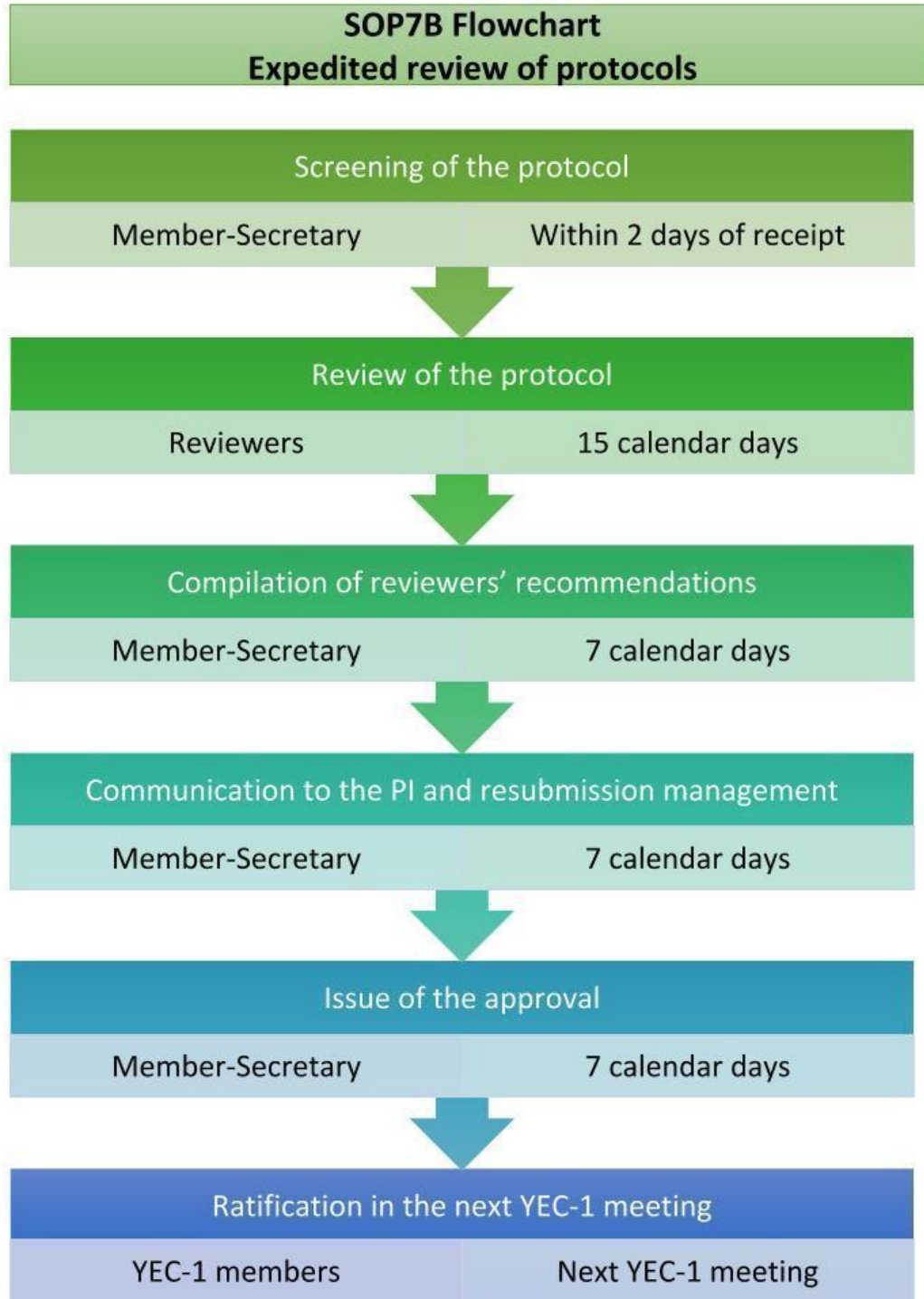
Ann2B SOP7B/v4:



Decision form for expedited review (Member-Secretary)

Protocol number:				
Title:				
Principal investigator:				
Department:				
Date of review assignment:				
Reviewer 1 decision:	Approved :	Resubmission: (Review by Member Secretary)	Resubmission: (Review by the reviewer)	For full review
Reviewer 2 decision:	Approved :	Resubmission: (Review by Member Secretary)	Resubmission: (Review by the reviewer)	For full review
Others' (IC/ other reviewer):	Approved :	Resubmission: (Review by Member Secretary)	Resubmission: (Review by the reviewer)	For full review
Final decision:				
1. Approved:				
2. Resubmission:				
3. Decision in the YEC-1 meeting (for full review)				
If approved:				
Frequency of periodic review	3 monthly	6 monthly	Annual	Any other
Site monitoring schedule:				
If decision referred to YEC-1 meeting: State reasons:				

8. Flowchart



9. Glossary:

CoI: Conflict of Interest

IC: Independent Consultant

ICF: Informed Consent Form

MoU: Memorandum of Understanding

PIS: Participant Information Sheet

ICMR: Indian Council of Medical Research