

Title: Expedited Review of Protocols

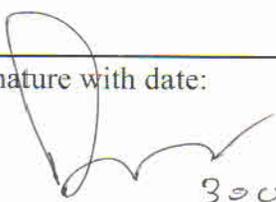
SOP Code: SOP7B/v3

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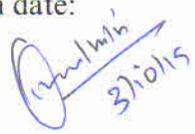
Prepared by:

Dr. Uma Kulkarni Convenor, SOP Sub-committee, YEC-1	Signature with date:  3/10/2019
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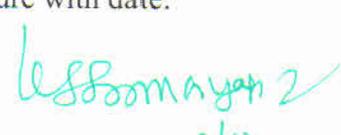
Reviewed by:

Dr. Ravi Vaswani Member, SOP Sub-committee, YEC-1	Signature with date:  3 OCT 19
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Approved by:

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

Registrar, Yenepoya deemed to be University.	Signature with date:  3/10
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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 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 “expedited review” as per the current guidelines fulfilling the criteria for “expedited” as per SOP07/v3, and/or as per the discretion of the Member-Secretary, and/or as per the discretion of the primary reviewer. The protocols will include
 - 2.1. Protocols submitted for initial review
 - 2.2. Resubmitted protocols
 - 2.3. Amended protocols
 - 2.4. Periodic and continuing 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
 - 3.2.2. Send the protocol package as soft copy (by email) to all the reviewers
 - 3.2.3. 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
 - 3.2.4. 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 approved expedited review protocols in the agenda of the YEC-1 meeting as per SOP08/v3 for ratification

3.3. The YEC-1 Secretariat will

- 3.3.1. Send the protocol and protocol related documents to the reviewers along with the assessment forms, 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 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. Detailed instructions:

4.1. Assignment of reviewers:

- 4.1.1. The Member-Secretary will assign two reviewers for protocols categorized for expedited review based on based on the type of study/research area and expertise of the members in reviewing such studies.
- 4.1.2. 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
- 4.1.3. Informed consent and the translation thereof by the layperson/ social scientist
- 4.1.4. MoUs, agreements, Insurance documents, indemnities, etc by the legal expert
- 4.1.5. If necessary, the Member-Secretary will assign one or two additional reviewers depending on the complexity and merit of each protocol
- 4.1.6. 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.
- 4.1.7. The Secretariat will record the names of the 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/v3)
 - 4.2.1.1. Conflict of interest: within 2 calendar days
 - 4.2.1.2. Inability to review within the given timeframe: within 2 calendar days

- 4.2.2. The Secretariat will inform the Member-Secretary of any communication from lead discussants/ 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 time
 - 4.2.3.2. The assigned reviewers declare a conflict of interest
 - 4.2.3.3. The initially assigned reviewer fails to review the protocol in the given time.
- 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 reviewers and ICs as assigned.
 - 4.3.2. The Secretariat will send the following documents to all the lead discussants/ 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 Independent consultants as per *SOP04/v3*
- 4.4. **Review process:**
 - 4.4.1. The reviewers will review the Expedited review protocols within the stipulated time as per the current ethical guidelines and regulations
 - 4.4.2. The YEC-1 members will review issues related to the protocol documents based on their role in the YEC-1
 - 4.4.2.1. Scientific members: Scientific and ethical issues (*Part A and B of Ann02/SOP7A/v3*)
 - 4.4.2.2. Social scientist/ theologian/ bioethicist: social/ religious and ethical issues (*Part C of Ann02/SOP7A/v3*)

- 4.4.2.3. Legal person: Legal documents and ethical issues (*Part D of Ann02/SOP7A/v3*)
- 4.4.2.4. Layperson: informed consent documents and ethical issues (*Part E of Ann02/SOP7A/v3*)
- 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.
- 4.4.5. Whenever applicable, 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 E of Ann02/SOP7A/v3*)
- 4.4.6. Whenever applicable, the social scientist/ theologian/ bioethicist will review the social and ethical issues in the protocol and protocol related documents (*Part B of Ann02/SOP7A/v3*) and send the completed review forms to YEC-1.
- 4.4.7. Whenever applicable, the legal person who is assigned to review the specific documents will do so in the form given as annexure (*Part D of Ann02/SOP7A/v3*) and send the completed review forms to YEC-1
- 4.5. **Guidelines for review of protocols:**
 - 4.5.1. **Scientific issues will be reviewed with emphasis on the following**
 - 4.5.1.1. Scientific validity
 - 4.5.1.2. Sample size and statistical tests
 - 4.5.1.3. Study design and methodology
 - 4.5.1.4. Inclusion and exclusion criteria
 - 4.5.1.5. Discontinuation criteria
 - 4.5.1.6. Risk to participants
 - 4.5.1.7. Benefits to the participants
 - 4.5.1.8. Validation of the tool
 - 4.5.1.9. Qualification and expertise of the research team
 - 4.5.1.10. Infrastructure
 - 4.5.1.11. Plans for medical management for study related injury

4.5.2. Ethical issues will be reviewed with emphasis on the following

- 4.5.2.1. Risk: benefit analysis
 - 4.5.2.2. Fair selection of participants
 - 4.5.2.3. Inclusion and exclusion criteria
 - 4.5.2.4. Withdrawal criteria
 - 4.5.2.5. Inclusion, justification and protection of vulnerable populations*
 - 4.5.2.6. Inducements, financial benefits and compensation
 - 4.5.2.7. Protection of privacy of the participants and their data
 - 4.5.2.8. Methods of ensuring confidentiality of the data especially in case of genetic studies
 - 4.5.2.9. Disposal/storage/sharing/reuse of samples/data
 - 4.5.2.10. Disclosure of potential conflicts of interest from members of the research study team
 - 4.5.2.11. Informed consent process including who, where and how
- 4.5.3. Social, religious and cultural issues will be reviewed with emphasis on the following:
- 4.5.3.1. Social value
 - 4.5.3.2. Religious issues, if any
 - 4.5.3.3. Cultural issues, if any
 - 4.5.3.4. Community considerations/ permissions
- 4.5.4. Legal issues will be reviewed with emphasis on the following:
- 4.5.4.1. Clinical trial agreement*
 - 4.5.4.2. Insurance documents
 - 4.5.4.3. Compensation plan
 - 4.5.4.4. Permissions for transport of samples
 - 4.5.4.5. Regulatory approvals*
 - 4.5.4.6. Budget
- 4.5.5. Informed consent document including Participant Information Sheet (PIS) and Informed Consent Form (ICF):
- 4.5.5.1. Invitation to participate in research,

- 4.5.5.2. Language and clarity of content in a layperson's language (PIS and ICF)
- 4.5.5.3. Avoidance of scientific jargon
- 4.5.5.4. Information about the methodology, risks, benefits associated with the research (PIS).
- 4.5.5.5. Provision of medical management, psychosocial support and compensation in case of study related injuries (PIS)
- 4.5.5.6. Use of biological material, its storage, future use, sharing, and disposal (PIS)
- 4.5.5.7. Use of data derived from samples, its storage, sharing, future use and disposal especially when the data is genomic or sensitive (PIS)
- 4.5.5.8. Provision for audio-visual recording of consent in case of clinical trials (ICF, PIS)
- 4.5.5.9. 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).
- 4.5.5.10. Statement of comprehension of the information provided and opportunity for clarification of doubts from the Principal Investigator (ICF, PIS)
- 4.5.5.11. Statement assuring maintenance of participant privacy (ICF, PIS)
- 4.5.5.12. Statement assuring participant data confidentiality (ICF, PIS)
- 4.5.5.13. Compensation for participation, whether there is a chance of undue inducement (PIS)
- 4.5.5.14. Details of the contact person(s) from the study team and their phone numbers (PIS)
- 4.5.5.15. Details of the Ethics committee Chairperson / Member-Secretary and their contact details

- 4.5.5.16. Provision of signatures of participants, investigators or the person conducting the informed consent process, the independent witness with dates (ICF)
- 4.5.5.17. Translations, completeness and accuracy of translation into local language (PIS and ICF)
- 4.5.5.18. Back translation to English (in case of regulatory clinical trials) (PIS and ICF)
- 4.5.5.19. Translation and back-translation certificates (in case of regulatory clinical trials) (PIS and ICF)

4.6. Delay in the review process:

- 4.6.1. If the 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
- 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 15 calendar days of review assignment and a second reminder after 20 calendar days to speed up the review.
- 4.6.3. If the reviewers do not return the assessment forms even after 20 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/v3)

- 4.7.1. The standard assessment form 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:

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

4.8.1.3. Decision in YEC-1 meeting

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 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:

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 decision)

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/v3

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

4.11.2. In case of resubmission of protocols:

4.11.2.1. The Member-Secretary will compile the suggestions, clarifications and recommendations of the reviewers and communicate with the PI.

- 4.11.2.2. The resubmission is managed as per SOP09/v3. The letter asking for resubmission is sent to the PI as per the format in Ann01/9A/v3.
- 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/v3.
- 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.
- 4.14.1.2. If any of the 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 discussed as per full review in the next YEC-1 meeting as in SOP08/v3.

- 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/v3 and managed as per SOP7A/v3

4.15. The approval letter 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. 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. Reference to other SOPs

- 5.1.1. SOP 06/V3: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review
- 5.1.2. SOP 07/V3: Categorization of Submitted Protocols for Ethics Review
- 5.1.3. SOP 7A/V3: Full Review Protocols
- 5.1.4. SOP 08/V3: Agenda Preparation, Meeting Procedures and Recording of Minutes
- 5.1.5. SOP 9A/V3: Review of Resubmissions of protocols
- 5.1.6. SOP9B/v3: Review of Amended Protocol and related documents



6. Annexures:

- 6.1. Ann01/SOP7B/v3: Request letter for review of protocol
- 6.2. Ann02/SOP7B/v3: Decision form for expedited review

7. Other related annexures

- 7.1. Ann02/SOP7A/v3 - Study assessment form for primary reviewer
- 7.2. Ann05/SOP7A/v3 - Format of study approval letter (same format to be followed except the meeting details and members details).

Ann01/SOP7B/v3

Ann01/SOP7B/v3: Request letter for review of protocol

PART A

To

Name of the Reviewer:

Dear Sir/Madam,

You have been assigned to review the given EXPEDITED REVIEW protocol as:

1. 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)

	I have a conflict of interest	
	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

7. Flowchart

