


Title: Expedited Review of Research Study Protocols

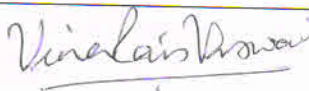
SOP Code: SOP7B/v2

Effective Date: 01/08/2016


Prepared by:

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with date:  30/07/2016
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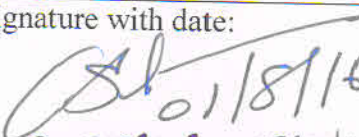
Reviewed by:

Dr. Vina Vaswani Member-Secretary, YUEC	Signature with date: 30/7/2016 
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Approved by:

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with date:  3/8/16
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Notified by:

Registrar, Yenepoya University vide notification no. YUReg/ACA/YUEC/FERCAP/01/2016	Signature with date:  01/8/16 Dr. G. Shree Kumar Menon Registrar
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Yenepoya University
Mangaluru - 575 018

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Notified by:

Registrar, Yenepoya deemed to be University vide notification no. YU/REG/ACA/YEC- 1/FERCAP/01/2016 dated 01/08/2016	Signature with date:
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1. Purpose

The purpose of this SOP is to describe in detail the method of ‘expedited review’ of a research protocol submitted to the YEC-1 for ethical clearance.

2. Scope:

The SOP applies to the initial review of all research protocols submitted to the YEC-1 for ethical clearance categorized by the Member-Secretary/Jt Secretary under “expedited review” as per the ICMR Ethical guidelines for research on human participants, where the protocol carries not more than minimal risk to the participants and fulfils the criteria for expedited review as per SOP07/v2 and is received complete in all aspects of documentation, at least 14 calendar days prior to the date of the next YEC-1 meeting.

3. Responsibility:

3.1 Member-Secretary:

- 3.1.1 The Member-Secretary/Jt Secretary will do an initial screening of the protocol.
- 3.1.2 The Member-Secretary/Jt Secretary will categorize the protocols into ‘expedited review’ as per the ICMR ethical guidelines for research on human participants based on the initial screening.
- 3.1.3 The Member-Secretary/Jt Secretary will assign one or two reviewers for each study protocol.
- 3.1.4 The Member-Secretary/Jt Secretary will communicate the name(s) of the reviewers to the YEC-1 Secretariat.
- 3.1.5 If any of the YEC-1 members assigned to review the protocol declares a conflict of interest or declares inability to complete the assessment of the protocol within one week, he/she will communicate the same to the YEC-1 Secretariat within 2 days of receipt of the document package. The Member-Secretary/Jt Secretary will assign an alternative member to review the protocol.

3.2 YEC-1 Secretariat:

- 3.2.1 YEC-1 Secretariat will create a folder for each research protocol as soon as the completed protocol submission is received.
- 3.2.2 YEC-1 Secretariat will distribute the complete protocol submission to the reviewers assigned by the Member-Secretary/Jt Secretary via the email id of YEC-1

ethcom@yenepoya.edu.in or as a hard copy, as per the preference declared by the YEC-1 members

- 3.2.3 YEC-1 Secretariat will distribute the assessment form along with the protocol to each reviewer, with a covering letter (Ann01/SOP7B/v2).
- 3.2.4 YEC-1 Secretariat will list the protocol in the 'expedited review for ratification' in the agenda for the next YEC-1 meeting after issuance of ethics committee approval.
- 3.2.5 YEC-1 Secretariat will inform the Member-Secretary/Jt Secretary of any communication from the assigned reviewer regarding the completed assessment form, inability to complete the review process in 7 calendar days, or issues of conflict of interest as communicated by the members.
- 3.2.6 If the reviewer does not return the assessment form within 7 calendar days, the Secretariat will send a reminder to the reviewer by email/telephonic call.
- 3.2.7 The Secretariat will record and file the assessment form and the decisions of the reviewers in the protocol file.
- 3.2.8 The Secretariat will communicate the observations of the reviewers after masking the name of the reviewer to the principal investigator through an email with a request to respond within 2 weeks.

3.3 YEC-1 members:

- 3.3.1 The YEC-1 member identified to do the 'expedited review' will declare any conflict of interest with the protocol received for initial review, within 2 working days after receiving the protocol for review.
- 3.3.2 If the YEC-1 member foresees an inability to complete the initial review process within one week, he/she will declare it within 2 days of receiving the protocol for review.
- 3.3.3 The YEC-1 members assigned to review a protocol, will do it as per the assessment form (Ann02/SOP7B/v2).
- 3.3.4 The YEC-1 members will record their observations and comments in detail on the assessment forms.
- 3.3.5 The YEC-1 members after reviewing the protocol will declare their endorsement on the assessment form as

➤ Approved

- Approved with minor suggestions
 - Resubmit with major modifications
 - Disapproval
- 3.3.6 The YEC-1 member after reviewing the protocol will sign and date the assessment form.
- 3.3.7 The YEC-1 member will return the completed assessment form as soft copy by email to ethcom@yenepoya.edu.in or as hard copy to the Secretariat, as the case may be.
- 3.3.8 The YEC-1 member will complete the review process within the time frame of 7 calendar days from receiving the protocol for review.
- 3.3.9 After reviewing, if the reviewer feels that the protocol categorized under 'expedited review' by the Member-Secretary should be considered for 'full review', the members have the freedom to communicate the same with the Member-Secretary/Jt Secretary entering the same suggestion in the assessment form.

4 Detailed instructions:

4.1 Procedure for appointment of primary reviewers:

- 4.1.1 The Member-Secretary/Jt Secretary is responsible for assigning one or two primary reviewers for each protocol categorised as requiring 'expedited review'.
- 4.1.2 If selecting 2 reviewers, the Member-Secretary/Jt Secretary will preferably include one clinician and one non-clinician for reviewing each protocol.
- 4.1.3 The Member-Secretary/Jt Secretary will assign the reviewers based on each study topic, the expertise of the members in reviewing such studies and relation to the field of study.
- 4.1.4 If necessary, the Member-Secretary/Jt Secretary will assign additional reviewers, depending on the merit and complexity of each protocol.
- 4.1.5 The Member-Secretary/Jt Secretary, can also additionally assign the protocol for review by an independent consultant. Even reviewing members can suggest this if necessary. The decision of the Member-Secretary is final.
- 4.1.6 The Member-Secretary will communicate the names of the reviewers to the Secretariat within two working days of protocol submission

4.2 Distribution of protocols for review:

- 4.2.1 The YEC-1 Secretariat will record the names of the reviewers, as recommended by the Member-Secretary/Jt Secretary, for each protocol in the assessment forms.

- 4.2.2 The YEC-1 Secretariat will send the duly completed request letter to the reviewer with details of the protocol and the date by which the review has to be completed.
- 4.2.3 The Secretariat will send the complete submission to the reviewers along with the assessment forms.
- 4.2.4 If the reviewers have opted for soft copies of the protocols, they will be emailed to them at their official email id from the official email id of YEC-1 ethcom@yenepoya.edu.in.
- 4.2.5 If the reviewers have opted for hard copies of the protocols, then they will be reviewed by the reviewers in the YEC-1 safe room or in the office of the reviewer.
- 4.2.6 The following documents will be sent to the reviewer:
- The request letter for reviewing the protocol
 - The protocol submission form and related documents
 - The assessment form

4.3 Receiving the complete protocol submission for review

- 4.3.1 The reviewer will receive the complete protocol submission and verify the contents.
- 4.3.2 The reviewer will notify the YEC-1 Secretariat, immediately, if any of the documents are found missing.
- 4.3.3 The reviewer will inform the YEC-1 Secretariat if he/she has a conflict of interest within 2 days of receiving the protocol.
- 4.3.4 The reviewer will inform the Secretariat within 2 days if he/she is unable to complete the assignment of reviewing the protocol within 7 calendar days of receiving the protocol

4.4 Reviewing of the protocol:

- 4.4.1 The reviewer will consider the following criteria while reviewing the protocol and the submitted documents (Ann06/SOP7A/v2 and Ann2A/SOP7B/v2):
- Potential risks and harm to participants
 - Potential benefits
 - Selection of participants and method of recruitment especially for studies involving vulnerable population
 - Inducements, financial benefits and compensation
 - Protection of privacy of the participants and their data

- Methods of ensuring confidentiality
- Community considerations
- Qualification of the investigators and adequacy of site facilities
- Disclosure of conflicts of interest

4.5 Reviewing of the informed consent (Ann06/SOP7A/v2 and Ann2A/SOP7B/v2)

- 4.5.1 Content and language of the participant information sheet including clarity of methodology and the risks and benefits associated
- 4.5.2 Statement of voluntariness
- 4.5.3 Statement of choice of Refusal or withdrawal from study
- 4.5.4 Statement of comprehension of the information and clarification of doubts from the Principal investigator
- 4.5.5 Procedure of informed consent process
- 4.5.6 Translation of the informed consent and participant information sheet
- 4.5.7 Contact persons and their phone numbers
- 4.5.8 Statement of maintaining privacy
- 4.5.9 Statement ensuring confidentiality
- 4.5.10 Compensation for participation, whether there is a chance of undue inducement
- 4.5.11 Provision of medical and psychosocial support
- 4.5.12 Medical management of study related injuries, if any
- 4.5.13 Compensation of study related injuries, if any
- 4.5.14 Use of biological material, its use, its storage and possibility of future use
- 4.5.15 Possibility of deriving sensitive information from the biological samples, if any and the possible harm
- 4.5.16 Provision of signatures of participants, investigator or the person conducting the informed consent process, the witness with dates

4.6 Use of standard assessment forms:

- 4.6.1 The standard assessment form is designed to ensure a standard review process by each reviewer
- 4.6.2 The assessment form will help in ensuring that all the elements of research protocol are reviewed and documented

4.6.3 Each reviewer will go through the protocol and make comments/ suggestions and recommendations in the assessment form

4.6.4 The duly filled, signed and dated assessment forms are returned to the Secretariat along with the complete protocol submission

4.7 Compilation of the assessment reports:

4.7.1 The YEC-1 Secretariat will collect the assessment forms from each of the reviewers (soft or hard copy forms) and file the copies in the respective file

4.7.2 The file along with the reviewers' reports is kept ready for deliberation in the YEC-1 meeting during ratification of the expedited review protocols.

4.8 Decision making

4.8.1 The Member-Secretary will discuss the comments and recommendations of the reviewers from the assessment forms with the Chairperson

4.8.2 The final decision on the ethical approval of the protocol is recorded as

4.8.2.1 Approved

4.8.2.2 Approved pending minor modifications

4.8.2.3 Resubmit (major modifications)

4.8.2.4 Disapproved

4.8.3 The Member-Secretary and the Chairperson will then take a decision based on the recommendations

4.8.3.1 If the two reviewers have recommended the protocol, then a decision of issuing the ethical clearance is taken. Ethical clearance is issued within 2 days of the decision.

4.8.3.2 If either or both the reviewers have queries regarding the protocol, then the Member-Secretary will communicate the queries to the principal investigator after masking the name of the reviewer within 2 days. In such a case, the principal investigator is expected to send the revised protocol within 15 days. Once the revised protocol is received, the document is sent to the concerned primary reviewers and decision made.

4.8.3.3 If one or both reviewers have rejected the protocol, then the protocol is included for 'full review' in the next YEC-1 meeting.

4.8.3.4 Once approved, the protocol is listed under the 'expedited review' category in the agenda of the next YEC-1 meeting.

4.9 YEC-1 meeting:

- 4.9.1 The protocol listed under the ‘expedited review’ category in the agenda of the YEC-1 meeting is taken up for discussion during the meeting.
- 4.9.2 The Member-Secretary will read out the list of all the protocols under the ‘expedited review category’
- 4.9.3 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.
- 4.9.4 The primary reviewer/Member-Secretary will brief the members, the summary of the study and read out the comments and recommendation from the assessment forms.
- 4.9.5 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.
- 4.9.6 The Member-Secretary assisted by another YEC-1 member or the Secretariat will minute the proceedings of the discussions of each protocol.

4.10 The communication of the final decision:

- 4.10.1 The approval letter is sent to the principal investigator within two days of the expedited meeting of the Member-Secretary and the Chairperson and within 14 working days after complete submission to YEC-1.
- 4.10.2 The approval letter will contain the following matter
 - Study reference number
 - Study title
 - A list of the versions of the protocol documents approved
 - Validity of the approval
 - List of participating members in the meeting
 - Summary of the guidance, advice and decision that the YEC-1 members have reached in the meeting
 - Site monitoring and its proposed frequency
 - Other expectations from the principal investigator, if any
 - Need for submission of status report, closure report at the end of the period of validity
 - The Secretariat will verify the correctness of the wordings and spellings in all the letters

- Signature of the YEC-1 Member-Secretary with date
- The letter is communicated to the principal investigator within 2 days as a hard copy.

4.11 Storage of documents:

4.11.1 The Secretariat will maintain all documents related to the protocol review (assessment forms by both reviewers, statements of the subject expert, decision form, and the copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed protocol.

4.11.2 The Secretariat will store the file on an appropriate shelf in the designated cabinet.

5. Reference to other SOPs

1. SOP06/v2: Management of Research Study Protocol and Study Related documents Submitted for Ethics Review
2. SOP07/v2: Categorization of Submitted Protocols for Ethics Review
3. SOP7B/v2: Expedited Review of Research Study Protocols
4. SOP08/v2: Agenda Preparation, Meeting Procedures and Recording of Minutes
5. SOP09/v2: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

6. Annexures

1. Ann01/SOP7B/v2 - Letter to the YEC-1 Members requesting initial review with study assessment form for expedited review
2. Ann2A/SOP7B/v2- Protocol assessment form for expedited review
3. Ann2B/SOP7B/v2 - Decision form for expedited review
4. Ann2C/SOP7B/v2 - Approval letter format in case of Expedited Review
5. Other related annexures
 - A. Ann02/SOP7A/v2 - Study assessment form for primary reviewer
 - B. Ann03/SOP7A/v2 - YEC-1 decision form
 - C. Ann04/SOP7A/v2 - Format of study approval letter
 - D. Ann05/SOP7A /v2- Guidelines for reviewing a study protocol

Ann01/SOP7B/v2

Letter to the YEC-1 Members requesting initial review with study assessment form for expedited review

Date:

To,
Dr./Mr./Ms.
Member, Yenepoya Ethics Committee - 1
Yenepoya deemed to be University, Mangaluru

Subject: Expedited review of protocol/s

Reference: YEC-1 protocol No titled

Dear Member,

You are requested to review the following documents that have been submitted to the YEC-1 for review.

1. YEC-1 protocol No titled

The protocol has been categorized for expedited review. You are requested to fill the review assessment form enclosed and send to the YEC-1 Secretariat within 7 working days from the date of this letter. If you find any documents missing, kindly inform the undersigned within two days of receiving the document package. If you have any conflict of interest in reviewing this protocol, kindly inform the undersigned within the next two days.

If you feel you are unable to complete the review of the protocol within 7 days, kindly send back the document package along with a written letter/email stating the reason, within 2 days of receiving the document package.

The decision to provide expedited review for this protocol has been made by the Member-Secretary/Jt Secretary/Chairperson, based on the guidelines in the ICMR Guidelines for Ethical Issues in Biomedical Research (2006). Should you feel differently, please feel free to recommend this in the reviewer's assessment form.

Thank you,
Yours sincerely,

Signature of Member-Secretary/Chairperson with date

**Ann2A/SOP7B/v2
Protocol assessment form for expedited review**

YEC-1 Protocol Number:		Date of receipt at YEC-1 office:	
Project Title:			
Name of the Principal Investigator		Designation and affiliation:	Contact number:
Does the reviewer wish to declare a conflict of interest? Yes / No <i>(If yes, then please specify the conflict herein and return the document package to the YEC-1 Secretariat within two days of receipt of the package)</i>			
Total number of participants to be recruited at this site (sample size):			
Total number of study sites:			
Sponsor (if any):			
Duration of the Study: 3 months / 6 months / 1 year / 2 years / more than 2 years			
Reviewer's name :			
Type of the Study:	<input type="checkbox"/> Intervention <input type="checkbox"/> Epidemiology <input type="checkbox"/> Observation <input type="checkbox"/> Document based <input type="checkbox"/> Genetic <input type="checkbox"/> Social Survey <input type="checkbox"/> Questionnaire based study <input type="checkbox"/> Others, specify.....		

Description of the Study in brief: Mark whatever applied to the study.				
<input type="checkbox"/> Randomized <input type="checkbox"/> Open-labeled <input type="checkbox"/> Questionnaire-based <input type="checkbox"/> Double blinded <input type="checkbox"/> Placebo controlled <input type="checkbox"/> Treatment controlled <input type="checkbox"/> Cross-over <input type="checkbox"/> Parallel <input type="checkbox"/> Interim Analysis <input type="checkbox"/> Use of Tissue samples <input type="checkbox"/> Use of Blood samples <input type="checkbox"/> Use of genetic materials				
SI No	Ethical issue under consideration	Yes	No	Comments
1	Has the study been approved by the concerned Scientific Review Board?			
2	Please assess the risk that the participant being subjected to if he/she is recruited in the study, as per the ICMR guidelines: a. Minimal or less than minimal risk? ----- b. More than minimal risk?			
3	If the answer to the above is (b) then is an expedited review justified? (In case the answer is 'No' then please consider recommending full review while submitting to the YUEC Secretariat)			
4	Is the study scientifically sound enough to expose the patient to the risk or harm? (if no, please clarify in the comments column) <i>(Please note that your entries in the comments column will be anonymously communicated to the PI and amendments/revisions/resubmissions will be sought. Therefore please make clear, unambiguous comments that will convey the requirements to the PI without confusion. Please avoid the use of judgmental terms and words)</i>			

5	Is the overall risk-benefit ratio acceptable?			
6	a. Does the study involve vulnerable populations (pregnant woman, foetus , neonates, children, mentally challenged, seriously or terminally ill, economically or socially backward and/or healthy volunteers)?			
	b. If yes, then has the PI submitted a justification strong enough to approve the study?			
	c. If yes, would you like to recommend this for full review?			
7	a. Does the study involve special populations (prisoners, institutionalized persons such as convicts, students, nurses, etc)?			
	b. If yes, then is the presence of the PI or other study team members likely to influence the choice of the participant, such that his/her autonomy is compromised?			
	c. Has the PI submitted a justification strong enough to approve the study?			
	d. Would you like to recommend this for full review?			
8	a. Has the PI provided enough information to ensure privacy of the participant during the recruitment phase and study phase?			
	b. Has the PI provided enough information to ensure that the confidentiality of the data or patient identifiers will be maintained?			
9	Does the informed consent document address or state the following items:			
	a. The participant will be provided enough information (including study title & PI name)			
	b. This will be provided in a language that he/she understands			
	c. The participant will be given adequate time to understand the implications of consenting			
	d. Opportunity to ask questions from the PI or a member of the study team			
	e. Some method of assessing the comprehension of the participant will be undertaken			
	f. Participant's consent is voluntary and free of coercion			
	g. Option to refuse without comprising patient rights			
	h. Option to voluntarily withdraw at any stage of research without compromising patient rights			

	i. Option for the participant to retain one copy of the consent form <i>OR</i> one copy of the participant information sheet			
	j. Maintaining privacy of the participant and confidentiality of the data			
	k. Permission to publish the data while protecting privacy and confidentiality			
	l. Invitation to contact the PI or a study team member for clarification with adequate contact details			
	m. Place for signature, name and date for the participant and/or legally authorized representative and a study team member			
	n. Place for name, date and signature of an independent witness, in case the participant is illiterate or unable to sign			
	o. Sample of the informed consent document provided in a local language			
10	If the PI is requesting an informed consent waiver, do you recommend this based on the ICMR guidelines			
11	Participant Information Sheet:			
	a. Participant information sheet written in simple language without use of jargon, such that a student of standard VIII would be able to understand			
	b. Adequate information provided about			
	i. the title of the study and PI details			
	ii. the purpose of the study			
	iii. duration of the study			
	iv. why he or she is being selected			
	v. voluntary nature of the enrolment			
	vi. participants responsibilities and expected cooperation			
	vii. details of the intervention			
	viii. the likely benefits to the participant			
	ix. compensation for time lost			
	x. risks, harms and compensations			
	xi. protection of privacy of the participant			
	xii. confidentiality of the data			
	xiii. anonymity of the data when shared			
	xiv. invitation to seek clarification after adequate time provided			
	xv. details of the person who will clarify			
	xvi. details about future use of samples or data			

12	Has the compensation been addressed adequately			
13	Does the protocol spell out how adverse events will be handled, and who will bear the cost			
14	Is there a conflict of interest. If yes, does the protocol spell out the how it will be mitigated			
15	Has a budget been provided			
16	Has a time line been provided			

Any other comments:

Provisional Decision:

- Approved
- Approved with modifications:

Modification suggested:

- Minor in nature
- Major in nature
 - **Resubmission**
 - **Full Review**
- Disapproved

Reason for Resubmission/ Full review/ Disapproval:

Signature

Name of the YEC-1 member:

Date:

Ann2B/SOP7B/v2

Decision form for expedited review

YEC-1 Protocol Number:	Date of receipt at YEC-1:	
Project Title:		
Name of the Principal Investigator	Department:	Contact number:
Reviewer 1: Recommendation:		
Reviewer 2: Recommendation:		
Final Decision: <input type="checkbox"/> Approved <input type="checkbox"/> Approved with modifications: Modification suggested: <input type="checkbox"/> Resubmission <input type="checkbox"/> Full Review <input type="checkbox"/> Disapproved Reason for Resubmission/ Full review/ Disapproval: Signature Name of the Member-secretary/ Chairperson:		

Ann2C/SOP7B/v2
Approval letter format in case of Expedited Review

Dear Dr. _____

Principal investigator

Protocol No:

The Yenepoya Ethics Committee - 1 approves your protocol number _____ titled _____ after

reviewing the following documents through an expedited review process.

1. _____ Version:

2. _____

3. _____

It is understood that the study will be conducted under your direction, as per the submitted protocol with a total of _____ research participants.

The approval is valid up to the time of study completion or a period of one calendar year, whichever is earlier.

It is the responsibility of the Principal investigator to **inform** the YEC-1 about any on site serious adverse event (SAE), expected or any unexpected, or death report urgently, within 24 hours (even if there is holiday) as per the formats specified in SOP09 by email or a letter.

It is the responsibility of the Principal investigator to send the detailed **report** of the SAE or death after due analysis to the chairman of YEC-1 and the head of the institution within 10 calendar days of SAE or death.

It is the responsibility of the sponsor (whether a pharmaceutical company or an institution) or representative, who so ever had obtained permission from the Licensing Authority for conduct of the clinical trial, in case of injury or death of participant(s) occurring during the trial, to make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations or changes of the protocol and/or Informed Consent Document should be initiated without prior written approval by the YEC-1 of an appropriate amendment.

The YEC-1 expects that the investigator should promptly report to YEC-1 any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than the validity period of the YEC-1 approval, it is the responsibility of the Principal investigator to submit the continuing review within one month of the due date on or before xxxxxx.

Once the study is completed, it is the responsibility of the principal investigator to submit the closure report with the summary of the study

Signature of the Member-Secretary

Date:

i.Flowchart

