Title: Categorization of new research protocols for initial review

SOP Code: SOP07/v2

Effective date: 01/08/2016

Prepared by:

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

Reviewed by:

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Approved by:

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

Notified by:

Registrar Yenepoya University vide notification no. YUReg/ACA/YUEC/FERCAP/01/2016	Signature with date 1/8/16 Dr. G. Shreekumar Menon Registrar Yenepoya University Mangaluru - 575 018

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1. Purpose

The purpose of this SOP is to describe the procedure for categorizing new research protocols submitted to the Yenepoya Ethics Committee - 1 for initial review into full review/expedited review or exemption from review.

2. Scope:

The SOP covers the process of categorization of new research protocols submitted to the Yenepoya Ethics Committee - 1 for initial review. The categorization process is not applicable to subsequent submissions.

3. Responsibilities:

3.1 Member-Secretary/Jt Secretary:

3.1.1 It is the responsibility of the Member-Secretary/Jt Secretary to categorize the new research protocols submitted to the YEC-1 for initial review. This is based on an initial screening of the protocol. The categorization will be done based on the possible risk to the research participants into any of the three types of review processes[1]:

- Full review
- Expedited review
- Exemption from review.

3.1.2 In the case of a protocol expected to be kept for "full review", the Member-Secretary/Jt Secretary will make the decision and communicate the same to the Secretariat for further action

3.1.3 If, during the review process, the reviewer considers a change in the review process of a given protocol, then it is the responsibility of the Member-Secretary/Jt Secretary to consider the change of review category and make the final decision of categorization of protocols. The final decision rests with the Member-Secretary/Jt Secretary. Once a review process is identified and the initial review completed, the review process will not be changed.

[1] *http://www.icmr.nic.in/ethical_guidelines.pdf accessed on 15 July 2016 at 10.05 hours*

3.2 Secretariat:

3.2.1 It is the responsibility of the Secretariat to enter the category of review process of each protocol, as decided by the Member-Secretary/Jt Secretary and enter the same in the protocol database.

3.2.2 It is the responsibility of the Secretariat to ensure that the documents in the protocol document package are complete as per the protocol submission checklist. Any deficiencies thereof should be communicated with the PI and the protocol kept pending for review till such time that the PI submits all the requisite documents (Ann2A/SOP06/v2 for regulated clinical trials and Ann2B/SOP06/v2 non-regulated academic studies).

3.2.3 It is the responsibility of the Secretariat to inform the Member-Secretary of the protocols received (complete in documentation), within 2 calendar days of receipt.

3.2.4 It is the responsibility of the Secretariat to change the category of review process of the concerned protocol, if the Member-Secretary/Jt Secretary makes changes in the same, based on the views of the reviewing YEC-1 members. This has to be done before the communication with the PI.

3.2.5 It is the responsibility of the Secretariat to ensure that this change in type of review is communicated with the Chairperson YEC-1.

3.2.6 It is the responsibility of the Secretariat YEC-1 to send email reminders once in 7 calendar days to the reviewers who are delayed in submitting the initial reviews.

3.3 Chairperson:

It is the responsibility of the Chairperson to make of note of all the decisions made by the Member-Secretary/Jt Secretary regarding categorization of the protocols submitted to the YEC-1 for initial review.

3.4 Members:

3.4.1 While reviewing the protocols, the members have the option to suggest a change of category of review process, stating reasons for the same, even if it has been otherwise assigned by the Member-Secretary/Jt Secretary. The members make this suggestion in

the protocol review assessment form, providing good justification for the change in review type. In case the Member-Secretary/Jt Secretary feel otherwise, the matter can be referred to the Chairperson, whose decision will be final and binding.

3.4.2 Members have to accept the protocols assigned to them by the YEC-1 Secretariat and apply themselves to the task of completing the initial review within the stipulated time period (SOP7A, 7B and 7C/v2).

3.4.3 If a member perceives a conflict of interest, he/she has to return the document stating the conflict of interest (see SOP02/v2) within a period of 2 calendar days from receipt of protocol document package.

4. Detailed instructions:

4.1 Receiving of research protocols for initial review:

4.1.1 The Secretariat will ensure that the protocol documents submission is complete in all aspects as per the check list (Ann2ASOP06/v2 and Ann2B/SOP06/v2). Any deficiencies will be communicated with the PI and appropriated before forwarding the documents to the Member-Secretary/Jt Secretary for categorization of the protocols into the review types.

4.1.2 All new regulatory clinical trial proposals for initial review, complete in all aspects of documentation required from the PI, received by YEC-1, at least 28 calendar days prior to the date of the next YEC-1 meeting will be considered for keeping in the agenda of that meeting, for “full review”.

4.1.3 Clinical trial protocol documents, complete in all aspects of documentation from the PI, but received less than 28 calendar days from the date of the next meeting will be kept for “full review” in the YEC-1 meeting after the next. For all other protocols determined as “full review” the time period for submission will be 14 calendar days prior to YEC-1 meeting.

4.1.4 All other types of protocols received by the YEC-1 for initial review, complete in all aspects of documentation, will be reviewed initially and the review comments/ethical clearance will be communicated to the PI within 14-28 calendar days.

Forwarding research protocols for categorization to Member-Secretary/ Jt Secretary:

4.1.5 The YEC-1 Secretariat will forward the document to the Member-Secretary/Jt Secretary within 2 calendar days, or alternately the Member-Secretary/Jt Secretary can decide the category in the YEC-1 office itself.

4.1.6 Upon receiving the forwarded protocol for initial review, from the Secretariat, the Member-Secretary/Jt Secretary will do an initial screening and categorization of the protocol within 2 calendar days.

4.2 Categorization of the new protocols for the review process:

4.2.1 The Member-Secretary/Jt Secretary will categorize the protocols received for initial review into three types of review processes, as listed in 3.1.1 above and record the categorization (Ann01/SOP07/v2).

4.2.2 The YEC-1 Secretariat will communicate full review protocols and categorization changes, to the Chairperson.

4.2.3 Once a decision is made, the Member-Secretary/Jt Secretary will assign the category to each protocol and communicate the same to the YEC-1 Secretariat.

4.3 Criteria for categorization of protocols received for initial review:

4.3.1 The Member-Secretary/Jt Secretary will follow the Ethical Guidelines for Biomedical research on human participants published by the Indian Council of Medical Research (*ibid*) for categorization. This will be based on assessment of risk, a brief description of which is provided below in the section 'Glossary'.

4.3.2 In case of any dispute, the ICMR guidelines (*ibid*) will be the reference source. If the ICMR guideline does not clarify the matter, the Schedule Y or the Declaration of Helsinki may be referred.

4.4 Full review:

4.4.1 Protocols involving any one or more of the following characteristics will be sorted under this category of review:

- Research involving more than minimal risk to human participants

- Any research involving vulnerable population, exposing participants to more than minimal risk
- Research involving invasive procedures
- Research involving potentially harmful non-invasive tests like radiographic and other potentially harmful methods

The final authority for this assigning of review type is the Member-Secretary, with information to the Chairperson YEC-1.

4.4.2 Research protocols submitted to the YEC-1 for initial review which are sorted under the category of 'full review' will be reviewed by all YEC-1 members. In addition, two reviewers (assigned as per SOP7A/v2) will be identified as lead discussants who will – in brief – inform the members about the protocol, during the meeting.

4.4.3 Additional review by subject experts, referred to as independent consultants (assigned as per SOP03/v2) may be considered.

4.4.4 Research protocols sorted under this category and within the timeframe specified, will be listed in the agenda for the next YEC-1 meeting and presented for deliberation and discussion.

4.5 Expedited review:

4.5.1 Protocols involving the any one or more of the following characteristics are sorted under this category of review

- Research involving no more than minimal risk to human participants
- Research involving medical data, documents or specimen that have already been collected for diagnostic purpose or will be collected for on-going treatment.
- Research in emergency situations
- Research in disaster management
- Research involving non-invasive procedures already proven to be safe for use on human subjects. This excludes radiographic and other potentially harmful methods.

4.5.2 In some circumstances, protocols that appear to meet low risk criteria that meet the requirement of inclusion under 'exemption from review' may need to be reviewed by the YEC-1 because of requirements of the publisher of the research or the funding

agency, or other stakeholders, in which case such protocols will be categorized as 'Expedited review' or 'Full review' based on the assessment by Member-Secretary/Jt Secretary.

4.5.3 Research protocols submitted to the YEC-1 for initial review which are sorted under this category of 'expedited review' are reviewed independently by two reviewers (assigned as per SOP7B/v2 and if required by subject experts (ICs) (assigned as per SOP03/v2),

4.6 Exemption from review:

4.6.1 Protocols involving the any one or more of the following characteristics are sorted under this category of review:

- Research not involving human participants
- Research involving anonymized medical data or human tissue
- Research assessed as less than minimal risk to human participants

4.6.2 Examples of protocols which may be included under this category

- Research on educational practices (provided data are anonymized)
- Research on microbes cultured in the laboratory (provided data are anonymized and de-linked from any possible identifiers)
- Research on cell lines (provided data are anonymized and de-linked from any possible identifiers)
- Research on cadavers or death certificates which do not bear any identifying personal data

4.7 Further management of protocols:

4.7.1 The protocols are further managed as per the SOPs for various categories of review

- SOP03/v2 for Independent consultants
- SOP06/v2 for Management of research protocols and study related documents
- SOP7A/v2 for Full review
- SOP7B/v2 for Expedited review
- SOP7C/v2 for Exemption from Review

5. Reference to other SOPS:

5.1 SOP03/v2

5.2 SOP6/v2

5.3 SOP7A/v2

5.4 SOP7B/v2

5.5 SOP7C/v2

6. Glossary:

6.1 Minimal risk: It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. *Example for minimal risk:* A retrospective review of patient case records to determine the incidence of disease/recurrence of disease

6.2 Less than minimal risk: Research, in which there is no known physical, emotional, psychological, or economical risk to the study participants. This research qualifies as exempt provided it does not involve vulnerable groups

7. Annexures:

Ann01/SOP07/v2

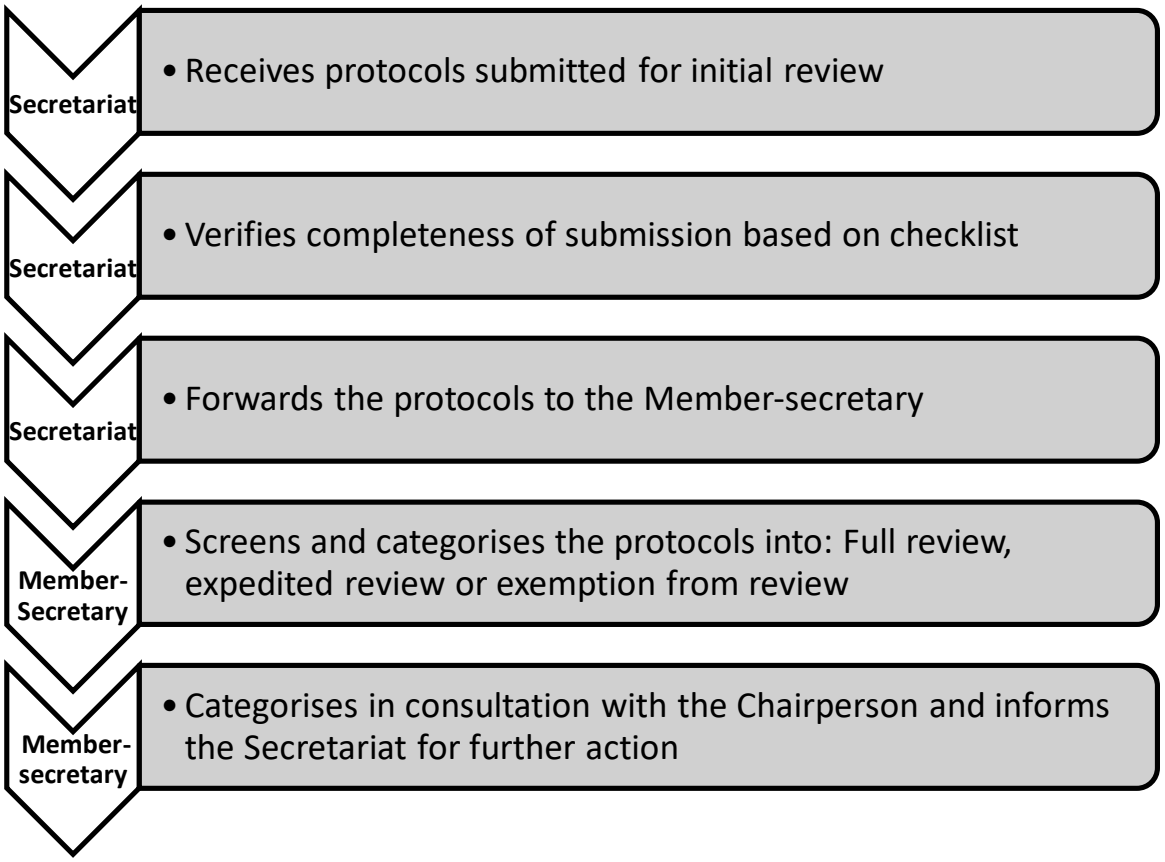
Categorization by Member-Secretary and identification of primary reviewers/ independent consultants

- ☐ Full review
- ☐ Expedited review
- ☐ Exempt from review

Action	Details	Date identified	Date communicated
Primary reviewers identified by Member-Secretary/Jt Secretary	1. 2. 3. 4.		
Independent consultant identified by Member-Secretary/Jt Secretary	1. 2.		

Signed by Member-Secretary/Jt Secretary (with date):

8. Flowchart


Secretariat
• Receives protocols submitted for initial review
Secretariat
• Verifies completeness of submission based on checklist
Secretariat
• Forwards the protocols to the Member-secretary
Member-Secretary
• Screens and categorises the protocols into: Full review, expedited review or exemption from review
Member-secretary
• Categorises in consultation with the Chairperson and informs the Secretariat for further action