


**Title: Preparation of Standard Operating Procedures for Yenepoya University Ethics
Committee**


SOP Code: SOP01/v2

Effective Date: 01/08/2016


Prepared by:

Dr. Ravi Vaswani Member, YUEC	Signature with date  8-17/16
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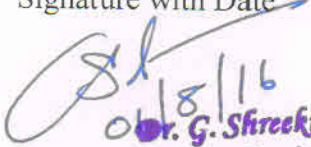
Reviewed by:

Dr. Vina Vaswani 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. Sireekumar Monon Registrar Yenepoya University Mangaluru - 575 018
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Title: Preparation of Standard Operating Procedures - Yenepoya Ethics Committee - 1

SOP Code: SOP01/v2

Effective Date: 01/08/2016

Prepared by:

<p>Dr. Ravi Vaswani Member, YEC-1</p>	<p>Signature with date</p>
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Reviewed by:

<p>Dr. Vina Vaswani Secretary, YEC-1</p>	<p>Signature with Date</p>
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Approved by:

<p>Dr. Sayeegeetha Hegde Chairperson, YEC-1</p>	<p>Signature with Date</p>
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Notified by:

<p>Registrar, Yenepoya University vide Notification No. YU/REG/ACA/YEC- 1/FERCAP/01/2016 dated 01/08/2016</p>	<p>Signature with Date</p>
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for drafting, reviewing, distributing and amending SOPs of Yenepoya Ethics Committee - 1 (YEC-1). The SOPs provide clear, unambiguous instructions so that all the activities of the committee are conducted in an orderly, fair and transparent manner, in accordance with Indian regulations and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of drafting, reviewing, distributing and amending the SOPs of YEC-1.

3. Responsibilities

3.1 Role of the Chairperson, YEC-1

It is the responsibility of the Chairperson, YEC-1 to

- nominate SOP team(s) to formulate new SOP(s) or to revise/amend existing SOP(s)
- approve the SOP(s)
- sign and date the approved SOP(s)

Note: The SOP team(s) shall be notified by the University under a notification from the office of the Registrar, Yenepoya University. The SOP(s) approved by the Chairperson shall be notified by the office of the Registrar, Yenepoya University. The latter shall ensure that these are widely made available to all researchers, on the University website.

3.2 Role of the Secretariat, YEC-1

The Secretariat, YEC-1, will assist the Chairperson to

- formulate an SOP Team(s)
- co-ordinate activities of drafting, reviewing, distributing and amending SOP(s)
- ensure that all the YEC-1 members and involved administrative staff of YEC-1 have access to the SOP(s)
- ensure that all YEC-1 members and involved staff are working according to current version of SOP(s)
- maintain an up-to-date distribution list for each SOP(s) distributed to the YEC-1 members

3.3 Responsibilities of the YEC-1 SOP team

The YEC-1 SOP team will

- assess the request(s) for SOP(s) revision in consultation with the Secretariat, Member-Secretary and Chairperson
- formulate and/or revise/amend SOP(s) by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the YEC-1.
- propose new/modified SOP(s) as needed (vide supra)
- draft the SOP(s) in consultation with the YEC-1 members and involved administrative staff of YEC-1
- review the draft SOP(s)
- submit the draft for approval to Chairperson & University authorities

3.4 Responsibilities of YEC-1 members and involved administrative staff of YEC-1

The YEC-1 members and involved administrative staff of YEC-1 will

- sign and date the approved SOP(s) when they receive it
- maintain a personal file of all the current SOP(s) received
- destroy all the old versions of the SOP(s) that are in their possession
- familiarize themselves with the content of the SOPs and
- maintain adherence to the guidelines in the SOPs

4. Detailed instructions

4.1 Identification of the need for new or amendment of current SOP

4.1.1 Any member of the YEC-1 or Secretariat who would feel the requirement of a revision or notices an inconsistency/discrepancy /has any suggestions on how to improve the existing SOP(s) or requests to design an entirely new SOP can put forth a formal request to the YEC-1 Chairperson either as an email/letter/verbal request in a meeting.

4.1.2 Once this request is approved by the Chairperson, the Secretary will inform all the YEC-1 members at a regular YEC-1 meeting.

4.1.3 If the majority of members agree to the request, appropriate SOP team(s) will be nominated by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP, with due approval from Yenepoya University.

4.1.4 If majority of YEC-1 members do not agree, no further action will be taken and the

Member-Secretary will inform the member of the YEC-1 or Secretariat who made the request for modification of the SOP(s).

4.2 Appointment of the SOP Team(s)

The Chairperson will nominate members to the SOP Team(s) consisting of the Member-Secretary, two or more members of YEC-1, and based on inputs from Member-Secretary two or more members from Yenepoya University, who have a thorough understanding of the ethical review process.

4.3 Listing all relevant procedures

The SOP team will write down step-by-step all the procedures of the YEC-1 that are to be standardized in the form of SOP. Each procedure will be organized, structured and named.

4.4 Drafting of the new SOP

The SOP team will identify one or more designated members and assign the various SOP drafts to them.

4.5 Versions for the SOPs

4.5.1 Each SOP should be given a number and a title that is self-explanatory and easily understood.

4.5.2 A unique code number with the format SOPxx/vy will be assigned to each SOP item by the Secretariat. “xx” will be a two-digit number assigned specifically to each activity-based SOP. “v” refers to version SOP and “y”, a number identifying the version. Thus the first SOP of the current version would be SOP01/v2.

4.6 Annexures for the SOP

Each SOP may have annexures which are forms or templates to be used by YEC-1 members, Principal Investigators (PI) or other stakeholders. Each annexure will be given a unique code number with the format Ann“pp”/SOP“xx”/v“y”. “Ann” refers to annexure form, “pp” is a two-digit number, in serial order for the various annexures, and “xx”/v“y” refers to the SOP number and its version. For example, Ann01/SOP01/v2 means annexure form/template number 1 from SOP01/v2.

4.7 General SOP structure

- 4.7.1 Each SOP will be prepared according to the standard template given in Ann01/SOP01/v2.
- 4.7.2 Each page of the SOP will bear a header. The Institutional logo will be in the left margin of the header, the ethics committee name and title of the SOP will be in the centre of the header, and the SOP number/version and effective date (*dd/mm/yyyy*) i.e. date of approval of the SOP by the Chairperson, will be on right margin of the header.
- 4.7.3 There will be a footer that will bear the page number as page p of q (total) pages.

4.8 Review of the draft SOP

- 4.8.1 The draft SOP written by one or more members of the SOP team will be reviewed by another member(s) of the SOP team. The reviewer will sign with date of review.
- 4.8.2 After incorporating the suggestions put forth by the SOP reviewer(s), a copy of the revised draft SOP will be sent to the Member-Secretary, with a request to bring it up in the agenda of the next YEC-1 meeting for formal approval from the YEC-1 members, before forwarding it to the Office of the Registrar for notification.

4.9 Supersession of previous SOP(s)

If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form appended as an annexure (Ann02/SOP01/v2) along with description of the main change(s).

4.10 Preparation and submission final draft

- 4.10.1 The SOP Team will submit the reviewed SOP to the YEC-1 Members who will review it in the meeting.
- 4.10.2 The suggestions that are agreed upon by the members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- 4.10.3 The extract of the relevant resolution of the YEC-1 meeting minutes will be attached to the SOP as an annexure (Ann“xx”/SOP “yy”/v“z”). In the case of this SOP, this annexure will be Ann03/SOP01/v2.

4.11 Approval of the new/revised/amended SOP(s)

4.11.1 The authors, reviewers and the Chairperson will sign and date the SOP on the first page of the SOP document. The date of approval signed by the Chairman will be declared as the effective date from which the SOP will be implemented.

4.11.2 The same page will also bear the signature of the Registrar, Yenepoya University as having accepted the document for notification.

4.12 Dissolution of the SOP team

The SOP team(s) would stand automatically dissolved once the YEC-1 takes final decision regarding the SOP(s) and the Registrar notifies the new SOP(s).

4.13 Implementation, distribution and filing of SOPs

4.13.1 The approved SOP(s) will be implemented from the effective date.

4.13.2 The Member-Secretary will discuss the approved SOP(s) with the involved administrative staff of the EC and instruct them to implement it accordingly.

4.13.3 The approved SOP(s) will be distributed to the YEC-1 members and a log will be maintained as per the annexure (Ann“xx”/SOP“yy”/v“z”). In this case, it will be Ann 04/SOP 01/v2.

4.13.4 One complete original set of current SOP will be filed in the SOP Master file, by the YEC-1 Secretariat in the YEC-1 office.

4.13.5 When the revised version is distributed, all the YEC-1 members will be requested to destroy their earlier version. Only one copy of the earlier version will be filed in the file entitled ‘Past SOPs of the YEC-1’ by the YEC-1 Secretariat in the YEC-1 office, in the Master File.

4.13.6 YEC-1 members and Secretariat will review the SOPs at least once in every 3 years.

5. Annexures

5.1 Ann01/SOP01/v2 - Template for SOPs

5.2 Ann02/SOP01/v2 - Documentation of History of the SOPs

5.3 Ann03/SOP01/v2 - Extract of the relevant resolution

5.4 Ann04/SOP01/v2 - Log of the YEC-1 members receiving SOPs

5.5 Ann05/SOP01/v2 - List of SOPs of the YEC-1

Ann01/SOP01/v2

Template for Standard Operating Procedures

Logo of institution	YEC-1	SOP Code: SOP xx/vy
	Title of the SOP	Effective date: aa/bb/cccc
<p>Title: Title which is self-explanatory and easily understood</p> <p>SOP Code: SOP xx/vy</p> <p>Effective date: aa/bb/cccc</p> <p>Prepared by : xxxxxxxxxxx Signature with date -----</p> <p>Reviewed by: xxxxxxxxxxx Signature with date -----</p> <p>Approved by: xxxxxxxxxxx Signature with date -----</p> <p>Notified by: xxxxxxxxxxx Signature with date -----</p> <p>Table of Contents:</p> <ol style="list-style-type: none"> 1. Purpose: <i>Summarizes and explains the objectives of the procedure.</i> 2. Scope: <i>States the range of activities that the SOP applies to.</i> 3. Responsibility: <i>Refers to person(s) assigned to perform the activities involved in the SOP</i> 4. Detailed instructions: <i>Describes procedures step by step in short and clear sentences</i> 5. Annexure: <i>Forms to capture information pertaining to the SOP instructions</i> 6. Flow chart: <i>Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity</i> 		
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Ann02/SOP01/V2

Documentation of History of the SOPs

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

Details of superseded SOP

Ann03/SOP01/v2

Extract of the relevant resolution of the minutes of the YEC-1 meeting

Attach the extract of the relevant resolution of the YEC-1 meeting.

Ann04/SOP01/v2

Log of the YEC-1 members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Ann05/SOP 01/v2
List of SOPs of the YEC-1

No	Title of the Standard Operating Procedures (SOPs)	SOP No.
1	<i>Preparation of Standard Operating Procedures for Yenepoya Ethics Committee - 1</i>	<i>SOP01</i>
2	<i>Constitution of Yenepoya Ethics Committee - 1 (YEC-1), Selection, Roles and Responsibilities of Members of the YEC-1</i>	<i>SOP02</i>
3	<i>Handling Conflict of Interest among Ethics Committee Members</i>	<i>SOP03</i>
4	<i>Selection and Responsibilities of Independent Consultants</i>	<i>SOP04</i>
5	<i>Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee - 1 or attend YEC-1 meeting</i>	<i>SOP05</i>
6	<i>Management of Submission of Research Study Protocol and Study Related Documents</i>	<i>SOP06</i>
7	<i>Categorization of Submitted Protocols for Ethics Review</i>	<i>SOP07</i>
7A	<i>Initial Full Review of Research Study Protocols</i>	<i>SOP7A</i>
7B	<i>Expedited Review of Research Study Protocols</i>	<i>SOP7B</i>
7C	<i>Exemption from Ethics Review of Research Study Protocols</i>	<i>SOP7C</i>
8	<i>Agenda Preparation, Meeting Procedures and Recording of Minutes</i>	<i>SOP08</i>
9	<i>Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol</i>	<i>SOP09</i>
10	<i>Continuing Review of Study Protocols</i>	<i>SOP10</i>
11	<i>Review of Protocol Deviations / Violations</i>	<i>SOP11</i>
12	<i>Review of Serious Adverse Events (SAE) Reports</i>	<i>SOP12</i>

13	<i>Review of Study Completion Reports</i>	<i>SOP13</i>
14	<i>Management of Premature Termination / Suspension / Discontinuation of the Study</i>	<i>SOP14</i>
15	<i>Request for Waiver of Written Informed Consent and Waiver of Consent</i>	<i>SOP15</i>
16	<i>Site Monitoring and Post-Monitoring Activities</i>	<i>SOP16</i>
17	<i>Dealing with Participants' Requests and Complaints Coming to Ethics Committee</i>	<i>SOP17</i>
18	<i>Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents</i>	<i>SOP18</i>
19	<i>Reviewing Proposals involving Vulnerable Populations</i>	<i>SOP19</i>
20	<i>Preparing for Ethics Committee Audit/ Inspection</i>	<i>SOP20</i>
21	<i>Training and Assessment of Ethics Committee Members</i>	<i>SOP21</i>

1.6 Flow Chart

