NAAC Accredited A+ with CGPA3.47

Title: Special Consideratons for Clinical trials in ayurveda, siddha ,unani, homeopathy,yoga and naturopathy Protocol Submission

SOP Code: YEC2/SOP22/v2

Prepared by:

Dr. Hari Kishore Bhat Member YEC2 SOP Subcommittee	Signature with date 24/FEB/2024

Reviewed by:

Dr. Reeti Rastogi Member YEC2 SOP Subcommittee	Signature with Date 24/02/2024

Approved by:

Dr. Animesh Jain Chairperson , YEC2	Signature with Date 24/02/24

Notified by:

Registrar, Yenepoya (Deemed to be university)	Signature with Date 24/02/24 Registrar YENEPOYA (Deemed to be University)

Details of superseded SOP22/v1

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP22/v2

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. K. Leena Pramod	v2	24.02.2024	1. New Reference Added 2. Version of SOP changed 3. Added for SOP A. B etc.

Table of contents

1. Purpose

The purpose of this SOP is to describe methodology for assessment of study protocols and Clinical Trials in Ayurveda, Siddha, Unani, Yoga and Naturopathy by Yenepoya Ethics Committee 2 (YEC 2) Members and the Secretariat

2. Scope

The scope of this SOP includes:

- Submission of study protocol and related documents for initial review of the protocol
- Resubmission of protocols
- Submission of protocol amendments
- Submission of written communications related to
- Continuing review of approved protocols
- Protocol completion or termination or status
- Protocol deviations/violation
- Serious adverse events initial report/follow up/final report

The protocols related to AYUSH drugs and methods of treatment studies and Yoga and Naturopathy systems will be reviewed.

3. Responsibility:

3.1 . YEC 2 Secretariat:

3.1.1 The YEC 2 Secretariat will be responsible for receiving the protocols and related documents submitted to the YEC 2.

3.1.2 At the time of submission, the secretariat will check the protocols for completeness as per the standard checklist (YEC2/Ann2A/SOP06/v2; YEC2/Ann2B/SOP06/v2) before accepting it.

3.1.3 The Secretariat will record the important details of submission in the entry log book which includes name, department and institution of the Principal Investigator, date of application, date of clearance from the Scientific Review Board (if applicable) and the date of submission to YEC 2.

3.1.4 The YEC 2 Secretariat will ask the Principal Investigator to submit the soft copy by email (after making modifications as advised by the scientific review board) to **yec2@yenepoya.edu.in**

3.1.5 The YEC 2 Secretariat will present the protocols to the YEC 2 Member-Secretary/Joint Secretary for categorization for initial review and allocation of reviewers.

3.1.6 YEC 2 Secretariat will distribute the protocols to the reviewers as identified by the Member-Secretary by email or hard copy (as applicable for individual reviewers).

3.1.7 YEC 2 Secretariat will receive the reviewers' response and act according to the report as follows:

3.1.7.1 If the reviewer suggests modifications in the protocol, the secretariat will, in consultation with the Member-Secretary, communicate the same with the investigator via email.

3.1.7.2 If the reviewer approves the protocol, the same will be communicated to the Member-Secretary.

3.1.8 YEC 2 Secretariat will enter the details of the protocol in the database of the YEC 2 Secretariat computer and update the details as the process of review is happening.

3.1.9 If the reviewer does not respond with the review report within 7 working days after sending the proposal for review, the Secretariat will send them a reminder.

3.2 The Member-Secretary:

3.2.1 Upon receiving the protocol for initial review, the Member-Secretary/Joint Secretary will allocate the primary and if necessary, the secondary reviewer based on the subject of research and the expertise of the reviewers

3.2.2 Upon receiving other protocols or related documents for review the Member-Secretary/Joint Secretary will be responsible for managing the reviews as per various SOP and the timeframes.

3.2.3 The Member-Secretary/Joint Secretary will be responsible for assigning the reviewers for each protocol

4. Detailed instructions:

4.1 Decision making and timing: When the Principal Investigator (PI) submits a research proposal to the YEC 2 Secretariat for review, the decision under any of the following sections will be taken within the specified time period:

4.1.1 New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols (and related documents):

4.1.1.1 In the case of regulated clinical trials, the protocol, complete in all documentation, *submitted at least four weeks* prior to the forthcoming YEC 2 meeting, will be reviewed and included for discussion under the category of full review. In the case of all other protocols classified for "full review" or "expedited review" or "exempt from review", completed documentation should be submitted at least 2 weeks prior to the date of the forthcoming YEC 2 meeting. The meeting dates for the calendar year will be put up on the website of the University (www.yenepoya.edu.in)

4.1.1.2 Submission of SAE (On-Site): The SAEs will be reviewed and forwarded to the SAE subcommittee on an urgent basis as per the timelines stated in YEC2/SOP09/v1 for initial and detailed reporting of SAE.

4.1.1.3 Resubmissions for full review: Resubmission documents which are for consideration at the full review of the YEC 2 meeting must be submitted to YEC 2 Secretariat, *at least 15 working days* prior to the date of the forthcoming meeting.

4.1.1.4 Other documents: All other communications to the YEC 2 that need to be tabled in the agenda should reach YEC 2 Secretariat, *at least 7 working days* prior to the date of the forthcoming meeting.

4.1.2 Initial review application:

4.1.2.1 Check for submission items: The Secretariat will check the hard and soft copies of the following items:

- One hard copy set of the research protocol (after making all the necessary changes as suggested by the respective scientific review boards) to be submitted to the YEC 2 secretariat.

- The soft copy of the research protocol (after making all the necessary changes as suggested by the respective scientific review boards) to be sent by email to **yec2@yenepoya.edu.in** from the email id of the principal investigator.
- A completely filled YEC 2 Project Submission Application Form for Initial Review (YEC2/Ann1A/SOP06/v2 for regulated clinical trials or YEC2/Ann1B/SOP06/v2 for non-regulated academic trials)
- The marked checklist (YEC2/Ann2A/SOP06/v2 in case of regulated clinical trials and YEC2/Ann2B/SOP06/v2 in case of non-regulated academic trials)
- Duty Delegation Log of the Study team (YEC2/Ann03/SOP06/v2)

4.1.2.2 Verify contents of the submitted documents:

The secretariat will use the checklist (YEC2/Ann2A or 2B/SOP06/v2) to confirm whether all the ticked documents are present in the application. The Secretariat will ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the YEC 2 to review). All the following documents must be in the file before it is sent out to the reviewers for ethical review:

- Covering letter to Member Secretary/Chairperson (A)
- Project submission application form for initial review (C)
- Protocol (A)
- Forwarding letter/acknowledgment from concerned scientific review board - A
- Amendments to protocol (if any suggested by the Scientific Review Board) (A)
- Informed consent document: In English and Kannada/Malayalam (if applicable), along with back translations in English (in case of regulated clinical trials). (A)
- Patient information sheet in English and Kannada/Malayalam (if applicable) along with back translations (in case of regulated clinical trials). (A)
- Translation and Back translation certificates (if applicable) (C)
- Amendments to the Informed consent form (if any) (A)
- Case record form (A)

- Recruitment procedures including advertisement, notices, letters to doctors, permission letters from hospital (if and whichever applicable) (C)
- Regulatory permissions (Central Council for Research in Ayurvedic Sciences, DCGI AYUSH Approval, etc; whenever applicable) (C)
- Undertaking to DCGI AYUSH (If applicable) (C)
- Administrative sanctions from the Head of the institution or MoU in case of studies involving collaborative work or in case of seeding samples to laboratories of other Centers or institutions (A)
- Ministry of External Affairs permission to send samples out of country (if applicable) (A)
- Curriculum vitae of all investigators (C)
- Training certificates [C, A(if applicable)]
- GCP training certificate of the PI (within last 3 years) (C)
- Certification in Research Methodology of the PI (C)
- List of on-going research projects undertaken by the Principal Investigator [C, A (if applicable)]
- Drug/device brochure (C)
- Details of funding and fund allocation [C, A (if applicable)]
- Clinical trial agreement with sponsors, investigators, and head of the institution (C)
- Insurance policy (policy details) of the participants indicating conditions of risk coverage, data of commencement and expiry of risk coverage. (C)as per category of risk involved in the study: Less than minimal risk, Minimal risk, Minor increaseover minimalrisk or Low risk and More thanminimal risk orHigh risk as per Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research 2017.
- Indemnity policy with details. (C)
- Ethics Committee clearance of other centers (if applicable) [C, A (if applicable)]
- Institutional Stem cell Research Committee approval (if applicable)

- Documentation of clinical trial registration (if available)
- Processing fee payment receipt (*See Guidelines for investigators)* (C)
- If the PI is not from Ayush fraternityin the traditional system, thenthe PI should undergo training to conduct the trial or have a Co-guide from Ayush fraternity .

.

Note: C = Regulated clinical trial; A = All others

4.1.2.3 Complete the submission process:

- The secretariat will check the submission checklist for completion
- Stamp the receiving date on the first page/last page of the covering letter and initial it.
- Make a photocopy of the completed document receipt form YEC2/Ann04/SOP06/v2 and return the original copy of the YEC2/Ann04/SOP06/v2 to the applicants for their records.
- Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
- Number the project file as **YEC2/ AYUSH /A**(or)**Y**(or)**U**(or)**S**(or)**H/YEAR/ NUMBER.** This number is quoted for all future communications concerning the protocol. (A= Ayurveda;Y=Yoga &Naturopathy's=Unani;S=Siddha:H=Homeopathy)

4.1.2.4 Dispatch and store received documents:

- The Secretariat will make photocopies of the protocols only if the reviewers assigned request for hard copies. Otherwise all the document communications will be done through the official email of YEC 2 ,**yec2@yenepoya.edu.in**
- The Secretariat will ensure the protocol attaches the checklist YEC2/Ann2A/SOP 06/v2 or YEC2/Ann2B/SOP06/v2.
- The secretariat will file all assessment forms as determined by the type of submission and type of review.
- The documents will be dispatched for review to the reviewers by email within 2 days of receiving the submission.

- The secretariat will follow the colour code for files for various types of research protocols

  Green for funded projects
  Yellow for dissertations and theses
  Blue for faculty project

4.1.3 Resubmission of protocol with corrections and amendment of protocols:

4.1.3.1 All resubmissions will be made as hard copy submitted to the YEC 2 Secretariat along with a covering letter and a soft copy which emailed to **yec2@yenepoya.edu.in**

4.1.3.2 The Secretariat will verify the completeness of the documents.

4.1.3.3 In case of minor changes/amendments, the same version is submitted with changes highlighted

4.1.3.4 In case of major changes or amendments, the resubmission is numbered as version 2 (written as v1 in the header).

4.1.3.5 The protocol related documents which do contain changes/amendments which are already submitted and approved by the YEC 2 are not required to be submitted again.

4.1.3.6 The secretariat will submit the documents to the Member-Secretary/Joint Secretary.

4.1.3.7 The Member-Secretary/Joint Secretary will decide the review process under which the resubmissions and amended protocols will be categorized.

4.1.3.8 The protocol management will follow the relevant SOPs depending on the type of review process

- Full review: YEC2/SOP7A/v2
- Expedited review: YEC2/SOP7B/v2

4.1.4 Annual continuing review of approved protocols, amended protocols and related documents/ study completion documents/termination reports, SAE reports, protocol deviation:

4.1.4.1 The YEC 2 will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

4.1.5 ***Processing Fees for YEC 2 review***

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

SNo	Category of review	Pharma industry sponsored Research	Govt. sponsored / NGO Research	Academic or Investigator initiated Research
1.	New study protocol	Rs. 25,000 /-	Rs. 25,000 /-	Nil
2.	Continuing review (per review)	Rs. 15,000 /-	Rs.10,000 /-	Nil
3.	Protocol Amendment (per amendment review) (if applicable)	Rs. 15,000 /-	Rs. 10,000 /-	Nil

5. Reference to other applicable SOPs and Annexures

5.1 YEC2/SOP06/v1: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

5.2 YEC2/SOP7A/v1: Full-Board Review of Research Study Protocols

5.3 YEC2/SOP09/v1: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

5.4 YEC2/SOP15/v1: Request for Waiver of Written Informed Consent and Waiver of

Consent YEC2/Ann1A/SOP06/v1: Project submission application form for initial review for drug trials and other regulatory studies (Industry and Government sponsored studies).

5.5 YEC2/Ann1B/SOP06/v1: Project submission application form for initial review for academic (non-regulatory) studies.

5.6 YEC2/Ann2A/SOP06/v1: Checklist protocol submission for initial review of regulated clinical trials

5.7 YEC2/Ann2B/SOP06/v1: Checklist protocol submission for initial review of academic (non-regulated) studies

5.8 YEC2/Ann03/SOP06/v1: Duty Delegation Log of Study team

5.9 YEC2/Ann04/SOP06/v1: Document Receipt Form

6. Declaration

The review process will comply with the guidelines mentioned in the Good clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medcine(GCP-ASU), Department of AYUSH, Ministry of Health & Family welfare, Government of India, March 2013(www.indianmedicine.nic.in) and Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (E 6 GCP R 1 - July 1996 ~ R 2 - June 2015) while conducting the research study.

7. Reference

1. General Guidelines For Drug Development Of Ayurvedic Formulations. Central Council for Research in Ayurvedic Sciences Ministry of Ayush, Government of India New Delhi. Guideline Series I, First edition2018
2. General Guidelines for Safety/Toxicity Evaluation OF Ayurvedic Formulations. Central Council for Research in Ayurvedic Sciences Ministry of Ayush,

Government of India New Delhi. Guideline Series II, First edition2018

3. General Guidelines for Clinical Evaluation of Ayurvedic Interventions. Central Council for Research in Ayurvedic Sciences Ministry of Ayush, Government of India New Delhi. Guideline Series III. First edition2018.
4. Good clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine(GCP-ASU), Department of AYUSH, Ministry of Health & Family welfare, Government of India, (https://ccras.nic.in/general-guideline-series/) accessed in 2024
5. National Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017),

8. Flowchart:

No.	Activity	Responsibility
1	Receive Submitted Packages	YEC 2 Secretariat
2	Initial Review Application	YEC 2 Secretariat
3	Resubmission of Protocols with Corrections	YEC 2 Secretariat
4	Protocol Amendments	YEC 2 Secretariat
5	Annual Continuing Review of Approved Protocols	YEC 2 Secretariat
6	Protocol Completion	YEC 2 Secretariat