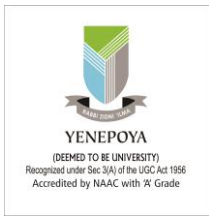


General instructions for protocol submission for ethical clearance

1. All applications must be signed by all investigators and other relevant authorities of the university as applicable.
2. Applications must be addressed to the Member Secretary, Yenepoya Ethics Committee 2.
3. If the study site is outside the University, permission letter of the concerned authorities also should be enclosed as annexure with the protocol.
4. Kindly submit a letter of acceptance from the respective Scientific Review Board (SRB) with the protocols.
5. Submit the protocol after making necessary changes as notified by the SRB.
6. All applications must be submitted as one print copy and one soft copy (sent through mail).
7. Only soft copy submission will not be accepted and incomplete forms will not be considered.
8. Applications received prior to fifteen days before the scheduled ethics committee meeting will be eligible to be heard.
9. Mention the Version Number on the right top corner of each page. For example: The first submission is Version 1, the first revised submission is Version 2, the second revision submission is Version 3 and so on.
10. It is the primary investigator's (PI) responsibility to submit the corrections advised within the stipulated time.
11. If required, the PI may be invited by the Secretary of YEC2, to clarify ethical doubts, either orally, or in writing or in the form of a presentation. In such an event, the PI personally has to make himself/ herself available for the clarifications. In the unusual event wherein the PI is unable to be present (genuine reason subject to discretion of the Member secretary), an alternative date can be suggested.
10. Six-monthly progress reports and study closure report are mandatory.



YENEPOYA ETHICS COMMITTEE 2

-2 Floor

Yenepoya Dental College

yec2@yenepoya.edu.in

Ext. Phone Number – 2063

11. Any change in the title, objectives, methodology and/or analysis requires reporting to the ethics committee, which will then decide on whether fresh application for ethical clearance is required.

12. Any study conducted on the employees, students and staff members of the university - the PI requires to submit YEC2/Ann 04 /SOP 19/v1.

13. Decisions on ethical waiver, expedited review or full review rest solely with YEC2. In case a PI seeks a Wavier of Consent, the PI can request the Ethics Committee for the same.

14. There will be on-site monitoring once in 6 months wherein Participant Information Sheet (PIS), Informed Consent (IC) and data collected will be scrutinized.

15. Record of acknowledgement (in the form of signature) of having given the PIS to study participant should be maintained by the investigator.

16. PIS and IC template should be strictly adhered to and it should be in accordance with the ICMR guidelines.

17. Any queries, Kindly contact:

Yenepoya Ethics Committee 2
Basement (-2 Floor)
Yenepoya Dental College
Yenepoya (Deemed to be University)
Extension Phone Number: 2063