

**YENEPLOYA ETHICS COMMITTEE 2**  
**Yenepoya (Deemed to be University)**  
**Floor -2(Basement), Yenepoya Dental College, Mangalore-575018**  
**yec2@yenepoya.edu.in,(0824)2206000- Extension Number - 2063**  
**DCGI Registration No.: ECR/1337/Inst/KA/2020**  
**DHR registration No.: EC/NEW/INST/2023/KA/0276**

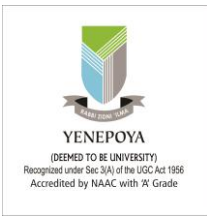
**YEC2/Ann2B/SOP06/v2**  
**Checklist for Protocol Submission to**  
**Yenepoya Ethics Committee 2 ethical clearance for clearance**

**Instructions to fill:**

- *Please fill out the soft copy of this form, print and take signatures, wherever applicable*
- *Incomplete files will not be accepted*
- *Write Not Applicable (NA) if question is not applicable for this study*
- *Do not leave any questions unanswered*
- *Strictly do not edit/delete the content or formatting of this form*
- *Write annexure numbers whenever documents are referred to in the application form*

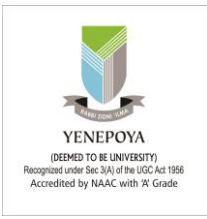
| No | Document   |                               |  |                               |     | Date of submission | Page no |
|----|--|-------------------------------|--|-------------------------------|-----|--------------------|---------|
| 1  | Letter to Member Secretary   | Guide signature               | Head of the department (HOD) signature | PI signature                  |     |                    |         |
|    |  |                               |  |                               |     |                    |         |
| 2  | Project & Proposal hard copy   | <b>Header of the protocol</b> | Y/N                                    | <b>Footer of the protocol</b> | Y/N |                    |         |
|    |  | Version number                |  | Page no                       |     |                    |         |
|    |  | Title                         |  | For example (1 of 30)         |     |                    |         |
|    |  | Date of submit the protocol   |  |                               |     |                    |         |
| 3  | Project & Proposal Soft copy<br><br>E-mail to <a href="mailto:yec2@yenepoya.edu.in">yec2@yenepoya.edu.in</a><br><i>(Please note that there should be no discrepancy between the hard copy and the soft copy submitted)</i> | <b>Header of the protocol</b> | Y/N                                    | <b>Footer of the protocol</b> | Y/N |                    |         |
|    |  | Version number                |  | Page no                       |     |                    |         |
|    |  | Title                         |  | For example (1 of 30)         |     |                    |         |
|    |  | Date of submit the protocol   |  |                               |     |                    |         |





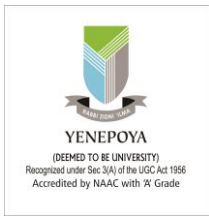
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|    |   |  |         |                               |         |                    |
|----|---|--|---------|-------------------------------|---------|--------------------|
| f. | <p>Type of study</p> <ol style="list-style-type: none"> <li>1. <b><u>Qualitative study</u></b> <ul style="list-style-type: none"> <li>• Experimental,</li> <li>• Quasi experimental study,</li> <li>• Survey study ,</li> <li>• Correlation study</li> </ul> </li> <li>2. <b><u>Quantitative study</u></b> <ul style="list-style-type: none"> <li>• Ethnography</li> <li>• Case study</li> <li>• Historical study</li> </ul> </li> <li>3. Descriptive study</li> <li>4. Cross Sectional</li> <li>5. Prospective study</li> <li>6. Retrospective</li> <li>7. Observation study</li> <li>8. Genetic study</li> <li>9. Document based study</li> <li>10. Intervention</li> <li>11. Epidemiological</li> </ol> <p>Any other specify,-----</p> <p><b>(Please write in the box)</b></p> |  |         |                               |         |                    |
| g) | <p>Description of the study<br/>(write here whatever applicable to your study )</p> <p>Randomized</p> <p>Open-labelled</p> <p>Questionnaire-based</p> <p>Double blinded</p> <p>Placebo controlled</p> <p>Treatment controlled</p> <p>Cross-over</p> <p>Parallel</p> <p>Interim Analysis</p> <p>Use of Tissue samples</p>  |  | Y/<br>N | If any other<br>(write here ) | Page no | Date of submission |



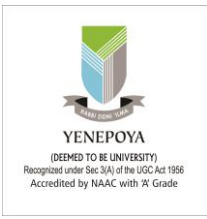
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|  |  |     |    |         |                    |
|--|--|-----|----|---------|--------------------|
|  | Use of Blood samples   |     |    |         |                    |
|  | Use of genetic material  |     |    |         |                    |
| h  | Detailed methodology   | YES | NO | Page No | Date of submission |
|  | i. Materials/Tools   |     |    |         |                    |
|  | ii. Study design   |     |    |         |                    |
| i  | Ethical Issues   | YES | NO |         |                    |
|  | a) Recruitment of participants will start only after the ethical clearance   |     |    |         |                    |
|  | b) Have you attached PIS   |     |    |         |                    |
|  | English /Kannada /Malayalam  |     |    |         |                    |
|  | c) Have you attached ICF   |     |    |         |                    |
|  | English /Kannada/Malayalam   |     |    |         |                    |
|  | d) In PIS and ICF how will you assess the comprehension to the participants (  |     |    |         |                    |
|  | e)Permission to use photographs /Samples   |     |    |         |                    |
|  | f)How the sample will be discarded   |     |    |         |                    |
|  | g) Risk/Benefit Analysis<br><br><b>Risk</b> , (mentioned 2points in each)<br><br>If Yes, How the risk will be addressed and by whom?<br><br><b>Benefit</b> (mentioned 2points in each) |     |    |         |                    |
| h) How will ensure privacy of the participants |  |     |    |         |                    |



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|   |   |              |    |                                      |                              |  |  |
|---|---|--------------|----|--------------------------------------|------------------------------|--|--|
|   | i) Maintenance of confidentiality of data   |              |    |                                      |                              |  |  |
|   | j) Sharing of samples/data                  |              |    |                                      |                              |  |  |
|   | k) Compensation to participants             |              |    |                                      |                              |  |  |
|   | l) Ensuring standard of care to participant |              |    |                                      |                              |  |  |
| J | Budget                                      |              |    | If applicable<br>(Write the details) | Not applicable               |  |  |
|   |   |              |    |                                      |                              |  |  |
| k | Gantt Chart                                 |              |    | Yes                                  | No                           |  |  |
|   |   |              |    |                                      |                              |  |  |
| l | Questionnaire                               | Yes          | No | No of Questions                      | Time                         | Validation<br>YES/<br>NO<br><br>If yes(A<br>ttach<br>valida<br>tion<br>certifi<br>cate |  |
|   |   |              |    |                                      |                              |  |  |
| m | Sample size                                 | No of sample |    | Reference article                    | Statistician approval letter |  |  |
|   |   |              |    |                                      |                              |  |  |



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| N | Inclusion criteria<br><br>(Please tick which applicable) | General population | Vulnerable population<br>( Pregnant women/ Children below 18 years/elderly/ Terminal Illness<br><br>• Annexure for research involving pregnant women available in website |  |  |
|---|--|--------------------|---|--|--|
|   |  |                    |   |  |  |
|   |  |                    |   |  |  |

**DECLARATION BY THE PG STUDENT AND THE GUIDE /PRINCIPAL INVESTIGATOR**

We hereby declare that the information given above is true and that we will comply with the all the stipulations/recommendations mentioned in the New Drugs and Clinical Trials Rules 2019, the current ICMR guidelines, any other recent notification/s from CDSCO (updated as applicable), the Indian GCP Guidelines and the Declaration of Helsinki, while conducting the research study.

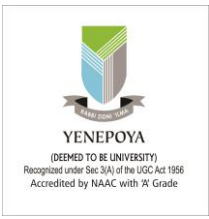
We hereby declare that neither the PI, nor the Co-PI, nor any other members of the research team are concurrently involved as research team members in a similar study or another study using the same set of participants, as this one.

We also ensure that the Principal Investigator/Institution (for non-funded studies) will pay for the expenses for the treatment and/or compensation of research-related injury, as deemed necessary by Yenepoya Ethics Committee 2

Signature/s of the Principal-investigators/Co investigator with date:

- 1.
- 2.
- 3.
- 4.
- 5.

Signature of Guide/Co guide with date:



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1.

2.

Signature of the Co-ordinator with date

1.

2.

Forwarded by Heads of Department(s)

Signature/s with date of Heads of Department(s):

Stamp/Seal of the Department(s)