**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 | **Header of the protocol** | | Y/N | **Footer of the protocol** | Y/N |  |  |
| Version number | |  | Page no  For example (1 of 30) |  |
| Title | |  |
| Date of submit the protocol | |  |
| 3 | Project &Proposal Soft copy  E-mail to [yec2@yenepoya.edu.in](mailto:yec2@yenepoya.edu.in) *(Please note that there should be no discrepancy between the hard copy and the soft copy submitted)* | **Header of the protocol** | | Y/N | **Footer of the protocol** | Y/N |  |  |
| Version number | |  | Page no  For example (1 of 30) |  |
| Title | |  |
| Date of submit  the protocol | |  |

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| 4. | Approval from SRB | Date of submit to SRB | | Date of approval from SRB with  SRB no | | SRB  corrections incorporated YES/NO  If yes, please mention page number and highlight. | | | |  | |  | |  |
|  | |  | |  | | | |  | |  | |  |
| 5 | Detailed protocol | | | | | | | | | | Page no | | Date of sub miss  ion | |
| a. | Title (write the title in the box) | |  | | | | | | | |  | |  | |
| b. | Study site | | Permission letter (If required )  Y/N | | | | | | | |  | |  | |
| c. | Source of data | |  | | | | | | | |  | |  | |
| d. | Sponsor  (Write the details of the sponsor if applicable ) | |  | | | | | | | |  | |  | |
| e. | Duration of the study | | 3  months | | 6  months | | 1yr | 2yr | More than  2 yr | |  | |  | |
|  | |  | |  |  |  | |

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| f. | Type of study  1. **Qualitative study**   * Experimental, * Quasi experimental study, * Survey study , * Correlation study   2. **Quantitative study**   * Ethnography * Case study * Historical study  1. Descriptive study 2. Cross Sectional 3. Prospective study 4. Retrospective 5. Observation study 6. Genetic study 7. Document based study 8. Intervention 9. Epidemiological   Any other specify,------------  (**Please write in the box**) |  | | |  | |  |
| g) | Description of the study  (write here whatever applicable to your study ) |  | Y/ N | If any other (write here  ) | Page no | Date of submiss ion | |
| Randomized |  |  |  | |
| Open-labelled |
| Questionnaire-based |
| Double blinded |
| Placebo controlled |
| Treatment controlled |
| Cross-over |
| Parallel |
| Interim Analysis |
| Use of Tissue samples |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 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  **Risk ,** (mentioned 2points in each)  If Yes, How the risk will be addressed and by whom?  **Benefit** (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 (Write the details | | | Not applic  able |  |  |
|  | | |  | | |  |
| k | Gantt Chart | | | Yes | | | No |  |
|  | | |  |
| l | Questionnaire | Yes | No | No of Questions | | T  i m e | Valid ation YES/ NO  If yes(A ttach valida tion certifi cate |  |  |
|  |  |  |  | |  |  |
| m | Sample size | No of sample | | Reference article | | Statistici an  approval letter | |  |  |
|  | |  | |  | |  |  |

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| --- | --- | --- | --- | --- | --- |
| N | Inclusion criteria  (Please tick which applicable) | General population | Vulnerable population  ( Pregnant women/ Children below 18 years/elderly/ Terminal Illness   * 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:

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)