**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 ofsubmission | Pageno |
| 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 noFor example (1 of 30) |  |
| Title |  |
| Date of submit the protocol |  |
| 3 | Project &Proposal Soft copyE-mail to 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 noFor example (1 of 30) |  |
| Title |  |
| Date of submitthe protocol |  |

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| 4. | Approval from SRB | Date of submit to SRB | Date of approval from SRB withSRB no | SRBcorrections incorporated YES/NOIf yes, please mention page number and highlight. |  |  |  |
|  |  |  |  |  |  |
| 5 | Detailed protocol | Page no | Date of sub mission |
| 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 | 3months | 6months | 1yr | 2yr | More than2 yr |  |  |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| f. | Type of study1. **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 ofsubmission |
| 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 theparticipants ( |  |  |  |  |
| 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 theparticipants |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | i) Maintenance of confidentialityof 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 applicable |  |  |
|  |  |  |
| k | Gantt Chart | Yes | No |  |
|  |  |
| l | Questionnaire | Yes | No | No of Questions | Ti m e | Valid ation YES/ NOIf yes(A ttach valida tion certifi cate |  |  |
|  |  |  |  |  |  |
| m | Sample size | No of sample | Reference article | Statistici anapproval letter |  |  |
|  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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)