**FORMAT FOR SUBMISSION OF PROJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF S-VYASA**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Title of the Study |  | | | |
| 2. Name of Investigators / co-Investigators with designation and division | Signatures | | | No. of Projects already with Investigator |
| 2.1 | 2.1 | | |  |
| 2.2 | 2.2 | | |  |
| 2.3 | 2.3 | | |  |
| 2.4 | 2.4 | | |  |
| 2.5  (Expand if there are more co-investigators) | 2.5 | | |  |
| 3. Objectives of the study | 3.1 | | | |
| 3.2 | | | |
| 3.3 | | | |
| 3.4 | | | |
| 3.5 | | | |
| 4. Justification for conduct of this study |  | | | |
| 5. Methodology | | | | |
| 5.1. SAMPLE SIZE and the BASIS  (Kindly indicate the relevant statistical assumptions and way in which the sample size has been obtained) |  | | | |
| 5.2. Inclusion criteria | a) | | | |
| b) | | | |
| c) | | | |
| d) | | | |
| 5.3. Exclusion criteria | a) | | | |
| b) | | | |
| c) | | | |
| d) | | | |
| 5.4. Control(s) |  | | | |
| 5.5. Study design |  | | | |
| 5.6. Assessment |  | | | |
| 5.7. Investigations related to projects |  | | | |
| 5.8 Permission to use copyrighted Questionnaire/proforma |  | | | |
| 5.9 Others |  | | | |
| 6.a.) Methods adopted for standardization of the proposed intervention/ treatment protocol |  | | | |
| 6.b.) Standard therapy/ Primary Intervention |  | | | |
| 7. Plans to withdraw standard therapy during conduct of research (Underline the option) | Yes/No  Remarks: | | | |
| 8. Plan for provision of coverage of medical risk (s) during the study period |  | | | |
| 9. How you will maintain confidentiality of subject? |  | | | |
| 10.a) Total Budget (Approx. in INR) |  | | | |
| 10.b) Who will bear the cost of investigation/drugs/intervention (Highlight the option) | 1. Subjects 2. Investigator 3. Private Funding  4. Other Agencies (Name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 11. Participant Informed Consent Form (Underline the options if you have attached) | * Attached English version * Attached Local language version * *Certified that Local language version is a true*   *translation of English version* | | | |
| 12. Conflict of interest for any other Investigator(s) (if yes, please explain in brief) | Yes/No | Explanation (if Yes) | | |
| 12.a) Is there a financial conflict of interest? |  |  | | |
| 12.b) I or my immediate family members own or control shares of the concerned company |  |  | | |
| 12.c) I or my immediate family members have a proprietary interest in the product that I have contracted to test |  |  | | |
| 12.d) I or my immediate family members have a financial interest in the sponsoring company or product being studied |  |  | | |
| 12.e) I or my immediate family members have received material/other benefit from the sponsoring company |  |  | | |
| 13. Has work on this project started? (Underline the option) | Yes/No  *(Please enclose a separate certificate to this effect).* | | | |
| 14. Attached documents (if any) (Underline the option) | 14.1 Covering letter, through proper channel. | | (Yes/No) | |
| 14.2 Copy of the detailed protocol is mandatory. | | (Yes/No) | |
| 14.3 Brief CV of all the Investigators (including No. of projects with Principal Investigator) | | (Yes/No) | |
| 14.4 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines | | (Yes/No) | |
| 14.5 In case of multicentre study, IEC clearance of other centres must be provided | | (Yes/No) | |
| 14.6 Definite undertaking as to who will bear the expenditure of injury related to the project | | (Yes/No) | |
| 14.7 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) | | (Yes/No) | |
| 14.8 Permission as mentioned in column 5.8 | | (Yes/No) | |
| 14.9 Certificate /undertaking as mentioned in column 13 | | (Yes/No) | |
| 14.10 Others | | (Yes/No) | |
| 15. In case of clinical trials CTRI status |  | | | |
| 16. Are Vulnerable subjects included? Please state Yes or No against Each item (Underline the option) | | | | |
| Pregnant women  Yes/No | Terminally ill  Yes/No | | | Special Groups  Yes/No |
| Children (below 18 years)  Yes/No | Seriously ill  Yes/No | | | Students  Yes/No |
| Elderly (60 years and above)  Yes/No | Service providers  Yes/No | | | Physically Challenged  Yes/No |
| Foetuses  Yes/No | Economically Backward  Yes/No | | | Captives  Yes/No |
| Prisoners  Yes/No | Socioeconomically disadvantaged individuals Yes/No | | | Institutionalized  Yes/No |
| Destitute  Yes/No | Mentally challenged  Yes/No | | | Armed Forces  Yes/No |
| Individuals with Cognitive or Intellectual Disabilities  Yes/No | Individuals with limited literacy or language proficiency  Yes/No | | | Ethnic or racial minorities  Yes/No |
| Refugees and Displaced Persons  Yes/No | Homeless Individuals  Yes/No | | | Communicable disorders  Yes/No |
| Sexual and Gender Minorities  Yes/No |  | | |  |
| Others (Specify) | | | | |
| **17. Has the study been reviewed by the (Comprehensive Project Evaluation Board) CPEB?** Yes/No (Underline the option) | | | | |
| **CPEB Number:** | | | | |
| **CPEB Risk Category:** | | | | |
| **18. Nature of the Project:** 1.BSc 2. MSc 3. PhD 4. MD 5. BNYS 6. Faculty Project  7. Funded Project (Underline the option) | | | | |