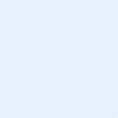
|  |  |
| --- | --- |
| **Logo of the Institute** | **(Annexure 8)**  **Application form for Clinical Trials**    ***(Name of the Institution)***  **EC Ref. No*.(****for office use):* |

|  |
| --- |
| Title of study:  Principal Investigator (Name, Designation and Affiliation) : |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. 1. | |  |  | | --- | --- | | Regulatory trial | Academic trial |  1. Type of clinical trial   CTRI registration number:       NABH accreditation number       EC registration number: |
| 1. 2. | If regulatory trial, provide status of CDSCO permission letter   |  | | --- | | Approved and letter attached | | Applied, under process | | Not applied (State reason) | |
| 1. 3. | Tick all categories that apply to your trial   |  |  |  |  | | --- | --- | --- | --- | | Phase - I |  | Phase II |  | | Phase III |  | Phase IV or Post Marketing Surveillance |  | | Investigational medicinal products |  | Investigational New drug |  | | Medical devices |  | New innovative procedure |  | | Drug/device combination |  | Bioavailability/Bioequivalence studies |  | | Non-drug intervention |  | Repurposing an existing intervention |  | | Indian system of medicine (AYUSH) |  | Stem cells |  | | Phytopharmaceutical drug |  | Approved drug for any new indication or new route of administration |  | | Others (specify) | | | | |
| 1. 4. | Trial design of the study (May choose more than one)   |  |  |  |  | | --- | --- | --- | --- | | Randomized |  | Factorial |  | | Non randomized |  | Stratified |  | | Parallel |  | Adaptive |  | | Cross-over |  | Comparison trial |  | | Cluster |  | Superiority trial |  | | Matched-pair |  | Non-inferiority trial |  | | Others (specify) |  | Equivalence trial |  |  1. If there is randomization, how will the participants be allocated to the control and study group(s)?      1. Describe the method of allocation concealment (blinding / masking), if applicable |
| 1. 5. | List the primary / secondary outcomes of the trial. |
| 1. 6. | Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any Other Agency such as public relation/Human resource? Yes  No  If yes, Name and Contact details:  State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)   |  |  |  |  | | --- | --- | --- | --- | | Project management |  | Clinical and medical monitoring |  | | Regulatory affairs |  | Data management |  | | Statistical support |  | Medical writing |  | | Site management |  | Audits, quality control, quality assurance |  | | Finance management |  | Recruitment and training |  | | Administrative support |  | Others (specify) |  | |  | | | | |
| 7. | Please provide the following details about the intervention being used in the protocol |
|  | I. Drug/s, device/s and/or biologics; If yes, provide regulatory approval details  Yes  No  NA |
|  | II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details Yes  No  NA |
|  | III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics |
|  | IV. Provide details of patent of the drug/s, device/s and biologics. |
| 8. | Describe in brief any preparatory work or site preparedness for the protocol? Yes  No NA  If yes, (100words) |
| 9. | Is there an initial screening/ use of existing database for participant selection? Yes  No  NA  If Yes, provide details*22* |
| 10. | Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address them. Yes No NA |
| 11. | Does the study use a placebo?  If yes, justify the use of the placebo and risks entailed to participants. Yes  No  NA |
| 12. | Will current standard of care be provided to the control arm in the study? Yes No  NA  If no, please justify. |
| 13. | Are there any plans to withdraw standard therapy during the study ?If yes, please justify.  Yes No  NA |
| 14. | Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes No  NA |
| 15. | Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes No |
| 16. | Participant Information Sheet(PIS) and Informed Consent Form (ICF)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | English |  | Local language  (Certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants) |  | Other*(Specify)* |  |   List the languages in which translations were done  Justify if translation not done  22In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same |
| 17. | Involvement/consultation of statistician in the study design Yes  No  NA |
| 18. | Is there any insurance coverage of the trial? If yes, provide details. Yes  No |
|  | i. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Please provide details. Yes  No    ii. Is the PI trained in GCP in last 3 years?. If yes, Please enclose certificate Yes  No |

Signature of PI: Click here to enter a date.