Annexure 6. Application Form for Clinical Trials

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number:
   NABH accreditation number EC registration number:

2. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached ☐
   Applied, under process ☐
   Not applied (State reason)

3.

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) ☐			

Tick all categories that apply to your trial

4. Trial design of the study (May choose more than one)

I.

Randomized	☐	Factorial	☐
Nonrandomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched pair	☐	Non-inferiority trial	☐
Others (specify)	☐	Equivalence trial	☐

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

III. Describe the method of allocation concealment (blinding / masking), if applicable

5. List the primary / secondary outcomes of the trial.

6. Is there a Contract Research Organization (CRO) /Site Management Organization (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)	☐

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, (100 words)

9. Is there an initial screening/ use of existing database for participant selection?
Yes ☐ No ☐ NA ☐
If Yes, provide details (*In order to select participants for your protocol 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)*

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 ☐

Does the study use a placebo?
If yes, justify the use of the placebo and risks entailed to participants.
Yes ☐ No ☐ NA ☐

Will current standard of care be provided to the control arm in the study?
Yes ☐ No ☐ NA ☐
If no, please justify.

Are there any plans to withdraw standard therapy during the study ?If yes, please justify.
Yes ☐ No ☐ NA ☐

Are there any rules to stop the protocol in case of any adverse events? If yes, please specify.
Yes☐ No☐ NA☐

Does the study have a Data and Safety Monitoring Plan? If no, please justify.

Yes☐ No☐

. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other *(Specify)* ☐

(Certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

List the languages in which translations were done

Justify if translation not done

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☐

19. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Please provide details.
Yes☐ No☐

20. 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.