Application Form for Clinical Trials

1. Title of the study……

   ……...
2. Principal investigator (Name, designation and affiliation) ……..

   ……...
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)			

4. Trial design of the study (can tick more than one)

Randomized	☐	Non-randomized	☐
Factorial	☐	Parallel	☐
Stratified	☐	Adaptive	☐
Cross-over	☐	Comparison Trial	☐
Cluster	☐	Superiority Trial	☐
Matched Pair	☐	Non-inferiority Trial	☐
Others (specify)	☐	Equivalence Trial	☐

- If there is randomization, how will the participants be allocated to the control and study group(s)?
  ……
  ……
  ……
  ……..
- Describe the method of allocation concealment (blinding / masking), if applicable
  ……
  …….

5. List the primary and secondary outcomes of the proposed 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)	☐

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; Yes / No/ NA

If yes, provide regulatory approval details …….

…….

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. Yes/ No/NA

If yes, provide details ……

……

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 details22 ……

……

……

10. Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? Yes/ No/NA

If yes, provide details of arrangements made to address them……

…….

……..

11. Does the study use a placebo? Yes/No/NA

If yes, justify the use of the placebo and risks entailed to participants……

……..

……..

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? Yes/No/NA

If yes, please justify……..

……..

……..

14. Are there any rules to stop the protocol in case of any adverse events? Yes/No/NA

If yes, please specify……
…….
…….

15. Does the study have a Data and Safety Monitoring Plan? Yes/No

If no, please justify ……
……
……

16. 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)

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? Yes/No/NA

If yes, provide details……
……...

(1) Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Yes/No

Please provide details……

(2) Is the PI trained in GCP in last 3 years? If yes, please enclose certificate Yes/No

Signature of PI