Annexure 2
AX 02/SOP 05-A/V 7
Application Form for Clinical Trial/Academic Clinical Trial

Study Title: .....

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Principal Investigator (Name, Designation & Affiliation): .....

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1. **Type of Clinical Trial** Regulatory Trial ☐ Academic Trial ☐

   CTRI Registration Number: .....

2. **If Regulatory Trial, provide status of CDSCO permission letter**

   Approved and letter attached ☐ Applied, under process ☐

   Not applied (State Reason) ☐

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)	☐	Others *(Specify)*	☐

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4. **Trial Design of the study**

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

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5. **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)*	☐

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6. 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 ……

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   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. ……

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   III. Provide contact details of who prepared and/or is manufacturing the drug/s, device/s and biologics.

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   IV. Provide details of patents of the drug/s, device/s and biologics.

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7. Justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

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8. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

   If No, please justify .....

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9. Justify any plans to withdraw standard therapy during the study. Yes ☐ No ☐ NA ☐

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10. Describe the rules to stop the protocol in case of any adverse events. Yes ☐ No ☐ NA ☐

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11. Provide details of Data and Safety Monitoring Plan. Yes ☐ No ☐

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Signature of Principal Investigator (PI) with Date: .....