# Annexure 2
# AX 02/SOP 05-A/V 7.1
# 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:** .....