# Annexure 2

(Annexure 8)

## Application Form for Clinical Trials

## INSTITUTIONAL ETHICS COMMITTEE (IEC)

**Seth GS Medical College and KEM Hospital, Mumbai.**

Project Registration No. .....

Title of study: .....

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

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

   CTRI registration number: .....  NABH accreditation 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

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

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

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

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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: .....

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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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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 ☐

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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. If yes, provide details. Yes ☐ No ☐ NA ☐

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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 patent of the drug/s, device/s and biologics.

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8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, (100words).....

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9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22].....

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10. Provide details of anticipated incidence, frequency and duration of adverse events related to the intervention.

If yes, what are the arrangements made to address them ? Yes ☐ No ☐ NA ☐

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

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

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

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

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[22] *In 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*

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)* ☐

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List the languages in which translations were done .....

Justify if translation not done.....

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17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Provide details of insurance coverage of trial Yes ☐ No ☐

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I. Medical Council of India (MCI) or the State Medical Council registration details of Principal Investigator

Yes ☐ No ☐

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II. GCP training in last 3 years by investigators. Please enclose PI certificate Yes ☐ No ☐

Signature of PI: ..... dd mm yy