



(Annexure 18)  
**Application Form for Clinical Trials**  
 Chennai Fertility Centre and Research Institute

IHEC Ref. No. (For office use): \_\_\_\_\_

Title of study: \_\_\_\_\_

\_\_\_\_\_

Principal Investigator (Name, Designation and Affiliation): \_\_\_\_\_

\_\_\_\_\_

1. Type of clinical trial                      Regulatory trial                       Academic trial   
 CTRI registration number: \_\_\_\_\_ NABH accreditation number: \_\_\_\_\_ IHEC 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                            | <input type="checkbox"/> | Phase II  | <input type="checkbox"/> |
| Phase III                          | <input type="checkbox"/> | Phase IV or Post Marketing Surveillance                             | <input type="checkbox"/> |
| Investigational medicinal products | <input type="checkbox"/> | Investigational New drug  | <input type="checkbox"/> |
| Medical devices                    | <input type="checkbox"/> | New innovative procedure  | <input type="checkbox"/> |
| Drug / device combination          | <input type="checkbox"/> | Bioavailability / Bioequivalence studies                            | <input type="checkbox"/> |
| Non-drug intervention              | <input type="checkbox"/> | Repurposing an existing intervention                                | <input type="checkbox"/> |
| Indian system of medicine (AYUSH)  | <input type="checkbox"/> | Stem cells  | <input type="checkbox"/> |
| Phytopharmaceutical drug           | <input type="checkbox"/> | Approved drug for any new indication or new route of administration | <input type="checkbox"/> |
| Others (specify)                   | <input type="checkbox"/> |   | <input type="checkbox"/> |

\_\_\_\_\_

4. Trial design of the study

- |                  |                          |                       |                          |
|------------------|--------------------------|-----------------------|--------------------------|
| I. Randomized    | <input type="checkbox"/> | Factorial             | <input type="checkbox"/> |
| Non randomized   | <input type="checkbox"/> | Stratified            | <input type="checkbox"/> |
| Parallel         | <input type="checkbox"/> | Adaptive              | <input type="checkbox"/> |
| Cross-over       | <input type="checkbox"/> | Comparison trial      | <input type="checkbox"/> |
| Cluster          | <input type="checkbox"/> | Superiority trial     | <input type="checkbox"/> |
| Matched-pair     | <input type="checkbox"/> | Non-inferiority trial | <input type="checkbox"/> |
| Others (specify) | <input type="checkbox"/> | Equivalence trial     | <input type="checkbox"/> |

\_\_\_\_\_

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.

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6. Is there a Contract Research Organization (CRO) / Site Management Organization (SMO) / Any other agency such as public relation / human resource?

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     | <input type="checkbox"/> | Clinical and medical monitoring            | <input type="checkbox"/> |
| Regulatory affairs     | <input type="checkbox"/> | Data management                            | <input type="checkbox"/> |
| Statistical support    | <input type="checkbox"/> | Medical writing                            | <input type="checkbox"/> |
| Site management        | <input type="checkbox"/> | Audits, quality control, quality assurance | <input type="checkbox"/> |
| Finance management     | <input type="checkbox"/> | Recruitment and training                   | <input type="checkbox"/> |
| Administrative support | <input type="checkbox"/> | Others (specify)                           | <input type="checkbox"/> |

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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. 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 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, provide details (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<sup>22</sup> \_\_\_\_\_

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10. Is 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. \_\_\_\_\_

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

If Yes, justify the use of the placebo and risks entailed to participants. \_\_\_\_\_

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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. Are there any plans to withdraw standard therapy during the study? Yes  No  NA

If yes, please justify. \_\_\_\_\_

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

If yes, please specify. \_\_\_\_\_

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

If no, please justify \_\_\_\_\_

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<sup>22</sup> 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.



## 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  
 Other (Specify)  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 ?

Yes  No

If yes, provide details. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

I. Is the PI registered with National Medical Council (NMC) or the State Medical Council registration? Yes  No

Please provide details. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

II. Is the PI trained in GCP in last 3 years?

Yes  No

If yes, Please enclose certificate \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of PI: \_\_\_\_\_

dd mm YYYY