(Annexure 8)

# Application Form for Clinical Trials

Institute Ethics Committee
Indian Institute of Technology, Delhi

**EC 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:..... EC 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) | ☐ | Stem cells | ☐ |
| Phytopharmaceutical drug | ☐ | Approved drug for any new indication | |
| Others (specify) | ☐ | or new route of administration | ☐ |

.....

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 | ☐ |

.....

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.

……

……

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: ……

……

……

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; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

……

……

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 ☐

……

……

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, provide details (100words)……

……

……

……

……

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

If Yes, provide details[22]

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

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? If yes, please justify. Yes ☐ No ☐ NA ☐

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

[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)* ☐

……

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? If yes, provide details. Yes ☐ No ☐

……

……

……

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

……

……

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: …… dd mm yy

(Annexure 9)

# Serious Adverse Event Reporting Format (Clinical trials)

Institute Ethics Committee
Indian Institute of Technology, Delhi

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

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

.....

.....

1. Participant details :

| Initials and Case No./ Subject ID | Age at the time of event | Gender | Weight:.....(Kgs) |
|---|---|---|---|
| ..... | ..... | Male ☐ | Height:..... (cms) |
| ..... | | Female ☐ | |

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd | mm | yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐ By Sponsor – Related ☐ Unrelated ☐ By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd | mm | yy Date of reporting: dd | mm | yy

5. Onset lag time after administration of intervention: ..... Location of SAE (Clinic/Ward/Home/Other) .....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd | mm | yy Stop date: dd | mm | yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd mm yy

.....

.....

II. Relevant test/laboratory data with dates: dd mm yy

.....

.....

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

.....

.....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

| | | | |
|---|---|---|---|
| Death | ☐ | Congenitial anomaly | ☐ |
| Life threatening | ☐ | Required intervention to prevent | |
| Hospitalization-initial or prolonged | ☐ | permanent impairment / damage | ☐ |
| Disability | ☐ | Others *(specify)* | ☐ |

.....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

| | | | |
|---|---|---|---|
| Fatal | ☐ | Recovered | ☐ |
| Continuing | ☐ | Unknown | ☐ |
| Recovering | ☐ | Other *(specify)* | ☐ |

.....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

.....

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