



(Annexure 9)
Application Form for Clinical Trials

Apollo Institute of Medical Sciences & Research, Chittoor Andhra Pradesh.517127

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 III

Investigational medicinal products

Medical devices

Drug/device combination

Non-drug intervention

Indian system of medicine (AYUSH)

Phytopharmaceutical drug

Others (specify)

Phase II

Phase IV or Post Marketing Surveillance

Investigational New drug

New innovative procedure

Bioavailability/Bioequivalence studies

Repurposing an existing intervention

Stem cells

Approved drug for any new indication or new route of administration

4. Trial design of the study

I. Randomized

Non randomized

Parallel

Cross-over

Cluster

Matched-pair

Others (specify)

Factorial

Stratified

Adaptive

Comparison trial

Superiority trial

Non-inferiority trial

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	<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"/>

.....

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 details²².....

.....
.....
.....

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?

If no, please justify. Yes No NA

.....
.....

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 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 and
Other(Specify) 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? 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