

**Annexure 04/SOP/06/V2.1**

**For Clinical Trials**

**(Additional information to be provided with application form)**

SMVMCH-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:

1. If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached Applied, under process

Not applied (state reason)

1. 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)

1. 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

1. If there is randomization, how will the participants be allocated to the control and study group(s)?
2. Describe the method of allocation concealment (blinding / masking), if applicable.
3. List the primary / secondatry outcomes of the trial.
4. 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 al 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)

1. Please provide the following details about the intervention being used in the protocol
2. Drug/s, device/s, and / or biologics; if yes, provide regulatory approval details. Yes No NA
3. Al ready 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
4. Provide contact details of who prepared and / or is manufacturing the drug/s, device/s and biologics.
5. Provide details of patent of the drug/s, device/s and biologics
6. Describe in brief any preparatory work or site preparedness for the protocol? Yes No NA

If yes, (100 words)

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

If Yes, provide details*(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)*

1. Provide details of anticipated incidence, frequency and duration of adverse events related to the intervention. Yes No NA

If yes, what are the arrangements made to address them ?

1. Justify the use of the placebo and risks entailed to participants. Yes No NA
2. Will current standard of care be provided to the control arm in the study? Yes No NA

If no, please justify.

1. Justify any plans to withdraw standard therapy during the study. Yes No NA
2. Describe the rules to stop the protocol in case of any adverse events. Yes No NA
3. Provide details of Data and Safety Monitoring Plan. Yes No
4. 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 don

1. Involvement/consultation of statistician in the study design Yes No NA
2. Provide details of insurance coverage of trial Yes No
3. Medical Council of India (MCI) or the State Medical Council registration details of Principal Investigator Yes No
4. Whether investigator has undergone GCP training? Yes No

If no, research work can be initiated only after submission of GCP training certificate.

Signature of PI with date: