Title: Management of Submission of Research Study Protocol and Study Related Documents

Note: Amended and approved on 23.04.2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the SMVMCH-EC manages protocol and other document submission.

2. Scope

The scope of this SOP includes:

- Submission of Research Project and related documents for Initial Review of the Protocol
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to
  - Continuing Review of Approved Protocols
  - Protocol completion/Termination
  - Protocol deviations/violation
  - SAE initial/ follow up/ final reports
  - Submission of Protocol deviations, Protocol violations

3. Responsibility

It is the responsibility of the EC Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the appropriate member of the EC and ensure that the communication reaches the concerned recipient.

4. Detailed Instructions

4.1 Receive study protocols/ documents

The Principal Investigator (PI) will submit a research proposal to the EC office for review and decision under any of the following 5 sections within the specified time period:

- *New Proposals for Initial Review/ Re-submission of Protocols with Corrections/ Amended Protocols and related documents:*

  Projects should be submitted on the 20th of the month for consideration in the next monthly meeting of the EC. (This date can be as per individual EC's policy).

  Submission of SAE (On-Site): As per the timelines stated in SOP 9/V2 for initial and detailed reporting of SAE.

- All other documents for consideration at the full board meeting (except those related to participant safety, which may be submitted any time) must be submitted at least 72 hours in advance of the meeting to be considered in the next meeting agenda.

4.2 Initial Review Application

- *Check for submission items:* The Secretariat will check the hard and soft copies of the following items: (Two sets - one original and one set of xerox copy and labeled CD or pen drive containing the soft copy)

1. Covering letter addressed to Chairman of EC (*AX 01/SOP 06/V2.1)*
2. Checklist of proposal submission to the EC (*AX 02/SOP 06/ V2.1)*
3. Research Project Application Form for Initial Review by SMVMCH-EC (*AX 03/SOP 06/ V2.1*
4. Proposal and related documents like proforma / Questionnaire / Investigator brochure / advertisement (as per the research committee format)
5. Additional information to be provided with application form for Clinical trials (*AX 04/SOP 06/ V2.1)*
6. Additional information to be provided with application form for human genetics testing research (*AX 05/SOP 06/ V2.1)*
7. Additional information to be provided with application form for socio behavioral and public health research (*AX 06/SOP 06/ V2.1)*
8. Curriculum Vitae for investigators to be attached with application form (only for clinical trials) (*AX 07/SOP 06/ V2.1)*

9. GCP training of investigator (only for clinical trials)
10. Research Committee comments & response template
11. Research Committee Approval letter

- *Verify contents of Submitted Documents:* The Secretariat will:
  - Use the checklist (*AX 02/SOP 06/V2)* to confirm whether all the ticked documents are there in the application
  - The Secretariat will then ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the EC to review). All the following documents must be in the docket
    - Cover letter
    - Research project submission application form for initial review by SMVMCH - EC
    - Additional information to be provided with application form for clinical trials
    - Additional information to be provided with application form for human genetics testing research
    - Additional information to be provided with application form for socio behavioral and public health research
    - Brief CV of all Investigators (for clinical trials)
    - Good Clinical Practice (GCP) training of investigators (for clinical trials)
    - Research Committee comments and response template
    - Research Committee approval letter
    - EC clearance of other centers (for multicentric research)
    - Agreement between collaborating partners (for multicentric research)
    - MTA between collaborating partners (for multicentric research)
    - Insurance policy/certificate (if applicable)
    - Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification

- Copy of contract or agreement signed with the sponsor or donor agency (if applicable)
- Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol (if applicable)
- Copy of the detailed protocol (section A – C)
- Investigators Brochure (If applicable for drug/biologicals/device trials)
- Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) (if applicable)
- Assent form for minors (12-18 years) (English and Translated) (if applicable)
- Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated) (if applicable)
- Advertisement/material to recruit participants (fliers, posters etc) (if applicable)
- Permission from following governing authorities (if required)
    - CTRI
    - DCGI
    - HMSC
    - NAC-SCRT
    - ICSCR
    - RCGM
    - GEAC
    - BARC
    - Tribal Board

CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee;NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC-Bhabha Atomic Research Centre

- **Complete the submission process:** The Secretariat will:
  - Complete the checklist of submission
  - Stamp the receiving date on the first page/last page of the covering letter and initial it.
  - Make a photocopy of the completed document receipt form *AX 04/SOP 06/V2* and return the original copy of the *AX 04/SOP 06/V2* to the applicants for their records.
  - Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
  - Number the project file as SMVMCH – EC No: Number (00)/ year (0000)
- *Dispatch and Store the received Documents:* The Secretariat will

o Prepare 2 sets of a protocol package containing completed application form, protocol related documents along with checklist and send 1 set to the EC members along with a copy of Project Assessment Form for Initial Review *AX 02/SOP 07A/V2* after the last day of submission is over, ensuring at least 15 days for review before the next meeting *(if applicable)*.

- Store the appropriately labeled original protocol documents in the designated storage area in the EC office.
- If the EC members prefer to receive and review soft copies, these are sent in a CD/pen drive along with a copy of Project Assessment Form for Initial Review *AX 02/SOP 7A/V2* after the last day of submission is over, ensuring at least 15 days for review before the next meeting.

4.3 Resubmission of Protocols with corrections and Amendments of protocol/ related documents

- For resubmitted protocol, the PI will submit one soft copy and one hard copy of the amended Protocol and related documents (as per SOP 09/V2).
- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment.

- The protocol related documents which do not require to be changed and are already submitted for the EC office during initial review are not required to be submitted again. *(EC can decide as per policy)*
- The Secretariat will present the docket to the Member Secretary
- The Member Secretary (MS) will decide
  a. if it is a resubmitted protocol it will follow all steps as per Section 4.5 of SOP 7A/V2 (Initial review)
  b. if it is an resubmitted protocol based on query response, the Member Secretary will handle it as decided in the meeting (e.g. Carry out review by one or more member(s) selected by the Chairman. The selected members are normally those who reviewed and recommended the previous version of that protocol or keep on full board agenda)

4.4 Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations

The EC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, Study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

4.5 Processing Fees for EC review

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non-refundable are as given in the following table:

S. No	Category of review	Pharma industry sponsored research	Govt. sponsored / NGO research	Academic or investigator initiated research
1.	New study protocol	Rs. xxxx/-	Rs. xx /-	Rs. xx /-
2.	Continuing review (per review)	Rs. xxxx/-	Rs. xx /-	-
3.	Protocol Amendment (per	Rs. xxxx/-	Rs. xx /-	-

	amendment review) (if applicable)			
4.	Providing one photocopy of submitted study documents lost by the investigator amount for 10 pages document, over 10 pages, Rs. 1 per page)	Rs. xxxx/-	Rs. xx /-	Rs. xx /-

5. Reference to other applicable SOPs

SOP 7A/V2: Full-Board Review of Research Study Protocols

SOP 09/V2: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

SOP15/V2: Request for Waiver of Written Informed Consent and Waiver of Consent

6. Annexures

Annexure 1- Covering letter addressed to Chairman of EC (*AX 01/SOP 06/ V2.1)*

Annexure 2 – Checklist for proposal submission to the EC (*AX 02/SOP 06/ V2.1)*

Annexure 3 – Research project application form for initial review by SMVMCH – EC *(AX 03/SOP 06/ V2.1)*

Annexure 4 – Additional information to be provided with application form for clinical trials (*AX 04/SOP 06/ V2.1)*

Annexure 5 – Additional information to be provided with application form for human genetics testing research *(AX 05/SOP 06/ V2.1)*

Annexure 6 – Additional information to be provided with application form for socio-behavioural and public health research (*AX 06/SOP 06/ V2.1)*

Annexure 7 – Format for curriculum vitae for investigator to be attached with application form (for only clinical trials) (*AX 07/SOP 06/ V2.1)*

Annexure 1: AX 01/SOP 06/V2.1

Covering letter

To

Date:

The Chairman
SMVMCH-EC (Human Studies)
Sri Manakula Vinyagar Medical College and Hospital
Puducherry.

(Through Head of the Department)

Sir,

Please find attached the research proposal titled " " for review by the Institutional Ethics Committee of Sri Manakula Vinyagar Medical College and Hospital, Puducherry

Thanking you,

Signature :
Name :
Academic Position :
Department :
E-mail ID :
Mobile number :

Outward: SMVMCH/Dept. of _____/CL-EC/ /20 Date:

Forwarded
Signature
Head of the Department

Annexure 2: AX 02/SOP 06/V2.1

Checklist for proposal submission to the Ethics Committee

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter					
2.	Application form for initial review by SMVMCH-EC					
3.	Additional information to be provided with application form for clinical trials					
4.	Additional information to be provided with application form for human genetics testing research					
5.	Additional information to be provided with application form for socio-behavioral and public health research					
6.	Brief CV of all Investigators*					
7.	Good Clinical Practice (GCP) training of investigators*					
8.	Research Committee comments and response template					
9.	Research Committee approval letter					
10.	EC clearance of other centers**					
11.	Agreement between collaborating partners**					
12.	MTA between collaborating partners**					
13.	Insurance policy/certificate					
14.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification					
15.	Copy of contract or agreement signed with the sponsor or donor agency					
16.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol					
PROPOSAL RELATED						
17.	Copy of the detailed protocol (section A – C)					
18.	Investigators Brochure (If applicable for drug/biologicals/device trials)					
19.	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)					
20.	Assent form for minors (12-18 years) (English and Translated)					
21.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated)					
22.	Advertisement/material to recruit participants (fliers, posters etc)					

** Incase of Clinical trial* ***For multicentric research.*

MTA-Material transfer agreement;

PERMISSION FROM GOVERNING AUTHORITIES						
	Other permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
23.	CTRI					
24.	DCGI					
25.	HMSC					
26.	NAC-SCRT					
27.	ICSCR					
28.	RCGM					
29.	GEAC					
30.	BARC					
31.	Tribal Board					
32.	Others (Specify)					

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
33.						
34.						

CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee;
NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR- Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

SMVMCH – EC Office use

Risk categorization

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

Type of review:

1. Exempt review ☐ 2. Expedited review ☐ 3. Full board review ☐

Primary reviewer:

Remarks

Signature of
Member Secretary / Asst. Member Secretary

Signature of
Chairman

Annexure – 03/SOP-06/V2.1

Research Project Application Form for Initial Review by SMVMCH – Ethics Committee

SMVMCH-EC Ref. No. (for office use) :

General Instructions:

a. Tick one or more as applicable. Mark NA if not applicable
b. Attach
c. additional sheets if required
d. May select more than one option

SECTION A – BASIC INFORMATION

1. ADMINISTRATIVE DETAILS
   a. Name of Principal Investigator:
   b. Department/Division:
   c. Date of submission:
   d. Type of review requested :

   (*Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review)*

   Exemption from review ☐ Expedited review ☐ Full committee review ☐

   e. Title of the study:

   f. Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication (E-mail ID & Mobile No)
Principal Investigator/Guide			
Co-investigator/student/fellow			

   g. Number of studies where applicant is a:
      i. Principal Investigator at time of submission
      ii. Co Principal Investigator at time of submission

h. Duration of the study:

2. FUNDING DETAILS AND BUDGET
   a. Total estimated budget for site :
   b. Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH
   a. Lay summary (*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it)* (within 300 words):

b. Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐	Biological samples	☐	Systematic Review	☐
Quantitative	☐	Mixed Method	☐	Any others *(Specify)*	☐

4. METHODOLOGY

a. Sample size/ number of participants *(as applicable)*

.....

.....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .

b. Is there an external laboratory/outsourcing involved for investigations? Yes☐ No☐ NA☐
(*If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU)*

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a. Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable persons/ Special groups ☐

Others ☐ (Specify).....

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)*.....

b. (i) Will there be vulnerable persons / special groups involved ? Yes☐ No☐ NA☐

(ii) If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐
Differently abled (Mental/Physical) ☐
Elderly ☐
Economically and socially disadvantaged ☐
Terminally ill (stigmatized or rare diseases) ☐
Pregnant or lactating women ☐
Employees/Students/Nurses/Staff ☐
Institutionalized ☐
Refugees/Migrants/Homeless ☐

Any other *(Specify)*:.....

(iii) Provide justification for inclusion/exclusion

(iv) Are there any additional safeguards to protect research participants?

c. Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐

d. Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐

e. Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Yes ☐ No☐

If yes, Monetary ☐ Non-monetary ☐

6. BENEFITS AND RISKS

(i) Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk:

(For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1)

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

(ii) Describe the risk management strategy:

a. What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks

b. Are adverse events expected in the study? Yes ☐ No ☐ NA ☐

(The term adverse events in this regard encompass both serious and non-serious adverse events)

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify

7. INFORMED CONSENT

a. Consent planned for :

Waiver of consent ☐ Informed Witnessed consent ☐

Consent from LAR (If so, specify from whom) ☐ For children<7 yrs parental/LAR consent ☐ Verbal assent from minor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Audio-Video (AV) consent (required for regulatory clinical trials involving vulnerable population) ☐

Other ☐

If waiver of consent requested for, then specify the reason (tick the box)

1. Research on publicly available information/ Documents/ Records/ Works/ Performances/ Reviews/ Quality assurance studies/ Archival materials or third- party interviews ☐
2. Research on anonymised biological samples from deceased individuals/ Left over samples after clinical investigation/ Cell lines or cell free derivatives like viral isolates/ DNA or RNA from recognized institutions or qualified investigators/ Samples or data from repositories or registries etc. ☐
3. Emergency situations - Epidemic/ Outbreak ☐

b. Who will obtain the informed witnessed consent?

PI ☐

CO PI ☐

c. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐

(Specify).....

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

If translation has not been done, please justify.....

d. Provide details of consent requirements for previously stored samples if used in the study? (*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8)*

e. Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Right to withdraw research ☐	Storage of samples ☐	Statement that study involves ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Sponsor contact information ☐
Others(Specify) ☐		

8. PAYMENT/COMPENSATION

a. Who will bear the costs related to participation and procedures? (*Enclose undertaking from PI confirming the same)*

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ (specify)

b. Is there a provision for free treatment of research related injuries? Yes ☐ No ☐

If yes, then who will provide the treatment?

c. Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐

Sponsor ☐ Institutional corpus fund ☐ Project grant ☐ Insurance ☐

d. Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐

9. STORAGE AND CONFIDENTIALITY

a. Identifying Information: Study Involves samples/data *(specify)*:

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐

Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

b. Who will be maintaining the data pertaining to the study?

c. Where will the data be analyzed and by whom? (*For example, a data entry room, a protected computer etc)*

d. For how long will the data be stored?

e. Do you propose to use stored samples/data in future studies? Yes☐ No☐ Maybe ☐
If yes, explain how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a. Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐

b. Will you inform participants about the results of the study? Yes ☐ No ☐

c. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐No☐ NA ☐

d. Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes☐ No ☐

e. Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details
Yes ☐ No☐

f. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)

- ☐ I/We certify that the information provided in this application is complete and correct.
- ☐ I/We confirm that all investigators have approved the submitted version of proposal/related documents.
- ☐ I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guide-lines.
- ☐ I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
- ☐ I/We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
- ☐ I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
- ☐ I/We declare that the expenditure in case of injury related to the study will be taken care of.
- ☐ I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
- ☐ I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
- ☐ I/We confirm that we will maintain accurate and complete records of all aspects of the study.
- ☐ I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
- ☐ I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
- ☐ I/We have the following conflict of interest (PI/Co-PI):

.....

.....

Name & Signature of PI with date

Name & Signature of Co-PI with date

Name & Signature of Co-PI with date

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:
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)	☐

4. 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	☐

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

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

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

6. 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	☐	linical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	ecruitment and training	☐
Administrative support	☐	Others (specify)	☐

7. Please provide the following details about the intervention being used in the protocol
a. Drug/s, device/s, and / or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐A ☐ ☐

b. 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 ☐A ☐ ☐

c. Provide contact details of who prepared and / or is manufacturing the drug/s, device/s and biologics.

d. 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 ☐A ☐ ☐
If yes, (100 words)

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

10. 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 ?

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

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

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

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 don

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

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

I. Medical Council of India (MCI) or the State Medical Council registration details of Principal Investigator ☐ Yes☐
No

II. 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:

Annexure 05/SOP-06/V2.1

For Human Genetics Testing Research

(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. Describe the nature of genetic testing research being conducted.
   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Explain the additional safeguards provided to maintain confidentiality of data generated.

3. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes☐ No☐ NA☐
4. If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

5. Is there involvement of secondary participants? Yes☐No☐NA ☐
   If yes, will informed consent be obtained? State reasons if not.

6. What measures are taken to minimize/mitigate/eliminate conflict of interest? Yes☐No☐NA ☐

7. Is there a plan for future use of stored samples for research? Yes☐ No☐
   If yes, has this been addressed in the informed consent ?
8. Is the study a gene therapy trial? If yes, is there approval from local EC and DBT (*Department of Biotechnology)*? Yes☐No☐

Signature of PI with date:

Annexure 06/SOP-06/V2.1

For Socio-Behavioral and Public Health Research

(Additional info to be provided with application form)

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Data Collection method used in the study

   Focus group ☐ Questionnaire/ Survey ☐ Observation ☐
   Interviews ☐ Documents and records ☐ Ethnographies / oral history/ case studies ☐
   Other (specify) ☐

   If it is an interview, will there be audio-video recording of participants interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

2. Type of informed consent used in the study.

   Individual consent ☐ Gate-keeper consent ☐ Community consent ☐
   Others ☐ (specify)_____

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

4. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified. (e.g.: suicide or infanticide) Yes ☐ No ☐ NA ☐

5. Are cultural norms / Social considerations / Sensitivities taken into account while designing the study and participants recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

8. I. Type of risk related to procedures involved in the study

   Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

   Describe the risk minimization strategies.

   II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

III. Describe how do societal benefits outweigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale deception. Yes ☐ No ☐

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI with date:

Annexure 07/SOP-6/V2.1

Format for Curriculum Vitae for investigators
(To be attached with application form for only clinical trials)

SMVMCH-EC Ref. No. (for office use) :

Name:

Present affiliation (Job title, department and organization)

Address (full work address):

Telephone number: Email address:

Qualifications:

Professional registration (Name of body, registration number and date of registration):

Relevant research training / experience in conduct of clinical trials:

Relevant publications (Clinical trials)

Signature with date

7. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	EC Secretariat
2	Initial Review Application	EC Secretariat
3	Resubmission of Protocols with Corrections	EC Secretariat
4	Protocol Amendments	EC Secretariat
5	Annual Continuing Review of Approved Protocols	EC Secretariat
6	Protocol Completion	EC Secretariat

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/

	Name	Designation	Signature
Prepared	Dr. Vimal. M	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. R. N. Kagne	Member Secretary	
	Dr. Amol Dongre	Member	23/9/19
Approved	Dr. T. Thiagarajan	Chairman	23/09/2019
Issued	Dr. D. Rajagovindan	Director, SMVMCH	