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

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

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 the research proposal to the EC office for review and decision under any of the following sections within the specified time period:

- *New Proposals for Initial Review*

- *Re-submission of Protocols with Corrections*
- *Amended Protocols and related documents*
- *Submission of SAE (On-Site):* As per the timelines stated in SOP 9/V4 for initial and detailed reporting of SAE.

All the documents for consideration at the full board meeting (expect 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 as a PDF file)

- Cover letter addressed to secretariat of the EC (AX01/SOP 06/V4)
- Check list for proposal submission to the EC (AX02/SOP 06/V4)
- Research project submission application form for initial review by SMVMCH – EC (AX03/SOP 06/V4)
- Additional information to be provided with application form for clinical trials (AX04/SOP 06/V4)
- Additional information to be provided with application form for human genetics testing research (AX05/SOP 06/V4)
- Additional information to be provided with application form for socio behavioral and public health research (AX06/SOP 06/V4)
- Brief CV of all Investigators (for clinical trials) (AX07/SOP 06/V4)
- 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 multi centric research)
- Agreement between collaborating partners (for multi centric research)
- MTA (Material Transfer Agreement) between collaborating partners (for multi centric research)
- Insurance policy/certificate (if applicable)

- Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification (if applicable)
- Copy of contract or agreement signed with the sponsor or donor agency (if applicable)
- 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 as per EC template (AX08/SOP 06/V4)
- Investigators Brochure (If applicable for drug/biologicals/device trials)
- Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated) (if applicable)
- Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) (if applicable) (AX 09/SOP06/V4)
- Assent form for minors (12-18 years) (English and Translated) (if applicable) (AX 10/SOP06/V4)
- Advertisement/material to recruit participants (fliers, posters etc) (if applicable)
- Permission from governing authorities (if required)

Verify contents of Submitted Documents: The Secretariat will:

- Use the checklist (*AX 02/SOP 06/V4)* 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).

Complete the submission process: The Secretariat will:

- Verify the checklist of submission
- Stamp the SMVMCH-EC logo and receiving date on the first page of the covering letter.
- 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

- Prepare 2 sets of a protocol package containing completed application form, protocol related documents along with checklist and send 1 set to the primary reviewers along with a copy of Study Assessment Form for Initial Review *AX 02/SOP 07A/V4* after the last day of submission is over, ensuring at least 10 days for review before the next meeting. The soft copy will be emailed to all the EC members within the same time frame.
- Store the appropriately labeled original protocol documents in the designated storage area in the EC office.

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/V4).
- 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/V4 (Initial review)

  b. If it is a 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 Proposal review fee for regulatory studies

- The EC will charge the following fees for initial and continuing review of PHARMA sponsored research projects (regulatory clinical trials).

Type of Review	Fee
Initial Review	Rs. 50,000
Continuing Review	Rs. 25,000

- No fees will be charged for initial or continuing review of academic clinical trials and observational studies undertaken by faculties, postgraduate and undergraduate students of SMVMCH.

5. Reference to other applicable SOPs

SOP 7A/V4: Full-Board Review of Research Study Protocols

SOP 09/V4: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

SOP15/V4: 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/ V4)*

Annexure 2 – Checklist for proposal submission to the EC (*AX 02/SOP 06/ V4)*

Annexure 3 – Research project application form for initial review by SMVMCH –

EC *(AX 03/SOP 06/ V4)*

Annexure 4 – Additional information to be provided with application form for clinical trials (*AX 04/SOP 06/ V4)*

Annexure 5 – Additional information to be provided with application form for human genetics testing research *(AX 05/SOP 06/ V4)*

Annexure 6 – Additional information to be provided with application form for socio-behavioural and public health research (*AX 06/SOP 06/ V4)*

Annexure 7 – Format for curriculum vitae for investigator to be attached with application form (for only clinical trials) (*AX 07/SOP 06/ V4)*

Annexure 8 – Research protocol submission format (*AX 08/SOP 06/ V4)*

Annexure 9 – Template for participant information sheet (PIS) and participant informed consent form (ICF) (*AX 09/SOP 06/ V4)*

Annexure 10 – Template for assent form (*AX 10/SOP 06/ V4)*

Annexure 1: AX 01/SOP 06/V4
Covering letter

To

Date:

The Secretariat
SMVMCH-EC (Human Studies)
Sri Manakula Vinyagar Medical College and Hospital
Puducherry.
(Through Head of the Department)

Sir / Madam,

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

Submission type :

New proposal for initial review	☐	
Re-submission of protocol with corrections	☐	
Amended protocol	☐	
Continuing review of approved protocols	☐	
Study completion / termination report	☐	
Protocol deviation / violation	☐	
SAE initial/ follow up / final report	☐	
Any other	☐	(Specify:)

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/V4

Checklist for proposal submission to the Ethics Committee

S. No	Items	Yes	No	NA	Page 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.	Request for exempt from review / expedited review					
7.	Brief CV of all Investigators*					
8.	Good Clinical Practice (GCP) training of investigators*					
9.	Research Committee comments and response template					
10.	Research Committee approval letter					
11.	Declaration from guide for PG thesis & UG studies					
12.	EC clearance of other centers**					
13.	Agreement between collaborating partners**					
14.	MTA between collaborating partners**					
15.	Insurance policy/certificate					
16.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification					
17.	Copy of contract or agreement signed with the sponsor or donor agency					
18.	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						
19.	Copy of the detailed protocol as per EC template					
20.	Investigators Brochure (If applicable for drug/biologicals/device trials)					
21.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated)					
22.	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)					
23.	Assent form for minors (12-18 years) (English and Translated)					
24.	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**
25.	CTRI					
26.	DCGI					
27.	Others (Specify)					
ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.						
29.						

CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India

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For SMVMCH – EC Office use only

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:

Signature of
Member Secretary / Asst. Member Secretary

Signature of
Chairman

Annexure – 03/SOP-06/V4

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 ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally ill (stigmatized or rare diseases) ☐

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 ☐	Storage of samples ☐	Statement that study involves research ☐
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/V4

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/V4

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/V4

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/V4

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

Annexure 08/SOP-6/V4

Research protocol submission format to the SMVMCH-EC

Version Number: **Date:**

1. **Title of the Study** :
2. **Introduction:** (Need for the present study)
3. **Objectives:** (Primary and secondary)
4. **Review of literature:** (Study by study review from past to present)

   Gaps in the literature, which the present study is going to address or specify the novelty, the present research
5. **Material and Methods:**

   Setting:

   Study design:

   Study participants:

   Study duration:

   Sample size:

   Sampling: (Sampling procedure, Inclusion\Exclusion Criteria, Blinding & Randomization)

   Data collection procedure: (Questionnaire\Data collection proforma\ Details of measurement\Biological sample collection)

List of variables	Measurement plan

Anticipated Biases in the study	Plan to address the anticipated biases

Analysis plan: (Details on data entry and storage, Use of software - Name & Version)

Variable	Name of variables	Analysis plan

6. **Implications of the study**
7. **Gantt chart:**
8. **Acknowledgements (if any):**
   We acknowledge the Epidemiology Unit of Department of Community Medicine for their technical support

Annexure 9: AX 02/SOP 06/V4

Template for Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)

Informed Consent Document: Part I – Participant Information Sheet (PIS)
Version Number: **Date:**

[Instructions – This information sheet should address the participant of this study. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While preparing the PIS, the investigator must ensure that the information provided is in a simple and unambiguous language (avoid medical jargons) which can be understood by the participant. Please avoid copying & pasting from PIS of other study protocols.

Study title: .....

Dear Participant,

You are invited to take part in a research study. Before you participate in this study, it is important for you to understand why this is being carried out. If you have any doubts regarding the procedure and purpose of the study or if you want more information, you are free to ask the contact person mentioned below.

1. What is the purpose of the study?

2. Why have you been chosen?

3. Do you have to take part?

4. What will happen to you if you take part?

5. What is the duration of the study and the expected number of participants?

6. What do you have to do?

7. What is the procedure or drug that is being tested? (Mention the probability of random assignment for randomized trials)

8. What are the alternatives for diagnosis or treatment?

9. What are the possible benefits of taking part?

10. What are the possible disadvantages or risks of taking part? Mention what measures will be taken to minimize the risk, if any.

11. What are the provisions for treatment of research related injury?

12. Will compensation be provided to you in case of research related injury?

13. What are the possible current and future uses of the biological material collected or data to be generated from the research?

14. What if new information becomes available?

15. Will your taking part in the study be kept confidential?

16. What will happen to the results of the study?

17. Who is organizing the research study?

18. Who has reviewed the study?

19. Contact details of investigator for further information:

CONTACT PERSON:
Name of the Principal Investigator
Designation
Name of the Institute
(Phone and email ID of the Investigator)
Ph.: xxxxxxxx, Email-xxxxxxxxxxxxxxx

20. Contact details of Institutional Ethics Committee (for appeal against violation of your rights):

SMVMCH Ethics Committee
Sri Manakula Vinayagar Medical College and Hospital
Kalitheerthalkuppam, Madagadipet,
Puducherry - 605 107
Phone no: 0413 – 2643000, 2643014
Email: smvmchec@smvmch.ac.in

I wish to thank you for taking your time to participate in the study.

Date: **Place:**

Signature of investigator **Signature/Thumb impression of participant**

Signature of witness

Informed Consent Document: Part II – Informed Consent Form (ICF)

Version Number: **Date:**

Participant's Name

Address:

Title of the study:

The details of the study have been provided to me in writing and explained to me in my own mother tongue. I confirm that I have understood the purpose and procedure of the above study and that I had the opportunity to ask questions. I confirm that I have understood about the compensation and the risks and benefits involved in this research. I understand that my participation in the study is voluntary and that I am free to withdraw from the study at any time, without giving any reason whatsoever, and without my routine medical care in this hospital being affected. I was assured that the result of the study will be used only for scientific purpose(s) and I will not restrict the use of the results. I have also received a copy of the consent form giving the "Information for participants of the study".

I fully consent for my participation in the above mentioned study.

(I also consent/ do not consent to the use of my stored biological samples or related data for future scientific purposes, if applicable)

(I also consent / do not consent to be contacted over telephone for study purposes/ knowing the results – if applicable)

Signature/Left thumb impression of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness for illiterate participants:

Signature of the investigator: _____Date: _____

Annexure 10/SOP-6/V4
Template for Assent Form

(For Children 12-18 years of age)

Version Number: **Date:**

(Note: This form should be submitted along with informed consent document addressed to the parents / legally accepted representative)
Project title:

Child Participants Name: Age of Child:

Parent / LAR's Name :

We are doing a research study about **.....(purpose in simple language).** A research study is a scientific way to learn more about people. In this study we will be ..... **(description of the study - Procedures, Drugs to be used, risks, discomfort, in simple language).**

Everyone who takes part in this study will **NOT** benefit directly. A benefit means that something good happens to you. The possible benefits from this study might be ..... **(details of possible benefits of participation)**

If you do not want to be in this research study, we will tell you what other kinds of treatments are there for you. **(for research projects that offer treatment or intervention.)**

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You can be in this study if you want to be. If you decide to stop after we begin, that's okay too.

Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

Sign your name here Date

Signature of parent / legally accepted representative Date

Signature of Witness 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/
2. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019.Availablefrom: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

	Name	Designation	Signature
Prepared	Dr. Girija. S	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. Vimal. M	Member Secretary	
Approved	Dr. Thiagarajan. T	Chairman	
Issued	Dr. R. N. Kagne	Dean	