Sri MANAKULA VINAYAGAR

Medical College and Hospital

PROTECTING RESEARCH PARTICIPANTS

AND

GUIDING INVESTIGATORS

Version number: 4

Effective Date: 02nd January, 2024

STANDARD OPERATING PROCEDURES

FOR

INSTITUTIONAL ETHICS COMMITTEE (HUMAN STUDIES)

SMVMCH-EC

Standard Operating Procedures
Version **4**

Institutional Ethics Committee (Human Studies)
Sri Manakula Vinayagar Medical College and Hospital
(SMVMCH-EC)
Puducherry – 605107

Date published: 02nd January, 2024

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PREFACE

Sri Manakula Vinayagar Educational Trust was formed with the avowed objective of imparting quality technical education and medical education especially to the weaker sections of the society. Sri Manakula Vinayagar Medical College & Hospital is an Ultra-modern multi-specialty tertiary care hospital and a medical research center.

The institute is also active in research in various fields of modern medicine & health and medical education. A research committee at institute level looks after the research activities and there is an Institute Ethics Committee (Human Studies) which provides protecting to participants and guidance to investigators for the research work.

The research work is conducted and research papers are published by faculty, postgraduate and undergraduate students every year. There is an Institute Ethics Committee (human studies) which reviews all the research proposals by investigators who conduct research in this institute. As Ethics Committee plays a major role in protecting to participants and guidance to investigators, Standard Operating Procedures (SOP) for Ethics Committee is an important document for any educational institute involving in research. It's also necessary to update the SOP on regular basis.

I congratulate Dr. Vimal. M, Professor of Pathology, Dr. Girija. S, Professor and Head of General Medicine and Dr. Nishanthi. A, Associate Professor of Pharmacology of Sri Manakula Vinayagar Medical College and Hospital Ethics Committee for bringing out version 4 of SMVMCH-EC SOP.

I am confident that SMVMCH-EC SOP version 4 (amended by incorporating latest national and international ethical guidelines) will help all the researchers for preparing the research protocols and ensure smooth functioning of the our Institute Ethics Committee named as Sri Manakula Vinayagar Medical College & Hospital Ethics Committee (SMVMCH-EC).

Dean,
Sri Manakula Vinayagar Medical College &
Hospital,
Puducherry

Dr. KAGNE. R.N
DEAN
SRI MANAKULA VINAYAGAR
MEDICAL COLLEGE & HOSPITAL
KALITHEERTHALKUPPAM,
PUDUCHERRY-605107.

Preamble

Vision

Our vision is to ensure the safety and wellbeing of human beings by reviewing and enforcing ethical and scientific conduct of research process.

Mission

Our mission is to protect human research participants, researchers and institution by ensuring that:

- the rights, safety and wellbeing of the research participants are protected,
- the safety and protection of researchers,
- the institutional reputation and dignity will be protected and
- research is conducted according to the Indian regulations and relevant national (ICMR 2017 guidelines on biomedical research) and international ethical guidelines.

History of the SMVMCH Ethics Committee

Sri Manakula Vinayagar Medical College and Hospital was established in the year 2004 and Medical Council of India permitted to start MBBS course in the year 2006. The ethics committee (EC) was constituted in the year 2007. It was registered with DCGI in the year 2014 and since then it was named as SMVMCH Ethics committee (SMVMCH-EC) vide file no. ECR/1088/SMVMCH/Inst/PY/2013; dated: 10.12.2014 It was re-registered with DCGI in the year 2018 vide file no. ECR/1088/SMVMCH/Inst/PY/2013/Re-registration-2017; dated: 28.03.2018.

S. No	Name of the Chairman	From Date	To Date
1.	Dr. A. Shaw Nawan Khan	28.06.2007	19.08.2008
2.	Dr. D. Rajagovindan	20.08.2008	27.06.2010
3.	Dr. Selvaraj Stephen	28.06.2010	29.05.2013
4.	Dr. Gautam Roy	30.05.2013	27.03.2018
5.	Dr. T. Thiagarajan	28.03.2018	Till date

S. No	Name of the Secretary	From date	To date
1	Dr. Maruthi Shripati Sawadkar	28.06.2007	17.01.2011
2	Dr. R. N. Kagne	18.01.2011	22.09.2020
3	Dr. Vimal. M	23.09.2020	Till date

The SOP (Standard Operating Procedure) of SMVMCH-EC on Protecting research participants and guiding investigators, was first developed in the year 2013 (version 1) by Dr. R.N. Kagne (Member Secretary) and Dr. Amol R. Dongre (Member). The SOP booklet had 50 pages and contained 12 SOPs with supporting forms and documents (annexures). The SOP booklets

photocopy was provided to all the members of the SMVMCH-EC. Also, the scanned pdf copy was provided on the college website for open access to the researchers. The first amendment of the SOP (version 2) was done by the SOP committee in the year 2018 by Dr. R.N. Kagne (Member Secretary), Dr. Amol R. Dongre (Member), Dr. Vimal. M (Member), and Dr. Nishanthi. A (Member), after the SIDCER survey of the SMVMCH Ethics Committee. The second amendment of the SOP (version 3) was done by the SOP committee in the year 2021 by Dr. Vimal. M (Member Secretary), Dr. Nishanthi. A (Member) and Dr. Ganesh. R (Member), after the NABH inspection of the SMVMCH-EC. The third amendment of the SOP (version 4) was done by the SOP committee in the year 2024 by Dr. Vimal. M (Member Secretary), Dr. Girija. S (Member) and Dr. Nishanthi. A (Member) after the NABH inspection of the SMVMCH-EC.

Documentation of History of the SOPs

Details of superseded SOP

Name of the team of authors	SOP version number	Effective date	Comments (if any)
Dr. R.N. Kagne and Dr. Amol R. Dongre	Version 1.0	21.11.2013	First written SOP
Dr. R.N. Kagne, Dr. Amol R. Dongre, Dr. Vimal. M, and Dr. Nishanthi. A.	Version 2.0	01.11.2018	Major Revision after SIDCER Survey (3-5 October 2018) recommendations.
Dr. Vimal. M, Dr. Nishanthi. A, and Dr. Ganesh. R	Version 3.0	31.12.2021	Major Revision after NABH inspection (24th December 2021) and their recommendations.
Dr. Vimal. M, Dr. Girija. S and Dr. Nishanthi. A,	Version 4.0	02.01.2024	Major Revision after NABH inspection (01st December 2023) and their recommendations.

The Director of the Institute has been empowered to appoint the Chairman and Member-Secretary of SMVMCH -EC. The Director in consultation with the Chairman and Member-Secretary will appoint all other office bearers, and members. The appointed members detail list along with prescribed registration/re-registration format will be processed for approval by DCGI. Only after the approval from DCGI, the newly re-registered body of SMVMCH-EC will start functioning.

SMVMCH-EC shall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers of students and faculties of Sri Manakula Vinayagar Medical College and Hospital.

SMVMCH-EC is functionally autonomous. Its activities lie outside the administrative jurisdiction of the Director of SMVMCH, except in the dispute cases where he will be the appellate authority and has the administrative right for decision making.

Approval of SOP (Names) for Version 2

Prepared by

Name	Designation in EC
Dr. Vimal. M	Member
Dr. Nishanthi. A	Member

Reviewed by

Name	Designation in EC
Dr. R.N. Kagne	Member secretary
Dr. Amol R. Dongre	Member

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. D. Rajagovindan	Director

Approval of SOP (Names) for Version 3

Prepared by

Name	Designation in EC
Dr. Nishanthi. A	Member
Dr. Ganesh. R	Member

Reviewed by

Name	Designation in EC
Dr. Vimal. M	Member secretary

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. R. N. Kagne	Dean

Approval of SOP (Names) for Version 4

Prepared by

Name	Designation in EC
Dr. Girija. S	Member
Dr. Nishanthi. A	Member

Reviewed by

Name	Designation in EC
Dr. Vimal. M	Member secretary

Approved by

Name	Designation in EC
Dr. Thiagarajan. T	Chairman

Issued by

Name	Designation
Dr. R. N. Kagne	Dean

List of Members of the SMVMCH-EC (2017-2020)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. R. N. Kagne	Member Secretary
3.	Dr. Amol Dongre	Clinician
4.	Dr. Bupathy. A	Clinician
5.	Dr. Gautam Roy	Clinician
6.	Dr. Girija. S	Clinician
7.	Dr. T. Mahalakshmy	Clinician
8.	Dr. P. Ravikumar	Clinician
9.	Dr. D. Rajagovindan	Basic Medical Scientist
10.	Dr. Nishanthi. A	Basic Medical Scientist
11.	Dr. Sandhiya. S	Basic Medical Scientist
12.	Dr. Vimal. M	Basic Medical Scientist
13.	Mr. Saravanan	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Malar. R	Social Scientist

Secretariat: Mrs. Gajalakshmi

List of Members of the SMVMCH-EC (2021-2022)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. Vimal. M	Member Secretary
3.	Dr. Bupathy. A	Clinician
4.	Dr. Girija. S	Clinician
5.	Dr. P. Ravikumar	Clinician
6.	Dr. K. N. Viswanathan	Clinician
7.	Dr. Suresh Kumar. S	Clinician
8.	Dr. T. Mahalakshmy	Clinician
9.	Dr. Amol R Dongre	Clinician
10.	Dr. Nishanthi. A	Basic Medical Scientist
11.	Dr. Ganesh. R	Basic Medical Scientist
12.	Dr. Sandhiya. S	Basic Medical Scientist
13.	Mrs. Meenakshi	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Chitra Shah	Social Scientist

Secretariat: Mr. Vijai. A

List of Members of the SMVMCH-EC (2022-Till Date)

The Patrons

S. No.	Name	Designation
1	Thiru.Dhanasekharan M	Chairman & Managing Trustee
2	Thiru.Sukumaran SV	Vice-Chairman
3	Thiru.Narayanasamy K	Secretary
4	Dr.Rajagovindan D	Director
5	Dr.Kagne RN	Deputy Director and Dean

The Members

S. No	Name of Recipients	Designation
1.	Dr. Thiagarajan. T	Chairman
2.	Dr. Vimal. M	Member Secretary
3.	Dr. Bupathy. A	Clinician
4.	Dr. Girija. S	Clinician
5.	Dr. P. Ravikumar	Clinician
6.	Dr. K. N. Viswanathan	Clinician
7.	Dr. Suresh Kumar. S	Clinician
8.	Dr. T. Mahalakshmy	Clinician
9.	Dr. Amol R Dongre	Clinician
10.	Dr. Bhagwati Wadwekar	Clinician
11.	Dr. Nishanthi. A	Basic Medical Scientist
12.	Dr. Sandhiya. S	Basic Medical Scientist
13.	Mr. Dhanaselvam	Lay Person
14.	Mr. A. Karunamoorthy	Legal Expert
15.	Mrs. Chitra Shah	Social Scientist

Secretariat: Mr. Vijai. A

List of Independent consultants of SMVMCH-EC

Sl. No.	Name	Qualification	Specialty
1	Dr. Ashish Anand Susvirkar	MD (Medicine), DM (Neurology)	Neurology
2	Dr. P. Ravi Kumar	MD (Medicine), DNB (Nephrology)	Nephrology
3	Dr. Ashida. T. S.	MD (Medicine), DNB (Cardiology)	Cardiology
4	Dr. Thirumal. P	MD (Paediatrics), DM (Gastroenterology)	Gastroentrology
5	Dr. Karthik S Bandari	MS (Surgery), M.Ch.(Paediatric Surgery)	Paediatric Surgery
6	Dr. Shivaji. P.R	MS (Surgery), DNB (Urology)	Urology
7	Dr. Elangovan. D	M.B.B.S, M.Ch. (Neuro Surgery)	Neurosurgery
8	Dr. Vijayeswaran. N	MS (Surgery), M.Ch.(Neuro Surgery)	Neurosurgery
9	Dr. Arun Kumar Arasappa	MS (Surgery), M.Ch. (Cardio Vascular & Thoracic Surgery)	Cardiothoracic Surgery
10	Dr. Riaz. B	MS (Surgery), M.Ch. (Cardio Vascular & Thoracic Surgery)	Cardiothoracic Surgery
11	Dr. Ravi Sankar. P	MS (Surgery), M.Ch.(Oncology Surgical)	Surgical Oncology
12	Dr. Vijay Ganapathy. S	MS (Surgery), M.Ch.(Urology)	Urology
13	Dr. Vijayaraghavan. N	MS (Surgery), M.Ch. (Plastic Surgery)	Plastic Surgery
14	Dr. Damodara Kumaran. P	MD (Radio Theraphy), Diploma (Radio Theraphy)	Radiotheraphy & Oncology

List of Abbreviations / Acronyms

SOP Version: 4; Effective Date: 02.01.24

AX	- Annexure
CV	- Curriculum vitae
COI	- Conflict of interest
CFR	- Code of Federal Regulations
CDSCO	- Central Drug Standard Control Organization
CRT	- Cluster randomized trials
CTRI	- Clinical trial registry – India
DSMB	- Data Safety Monitoring Board
EC	- Ethics Committee
FERCI	- Forum for Ethics Review Committees in India
GCP	- Good Clinical Practice
GLP	- Good laboratory practices
HOI	- Head of the Institute
ICMR	- Indian Council of Medical Research
IC	- Independent Consultants
IRB	- Institutional review board
ICD	- Informed consent document
ICF	- Informed consent form
MOU	- Memorandum of understanding
PI	- Principal Investigator
SIDCER	- Strategic Initiative for Developing Capacity in Ethical Review
SOP	- Standard Operating Procedures
SMVMCH-EC	- Sri Manakula Vinayagar Medical College and Hospital Ethics Committee
SAE	- Serious adverse events
TOR	- Terms of reference

GLOSSARY

Accountability	The obligation of an individual or organization to account for its activities, accept responsibility for them and to disclose the results in a transparent manner.
Adverse event	Any untoward medical occurrence in a patient or participant involved in a study which does not necessarily have a causal relationship with the intervention. The adverse event can therefore be any unfavorable or unintended sign or experience, whether or not related to the product under investigation.
Appellate authority	It decides on the appeal filed against a decision of the lower authority. Its mandate is to ensure that due process of law is followed.
Assent	To agree or approve after thoughtful consideration an idea or suggestion to participate in research by a young person below the age of 18 years who is old enough to understand the implications of any proposed research but not legally eligible to give consent. The assent has to be corroborated with informed consent of parent/ LAR
Audit	A systematic and independent examination of research activities and documents to determine whether the review and approval activities were conducted, data recorded and accurately reported as per applicable guidelines and regulatory requirements.
Autonomy	The ability and capacity of a rational individual to make an independently informed decision to volunteer as a research participant.
Biomedical and health research	Research including studies on basic, applied and operational research designed primarily to increase the scientific knowledge about diseases and conditions (physical or socio-behavioral), their detection, cause and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation including clinical research.
Beneficence	To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.
Caregivers	A caregiver or care is an unpaid or paid person who helps another individual with illness or impairment with daily activities/ performance.
Case record/ report form (CRF)	Case record form or case report form is a printed, optical or electronic document designed to record all the required information in the protocol on each study participant for reporting to the sponsor.
Clinical research	Research that directly involves a particular person or group of people to study the effect of interventions, or uses materials/data from humans indirectly, such as their behavior or samples of their tissue for prevention, treatment and diagnosis of a disease condition/health disorder
Clinical trial	As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) and /or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical

	trial intended for academic purposes in respect of approved drug formulations for any new indication or new route of administration or new dose or new dosage form
Clinical trial registry	An official platform for registering a clinical trial, such as Clinical Trial Registry-India
Clinician	A person with recognized medical qualification and expertise/ training
Cognitive impairment	When a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.
Coercion	An overt or implicit threat of harm to a participant which is intentional to force compliance.
Collaborative research	An umbrella term for methodologies that actively engage researchers, communities and/ or policy makers in the research process from start to finish.
Compensation	Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in biomedical and health research.
Confidentiality	Keeping information confidential which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission
Confidentiality agreement	Secrecy or non-disclosure agreements designed to protect trade secrets, information and expertise from being misused by those who have learned about them.
Contract Research Organization (CRO)	An institution or service organization which represents a sponsor in providing research support/services on a contractual basis nationally or internationally.
Custodian	A person who has responsibility of taking care of or protecting entrusted assets, either biological samples or data
Debriefing	A process of providing a summary update of a condition or situation to the affected or concerned parties. It is an important ethical consideration in studies involving deception. Such post experimental follow-up is considered beneficial even if no deception is used or there is only minimal risk to participants
Deception	Deception occurs when investigators provide false or incomplete information to participants to misleading them to achieve the study objectives and for larger public good. Research employing any type of deception should undergo full committee review.
Distributive justice	Fair distribution of burden, resources and benefits. In research, it means fair selection of participants.
Ethicist	One whose judgement on ethics and ethical codes is based on knowledge/experience through qualification or training.
Exploitation	The action or fact of treating someone unfairly in order to benefit from their participation.
Exploratory research	Preliminary research conducted to gain insights for a problem that has not yet been clearly defined.
Impartial witness	A literate person, who is independent of the research and would not be

	unfairly influenced by people involved with the study, who attends the informed consent process if the participant and/or their LAR cannot read, and understand the informed consent form and any other written information supplied to the participant.
Independent consultant	An expert who gives advice, comments and suggestions to the EC and has no affiliation to the institute or researchers proposing the research protocols. This individual has no voting power for decision making.
Inducement	A motive or consideration that leads one to action or to additional or more effective actions without considering the harm that may occur
Informed consent document (ICD)	Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate.
Justice	Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.
Lay person	A literate person who has not pursued a medical science/health related career in the last 5 years and is aware of the local language, cultural and moral values of the community.
Legal expert	A person with a basic degree in law from a recognized university, with experience
Legally acceptable representative (LAR)	A person who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.
Legally authorized representative (LAR)	A person who, under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the ethics committee.
Maleficence	The act of committing harm or a harmful act.
Marginalized communities	A group of people actively separated or excluded from the rest of society.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of a healthy individual or general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant since it would be undertaken as part of current everyday life
Non therapeutic trial	A trial which is unlikely to produce any direct benefit to the participants involved. The aim of a non-therapeutic trial is to obtain knowledge which may contribute towards the future development of new forms of treatment or procedures.
Ostracization	To exclude, by general consent, from society, friendship, conversation,

	privileges, etc
Particularly vulnerable tribal group (PVTG)	These are a special class of tribal groups, classified as such by the Government of India, due to their especially low development indices when compared to other local tribes. These were classified under the Dhebar Commission (1960–1961), so as to better facilitate their growth, at par with other scheduled tribes on a national scale, and help them to get included in mainstream development, while using their indigenous knowledge. They have a pre-agricultural system of existence as mainly hunters with zero or negative population growth, extremely low level of literacy and no written language.
Pilot studies	A pilot study, project or experiment is a small-scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project.
Pivotal trial	A clinical trial or study intended to provide evidence for drug marketing approval from the licensing authority; usually a Phase III study which presents the data that the licensing authority uses to decide whether or not to approve a drug. A pivotal study will generally be well-controlled, randomized, of adequate size, and whenever possible, double-blind.
Post-marketing surveillance	The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market. This is an important part of the science of pharmacovigilance.
Professional competence	The broad professional knowledge, attitude and skills required in order to work in a specialized area or profession
Principal investigator	An individual or the leader of a group of individuals who initiates and takes full responsibility for the conduct of biomedical health research; if there is more than one such individual, they may be called co-principal investigators/ co-investigators
Psychosocial harm	Research, particularly psychology studies, can put participants in situations that may make them feel uncomfortable while learning about their reaction to a situation. The result can be psychological harm that can manifest itself through worry (warranted or unwarranted), feeling upset or depressed, embarrassed, shameful or guilty, and/or result in the loss of self-confidence.
Quorum	Minimum number and/or kind of EC members required for decision making during a meeting.
Research-related injury	Harm or loss that occurs to an individual as a result of participation in research, irrespective of the manner in which it has occurred, and includes both expected and unexpected adverse events and serious adverse events related to the intervention, whenever they occur, as well as any medical injury caused due to procedures.
Risk	Probability of harm or discomfort to research participants. Acceptable risk differs depending on the conditions inherent in the conduct of research.
Serious adverse event (SAE)	An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or

	requirement of intervention to prevent permanent impairment or damage.
Sexual minorities	A group whose sexual identity, orientation or practices differ from majority of the surrounding society. It refers to lesbian, gay, bisexual and transgender (LGBT), queer (including the third gender) or intersex individuals.
Social scientist	A person who is an expert on societal and social behavior with specialization/experience in the area.
Socio-behavioral research	Refers to the socio-behavioral studies on response of individuals, groups, organizations or societies to external or internal stimuli.
SOP (standard operating procedure)	Detailed written instructions in a certain format describing all activities and actions to be undertaken by an organization to achieve uniformity in performance of a specific function
Sponsor	An individual, institution, private company, government or nongovernmental organization from within or outside the country who initiates the research and is responsible for its management and funding.
Stigmatization	Negative perceptions about an individual because of perceived differences from the population at large. It may occur on the basis of physical appearance, race or sex.
Surrogate	A substitute or deputy for another person in a specific role.
Theologian	A person who is an expert in the study of religious faith(s), including the system of spirituality, practice and experience about the nature of the divine
Test of understanding	A simple oral or written test designed to identify if the participant has understood the details related to her/his voluntary participation in research before signing the ICD form. (Questions such as "If you decide not to take part in this research study, do you know what your options are?", "Do you know that you do not have to take part in this research study, if you do not wish to?", "Do you have any questions?", etc. will clarify the understanding of the participant.)
Transparency	It implies intentional openness, communication, and accountability operating in such a way that it is easy for others to see what actions are performed.
Therapeutic misconception	It is a misconception by participants believing that the purpose of clinical trials/research study is to administer treatment rather than to conduct research.
Undue inducement	Offer of disproportionate benefit in cash or kind that compromises judgment which may lead to acceptance of serious risks that threaten fundamental interests.
Unexpected ADR	An adverse reaction, the nature or severity of which is not described in the informed consent/information sheet or the applicable product information, such as an investigator's brochure for the unapproved IP or package insert/summary of product characteristics for an approved product.
Vulnerability	Vulnerability in research pertains to individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens or social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

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Title: Preparation of Standard Operating Procedures (SOP) for Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH –EC)

1. Purpose

The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of the SMVMCH-EC. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with ICMR guidelines (Indian regulations) and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the SMVMCH-EC.

3. Responsibility

It is the responsibility of the Member Secretary in consultation with Chairman of the SMVMCH-EC to appoint an SOP team to formulate a new SOP/s or to revise existing SOP/s. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP/s of the SMVMCH-EC.

3.1 Secretariat of the IEC will

- assist Member Secretary to formulate an SOP Team
- co-ordinate activities of writing, reviewing, distributing and amending SOP/s
- ensure that all the IEC members and involved administrative staff have access to the SOPs
- ensure that all the IEC members and involved staff are working according to current version of SOP/s
- maintain an up-to-date distribution list for each SOP/s distributed to the SMVMCH-EC members.
- maintain a file of all current SOP/s and the list of SOP/s

- maintain a file of all past SOPs of the SMVMCH-EC
- ensure that the latest version of the SOP is uploaded at the institute website.

3.2 Member Secretary of the EC will

- assess the need(s) for SOP/s revision
- consult with Chairman of the SMVMCH-EC to appoint an SOP team
- coordinate activities of writing, reviewing, distributing and amending SOPs
- submit the draft for approval to Chairman

3.3 SOP team will

- assess the request(s) for SOP/s revision in consultation with the Member Secretary and Chairman
- propose new / modified SOP/ s as needed
- draft the SOP/s in consultation with the IEC members and involved administrative staff
- review the draft SOP before submitting to full board meeting

3.4 Chairman of the EC will

- appoint SOP Team
- approve the SOP/s
- sign and date the approved SOP/s

3.5 SMVMCH-EC members will

- review and approve the draft SOPs
- sign and date the approved SOPs
- maintain a copy of all SOPs

4. Detailed instructions

4.1 Identify the need for new or amendment of current SOP/s

Chairman, Member Secretary or any member of the EC who would feel the requirement of a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOP/s or requests to design an entirely new SOP/s can put forth his request by writing to the SMVMCH-EC either as an email/letter/verbal request in a meeting. The Chairman will inform all the SMVMCH-EC members about this request at a regular full-board SMVMCH-EC meeting.

If the SMVMCH-EC committee agrees to the request, an appropriate SOP team will be appointed by the Chairman and designated the task to proceed with the revision process/ formulation process of the SOP. If the SMVMCH-EC committee members do not agree, no further action will be taken. If the member, who made the request for modification of the SOP, is absent for regular full-board SMVMCH-EC meeting then he will be informed by the Chairman.

4.2 Appointing the SOP Team

- The Chairman will constitute an SOP Team consisting of the Member Secretary and two or more members of the SMVMCH-EC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps as described in sections **4.3-4.7.**

4.3 List all relevant procedures

- Write down step by step all the procedures of the SMVMCH-EC that are to be standardized in the form of an SOP
- Organize, divide and name each process

4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairman.
- Each SOP should be given a number and a title that is self-explanatory and easily understood. A unique code number with the format SOP xx/Vy will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version. The first SOP of the current version would be SOP 01/V1 i.e. it is SOP number 01 with version 1.
- Each SOP may have annexures which are forms to be filled in by various stakeholders [EC or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form, pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example AX 01/SOP01/V1 means annexure form number 1 belonging to SOP 01/V1.
- Each SOP will be prepared according to the standard template in AX 01/SOP01/V1.
- Each page of the SOP will bear the header which will have the effective date i.e. the date of approval (aa/bb/cccc) of the SOP by the Chairman. The SOP number will be on the right hand corner with the logo of the Institution and title of the SOP while the footer will bear the page number in center as page p of q (total) pages.
- The draft SOP prepared by the SOP team will be circulated to all the EC members by the Member-Secretary.

4.5 Write and review a revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (*AX 02/SOP01/V4*) along with description of the main change/s.
- The rest of the steps are as described in **Section 4.4**.

4.6 Prepare and submit final draft

- The new / revised SOP will be reviewed at SMVMCH-EC meeting.
- The suggestions that are agreed upon by the SMVMCH-EC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team would stand automatically dissolved once the SMVMCH-EC takes final decision regarding the SOP.

4.7 Approve the new / revised SOP

- The final version will be presented to the Chairman for review and approval.
- The authors, reviewers and the Chairman will sign and date the SOP on the first page of the SOP document. Chairman and Member Secretary will sign and date the last page of each new / reviewed SOP/s and Secretariat of the SMVMCH-EC office will put the stamps of Chairman and Member Secretary below their signature with SMVMCH-EC office round stamp. This date of approval will be declared as the effective date from which the SOP will be implemented. The face page may also contain signature of Head of the Institution as having accepted the document.

4.8 Implement, distribute and file SOPs

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- The approved SOP will be distributed to the SMVMCH-EC members and a log will be maintained as per the annexure - *AX 03/SOP 01*.
- One complete original set of current SOP will be filed in the SOP Master file, by the EC Secretariat in the EC office.
- When the revised version is distributed, all the EC members will be requested to destroy their earlier version. Only one copy of the earlier version will be filed in the file entitled 'Past SOPs of the SMVMCH-EC' by the EC Secretariat in the EC office.
- The SMVMCH-EC members will review the SOPs once in every 3 years.

5. Reference to the other SOP: NIL

6. Annexures

Annexure 1 *AX 01/SOP01/V4*- Template for SOPs

Annexure 2 *AX 02/SOP01/V4*- Documentation of History of the SOPs

Annexure 3 *AX 03/SOP01/V4*- Log of the IEC members receiving

Annexure 4 *AX 04/SOP01/V4*- List of SOPs of the EC

Annexure 1: AX 01/SOP01/V4

Template for Standard Operating Procedures

SOP Number	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code (with version)	*SOP Title*	Effective Date

Title

Main Text:

1. **Purpose**: *Summarizes and explains the objectives of the procedure.*

2. **Scope:** *States the range of activities that the SOP applies to.*

3. **Responsibility**: *Refers to person(s) assigned to perform the activities involved in the SOP*

4. **Detailed instructions**: *Describes procedures step by step in short and clear sentences*

5. **Reference to other applicable SOP:** *Refers to the cross references in the SOP version 2*

6. **Annexure**: *Forms to capture information pertaining to the SOP instructions*

7. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity.*
8. **Reference:** *Refers to the references used for framing the SOP*

Annexure 2: AX 02/SOP01/V4

Documentation of History of the SOPs

Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Remarks

Annexure 3: AX 03/SOP01/V4

Log of the EC members receiving SOPs

S. No	Name of Recipients	Designation	SOP Code number	No. of Copies	Signature and Date

Annexure 4: AX 04/SOP 01/V4

List of SOPs of the Institutional Ethics Committee

No	Title of the Standard Operating Procedures (SOPs)	SOP No.

7. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amendment of current SOP	Any member of SMVMCH-EC, Member Secretary / Chairman
2	Appoint the SOP Team(s)	Chairman
3	List all relevant procedures	SOP Team
4	Write and review a new SOP	SOP Team
5	Write and review a revised SOP	SOP Team
6	Prepare and submit final draft	SOP Team
7	Final decision regarding the SOP	All member present for SMVMCH-EC meeting along with Chairman and Member Secretary
8	Approve the new/revised SOP	Chairman
9	Implement, distribute and file SOPs	IEC members and 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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.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	

Title: Constitution of SMVMCH Ethics Committee (EC), Selection, Roles and Responsibilities of Members of the EC

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provides the framework for constitution, selection, roles and responsibilities of the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) and procedures for maintaining confidentiality of all activities and documents.

2. Scope

This SOP applies to the constitution of the EC, selection, roles and responsibilities of members of the EC and maintenance of confidentiality of all activities and documents.

3. Responsibility

The selection of Chairman, Member Secretary and EC members will be done by the Director. It is the responsibility of all the EC members and the Secretariat to read, understand, follow and respect this SOP.

4. Detailed Instructions

4.1 Composition of the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee

The EC will be established by the Director. The Chairman and EC members can suggest names of potential members but the final decision will remain with the Director.

- Its hierarchical position in the organization and authority under which it is established will be clearly indicated (*AX 02/SOP 02/V4)*
- The EC will be multidisciplinary and multi-sectoral in composition.
- The EC will be composed of at least 7 members up to a maximum of 15 (as per current CDSCO requirements and 2017 ICMR guidelines). A minimum of 5 members should be present to meet the quorum requirements of which minimum one non affiliated member

should be present, preferably, the lay person should be part of the quorum. The quorum for reviewing regulating clinical trials should be in accordance with current CDSCO requirements. No decision is valid without fulfillment of the quorum.

- The members will
  - ✓ include a combination of medical and non-medical, scientific and non-scientific persons including lay person to represent the different points of view.
  - ✓ have differing backgrounds to promote complete and adequate review of research.
  - ✓ Have the required qualifications as prescribed by applicable regulations and guidelines from time to time
  - ✓ Have the expertise, time and commitment to perform all functions
- The EC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/ research site.
- Preferably 50% of the members should be non-affiliated or from outside the institution.
- The EC may invite member(s) of specific patient groups or other special interest groups for an EC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (*AX 05/SOP 02/V4)* and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have right to vote. (See SOP 05/V4)
- The Composition shall be as follows:
  - ✓ Chairman (non -affiliated to the institution)
  - ✓ Vice-Chairman (non-affiliated to the institution)
  - ✓ One Member Secretary (institutional)
  - ✓ One Assistant Member Secretary (institutional)

- ✓ One or more persons from basic medical science. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist - affiliated/Non affiliated
- ✓ One or more Clinician - affiliated/Non affiliated
- ✓ One legal expert – affiliated/Non affiliated
- ✓ One social scientist/philosopher, ethicist or theologian - affiliated/Non affiliated
- ✓ One or more lay person - non affiliated

4.2 Criteria for selection of members of EC

Chairman

- From outside the institution.
- A well respected person from any background with prior experience of having served/serving in an EC.

Vice-Chairman (if applicable)

- From outside the institution.
- A well respected person from any background with prior experience of having served/serving in an EC.

Member-Secretary and Assistant Member-Secretary

- Will be a staff member of the institution.
- Preferably be a medical professional with state medical council recognized postgraduate degree.
- Should have domain speciality experience, clinical research and ethics knowledge, personal interest and capacity, good communication skills.

Members

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the EC. They should not have any known record of professional misconduct.
- Medical scientists and clinicians should have post graduate qualifications.

- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests (See SOP 03/V4).

4.3 Agreement regarding Maintenance of Confidentiality

- It is the responsibility of each EC member, reviewing research project or attending EC meetings, to read, understand, accept and sign the agreement contained in the confidentiality Form (*AX 03A/SOP 02/V4*).
- The staff of the secretariat will sign confidentiality agreement which should be filed with the EC.(*AX 03B/SOP 02/V4)*
- The Secretariat will obtain the signature of the EC Chairman on the Confidentiality form.
- The secretariat will provide EC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and EC Chairman) and acknowledge the receipt of agreement with their signature.
- The Secretariat will keep the original copies of the signed Agreements in the EC office in the file entitled 'Confidentiality Agreement file" for members and photocopies of the agreement in the individual member's files.

4.4 Tenure of Membership

- The tenure of EC members will be for a period of 3 years from the date of appointment. A particular member cannot hold membership for more than two continuous tenures.

4.5 Appointment of New Members

a) The EC members will be appointed by the Director.

b) New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as stated in this SOP

New members will be identified by the Chairman according to the membership requirement (i.e. as per the composition specified in Section 4.1 of this SOP) ensure that the potential member fulfils the conditions of appointment. The names of new

members to be appointed may be suggested by the EC members and the Chairman to the Director. The final decision regarding appointment of members will be taken by the Director.

4.6 Conditions to be fulfilled by a member after appointment

Members to be appointed on the EC will need to fulfill the following conditions:

- Members must submit
  - ✓ a recent signed CV
  - ✓ training certificates in Ethics and/ or GCP.
- Members must be willing to
  - ✓ publicize his/her full name, profession and affiliation.
  - ✓ sign the Confidentiality Agreement (as per Annexure 3A/SOP 02/V4) and regarding meeting, deliberations, applications, information on research participation and related matters.
  - ✓ read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement/form (See SOP 03/V4).

4.7 Resignation and Disqualification of Members.

- Resignation: An EC member may resign from membership by submitting a letter of resignation to the Chairman. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairman.
- Disqualification for conduct unsuitable of an EC member: A member may be disqualified from continuance should EC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an EC member.
  - (i) The process will be initiated if EC Chairman or Member-secretary receives a communication in writing (provided by EC member or a member of the public) alleging misconduct by a member.
  - (ii) The Chairman will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairman, the matter is of grave significance where integrity of EC could be questioned, the Chairman may suspend

the membership of the concerned EC member till final decision is taken by EC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an EC member and will not perform any duties of EC member.

(iii) The Chairman may call for a meeting of the EC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the EC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.

(iv) The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairman will convey the disqualification to the concerned member through a written communication.

- Disqualification for not attending EC meetings: A member may be disqualified from EC membership if the member fails to attend more than 3 regular consecutive EC meetings without prior intimation. The process conducted will be as follows:

(i) The Member Secretary will inform Chairman (if required), in writing, if a member has not attended more than three consecutive regular meetings of the EC without prior intimation to the EC.

(ii) The Chairman will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular EC meeting.

(iii) A written communication will be sent to the concerned EC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned EC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairman

(iv) The matter will be discussed and reviewed at the EC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

- The Chairman or Member-Secretary will inform the EC members about the cessation of membership by a confidential written communication to the concerned and other members of EC will be informed during the upcoming meeting of EC.

4.8 Reconstitution of Ethics Committee

- Aleast 20% of the EC members will be changed every 3 years.
- Any change in EC membership will be communicated to the DCGI within 14 working days.

4.9 Training of the EC Members in Research Ethics

- An individual selected as a new member of the EC will be required to attend one meeting as an 'Observer' before being inducted as a member of the EC.
- Member Secretary or an EC member will provide introductory training in Research Ethics, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training.
- All members including Chairman and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The EC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the EC Members and Institutional faculty members.

4.10 Hierarchy

- There will be one Chairman, one Vice-Chairman, one Member Secretary and one Assistant Member Secretary.
- The Chairman and Vice-Chairman will head the committee.
- The Member Secretary and the Assistant Member Secretary will be the guardian of all documents and funds in the possession of the committee.
- Other EC members will be regular committee members with equal ranking.

4.11a Functions of Chairman

- The Chairman will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- The Chairman will be accountable for independent and efficient functioning of the committee
- The Chairman will conduct EC meetings and ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations
- The Chairman will preside over all elections as well as administrative and financial matters pertinent to the committee's functions.
- The Chairman will represent the EC at various meetings and forums.
- The Chairman will sign documents and communications related to EC functioning.
- The Chairman will Seek COI declaration from members and ensure quorum and fair decision making.
- The Chairman will handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- In case of anticipated absence of both Chairman and Vice-Chairman at a planned meeting, the Chairman will nominate a committee member as Acting Chairman or the members present may elect the Acting Chairman. The Acting Chairman should be non-affiliated and will have all the powers of the Chairman for that meeting.

4.11b Functions of Co- Chairman

- To act as Chair in the absence of Chairman and to perform all functions of Chairman.

4.12 Functions of the Member secretary

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received.
- Prepare, maintain and distribute study files.
- Schedule and organize EC meetings
- Prepare and maintain meeting agenda and minutes.

- Maintain EC documentation and to archive them.
- Sign documents and communications related to EC functioning.
- Communicate with the EC members and applicants/ investigators.
- Notify the Principal Investigator regarding EC decisions related to the submitted research proposal.
- Ensure training of EC members on SOP, regulatory requirements, bioethics and GCP
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Provide necessary administrative support for EC related activities to the Chairman.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- A reasonable fee for review may also be charged by the EC to cover the expenses related to optimal functioning in accordance to the institutional policies.
- Delegate various responsibilities to appropriate and authorized individuals
- Ensure adherence of EC functioning as per SOPs
- Prepare for accreditations and inspections
- Prepare compliance report
- Ensure availability of funds for smooth functioning of EC.

4.13 Functions of the Assistant Member Secretary

The Assistant Member Secretary will perform the same functions of Member Secretary in his/her absence.

4.14 Functions of EC members

- Attend EC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- Review, discuss and consider research Proposals submitted for evaluation.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.

- Do onsite visits whenever needed
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of EC meetings.
- Declare any conflict of interest in writing to the Chairman, if any, at each meeting.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the EC secretariat
- Provide an updated CV when requested for by the EC secretariat
- Carry out the work delegated by Chairman, Vice-Chairman, Member-secretary and Assistant Member-secretary
- Assist Chairman, Vice-Chairman, Member-secretary and Assistant Member-secretary in carrying out EC work as per SOPs
- Be updated on relevant laws and regulations

4.15 Functions of EC members – member specific role of Basic medical scientist

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4.16 Functions of EC members – member specific role of Clinician

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

4.17 Functions of EC members – member specific role of legal expert

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

4.18 Functions of EC members – member specific role of Social scientist

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

4.19 Functions of EC members – member specific role of Lay person

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any

4.20 Functions of Secretariat

- The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff.
- The Secretariat will support the Member Secretary and Assistant Member Secretary in all their functions
- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the EC.(*AX 03-B/SOP 02/V4)*
- The working rules for the Secretariat are stated in (AX 01/SOP 02/*V4*)

4.21 Types of projects reviewed by EC

The EC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects of (postgraduate students : MD, MS & PhD) research projects of undergraduate students carried out under guidance of teachers (e.g. Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self-funded / funded by institutional funding bodies.

4.22 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum.
- For the EC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation: one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community, **apart from** Member Secretary and Chairman as mandated by NDCT rules 2019.
- Without satisfying this condition, any decision taken by the committee shall remain null and void.
- In absence of the Chairman, Vice-Chairman will chair the meeting.

4.23 Honorarium to the Members

Reimbursement of travelling expense, accommodation (if required) and honorarium of Rs. 2000 per day will be given to the non – affiliated/external EC members, for attending the EC meetings.

4.24 Preparing an annual activity report of the EC for submission to the Head of the Institute

The Member Secretary will make a yearly activity report for submission to the Head of the Institute which will include the following elements:

a. Number and dates of the EC meetings of full board

b. Number of SAE subcommittee and any other subcommittee, as applicable) Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated
c. Number of approvals for full board review/ expedited review with decisions
d. Brief details about workshops, training programmes and other activities undertaken by the EC and those attended by EC members
e. Any other matter

5. Reference to other applicable SOPs

SOP 03/V4 - *Conflict of Interest Policy for Institutional Ethics Committee*

SOP 08/V4 - *Agenda Preparation, Meeting Procedures and Recording of Minutes*

6. Annexures

Annexure 1 *AX 01/SOP 02/V4* - EC Administrative Staff: Working rules

Annexure 2 *AX 02/SOP 02/V4* - Organizational Chart of the Institution

Annexure 3A *AX 03 A/SOP 02/V4* - Confidentiality Agreement Form for EC members

Annexure 3B *AX 03B/SOP 02/V4* – Confidentiality Agreement Form for Staff of the Secretariat

Annexure 1: AX 01/SOP 02/V4

The EC Administrative Staff: Working Rules

- There will be administrative officer / assistant /s and attendant/s /helper/s who will help the EC Chairman and Member-Secretary in executing functions of the EC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the EC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves may be recommended by EC members and discussed during regular EC meeting and will be recorded in minutes.
- The administrative staff will report to the Chairman and/or Member Secretary.
- The administrative staff will be appointed by the Head of the institute by conducting formal interviews.

Duties of Administrative officer/ assistant

- Correspondence with EC members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the EC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the EC records

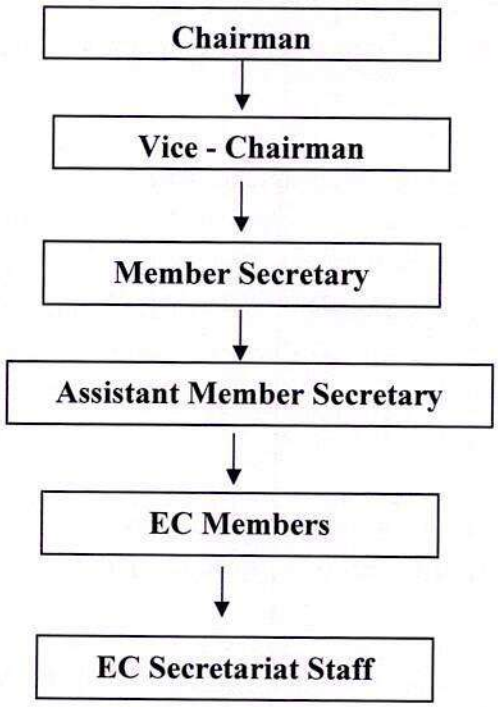
Duties of the attendant/s /helper/s

- Assisting the secretariat in arranging the EC meetings
- Dispatching sets of study documents to EC members and external experts
- Receiving the study related documents from and dispatching the EC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings

Annexure 2: AX 02/SOP 02/V4

Organizational flow chart of SMVMCH-EC

After the Director of SMVMCH constitutes the EC and after registration with DCGI, the newly registered body will function in the following hierarchical order.



Annexure 3A: AX 03A /SOP 02/V4

Confidentiality Agreement Form for SMVMCH-EC Members

In recognition of the fact, that I, _____

_____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the SMVMCH-EC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the EC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an EC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the EC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore,

the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

_____ _____

Undersigned Signature Date

Agreement on Confidentiality

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the **SMVMCH-EC**. A copy will be given to you for your records.*

In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairman upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Chairman's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

Signature Date

Annexure 3B: AX 03-B/SOP 02/V4

Confidentiality Agreement Form for Staff of the Secretariat

In recognition of the fact, that I,

_____

_____

(*Member's name, and his/her affiliation)* herein referred to as the "undersigned", have been appointed as a member of the SMVMCH-EC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the EC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an EC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the EC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the EC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the EC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written

Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the EC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

_____ _____

Undersigned Signature Date

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the ***EC****. A copy will be given to you for your records.*

In the course of my activities as a member of the EC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairman upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Chairman's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

_____ _____

7. Flow Chart

No.	Activity	Responsibility
1	Composition of the Ethics Committee	Director as per DCGI guidelines
2	Selection and appointment of Chairman	Director as per DCGI guidelines
3	Appointment of new members	Director as per DCGI guidelines
4	Conditions of appointment	All EC Members
5.	Initiation of the process of appointment	Secretariat
6.	Tenure of Membership	Chairman, EC Members and Secretariat
7.	Resignation and disqualification of Members	EC Members and Secretariat
8.	Quorum requirements	EC Members and 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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Handling Conflict of Interest among Ethics Committee Members

1. Purpose

The purpose of this SOP is to describe the process to identify and manage conflict of interest among Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH - EC) members.

2. Scope

This SOP covers the policy related to identification, declaration and management of conflict of interest and is applicable to all EC members.

3. Responsibility

All EC members (regular and alternate) are responsible for understanding definition of conflict of interest (COI) and for self-identifying and disclosing these. The Chairman would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

4. Detailed Instructions

- Every newly recruited EC member will sign the Conflict of Interest agreement form at the time of appointment (*AX 01/SOP 03/V4)*.
- Voluntary disclosure regarding COI by EC member - The EC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.

- EC members should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the EC.

a) If an EC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the EC Secretariat and return the documents.

b) If an EC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the EC secretariat so that the review is re-assigned to other members.

c) If an EC member has a COI for review of research study at a meeting, he or she will inform the Chairman and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for EC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.

d) Recusal - EC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.

e) If an EC member finds that he/she has a COI during the conduct of a research project approved by EC, he/she shall report the conflict to the EC at the next EC meeting.

- At the beginning of each meeting, the EC Chairman asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, EC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.
- If the Chairman has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion on such a project.

- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by EC member with the help of EC Chairman / Member Secretary
- The EC Chairman has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.
- The EC shall not approve a research study proposal where a COI is not managed or eliminated
- Management of CO – In case of a COI ,
  - EC members will disclose the COI as discussed above
  - EC members will not serve as reviewers
  - EC members will not influence the discussion and decision making of the concerned study by staying away during the EC meeting.
- EC Member Secretary and the Secretariat will record the points related to disclosure and management of COI of EC members in the EC minutes.

Definitions and Mandate

Definitions

- Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain. [*http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015*].
- Types of COI

  - A personal COI is said to exist when
    - There is immediate family relationship (spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an EC member or consultant or who receives 50% or more support from an EC member, regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators.

- EC member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financer.
- research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)

- A professional COI means the EC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.
- A financial COI for EC members and immediate family exists when the EC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated)..

Mandate

- *G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th February 2013* http://www.cdsco.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf *accessed on 23rd Oct 2018*

  2h. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

- *http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Oct 2018.*

  2.4.2.6. "A member must voluntarily withdraw from the EC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the Chairman prior to the review and should be recorded so in the minutes. If one of the

members has her/his own proposal for review, then the member should not participate when the project is discussed".

- *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107 accessed on 23rd Oct 2018.*

56.107 "No Institutional review board (IRB) may have a member participate in the IRB's initial or continuing review of any project in which the member *h*as a conflicting interest, except to provide information requested by the IRB. [45 CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 EC membership".

5. Reference to other applicable SOPs - Nil

6. Annexure

Annexure 1 *AX 01/SOP 03/V4*– Conflict of Interest Form/ Declaration for SMVMCH - EC Members at time of appointment

Annexure 2 *AX 01/SOP 03/V4* – Conflict of Interest Form/ Declaration for SMVMCH - EC Members during EC meeting

Annexure 1: AX 01/SOP 03/V4

Conflict of Interest Agreement Form for Ethics committee members at time of appointment

It is recognized that the potential for conflict of interest will always exist and resolution of the same is of paramount importance. It is the responsibility of SMVMCH EC members to voluntarily disclose any potential conflict of interest to the Chairperson. It is the responsibility SMVMCH EC Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

It is the policy of the SMVMCH Ethics Committee that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the SMVMCH Ethics Committee for Clinical Studies.

The Undersigned will immediately disclose to the Chairperson of the SMVMCH Ethics Committee any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

At the start of the EC meeting, the member should identify the proposal for which he/she has conflict of interest and document it in the Conflict of Interest Form/ Declaration for SMVMCH - EC Members during EC meeting (*AX 01/SOP 03/V4)*

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the SMVMCH Ethics Committee. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement. I shall abstain from any participation in discussions or recommendations in respect of such proposals.

_____ _____

Undersigned Signature Date

_____ _____

Chairperson's signature Date

Annexure 2: AX 01/SOP 03/V4

Conflict of Interest Form/ Declaration for SMVMCH-EC Members during EC meeting

I am aware of the policy of the SMVMCH-EC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the SMVMCH-EC.

I will refrain from the review process and /or discussion at the SMVMCH-EC meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

I declare relation to the proposal entitled

S. No	SMVMCH-EC No of Research Proposal	Name of the EC Member	Conflict of Interest	Signature
1.				
2.				
3.				
4.				

Signature of Chairman

Date

7. Flow Chart

No.	Activity	Responsibility
1	Determination of Conflict of Interest (COI)	EC Member
2	Disclosure and management of COI	EC Member
3	Ensuring declaration and management of COI during review process	EC Chairman
4	Recording of COI in minutes of EC meeting	EC Member Secretary/ Secretariat

8. References:

1. Part 56 -institutional review boards,Subpart B--Organization and Personnel, Sec. 56.107 IRB membership, 45 CFR 46.107(e) and 21 CFR 56.107(e)http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107 accessed on 23rd Oct 2018.
2. http://irb.northwestern.edu/sites/default/files/documents/hrp-050-sop-conflicting-interests-members.pdf accessed on 23rd Oct 2018.
3. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 23rd Oct 2018). Available from: http:// www.ferci.org/sops/
4. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
5. *G.S.R. 12(E). Registration of Ethics Committee. Ministry of Health and Family Welfare, Department of Health notification dated 8th February 2013* http://www.cdsco.nic.in/writereaddata/G.S.R%2072(E)%20dated%2008.02.2013.pdf *accessed on 23rd Oct 2018*
6. *http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Oct 2018.*
7. *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=56.107 accessed on 23rd Oct 2018.*
8. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Selection and Responsibilities of Independent Consultants

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of medical professionals as 'Independent Consultants' (IC) to the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC).

2. Scope

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion during the EC review process. It also defines the responsibilities of IC.

3. Responsibility

It is the responsibility of the Chairman/ Member Secretary/ EC member/s to nominate the name of one or more IC/s. The Chairman is responsible for endorsing the choice of IC nominated by EC Member Secretary/EC member/s. The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of ICs will be carried out by EC secretariat.

4. Detailed instructions

4.1 Recommendation of names of ICs and making a roster of ICs for the EC

- Chairman/ Member Secretary/ EC members will nominate the names of ICs from different specialties of Medicine.
- Member Secretary in consultation with Chairman will select a panel of IC(s) for the EC.
- Member Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/ electronic communication.
- After receiving written approval from ICs, a list of specialty wise ICs will be maintained by the secretariat in the EC records. The details of each IC (Name, designation, Affiliation, contact details and updated curriculum vitae) will be maintained in the EC records.

4.2 Consulting an IC during EC review process

- An EC member/ Member Secretary/ Chairman may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by the EC or from outside the roster; if during the review process of any given research study if it is felt that the study involves procedures or information that is not within the area of collective expertise of the EC members.
- The Member Secretary in consultation with Chairman (or at full board meeting; as deemed necessary) will decide identify and select the IC(s) outside the roster to be invited based on area of expertise, independence and availability.
- Member Secretary on behalf of the EC will invite IC(s) in writing to assist in the review of the research study and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through telephonic/ electronic communication.

4.3 Communication with ICs

- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for EC records and future reference.
- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement (*AX 01-A/SOP 04/V4)* and Conflict of Interest Agreement (AX 01-B/SOP 04/V4) for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairman/ Legal expert/ EC members.

4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairman.

- The Chairman will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).

4.5 Review of research study proposal

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) *AX 02/SOP 04/V4* to the IC(s). The IC(s) may be provided with a copy of 'Guidelines for Reviewers'.
- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed by Member Secretary in the EC meeting when the concerned study is being discussed.
- If deemed necessary, the Chairman or Member-secretary may seek additional information or clarifications from the IC in writing. Additional Information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairman or Member-secretary may invite the IC(s) to attend an EC meeting for providing additional information or clarifications that may be sought by EC members or Chairman. However, the IC will not participate in the decision making process on the research study.
- If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet or any other incidental expenses, etc.

4.6 Tenure of Services of IC

- The roster of ICs maintained at the EC office will be updated every 3 years
- For IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study is taken by the EC. The EC will document the termination of the services of IC by providing a letter thanking the IC for the services rendered.

4.7 ***Responsibilities of IC***

- If IC agrees to review a research proposal, he/she will comply with EC requirements of signing confidentiality and conflict of interest agreements.
- IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated period or by a stipulated date.
- IC will attend an EC meeting for providing additional information or clarifications, if invited by Member Secretary/ Chairman. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

Independent Consultant: An independent consultant is a subject expert in a specified field who gives advice, comments and suggestions upon review of the study protocols. He/she has no affiliation to the investigators proposing the research protocols.

5. Reference to other applicable SOPs - Nil

6. Annexures

Annexure 1 *AX 01-A/SOP 04/V4* - Confidentiality Agreement for an IC

AX 01-B/SOP 04/V4 - Conflict of Interest Agreement for an IC

Annexure 2 *AX 02/SOP 04/V4* - Study Assessment Form for an IC

Annexure 01-A: AX 01-A/SOP 04/V4

Confidentiality Agreement Form for an Independent Consultant

I,_____

_____ (Name and Designation) as a non-member of Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) understand that the copy / copies given to me by the EC is/are confidential. I shall use the information only for the indicated purpose as described by the EC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the EC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the Consultant with Date Chairman of EC with Date

Annexure 01-B: AX 01-B/SOP 04/V4

Conflict of Interest Agreement Form for Independent Consultants

- I understand that it is the policy of the EC that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the EC.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the EC to me.
- In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to EC and refrain from reviewing it.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature of IC with Date Chairman's Signature with Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

Signature with Date

[The original (signed and dated Agreement) will be kept on file in the custody of the EC. A copy will be given to you for your records]

Annexure 2: AX 02/SOP 04/V4

Study Assessment Form for an Independent Consultant

EC Protocol Number:	
Protocol Title:	
Comments on the protocol:	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	

Remarks:	Recommend approval Recommend approval after incorporation of changes Suggested Recommend disapproval (Please state Reasons) Any other (Please specify with reasons)
Name of the Consultant:_____ Reviewing the project: Signature with Date:	

7. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	EC Member, Member Secretary or Chairman
2	Selection and Appointment of IC(s)	Member Secretary in consultation with Chairman
3	Invitation to IC(s) on behalf of EC	Chairman/ Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	EC Secretariat

5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC, Chairman
6	Maintenance of a specialty-wise list/ roster of ICs	EC Secretariat
7	Reviewing documents pertaining to research project	IC

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. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Procedures for allowing Guest/ Observer to visit Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) or attend EC meeting

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) and the Guest/ Observer whenever he/she visits the EC Office or attends an EC full board meeting. The SOP is needed to ensure adequate protection of confidentiality of information related to research studies.

2. Scope

This SOP covers the procedures for allowing guest / observer to visit the EC Office and observe a meeting in progress.

3. Responsibility

- It is responsibility of Member Secretary in consultation with Chairman to decide whether a guest / observer may be allowed to visit the EC Office or attend an EC meeting.
- It is the responsibility of the guest/observers intending to attend an EC meeting to read, understand, accept and sign the agreement contained in the Confidentiality form prior to visiting EC/ attending an EC meeting.
- The Secretariat will ensure that the Confidentiality Form is duly signed and dated by the guest or observer for EC / EC meeting and will file it in EC records.

4. Detailed instructions

4.1 Receiving request from guest/observer to visit EC or attend EC meeting

- On receiving a written or verbal request from a guest regarding visiting the EC Office or to observe an EC meeting, the EC member/Member Secretary/ Secretariat will obtain permission from Chairman.

- The date and time of the visit to EC or for EC meeting will be informed to the guest/ observer preferably in writing/email.
- The request letter/email will be filed in EC records by the secretariat.

4.2 Filling up of Confidentiality Agreement Form

- Confidentiality Agreement Form (*AX 01/SOP 05/V4*) will be provided to the guest attendee/ observer on the day of visit/ at the time of meeting.
- The guest/ observer will read the form carefully before visit / or before commencement of the meeting and follow it.
- He/she will fill up the details in the form.

4.3 Ask questions, if any

- If there are any doubts, the guest/observer will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications.

4.4 Signing of Confidentiality Agreement Form

- The guest /observer will sign and date the document before a member of the Secretariat.
- He/she will return the signed form to the Secretariat.
- The Secretariat will obtain the signature of the EC Chairman on the Confidentiality / Agreement Form.
- The secretariat will provide guest or observer for EC a photocopy of the Confidentiality Agreement Form for their records (duly signed and dated by them and EC Chairman) and acknowledge the receipt of agreement by their signature.
- The Secretariat will keep the original copy of the signed Agreements at the EC office in the files entitled 'Confidentiality Agreement file for guests/observers, Independent Consultants (IC)'.
- The Secretariat will store the file in a secure cabinet with limited and named access.

4.5 Keep the Agreement in mind

- The guests /observer must implement the clauses of the signed Confidentiality Agreement Form.

5. Reference to other applicable SOPs - Nil

6. Annexures

Annexure 1 *AX 01/SOP 05/V4* Confidentiality Agreement for Guest/Observer to Sri Manakula Vinayagar Medical College and Hospital Ethics committee (SMVMCH-EC) Meeting

Annexure 1: AX 01/SOP 05/V4

Confidentiality Agreement Form

For Guest / Observer Attendees to Sri Manakula Vinayagar Medical College and Hospital Ethics committee (SMVMCH-EC) Meeting

I, _____ (name), understand that I am being allowed to visit EC office facility / attend the EC meeting on _____ at _____am as a Guest. The venue of the EC meeting will be _____. I may become aware of some confidential information during my visit to EC / during the course of the EC meeting. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

Signature of the Guest with Date

Chairman of EC with Date

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the EC -Chairman and me.

Signature of the Guest with Date

7. Flow chart

No.	Activity	Responsibility
1.	Receiving request from guest/ observer	EC Secretariat/ Member/ Member Secretary
2.	Allowing a guest/ observer	Chairman
3.	Informing guest/ observer about visit/ meeting date and time	EC Secretariat
4.	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5.	Filing of signed confidentiality form in EC records	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. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
3. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
4. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

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 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/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	

Title: Categorization of New Research Study Protocols Received for Initial Review

1. Purpose

The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process, to Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC).

2. Scope

This SOP covers the process of categorization of new research study protocols submitted to Sri Manakula Vinayagar Medical College and Hospital Ethics Committee for initial review. It does not cover subsequent submissions.

3. Responsibility

It is the responsibility of the Member-Secretary [in consultation with Chairperson (as applicable)] to categorize the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full committee review, expedited review and exemption from review.

4. Detailed Instructions

4.1 New proposals received for initial review

- New research study proposals received from the Research Committee of Sri Manakula Vinayagar Medical College and Hospital will be considered for review in the next meeting of the EC.
- The Secretariat will ensure that application of the research proposal 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).

4.2 New proposals forwarded to Member Secretary

- The Secretariat will forward the copy of the research proposal to the Member Secretary for initial screening within 5 working days of receiving the proposal.

- The Member Secretary will screen the research proposals and categorize the proposals as elaborated in Section 4.3 within 5 working days of receipt.

4.3 Categorization of New proposals for review by EC

The Member Secretary will categorize the proposals into three types. The types of review processes and the criteria to decide the type of review are explained below (*www.icmr.nic.in National Ethical Guidelines for Biomedical and Health Research involving on Human Participants, Indian Council of Medical Research, and October 2017*):

Full committee review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

- research involving vulnerable populations, even if the risk is minimal;
- research with minor increase over minimal risk (see Table 2.1 for further details);
- studies involving deception of participants (see section 5.11 for further details);
- research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
- major deviations and violations in the protocol;

- any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
- research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
- prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, for example;

- research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
- research involving clinical documentation materials that are non-identifiable (data, documents, records);
- modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
- revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
- minor deviations from originally approved research causing no risk or minimal risk;
- progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
- for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- research during emergencies and disasters (See Section 12 for further details).

Exemption from review

Proposals with less than minimal risk where there are no linked identifiers, for example;

- research conducted on data available in the public domain for systematic reviews or meta-analysis;
- observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
- quality control and quality assurance audits in the institution;
- comparison of instructional techniques, curricula, or classroom management methods;
- consumer acceptance studies related to taste and food quality; and
- public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

Glossary (*www.icmr.nic.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, October 2006*)

- **Less than minimal risk:** Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
- **Minimal risk:** Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
- **Minor increase over minimal risk or Low risk:** Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This

may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

- **More than minimal risk or High risk:** Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

5. Reference to other applicable SOPs:

- **SOP 06/V4**: *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP 7A/V4**: *Initial Full Board Review of New Research Study Protocols*
- **SOP 7B/V4**: *Expedited Review of New Research Study Protocols*
- **SOP 7C/V4**: *Exemption from the Ethics Review of Research Study Protocols*

6. Annexure; NIL

7. Flow Chart

No.	Activity	Responsibility
1	Receiving new research study proposal and related documents by a fixed date of the month	Secretariat
2	Verifying completeness of submitted research study documents	Secretariat
3	Forwarding of new proposals to Member-Secretary EC	Secretariat
4	Categorization of the Protocols into 3 categories: full board, expedited review and exemption from review process	Member-Secretary/ Member Secretary in consultation with Chairperson (if applicable)

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. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Initial Full Board Review of New Research Study Protocols

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) members will perform an initial review on a new research study protocol using the Assessment Form.

2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the EC. All research studies presented with more than minimal risk and which do not qualify for exemption (See SOP 7C/V4) or expedited review (See SOP 7B/V4), are covered in this SOP.

3. Responsibility

- The Member Secretary is responsible, after categorisation of the studies (as per SOP 07/V4), to forward the studies to the Secretariat.
- The EC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the EC members for review (If the study is categorised for Full Board review), and communicate the review results to the investigators.
- EC members (including Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the EC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The EC members are responsible for attending and participating actively in the discussion at the full Board Meeting
- The Member Secretary is responsible for setting up the Full Board Meeting (SOP 07A/V4)
- The EC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

- The Chairman is responsible to sign and date the decision in the EC Decision Form *AX 03A/SOP 7A/V4.*

4. Detailed instructions

4.1 Appointment of primary reviewers

- The Member Secretary/Chairman will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They should include one clinician and one non technical person as applicable. More than two may be appointed if necessary.

4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the cover letter to the EC Members requesting initial review (*AX 01/SOP 7A/V4*) and in the study assessment form *AX 02/SOP 7A/V4.*
- The Secretariat will send a packet *(soft copy)* to the EC members.
    - Letter to EC Members requesting Initial Review with study assessment form *AX 01/SOP 7A/V4*
    - Covering letter (AX 01/SOP 06/V4) and Checklist (AX 02/SOP 06/V4)
    - Research Study Application Form Submission *to EC (AX 03/SOP 06/V4)*
    - Protocol and related documents
    - Study assessment form *AX 02/SOP 7A/V4* in case it is to the Primary reviewer.

4.3 Receive the distributed protocol package

- The EC members will receive the protocol package with the Study Application Form as soft copy or as hard copy (for primary reviewer, if desired so).
- Designated primary reviewers will also receive the Study Assessment Form for Initial Review AX 02/SOP 7A/*V4*

4.4 Verify the contents of the package

- The EC member will verify all the contents.

- The EC member will check the meeting date to see if it is convenient to attend the meeting.
- The EC member will notify the EC Secretariat if any documents are missing or if the specified date of the EC meeting is not convenient to attend.

4.5 Review by the EC members

Review of the protocol

- The protocol will be reviewed by each member as per guidelines to review a study protocol described in *AX 06/SOP 7A/V4*.
- The EC member will consider the following criteria when performing the review of the study protocol and the study related documents:
  - Scientific design and conduct of the study
  - Risks and potential benefits
  - Selection of study population and recruitment of research participants
  - Inducements, financial benefits and financial costs
  - Protection of research participants' privacy and confidentiality
  - Community considerations
  - Qualifications of Investigators and assess adequacy of study sites
  - Disclosure or declaration of potential conflicts of interest
- The EC member will consider the following criteria when performing the review of the Informed Consent Document (as per *AX 06/SOP 7A/V4*)
  - Voluntary, non-coercive recruitment, participation/ withdrawal
  - Procedures for obtaining informed consent
  - Contents of the patient information sheet - title, objective, study design and procedures
  - Contents and language of the informed consent document
  - Translation of the informed consent document in the local languages
  - Language used – plain and easy to understand by general public

- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: as per applicable local regulations
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
- Provision for audiovisual recording of consent process in case of regulatory drug trials

4.6 Use of study assessment form for reviewers

- The assessment form is designed to standardize the review process.
- All reviewers will fill out the form (AX 01/SOP 7A/V4 - letter to EC members requesting initial review with study assessment form) and write their comments related to review of the research proposal.
- In addition, primary reviewers will use the study assessment form (AX 02/SOP 7A/*V4*) to ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting.
- The duly filled, signed and dated assessment forms will be returned along with the research protocols to the Secretariat 7 days prior to the meeting.

4.7 Gather the assessment reports

- The EC Secretariat will collect the Assessment Forms, comments from each reviewer and file in the original study file and converted into a soft copy for discussion at the meeting. If the comments come as a soft copy, these will be collated for discussion at the meeting.
- During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form.
- The comments of an independent consultant (if applicable) will be discussed by the member secretary.
- The other EC members shall give their comments right after the presentation.
- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the EC.
- The EC members will discuss and clarify the comments and suggestions.
- The Member secretary (assisted by the Secretarial staff) shall record the discussions
  - The final decision on the study will be recorded as: "Approved/ Disapproved/ Suggested recommendations (minor or major modifications) or any other in the meeting shall be made by voting or by majority consensus and will be recorded in the EC Decision Form (AX 03A/SOP 7A*/V4)* by the Member Secretary. The EC decision will be communicated to the PI in the intimation letter (AX 03B/SOP 7A*/V4)*
  - A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.
  - The following will not be eligible to vote
    - Member(s) of the committee who is/are listed as investigator(s) on a research proposal
    - An investigator or study team member invited for the meeting.

- An independent consultant invited for the meeting to provide opinion
- Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.
- The Committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary, to primary reviewers or to Full Board before final approval.
- The response and changes carried out may be considered for discussion at a future EC meeting.
- If the EC decision is 'Disapproved' or any other, the decision should be made on the basis of specific reasons, which are communicated by the EC to the principal investigator in the letter of notification.
- The Secretariat will obtain the signature of all the members and of the Chairman of the EC on the EC Decision Form *AX 03/SOP 7A/V4*.
- If the study is approved, the Committee will recommend monitoring for a study if it is so determined at the meeting depending on factors like risk is high in the protocol, the PI has a history of repeated protocol violations, PI has many protocols and any other reason so deemed.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the EC members.
- With the study protocol, the Assessment Form from all members and EC Decision Form will be filed in the study file by the Administrative Officer.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

4.9 Final communication of the EC decision taken on the study to the Principal Investigator

- The Secretariat will prepare an approval letter as *AX 04/SOP 7A/V4* to be sent to the Principal Investigator when the study is approved at an EC meeting.
- The letter contains, at a minimum:
  - Study reference number

- Study title
- A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- The approval is provided for the entire duration of the study.
- List of EC members present at the meeting when the study was approved.
- The Chairman / Member Secretary will sign the approval letter and the Secretariat will send it to the Principal Investigator within 14 days.

- If the Committee disapproves a study, the Secretariat immediately notifies the investigator in writing about the decision and the reason/s for not approving the study within 7 working days.
- A notifying letter to the investigator should state the following:

  "If you wish to appeal to this decision, please contact the EC and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the EC Chairman with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the EC office records."

- If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the EC. The Principal Investigator will be asked to respond to the letter of comments/queries within 10 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the EC office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.

4.10 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed documents.

- The Administrative Officer will store the file on an appropriate shelf in the designated cabinet.

5. References to Other Applicable SOPs

SOP 6/V4.: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V4: Categorization of Submitted Protocols for Ethics Review

SOP 07B/V4: Expedited Review of Research Study Protocols

SOP 07C/V4: Exemption from Ethics Review of Research Study Protocols

SOP 08/V4: Agenda Preparation, Meeting Procedures and Recording of Minutes

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

6. Annexures

Annexure 1 AX 01/SOP 7A/V4 - Letter to the EC Members requesting initial review with study assessment form

Annexure 2 AX 02/SOP 7A/V4 - Study assessment form for primary reviewer

Annexure 3A AX 03A/SOP 7A/V4 - EC decision form

Annexure 3B AX03B/SOP 7A/V4- Intimation letter to PI (Intimation of EC decision to PI)

Annexure 4A AX 04A/SOP 7A/V4 - Format of regulatory clinical trial approval letter (as per NDCT rules 2019)

Annexure 4B AX 04B/SOP 7A/V4 - Format of Interventional Research Study approval letter

Annexure 4C AX 04C/SOP 7A/V4 - Format of Observational Research Study approval letter

Annexure 5 AX 05/SOP 7A/V4- Undertaking by the investigator for regulatory clinical trials (As per NDCT rules 2019)

Annexure 6 AX 06/SOP 7A/V4 Guidelines for reviewing a study protocol

Annexure 1: ***AX 01/SOP 7A/V4***

Letter to EC Members requesting Initial Review with study assessment form

Dear member,

The next meeting of the EC will be held on XXX at XXX in XXXX.

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 5 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annex 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package (*AX 02/SOP 7A/V4*). Kindly confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting (Y/N)

Protocol Number : (as per EC records)	Date of receipt at EC office after review by E member (DD/MM/YY):	
Protocol Title :		
Name of the Principal Investigator	Designation	Department
Name of the Reviewer:		

Comments:

_____

_____

_____

Signature of EC member reviewing the study:		Date:

Annexure 2: ***AX 02/SOP 7A/V4***

Study Assessment Form to be used by the Primary Reviewer

IEC code number of Protocol :		Date (DD/MM/YY):	
Protocol Title :			
Principal Investigator:			
Department :			
No. of Participants:		No. of Study site (s) :	

Mark and comment on whatever items are applicable to the study.

S. No	Item	Comments (if any)
1.	Objectives of the Study ☐ clear ☐ unclear	
2	Need for Human Participants ☐ Yes ☐ No	
3	Methodology: (comment on sample size) ☐ clear ☐ unclear	
4 a.	Background Information and Data ☐ Sufficient ☐ Insufficient	
4 b.	Risk Assessment: A. Type of Risk anticipated to study participant: ☐ Psychological ☐ Physical ☐ Social ☐ Economical ☐ Legal B. ICMR Risk Categorization: ☐ Less than minimal risk ☐ Minimal risk ☐ Minor increase over minimal risk	

	☐ More than minimal risk	
4 c.	Benefit Assessment Yes No For participant ☐ ☐ For society / community ☐ ☐ Improvement in science ☐ ☐ If Yes, mention Direct/Indirect type of benefit for each category Direct Indirect For participant ☐ ☐ For society / community ☐ ☐ Improvement in science ☐ ☐	
4 d.	Exclusion Criteria ☐ Appropriate ☐ Inappropriate	
4 e.	Discontinuation and Withdrawal Criteria ☐ Appropriate ☐ Inappropriate ☐ NA	
5	Involvement of Vulnerable Participants: Yes ☐ No ☐	
6	Control Arms (placebo, if any) Yes ☐ No ☐ NA ☐	
7	Contents of the Informed Consent Document: ☐ clear ☐ unclear	
8	Language of the Informed Consent Document: ☐ clear ☐ unclear	
9	Inducement for Participation Unlikely ☐ Likely ☐	
10	Provision for Compensation for Participation	

	☐ Appropriate ☐ inappropriate ☐ NA	
11	Provision for Treatment for Study-Related Injuries ☐ Appropriate ☐ inappropriate ☐ NA	

Any other comments:

Reviewer's Signature with date:

Annexure 3A: ***AX 03/SOP 7A/V4***

Decision Form

Date of EC meeting: _____

Protocol number: _____

EC Protocol No. and Title:	
Principal Investigator:	Department:
Final Decision at the meeting:	☐ Approved ☐ Approved with modifications ☐ Resubmission ☐ Disapproved ☐ Reviewed at the Full Board meeting ☐ Review by any 2 / more EC members ☐ Monitoring required Reason:_____

Disapproved, Reasons:

_____

_____

_____

No.	Names of Members present	AP	AM	RS	DA	Signature

Note: *AP: Approved; AM: Approved with modification [(either primary reviewer/full board) if reviewed by full board again a decision form has to be filled; RS: Resubmission; DA: Disapproved.*

Comments:
No. of members voting for the decision:
No. of members voting against the decision:
No. of members abstaining from voting:

_____
Signature of Chairman **Date:** _____

Annexure 3 B: AX03B/SOP 7A/V4

Intimation letter to PI (Intimation of EC decision to PI)

To **SMVMCH –EC code no:**

Dear Dr.

SMVMCH Ethics Committee processed your research protocol entitled ""

Comments of the reviewers:

You are informed that you have to rectify your proposal based on the comments given by the members of the Ethics Committee and resubmit it for review by the Ethics Committee on or before Date: XXXX. One hard copy of the revised proposal addressed to the chairman should be submitted to the office of the Ethics Committee. Kindly note that the edited items must be highlighted by yellow colored highlighter.

Above entitled research work can be initiated only after SMVMCH-EC approval letter. SMVMCH-EC approval letter will be issued only after verification of edited copy of the protocol.

MEMBER SECRETARY

Annexure 4A: ***AX 04A/SOP 7A/V4***

Format of regulatory clinical trial approval letter (as per NDCT rules 2019)

To

Dr.

Dear Dr._____

The SMVMCH Institutional ethics committee (SMVMCH-EC) reviewed and discussed your application to conduct the clinical trial entitled "……."

on……..….(date).

The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated…….version No.(s) ……

(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure, dated ..... , Version no..... Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(d) Principal investigator's current Curriculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (AX 05/SOP 7A/V4).

The following members of the ethics committee were present at the meeting held on (date, time, place).

.....Chairperson of the ethics committee;

.....Member-Secretary of the ethics committee;

.....Name of each member with designation;

We approve the trial to be conducted in its presented form.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,

Member Secretary/ Chairman, EC
(Signed and dated by the EC Chairman or Member Secretary)

Annexure 4B: *AX 04B/SOP 7A/V4*

Format of Interventional Research Study Approval letter

Date XX/XX/XXXX

To,
Dr. xxxxxxxxxxxx,
Dept. of xxxxxxxxxxxxx.

Ref: The study no. EC/xxx/20xx entitled, "xxxxxxxxxx".
Sub: Letter no.

Dear Dr. XXXXx,
The meeting of the Institutional Ethics Committee (EC) was held on xxxxx at xxxx, in the xxxxxxxxxxxxx with xxxxx as Chairman.
xxxx members attended the meeting held on xxxx. The list of members who attended the meeting is as follows

Name of Members	Position on EC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The EC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The EC hereby approves the proposal entitled, "xxxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at XXXXXXXXXXXXX as per the submitted protocol.

This approval is valid for the entire duration of the study.

It is the policy of EC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the formats specified in SOP 09/V4 to the EC or by email if there is holiday. The report of SAE or death after due analysis shall be

forwarded by the Investigator to chairman of the EC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death.

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by EC of an appropriate amendment. The EC expects that the investigator should promptly report to EC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before XXXXXXXXXXX.

A copy of the final report should be submitted to the EC for review.

The EC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairman,
EC
(Signed and dated by the EC Chairman or Member Secretary)

Date of approval of the study: XX/XX/20XX

Annexure 4C: *AX 04C/SOP 7A/V4*

Format of Observational Research Study Approval letter

Date XX/XX/XXXX
To,
Dr. xxxxxxxxxxxx,
Dept. of xxxxxxxxxxxxx.

Ref: The study no. EC/xxx/20xx entitled, "xxxxxxxxxx".
Sub: Letter no.

Dear Dr. XXXXx,

The meeting of the Institutional Ethics Committee (EC) was held on xxxxx at xxxx, in the xxxxxxxxxxxxx with xxxxx as Chairman.

xxxx members attended the meeting held on xxxx. The list of members who attended the meeting is as follows.

Name of Members	Position on EC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The EC has reviewed and approved the following documents submitted for the above – mentioned clinical study.

1. Xxx
2. Xxx
3. xxx

The EC hereby approves the proposal entitled, "xxxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at Dept. of xxxx, _____ as per the submitted protocol.

This approval is valid for the entire duration of the study.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the EC of an appropriate amendment. The EC expects that the investigator should promptly report to the EC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before XXXXXXXXXXX.

A copy of the final report should be submitted to the EC for review.
The EC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairman,
EC
(Signed and dated by the EC Chairman or Member Secretary)
Date of approval of the study: XX/XX/20XX

Annexure 5: AX 05/SOP 7A/V4
Undertaking by the investigator for regulatory clinical trials (As per NDCT rules 2019)

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the

amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with date.

Annexure 6: AX 06/SOP 7A/V4

Guidelines for reviewing a study protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - ❑ Knowledge from the basic research may possibly benefit.
   - ❑ A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - ❑ Provide safety data or more competitive choices.
2. Does the study design will be able to give answers to the objectives? Whether
   - ❑ The endpoints are appropriately selected.
   - ❑ The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - ❑ The control arm is appropriately selected for best comparison.
   - ❑ The placebo is justified.
   - ❑ The number of study participants in non-treatment (or placebo) arm is minimized.
   - ❑ Unbiased assignment (e.g. randomization, etc.) is in practice.
   - ❑ Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - ❑ The sample group size appropriate with the given statistical assumptions.
   - ❑ Predictable risks are minimized.
   - ❑ The tests and procedures that are more than minimal risk are cautiously used.
   - ❑ Research participants deception is avoid.
   - ❑ Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
   - ❑ The study participants are adequately assessed and provided follow-up care, if needed.
3. Who will be the participants in the study? Whether
   - ❑ The described population is appropriate for the study.

- Predictable vulnerabilities are considered.
- It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
- There will be secondary participants.

4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?
   - Equitably include participants?
   - Properly exclude participants who can predictably confound the results?
   - Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?
5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants?
   - Use of a stepwise dose escalation with analysis of the results before proceeding?
   - Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and *in vitro* testing results?
   - Previous clinical results, if done?
   - Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
   - The selected dose based on adequate prior results?
   - Monitoring tests designed to detect expected possible risks and side effects?
7. Do the study and the informed consent process include issues of special concern, such as:
   - Waiver or alteration of consent?
   - Delayed consent (e.g., emergency treatment, etc.)?
   - Deception?
   - Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet The actual process of informed consent should:

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.
- Make sure that all information is understood and satisfied by the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.
- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be informally verified on a continuing basis.
- Continue to inform the participants throughout the study.
- Continue to re-affirm the consent to participate throughout the study.

Guidelines to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

   If the answers of (1) to (6) are "yes", placebo is not recommended.

   If any one or more answers are "no", placebo may be possible.
7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?
9) Does standard treatment have contraindications that prevent some research participants from being treated?
10) Is there substantial (≤25%) placebo response in this disease or symptom?

    If the answer of (7) *to* (10) *are "no", placebo is not recommended.*

    If any one or more answers are "yes", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening? *If yes, placebo is not acceptable.*
2) Is the use of placebo instead of treatment likely to lead to permanent damage? *If yes, placebo is not acceptable.*
3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?
   If yes, placebo is not acceptable.
4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?
   If answers of (4) *to* (6) *are "yes", placebo is not acceptable unless risk management is adequate.*

III. Risk management

1) Is there benefit in the overall management of the research participants?
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*
2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?
   - ☐ *No, consider placebo*
   - ☐ *Yes, placebo not recommended.*
3) Are research participants at high risk for the use of placebo excluded?
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*
4) Is the duration of the study the minimum necessary in relation to the action of the drug?
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*
5) Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*
6) Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?
   - ☐ *Not applicable.*
   - ☐ *Yes, consider placebo*

☐ *No, placebo not recommended.*

7) Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression?
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?
   - ☐ *Not applicable.*
   - ☐ *Yes, consider placebo*
   - ☐ *No, placebo not recommended.*

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?
   - ☐ *Not applicable.*
   - ☐ *Yes, consider placebo.*
   - ☐ *No, placebo not recommended.*

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?
   - ☐ *Not applicable.*
   - ☐ *Yes, consider placebo.*
   - ☐ *No, placebo not recommended.*

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?
   - ☐ *Yes, consider placebo.*

2) Are the risks of the test drug disclosed?
   - ☐ *Yes, consider placebo.*

3) Are the advantages of alternative treatments explained?
   - ☐ *Yes, consider placebo.*

Conclusions:

The use of placebo is ethically acceptable when

- ☐ Research participants are not exposed to severe or permanent harm by the use of placebo.
- ☐ Research participants under placebo will benefit from the overall treatment of the disease.
- ☐ Risks of the use of placebo are minimized.

☐ Risks are adequately disclosed in the consent form.

Guidelines to review advertisements

- Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:
  - The name and address of the researcher or research facility.
  - The purpose of the research or the condition under study.
  - In summary form, the criteria that will be used to determine eligibility for the study.
  - A brief list of benefits to participants, if any.
  - The time or other commitment required of the participants.
  - The location of the research and the person or office to contact for further information

- The EC reviews advertising to ensure that advertisements **DO NOT**:
  - State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
  - Include exculpatory language.
  - Emphasize the payment or the amount to be paid, by such means as larger or bold type
  - Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

7. Flow Chart

No.	Activity	Responsibility
1	Receive package or research proposal and research related documents package	Secretariat
2	Verify contents and distribute	Secretariat
3	Appointment of primary reviewers	Member Secretary/Chairman
4	Initial review of documents, Fill review assessment form	EC members
5	EC board meeting, discussion and decision	EC members, Member Secretary, Chairman
6	EC decision communicated to PI	Secretariat
7	Storage of study related documents with relevant correspondence	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

SOP 07B	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 07B/ V4	*Expedited Review of Research Study Protocols*	Effective Date: 02.01.2024

Title: Expedited Review of Research Study Protocols

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) members will perform an expedited review on a new research study protocol using the Assessment Form (AX 01/SOP 7B/V4).

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the EC. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review (SOP 07/V4) is covered in this SOP.

3. Responsibility

- The Member Secretary is responsible, after categorization of the projects (as per SOP 7/V4), to forward the projects to the Secretariat.
- The EC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the designated EC members for review (if the study is categorized for expedited review) and communicate the review results to the investigators.
- Designated EC members (including Member Secretary and/or Chairman) will be responsible for reviewing the research protocols and related documents within the given time frames.
- It is the responsibility of all the designated EC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.
- The EC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The Chairman is responsible to sign and date the decision in the EC Decision Form *AX 02/SOP 7B/V4.*

4. Detailed instructions

4.1 Appointment of reviewers

- After determining that the Protocol / Project qualify for an expedited review, the Member Secretary (in consultation with Chairman) will nominate two or more EC members to review the amended protocol.

4.2 Distribute the protocol package

- The Secretariat will fill in the required details in the nomination form to the EC Members requesting initial review (*AX 01/SOP 7A/V4*) and in the study assessment form *AX 02/SOP 7A/V4*.
- The Secretariat will send a packet *(hard or soft copy)* to the designated EC members.
  - Nomination letter to EC Members requesting Initial Review,
  - Study assessment form *AX 01/SOP7A/V4,*
  - Project Submission Application Form *AX 01/SOP06/V4*,
  - Protocol and related documents

4.3 Receive the distributed protocol package:

Designated EC members will receive the protocol package with the Project Application Form AX 01/SOP 06/V4, in a CD or pen drive or as hard copy (if desired so).

4.4 Verify the contents of the package

- The EC member will verify all the contents.
- The EC member will notify the EC Secretariat if any documents are missing

4.5 Review by the EC members

- EC members will review the protocol as described in Section 4.5 of SOP 7A/V4 within the stipulated time line.

- The comments of the EC members will be recorded on *AX 02/SOP 7B/V4.*

4.6 Gather the assessment reports.

The EC Secretariat will collect the Assessment Forms with the comments from each designated reviewer and file in the original study file

4.7 Decision and Communication of decision to PI and EC Full Board

- The Member Secretary will discuss the comments of the members with the Chairman and a decision about the protocol will be taken.
- If there are queries these will be sent to the PI within one working day after receipt by the Secretariat in consultation with Member Secretary.
- The reply from the PI will be discussed by the Member Secretary with the Chairman or the designated EC members and a decision be reached.
- The final decision will be recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V4.*
- The decision will be informed to the EC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairman, the project shall be discussed at the forthcoming full board meeting before final decision. The final decision by the Chairman is recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 7B/V4.*
- The Secretariat will send the Study approval letter to the PI.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing.
- The reasons for disapproval of a project will be specified in the letter sent to PI.
- The expedited review process should be completed within 14 working days.

5. References to other applicable SOPs

SOP 06/V4: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V4: Categorization of Submitted Protocols for Ethics Review

SOP 07A/V4: Initial Full-Board Review of Research Study Protocols

6. Annexures

Annexure 1 *AX 01/SOP 7B/V4* - Form for nomination of EC members for Review

Annexure 2 *AX 02/SOP 7B /V4* -Study Assessment Form for Expedited Review

Annexure 3: AX 03/SOP/7B/V4 - Additional information to be provided with Application Form for Expedited Review

Annexure 4: AX 04/SOP 7B/V4 - Approval letter format in case of Expedited Review

Annexure 1: AX 01/SOP 7B/V4

Form for nomination of EC Members for Review

Date: XXXX

To,

XXXXXXx,

Member, EC,

Ref: The project no. **EC/PHARMA-XX/20XX** entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the EC for review.

1. _____
2. _____
3. _____

The following members are nominated to review/ carry out an expedited review of the above-mentioned documents.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed (Annexure *AX 02/SOP 07A/V4*) and send to the EC office within 7 working days: _____

Signature of Member Secretary / Chairman with date

Annexure 2: *AX 02/SOP 7B/V4*

Study Assessment Form for Expedited Review

EC Protocol Number :	Date of receipt at EC office (DD/MM/YY):
Project Title : _____	

Name of the Principal Investigator	Department	Contact number

Total no. of Participants at the site:
No. of Study sites:
Sponsor:

Duration of the Study:

Reviewer's name :	
Type of the Study :	☐ Intervention ☐ Epidemiology ☐ Observation ☐ Document based ☐ Genetic ☐ Social Survey ☐ Others, specify.....

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized ☐ Open-labeled

☐ Double blinded ☐ Placebo controlled ☐ Treatment controlled

☐ Cross-over ☐ Parallel ☐ Interim Analysis

☐ Use of Tissue samples ☐ Use of Blood samples ☐ Use of genetic materials

Comments:

_____

(Review the protocol and related documents as per the guidelines stated in *AX 05/SOP 06/V4)*

Provisional Decision: ☐ Approved ☐ Resubmission

☐ Disapproved ☐ Full Board

☐ Approved with modifications

Reason for disapproval _____

_____

Name of the EC member _____

Signature _____ **Date** _____

Final Decision:

Approved YES NO

If disapproved, reasons for disapproval _____

_____

_____

Further revision or modification required/resubmission _____

_____

_____

Any Other _____

_____

Signature of the Chairman: _____ **Date:** _____

Annexure 3: AX 03/SOP/7B/V4

Additional information to be provided with Application Form for Expedited Review

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested?
   (Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2)

   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal ☐
   v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   vii. For multicentre research where a designated EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. ☐
   viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   ix. Any other (please specify) ☐

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

Annexure 4: AX 04/SOP 7B/V4

Approval letter format in case of Expedited Review

Date: xxxxxxxxx

To,

Dr. xxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through an expedited review process.

1. xxx

2.xxxxxxx

3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at as per the submitted protocol.

The EC approves the above mentioned study.

This approval is valid for the entire duration of the study.

It is the policy of EC that, it be informed about any onsite serious adverse event or any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to EC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of EC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the EC of an appropriate amendment. The EC expects thatthe investigator should promptly report to the EC any deviations from, or changes of, the protocol to eliminate immediate hazards to theresearch participants and about any new information that may affect adversely the safety of theresearch participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to EC for review.

Sincerely yours

xxxxxxxxxx

Member Secretary/ Chairman

Date of approval of the study: xxxxxx

7 . Flow Chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	Member Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review	Chairman
4.	Expedited process	EC Members/Chairman
5.	Decision of EC	Chairman
6.	Communicate with the EC and the Investigator	Member Secretary/ 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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Exemption from ethics review of research study protocols

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for exemption from ethics review and approval of a research protocol.

2. Scope

This SOP applies to the review of protocols categorized as suitable for exemption from review by the Member Secretary in consultation with the Chairman (as per SOP 07/V4). Any protocol that carries less than minimal risk and fulfills criteria for exemption from review (SOP 07/V4) is covered in this SOP.

3. Responsibility

- It is the responsibility of the Member Secretary in consultation with the Chairman to record the decision in the Exemption Form with reasons.
- The EC Secretariat is responsible for recording and filing the decision including the reasons for that decision.
- The Chairman must sign and date letter conveying the decision.

4. Detailed instructions

4.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form, Protocol and other documents submitted by the investigators.
- The Secretariat will check that the package is complete and will forward it to the Member Secretary for review

4.2 Determine protocols eligible for exemption from review

- The Member Secretary will screen the research study proposal and determine whether the study qualifies for exemption from review based on the criteria laid down in the Indian Council of Medical Research (ICMR) 2017 Ethical Guidelines. The proposals that involve less than minimal risk fall under this category.
- In some circumstances, research that appears to meet low risk criteria may need to be reviewed by the EC. This might be because of requirements of the publisher of the research or the organization which is providing funding resources, data, access to participants etc.

4.3 Exemption Process

- If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairman will review the brief summary of the project and the Exemption Form.
- The Member Secretary records the decision on the Exemption Form
- The Secretariat communicates the decision to the investigator.
- The Member Secretary / Chairman may keep the application for review and decision regarding exemption at the next full board meeting.

4.4 Communication

- The decision regarding request for Exemption from review, signed by the EC Chairman, will be forwarded by the Secretariat to the Principal Investigator within 14 working days after the decision regarding the exemption is taken.
- The Member Secretary will inform the EC members of the decision at the next regular meeting and minute it.

5. **References to other applicable SOPs**

   SOP 07/V4: Categorization of Submitted Protocols for Ethics Review

   SOP 07-A/V4: Initial Full-Board Review of Research Study Protocols

6. **Annexure**

   Annexure 1 *AX 01/SOP 7C/V4*- Additional information to be provided with Application Form for Exemption from Review

Annexure 01/SOP/7C/V4

Additional information to be provided with Application Form for Exemption from Review

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

Choose reasons why exemption from ethics review is requested? *(Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51Table 4.2.)*

i. Research on data in the public domain/ systematic reviews or meta-analyses. ☐
ii. Observation of public behavior/ information recorded without linked identifiers and disclosur ☐
would not harm the interests of the observed person
iii. Quality control and quality assurance audits in the institution ☐
iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
v. Consumer acceptance studies related to taste and food quality ☐
vi. Public health programmes by government agencies. ☐
(Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme o monitoring (where there are no individual identifiers)
vii. Any other (please specify in 100 words)

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

7. Flow Chart

No.	Activity	Responsibility
1	Receive the submitted documents.	EC Secretariat
2	Review of protocol and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairman	Member Secretary
4	Communicate the decision to the Investigator	EC Secretariat
5	Informing the decision to the members in the forthcoming meeting	Member Secretary
6	Recording and filing the decision	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, and minutes.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all EC meetings.

3. Responsibility

- It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the EC meeting
- The Chairman will review and approve the agenda
- Ensure adherence of SMVMCH-EC functioning to the SOP/s and the agenda of the meeting.
- It is the responsibility of the Member Secretary to ensure proper recording and dissemination of the minutes after the meeting is over.
- It is the responsibility of the Member Secretary to ensure accurate and complete documentation
- It is the responsibility of all members to read and approve the minutes sent to him/her.
- The Chairman will review and finally approve the minutes

4. Detailed instructions

4.1 Before each Board meeting

- The EC Full Board meeting will be scheduled every 3 months (4 meeting/ year)
- The date of the next meeting will be intimated to the EC members well in advance.

- The Member Secretary should ensure the risk assessment and type of review required for the proposal as per ICMR 2017 guidelines and allocate ample time to the proposals for discussion.

4.2 ***Preparation of meeting agenda***

- The Member Secretary assisted by the Secretariat will prepare the meeting agenda, according to the format in AX 01/SOP 08/V4 to include:
  1. Apologies
  2. Ensure quorum throughout the meeting by Chairman (preferably for each proposal)
  3. Reading and approving minutes of the previous meeting.
  4. All proposals for Initial full board Review
  5. Ratification of expedited and exempt for review proposals
  6. All resubmitted proposals for full board review.
  7. Review of Amended proposals related documents for Full Board review.
  8. Issues for consideration
     - Continuing review of study proposals
     - Review of Study Completion Reports
     - Review of premature study termination
     - Review of Site Monitoring Visit Reports
     - SAE reports/CIOMS forms/Safety letters
     - Minutes of SAE Subcommittee (if applicable)
  9. Issues to be discussed including emergency concerns/ EC policies/ training of Members/ revising SOPs/ any other issues raised by Member(s).
  10. Any other matter referred for EC opinion or issues to be informed to the members.

11. Report of any other subcommittee or group appointed/ designated by Chairman for any specific or general purpose.
12. Any other matter

- The Secretariat will collect and verify all forms/documents for completeness and keep ready in these papers in the meeting.
- The Secretariat will schedule proposals in the agenda as per date of receipt.
- Answers to the EC queries and amended study related documents (Protocol, ICD, CRF and IB) from the investigators received 7 days before and other types of documents received 3 days prior to the date of full board EC meeting will be included in the agenda.
- The agenda for the EC meeting is prepared 3 days in advance before the date of meeting
- Any study-related document (except if related to safety of a participant including SAE report) received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next EC meeting for discussion except in some cases when the matter is urgent and important (having direct bearing on the safety of the research participants such as SAE report or major protocol violation) in the opinion of the EC Secretary or Chairman.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the EC members telephonically and/ or *via* e-mail.
- The Secretariat will send *via* e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting.
- The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day.

4.3 During the meeting

- Meeting will be held as scheduled, provided there is required quorum.

- ✓ A minimum of five members present in the meeting room.
- ✓ The quorum should include both medical, non-medical or technical or/and non-technical members.
- ✓ Minimum one non-affiliated member should be part of the quorum.
- ✓ Preferably the lay person should be part of the quorum.
- ✓ The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements (NDCT rules 2019).
- ✓ No decision is valid without fulfillment of the quorum.
- ✓ If the quorum is not met during the meeting the clinical trial proposals will not be deliberated during the meeting and will be taken up for the next meeting for the review.

- At the discretion of the Chairman, guests may be allowed to observe the Board meetings (See SOP 05/V4). These guests may include a student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc. All guests are required to sign a confidentiality agreement prior to attending the meeting (SOP 05/V4).
- The Secretariat will obtain signatures on the Confidentiality Guests/ observers/ Independent Consultants prior to the start of the meeting (SOP 05/V4)
- The Secretariat will obtain the signatures of all the EC members on the attendance register.
- The Chairman will initiate the meeting after ensuring that the quorum has been met. The Chairman at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairman will ask the members whether anyone has any conflict(s) of interest in the proposals to be discussed and if so, to declare the conflict.

- The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict (e.g. members who are PIs or Co-Is) prior to the start of the meeting
- If a conflict of interest has been declared by a member the Chairman will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order organized in the agenda. However, the Chairman may allow adjustments in the order of issues to be discussed depending on the situation.
- In case of proposals submitted for initial review; the detailed instructions given in SOP 07/V4 will be followed.
- Investigators who have been asked by the EC secretariat to provide additional information or clarifications related to their project may do so by attending the EC meeting. The discussion amongst EC members will not be done while the investigator is in the meeting room.
- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

4.4 Decision making

- The final decision on each proposal / issue discussed in the meeting shall be by voting. A majority vote is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.

- Decisions will include approval, disapproval, request for modifications of a study, suspension or termination of an ongoing study (SOP 06/V4)
- The following will not vote at the meeting:
  - ✓ Member(s) of the committee who is/are listed as investigator(s) on a research proposal
  - ✓ An investigator or study team member invited for the meeting
  - ✓ An independent consultant invited for the meeting to provide opinion Specific patient groups invited for the meeting

- SMVMCH-EC can give one of the following decisions:
  - ✓ Approved – with or without suggestions or comments;
  - ✓ Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
  - ✓ Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or
  - ✓ Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/ revoking of permission.

- The schedule of the next meeting will be discussed and finalized by the members.

4.5 After the Board meeting

- The Secretariat will compose the summary of discussion and decision/s arrived in the meeting in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following:
  - ✓ Name of person preparing the minutes
  - ✓ Location where the meeting was held (city, state)

- ✓ Meeting number, date/duration of the meeting (time of commencement and end)
- ✓ Names of the EC members and guests attending the meeting
- ✓ Name of the individual serving as Chairman of the meeting
- ✓ Determination of a duly constituted quorum by the Chairman to proceed with the meeting

- Requirements for each study or activity requesting Approval:
  - ✓ Sponsor's name, if applicable
  - ✓ Protocol number/date/version of protocol, when available
  - ✓ Investigator's name
  - ✓ Names of the Primary Reviewers who presented their findings
  - ✓ Discussion as deemed appropriate by the Chairman
  - ✓ Follow-up action decided upon
  - ✓ Reference to the investigator approval letter that lists all changes requested by the board
  - ✓ Determination of the next requested continuing review.

- Requirements for each study or activity requesting Expedited Review:
  - ➢ Sponsor's name; if applicable
  - ➢ Protocol number, if applicable
  - ➢ Investigator's name
  - ➢ Lists of expedited approval requests and outcomes.
- Requirements for each Continuing Review Report:
  - ➢ Sponsor's name; if applicable
  - ➢ Protocol number, if applicable
  - ➢ Investigator's name
  - ➢ Indication of the Board's determination to continue, terminate, or amend the study
  - ➢ Lists of recommendations or actions to be taken up with the investigator, if applicable.

- Requirements for each Adverse Event notification and Final Report:
  - Sponsor's name; if applicable
  - Protocol number, if applicable
  - Investigator's name
  - Report or summary of report provided by the SAE sub-committee
  - Actions deemed appropriate by the Board's review
- Requirements for Termination of Approval:
  - Name of the Sponsor, if applicable
  - Protocol number, if applicable
  - Investigator's name; reason for termination.

4.6 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairman for review and approval within 7 working days of the meeting day.
- The Secretariat will email the minutes of the meeting to the EC members
- The Chairman indicates approval by signing and dating the minutes (after approval in the next meeting).

4.7 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Secretariat will file the EC Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the EC at the EC meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the EC meeting.

4.8 Calling an Emergency Meeting of EC

- The Member Secretary in consultation with Chairman may decide to call an emergency meeting for any one or more of the following reasons:
  - ✓ Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
  - ✓ Occurrence of unexpected serious adverse event(s).
  - ✓ Other reasons, as deemed appropriate by the Member Secretary/Chairman.
- The Secretariat will endeavor to contact each and every EC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting.
- The administrative officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which emergency meeting is scheduled or send the relevant details via email.
- During the meeting, the Chairman/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least four members (at least one scientific and one nonscientific member) are present, given the urgency of the matter under consideration. The EC members will act according to the relevant EC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

5. References to other applicable SOPs

SOP 05/V4 : Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend EC meeting

SOP 06/V4 : Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

SOP 07/V4 : Categorization of Submitted Proposals for Ethics Review

6. **Annexures**

Annexure 1 *AX 01/SOP 08/V4* - Agenda format

Annexure 1: AX 01/SOP 08/V4

Agenda Format

Agenda of the EC Meeting

Meeting No EC meeting nn/yyyy

Location of the meeting

Meeting Date

Meeting time

The Board meeting will proceed in the following sequences:

Period 1: Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict.

Period 2: A] New Protocol Presentation, Review, Discussion and reaching a decision by voting to approve/raise queries,

B] Review the responses forwarded by the principal investigator to the query letter/ resubmitted proposals

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical trial report/ Annual report / Termination reports.

E] To review Protocol Deviations / Violations

F] To review other Letters related to proposals

G] To review Monitoring reports

G] To inform about the EC meeting and to review the policy decisions

H] To inform about the SAE Subcommittee meetings and to review

SAE/Safety reports.

I] other points for discussion

Period 3: Issues reviewed and approved by the EC member Secretary and Chairman which are to be reported **for Consideration**

Period 4: **Issues to be informed to the members at Full Board** which are approved by the EC member Secretary and Chairman and letters already sent to the principal investigator

Period 5: Other issues of interest to the members

7. Flow Chart:

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a board meeting	SMVMCH-EC Secretariat
2	During the Meeting	SMVMCH-EC Secretariat, Members and Chairman
3	After the Board Meeting and Preparing the minutes	SMVMCH-EC Secretariat/ Member Secretary
4	Approval of minutes	SMVMCH-EC members / Chairman
5	Filing the minutes	SMVMCH-EC Secretariat
6	Calling an emergency meeting	Member Secretary in consultation with Chairman

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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_ Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Review of Resubmitted and Amended Protocols and Protocol-related Documents

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) manages resubmitted & amended study protocols.

2. Scope

This SOP applies to the review of

A. Study protocols and related documents that have been resubmitted to the EC by the Principal Investigator (PI) with clarifications and modifications sought by the EC in initial review

B. Amendments to study protocols and related documents that have been approved earlier

3. Responsibility

- It is the responsibility of the EC Secretariat to ensure the completeness of the documents submitted to the EC.
- A re-submitted protocol and related documents may be reviewed by either the Chairman and two or more EC members designated by the Chairman/ Member secretary, or all the EC members as per EC decision determined by the EC at the time of the initial review of the project during the full board EC meeting. This information would be recorded (during the meeting) on the EC Decision Form (*AX 03/SOP 7A/V4*).
- In the case of an amended study protocol and related documents, The Member Secretary/ Chairman will decide whether the proposed protocol amendment(s) needs to undergo a full board review or expedited review. If the amendment(s) is / are of administrative nature the Member Secretary/Chairman can recommend an expedited review, while if the amendment/s relate to participant safety or data capture, it should be recommended for full board review. Additionally, primary reviewers who had reviewed the initial submission may be asked to review the resubmitted protocol.

4. Detailed instructions

A] For resubmitted protocols

4A1. Receipt of resubmitted protocol and its distribution

- The Secretariat will verify if the PI has replied to EC queries within 10 days of receipt of the letter of comments by the EC.
- The Secretariat will check the resubmitted protocol & related documents (hard and soft copy) for the following items
    - Reply to the EC letter of comments
    - Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc. are submitted with the changes made to the documents either underlined or highlighted.
- The Secretariat will refer to the EC Decision Form (*AX 03/SOP 7A/V4)* on the given protocol and distribute the documents containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to
    - The Member Secretary for summarizing and including it on the agenda for full board discussion in the forthcoming meeting if the decision on the protocol was 'to be discussed at full board'
    - The Member Secretary summarizing and submit to Chairman for Approval if the decision on the protocol was 'Approved with minor revisions / recommendations as per SMVMCH-EC Decision Form.

4A2. Review of revised protocol by EC member/ Member Secretary/Chairman:

- The EC member/ Member Secretary/ Chairman will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the EC have been followed or adequately responded to.
- The EC member/ Member Secretary/ Chairman will make further comments where appropriate, in the Assessment Form for resubmitted protocol *AX 01/SOP 09/V4.*
- The Secretariat will retrieve the Assessment Form for resubmitted protocol *AX 01/SOP 09/V4* from the members/Member Secretary/Chairman.
- In case the decision is to discuss the revised protocol at the full board meeting, the Member Secretary will present a brief oral summary of the study design and the comments of the EC members/Chairman in the EC Full Board meeting.
- The Chairman shall entertain discussion on the protocol revision from all the EC members.
- The final decision regarding the research project shall be reached by voting ($2/3^{rd}$ majority of the members present and voting) and shall include one of the following:
- SMVMCH-EC can give one of the following decisions:

✓ Approved – with or without suggestions or comments;
✓ Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
✓ Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/ revoking of permission.

- In case the revised protocol is already approved through expedited review, the decision is informed to the members at the full board meeting.

B] For amended protocols

4B1. Receipt of protocol for amendments

- The documents for amendments (hard and soft copy) forwarded by the PI will be received by the Secretariat and verified.
- The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form *AX 02/SOP 09/V4*.
- The administrative staff will confirm that the amended version of the protocol and related documents are attached with the application and that the changes or modifications in the protocol are underlined or highlighted in the amended version.

4B2. Notify Member Secretary

- The Secretariat will inform the Member Secretary of receipt of the protocol amendment

4B3. Determine whether full review or review by designated members.

- After review of the materials, the Chairman / Member Secretary will determine whether the protocol requires a full board review or expedited review. The Chairman/Member Secretary will indicate this decision on the Protocol Amendment Assessment Form AX 02/SOP 09/V4
- The amended protocol/ protocol related document will require Full Board review if any of the following criteria are met:

  The Protocol amendment changes the risk-benefit assessment such as

  - a change in study design,
  - additional treatments or the deletion of treatments
  - changes in inclusion/exclusion criteria.
  - change in method of dosage formulation, such as, oral changed to intravenous
  - a significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)

- For regulatory studies, a protocol amendment with above changes would require DCGI approval
- For expedited review, members will be nominated by the Chairman/ Member Secretary.

4B4. Distribution to EC members

- The following documents will be distributed to the designated EC members as per the decision regarding review
  - The amendment's revision documents to clearly identify each change.
  - Protocol Amendment Assessment Form
- Whenever the decision is Full Board review, the Secretariat shall summarize the points for discussion regarding the amended protocol/protocol related documents and shall place the protocol amendment request on the agenda for discussion at the next convened meeting.

4B5. Protocol Amendment Review Process

- The EC member will review the amended documents and write his/her comments in the form - AX 02/SOP 09/V4.
- The reviewer may request the secretariat to keep the documents for full board discussion after review.
- The EC members performing the review must sign and date it and return it to the Secretariat after the review.

4B6. EC Decision on Amended Protocols

- In case the project is kept for full board review, the Member Secretary will present a brief oral summary of the study design and read the comments on the amended protocol/ protocol related documents in the meeting.

4B7. Recording of the decision

- This EC decision will be recorded by the Member Secretary in the EC Decision Form.

4B8. Communication of the Decision to the Principal Investigator

- If the EC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter i.e. AX 03/SOP 09/V4 to the Principal Investigator (PI) within 7 working days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 working days of the meeting.
- The letter of comments sent to the investigator shall state that the reply to the letter is expected within 10 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the EC office records.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

5. Reference to other applicable SOPs

- SOP 7A/V4 – Initial Full-Board Review of Research Study Protocols
- SOP 7B/V4 – Expedited Review of Research Study Protocols

6. Annexures

Annexure 1 *AX 01/SOP 09*/V4 - *A*ssessment of resubmitted protocol

Annexure 2 *AX 02/SOP 09*/V4 - Notification form for Amendments in protocol

Annexure 3 *AX 03/SOP 09*/V4 - Protocol Amendment/Document Amendment Approval letter

Annexure 1: AX 01/SOP 09/V4

Assessment of Resubmitted Protocol

Protocol Number Protocol Title:	
Number of review : ☐ 2nd Review ☐ 3rd Review ☐ 4th Review	
Principal Investigator:	Department:
Date of Initial Review by EC:	Date of Last Review:
The EC Decision recorded in the meeting minutes: (meeting held on _____) _____	

Opinion of the reviewer:

Revision or Modification according to the recommendation	☐ Yes	☐ No: Explain: _____
Approved	☐ Yes	☐ No
If disapproved, reasons for disapproval		
Further revision or modification required		
To be discussed at the forthcoming full board meeting		
Any Other		

Name of the Reviewer: 1) _____ **Signature:**

Date:_____

Name of the Reviewer: 2) _____ **Signature:**

Date:_____

Final Decision: Approved YES ☐ NO ☐

If disapproved, reasons for disapproval _____

_____

Further revision or modification required/ Resubmission ☐

_____

_____

Any Other ☐

_____

Signature of the Member Secretary/ Chairman:_____

Date: _____

Annexure 02/SOP-9/V4

Notification form for Amendments in protocol

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Date of Start of study:
2. Details of amendment(s)

S. No	Existing Provision	Proposed Amendment	Reason	Location in the protocol / ICD (*Location implies page number in the ICD/protocol where the amendment is proposed.)*

3. Impact on benefit-risk analysis Yes ☐ No ☐

   If yes, describe in brief:

   .....

   .....

4. Is any re-consent necessary? Yes ☐ No ☐

   If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

   Expedited review (No alteration in risk to participants) ☐

   Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI with date:

Annexure 3: AX 03/SOP 09/V4

Protocol Amendment/Document Amendment Approval letter

To

XXXXX (PI)

Department

Ref: - EC No. Project title

Dear Dr._____

We have received from you the following document(s).

1.

2.

At the Institutional Review Board meeting held on _____ the above mentioned documents were reviewed.

After consideration, the EC has decided to approve:

(a) The aforementioned study-related documents OR

(b) The following documents:

1.

2.

The members who attended this meeting held on _____ at which the above mentioned document was discussed are listed below.

2.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board.

OR

After reviewing the documents, the EC has decided to approve the aforementioned study-related documents.

Yours truly,

_____

Signature of EC Chairman/ Member Secretary with Date

7. Flowchart

No.	Activity	Responsibility
1.	Receive the Protocol amendment / Resubmitted protocol	EC Secretariat
2.	Notify the Member Secretary / Chairman of the EC	EC Secretariat
3.	Determine whether full board review / review by designated members is needed	EC Member Secretary / Chairman
4.	Nomination of Members for review	EC Chairman
5.	Distribution to EC members	EC Secretariat
6.	Protocol Amendment/ Revised documents Review	EC Members / Member Secretary / Chairman
7.	EC Decision	EC Member Secretary / Chairman
8.	Communication of the Decision to the Principal Investigator	EC Secretariat
9.	Store documents	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Continuing Review of Study Protocols

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how continuing review of previously approved protocols should be managed by the Institutional Ethics Committee (EC). The purpose of the continuing review is to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of already approved study protocols at pre-specified intervals. All the projects approved by the EC will be reviewed at least once a year or completion of the proposal whichever is earlier. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the EC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the EC Secretariat to remind the PIs and Member Secretary regarding continued review of protocols at the correct interval. All the approved protocols will be reviewed annually. It is the responsibility of the Member Secretary to ensure a decision regarding whether the project needs to be reviewed more frequently is taken during the EC meeting in which the project is finally approved. This must be recorded in the minutes. A fresh decision to increase review may be taken if required based on the SAE reports [As per ICMR 2017 guidelines, SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days)], monitoring reports, or safety concerns. This is responsibility of the SAE subcommittee and Member Secretary.

The EC is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding EC communication.

4. Detailed instructions

4.1 Determining the date of continuing review

- The date of the continuing review will always be at least once in the year or completion of the proposal whichever is earlier. The EC also should examine the means taken for medical management of SAE's.
- The EC may recommend more reviews during the approval process depending on the level of risk ("for cause" monitoring). This will be documented in the minutes.
- The following situations may justify "for cause" monitoring:
  - ✓ high number of protocol violations/deviations;
  - ✓ large number of proposals carried out at the study site or by the same researcher;
  - ✓ large number of SAE reports;
  - ✓ high recruitment rate;
  - ✓ complaints received from any adverse media report;
  - ✓ adverse information received from any other source;
  - ✓ non-compliance with EC directions;
  - ✓ misconduct by the researcher; and any other cause as decided by the EC.
- The Secretariat will inspect the minutes of meeting to set a timetable for continuing review.
- The Secretariat will identify and record the due dates for each project

4.2 Notifying the PI or the study team

The Secretariat will send a reminder to the PI as per the format *AX 01/SOP 10/V4* two months prior (if an annual review) or less as appropriate (if any special additional reviews are required) to the due date of continuing review.

4.3 Managing the continuing review package upon receipt

- The Secretariat will receive a package (soft and hard copy) submitted by the PI for continuing review of each approved protocol. Only one set (soft and hard copy) of continuing review report shall be submitted by the PI to the EC as per the format Continuing Review Application Form (*AX 02/SOP 10/V4)*.

4.4 Verifying the contents of the package

- The Secretariat will ensure that the contents of the package include the following documents:
    - Continuing Review Application Form (*AX 02/SOP 10/V4)*
    - The Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 10/V4)*

      answers on the application form and a discussion of scientific developments, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. must have been discussed in the attached narrative.

- The Secretariat will confirm complete information is appended and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (*AX 02/SOP 10/V4*).

4.5 Review process

- The Continuing review submission may undergo expedited review (as per the procedure described in SOP7B/V4) or full board review (as per the procedure described in SOP7A/V4) as deemed appropriate by the EC Chairman/ Member Secretary
- The EC Chairman/ Member Secretary/ Member/s will use the Continuing Review Application Form (*AX 02/SOP 10/V4)* to guide the review and deliberation process.
- The Secretariat will send the Continuing Review Application Form (*AX 02/SOP 10/V4)* to the designated EC members.
- The EC Chairman/ Member Secretary/ Member/s could reach one of the following decisions after review:
    1. Noted - The EC approves the continuation of the project without any modifications.
    2. Modifications recommended: The study protocols that have been suggested modifications by the EC may not proceed until the conditions set by the EC in the

decision have been met. The amendments and the required documents should be amended and submitted to the EC within one month for re-review.

3. The project cannot be continued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary on *AX 02/SOP 10/V4.*

- The EC Chairman will sign and date the EC decision on Continuing Review Report after a decision has been reached.
- The decision on continuing review taken by the Chairman/ Member Secretary/ Member/s will be informed to all EC members at the next full board meeting
- The continuing review report may be discussed at full board if deemed necessary by Chairman/Member Secretary.
- The EC Secretariat will maintain and keep the EC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process in the project file.

4.6 Communicating EC Decision to the PI

- The Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the Chairman/ Member Secretary/ EC Member/s.

4.7 Non-submission of continuing review report by principal investigator before or on due date.

- If a PI fails to submit the continuing review report before or on due date, the Secretariat will send a email reminder within 15 days after due date of review.
  If there is no response, the EC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to sending:

  a) A reminder letter again

  b) A letter asking explanation for non-submission

  c) A letter asking the PI to put recruitment of new participants on hold till report is submitted

d) Any other action as deemed appropriate by EC

5. References to other applicable SOP/s - nil

6. Annexures

Annexure 1 *AX 01/SOP 10/V4*- Reminder letter by the EC to principal investigator Annexure 2 *AX 02/SOP 10/V4*- Continuing Review / Annual report format

Annexure 1: AX 01/SOP 10/V4

Reminder letter by the EC to principal investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project no. Title: XXXXXX

The above referenced project was approved by the EC on XXXXXXX and is due for Continuing Annual/ Periodic Review by the EC. You are requested to submit an Annual/ Periodic status report in the prescribed format which is enclosed (Continuing Review Application Form *AX 02/SOP 07*) at the earliest, on or before XXXXX. (1 month period)

Signature with date _____

Member Secretary/ Chairman _____

Project No.:	**Date of EC approval:**
Project Title:	
Principal Investigator : **Department :**	

Annexure 2: AX 02/SOP 10/V4

Continuing Review / Annual report format

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Validity of approval:
2. Date of Start of study: Proposed date of Completion:

   Period of Continuing Report: - to -
3. Does the study involve recruitment of participants?

a. If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on follow up:.....

b. Enrolment status – ongoing / completed/ stopped

c. Report of DSMB Yes☐ No☐ NA ☐

(In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA)

d. Any other remark

e. Have any participants withdrawn from this study since the last approval?
   If yes, total number withdrawn and reasons:

4. Is the study likely to extend beyond the stated period? *(Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC)*
   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?
   If No, skip to item no. 6 Yes☐ No☐
   a. If yes, date of approval for protocol and ICD :
   b. In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes☐ No☐
      If yes, when / how

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐
   If yes, discuss in detail:

7. Have any ethical concerns occurred during this period? Yes☐ No☐
   If yes, give details:

8. a. Have any adverse events been noted since the last review? Yes☐ No☐

Describe in brief:

b. Have any SAE's occurred since last review? Yes☐ No☐
If yes, number of SAE's:…… Type of SAE's: ……..

c. Is the SAE related to the study? Yes ☐ No ☐
Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?
If yes, number of deviations ……
Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ?
Yes☐ No☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes☐ No☐

Any other comments:

Signature of PI with date:

7. Flow Chart

No.	Activity	Responsibility
1	Determine the date of continuing review	Administrative Officer / Secretariat
2	Notify the Principal Investigator or study team	EC Secretariat
3	Manage continuing review package upon receipt and verifying its contents	EC Secretariat
4	Notify the members of the EC	EC Secretariat
5	Review of Continuing review report	EC Secretariat, Members and Chairman
6	Prepare meeting agenda	EC Secretariat
7	Communicate the EC decision to the Principal Investigator	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR _Ethical_ Guidelines _2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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	

Title: Review of Protocol Deviations / Violations

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the EC when investigator(s)/ trial site(s) fail(s) to:

- follow the procedures written in the approved protocol,
- comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the Institutional Ethics Committee (EC) for the conduct of human research,
- respond to the EC requests regarding statutory, ethical, scientific or administrative matters.

2. Scope

This SOP applies to all EC approved research protocols involving human research participants.

3. Responsibility

The EC Secretariat is responsible for receiving deviation/ violation reports as per (*AX 01/SOP 11/V4*) submitted by the Principal Investigator (PI) /others and placing it on the agenda of the meeting. Reporting of deviation/ violation in any other reporting format will not be accepted. The EC members should review and take action on such reports.

4. Detailed instructions

4.1 Detection of Protocol deviation/ violation

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below):

a. Protocol deviation/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the EC.

b. The EC members performing monitoring of the project at trial site may detect protocol deviation/violation if the project is not been conducted as per protocol/ national/ international regulations.

c. The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements/ failure to respond to requests from EC within reasonable time limit/ failure to respond to communication made by EC.

d. The EC members may detect protocol deviation/ violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization.

e. The EC Secretariat and/ or EC members may become aware of a protocol deviation/ violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).

f. Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.

g. Any report/ communication brought to the notice of Member, Secretary/ Jt. Secretary/ Chairman of EC by an independent person.

h. Communication received from the Head of the Institution informing EC about an alleged protocol violation/ protocol deviation.

4.2 Receipt of protocol deviation / violation report by the Secretariat

1. The PI will report the protocol deviation/violation as per Annexure 1 *AX 01/SOP 11/V4*.
2. In case protocol deviation/violation is detected by any other person (See Section 5.1) and reported to the EC (there is no format for this), the Member Secretary will write to the PI to submit a protocol deviation/violation as per Annexure 1 *AX 01/SOP 11/V4*
3. The Secretariat will notify the Member Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 working days of receipt of the notification.

4.3 Actions to be taken

1. The action of the EC will be based on:
    - The nature and seriousness of the deviation / violation.
    - Frequency of deviation/ violation in the study in the past.
    - Frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI or in the same department.
2. Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the EC shall do the following (not limited to these actions):
    - Ask PI for written clarification as soon as the deviation is received
    - If the impact is serious, this report will be shared with the Chairman and two or more EC members designated by the Chairman.
    - If the impact of the protocol deviation is serious enough, the Member Secretary will instruct the Secretariat to call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny
    - The Secretariat will put up the information and communication at the next full board meeting for discussion.
3. The Member Secretary in consultation with EC members will review the information available and deliberate on it.
4. The Chairman will take a final decision depending on the seriousness of the violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by voting. A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as $2/3^{rd}$ of the voting members present at the meeting.
5. The decision taken by EC could include one or more of the following:

- Determine that no further action is required, or take other actions as appropriate.
- Inform the PI that the EC has noted the violation / deviation, and instruct the PI to ensure that deviations/ violations do not occur in future and to follow EC recommendations.
- Enlist measures that the PI would undertake to ensure that such deviations / violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation).
- Suggest modifications to the protocol.
- Alter the interval for submission of the continuing review/ annual project status.
- Ask for additional training of the investigator and study team
- Reprimand the PI.
- Seek additional information from the PI.
- Conduct audit of trial by the EC.
- Suspend the study till additional information is made available and scrutinized.
- Suspend the study till recommendations made by the EC are implemented by the PI and found to be satisfactory by the EC.
- Suspend the study for a fixed duration of time.
- Suspension or termination of the study.
- Revoke approval of the current study.
- Inform DCGI/ other relevant regulatory authorities.
- Keep other research proposals from the PI/ Co-PI under abeyance. Review and/ or inspect other studies undertaken by PI/Co-PI.

6. This final decision will be recorded on *AX 01/SOP 11/V4* by the Member Secretary.

4.4 Procedure for notifying the PI and other concerned authorities

- The Member Secretary will draft a notification letter.
- The signed letter by Member Secretary will be sent to the PI and Department Head(s) (if required on case to case basis) and Institutional Officials (if required on case to case basis).
- The EC secretariat will send a copy of the notification to the relevant national authorities (if required on case to case basis) and institutes (if required on case to case basis in case of multi-centric trials).

4.5 Definitions

Protocol Deviation and Protocol Violation:

Protocol Deviation- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IRB using the standard reporting form.

Protocol Violation- A protocol violation is a deviation from the IRB approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject. For example
   - A research subject received the wrong treatment or incorrect dose.
   - A research subject met withdrawal criteria during the study but was not withdrawn.
   - A research subject received an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study. For example
   - A research subject was enrolled but does not meet the protocol's eligibility criteria.
   - Failure to treat research subjects per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)

- Changing the protocol without prior IRB approval.
- Inadvertent loss of samples or data.

III. The deviation is a willful or knowing breach of human subject protection regulations, policies, or procedures on the part of the investigator(s). For example
- Failure to obtain informed consent prior to initiation of study-related procedures
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege status (credentialing)

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or institutional human subject protection regulations, policies, or procedures. For example
- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research or CC policies
- Repeated minor deviations.

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles. For example
- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

Minor Protocol Deviation- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

4.6 Records and follow up to be kept by EC secretariat

- The Secretariat will keep a copy of the notification letter in the respective project file.

5. References to other applicable SOP/s - nil

6. Annexures

Annexure 1 *AX 01/SOP 11/V4* - Protocol Violation / Deviation Reporting Form (Reporting by case)

Annexure 01/SOP/11/V4

Protocol Violation / Deviation Reporting Form (Reporting by case)

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Date of Start of study:
2. Participant ID: Date of occurrence:
3. Total number of deviations /violations reported till date in the study:

4. Deviation/Violation identified by:
   - Principal Investigator/study team ☐
   - Sponsor/Monitor ☐
   - SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :
   - Consenting ☐
   - Enrollment ☐
   - Laboratory assessment ☐
   - Investigational product ☐
   - Safety reporting ☐
   - Source documentation ☐
   - Staff ☐
   - Participant non-compliance ☐
   - Others (specify) ☐
6. Provide details of Deviation/Violation:

7. Corrective action taken by PI/Co-PI:

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

If yes, give details

Signature of PI with date

7. Flow Chart

No.	Activity	Responsibility
1	Detection and reporting of Protocol deviation/ violation	EC members/ Secretariat/ principal investigator
2	Receipt of protocol deviation / violation report	Secretariat
3	Review, board discussion, decision and action	EC Members, Member Secretary and Chairman
4	Notify the Principal Investigator/ concerned authorities of EC action	Secretariat
5	Maintain records	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. [National Institute of Health IRB Professional Administrators Committee Regulatory Process Workgroup Version 5.1, 11/18/2005 Available from https://www.genome.gov/Pages/Research/Intramural/IRB/Deviation_Violation_examples 8-07.pdf Accessed on 3rd June 2015]

3. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

4. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Review of Serious Adverse Event (SAE) Reports

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the SMVMCH-EC for any study under the oversight of the SMVMCH-EC.

2. Scope

This SOP applies to the review of SAE reports (Adverse events/ SAE onsite as well as SAEs of the multicenter studies occurring at other sites offsite) submitted to the EC.

3. Responsibility

It is the responsibility of the EC to review all SAEs reported to the EC in a timely manner.

4. Detailed instructions

4.1 SAE Subcommittee

- An SAE Subcommittee may be constituted within the EC for big institutions having a large number of SAE reports for review.
- The Serious Adverse Event (SAE) Subcommittee of the Institutional Ethics Committee' (EC) will review all serious adverse events (SAE) at the site / other sites involving human participants approved by EC.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

Composition of the SAE Subcommittee

- The SAE Subcommittee will be appointed by the **Chairperson of EC**
- The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
- The SAE Subcommittee will be composed of at least 5 and a maximum of 10 individuals who are members of the EC.
- The composition shall be as follows:

- Chairperson of the SAE Subcommittee
- One Executive Secretary
- At least one member with post graduate qualification in the discipline of
  - Medicine
  - Medical Pharmacology
  - Any other relevant clinical specialties in the institution

- EC Secretary will be Ex-Officio member of the SAE Subcommittee.
- The SAE Subcommittee may invite legal expert of the EC to provide opinion on the legal implication of adverse event.
- The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.
- The Head of the SAE Subcommittee/ Executive Secretary will sign minutes of the SAE Subcommittee meeting.
- In case of anticipated absence, the Head of SAE subcommittee will nominate a SAE subcommittee member as acting head. The acting Head will have all the powers of the Head of SAE subcommittee for that meeting.
- For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), executive secretary and Head/ Acting head of the SAE subcommittee.
- The SAE subcommittee will meet at least once in a week (or as often as required)

Membership requirements

- EC Members will be appointed to the SAE Subcommittee if they show willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.

- The Head of the Institute (HOI) is responsible for appointing the SAE Subcommittee members. The names of new members to be appointed may be suggested by the EC

members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

- The tenure of SAE Subcommittee will be for a continuous period of two (2) years from the date of appointment.
- The retiring member will be eligible to be appointed for the new tenure consecutively four times.
- An SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE Subcommittee. The member may or may not assign reasons for resignation.
- A SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend more than 5 regular consecutive SAE Subcommittee meetings without prior intimation. The Head of SAE Subcommittee will inform Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE Subcommittee. The Chairperson will take up the issue of disqualification for discussion at the full board meeting and allow the concerned SAE Subcommittee member to state his reasons for unauthorized absence.

Functions of the Executive Secretary of the SAE Subcommittee

1. To schedule and organize the SAE Subcommittee meetings.
2. To prepare and maintain meeting agenda and minutes.
3. To conduct SAE subcommittee meetings
4. To prepare the communication letters related to the adverse event reports.
5. To communicate with the EC members, regulatory authorities and investigators in timely manner.
6. To provide necessary administrative support for SAE Subcommittee related activities.
7. To ensure adherence of the SAE Subcommittee functioning as per SOPs

4.2 *Onsite SAE*

4.2.a. Receipt of SAE report

- The EC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:

i. Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in *AX 01/SOP 12/V4.*

ii. Due analysis should be submitted by the PI within 14 days from the occurrence of the SAE along with the format specified in *AX 02/SOP 12/V4.*

iii. Due analysis will also be submitted by the sponsor within 14 days in the format specified in *AX 02/SOP 12/V4.*

iv. The follow up reports of all on-site SAE till the event is resolved.

- The EC Secretariat will verify that the report is complete in all respects and that it has been received at the EC office within the specified timelines.
- If the report has been received beyond the specified time, it will be considered as a protocol violation and action should be taken as described in SOP 11
- The EC Secretariat will sign and write the date on which the report is received.
- The Secretariat will forward these reports to the EC Member Secretary or Executive Secretary of the SAE Subcommittee (if constituted) within two working days.

4.2 b. Review and Decision on SAE Reports and Communication to PI and Regulatory Authority by EC

- Any injury or death or permanent disability of a trial subject occurring during clinical trial or bioavailability or bioequivalence study due to any of the following reasons shall be considered as clinical trial or bioavailability or bioequivalence study related injury or death or permanent disability, namely:-

(a) adverse effect of the investigational product;

(b) violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event;

(c) failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol;

(d) not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo controlled trial;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol;

(f) adverse effect on a child in-utero because of the participation of the parent in the clinical trial;

(g) any clinical trial procedures involved in the study leading to serious adverse event.

- Member Secretary or Executive Secretary of the SAE will review the SAE report and present to the full board / SAE subcommittee (as applicable) for review and opinion.

- At the meeting of EC or SAE subcommittee, the SAE reports will be reviewed with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion. Where an injury occurs to any participant during clinical trial or bioavailability and bioequivalence study of a new drug or an investigational new drug, the sponsor, shall provide free medical management to such subject as long as required as per the opinion of investigator or till such time it is established that the injury is not related to the clinical trial or bioavailability or bioequivalence study, as the case may be, whichever is earlier. Formulae to determine the quantum of compensation in the cases of clinical trial related injury or death (As per New Drugs and Clinical Trials Rules, 2019) is given in AX03A/SOP12/V4 and Factor (F) for calculating the amount of compensation in the cases of clinical trial related injury or death is given in AX03B/SOP12/V4.

- If deemed necessary, a decision to hold emergency EC meeting may be taken to discuss about financial compensation. An emergency EC meeting will be scheduled within 7 days for the same.

- The Executive Secretary of the SAE subcommittee may refer the SAE report to full board for review if deemed necessary

Particip ant ID	Letter no./and date of reportin	Type of Report (I/FU)	Date of onset	whether study drug withheld	SAE Outc ome	Causality in the opinion of PI	Recommen dation(s) by the SAE Sub Committee

I-initial, FU- Follow-Up

- The minutes of the SAE Subcommittee/ EC meeting will include the information on SAE at the site along with the opinion on the above points on the onsite SAE .
- The minutes will be circulated to the EC members *via* email and approval/ objection will be sought from the members in a period of 5 working days.
- The EC secretariat will draft a formal letter to the concerned PI and inform him/ her about the EC decision. This letter will be signed and dated by the Member-Secretary or Chairperson (EC) and will be sent to the PI within a period of 7 days from the date of the SAE subcommittee meeting.

  The PI will be requested to reply to the query letter on the SAE report within 7 working days.

- The opinion regarding relatedness, medical management and compensation for research related injury will be communicated to the Central Licensing authority within 30 calendar days of receiving the report of the serious adverse event of death from the investigator, in case of regulatory clinical trials.
- The Administrative Officer will file a copy of these letters in the study file.

4.3. Reports of SAE Occurring at other Sites

The investigator will need to submit the SAEs occurring at other sites (CIOMS and SUSARS) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:.

Sr. No.	Country	Type of Report (I/FU)	SAE event	Date of onset	Date of report	Out come	Causality	
							Investigator	Sponsor

I-initial, FU-Follow up

- For every SAE term, a separate row of the above table is to be used (the SAE terms should not be combined).
- Causality to be stated as related (R) or not related (NR)
- The SAEs occurring at other sites will be reviewed by the Secretary of the EC / SAE Subcommittee (as applicable) and informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.

4.4. Onsite AE

The EC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the EC:

1. On site AE reports to be submitted by the PI annually in the continuing review report.
2. In view of the risk assessment of a given research proposal the EC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

- The EC Secretariat will verify that the report is complete in all respects and signed and dated by the PI and that it has been received at the EC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as deviation.
- For all the onsite AE reports received at the EC office, the Administrative Officer will forward these reports to the Member Secretary of EC for review.

- Member Secretary of EC may put the AE reports for discussion at full board if deemed necessary
- Queries, if any on the report will be communicated to the PI by the Member Secretary of EC following full board meeting
- The Administrative Officer will file a copy of these letters in the study file.

4.5. Review During the Full board EC meeting

- The EC Member Secretary will read out the minutes of all the weekly SAE Sub-committee meetings including the recommendations/ decisions of the SAE sub-committee (if constituted).
- In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
- The decision can be arrived at by consensus. If not agreed by consensus, the issue would be put for voting. (a majority vote for a decision is 2/3rd majority of the members present and voting)

4.6 Decision of EC on SAE review

The SAE Subcommittee/EC may take one or more of the following decisions on review of the SAE reports.

4.6a. Type of Actions Taken by EC/ SAE Subcommittee on Review of SAE Report:

Following detailed review of the SAE reports and related documents, the EC/ SAE Subcommittee (if constituted) can suggest one of the following actions:

- Note the information about the SAE in records for future reference.
- Request further follow up information and/ or additional details.
- Ask for periodic follow-up of the research participant till SAE is resolved

- Depending on complexities of issue, **EC/ SAE Subcommittee** may decide to seek opinion of outside expert consultant who is requested to respond within 14 working days.
- Provide recommendations regarding/ raise queries related to compensation for study related injury and death

4.6b. **Type of Actions Taken by EC following full board review**

- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents.
- Suspend the study till additional information is available.
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
- Suspend the study till amendments requested for by the EC are carried out.
- Suspend enrollment of new participants.
- Suspend certain activities under the protocol.
- Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.
- Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional
- Procedures, additional investigations, etc. as prescribed in the amendment.
- Terminate the study.
- Any other appropriate action.

- The decision shall be recorded in the minutes of the full board EC meeting.
- If the recommendation from the EC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the PI through telephone, fax or email within 24 hours. Such a

communication will be documented by the EC Member-Secretary in the study file. A formal letter to the PI informing about the EC recommendations in such situations will be sent within 5 working days of the EC meeting having taken place.

Definitions

1] Serious Adverse Event:

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

2] Serious Adverse Event or Serious Adverse Drug Reaction

An AE or ADR that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

3] Adverse Event

An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

5. References to other applicable SOPs

- **SOP 07A/V4** - *Initial Full-Board Review of Research Study Protocols*
- **SOP 08/V4** - *Agenda Preparation, Meeting Procedures and Recording of Minutes*
- **SOP 10/V4** - *Continuing Review of Study Protocols*

6. Annexures

Annexure 1 *AX 01/SOP 12/V4* –Data elements for reporting Serious Adverse Events occurring in a Clinical Trial or Bio-availability or Bio-equivalence study (As per New Drugs and Clinical Trials Rules, 2019)

Annexure 2A *AX 02A/SOP 12/V4* - Checklist for Onsite Serious Adverse Event submission

Annexure 2B *AX02B/SOP12/V4 – Onsite* Serious Adverse Event Analysis Report

Annexure 3A AX03A/SOP12/V4- Formulae to determine the quantum of compensation in the cases of clinical trial related injury or death (As per New Drugs and Clinical Trials Rules, 2019)

Annexure 3B AX03B/SOP12/V4- Factor (F) for calculating the amount of compensation in the cases of clinical trial related injury or death (As per New Drugs and Clinical Trials Rules, 2019)

Annexure 1: AX 01/SOP 12/V4

Data Elements for Reporting Serious Adverse Events
Occurring in a Clinical Trial or Bioavailability or
Bioequivalence Study (As per New Drugs and Clinical Trials Rules, 2019)

1. Patient Details:

   Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*

   Gender

   Age or date of birth

   Weight

   Height

2. Suspected Drug(s):

   Generic name of the drug*

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

Dosage form and strength.

Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).

Route of administration.

Starting date and time of day.

Stopping date and time, or duration of treatment

3. Other Treatment(s):

Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Serious Adverse Event:

Full description of the event, including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*

Start date (and time) of onset of event.

Stop date (and time) or duration of event.

Dechallenge and rechallenge information.

Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome

Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. Details about the Investigator*

Name and Address

Telephone number

Profession (specialty)

Date of reporting the event to Central Licencing Authority:

Date of reporting the event to ethics committee overseeing the site:

Signature of the Investigator or Sponsor

Note: Information marked * must be provided.

Annexure 2A: AX 02A/SOP12/V4

Checklist for Serious Adverse Event (SAE) submission

(For Onsite SAE)

S. No	**Details**		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death, Please tick (✓)**	**Death** ☐	**Other than Death** ☐
		Yes / No	**Page No.**
3.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		

7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Patient Details**		
a.	Initials & other relevant identifier (hospital/OPD record number etc.)		
b.	Gender		
c.	Age and/or date of birth		
d.	Weight		
e.	Height		
13.	**Suspected Drug(s)**		
a.	Generic name of the drug		
b.	Indication(s) for which suspect drug was prescribed or tested		
c.	Dosage form and strength		
d.	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e.	Route of administration		
f.	Starting date and time of day		
g.	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non- drug therapies, as for the suspected drug(s).		
15.	**Details of the events**		
a.	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b.	Start date (and time) of onset of reaction.		
c.	Stop date (and time) or duration of reaction.		
d.	Dechallenge and rechallenge information.		
e.	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a.	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		

b.	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c.	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	**Details about the Investigator**		
a.	CT Site Number, if any		
b.	Name		
c.	Address		
d.	Telephone/Mobile Number & Email		
e.	Profession (speciality)		
f.	Date of reporting the event to Licensing Authority:		
g.	Date of reporting the event to Ethics Committee overseeing the site:		
h.	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a.	Name & Address		
b.	Name of Chairman & Address		
c.	Telephone/Mobile Number		
d.	Email		
19.	Adverse Event Term/ Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a.	Duly filled SAE Form as per Appendix XI of Schedule Y		
b.	Laboratory investigations report /Discharge summary (if available and applicable)		
c.	Post-mortem report (if applicable)/ Any additional documents)		

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 2B: AX 02B/SOP 12/V4

Serious Adverse Event (SAE) Analysis Report

(For Onsite SAE)

S. No	**Details**		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death, Please tick (✓)**	**Death** ☐	**Other than Death** ☐
		Yes / No	**Page No.**
3.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Patient Details**		
a.	Initials & other relevant identifier (hospital/OPD record number etc.)		
b.	Gender		
c.	Age and/or date of birth		
d.	Weight		
e.	Height		
13.	**Suspected Drug(s)**		
a.	Generic name of the drug		
b.	Indication(s) for which suspect drug was prescribed or tested		
c.	Dosage form and strength		
d.	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)		
e.	Route of administration		
f.	Starting date and time of day		
g.	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non- drug therapies, as for the suspected drug(s).		
15.	**Details of the events**		
a.	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for		

	regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b.	Start date (and time) of onset of reaction.		
c.	Stop date (and time) or duration of reaction.		
d.	Dechallenge and rechallenge information.		
e.	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a.	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b.	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c.	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	**Details about the Investigator**		
a.	CT Site Number, if any		
b.	Name		
c.	Address		
d.	Telephone/Mobile Number & Email		
e.	Profession (speciality)		
f.	Date of reporting the event to Licensing Authority:		
g.	Date of reporting the event to Ethics Committee overseeing the site:		
h.	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a.	Name & Address		
b.	Name of Chairman & Address		
c.	Telephone/Mobile Number		
d.	Email		
19.	Adverse Event Term/ Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a.	Duly filled SAE Form as per Appendix XI of Schedule Y		
b.	Laboratory investigations report /Discharge		

	summary (if available and applicable)		
c.	Post-mortem report (if applicable)/ Any additional documents)		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for the amount of compensation to be paid?

What is the sponsor's assessment for the amount of compensation to be paid?

Has the participant made a claim? Yes No

If yes, for how much amount

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

Signature of the Principal Investigator : Date:_____

Annexure 3A: AX03A/SOP12/V4

Formulae to determine the quantum of compensation in the cases of clinical trial related injury or death (As per New Drugs and Clinical Trials Rules, 2019)

1. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per **Annexure 3B** (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0 Patient with high risk (expected survival between 6 to 24months)

(3) 2.0 Patient with moderate risk

(4) 3.0 Patient with mild risk

(5) 4.0 Healthy Volunteers or trial subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of clinical trial related injury (other than death): For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability: In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

Where :

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

(ii) Congenital anomaly or birth defect: The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;

(b) Early death due to anomaly;

(c) No death but deformity which can be fully corrected through appropriate intervention;

(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and

(iv) Reversible SAE in case it is resolved.

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalisation of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalisation of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization

Annexure 3B: AX03B/SOP12/V4

Factor (F) for calculating the amount of compensation in the cases of clinical trial related injury or death (As per New Drugs and Clinical Trials Rules, 2019)

Age	Factor
Not more than...	
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68

54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

7. Flowchart

No.	Activity	Responsibility
1	Receipt of SAE report	EC Secretariat
2.	Submission of SAE report to the SAE Subcommittee	EC Secretariat
3	Agenda and Minutes of the Subcommittee (if constituted)	Executive Secretary of the SAE Sub-committee (if constituted)
4.	Review and discussion of SAE report at the Subcommittee meeting (if constituted)	SAE Subcommittee members (if constituted)
5.	Review and discussion of SAE report at the full Board meeting	Member Secretary
6.	Communication of the EC decision about SAE review to the Licensing authority	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary
7.	Communication of the EC decision about SAE review to the principal investigator	Executive Secretary of the SAE Sub-committee (if constituted)/ Member Secretary,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. *[ICHGood-Clinical-Practice-Guideline http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline]*
3. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
4. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Review of Study Completion reports

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the Institutional Ethics Committee (EC).

2. Scope

This SOP applies to the review of the Study Completion Report which is a written report of every completed study submitted by the Principal Investigator (PI).

3. Responsibility

It is the responsibility of the Secretariat/ EC Chairman/ Member Secretary/ Member/s to review the study report and act on it.

4. Detailed instructions

4.1. Receipt of Study Completion Report

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – *AX 01/SOP 13/V4* from the PI. The study completion report is expected from the investigator within 1 month of completion of the study at the site.
- The Secretariat will follow instructions as in SOP 06/V4 (Management of Protocol Submission) for receiving and checking the report package.
- It is the responsibility of the EC Secretariat to review the report for completeness.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form- *AX 01/SOP 13/V4* and forward it to the Member Secretary within 7 working days of receipt.
- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

- If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per SOP 11/V4
- The Secretariat shall include the Study Completion Report Form in the agenda for EC members as per SOP 08/V4 for discussion at the full board meeting.

4.2. During the Board meeting

- The Member Secretary will present the report and members can discuss as needed.
- Following the discussion, the Chairman may take one of the following decision:
  a) noted / approved
  b) request for additional information / clarification
- The Secretariat will note the decision in the meeting minutes
- The Member Secretary will draft a letter to the PI conveying decision on the study completion report.
- The study shall be considered as closed if the decision by EC is "Noted" or "Approved".
- The Secretariat will accept and file the Report and get the Study Completion Report Form *AX 01/SOP 13/V4* signed by the Chairman.
- The final report will be placed in the master file and kept in the archival area.
- The Administrative Officer will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

5. Reference to other applicable SOPs:

- **SOP 06/V4**: *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP 08/V4:** *Agenda Preparation, Meeting Procedures and Recording of Minutes*
- **SOP 11/V4:** *Review of Protocol Deviations / Violations*

6. Annexures

Annexure 1 - Study Completion / Final report format (*Annexure 01/SOP/13/V4)*

Annexure 01/SOP-13/V4

Study Completion / Final report format

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval :
2. Date of start of study: Date of study completion:
3. Provide details of:
   a. Total number of study participants approved by the EC for recruitment:
   b. Total number of study participants recruited:
   c. Total number of participants withdrawn from the study (if any):

   Provide the reasons for withdrawal of participants (*Explanation for the withdrawal of participants whether by self or by the PI)* :

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

5. Describe the main ethical issues encountered in the study (if any)

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: Violation: Amendments:

7. Describe in brief plans for archival of records / record retention:

8. Is there a plan for post study follow-up? Yes☐ No☐

   If yes, describe in brief:

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?
   If yes, describe in brief: Yes☐ No☐

10. Is there a plan for post study benefit sharing with the study participants? ☐ Yes☐ No
    If yes, describe in brief:

11. Describe results (summary) with Conclusion (*For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready)* :

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC ? ☐ Yes☐
    No

14. Is medical management or compensation for SAE provided to the participants? ☐ Yes☐
    No
    If yes, provide details

Signature of PI with date:

7. Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	EC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	EC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	EC Secretariat
4	Review of the Study completion report for completeness and informing members at full-board meeting	Member-Secretary/
5	Inclusion of the report/ review at full-board meeting	EC Secretariat
6	Discussion and decision at the full board meeting	Member Secretary/ Chairman
7	Noting the decision in the minutes of the Meeting	EC Secretariat
8	Conveying decision to the Principal Investigator	EC Secretariat
9	Archiving all the study-related documents along with the Study completion report	Administrative Officer

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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf

3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Management of Premature Termination / Suspension / Discontinuation of the study

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (EC) manages premature termination/suspension/discontinuation of a research study.

Protocols may be terminated/suspended/discontinued at the recommendation of the EC, Data Safety Monitoring Board (DSMB), Principal Investigator (PI), Sponsor, Regulator or other authorized bodies wherein participant enrolment and follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study previously approved by the EC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility

It is the responsibility of the EC to manage the termination of any study (recommended for termination by Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by the EC) that the EC has previously approved. The Secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

4. Detailed instructions

4.1. Receipt of Recommendation for Study Termination.

- The Secretariat will receive the study protocol termination/suspension/discontinuation report submitted by the PI and verify the contents of the report for completeness (*AX 01/ SOP 14/V4*) and/or other documents (letter from PI / sponsor).

4.2. Review by the EC

- The Secretariat will inform the Chairman and Member Secretary regarding the recommendation for premature termination/ suspension/ discontinuation of study protocol and the termination/ suspension/ discontinuation report within 3 working days of receipt of the report.

- The Member Secretary/ Chairman shall review the report and either call for an emergency meeting or discuss the report at the regular full board meeting.
- The Secretariat will arrange for an Emergency meeting/ keep matter for discussion at full board meeting as per SOP 07A/V4.
- The Member Secretary in the meeting will inform members of the premature termination/ suspension/ discontinuation of the project and the reasons for the same.
- If the Premature termination/ suspension/discontinuation Report is unclear or more information is required from the PI, the Chairman shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairman shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.
- If the EC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days of the full board meeting

4.3 Notifying the Principal Investigator

- The Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.
- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 60 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full board meeting for discussion.
- The investigator may appeal or respond to the convened EC in writing.

4.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 5 years from the date of project Termination.

4.5 **Recommendation for Termination/ Suspension/**

Discontinuation *4.1 By PI / Sponsor*

- An investigator/ Sponsor may put on hold a previously approved research when in the judgment of the investigator/ Sponsor this is appropriate to protect the rights or welfare of participants or when new safety information has appeared in the literature, or evolved from this or similar research.

4.6 By EC

EC members/Chairman can prematurely terminate/ suspend/ discontinue the study in he following situations:

- protocol non-compliance/violation following which EC decides in full board meeting to terminate/ suspend/ discontinue the study.
  - SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
  - When research is not conducted in accordance with EC policies, is not in compliance with the local regulations or that has been associated with unexpected serious harm to participants.
  - Zero accrual for 1-2 years or long-term, low accrual.

Suspended protocols remain open and require continuing review.

The EC may revoke approval and recommend to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

5. References to other applicable SOPs

SOP 07A/V4 - *Initial Full-Board Review of Research Study Protocols*

6. Annexure

Annexure 1 - Premature Termination/Suspension/ Discontinuation Report Format

(*Annexure 01/SOP/14/V4)*

Annexure 01/SOP/14/V4

Premature Termination/Suspension/ Discontinuation Report Format

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

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Date of start of study:
2. Date of last progress report submitted to EC:
3. Date of termination/ suspension/discontinuation:
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation:

   Action taken post Termination/ Suspension/Discontinuation (if any):

5. Plans for post study follow up/withdrawal *(Describe post-termination/suspension/ discontinuation follow up plans if any. Also descr any withdrawal plans for the study)* (if any):

6. Details of study participants:

   Total participants to be recruited:_____ Screened:_____ Screen failure:

   Enrolled:_____ Consent Withdrawn:_____

   Reason (Give details):

   Withdrawn by PI:_____

   Reason(Give details):
   Active on treatment:_____Completed treatment: :_____ Participants on follow-up:_____ Participants lost to follow up: _____

   Any other:_____Number of drop outs:_____

   Reasons for each drop-out:

7. Total number of SAEs reported till date in the study:

   Have any unexpected adverse events or outcomes observed in the study been reported to the EC?
   Yes ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐
   If yes, provide details:

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐
   If yes, have you implemented that suggestion? Yes ☐ No ☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?
    Yes ☐ No ☐
    (e.g., making arrangements for medical care of research participants): If Yes, provide details

    Summary of results (if any):

    Signature of PI with date:

7. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/ suspension / discontinuation	EC Secretariat
2	Review and Discuss the Termination/ suspension/ discontinuation report	EC members, Member Secretary and Chairman
3	Notify the Principal Investigator	EC Secretariat
4	Store the Protocol Documents	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Waiver of written / verbal informed consent

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Ethics Committee (EC) may grant waiver for requirement of obtaining written or verbal informed consent.

2. Scope

This SOP applies to the all protocols submitted for review by the EC that ask for consent waiver.

3. Responsibility

It is the responsibility of the EC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the Application Form. The Chairman will sign and date letter conveying the decision.

4. Detailed instructions

- The Application Form *AX 01/SOP15/V4* is designed to standardize the process of applying for consent waiver.
- When a request for waiver of consent is received from the Principal Investigator (PI) to the EC in the given format *AX 01/SOP 15/V4*, the following steps are taken:
  - The EC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
  - The EC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. (as described in Annexure *AX 01/SOP 15/V4)*.
  - The EC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. (*This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted*).
  - The final decision (ratification) whether to grant the waiver is taken at a full board meeting

- The decision regarding approval / disapproval of waiver is informed to the Principal Investigator in writing. If the waiver is not granted, the EC will provide reasons for the same.

5. Annexure

Annexure 1 *AX 01/SOP 15/V4* Application form for requesting waiver of consent

Annexure 1 : AX 01/SOP 15/V4

Application form for requesting waiver of consent

1. **Principal Investigator's name:**

   _____

2. **Department:**

   _____

3. **Title of project:**

   _____

   _____

   _____

4. **Names of co-investigators and Department/s:**

   _____

   _____

   _____

5. Request for waiver of informed consent:

- Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by EC to consider waiver of consent).

  [1] Research involves 'not more than minimal risk'

  [2] There is no direct contact between the researcher and participant

  [3] Emergency situations as described in ICMR 2017 Guidelines

  [4]Any other (please specify)

- Statement assuring that the rights of the participants are not violated

  _____

- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

  _____

Principal Investigator's signature with date:

_____

Final decision at full board meeting held on:

_____

Waiver granted
Yes No
If not granted, ☐ ☐
reasons

_____

_____

_____

_____

_____

_____

Signature of the Chairman with Date: _____

<u>Type of research projects which may qualify for consent waiver:</u>

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The

following criteria (ICMR 2017 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. e.g. a retrospective review of patient case records to determine the incidence of disease / recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].

2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. e.g. *conducting interviews with citizens about their religious beliefs / people with HIV and AIDS / conducting phone interviews with homosexuals.*

   The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the EC.

   [In case of ***telephonic interviews***, waiver of written informed
   consent may be requested but verbal consent is mandatory].

   a. The following documents need to be submitted for the EC review for verbal consent

      - ✓ A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
      - ✓ The interview schedule (questions to be asked) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.

   b. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart indicating the participants as participant 1, participant 2, etc and a column indicating that verbal consent was given along with the date.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
4. 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.
5. In emergency situations when no surrogate consent can be taken. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the EC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he / she gains consciousness or to relative / legal guardian when available later.

7. Flow chart

S. No	Activity	Responsibility
1.	Receive the submitted documents	EC Secretariat
2.	Review of protocol and application for waiver of consent	EC Secretariat
3.	Decision regarding waiver of consent	EC Members at Full Board meeting
4.	Communicate the decision to the Investigator	EC Secretariat
5.	Recording and filing the decision	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Site Monitoring and Post-Monitoring Activities

1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (EC) approved protocol.

2. Scope

This SOP applies to all EC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the EC.

3. Responsibility

It is the responsibility of the Full Board or Chairman and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated EC member(s) to perform on-site monitoring of selected study site(s).

4. Detailed instructions

4.1. Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board.
- This is recorded in the EC decision form (AX 03/SOP 7A/V4) and in the EC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the EC, after approval by the Chairman.
- The reasons for identifying a particular site for "*for-cause monitoring*" could include any one or more of the following:
  - High number of protocol violations,
  - Large number of studies carried out at the study site or by the investigator,
  - Large number of Serious Adverse Events (SAE) reports,
  - High recruitment rate,

- Large number of Protocol deviations,
- Complaints received from participants or any other person,
- Frequent failure to submit the required documents
- Any other cause as decided by EC.

4.2. Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed
- The Chairman will identify and select one or more EC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected members will be given an appointment letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairman
- The Secretariat will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI (with a request to be available) and monitors.
- The monitor will receive from secretariat and review the relevant project documents and make appropriate notes.
- The Secretariat provided Monitors with relevant reference material / documents related to the project
- Monitors will carry with them Site Monitoring Visit Report Forms- AX 01/SOP 16/V4 and AX 02/SOP 16/V4 (if applicable) collected from the Secretariat.

4.3. During the visit

- The Monitor will follow the check list and:
  - check the log of delegation of responsibilities of study team,

- check if the site is using latest EC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
- observe the informed consent process, if possible,
- review randomly selected participants files to ensure that participants are signing the correct informed consent,
- check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study),
- check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable,
- verify that the investigator follows the approved protocol and all approved amendment(s), if any,
- ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
- verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,
- verify that the investigator is enrolling only eligible subjects,
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
- review the project files of the study to ensure that documentation is filed appropriately,
- review the source documents for their completeness,

- collect views of the study participants, if possible,

- The Monitor will fill the Site Monitoring Visit Report Form- AX 01/SOP 16/V4 and AX 02/SOP 16/V4 (if applicable), sign and date it.

4.4. After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 16/V4* and *AX 02/SOP 16/V4* (if applicable) to the EC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board EC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The EC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - Continuation of the project with or without changes,
  - Restrictions on enrollment,
  - Recommendations for additional training,
  - Recruiting additional members in the study team,
  - Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
  - Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairman and any one of the actions described above will be taken.

- The final decision taken at the full board EC meeting by the Chairman will be recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 16/V4*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

5. Reference to other applicable SOPs

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

6. Annexures

Annexure 1 *AX 01/SOP 16/V4* - Site Monitoring Visit Report

Annexure 2 *AX 02/SOP 16/V4* – Monitoring of Audiovisual recording of AV consent Process

Annexure 1: AX 01/SOP 16/V4

Site Monitoring Visit Report (Please tick the box corresponding to the answer)

EC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: ☐Investigator initiated ☐Pharma ☐Thesis	
Government agency ☐ Others _____	

Date of EC approval:

Date of Initiation of the study:

Duration of study:

Reason for monitoring: Routing

For-cause (State reasons)
Protocol Violations/Deviations
SAE reporting
Recruitment rate
Others

Last for monitoring done, if any:

Yes Date of last monitoring
No

Project Status:

1. Ongoing
2. Completed
3. Recruitment Completed
4. Follow up extension study
5. Suspended
6. Terminated

In case of the response to the above question is option 5 or 6, kindly provide reasons:

Recruitment Status:

Total patients to be recruited:
Screened
Screen failures
Enrolled
Withdrawn: Reason:

Discontinued: Reason:

Completed:

Active:

In case of the response to the above question is option 5 or 6, kindly provide reason/s: _____

Are the present study team members as per the list approved by the EC Yes No	Comment:
Are site facilities appropriate? Yes No	Comment:
Is the recent version of Informed Consent Document (ICD), after EC approval, used? Yes No	Comment:
Whether appropriate vernacular consent has been taken from all patients? Yes No	Comment:
Any other findings noted about the ICDs? Yes No	Comment:
Is recent EC approved version of protocol used? Yes No	Comment:
Have the eligibility, inclusion exclusion criteria been adhered to? Yes No	Comment:
Any adverse events found? Yes No	Comment:
Any SAEs found? Yes No	Comment:
Were the SAEs informed to EC within timelines specified by CDSCO? Yes No	Comment:

No. of deaths reported: ☐ Deaths unrelated to participation in the trial: ☐ Deaths possibly related to participation in the tri al: ☐ Deaths related to participation in the trial Any other non-death study related injury	_____ _____ _____ _____ Yes No NA Comments (If Any) _____ _____ _
Compensation paid for study related injury or death	☐ Yes ☐ No ☐ NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? Yes No	Comment:
Have the protocol non-compliance deviations/violations been informed to EC? Yes No	Comment:
Are all Case Record Forms up to date? Yes No	Comment:

Are storage of data and investigating products locked? Yes No	Comment:
How well are the participants protected? Good Fair Not good	Comment:
Any other remarks Yes No	Give details:
Duration of visit:_____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of EC members and representatives who attended monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the EC meeting held on _____

_____

_____

Signature of Chairman, EC with date

Annexure 2: AX 02/SOP 16/V4

Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):
   - Yes _____ No_____
   - Remarks:_____
2. The consent is taken in language the participant/LAR understands best and is literate in.
   - Yes _____ No_____
   - Remarks:_____
3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording
   - Yes _____ No_____
   - Remarks:_____
4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
   - Yes _____ No_____
   - Remarks:_____
5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
   - Yes _____ No_____
   - Remarks:_____
6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the EC.
   - Yes _____ No_____

- Remarks:_____

7. Explanation or narration by the person conducting the informed consent discussion.
   - Yes _____ No_____
   - Remarks:_____
8. Questions asked by the potential participant/LAR are answered satisfactorily.
   - Yes _____ No_____
   - Remarks:_____
9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.
   - Yes _____ No_____
   - Remarks:_____
10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.
    - Yes _____ No_____
    - Remarks:_____
11. Documentation of signatures of all those involved in the Informed Consent Process.
    - Yes _____ No_____
    - Remarks:_____
12. Clarity and completeness of AV recording
    - Yes _____ No_____
    - Remarks:_____
13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.
    - Yes _____ No_____
    - Remarks:_____

7. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	EC Member Secretary / Chairman
2	Identification of EC members for monitoring during meeting	Chairman
2	Inform Principal Investigator in writing	Secretariat
3	Review of EC protocol file prior to visit and collect Site Monitoring visit report from EC office	EC member
4	Review or monitoring of site	EC member
5.	Complete the monitoring report and present in EC meeting	EC member
6.	Communication of EC decision to PI	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

SOP 16	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 16/ V4	*Site Monitoring and Post-Monitoring Activities*	Effective Date: 02.01.2024

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

Title: Dealing with participants requests and/or Complaints to Institutional Ethics Committee

1. Purpose

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the Institutional Ethics Committee (EC).

2. Scope

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and well-being of the research participants participating in research studies by the EC.

3. Responsibility

It is the responsibility of the EC Secretariat and Chairman/ Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

4. Detailed instructions

- A request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the EC Member Secretary after entering into the request record form *AX 01/SOP 17/V4.*
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form AX 01/SOP 17/V4 and notify the Secretariat.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).

- The Secretariat will inform the Chairman about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairman will provide the information himself / herself or will designate one or more EC member(s) to provide such information.
- In case of a complaint received from a research participant:
  - The Member Secretary, in consultation with the Chairman will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairman will direct the Member Secretary to:
    - Appoint a subcommittee of two or more EC members for enquiry in order to resolve the matter.
    - Call an emergency meeting of two or more EC members for discussion or
    - Consider the matter for discussion at the next full board meeting
  - The Chairman/ Member Secretary/ designated EC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
  - The EC will insist on factual details to determine gap, if any, between truth and individual perception.
- The final decision will be taken by the Member Secretary in consultation with the Chairman based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.
- The information including any action taken or follow-up and final decision will be recorded in the form *AX 01/SOP 17/V4* and the form is signed and dated.
- The EC members will be informed about the action taken and the outcomes in the forthcoming EC meeting (in case of requests/ complaints not discussed in full board meeting) and record in minutes of the meeting.
- The Secretariat will place all documents in the relevant study file.

5. Reference to other applicable SOP: NIL

6. Annexure

Annexure 1 *AX 01/SOP 17/V4* – Request/ Complaint Form

Annexure 1: AX 01/SOP 17/V4

Request / Complaint Form

Date:	
Received by :	
Request/ Complaint received through:	❑ Telephone No. _____ ❑ Fax No. _____ ❑ Letter / Date _____ ❑ E-mail / Date _____ ❑ Walk-in / Date / Time _____ ❑ Other, specify _____
Participant's Name:	
Contact details **Address & Phone:**	
EC Project no.	

Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	_____ _____
Action taken:	_____
Reviewed by	_____
Final Decision	_____
Date of EC meeting (if applicable)	_____

Name & Signature of Member Secretary **Date**

7. Flowchart

No.	Activity	Responsibility
1.	Receiving the request/ query/complaint from research participant	EC Member Secretary/ Member
3.	Initiating process to identify the problem	EC Chairman/ Member Secretary
4.	Deliberations to arrive at solution	EC Chairman/ Member Secretary/ Members
5.	Communication with the research participant	EC Secretariat
6.	File the request document	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. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Maintenance of active study files, Administrative records of the ethics committee, Archival of closed files and retrieval of documents

1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Ethics Committee (EC), EC administrative documents, archival of closed files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and EC administrative documents by the EC Secretariat.

3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and EC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

4. Detailed instructions

4.1. Maintenance of the Active Study Files

- A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the EC office.
- All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of
    - All original research proposal documents (including Covering letter, checklist of submission, EC application form, research proposal, data collection formats, case report forms, investigators brochures, informed consent documents etc) reviewed and approved
    - Reviewer's assessment forms
    - Decision letters (intimation letters) sent to the investigators
    - Study approval letter

- Amendments and any other correspondence
- Study progress reports and interim reports
- Serious adverse event (SAE) report forms submitted by investigators
- Other record related to SAE, medical management and of trial participants and compensation paid
- Recommendations given by Ethics Committee for determination of compensation
- Records related to any order issued for premature termination of study with a summary of reasons thereof
- Final report of the study including microfilms, compact disks or video recordings
- Any other reports
- EC correspondances

- Strict confidentiality will be maintained for the contents of the files
- All active files will be kept secured in a file cabinet with controlled access.
- A log book for accessing the files by authorized staff & members will be maintained.

4.2. Maintenance of the EC Administrative Records

The EC records will include the following:

1. Constitution of EC (Authority letter)
2. EC members' records
   i. Appointment and acceptance letters of each member
   ii. Signed and dated confidentiality agreements
   iii. Updated Curriculum vitae (hard copy or soft copy)
   iv. Training records for each EC member (GCP, SOP)
   v. Documentation of resignations / terminations
3. EC membership roster - An EC roster will be maintained which will contain:
   i. Names of EC members
   ii. Age
   iii. Gender
   iv. Evidence of qualifications
   v. Role on the EC
   vi. Status of affiliation to institution (e.g., unaffiliated or affiliated)
   vii. Regular/ Alternate member to the EC (if applicable)

4. EC mandate
5. Correspondence related to changes in EC membership with DCGI, OHRP or any other concerned authority
6. EC attendance roster
6. Agenda and Minutes of EC meetings with signature of Chairman
7. Standard operating procedures (SOPs) of EC
8. Annual reports
9. Documents related to Workshops & conferences organized by EC (Continuing education for members & staff)
10. SOP training and distribution logs
11. National and International guidelines followed by EC

4.3. Maintenance of Closed Study Files

- Once the study file is closed (following completion/ premature termination), the related study files will be shifted to the EC Archival room.
- All closed study files will be archived in the EC archival room for a period of five years from the date of closure of the study.
- A log book for archival of study documents will be maintained.

4.4. Accessibility / Retrieval

- Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on SAEs) on request (*AX 01/ SOP 18/V4*) if authorized by Member Secretary/ Chairman.
- Representatives of regulatory authorities may have access at all times.
- A log book of retrieval of documents will be maintained.

4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for ECReview

- At the end of the archival period, the closed files will be shredded and disposed of by authorized EC personnel.

- Extra copies of protocols and documents submitted for EC review and any other extra copies will be shredded by authorized EC personnel after the EC meeting without any notification to PI.

- A formal disposal log will be maintained, providing details of documents that will be disposed. (*AX 02/ SOP 18/V4*)

5. Reference to other applicable SOP: NIL

6. Annexures

Annexure 1 AX/01/SOP 18/V4 Document Request Form

Annexure 2 AX/02/SOP 18/V4 Log for disposal of study documents

Annexure 1: AX 01/ SOP 18/V4

Document Request Form

Project No.:	
Project Title:	
Name of Principal Investigator (PI):	
Requested by:	
Documents requested:	
Purpose of the Request	
Signature of Requesting person:	
Signature of PI:	
Signature of Member Secretary / Chairman with date:	

Annexure 2: AX 02/ SOP 18/V4

Log for disposal of study documents

Project No.	Title	Name of Principal Investigator	No. of files	Date of EC Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

7. Flowchart

No.	Activity	Responsibility
1	Organize the contents of the active study files	EC Secretariat
2	Maintain the active study files and Administrative Documents	EC Secretariat
3	Archival of Study files	EC Secretariat
4.	Authorising retrieval of archived Documents	EC Member secretary/ Chairman
5.	Disposing closed study files and maintaining Document disposal log	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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Reviewing Proposals Involving Vulnerable Populations

1. Purpose

This Standard Operating Procedure (SOP) describes the requirements and process of review of research that involves vulnerable participants.

2. Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IEC.

3. Responsibility

- It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines.
- IEC Chairperson / Member Secretary are responsible for ensuring that IEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes.
- The Member Secretary/ Chairperson is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research and for securing consulting expertise as and when required for selected reviews.
- IEC member is responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion.

4. Detailed instructions

Definition and Mandate

4.1 Definition

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such

as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

[http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6 /E6_ R1_Guideline.pdf accessed on 23rd Nov 2015]

As per ICMR 2017 guidelines:

Following are some examples of vulnerable populations or groups:

• economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);

• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;

• children (up to 18 years);

• women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);

• tribals and marginalized communities;

• refugees, migrants, homeless, persons or populations in conflict zones,riot areas or disaster situations;

• afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;

• terminally ill or are in search of new interventions having exhausted all therapies;

• suffering from stigmatizing or rare diseases; or

• have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners)

4.2 Mandate

Gazette notification dated 31st July 2015, [G.S.R. 611(E)] has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of

new chemical entity/ new molecular entity.[**http://www.ferci.org/wp-content/uploads/2014/07/Gazette-Notification-31-July-2015-AV-consent.pdf]**

4.3. Reviewing protocols with vulnerable participants

- The protocol should be reviewed as per SOP 7A/V4. Additionally, the protocol should be reviewed to assess if the following points are addressed:
  - Can the research be performed in any other non-vulnerable participants?
  - Is there justification to use vulnerable population
  - Do the benefits justify the risks
  - Are the participants selected equitably
  - Have the measures to protect Autonomy of the vulnerable population been described
- IEC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.
- The review must address all points in the checklists for different vulnerable populations (Annexures 1 to 5- SOP 19).

As per ICMR 2017 guidelines: Categories of Risk

Type of risk	Definition/description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

4.4. Appointing Reviewers

The Member Secretary/Chairperson will appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols.

4.5. Duties of Secretariat

- Provide a suitable checklist to the investigator depending on the type of participants to be recruited for the study.
- Provide appropriate reference material or help reviewer locate the material relevant to vulnerable populations when specifically requested for, by a reviewing member.

4.6. Responsibilities of Reviewers

- IEC Members will review the protocol and the informed consent document or assent form as per this SOP and SOP 07A/V4.
- The IEC members will discuss the comments in the IEC meeting and letter regarding approval/modification/ disapproval will be sent to the principal investigator.
- The discussion will be documented in the minutes.
- The Member Secretary will ensure that the IEC recommendations have been incorporated in the revised protocol and protocol related documents.

4.7 Approval of the protocol

- The final version of the protocol will be approved at a full board meeting.
- Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

5. Reference to other applicable SOP: NIL

6. Annexure

NOTE: The following annexure apply to some sections of vulnerable participants. These checklists should be filled in by primary reviewer.

Annexure 1 *AX 01/SOP 19/V4* – Checklist: Requirements for Research Involving Children

Annexure 2 *AX 02/SOP 19/V4* - Checklist: Requirements for Research Involving Pregnant Women & Fetuses

Annexure 3 *AX 03/SOP 19/V4*- Checklist: Research Involving Cognitively Impaired Adults

Annexure 4 *AX 04/SOP 19/V4*- Checklist-Research Involving Students, Employees or Residents

Annexure 5 *AX 05/SOP 19/V4* – Checklist: Considerations for Genetic Research

[Adapted from http://www.kem.edu/wp-content/uploads/2014/04/SOP-24.pdf, Reviewing proposals involving vulnerable Populations http://www.kem.edu/wp- content/ uploads/ 2014/04/SOP-24.pdf]

Annexure 1: AX 01/SOP 19/V4

Checklist: Requirements for Research Involving Children

Study Title:

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve healthy children?			
a) If yes: Is the inclusion of healthy children justified?			
Are the studies conducted on animals and adults appropriate and justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
Are efforts being made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve possibility of findings which may have implications for other family members?(for eg. genetic risk, HIV infection, Hepatitis C)			

If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

RISK DETERMINATION	BENEFIT ASSESSMENT	PRIMARY REVIEWER RECOMMENDATION
Minimal * ☐	Direct benefit	Approvable
☐	No direct benefit	
Greater than minimal risk ☐	Potential benefit to child	Approvable
Greater than minimal risk ☐	No direct benefit, offer knowledge about child's condition/disorder	Approvable on case –by- case basis**

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Consent of both parents may be needed as applicable.

Any other comments of Primary Reviewer:

Primary Reviewer Signature and Date

Annexure 2: AX 02/SOP 19/V4

Checklist: Requirements for Research Involving Pregnant Women and Fetuses

Study Title:

When research involves pregnant women or fetuses

	Yes	No	NA
Are scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been referenced in the proposal to provide data for accessing potential risks to pregnant women and fetuses?			
Are there risks and benefits clearly identified and explained in the proposal?			
Is the risks to the fetus not greater than minimal?			
Do the benefits justify the risks in the study?			
Are risks minimization strategies mentioned in the proposals?			
Are there provisions for obtaining informed consent from the pregnant women or her legally authorized representative			
Are there provisions for fully informing the woman or her legally authorized representative, regarding the reasonably foreseeable impact of the research on the fetus or resultant child?			

Any other comments of Primary Reviewer:

Primary Reviewer Signature and Date

Annexure 3: AX 03/SOP 19/V4
Checklist- Research Involving Cognitively Impaired Adults

Study Title:

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant (All items must be "Yes")		
Yes	No	Is the recruitment of participants justified considering the rationale and objectives of the study?
Yes	No	The risk is justified by the anticipated benefit to the participants.
Yes	No	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches
Yes	No	Are there provisions to withdraw the participants, if they appear to be unduly distressed?
Yes	No	Is the proposed plan for the assessment of the capacity to consent adequate?
Yes	No	Will consent be taken from participants capable of being consulted?
Yes	No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes")		
Yes	No	Is the recruitment of participants justified considering the rationale and objectives of the study?
Yes	No	Are the foreseeable risks to the participants low?
Yes	No	Is the negative impact on the participant's well-being minimized and low?
Yes	No	Are there provisions for close monitoring of the participants?
Yes	No	Are there provisions for withdrawal of the participants if they appear to be unduly distressed?
Yes	No	Is the proposed plan for the assessment of the capacity to consent adequate?
Yes	No	Will consent be taken from participants capable of being consulted?
Yes	No	Does the consent document include provision for a legally authorized representative in case participants are not capable of being consulted?

Any other comments of Primary Reviewer:

Primary Reviewer Signature and Date

Annexure 4: AX 04/SOP 19/V4

Checklist: Research Involving Students, Employees or Residents

Study Title:

Participants who are students, employees or residents require special considerations.

Are there provisions for informing the participants that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to participants been minimized?	No	Yes
Are there provisions to assure the participants that the participation is voluntary (no signs of coercion)?	No	Yes
Are there provisions to assure the participants that their privacy and confidentiality will be protected?	No	Yes

Answers to all the above points should be YES for approval

Any other comments of Primary Reviewer:

Primary Reviewer Signature and Date

Annexure 5: AX 05/SOP 19/V4

Checklist: Considerations for Genetic Research

Study Title:

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable		
2. Will the results be disclosed? a) If yes, has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result? b) Will the results be used in management of current condition of patient?		
3. Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
4. Does the proposed study population comprise family members?		
5. Will family members be implicated in the studies without consent?		
6. Will the samples be destroyed in the future?		
7. Will the samples be used for future research		
8. Is genetic counseling being offered?		

Any other comments of Primary Reviewer:

Primary Reviewer Signature and Date

7. Flow Chart

No.	Activity	Responsibility
1	Appoint reviewers	Chairperson/ Member Secretary
2	Review the protocol	IEC members
3	Discussion at IEC meeting	IEC member
4	Communicating the decisions to principal investigator	IEC 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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Preparing for Ethics Committee Audit/ Inspection

1. Purpose

The purpose of this SOP is to guide SMVMCH-EC to prepare for an audit or inspection of the EC.

2. Scope

The SOP applies to all the EC members and the Secretariat.

3. Responsibility

It is the responsibility of the Member Secretary, Chairman, EC Members and the EC Secretariat to keep EC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

4. Detailed instructions

4.1 Definitions

- **Audit:**

I. A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). [*http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015*]

II. Audit of a Trial- A systematic verification of the study, carried out by persons not directly involved, such as:

(a) Study related activities to determine consistency with the Protocol

(b) Study data to ensure that there are no contradictions on Source Documents. The audit should also compare data on the Source Documents with the interim or final report. It should also aim to find out if practices were employed in the

development of data that would impair their validity.

(c) Compliance with the adopted Standard Operating Procedures (SOPs).

[*http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Nov 2015*]

- **Inspection:**

An official review/ examination conducted by regulatory authority(ies) of the documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the study. The inspection may be carried out at the site of the trial, at the sponsor's / or CRO's facilities and Ethics Committee in order to adherence to Good Clinical Research Practice.

[*http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf accessed on 23rd Nov 2015]*

[http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf accessed on 23rd Nov 2015]

4.2 Mandate

- On receiving information about the audit /inspection, EC Member Secretary and/ or EC member/s are given the responsibility by the Chairman to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and / or designated EC member/s will make arrangements in accordance with the steps mentioned in the checklist.(*AX 01/SOP 20/V4*)
- The studies with incomplete / missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

4.3 On the day/s of Visit

- Chairman / Member Secretary / designated EC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.
- The EC Chairman / Member Secretary / EC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/ designated EC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

4.4 Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated EC member/ Secretariat will review comments and recommendations of the auditor/inspector.
- On receipt of Audit/ Inspection Report the Chairman should implement corrective and preventive measures and set the timeline for implementation of corrections as stated by the auditor/inspector
- Action plan should be communicated by the Member Secretary/ designated EC member to the auditor/inspector after seeking approval of the Chairman.

A review date for an internal follow-up audit will be decided by the Chairman (if applicable).

The Member Secretary/ designated EC member should report the outcome of the internal follow-up audit to the Chairman

4.5 Recording the Audit/Inspection Visit

- The Member Secretary/ designated EC member/ Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.
- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.

5. References to other applicable SOP – NIL

6. Annexure

Annexure 1:*AX 01/SOP 20/V4*- Audit and Inspection Checklist

Annexure 1: AX 01/SOP 20/V4
Audit and Inspection Checklist

1. Date of letter of communication regarding audit/inspection:
2. Date(s) on which the audit/inspection has been agreed on:
3. To ensure the EC members and staff have been informed about the date/s and time.
4. To ensure availability of EC related information – mandate, terms of reference, organisation chart (in the print form) in the EC office.
5. To make sure of availability of latest copy /copies of signed SOPs in print form in the office and/ or in electronic form on the EC computer/s.
6. To review the SOPs and note details of any omissions or deviations, with reasons.
7. To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the EC office.
8. To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken.
   - Records regarding applications of research studies for review including protocols and

related documents Protocol Assessment Records – Comments of EC members, Meeting Agenda Minutes (documented in individual study file or separately in meeting records file)

- o Communication records with investigator (documented in individual study file)
- o Amendment Approvals (documented in individual study file)
- o SAE reports and SAE related communications with investigator and regulators
- o Protocol deviation/violation/exception reports(documented in individual study file)
- o Continuing and final completion/termination reports (documented in individual study file)

9. To ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of EC members.
10. To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.
11. To ensure measures for maintaining security of electronic database and office records.
12. To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as per the respective SOPs.
13. To ascertain proper labelling and indexing of study files and storage cabinets.
14. To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up audit(if applicable)
15. To report about findings and report received regarding audit/inspection to EC members at the full board EC meeting.
16. To make other arrangements (meeting venue for review of documents, catering, accommodation, travel) for the visit, as applicable.

7. Flow Chart

No.	Activity	Responsibility
1	Receipt of Audit/ Inspection notification	Member Secretary
2	Preparing for the audit	Member Secretary/ designated IEC member/ Secretariat
3	Presenting information and files to auditor/ inspector	Member Secretary/ designated IEC member/ Secretariat
4	Review comments/ recommendation of auditor/ inspector	Member Secretary/ designated IEC member/ Secretariat
5	Receipt of audit/ inspection report	Member Secretary/ designated IEC member
6	Planning corrective/preventive actions and setting timeline for their implementation	Chairperson
7	Conducting internal follow-up audit	Member Secretary/ designated IEC member
8	Recording the Audit/Inspection Visit	Member Secretary/ 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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: 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. T. Thiagarajan	Chairman	
Issued	Dr. R. N. Kagne	Dean	

Title: Training and Assessment of Ethics Committee Members & Assessment of IEC Functioning

1. Purpose

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the SMVMCH-EC members and the Secretariat.

2. Scope

The SOP applies to all the EC members and the Secretariat.

3. Responsibility

It is the responsibility of the EC Chairman with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the EC members and the Secretariat. The Chairman is responsible for assessment of all EC members and completes a self-assessment exercise at prescribed intervals.

4. Detailed instructions

4.1. *Topics for training*

EC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of EC members
- ✓ Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy Recent Developments in relevant health science specialties
- ✓ SOPs of the EC

Secretariat should have knowledge and relevant skills for conducting the following activities:

- ✓ Competency in working on Microsoft word, Excel, EC office software
- ✓ Maintenance of EC Database
- ✓ Communication skills- written and verbal
- ✓ Knowledge about the SOPs

4.2. Training of new EC Members

- Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.
- An individual selected as a new member of the EC will be required to attend one meeting as an 'Observer' before being inducted as a member of the EC. Member Secretary or an EC member will provide an introductory training to the new member. The new EC members would be encouraged to undergo online EC training programme too.
- The EC Member Secretary, member, Chairman will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The EC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the EC Members. At the end of the training program, a post test will be conducted to document the learning.
- The EC may sponsor or reimburse the expenses of an EC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).
- Any amendments and recent developments in the field of bioethics will be shared by EC Members in the full board meeting.

4.3. Training of the Secretariat

The EC Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairman.

4.4. Assessment of EC members

- The EC members' performance should be evaluated once a year using an assessment form (*AX 01/SOP 21/V4*) by the Chairman.
- The Chairman should do self-assessment once a year

*4.5. **Assessment of EC Functioning***

- Periodic self-assessment of the EC will be conducted with the help of the assessment form (*AX 03/SOP 21/V4),* along with Root Cause Analysis and Corrective and Preventive Action.

4.5. Maintenance of training records of the EC Members and the Administrative Staff

The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual EC members. The copies will be filed in the individual members' files. The records regarding training copies of the Secretariat will also be maintained in their respective files.

5. Reference to other applicable SOP: NIL

6. Annexures

Annexure 1AX 01/SOP 21/V4 - Self Assessment Form for EC Member Secretary/ Member

Annexure 2: AX 02/SOP 21/V4 - Self Assessment Form for EC Chairman

Annexure 3: AX 03/SOP 21/V4 - Self Assessment Form for IEC Functioning

Annexure 4: AX 04/SOP 21/V4 – Annual report for IEC Functioning

Annexure 1: AX 01/SOP 21/V4

Assessment Form for Ethics Committee Members

1. Current tenure
2. Terms served
3. Training received
4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. No of projects reviewed per meeting as secondary reviewer
8. Participation in SAE report review process- yes/no
9. Participation in site monitoring visits - yes/no
10. Number and type of continuing training workshops organised for EC members (applicable to Member Secretary
11. Number and type of continuing training workshops organised for staff of the EC secretariat (applicable to Member Secretary)
12. Any other significant contribution to the field of research ethics
13. Remarks by the Chairman on the self-assessment

Annexure 2: AX 02/SOP 21/V4

Self-Assessment Form for EC Chairman

1. Current tenure-
2. Terms served -
3. Training received -
4. Type of training received -
5. No. of meetings held in current year -
6. No of meetings attended-
7. Whether quorum requirement fulfilment ensured as per schedule Y in EC meetings
8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics
10. Any other comments

Annexure 3: AX 02/SOP 21/V4
Self-Assessment Form for IEC Functioning

1. Adequate time is allotted to review the expedited protocols. Yes/No
2. The time allotted for review of full-review protocols is adequate. Yes/No
3. The checklist provided for review of protocols is appropriate. Yes/No
4. Reminders are sent by the secretarial staff if timeline for review is missed. Yes/No
5. The SOPs, guidelines and regulations are provided by IEC for reference. Yes/No
6. Confidentiality of the documents is adequately maintained. Yes/No
7. Training programs are conducted regularly. Yes/No
8. Training programs conducted by IEC are useful. Yes/No
9. In decision making on proposals; members are free to express their dissent. Yes/No
10. IEC meetings are conducted as per SOP (time, quorum, discussion, decision making). Yes/No
11. The IEC manages conflict of interest as per the SOP. Yes/No
12. The EC meeting duration is adequate for reviewing the submitted protocols. Yes/No
13. The functioning and decision making of the IEC is independent. Yes/No
14. The meeting- agenda and notes are circulated well ahead of the meeting. Yes/No
15. The meeting minutes are circulated within 1 week for EC members approval. Yes/No
16. The review process includes both scientific and ethical issues in the protocols. Yes/No
17. Every member is able to freely contribute to discussion and deliberation of protocols in the meeting. Yes/No
18. The SOPs are clear and practical. Yes/No
19. The venue and arrangement of the meetings is adequate. Yes/No
20. What according to you is the strength of the IEC?
21. What according to you needs improvement?

Annexure 4: AX 04/SOP 21/V4

Annual report for IEC Functioning

No: outward/SMVMCH-ECO/AR/ / XXXX Date: XX.XX.XXXX

EC Meeting conducted:

Total number of meetings conducted in the year XXXX:

EC Meeting dates:

Proposal Reviewed:

Total number of proposals reviewed:

Total number of proposals approved without modifications:

Total number of proposals approved with modifications:

Total number of proposals rejected:

Total number of faculty proposals reviewed:

Total number of PG student's proposals reviewed:

Total number of UG student's proposals reviewed:

Trainings Conducted:

No. of training program:

Date of training program:

Mode of training program:

Speakers for the program:

No. of EC members attended:

Any other Information (If required):

MEMBER SECRETARY

Signature & date with Stamp

7. Flow Chart

S. No	Activity	Responsibility
1	Ensuring Training of EC Members	EC Member Secretary/Chairman
2	Training of Secretariat	EC Member Secretary/Members
3	Assessment of performance of members	EC Chairman
4	Assessment of EC of performance of Chairman	EC Chairman (self evaluation)

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. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_ Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

SOP 21	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: **SOP 21/ V4**	***Training and Assessment of Ethics Committee Members & Assessment of IEC Functioning***	**Effective Date: 02.01.2024**

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

1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the COVID-19 outbreak.

2. Scope:

This SOP covers the functioning, information and procedures followed by Institutional Ethics Committee – Sri Manakula Vinayagar Medical College and Hospital (SMVMCH) during pandemic times.

3. Procedures & Responsibilities:

S.No	Procedure	Responsibility
	Submission and initial review	
a.	Submit research proposal (electronically)	Researchers
b.	Receive, record, verify completeness and allot reference no.	Secretariat/ Member Secretary
c.	Categorize depending on risk (Exempt/ Expedited, Full committee), identify need for review by experts/ independent consultants/ patient /others; and designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform review of documents as described in *Table 4.3 of ICMR National Ethical Guidelines*, fill study assessment form	Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (*Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson*).	Secretariat / Member Secretary

S.No	Procedure	Responsibility
	Virtual EC meeting	
f.	Open the meeting, determine quorum (*Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries* Agenda	Chairperson
g.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional)
h.	Present observations on item reviewed	Reviewers
i.	Discuss further on the item and reach consensus	SMVMCH-EC members
j.	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	Secretariat / Member Secretary
k.	Record minutes of meeting, ratify approved decisions of exemption/expedited review before closing meeting	Member Secretary/ Chairperson
	Post meeting activities	
l.	Communication of decision and maintaining records.	Secretariat/ Member Secretary
m.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non- compliance, violation, complaints etc.	Member Secretary in consultation with Chairperson

4. Detailed instructions:

1. The Covid related research proposals will be initially reviewed by the Institutional Clinical Review Board which will verify the appropriateness of the research, investigators and their qualifications and will issue the permission letter to carry out the research in the Institution.
2. The Research Proposal then will be submitted electronically with supporting documents to SMVMCH-EC. It should contain the following documents as per SOP 06/V2.2:
   - 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 multicentric research)
- Agreement between collaborating partners (for multicentric research)
- MTA (Material Transfer Agreement) 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 (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)

3. Once received, the secretariat will verify protocol for completeness (if not ask PI) and number.
4. Member Secretary to categorize research into full review, expedited review or exemption from review.
5. Member Secretary (in consultation with Chairperson) will identify need for review by subject experts, independent consultants, special invitees, patient representatives, others for prior review or to present views during the meeting.
6. The project for full review will be included in agenda of virtual full-committee meeting to be scheduled at the earliest by the Member Secretary in consultation with the Chairperson.
7. The members will be briefed about the technological requirements and virtual platform used for the conduct of the meeting.
8. Quorum requirements for review will be applicable as per Section 4.8.4 ICMR National Ethical Guidelines, 2017.
9. Review procedures as per ICMR National Ethical Guidelines will also hold good for the virtual web ethics meeting.

5. References:

1. ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017

2. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During COVID-19 Pandemic 2020

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