Standard Operating Procedures
Institutional Human Ethics Committee

Version No. 4.5
Effective Date: 01st January, 2021

PSG Institute of Medical Sciences & Research

Avinashi Road, Peelamedu, Coimbatore 641 004, Tamil Nadu, India

Standard Operating Procedures

Version 4.5

Institutional Human Ethics Committee
PSG Institute of Medical Sciences & Research
Coimbatore, India.

Date published: 01st January, 2021

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List of Abbreviations / Acronyms

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Abbreviation / Acronym	Full Title/Description
ADR	Adverse Drug Reaction
AE	Adverse Event
BA	Bio-availability
BE	Bio-equivalence
CDSCO	Central Drugs Standard Control Organization
CFR	Code of Federal Regulations
CIOMS	Council for International Organizations of Medical Sciences
CoI	Conflict of Interest
Co-I	Co-Investigator
CRF	Case Record Form
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
DCR	Drugs and Cosmetic Rules, 1945
DGFT	Directorate General of Foreign Trade
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
ELSI	Ethical, Legal and Social Issues
FDA	Food and Drug Administration
FDC	Fixed Dose Combination
FERCAP	Forum for Ethical Review Committees in Asia and the Western Pacific Region
FWA	Federal wide Assurance
GCP	Good Clinical Practice
HMSC	Health Ministry's Screening Committee
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Committee on Harmonization
ICMJE	International Committee of Medical Journal Editors
ICMR	Indian Council of Medical Research
IND	Investigational New Drug
IHEC	Institutional Human Ethics Committee
IORG	IRB Organization
ISI	Indian Standards Institute
LAR	Legally Acceptable/ Authorized Representative
MoU	Memorandum of Understanding
MTA	Material Transfer Agreement
NCE	New Chemical Entity
NDA	New Drug Application
NIH	National Institutes of Health
NOC	No-objection Certificate
OHRP	Office for Human Research Protections
PI	Principal Investigator
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
PSG IMS&R	PSG Institute of Medical Sciences & Research
WHO	World Health Organization
WMA	World Medical Association

Approval of SOPs with signatures

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The below mentioned SOPs are part of IHEC SOP Manual V 4.3

SOP 01-V 4
SOP 02-V 4
SOP 03-V 4
SOP 04-V 3.1
SOP 05-V 3.0
SOP 06-V 3.0
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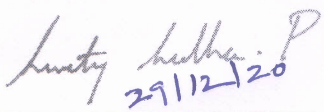
SOP 13-V 4
SOP 14-V 4
SOP 15-V 1.2
SOP 16-V 1.2
SOP 17-V 2.1
SOP 18-V 4
SOP 19-V 1

Authors:

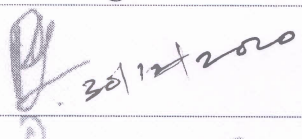
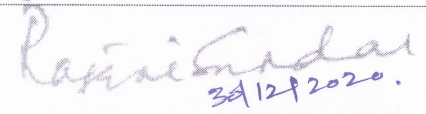
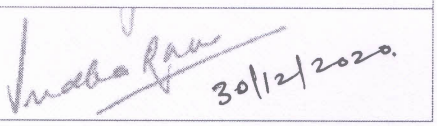
Name and Position on the IHEC	Signature with date
Dr Subhashini G (Member, IHEC – until 04 June 2019)	G. Subhash
Dr D Vijaya (Member - Secretary, IHEC - until 30 Sep.2019)	28/12/2020
Dr S Karthikeyan, Member-Secretary	Karthikeyan 28/12/2020

Reviewed by:

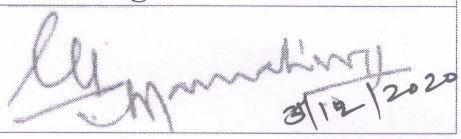
Name and Position on the IHEC	Signature with date
Mr B Antony Raj, Member	29/12/2020
Dr. K. Bhuvaneswari	K. Bhuvaneswari. 29/12/2020
Mr Gowpathy Velappan, Member	30/12/2020
Dr A Jayavardhana, Member	28/12/2020
Mr B Manigandan, Layperson	30/12/2020
Mrs M Nirmala, Alternate Member - Secretary	29/12/2020
Dr R Senthurselvi, Member	30/12/2020
Dr V Sivakumar, Member	29/12/2020

Mrs P Sweety Subha , Member	

Approved by:

Name and Position on the IHEC	Signature with date
Dr Parag K Shah (Vice-Chairperson, IHEC)	
Dr Rajani Sundar (Chairperson IHEC)	
Dr Sudha Ramalingam, Director – Research & Innovation	

Accepted by:

Name and Position on the IHEC	Signature with date
Dr S Ramalingam, Dean	

List of Members of the IHEC (in alphabetical order)

Offices held in IHEC, if any, are shown against the names in parenthesis; also mentioned against their names are area of expertise, affiliation and sex.

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Sl. No.	Name of the Member of IHEC	Area of Expertise	Affiliated to PSG IMS&R or not	Sex
1	Mr B Antony Raj	Social Sciences	Non-affiliated	Male
2	Dr K Bhuvaneswari	Clinical Pharmacology, Bioethics	Affiliated	Female
3	Mr Gowpathy Velappan	Law	Non-affiliated	Male
4	Dr S Karthikeyan	Public Health, Epidemiology, Bioethics	affiliated	Male
5	Mr B Manigandan	Commerce, Law	Non-affiliated	Male
6	Mrs M Nirmala	Nursing	Affiliated	Female
7	Dr Parag K Shah	Ophthalmology	Non-affiliated	Male
8	Dr Rajani Sundar	Anaesthesiology	Non-affiliated	Female
9	Dr S Ramesh	Paediatrics	Affliliated	Male
10	Dr R Senthurselvi	Pharmacology	Non-affiliated	Female
11	Dr V Sivakumar	Pharmacy	Affiliated	Male
12	Dr R Sujatha	Biochemistry	Affiliated	Female
13	Mrs P Sweety Subha	Physiotherapy	Affiliated	Female

List of independent consultants

Name	Department
Dr M S Prasanth Kumar	Anaesthesiology
Dr D Vijaya	Biochemistry
Dr K Tamilarasu	Cardiology
Dr Reena Rai	Dermatology
Mrs V Kavitha	Dietary
Dr S Sujith Kumar	General Medicine
Dr S Rajesh Kumar	General Surgery
Dr R Balakrishnan	Neurology
Dr Seetha Panicker	Obstetrics & Gynaecology
Dr T V Chitra	Obstetrics & Gynaecology
Dr D Sundar	Ophthalmology
Dr N Venkatesh Kumar	Orthopaedics
Dr S M Arvindkumar	Orthopaedics
Dr Sudha Ramalingam	PSG Centre for Research and Bioethics
Dr Nabeel M K	PSG Centre for Research and Bioethics
Dr R Karthikeyan	Respiratory Medicine

List of amendments

S.no	Date	Section	Amendment	Reason	Page no.
1	29.09.17	Preamble 8.4 c	Investigator requirement for medical projects	Policy decision to for appropriate selection of participant.	22
2	15.10.17	8.4.8	Approval letter	Recommendation by disciplinary committee	114
3	20.10.17	1.4.1	SOP committee	Sop committee member list update Upcoming accreditation	23
4	03.05.2018	List of members of the IHEC	Lay person	Change in lay person	8
5	16.01.2019			New ICMR Guidelines	
6	01.07.2019	List of Members & Roles		New ICMR Guidelines	8
7	01.01.2021			SIDCER recommendations	
8	01-01-2021	List of Members MOU & Authorship clauses included			
9	01.10.2021	List of Members			8

Glossary of Terms

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Active Study File: A file containing protocol, supporting documents, records, communications and reports that correspond to an ongoing approved study

Adverse Drug Reaction: In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

Adverse Event: Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

Agenda: A list of meeting activities in the order in which they are to be taken up.

Amendment protocol documents: In the course of the study, the PI may decide to make changes in the protocol and / or Informed Consent Documents. A package of the amended parts (changes intended) and related documents of the protocol, previously approved by the IHEC, PSG IMS&R.

Ancillary care: Ancillary care refers to providing investigation and treatment for conditions that occur during the course of trial that are unrelated to the original condition/study for which the study participant was enrolled.

Appellate authority: If the study participant is not satisfied with the decision of the IHEC, s/he may appeal to the Dean, PSG IMS&R for remedial action, who is the appellate authority.

Archival: Storage of closed study files.

Assent: Assent is the process by which minors (aged 7-18 years) agree (express willingness) to participate in a research study. These minors are too young to give informed consent but who are old enough to understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as study participants. However, assent by itself is not sufficient. If assent is given, informed consent must still be obtained from the subject's parents or guardian.

Categorization of study protocols for review: Categorization of study protocols received for types of review viz., exempt, expedited and full board review, based on the risk involved.

Closed Study File: A file corresponding to a study which has been completed or terminated or discontinued or suspended or not initiated is considered to be closed file

Confidentiality: Protection of information related to research and research participants and non-disclosure to un-authorized individuals.

Continuing Review: Periodic review of the progress of the approved protocols. Generally this is done once in a year from the date of start of the project for the duration of the study. It may be done earlier depending on the risk involved in the study, as decided by the IHEC.

Deviation / Non-compliance / Violation: Any change, divergence, or departure from the study design or procedures of a research protocol as approved by the IRB /Investigators not performing the study in compliance with the approved protocol, ICH GCP, CDSCO/FDA regulations/ and/or fail to respond to the IHEC request for information/action.

Document: Document may be of any forms, e.g., paper, electronic version (soft copy of documents as e-mail text, saved in MS-Word, PDF, etc.,), fax, audio or video tape, images, etc., that contains information belonging to IHEC.

Effective date: The date of approval of the SOPs signed and dated by the Chairperson, IHEC, PSG IMS&R, and subsequently the SOP is implemented from that date.

Exemption from review: A research study with less than minimal risk for the study participants can be exempted from review when it does not require the full board/ expedited committee review for its approval by the IHEC .This has to be decided by the IHEC only and not the Investigators.

Expedited review/meeting: A review process by IHEC subcommittee comprising of Chairperson, Member-Secretary and two identified members of the IHEC, who then report the decision to the full board in a formal meeting. An expedited review is an accelerated review of proposals identified for such review, for example, minor changes to the approved protocol, for research proposals involving no more than minimal risk to the research participants and documents of minor nature.

Full Board / Regular Review: Review of initial, resubmitted, continuing review, amendments of protocols and or ICFs and any other documents which are tabled in a formally convened meeting of the full IHEC committee for detailed discussion and decisions. In the full board review meeting, a majority of the membership of IHEC is present including those members with requisite portfolio. Research studies involving more than minimal risk to human study participants are required by federal regulations to be reviewed by the IHEC full board. In addition to this, research that is considered minimal risk may also be referred to the full board for review if the study involves vulnerable populations, or those referred to it by the expedited committee.

IHEC members: Individuals serving as regular members of the Institutional Human Ethics Committee, PSG IMS&R. The Committee has been constituted in accordance with the EC membership requirements set forth in NDCT 2019.

IND: Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

Independent Consultants: An independent consultant in the IHEC is a subject expert in a specified field identified and appointed by the Dean, PSGIMSR to work with the primary

reviewer in the review of a protocol. A list of independent consultants is maintained at the IHEC. If a project requires additional expertise than those of the IHEC members, an independent consultant of the related specialty is invited to review the project. However, an independent consultant cannot take part in the decision making process.

Informed consent: Is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information voluntarily agrees to participate. The individual has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Institutional Human Ethics Committee (IHEC): It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in any research and to provide public assurance of that protection.

Investigator's Brochure: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of these product(s) in Human Study Participants.

Less than minimal risk: Research in which there is no known physical, emotional, psychological, or economical risk to the study participant. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.).

Master SOP files: An official collection of the Standard Operating Procedures (SOP) of IHEC, PSG IMS&R accessible to all research investigators, IHEC members, auditors and government inspectors as a paper copy with an official stamp and the approval signatures.

Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life 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.

Example for minimal risk: A retrospective review of patient case records to determine the incidence of disease/ recurrence of disease.

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.

Minutes: An official written record of proceedings of an IHEC meeting.

Parental consent: In general, one or both parents or a guardian must be provided with the information ordinarily required for informed consent, so that they may decide whether to allow their child to participate.

Phase I Trial: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II Trial: The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

Phase III Trial: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV Trial: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Post-marketing surveillance: Post marketing surveillance (PMS) refers to identification of adverse events that did not appear during the drug approval process.

Primary Reviewer: A member of IHEC to whom review of a given study is assigned to do the technical and ethical review from the time of submission till the completion of the study. For each protocol, there will be two primary reviewers – one for scientific / technical and ethical review and the other for review of ICF. They complete the protocol review form and present their observations before the board.

Protocol deviation and Protocol violation: 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 been approved by the IHEC. (see explanation given at the end of the "Glossary" section). A protocol violation is a deviation from the IHEC approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data.

Protocol Review Form: An official record that documents the protocol review process by the IHEC members including primary reviewers and independent consultants.

Protocol Waiver: It is analogous to a Protocol Deviation, except that prior IHEC approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not.

e.g., A prospective decision by a sponsor or investigator to permit accrual of a participant who does not satisfy the approved inclusion / exclusion criteria for enrollment.

Quorum: Minimum number of IHEC members with specific qualifications necessary to act on any proposal presented at the meeting for action.

Renewal of approval: The approval of a research protocol by IHEC, PSG IMS&R is usually for a period of one year from the date of approval. Renewal of approval is given by IHEC if PI wants to extend the study beyond this period

Revision date: Date/year by which the SOP is revised or reviewed.

SOP (Standard Operating Procedure): Detailed, written instructions, in a prescribed format, describing activities and actions undertaken by the IHEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to

simplify the functioning, whilst maintaining high standards of New Drugs and Clinical Trials Rule 2019

SOP Committee: The members selected from the IHEC, PSG IMS&R identified by Chairperson in addition to the Member-Secretary and administrative staff, who oversee the creation, preparation, review, and periodic revision of the SOPs of IHEC, PSG IMS&R.

SOP Manual: A collection of (all the) SOPs (and their Annexe) put together in book format.

SOP Recipients: IHEC Members, Investigators, Sponsors, CROs, IHEC Secretariat Staff and Administrators.

Status Report: Report summarizing the progress of the approved study as of a stated period of time.

Study File: It is a file comprising of all essential documents and correspondence related to the study / protocol.

Study Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

Superseded/Obsolete SOPs of the IHEC: A collection of superseded (previous / obsolete) official versions of SOPs and relevant information regarding changes and preplanned deviations.

Technical advisor SAE : An Independent Consultant in the IHEC appointed by the Dean, PSGIMSR to review the SAEs and Adverse Event reports received by the IHEC and present a report during the monthly full board review meeting

Vulnerable subjects: A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally differently-abled persons, refugees, displaced persons, students, staff and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

Waiver of Consent: The IHEC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IHEC finds and documents that:

i. The research involves no more than minimal risk to the subjects;
ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
iii. The research could not practicably be carried out without the waiver or alteration;
iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation and
v. Alternate methods of recording consent such as audio visual methods are provided.

Preface

SOP Version 4.5	Effective Date: 01.01.21

Dr Rajani Sundar
Head – Anaesthesiology
G Kuppuswamy Naidu Memorial Hospital
Coimbatore
Chairperson, PSG Institutional Human Ethics Committee

This revised Standard Operating Procedure Version 4 for the activities of the Institutional Ethics Committee has taken within it the essence of our experience in the field of Human Ethics. This SOP has been augmented in scientific temper.

In the present juncture when India is emerging clearly into a lead position in medical and pharmaceutical research, It is but very much essential that this new version of SOP has been brought out which can go a long way in setting the future standards of research in ethics.

Having been associated with the PSG IMS-R Institutional Human Ethics Committee since it's formative period, I witnessed it's principle based operations as a team. This basic policy is perpetuated in this Ethics Committee. This philosophy has been the catalyst for taking up the Accreditation by SIDCER. This exposure has brought in a major revision of the SOP of the ethics committee. This present Version .1 of the SOP is the result of direct and sincere efforts to set in high ethical standards in protecting the human participants in the conduct of research.

Sd/-

Rajani Sundar

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Foreword

SOP Version 4.5	Effective Date: 01.01.21

Ramalingam Sankaran
Dean
PSG Institute of Medical Sciences and Research

Human mind is curious as well as ambitious. It uses the sense of curiosity to fulfill its ambitions. One of the byproducts of this process is invention of systematic research. However, it is important to realize that all these - curiosity, ambition, and systematic research - are not value-neutral. They are human traits and endeavors which are expected to embody certain positive values, chief among which are respect for human autonomy, justice, beneficence, and non-maleficence. Biomedical research, though employs the methods of science and explores the biomedical realm, is fundamentally a social enterprise that should consider human good at each step of the way. The field of Bioethics addresses all these.

We at PSG IMSR are very proud of our Ethics Committee. Since its early days, it has believed in the importance of its role in ensuring scientifically and ethically sound research. Through baby steps, it has grown now to an adolescent and a young adult capable of working harder and rising to greater heights. This Book of Standard Operating Procedure is a step in the right direction. It is being published as a part of updating ourselves to seek accreditation by SIDCER, and ensure that we do our jobs second to none.

I thank the SOP team for the hard work and dedication. You deserve a special note of congratulations and thank you.

I hope all investigators at PSG follow this SOP in letter and spirit.

Sd/-

Ramalingam Sankaran

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Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research	
Preamble	
SOP Version 4.5	**Effective Date: 01.01.21**

1.0 Vision

Our vision is to contribute to human welfare by ensuring a research process that combines highest integrity and safety of human research participants.

2.0 Mission

Our mission is to protect human research participants by ensuring that:

- participants' rights and welfare are adequately protected,
- research is guided by the ethical principles enunciated in ICMR Guidelines
- research is conducted with the highest level of expertise and integrity, and
- research complies with all applicable laws, policies and regulations, and
- building capacity for the same.

2.1 The IHEC, PSG IMS&R is constituted to ensure a competent and unbiased review and evaluation of all scientific and ethical aspects of the research projects they receive and ensure the ethical conduct of the same.

We do the following to fulfill our Mission….

2.2 The IHEC, PSG IMS&R shall be multidisciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community.

2.3 The IHEC, PSG IMS&R shall be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve.

2.4 The IHEC, PSG IMS&R shall establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties of the IHEC, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures, and the quorum requirements.

2.5 The IHEC, PSG IMS&R shall act in accordance with its written standard operating procedures (SOP).

2.5.1 SOP Manual

This document entitled "Standard Operating Procedures" has 19 (nineteen) individual SOPs as listed in the List of SOPs of Institutional Human Ethics Committee (SOP 01-V 4 / ANX 01-V 1.0) on various procedures to be followed by the IHEC of PSG IMS&R. This collection of SOPs and its Annexure shall be collectively known as the "SOP Manual".

3.0 Objectives

The IHEC is committed to follow all national and international ethical guidelines in biomedical research involving human study volunteers. The IHEC specifically intends to:

3.1 Ensure an unbiased competent and continuous **review of scientific and ethical aspects** of the project proposals received by it in an objective manner.

3.2 Provide input to the researchers on all aspects of safety and welfare of research participants, following review of the proposals.

4.0 Remit of and compliance with the Standard Operating Procedures (SOP)

The provisions enshrined in this (current) version of standard operating procedures (SOP) shall be applicable to all studies which are currently live, even if approval was granted during the currency of an earlier version of the SOP. Principal investigators (PIs) of studies and IHEC members are requested to familiarize themselves with the changes made in the SOP from previous versions.

5.0 Brief History of the Institution

PSG Institute of Medical Sciences & Research (PSG IMS&R), is one of the nearly 25 institutions being administered by PSG & Sons' Charities, Coimbatore, India. The Trust was established in 1926, while PSG IMS&R was established in the year 1985 and its Institutional Human Ethics Committee (IHEC) was constituted in the same year.

As per the order of the Managing Trustee of PSG & Sons' Charities, Coimbatore, India, the Dean, PSG IMS&R, has been empowered to appoint the Chairperson. The Dean in consultation with the Chairperson will appoint the Member-Secretary. All other office bearers, and members will be appointed only through a consultative process among the Dean, Chairperson and Member-Secretary. It is reiterated that though all appointment orders of IHEC members are signed by the Dean, the powers of the Dean are by no means absolute, and it is only through consultative process and explicit concurrence of all concerned that IHEC office bearers, and members can be chosen in strict accordance with the policies laid down in the SOP.

6.0 History of IHEC, PSG IMS&R

6.1 Profile of IHEC

Name of the Ethics Committee: Institutional Human Ethics Committee (IHEC), PSG IMS&R

Year Established: 1985

6.2 Autonomy of IHEC, PSG IMS&R

Autonomy of IHEC must be unfettered, and absolute. It should function without fear or favor, and be able to adhere to the SOPs without hindrance or intimidation. IHEC should be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources. The SOP is the supreme governing document of IHEC thus ensuring its autonomy.

6.3 Jurisdiction of the Institutional Human Ethics Committee, PSG IMS&R

The Institutional Human Ethics Committee (IHEC) of PSG Institute of Medical Sciences & Research (PSG IMS & R) shall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers in the following Institutions:

1. PSG Institute of Medical Sciences & Research *
2. PSG College of Nursing
3. PSG College of Pharmacy
4. PSG College of Physiotherapy
5. PSG Offshore Healthcare Management Services
6. PSG College of Technology including PSG College of Tech and Applied Research
7. PSG College of Arts & Science
8. PSG Institute of Management
9. PSG Sarvajana Higher Secondary School
10. PSG Public Schools
11. Aravind Eye Hospital, Coimbatore
12. Lotus Eye Hospitals, Coimbatore
13. AVP Research Foundation, Coimbatore

This includes both intramural and extramural research by faculty and students.

* PSGIMS&R includes the affiliated PSG hospitals, and the outreach urban and rural health centers

6.4 Jurisdiction: Administrative requirements

All proposals originating from institutions other than PSG IMS&R, paramedical institutions (Nursing, Pharmacy, Physiotherapy), Aravind Eye Hospitals, Lotus Eye Hospitals and AVP Research Foundation must be routed to the IHEC through the Dean, PSG IMS&R. The IHEC will not accept study proposals from such institutions which are not routed through the Dean, PSG IMS&R.

6.5 Jurisdiction: Approval given to studies

The validity of approval of the IHEC, PSG IMS&R is restricted for studies to be carried out

- within the physical premises of PSG Institutions listed in paragraph 8.0. and/or
- in settings expressly approved by the IHEC, PSG IMS&R

Please note:

All studies including clinical trials proposed to be conducted in PSG IMS&R must obtain approval from the IHEC of PSG IMS&R. Approval given by ethics committee of another

institution to carry out a study shall not be valid for carrying out the same study in PSG Institutions listed under paragraph 8.0.

6. 6 Validity of approval given to multi-centric studies by the IHEC of PSG IMS&R

For centres other than those listed under Para 8.0, investigators need to obtain approval from their own centres also.

6.7 Jurisdiction and validity of approval

Research proposals submitted to the IHEC, PSG IMS&R by researchers from Institutions other than those listed under Para 8.0 above will be considered on a case-by-case basis. In such cases, researchers must adhere to the following conditions:

a. For research involving data collection from PSG IMS&R by researchers other than those from institutions listed under Para 8.0 above

i. Letter of introduction from their respective Head of the institution
ii. Letter of consent from research guide
iii. Letter from Head of the institution and / or Guide describing the need for collecting data from PSG IMS&R
iv. Approval letter from the researcher's institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee) and
v. All other documents required for scrutiny by IHEC, PSG IMS&R

b. For researchers from PSG IMS & R involving data collection outside institutions listed under Para 8.0 above

i. Letter from Head of the institution and / or Guide describing the need for collecting data outside PSG
ii. Approval letter from the researcher's institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee)
iii. All other documents required for scrutiny by IHEC, PSG IMS&R for scrutiny of study protocols
iv. Samples from participant for research projects approved by PSGIMS&R IHEC shall be collected from PSG Hospitals or its approved sites only

c. For studies involving human participants or data, one Medical personnel with at least MBBS qualification to be included as a co investigator for the proposals submitted by non medical researchers.

d. For Collaborative research projects between PSGIMS&R and non- PSGIMS&R conducted at PSGIMS&R and hospitals by researchers/ research organization, Memorandum of Understanding agreement (MOU) between Institution and researchers/research organization to be submitted to the office of research .

e. An Authorship agreement between researchers/research organization outside PSGIMS&R and investigators from PSGIMS&R for Collaborative research projects to be submitted along with MOU to the office of research .

f. An Authorship agreement between interdepartmental researchers from PSGIMS&R to be submitted to the office of research .

g. An Authorship agreement between researchers from PSGIMS&R and Allied health institutions of PSGIMS&R to be submitted to the office of research .

h. Both these documents should accompany the IHEC application documents.

7.0 Standard Operating Procedures (SOP) of PSG IMS&R

Since its inception, until 2006, PSG IMS&R was considering the ICMR ethical guidelines as its SOP. It was in the year 2007, that the IHEC of PSG IMS&R scripted and adopted its own SOP document, again based largely on the ICMR template.

The SOP of PSG IMS&R has been revised sixteen times. The milestones of the IHEC SOPs are shown in the table below:

SOP Version No.	Effective date	Remarks
1.0	January 01, 2007	First written SOP
2.0	January 01, 2011	Major revision based on self-audit of functioning of the IHEC vis-à-vis the SOP and new developments
2.1	January 12, 2011	Minor revision
2.2	May 05, 2011	Minor revision
2.3	August 02, 2011	Minor revision
3.0 (Draft)	October 02, 2012	Major revision as a prelude to SIDCER Survey
3.0 (Final)	October 26, 2012	Major Revision after SIDCER Survey
3.1	November 30, 2012	Minor revisions suggested by the SOP Committee
4.0	September 21, 2015	Major Revision after SIDCER Re Survey
4.1	September 08, 2016	Minor revision
4.2	September 29, 2017	Minor revision
4.2	October 03, 2017	Minor revision
4.2	October 15, 2017	Minor revision
4.3	January 16, 2019	Minor revision
4.3	July 01, 2019	Minor revision
4.4	October 07, 2019	Minor revision
4.5	January 01, 2021	Minor revision
4.5	October 01, 2021	Minor revision

8 Business Address of Ethics Committee

Academic Block, 1st Floor,
PSG Institute of Medical Sciences & Research
Avinashi Road, Peelamedu, Coimbatore 641 004, India
Phone: +91-0422-2570170 Extension: 5818
Fax: +91-0422-2594400
E mail: ihec@psgimsr.ac.in

9 Registration / Recognition

9.1 **IORG:** Registered with the IORG of OHRP, United States Department of Health & Human Services. (IORG Number 0006807)

9.2 **Federal wide Assurance:** Registered with the Federal wide Assurance of the OHRP, United States Department of Health & Human Services (FWA Number 00017438)

9.3 **SIDCER Recognition:** SIDCER Recognition was accorded to the IHEC in November, 2012 and re-accredited in November, 2015 & November, 2019

9.4 **DCGI Registration :**DCGI Re-registration was obtained on 08 November 2019 under New Drugs and Clinical Trials Rules 2019 (**ECR/252/Inst/TN/2013/RR-19)**

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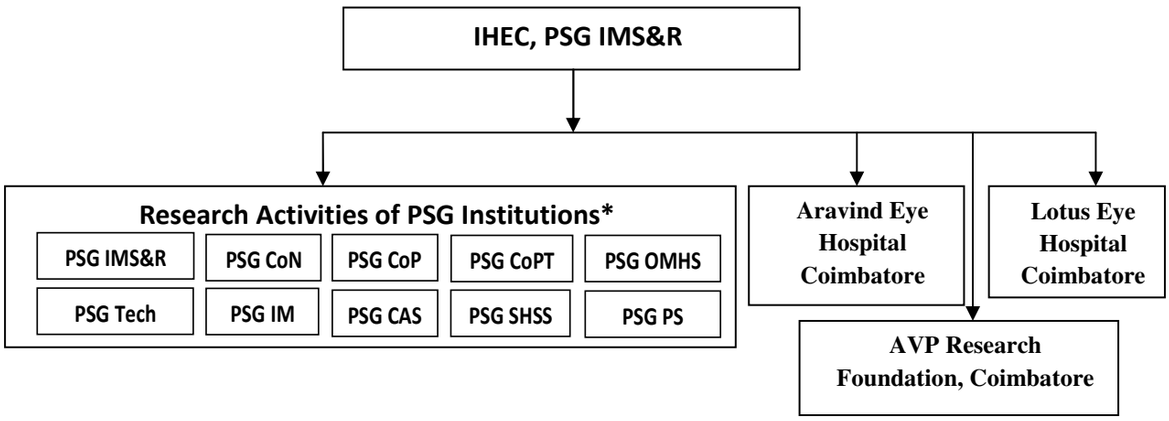
Flowchart: Jurisdiction and Independence of IHEC, PSGIMS&R



IHEC, PSG IMS&R is functionally autonomous. Its activities (as listed in this SOP) lie outside the administrative jurisdiction of the Deans / Heads of PSG Institutions listed above.

***List of abbreviations:** PSG IMS&R: PSG Institute of Medical Sciences & Research; PSG CoN: PSG College of Nursing; PSG CoP: PSG College of Pharmacy; PSG CoPT: PSG College of Physiotherapy; PSG OHMS: PSG Offshore Health Management Services; PSG Tech: PSG College of Technology including Itech; PSG CAS: PSG College of Arts & Science; PSG IM: PSG Institute of Management; PSG SHSS: PSG Sarvajana Higher Secondary School;

Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Human Ethics Committee (IHEC), PSG IMS&R	**SOP 01**
SOP Number: SOP 01-V 4.1	**Effective Date: 01.01.21**	

1.1 Purpose

This SOP describes the process for writing, reviewing, distributing, and amending SOPs within the IHEC, PSG IMS&R.

1.1.1 The SOPs will provide clear, unambiguous instructions to conduct activities of the IHEC in accordance with the ICMR guidelines 2017, , WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011), ICH (International Conference on Harmonization) New Drugs and Clinical Trials Rule 2019, 45 CFR 46, CIOMS guidelines and WMA-Declaration of Helsinki.

1.2 Scope

This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the IHEC, PSG IMS&R, Aravind Eye Hospital, Lotus Eye Hospital and AVP Research Foundation.

1.3 Responsibility

It is the responsibility of Chairperson of the IHEC to appoint the SOP Committee to formulate the SOPs. SOP committee comprising the Member-Secretary of the IHEC and two/three members identified from the IHEC, will draft an SOP, get it reviewed and approved by the other IHEC members and amend it as and when required. All members of IHEC will review the SOPs and approval will be given by the Chair of IHEC and accepted by the Dean, PSG IMS&R as authorized by the Managing Trustee, PSG & Sons Charities.

1.3.1. Secretariat of IHEC

- Co-ordinates activities of writing, reviewing, distributing, and amending SOPs
- Maintains on file all current SOPs and the list of SOPs
- Maintains an up-to-date distribution list of each SOP circulated to IHEC members
- Maintain a record of the investigators to whom SOPs are distributed against a requisition
- Ensures all IHEC members and involved administrative staff have access to the SOPs
- Ensures the IHEC members and involved staff are working according to current version of SOPs
- Maintain a file of all past SOPs of the IHEC
- Assist in the formulation of SOP and its implementation

1.3.2 SOP Committee (appointed by the Chairperson and consisting of Member-Secretary of IHEC and two-three other IHEC members)

- Assess the request(s)for SOP revision in consultation with the Chairperson

- Propose new / modified SOPs as and when needed
- Select the format and coding system for SOPs
- Draft the SOP in consultation with the IHEC members
- Review the draft SOP
- Submit the draft to Chairperson for approval

1.3.3 Chairperson of the ethics committee

- Appoints the SOP Committee
- Reviews and approves the SOPs
- Signs and dates the approved SOPs

1.3.4 IHEC members

- Review, sign and date SOPs
- Return all out-of date SOPs to IHEC office
- Maintain a record of all SOPs received

1.4 Detailed instructions

1.4.1 Identify the need for new or amendment to existing SOPs

Any member of the IHEC, IHEC secretariat or administrative staff or investigators, can make a request for revision when s/he notices an inconsistency / discrepancy / has any suggestions on how to improve the existing SOPs/ during annual periodic reviews or requests to design an entirely new SOP can put forth his request by using the Request Form for Formulation of new SOP / Revision of an SOP Form (SOP 01-V 4 / ANX 06-V 1.0) to make a request. This request is submitted to the Chairperson, IHEC. The Chairperson will inform all IHEC members about this request in a regular full board meeting.

If IHEC members agree to the request, the Chairperson will appoint an appropriate SOP Committee comprising Member-Secretary, and two/three members from IHEC, as well as drawing inputs from independent consultants as required. The designated team will proceed with the task of revision / formulation process of the SOP. If IHEC members do not agree to the request, no further action will be taken.

The Chairperson will inform the person / IHEC member who made the request for modification of the SOP in writing about the decision.

1.4.2 Appointment of SOP Committee

The Chairperson will constitute an SOP Committee consisting of the Member-Secretary and two - three more members of the IHEC who have a thorough understanding of the ethical review process. The term of SOP Committee shall be for a period of one year, renewable with or without change of members. All members of the SOP Committee shall be members of the IHEC. If the term of a member of the SOP Committee as member of IHEC expires, that member shall automatically cease to be a member of the SOP Committee from that date.
The SOP Committee will carry out the following steps (1.4.3-1.4.7):

1.4.3 Steps involved in the genesis of SOPs

- Write in detail the procedures of the IHEC, step-wise
- Name each process
- Make a list of SOPs with coding reference (SOP 01-V 4 / ANX 01-V 1.0)

1.4.4 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood.

A unique code number will be assigned to each SOP by the IHEC Secretariat through a coding system as described below:

1.4.5 SOP numbering pattern

1.4.5.1 Each SOP will be given unique two-digit number e.g., SOP 01, SOP 02, SOP 03 and so on.

1.4.5.2 Whenever a revision is undertaken, that will be suffixed to the SOP number – known as the version number, indicated with the alphabet V in capital letters.

1.4.5.2.1 If the revision is major, the version number will be indicated (after writing the SOP number) with V followed by a space, one numeric followed by a period and then by a zero (for example, third major revision to SOP 01 will be indicated thus: SOP 01-V 3.0).

1.4.5.2.2 If the revision is minor, the version number will be indicated (after writing the SOP number) with V followed by a space, one numeric followed by a period and then by a numeric (decimal) other than zero (for example, the second minor revision since the third major revision to SOP 04 will be indicated thus: SOP 04-V 3.2).

1.4.5.3 Similarly, all Annexes and Appendices will also be numbered in the same pattern. Examples of SOP, Annex, and Appendix numbering with version numbers are shown in the table below:

Table: SOP, Annex and Appendix numbering pattern - examples

SOP No.	SOP Version No.	Annex No.	Annex Version No.	Appendix No.	Appendix Version No.	Will be written as
01	3.0					SOP 01-V 3.0
09	2.4					SOP 09-V 2.4
12	4	04	1			SOP 12-V 4/ANX 04-V1.0
09	1.0	06	4			SOP 09-V1.0/ANX 06-V4
03	4.1			01	1.1	SOP 03-V4.1/APP 01-V1.1
15	2.0			02	3.0	SOP 15-V2.0/APP 02-V3.0

The first two pages of each SOP document will be signed and dated by the authors, the IHEC members who have reviewed the SOPs, IHEC Chairperson who has approved and the Dean, PSG IMS&R accepted it (under authorization by the Managing Trustee, PSG & Sons Charities). Subsequently the SOP will be implemented from that date.

1.4.6 Pagination and blank pages

All pages, including blank pages in this SOP Manual will be continuously numbered.

In this SOP Manual, each Section / SOP starts on a fresh, right-hand side page. If the previous SOP ends on right-hand side, the next left-hand side page will be left blank (but will be included

for page numbering), in order to start the next SOP from a right-hand side page. No right-hand side page in this SOP Manual will be left blank.

1.4.7 Preparation and submission of final draft

- All the members of IHEC will review the draft / revised SOP.
- During respective IHEC meetings, members can put forth their suggestions / comments on the draft / revised SOP.
- The suggestions agreed upon unanimously by all IHEC members will be incorporated and the final draft SOP will be formulated.

1.4.8 Final Approval of new/revised SOP

The final version will be presented to the Chairperson of IHEC for review and approval. The Chairperson will sign and date the SOP on the first page of the SOP document. This date of approval is declared as the effective date for implementing the SOP.

This approved document will then be circulated to all the stakeholders, and be made available in public domain.

1.4.9 Implementation, distribution, filing current SOPs

- Approved SOPs will be implemented from the effective date.
- The secretariat will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly.
- Approved SOPs will be distributed to IHEC members according to the distribution list (SOP 01-V 4/ANX 05-V 3.0)
- When the SOP is revised, members and investigators will be provided with a soft copy (by e-mail) with a request to use the newer version w.e.f. the date of implementation and discard the older version.
- One complete original/ Master copy of current SOPs will be maintained in the, "IHEC current SOP file" by the IHEC Office.
- Photocopies of these SOPs can be considered current or official/ controlled copy, if stamped and signed by Member-Secretary or Alternate Member-Secretary.
- An SOP distribution log is maintained in the IHEC Secretariat. (SOP 01-V 4/ANX 05-V 3.0).

1.4.10 Archival of superseded/ obsolete SOPs

A copy of the old version will be clearly marked "Superseded/ Obsolete" and archived in a master file. The process of evolution of previous SOPs of the IHEC will be documented in a defined format. (SOP 01-V 4/ANX 04-V 1.0).

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SOP 01-V 4 / ANX 01-V 1.0

List of SOPs of Institutional Human Ethics Committee

Sl. No.	SOP TITLE	SOP NUMBER
	Preamble (including history of IHEC and evolution of its SOP)	V 4
1.	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing, & Amending SOPs for the Institutional Human Ethics Committee (IHEC), PSG IMS&R	01-V4
2.	Constitution of Institutional Human Ethics Committee, PSG IMS&R	02-V4
3.	Management of Protocol Submissions	03-V4
4.	Receiving, Categorization and Assigning to Primary Reviewers / Independent Consultants and sending it to Members	04-V3.0
5.	Exemption from the Ethical Review for Research Projects	05-V3.0
6.	Expedited Review of Submitted Protocol	06-V3.0
7.	Full Board Review of Submitted Protocol	07-V3.2
8.	Agenda Preparation, Meeting Procedures and Recording of Minutes	08-V3.2
9.	Review of Amended protocol / Protocol related documents	09-V3.2
10.	Continuing review of study Protocols	10-V3.2
11.	Review of Protocol Deviation / Non-Compliance / Violation / Waiver	11-V1.2
12.	Review of Serious Adverse Events (SAE) Reports	12-V3.2
13.	Review of study completion reports	13-V3.2
14.	Management of Premature Termination / Suspension / Discontinuation of the study	14-V3.2
15.	Review of Waiver of Written Informed Consent and Waiver of Consent	15-V1.2
16.	Site Monitoring and post-monitoring activities	16-V1.2
17.	Dealing with participants' requests and complaints	17-V2.1
18.	Maintenance of Active Project Files, Archival of closed files and Retrieval of documents	18 –V3.2
19.	Vulnerable population	19-V 1.0

SOP 01-V 4/ANX 02-V 1.0

Template for Standard Operating Procedures

Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research	
Title: Title which is self-explanatory and is easily understood	
SOP No: SOP ##-V#.##	Page: a of b
Effective date: DD/MM/YYYY	

SOP 01-V 4 / ANX 03-V 1.0

Document History of the SOP Manual

Names of the SOP Committee members	Version	Effective date (dd-mm-yyyy)

SOP 01-V 4 / ANX 04-V 1.1

Details of Superseded/ Obsolete SOP

Name of the Author(s)	Version	Date of ratification (dd-mm-yy)	Date of implementation (effective date) (dd-mm-yy)	Describe the main change

SOP 01-V 4 / ANX 05-V 3.3

Log of the IHEC members receiving SOPs (In alphabetical order)

Sl. No.	Name of Recipients	Designation	SOP Number	No. of Copies	Signature	Date
1	Mr B Antony Raj	Member				
2	Dr K Bhuvaneswari	Member				
3	Mr Gowpathy Velappan	Member				
4	Dr S Karthikeyan	Member-Secretary				
5	Mr B Manigandan	Member				
6	Mrs M Nirmala	Alternate Member-Secretary				
7	Dr Parag K Shah	Vice-Chairperson				
8	Dr Rajani Sundar	Chairperson				
9	Dr S Ramesh	Member				
10	Dr R Senthurselvi	Member				
11	Dr Sivakumar V	Member				
12	Dr R Sujatha	Member				
13	Mrs Sweety Subha P	Member				

SOP 01-V 4 / ANX 06-V 1.0

Request for Formulation of new SOP / Revision of SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

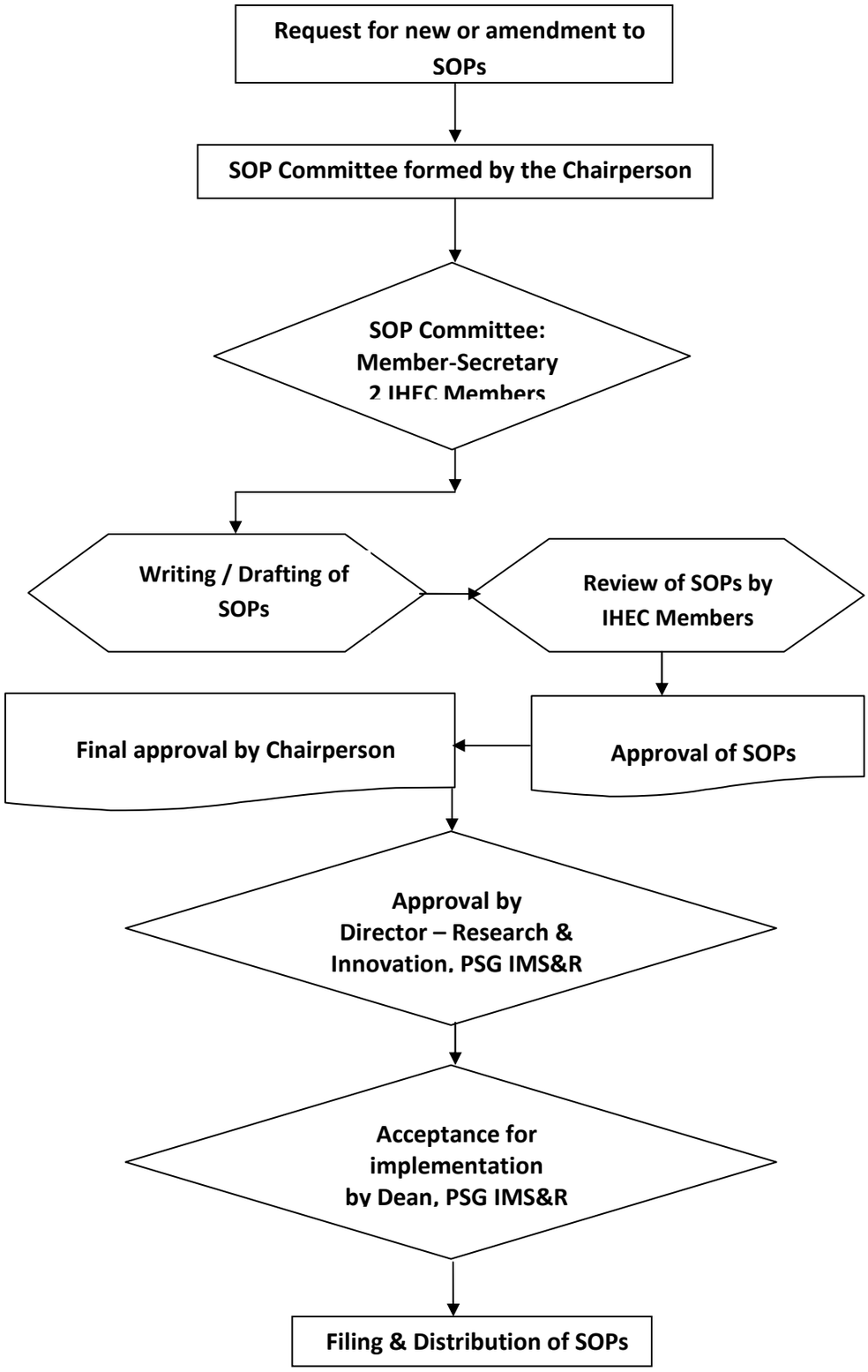
SOP No.			
Title:			
Details of problems or deficiency in the existing SOP			
Need to formulate an entirely new SOP (i.e. SOP not existing previously)			
Identified by:		Date (DD/MM/YYYY):	
Discussed in IHEC Meeting held on :-			
SOP revision required:	Yes		No
New SOP to be formulated:	Yes		No
Date SOP revised:			
Date SOP approved:			
Date SOP becomes effective:			

SOP 01-V 4 / ANX 07-V 2.1

Log of SOP recipients (non-members)

No.	Name of Recipients	Designation	SOP No. & Version	No. of controlled Copies	Date
1.					
2.					
3.					
4.					
5.					
6.					

Flowchart: Preparation & Amendment of SOPs (SOP 01)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Constitution of Institutional Human Ethics Committee, PSG IMS&R	**SOP 02**
SOP Number: SOP 02-V4	**Effective Date: 01.01.21**	

2.1 Purpose

To constitute the Institutional Human Ethics Committee as per the National guidelines to ensure human participant protection.

2.2 Scope

The SOP applies to the formation of the IHEC

The IHEC is committed to ensure human participant protection by

- Reviewing the proposals as per the National guidelines in a transparent manner
- To function as a forum for redressal of complaints on ethical issues, from study participants and their families
- Communicate to the investigators the importance of ensuring ethics in the process of research

.

2.3 Responsibility

The Chair person will be selected and appointed by the Dean under the authority given by the Managing Trustee, PSG & Sons' Charities. The Dean, in consultation with Chairperson, will appoint the Member-Secretary and the other IHEC members.

2.4 Guidelines Followed

The IHEC shall comply with the following national and international ethical guidelines:

International guidelines

- WMA-Declaration of Helsinki (1964 and all subsequent amendments)
- Nuremburg Code (1947)
- Council of International organizations of Medical Sciences (CIOMS)
- Belmont Report 1979
- International Ethical Guidelines for Biomedical Research Involving Human Study Participants (Geneva 2002),
- European Convention on Human Rights and Biomedicine 1977
- 45CFR 46
- Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000 and its amendment in 2011)
- ICH-GCP 2016

National guidelines

The IHEC establishes its own Standard Operating Procedures based on the:

- ICMR Ethical Guidelines for Biomedical research on Human Participants (2018)
- New Drugs and Clinical Trials Rule 2019
- National Guidelines for SAE reporting (2011)
- National Guidelines for Ethics Committees reviewing Biomedical and Health Research during COVID-19 pandemic

The IHEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

2.5 Composition

The Institutional Human Ethics Committee will be multidisciplinary and multi-sectorial in composition.

The committee is composed of a minimum of 8 and maximum of 15 members. It includes scientific and non-scientific, clinicians and non - clinicians, clinical pharmacologist, a social scientist, lawyer, /expert in ethics, layperson needed to represent different point of view.

The committee should have adequate representation of age, gender and community to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism.

2.5.1 Structure of IHEC

The composition should be as follows:-

1. Chairperson (not – affiliated to PSG Institutions)
2. Vice-Chairperson (not – affiliated to PSG Institutions)
3. Member-Secretary (PSG IMS&R Staff member)
4. Alternate Member-Secretary (PSG IMS&R Staff member)
5. 1-2 clinicians
6. Basic medical scientists
7. Clinical Pharmacologist.
8. One legal expert or retired judge or medico-legal expert
9. One social scientist / representative of non-governmental voluntary agency
10. One philosopher / ethicist / theologian
11. Lay person from the community (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)

2.5.2 Terms of Appointment

2.5.2.1 Duration

The members of the IHEC, PSG IMS&R will be appointed for a period of 3 years. The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the IHEC, and the regular input of fresh ideas. The membership can be renewed for another term of 3 years. However there will be a break of one year, after two terms before re-appointment.

Extension of membership will be based on the recommendation of the Chairperson and Member-Secretary of IHEC.

Exemptions: As a very special case, when situation demands, tenure of the members may be further extended by another term.

For example, the current members who (i) are completing two terms in year 2013 and (ii) were retained in re-constitution that took place in September 2012 are being given an extension of one more term in view of their expertise and the fact that they have undergone extensive training as part of the SIDCER Recognition Process in 2012.

2.5.2.2 Renewal

The membership will be renewed after the stated term of 3 years

The process of renewal will be as follows:

Selection of Member-Secretary/Alternate Member-Secretary and other members should be done 6 months in advance. Member-Secretary designate should be inducted in the committee as a member before he/she takes on the mantle in the new IHEC.

Other members-designate may attend the board meeting as observers before starting their tenure as IHEC member. They should read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form (SOP 02-V2.1 / ANX 03–V3.0) at the beginning of the IHEC meeting.

If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated below – section 2.5.3.

2.5.2.3 Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the appointing authority for the same. IHEC members (including Member-Secretary) who decide to resign must inform the Dean, PSG IMS&R and Chairperson, IHEC in writing about their intention to resign by citing reasons for the same at least 30 calendar days prior to the next scheduled meeting

In case of resignation of the Chairperson, s/he is required to inform the Dean 30 calendar days prior to her/his resignation. . If there is a situation which warrants an emergency resignation of a member where he/she could not give a 30 day notice, his/her resignation may be accepted.

In case of resignation, Dean, PSG IMS&R would appoint a new member, falling in the same category of membership if it is a mandated category per New Drugs and Clinical Trials Rule 2019. Dean appoints Member-Secretary and Chairperson as per the procedure described in this SOP.

2.5.2.4 Termination / Disqualification procedure

A member may be relieved or terminated of his/her membership in case of:

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds
- If a regular member fails to attend more than 3 meetings of IHEC. The membership

shall be reviewed by the IHEC and a letter of reminder will be sent to the concerned member. If deemed necessary, the IHEC may decide to terminate the membership and recommend to the Dean, PSG IMS&R, by the Chairperson IHEC for necessary action

- Relocate to another city

In any such situation/circumstances, Dean, PSG IMS&R will serve a letter of termination to the member citing the reason. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IHEC meeting and IHEC membership circular/ roster will be revised.

2.5.2.5 Members going on long leave

Long leave refers to a duration of leave that is taken as one month (30 days) or above. If a situation occurs when a member is required to go on long leave for professional and personal reasons the following will be followed

a) *If the period of leave is less than or equal to 6 months and the IHEC appointment term is valid for more than 6 months*
He/she can continue as the member of IHEC if she/he wants to do so. If not the member should tend her/his resignation from IHEC prior to going on leave as per the clause described in 2.5.2.3.If the member intending to go on leave is an office bearer (see 2.6 below for definition of office bearers) the same rules will be implemented. In addition, any suitable, consenting member of the IHEC can hold the post of the office bearer until she/he returns.

b) *If the member is going on leave for more than 6 months* she/he should tend her resignation from the IHEC as per clause 2.5.2.3 even if the term of the member is valid. This is to ensure efficient and uninterrupted functioning of IHEC review mechanism. A suitable replacement of the member in the same/similar specialty will be inducted to IHEC. This will be applicable to all the office bearers of the IHEC too.

2.5.2.6 Conditions of Appointment

a. Name, age, sex, profession, and affiliation of IHEC members will be publicized through the PSG IMS&R website and notice boards (and that of the PSG institutions for whom PSG IMS&R reviews study protocols).
b. Members must accept the appointment in writing.
c. Submit a CV and training certificates in Ethics and /or GCP.
d. Disclose any Conflict of interest.
e. Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines and the ICMR code & IHEC, PSG IMS&R SOPs.
f. All Members (including Chairperson, Vice-Chairperson, Member-Secretary and Alternate Member-Secretary) are required to sign the confidentiality agreement Conflict of Interest statement (SOP 02-V4 / ANX 01-V 3.0 & SOP 02-V4 / ANX 02 V 3.0) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IHEC in the course of its work.
g. An investigator can be a member of the IHEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has presence as a PI, Co-PI or Co-I or potential conflict of interest.

2.6 Office Bearers

The IHEC will have the following office bearers who have the expertise and professional qualifications to review what comes in:

2.6.1 Chairperson and Vice-Chairperson

The IHEC Chairperson and Vice-Chairperson should be highly respected individuals. They should be fully capable of managing the IHEC and the matters brought before it with fairness and impartiality. They should give opportunities to the members to have a frank and free expression of their views. Vice-Chairperson officiates as the Chairperson in his/her absence.

2.6.1.1 Appointment:

The Chairperson will be appointed by the Dean, PSG IMS&R and under authorization by the Managing Trustee, PSG & Sons Charities. The Vice-Chairperson will be appointed by the Dean, PSG IMS&R in consultation with the Chairperson, IHEC from amongst the members.

2.6.1.2 Criteria for selection of Chairperson and Vice-Chairperson

The Chairperson and Vice-Chairperson are selected based on their experience as members of ethics committee. The Chairperson should preferably be a medical professional. A person in order to be considered for the post of Chairperson and Vice-Chairperson should have the experience of serving in an ethics committee and should not be affiliated to PSG Institutions.

2.6.1.3 Terms of Reference for Chairperson and Vice-Chairperson

i. Ensure that the entire committee is functioning in conformity with its SOP.
ii. Protection of safety, rights and confidentiality of the research participants.
iii. Participate in the IHEC meeting regularly.
iv. Monitor the review procedures
v. Maintain confidentiality of the documents and deliberations of the IHEC meetings.
vi. Declare conflict of interest, if any.
vii. To participate in continuing education activities in biomedical ethics and biomedical research and encourage members to do so.
viii. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC secretariat
ix. To be updated on relevant laws and regulations

2.6.2 Member-Secretary and Alternate Member-Secretary

The IHEC Member-Secretary and Alternate Member-Secretary should be highly committed to the IHEC work and culture. They should be fully capable of managing the IHEC and the matters brought before it with fairness and impartiality. They should be able to run the committee's affairs with due attention to deadlines, and processes set forth in SOP. Alternate Member- Secretary officiates as the Secretary in his/her absence. The Member-Secretary shall request in writing the alternate Member-Secretary to officiate on her/his behalf at least one working day in advance, with a copy to Chairperson-Vice-Chairperson and the Dean, PSG IMS&R.

2.6.2.1 Appointment

They will be appointed by the Dean, PSG IMS&R in consultation with the Chairperson, IHEC.

2.6.2.1.1 Criteria for selection of Member-Secretary and Alternate Member-Secretary

The Member-Secretary and Alternate Member-Secretary of IHEC will be a staff member of PSG IMS&R. The Member-Secretary should preferably be a medical professional. Apart from their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile, the Member-Secretary and Alternate Member-Secretary are selected based on their experience as members of ethics committee or its scientific review committee.

2.6.2.1.2 Terms of Reference for Member-Secretary and Alternate Member-Secretary

i. Ensure that members and research investigators are functioning in conformity with the IHEC's SOP.
ii. Liaisoning between the Chairperson/Vice-Chairperson, IHEC and Dean PSG IMS&R and updating them about the developments
iii. Liaisoning between the IHEC members and Dean, PSG IMS&R
iv. Communicating with Chairperson/Vice-Chairperson, members and Principal Investigators
v. Protection of safety, rights and confidentiality of the research participants.
vi. Categorization of study proposals received
vii. Assigning categorized study proposals to primary reviewers
viii. Guiding the office staff in the day-to-day functioning of the IHEC Secretariat
ix. Overseeing documentation and archiving of study documents (Preparation, maintenance and distribution of study files).
x. Overseeing the maintenance of a database of all proposals received, reviewed and archived
xi. Convening IHEC Expedited Committee Meeting as and when required (with the help of the IHEC Secretariat staff)
xii. Convening IHEC Full Board Review Meeting regularly (once in a month) (with the help of the IHEC Secretariat staff)
xiii. Preparation of agenda and minutes of the meetings (with the help of the IHEC Secretariat staff)
xiv. Communicating with IHEC members and PIs (with the help of IHEC Secretariat staff)
xv. Monitor the review procedures
xvi. Participate in the IHEC meeting regularly.
xvii. Maintain confidentiality of the documents and deliberations of the IHEC meetings.
xviii. Declare conflict of interest, if any.
xix. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC Secretariat
xx. To be updated on relevant laws and regulations
xxi. To participate in continuing education activities in biomedical ethics and biomedical research and encourage members to do so.
xxii. Arrangement of training for personnel and IHEC members

2.7 Members

2.7.1 Appointment

All members shall be appointed by the Dean, PSG IMS&R in consultation with the Chairperson and Member-Secretary of IHEC

2.7.1.1 Criteria for selection of members:

All members, except the lay person and legal expert should have passed a post-graduate degree course in their own subject area and should have attended at least one training programme on ethics. Apart from their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and profile. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in domain field and no known record of professional misconduct.

New members will be identified according to the requirement i.e. as per the composition specified in Section 2.5 of this SOP and provided the potential member fulfils the conditions of appointment as defined in 2.5.3 of this SOP.

2.7.1.2 Terms of Reference of the IHEC members

The following are the terms of reference of the IHEC members and their specific roles are stated in their appointment letters

i. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.
ii. Participate in the IHEC meeting.
iii. Review & discuss research proposals submitted for evaluation.
iv. Review progress reports and monitor ongoing studies.
v. Monitor SAEs and recommend appropriate action(s).
vi. To do onsite visits wherever needed
vii. Maintain confidentiality of the documents and deliberations of the IHEC meetings.
viii. Declare conflict of interest, if any.
ix. To carry out work delegated by Chairperson.
x. To participate in continuing education activities in biomedical ethics and biomedical research.
xi. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC secretariat
xii. To be updated on relevant laws and regulations

2.8 Independent Consultants

The IHEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IHEC on proposed research protocols, when the Chairperson / Member-Secretary or the IHEC members determine that a study will involve procedures or information that is not within the area of expertise of the IHEC members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g. genetic disorders, stem cell research etc.) or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement (SOP 02-V4 / ANX 03 V 3.0) regarding meeting, deliberations, and related matters. These consultants or subject experts offer their views on the proposed research but cannot take part in decision making.

2.8.1 Appointment

All Independent Consultants shall be appointed (as and when required) by the Dean, PSG IMS&R in consultation with the Chairperson and Member-Secretary of IHEC. Independent Consultants may be from within or outside PSG Institutions.

2.8.1.1 Criteria for Selection

The Independent Consultants should be subject experts in their field. They should be willing to spare time to review, and give their expert comments on the projects allotted to them. They should also be able to attend the IHEC proceedings as and when requested.

2.8.1.2 Terms of Reference for Independent Consultants

i. Will study the protocols given to them for review
ii. Give expert comments and their opinion to the IHEC
iii. Be present in the IHEC meetings when requested
iv. Declare conflict of interest, if any.

2.9 Secretariat

Secretariat is composed of Member-Secretary, Alternate Member Secretary, IHEC and the administrative supporting staff. The supporting staff consists of staff members of IHEC, PSG IMS&R appointed by the Dean, PSG IMS&R.

2.9.1 The secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Maintain a database of all proposals received, reviewed and archived
- Preparation, maintenance and distribution of study files
- Organizing IHEC meetings regularly
- Preparation of agenda and minutes of the meetings
- Maintaining IHEC documentation and archive
- Communicating with IHEC members and PIs
- Arrangement of training for personnel and IHEC members
- Providing necessary administrative support for IHEC related activities to the Member-Secretary, IHEC

2.9.1.1 The IHEC Administrative Staff: Working Rules

a. There will be administrative assistant/s and attendant/s / helper/s who will help the IHEC Chairperson and Member-Secretary in executing functions of the IHEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IHEC. 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 may be recommended by IHEC members during regular IHEC meeting and will be recorded in minutes; these are forwarded to the Dean, PSG IMS&R.

b. The administrative staff will be appointed by conducting formal interviews (to be conducted by panel of experts appointed by the Dean, PSG IMS&R.

2.9.1.2 Terms of Reference for the administrative officer/s/staff

a. Correspondence with the IHEC members and external experts
b. Correspondence with the investigators
c. Pre and post arrangements of IHEC meetings
d. Preparing agenda and minutes of the IHEC meetings
e. Answering queries of the investigators
f. Filing study related documents
g. Archiving and maintaining the study files

2.9.1.3 Duties of the attendant/s /helper/s (as assigned by the Member-Secretary / Secretariat office in-charge)

a. Assisting the secretariat in arranging the IHEC meetings
b. Dispatching sets of study documents to IHEC members and external experts
c. Receiving the study related documents from and dispatching the IHEC letters to the investigators
d. Filing study related documents
e. Archiving and maintaining the study files

All staff of PSG IHEC secretariat will follow the rules and regulations as per PSGIMS&R norms

2.9.2 Office Facilities

The IHEC has a dedicated office room with designated rooms for member secretary, alternate member secretary, secretarial staff with necessary office equipments and storage space. The office is also provided with board room for conduction of meetings, a class room for training and an archival room for storage of closed files. There are adequate secretarial staff and supporting staff to manage the work load.

2.10 Quorum Requirements

The quorum of IHEC is decided by the presence of 50% plus one members of the total strength. In case of clinical trials as per the revised New Drugs and Clinical Trials Rule 2019, the following specialties should be represented in the meeting.

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician
3. One legal expert
4. Social scientist/Philosopher/ theologian/ethicist
5. Lay person

Without satisfying these conditions, any decision taken by the committee shall remain null and void.

- A quorum 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.
- No quorum should consist entirely of members of one profession or one sex.
- In absence of the Chairperson, Vice-Chairperson will chair the meeting. On a rare occasion of absence of both, any member who is independent of the institution will chair the meeting as Acting Chairperson.

2.11 Decision making

- Decision is arrived at by consensus, if consensus not possible, voting is carried out.
- Opinions of absent members that are transmitted by mail, video conferencing or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.
- Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.
- Any subject expert - Independent Consultant who is attending the meeting will take part in discussion and offer their expert comment – but will not take part in decision making.

2.12 Training for IHEC Members and identifying opportunities for improvement

IHEC members have a need for initial and continued education and training regarding the ethics and science of biomedical research.

All IHEC members must be conversant with ICMR Guidelines for Research involving Human Participants, New Drugs and Clinical Trials Rule 2019 and ICH-GCP Guidelines, Current National Guidelines / Regulations, 45 CFR 46 and WMA-Helsinki Declaration.

IHEC members will receive introductory training in ethical aspects of biomedical researches and functioning of IHEC and will be exposed to ongoing opportunities for enhancing their capacity for ethical review. The IHEC will request the PSG Center for Research and Bioethics to organize the training programs as and when required.

- A new member will be inducted one month prior and will be requested to be an 'observer' for the first board meeting. An introductory briefing will be provided by the Member-Secretary.
- If the member is inducted to the IHEC in the event of sudden termination/resignation of the members the new member need not fulfill the requirement of an "Observer" in the first board meeting. The member who replaces the old member would preferably hold a qualification in bioethics or should have undergone training in bioethics/ research ethics (within the last one year).
- However he/she will attend the Ongoing training programs in the institution.
- The IHEC will make an Annual Training Calendar identifying areas of training for the members at regular intervals
- The IHEC members will be encouraged to receive ongoing training by attending workshop at least once every year.
- The Institution also runs a Post Graduate Diploma in Bioethics which members are encouraged to undergo.

2.13 Annual report of the IHEC

- Annual activity report (including details of study proposals received) should be prepared and submitted to the Dean, PSG IMS&R and other relevant authorities

2.14 Self assessment

- For continuous improvement of quality assurance of its services, the IHEC will undergo self assessment annually or as and when required As a part of PSG Hospitals NABH internal audit, self assessment will be done once in six months.

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SOP 02-V 4 / ANX 01-V 3.0

Confidentiality Agreement form for IHEC Members

In recognition of the fact, that I, Dr./Mr./Ms……..…… herein referred to as the "Undersigned", has been appointed as a member of the Institutional Human Ethics Committee (IHEC), would be asked to assess research studies involving Human Study Participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

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

Whereas, the fundamental duty of an IHEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IHEC 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 Human Study Participants;

The undersigned, as a member of the IHEC 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 IHEC. 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, 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 IHEC.

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 my performance of this agreement is consistent with the Institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality / Non-Disclosure Agreement

In the course of my activities as a member of the IHEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to 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 return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr./Mr./Ms./Master …….. have read and I accept the aforementioned terms and conditions as explained in this agreement.

Signature
Date

Chairperson, IHEC
Date

SOP 02-V 4 / ANX 02-V 3.0

Conflict of Interest Agreement form for IHEC Members

In recognition of the fact, that I, Dr./Mr./Ms. ……..…… herein referred to as the "Undersigned", has been appointed as a member of the Institutional Human Ethics Committee (IHEC), would be asked to assess research studies involving Human Study Participants in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

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

Whereas, the fundamental duty of an IHEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IHEC 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 Human Study Participants;

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

It has been recognized that the potential for conflict of interest will always exist but has faith in the IHEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of Human Study Participants.

In accordance of the policy of the IHEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IHEC.

Signature Date

The Undersigned will immediately disclose to the Chairperson of the IHEC any actual or potential conflict of interest that I 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.

If an applicant submitting a protocol believes that an IHEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IHEC member(s) in question.

The committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IHEC review or approval except to provide information requested by the Committee.

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

In the course of my activities as a member of the IHEC, whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr./Mr./Ms. ……..…….. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature
Date

Chairperson, IHEC PSG IMS&R
Date

SOP 02-V 4 / ANX 03-V 3.0

Confidentiality and Conflict of Interest Agreement Form for Independent Consultants

Agreement on Confidentiality

I, Dr./Mr./Ms. ……..…….. (Name and Designation) as a non-member of IHEC understand that the copy (ies) given to me by the IHEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IHEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IHEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Agreement on Conflict of Interest

In the course of my activities as an Independent Consultant of the IHEC, whenever I have a conflict of interest, I shall immediately inform the committee about it and / or shall refrain from giving my expert comments on the project on this ground.

I, Dr./Mr./Ms. …….. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature
Date

Chairperson of IHEC
Date

I, Dr./Mr./Ms. …….. (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IHEC and me.

Signature of the recipient Date

SOP 02-V 4 / ANX 04-V 3.0

Confidentiality Agreement Form for Observer Attendees to IHEC, PSG IMS&R Meetings

I, Dr./Mr./Ms. _____, understand that I am allowed to attend the IHEC meeting scheduled on _____at _____am/ pm as an Observer.

I understand that I should not take part in the discussions or decision making process during the meeting.

The meeting will be conducted in the IHEC Meeting room, PSG IMS&R.

In the course of the meeting of the IHEC some confidential information may be disclosed or discussed.

Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

Signature of the Observer Date

Chairperson of IHEC Date

I, ……. (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IHEC and me.

Signature
Date

SOP 02-V 4 / ANX 05-V 1.0

Template for IHEC appointment letter

Date ……

Dr xxxxxxx
xxxxxxxxxxxxxx
xxxxxxxxxxx
xxxxxxxxxx
Coimbatore

Dear Dr xxxxxxxx,

I am pleased to invite you to be a Member of the Institutional Human Ethics Committee (IHEC), PSG IMS&R. As a Member of the IHEC, you will be expected to earmark time and actively contribute by participating in its meetings, reviewing study proposals, and any other work that may be assigned to you related to IHEC and its function. The IHEC meets once in a month.

Please note that your term in the IHEC, PSG IMS&R is for a period of three years from the date of appointment as member of IHEC viz., **date**. As a matter of policy, members of the IHEC, PSG IMS&R are not paid any honorarium for the services rendered to it. You will be provided initial and continuing education on biomedical/research ethics.

A copy each of the current version of the Standard Operating Procedure and links to important national and international guidelines are being sent to you by e-mail. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.

Your major responsibilities as a member of the IHEC are:

i. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants
ii. Participate in the IHEC meeting.
iii. Review and discuss research proposals submitted for evaluation.
iv. Review progress reports and monitor ongoing studies.
v. Monitor SAEs and recommend appropriate action(s).
vi. Maintain confidentiality of the documents and deliberations of the IHEC meetings.
vii. Declare conflict of interest, if any.
viii. To carry out work delegated by Chairperson, Vice-Chairperson & Member-Secretary.

ix. To participate in continuing education activities in biomedical ethics and biomedical research.
x. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC secretariat
xi. To do onsite visits wherever needed
xii. To be updated on relevant laws and regulations

I request you to sign with date on the photocopy of this letter as a token of acceptance and return it to the Secretariat of IHEC, along with the Nil Disclosure Agreement and Conflict of Interest Statement in the attached template. I further request you to send an updated CV of yours (with signature and date) along with a copy each of certificates of training programmes attended by you in the area of ethics, to the IHEC Secretariat.

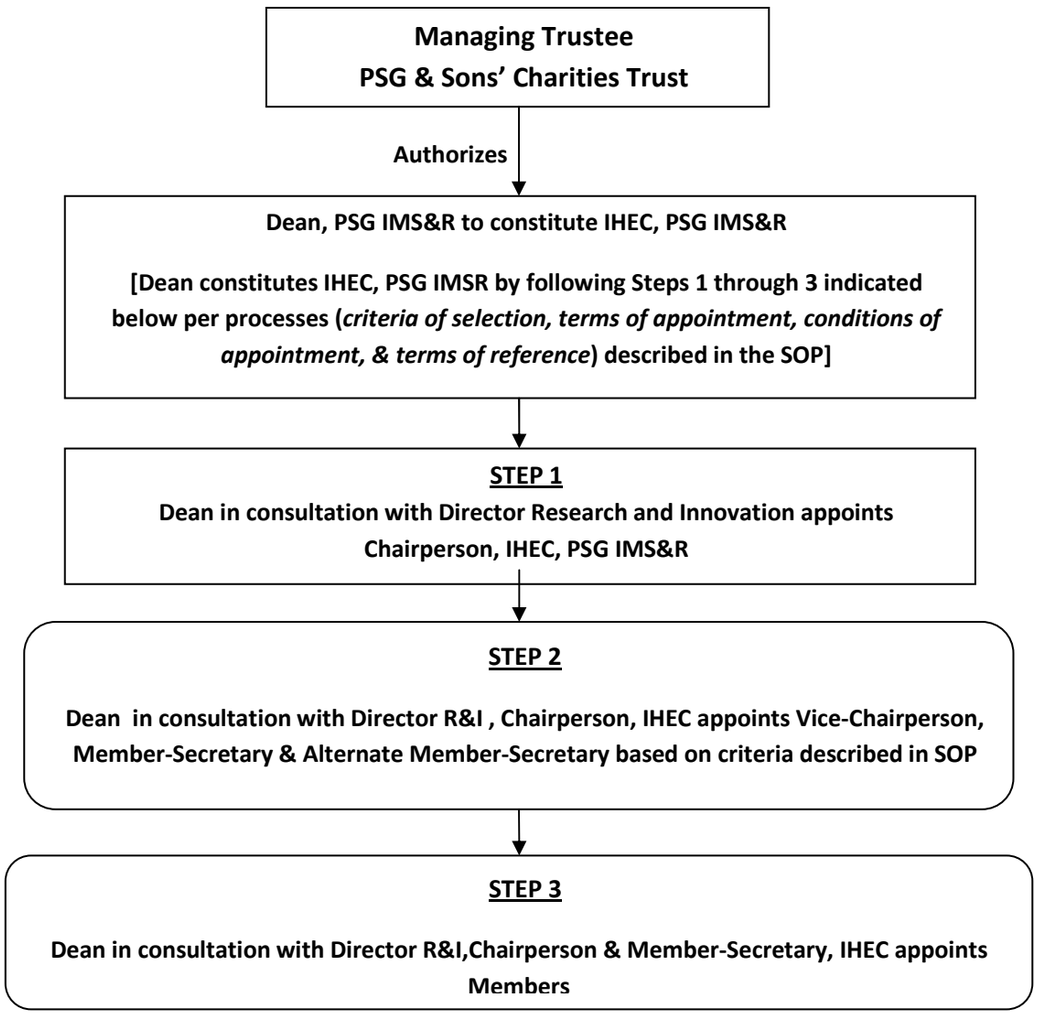
I thank you in anticipation and look forward to your active contribution towards the strengthening of IHEC, PSG IMS&R.

With regards

Yours sincerely

Dean

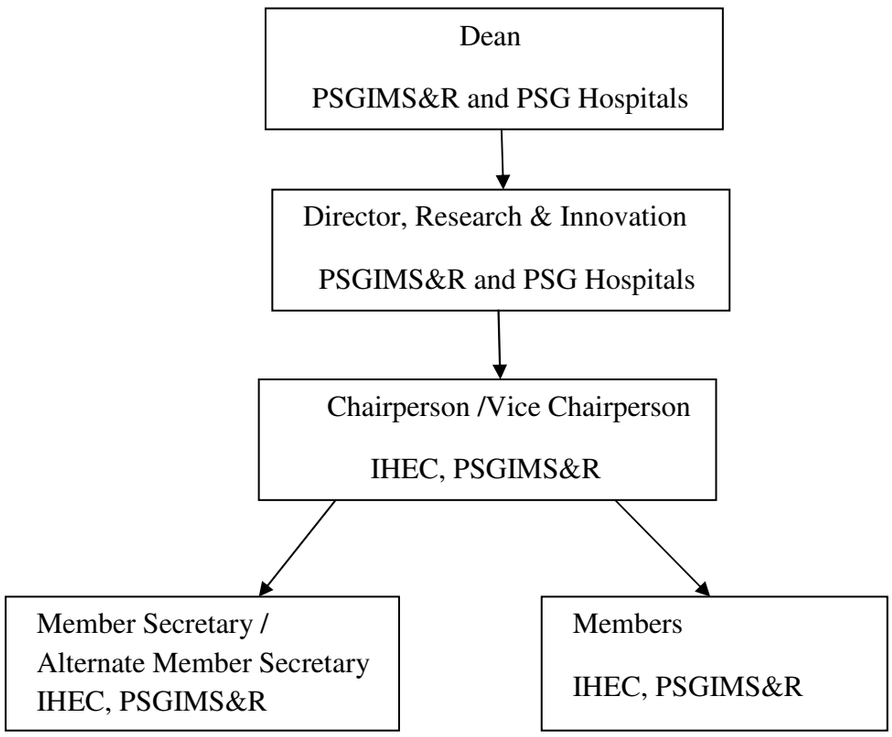
Flowchart: Constitution of the Institutional Human Ethics Committee (IHEC), PSG IMS&R (SOP 02)



Institutional Human Ethics Committee

PSG Institute of Medical Sciences and Research

IHEC PSGIMS&R	Organisational Structure	Version 2 w.e.f. 01.05.2019



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Management of Protocol Submissions	**SOP 03**
SOP Number: SOP 03-V4	**Effective Date: 01.01.21**	

3.1 Purpose

This SOP is designed to describe and act as a guideline for the IHEC Secretariat to manage research protocol submissions and related processes.

3.2 Scope

The scope includes the following -

- Submission for initial review
- Resubmission of protocols with modifications
- Submission of Protocol amendments and any other amendments
- Submission of SAE reports
- Submission of Protocol deviations, Protocol violations
- Submission of application for Continuing review of approved protocols
- Submission of Protocol completion/termination reports

3.3 Responsibility

It is the responsibility of the IHEC Secretariat to receive, record and distribute the protocols for review by the IHEC and communicate the decisions to PI in a prescribed format.

All project proposals submitted (both hard and soft copies) are first forwarded by IHEC Secretariat to the Member-Secretary for categorization and further review.

3.4 Detailed process

3.4.1 Submission of Documents:

The PI can submit research proposal to the IHEC secretariat for review and approval under any of the 5 sections mentioned below within the specified time period mentioned below:

3.4.1.1 New proposals for Review:

- Fifteen days prior to the upcoming IHEC meeting

3.4.1.2 Re-submission of Protocols with Corrections:

- 15 days from the date of receipt of IHEC decision letter

3.4.1.3 Protocol Amendment or any other Amendments:

- Fifteen days prior to the IHEC meeting

3.4.1.4 Submission of SAE (On-Site):

For all clinical trials approved by DCGI the SAE will be submitted by the PI to the licensing authority, the EC and the sponsor within 24 hours. The detailed report of SAEs, after due analysis, should be forwarded by the investigator and sponsor to Chairman of the EC, Licensing Authority and the Head of the Institution within fourteen Calendar days of occurrence of the SAEs. The causality analysis and suggested compensation will be forwarded to the licensing authority within 30 days and minuted.

3.4.1.5 Submission of protocol deviations / violations:

- Within 7 days of occurrence.

3.4.1.6 Continuing Review of Approved Protocols:

- Fifteen days prior to the scheduled review/expiry date

3.4.1.7 Protocol Completion / Termination:

- Within 30 days of completion / termination

3.4.2 Receiving and Verifying Contents of Submitted Protocols

i. Secretariat will check the protocol documents as per the checklist attached to the Study Protocol Submission Forms (SOP 03-V 4/ANX 01-V 4, SOP 03-V 4/ANX 02-V 4, SOP 03-V 4/ANX 03-V 4) to ensure that all required forms and materials are submitted (see guidelines to prepare informed consent: SOP 03-V 4/ANX 06-V 1.0)
ii. Verification includes
    a. Duly filled and signed Study Protocol Submission Forms (SOP 03-V 4/ANX 01-V 4, SOP 03-V 4/ANX 02-V 4, SOP 03-V 4/ANX 03-V 4)
    b. Study protocol
    c. Other relevant documents (SOP 03-V 3.0/ANX 04-V 3.0, SOP 03-V 3.0/ANX 05-V 2.0)
iii. Return the protocol documents to the applicants, if the documents are incomplete, clearly stating the missing items.

3.4.2.1 The Secretariat will

i. Stamp, sign & date the receipt on the cover letter confirming receipt of the documents along with fee, wherever applicable.
ii. Assign study proposal number, stamp and sign with date on the last page of the Protocol Submission Forms (SOP 03-V 4/ANX 01-V 4, SOP 03-V 4/ANX 02-V 4, SOP 03-V 4/ANX 03-V 4, SOP 03-V 4/ANX 01-V 1.0), make a photocopy of the same and return a copy to the applicant for their records.
iii. Count for correct numbers of copies of protocol documents (03 hard copies and one soft copy (PDF version preferred) For drug trials a copy of the protocol may be given in a CD-ROM.
iv. The hard copies will be stored in locked cupboards in IHEC office and soft copy of IHEC submission form /study protocol accepted by email will be saved in the designated folder in the hard disk of the IHEC computer, and password protected.
vi. Record the date of receipt, number of copies and the name of the receiver in the study protocol submission form in the designated space.
vii. Maintain a database of proposals received in an Excel format
viii. File and store the received documents, which include original protocol file and

copies of the protocol to be distributed for review.

ix. All correspondence for the projects should quote the study proposal number, assigned by the IHEC, PSG IMS&R.

3.5 Detailed description of Study Protocol Submission

The study protocol submission involves submission of the following documents (three hard copies and soft copy thro' email) along with relevant supporting documents for scientific and ethical review. These are –

i. Duly filled in Study Protocol Submission Form (SOP 03-V 4/ANX 01-V 4, SOP 03-V 4/ANX 02-V 4, SOP 03-V 4/ANX 03-V 4, SOP 03-V 4/ANX 01-V 1.0). Incomplete forms and submissions without relevant documents will NOT be accepted by the IHEC; they will be returned to the PI without assigning study number.
ii. Proof of payment of fee for review, if applicable (see Para **3.12** on **Fee Structure**)
iii. Decision of other Ethics Committees (If applicable)
iv. Study Protocol
v. Essential Documents.
   a. Participant Information Sheet in English and Tamil and when necessary in other regional languages
   b. Informed Consent Forms (ICFs), (SOP 03-V 3.0/ANX 08-V 3.0) in English and Tamil and when necessary in other regional languages
   c. Assent Forms and Parent / LAR consent forms (if children / adolescents between >12 – 18 years of age are participants in the trial study) - in English and Tamil and when necessary in other regional languages (SOP 03-V 3.0/ANX 09-V 2.0, SOP 03 – V4/ANX 10 – V3.0
   d. Case Record Form
   e. Signed and dated current curriculum vitae of the investigators indicating qualifications and relevant experience.
   f. For exchange of biological material in international collaborative study an MoU / MTA between the collaborating partners, if applicable
   g. Health Ministry Screening Committee (HMSC) clearance, if applicable
   h. Any other information relevant to the study

vi. In addition the following documents are mandatory for pharma-sponsored clinical trials:
   a. Investigator's Brochure
   b. Agreement to comply with national and international ethical guidelines and GCP protocols
   c. Details of Funding agency / Sponsors and fund allocation
   d. Regulatory clearance for all types of studies from appropriate regulatory authorities i.e. DCGI approval, DGFT approval (for export of study samples), ICMR, DBT, other local government agencies (as applicable)
   e. Clinical Trial Agreement between the collaborators / between the sponsors, investigators and the head of the institution(s)
   f. Insurance policy for study participants indicating conditions of coverage, amount payable to the study participants, date of commencement and date of expiry of coverage of risk
   g. Indemnity insurance policy for study participants clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk

3.6 Re-submission of Protocols with corrections as per IHEC suggestions

- For re-submitted protocol, the PI will submit three hard copies and one soft copy of the amended Protocol along with summary of changes, modifications made with page number and related documents clearly highlighted / demarcated sections which have undergone amendment (two copies to the Primary Reviewers and the other for records purposes in the IHEC Secretariat).
- The IHEC Secretariat will verify the completeness (3.4.2)

3.7 Research Protocol Amendments and other study related documents

- The PI will submit three hard copies and one soft copy of the protocol amendments or any other study related documents to the IHEC Secretariat.
- The IHEC Secretariat will verify the completeness as per checklist for the contents of submitted package.
- The PI will highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF.

The review process is further elaborated in SOP 09 - V 3.2

3.8 Submission of SAE details

- The PI will submit three hard copies and one soft copy of SAE to the IHEC Secretariat.
- The review process is further elaborated in SOP 12-V 3.3

3.9 Submission of protocol deviation/ violations

- The PI will submit three hard copies and one soft copy of protocol deviation-Violations to the IHEC Secretariat.
- The review process is further elaborated in SOP 11-V 1.2

3.10 Continuing Reviews of Approved Protocols

i. The IHEC will send first reminder for continuing review two months prior to the scheduled review / expiry period (six months or one year from the start of the study based on the risk involved) as per the IHEC approval letter. If there is no response from the investigator subsequent reminders sent at 2 weeks interval.. If the investigator fails to respond to the final reminder, his/her future projects will be considered for IHEC review only on submission of the report.

ii. The IHEC will receive three hard copies and one soft copy of Annual Study Report / Continuing Review Report/ Progress report/Request for extension of approval of the project in the prescribed format (SOP 10- V 3.2 / ANX 01-V3.0) and related documents.

iii. The IHEC Secretariat will verify the completeness of these documents and record her/his signature with date.

iv. The review process is further elaborated in SOP 10-V 4.

3.11 Study Completion /Termination

i. The IHEC will receive three hard copies and one soft copy of Study Completion Report in the prescribed format (SOP 13-V 3.2 / ANX 01-V 3.0, SOP 13 – V3.2 / ANX 01-V 3.0).
ii. The IHEC Secretariat will verify the completeness of the Study Completion Report Form filled by the PI.
iii. The review process is further elaborated in SOP 013-V 3.2 / SOP 14-V 3.2.

3.12 Fee Structure

Fees for reviewing various categories of study proposals / documents in Indian Rupees (INR); non-refundable (see table below and its footnote):

Sl. No.	Category of review	Clinical Trial, sponsored (all institutions, including PSG institutions)	Non-PSG Institutions
1	New study protocol	Rs. 50,000/=	Nil
2	Continuing review (per review)	Rs. 10,000/=	Nil
3	Protocol Amendment (per amendment review)	Rs. 3,000/=	Nil
4	Providing photocopy of submitted study documents lost by the investigator*	Rs. 5,00/=	Nil

* Amount shown here is minimum applicable rate for currently live studies and / or studies which have not completed three years from the date of initial approval. One copy each of upto ten pages will be given free of charge for the minimum rate (Rs.50/=). Documents in excess of 10 pages will be charged extra at the rate of Re. 1/= per page. For closed studies and studies which have completed more than three years from the date of initial approval, add Rs. 50/= per year from the date of closure or date of expiry of three years from the date of initial approval.

******

SOP 03- V4/ANX 01- V 4.2
PSG Institute of Medical Sciences & Research, Peelamedu, Coimbatore 641 004, India
Phone: +91-0422-2570170 Extension No.: 5818 Fax: +91-422-2594400
Institutional Human Ethics Committee
E-mail: ihec@psgimsr.ac.in

Study Protocol Submission Form (Regulatory Trials)

(Three hard copies and one soft copy to be sent to the IHEC Secretariat)

1. IHEC PSG IMS&R Study Proposal No.	

2. Title of the Study:

3. Name, affiliation and qualifications of the research investigators

Sl. No.	Name of the Investigators (starting with PI)	Institutional ID No.	Department & Institution	Qualifications (with subject)	Role in the proposed study*	Signature
(i)						
(ii)						
(iii)						
(iv)						
(v)						
(vi)						

* Roles and responsibilities of investigators: choose the appropriate codes (A to T) below and write them against their name in the appropriate column above

A. Concept	K. SAE evaluation and reporting
B. Design	L. Examination of patients on follow-up
C. Screening of patients	M. Data collection and monitoring of data
D. Selection and recruitment of study participants	N. Interpretation of data
E. Informed consent	O. Statistical analysis & Interpretation
F. Selection & Recruitment of patients	P. Maintaining patients file and master file of project
G. Laboratory investigations	Q. Drafting final report
H. Laboratory report interpretation	R. Submission of final report to funding agency and IHEC
I. Treatment decision	S. Publication
J. Patient evaluation	T. Any other, please specify

4. Contact Information of the Principal Investigator (corresponding investigator)

4a. Mobile Number	
4b. Department Phone Extension Number	

5. Contact Address of Sponsor:					
6. Clinical Trials:					
Does the study involve use of :					
Drug	Devices	Vaccine	Alternate System of Medicine	Any Other (specify):	
i. Is it approved and marketed in:		India		Other countries (specify):	
7. Duration of study:					
8. Sampling Methods and Sample Size					
Sample size		Total		At our site	
Justify the sample size at our site					
9. Will the sample(s) collected from the patients be sent abroad?			Yes	No	
a. If Yes, justify with details of collaborators:					
b. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?			Yes	No	
10. Consent :					
10 (a) Consent :		Written		Audio-visual	
Consent form should include the following details:					
Understandable language (English & local)			Alternatives to participation		
Statement that study involves research			Confidentiality of records		
Sponsor of study, if applicable			Consent for future use of biological material, if applicable		
Purpose and procedures			Statement that consent is voluntary		
Risks & Discomforts			Right to withdraw		
Benefits			Contact information of PI and IHEC		
10 (b) Who will obtain the consent	PI / Co-PI	Research Staff	Nurse / Counselor	Other (Specify)	

11. Conflict of Interest		
(i) Do you have conflict of interest? (financial/nonfinancial) (ii) If Yes, specify :	Yes	No

12. Storage and archival of study documents
Specify the **period** and **site** of storage of study documents:

13. Permission to collect data from departments (attach permission letters in separate sheet). **Write below the names of departments and institutions from where samples are to be collected.** It is the responsibility of the PI to obtain permission from each and every department of PSG IMS&R involved in data collection (and heads of departments as well as institutions, if samples are collected and/or diagnostic or imaging services are used from the respective departments / institutions) by furnishing all necessary information (including purpose, sample size, cost involved, etc., to the heads of the departments concerned).

14. Checklist of documents to be submitted with the Study Protocol Submission Form

Item Description	Yes	No	NA
1. Covering Letter			
2. Brief description of proposal (Study Protocol)			
3. Informed Consent form (in English)			
4. Informed Consent form (in all relevant regional languages)			
5. Copy of questionnaire (in English)			
6. Copy of questionnaire, translated version (in all relevant regional languages)			
7. HMSC/DCGI/DBT/~~BARC~~ clearance if obtained			
8. Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from those departments of PSG IMS&R			
9. CV of ALL Investigators (including Guide)			
10. Investigator's brochure (IB) for recruiting Participants			
11. Copy of advertisements / recruitment documents, if any			
12. Copy of clinical trial protocol			
13. Fee for review			

14. Material Transfer Agreement (MTA)			
15. Clinical Trial Agreement (CTA)			
16. Insurance coverage certificate (for study participants)			
17. Indemnity insurance certificate (for the study team)			
18. CTRI Number			
19. Other (specify):			

15. Signature of PI

Undertaking:
I hereby agree to abide by the ethical principles set out in relevant Guidelines/Regulations/Institutional Policies.
I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Name:

Designation, Department & Name of the Institution:

Date: Signature of PI

15. Forwarded by the Head of PI's Department

Name of the Head of the Department:

Signature of the Head of the Department with date:

SOP 03-V 4 / ANX 02-V 4.2

PSG Institute of Medical Sciences & Research, Peelamedu, Coimbatore 641 004, India
Phone: +91-0422-2570170 Extension No.: 5818. Fax: +91-422-2594400
Institutional Human Ethics Committee
E-mail: ihec@psgimsr.ac.in

Study Protocol Submission Form (Other than Regulatory Trials)

(Three hard copies and one soft copy to be sent to the IHEC Secretariat)

1. IHEC PSG IMS&R Study Proposal No. (to be assigned by	

2. Title of the Study:

3. Name, affiliation and qualifications of the research investigators

Sl. No.	Name of the Investigators (starting with PI)	Institutional ID No.	Department & Institution	Qualifications (with subject)	Role in the proposed study*	Signature
(i)						
(ii)						
(iii)						
(iv)						
(v)						
(vi)						

* Roles and responsibilities of investigators: choose the appropriate codes (A to T) below and write them against their name in the appropriate column above.

A. Concept	K. SAE evaluation and reporting
B. Design	L. Examination of patients on follow-up
C. Screening of patients	M. Data collection and monitoring of data
D. Selection and recruitment of study participants	N. Interpretation of data
E. Informed consent	O. Statistical analysis & Interpretation
F. Selection & Recruitment of patients	P. Maintaining patients file and master file of project
G. Laboratory investigations	Q. Drafting final report
H. Laboratory report interpretation	R. Submission of final report to funding agency and IHEC
I. Treatment decision	S. Publication
J. Patient evaluation	T. Any other, please specify

4. Contact Information of the Principal Investigator (corresponding investigator)

4a. Mobile Number	
4b. Department Phone Extension Number	

5. Grouping:	S = Self funded	E = Extramural Funding (non-PSG IMS&R funded)	I = Intramural Funding (PSG IMS&R funded)

Tick (✓) all that are applicable

6. If funded, contact Address of Sponsor:

7. Clinical Trials: Yes / Not Applicable

If Yes does the study involve use of :

Drug	Devices	Vaccine	Alternate ystem of Medicine	Any Other (specify):	

ii. Is it approved and marketed in:	India	Other countries (specify):

8. Please <u>attach</u> the description of the proposal including following details: (Please attach a separate sheet)

- Introduction
- Review of literature
- Justification for study
- Aim(s) & objectives
- Study design
- Study population
- Sample size and its justification
- Inclusion / exclusion criteria
- Methodology (with flow-chart)
- Storage & disposal procedures of biological / hazardous material (if needed for your project)
- Potential risks & benefits
- Statistical analysis
- Itemized budget
- National significance with rationale
- References

9. Duration of study	

10. Consent :

10 (a) Written consent form should include the following details:

Understandable language (English & local)	Alternatives to participation
Statement that study involves research	Confidentiality of records
Sponsor of study, if applicable	Consent for future use of biological material, if applicable
Purpose and procedures	Statement that consent is voluntary
Risks & Discomforts	Right to withdraw
Benefits	Contact information of PI and IHEC

10(b) Who will obtain the consent?	PI / Co-PI	Research Staff	Nurse / Counselor	Other (Specify)

10 (c) If consent is not applicable to your research project / study, please submit a waiver of consent application form and confidentiality statement to IHEC

11. Conflict of Interest		
(i) Do you have conflict of interest? (financial/nonfinancial) (ii) If Yes, specify :	Yes	No

12. Storage and archival of study documents
Specify the **period** and **site** of storage of study documents:

13. Dissemination of study result	
Proposal plan for reporting and dissemination of study results (Tick [✓] all that are applicable)	Peer-reviewed scientific journals
	Conference presentation
	Internal report
	Submission to regulatory authorities
	Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators
	Other ……..

14. Permission to collect data from departments (attach permission letters in separate sheet).
Write below the names of departments and institutions from where samples are to be collected.
It is the responsibility of the PI to obtain permission from each and every department of PSG IMS&R involved in data collection (and heads of departments as well as institutions, if samples are collected and/or diagnostic or imaging services are used from the respective departments / institutions) by furnishing all necessary information (including purpose, sample size, cost involved, etc., to the heads of the departments concerned).

15. Permission to carry out the study elsewhere (outside PSG IMS&R): Yes / No

If study will be conducted fully or partially outside the PSG IMS&R, please describe the need, permission from institution(s), health centre(s), local government/administrative bodies, etc. Attach permission letters obtained already, if any.

16. Checklist of documents to be submitted with the Study Protocol Submission Form			
Item Description	**Yes**	**No**	**NA**
1. Covering Letter			
2. Brief description of proposal (Study Protocol)			
3. Informed Consent form (in English)			
4. Informed Consent form (in all relevant regional languages)			
5. Waiver of consent			
6. Confidentiality agreement signed by ALL investigators			
7. Copy of questionnaire (in English)			
8. Copy of questionnaire, translated version (in all relevant regional languages)			
9. Advertisements or recruitment documents, if any			
10. Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from those departments of PSG IMS&R			
11. CV of ALL Investigators (including Guide)			
12. Other (specify):			

17. Signature of PI

Undertaking:
I hereby agree to abide by the ethical principles set out in relevant Guidelines/Regulations/Institutional Policies.
I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Name:

Designation, Department & Name of the Institution:

Date: Signature of PI

18. Name and Signature of the Research Guide

I have reviewed this project proposal and consent to guide this project.

Name of the Guide:

Designation, Department & Name of the Institution:

Date: Signature of the Guide

19. Forwarded by the Head of PI's Department

I am forwarding the above project submitted by …… Principal Investigator from my Department. I endorse the project and have 'no objection' for submission for consideration by the IHEC, PSG IMS&R.

I concur with the participants / investigators included in the study.

The department has adequate facilities to carry out this study.

The investigators are permitted to use the facilities available in this department to carry out the study.

Name of the Head of the Department:

Signature of the Head of the Department with date:

SOP 03-V 4 / ANX 03-V 2.1

PSG Institute of Medical Sciences & Research, Peelamedu, Coimbatore 641 004, India
Phone: +91-0422-2570170 Extension No.: 5818 Fax: +91-422-2594400
Institutional Human Ethics Committee
E-mail: ihec@psgimsr.ac.in

IHEC Application form for Case Reports

(Three hard copies and one soft copy to be sent to the IHEC Secretariat)

1. IHEC PSG IMS&R proposal number (to be assigned by IHEC Secretariat)	
2. Title of the Case Report:	

I. Details of the Authors

Investigators / Co-Investigators Names	Qualifications with subject of specialization	Designation and Departmen	Institution	Institutional ID	Signature

II. Details of the Patient

a. Outpatient/Inpatient Number

b. Reason for submitting this case report (Please check a box)

☐ Reminder of important clinical lesson
☐ Findings that shed new light on the possible pathogenesis of a disease or an adverse effect
☐ Learning from errors
☐ Unusual presentation of more common disease/injury
☐ Rare disease
☐ New disease
☐ Novel diagnostic procedure
☐ Novel treatment (new drug/intervention; established drug/procedure in new situation)
☐ Unusual association of diseases/symptoms

☐ Unexpected outcome (positive or negative) including adverse drug reactions
☐ Public Health importance
☐ Others (specify)

c. Does the patient belong to the vulnerable group?

☐ Foetus/Neonates
☐ Children
☐ Pregnant woman
☐ Elderly
☐ Orphans
☐ Prisoners
☐ Decisionally impaired (Mentally challenged, comatose etc)

d. Are you planning to publish photograph(s) of the patient?
☐ Yes ☐ No

If yes, please attach a copy of the photograph(s)

e. Are you planning to publish laboratory data such as peripheral smears or biopsy pictures/X rays MRI/CT scan of the patient?
☐ Yes ☐ No

If yes, please attach a copy of the data

III. Briefly describe how the patient's confidentiality and privacy will be maintained? (Please tick)

☐ Name and identifiers (DOB, Address, Phone number) will not be revealed in case report
☐ Face or any other body parts will be camouflaged in photographs
☐ Personal Identifiers will be masked in all investigation reports and CT /MRI/X-ray/Biopsy Images

IV. Purpose of the case report (tick): Publication / Presentation in Conference

If for presentation in Conference, please provide:

a. Title of the Conference:

b. Date of Conference:

c. Oral/poster presentation:

d. Last date for submission of abstract:

Kindly enclose 3 hard copies and one soft copy the following documents to IHEC Secretariat:

a. Covering letter to the IHEC
b. Application form
c. Informed consent form which will be used to obtain consent from the patient (or consent waiver form and confidentiality agreement signed by all authors)
d. A brief write up of the case which you intend to publish with associated documents like photographs, reports etc.
e. CV of authors

Checklist of documents to be submitted with the Case Report Submission Form		
Item Description	**Yes**	**No**
a. Covering letter		
b. Application form		
c. Case Report		
d. Informed Consent (ICF)		
e. Consent waiver (If ICF not included)		
f. Confidentiality agreement signed by all authors (If ICF not included)		
g. CV of Authors		

Declaration by Principal Investigator

- I understand that the proposed activity will be assessed by the Institutional Human Eth Committee to determine whether the activity is classified as a Case report / Project
- I understand that I may be asked to complete another application should the case reports considered as a research project.
- I understand should any changes be made to the original activity as outlined above that I sho contact the IHEC for advice on whether or not a full research application would be subsequer required. I will also inform the IHEC of any changes in writing, so these may be reviewed.

Principal Investigator's Name	
Principal Investigator's Signature	
Forwarded by PI's Dept. Head	
Department:	
Name of the Head of Department	
Signature:	
Permitted by the Head of the Department involved in Patient Management	
Department:	
Name of the Head of Department	
Signature:	

SOP 03-V 4 / ANX 04-V 3.1

Statement of ongoing studies
(applicable to faculty non-pharma sponsored studies, postgraduate students, and undergraduate students/CRRIs)

(This is a template. You may wish to prepare this statement in landscape orientation)

IHEC requires a Principal Investigator/Co-Investigator to be involved in no more than 8 (eight) studies at a time. In order for us to determine whether the submission of current project is in accordance with the policy, we request you to kindly fill in the details of all your studies.

Name of the Principal Investigator:

Study details as on (Date):

(Please give below details for all studies you have done till date you are filling in this form)

Sl. No.	Study title (include all studies that you have conducted / initiated since five years ago)	IHEC Study No.	Date of Approval	Date of Initiation	Date on which study closure report / last progress report was submitted to IHEC
1					
2					
3					
4					
5					
6					
7					
8					

Signature of the Principal Investigator:

SOP 03-V 4 / ANX 05-V 2.1

Statement of ongoing studies

(applicable to Pharma-sponsored clinical trial-studies)

(This is a template. You may wish to prepare this statement in landscape orientation)

IHEC requires a Principal Investigator to be involved in no more than 8 (eight) Clinical Trials at a time. In order for us to determine whether the submission of current project is in accordance with the policy, we request you to kindly fill in the details of all your studies.

Name of the Principal Investigator:

Study details as on (Date):

(Please give below details for all studies you have done till date you are filling in this form)

Sl. No.	Study Name (Please fill in all studies you have done in the past 5 years till date you are filling in this form)	Volunteer Recruitment Statistics		Study Status		LPLV due on (if study still active)
		How many volunteers were you required to recruit at PSG IMSR site for the study?	How many have you recruited?	Site Closure Done Study Closed (No Last Patient Last Visit (LPLV) due) but site closure NOT done	Study Still Active (All studies with LPLV due are considered active)	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Signature of your Clinical Trial Coordinator:

Principal Investigator's Endorsement of Details:

SOP 03-V 4 / ANX 06-V 3.1

Guidelines for preparing ICD and Sample format of an Informed Consent Document

Guideline for preparation of the informed consent document	
While submitting your project proposal to the Institutional Human Ethics Committee, ensure that you have included an informed consent form that is prepared as per the guidelines for ICH – GCP, ICMR ethical guidelines 2018, and the Declaration of Helsinki (2013 or later versions as applicable), National Guidelines for Biomedical and Health Research Involving Human Participants (2017), New Drugs and Clinical Trials Rule 2019 and other relevant regulations and guidelines. The consent document must necessarily include the following points listed below. Any further information you wish to add, is your choice.	
The following are instructions for devising Informed Consent Document:	
-	Informed consent forms in English and Tamil and other relevant understandable regional languages, if need be
-	All the consent documents must have Version No, Date, Page no in the footer
-	Separate forms should be prepared when minors (children) and other vulnerable groups are study participants; assent form for the minors (teenagers) and other vulnerable groups and consent document for the parents/LAR, different study groups.
The consent document must necessarily include the points listed in SOP 03- V4/ANX 08 – V 3.0 and any further information you wish to add.	

SOP 03-V 4 / ANX 07-V 3.1

Template for devising an "Informed Consent Document"
(Include or exclude information, as applicable)

Informed Consent Document

[The title of the project here exactly as it is in the project design with names of Principal Investigator and all other investigators.]

Introduction:

You are invited to participate in a Research. This document gives you a description of the study/trial in which you are being asked to participate. Your participation in this study is voluntary, and you can enquire about all details before giving your written consent to participate in the study.

Purpose:

The purpose of this study is to:

Information:

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, non-technical & direct language.

Graphics could be used if helpful in making the text meaningful to the research subject.

If this is a randomized trial, details of both arms of the trial must be explained in writing to the participant being enrolled.

State the amount of time required of the participant per session, for the total duration of study and the expected duration of the study.

If applicable to your study, list:

i. The number of participants who will be participating in the research.
ii. Information concerning audio-taping or filming.
iii. If tissues or biological samples are being retained for research, describe what will be done to the tissues in simple lay person's terms.

Alternative treatments:

Disclose appropriate alternative treatments available, if any.

Risks:

List the foreseeable risks, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks, or treat them should they occur. Explanation of anticipated side effects, and even rare side effects, or known idiosyncratic reactions.

Costs:

Describe the cost for participating in the study to the participant. The information must be written in clear terms regarding the cost which will be borne by sponsors/Principal Investigator/s of the project, and study participant.

Reimbursement for Participation:

Describe plan to reimburse or compensate participant for the inconvenience, time spent and for expenses incurred. If yes, the amount of payment proposed. Discuss travel details for study participants and / or attendant who need to come for follow-up, and spell out methodology for the reimbursement for travel and incidental expenses.

Emergency Medical Treatment:
(If applicable, add here)

If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge (list PI name and phone number).

Describe available medical treatment in case of complications.

Benefits:

List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

Also mention that the many of the most effective treatments used today are the result of clinical trials done in the past.

Confidentiality:

The information in the study records will be kept confidential and the clinical charts will be housed in the PSG IMS&R. Data will be stored securely and will be made available only to persons conducting the study and to the regulatory authorities. The data will not be made available to another individual unless you specifically give permission in writing. No reference will be made in oral or written reports which could link you to the study. Result of the project will be communicated to the participants if they are interested to know. The participants and the community have a right to know the outcome of the research.

Compensation for protocol Related Injury:

Describe the details of compensation or insurance for protocol related injury to the study participant. Explain who will bear the cost in case of trial related injury?

Ancillary Care:

Ancillary care refers to providing investigation and treatment for conditions that occur during the course of trial that are unrelated to the original condition/study for which the study participant was enrolled.

Contact:

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], and [Office Phone Number]. If you have questions about your rights as a participant, contact the Member-Secretary, IHEC [Name], at [Office Address], and [Office Phone Number].

Participation:

Your participation in this study is voluntary; you may decline to participate at anytime without penalty and without loss of benefits to which you are otherwise entitled.

If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician

If you withdraw from the study before data collection is completed, your data will not be entered in the project report if that will not affect the outcome. Your legal rights will not be affected by signing this document.

Informed Consent Document

I have been explained, and have read and understood the above information and voluntarily agree to participate in this study. I have received a copy of this form.

Participant's name (print):	
Participant's signature / thumb impression:	
Address (capital letters):	
Phone Nos.:	
Legally Acceptable Representative (LAR) name:	
Legal Representative signature & date:	
Witness's name (Print):	
Witness's signature & date:	
Name of PI or the person administering the consent (Print):	
PI or person's Signature & date:	

Note to Investigators Regarding the Process of Administering Informed Consent

(The templates for Participant Information Sheet have been provided herewith):

The prospective participant should be given Participant Information Sheet first.

The participant should then be encouraged to read the Information Sheet and think over, preferably for a period of 24 hours. Following which, the person responsible for administering the Informed Consent should explain the procedures in simple language understandable by the participant. The participant may also be given a questionnaire to ensure that he/she has understood the procedures and their involvement in the study. The informed consent form should be signed by the participant only after ensuring that the participant is now prepared for informed decision making.

The PIs are urged by the IHEC to download and use the wording in the glossary available on the PSG IMS&R website and follow the sample format of Informed Consent Form, unless the PI support reasons for alternative wording.

Use of alternative wording or different format may slow down the review process. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

The Informed Consent Form must have the name and Telephone No. of the Principal Investigator or of any other co-investigator, as the participant must know whom to contact in case of an emergency, or even to seek answers to their queries.

The consent form must be dated.

If the prospective participant so desires, a Xerox copy of the Informed Consent Form must be given to him/her.

Copies of the consent form must be available in English and Tamil and in any other language, if needed.

Please tailor your ICD to suit the needs of our local population, and if this is a multinational Pharma based project, an additional ICD specifically designed for our participants may be used.

Separate forms for each group in a controlled study should be prepared when minors are used; one for the mature minors (teenagers) and other vulnerable groups and one for the parents or guardians (LAR). Please make provision for the assent of the child to the extent of the child's capabilities such as in the case of minors and adolescents. Please make provision on the form for signatures/thumb impression of the participant/parent or legal guardian, if minor and of the investigator, or person administrating the consent form, and of a witness.

If your form is more than one page, there should be a line at the bottom of each page for the participant's initials, except for the last page where the signature is obtained.

Be sure to include any elements of informed consent that are appropriate to your study.

If informed consent form requires more than one page, print the informed consent form front to back.

SOP 03-V 4 / ANX 08-V 2.2

Institutional Human Ethics Committee
PSG Institute of Medical Sciences and Research, Coimbatore

Assent to be in a Research Study
For children between >12-18 years old

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something related to health and disease. Dr. ……. and some other doctors are doing a study to learn more about……. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

We want to find out ……
So we are getting information from lots of boys and girls like you.
In the whole study, there will be about …… children.

What will happen to you if you are in this study?

Only if you agree, two things will happen:

1. A small amount of your blood will be drawn. That means it will be taken by a needle in your arm. This will happen……..times.

   *[If some or all of blood draws would be done anyway as part of child's clinical care, emphasize here what will be done **extra** for the study.]*

2. The doctors will do some tests on…….
3. You will need to answer some questions about ……..

Will this study hurt?

The stick from the needle to draw your blood will hurt, but the hurt will go away after awhile.

Will you get better if you are in this study?
No, this study won't make you feel better or get well. But the doctors might find out something that will help other children like you later.

Will everybody come to know about my condition? (Confidentiality)
We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study

Is this bad or dangerous for me? (Risks involved)

Reimbursement or compensation for the inconvenience: Yes/No

If yes describe the plan

Emergency Medical Treatment: If applicable, add here along with available medical treatment in case of complications.

Compensation for protocol Related Injury: Yes /No

If yes describe the details of compensation or insurance for protocol related injury to the study participant. Explain who will bear the cost in case of trial related injury?

Do I get anything for being in the research?
[Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating]

Will you tell me the results?
[Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.]

Do you have any questions?
You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?
No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you. *This will not affect in any way your future treatment in this hospital.*

Who can I talk to or ask questions to?
List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

The doctor will give you a copy of this form to keep.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION
I have explained the study to _____(*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

_____ _____
Signature of Person Conducting Assent Discussion Date

_____
Name of Person Conducting Assent Discussion (*print*)

Part 2: Certificate of Assent

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

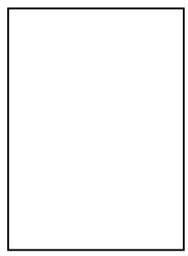
I do not wish to take part in the research and I have <u>not</u> signed the assent below._____ (initialed by child/minor)

<u>Only if child assents:</u>
Print name of child _____
Signature of child: _____
Date:_____
day/month/year

If illiterate:
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

*Print name of witness (not a parent)*_____ *AND Thumb print of participant*
Signature of witness _____
Date _____
Day/month/year



I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

**Modified from the Informed Assent form template for children/minors –World Health organization*

SOP 03-V 4 / ANX 09-V 3.2

Institutional Human Ethics Committee
PSG Institute of Medical Sciences and Research, Coimbatore

Parental / LAR Consent Form

Title of Study:

Name of the Principal Investigator:

Department:

Your (son/daughter/child/infant/adolescent youth) is invited to participate in a study of (describe the study).

My name is _____and I am a _____ at PSG Institute of Medical Sciences and Research, Coimbatore. This study is (state how study relates to your program of work or your supervisor's program of work).

I am asking for permission to include your (son/daughter/child/infant/adolescent youth) in this study because

I expect to have …… (Number) participants in the study.

If you allow your child to participate, (state who will actually conduct the research) will (describe the procedures to be followed) ……..……

Any information that is obtained in connection with this study and that can be identified with your (son/daughter/child/infant/adolescent youth) will remain confidential and will be disclosed only with your permission. His or her responses will not be linked to his or her name or your name in any written or verbal report of this research project.

Reimbursement or compensation for the inconvenience: Yes/No

If yes describe the plan

Emergency Medical Treatment: If applicable, add here along with available medical treatment in case of complications.

Compensation for protocol Related Injury: Yes /No

If yes describe the details of compensation or insurance for protocol related injury to the study participant. Explain who will bear the cost in case of trial related injury?

Your decision to allow your (son/daughter/child/infant/adolescent youth) to participate will not affect your or his or her present or future relationship with PSGIMS&R or PSG Hospitals or (include the name of any other institution connected with this project). If you have any questions about the study, please ask me. If you have any questions later, call me at …… If you have any questions or concerns about your (son/daughter/child/infant/adolescent youth)'s participation in this study, call……..

You may keep a copy of this consent form.

You are making a decision about allowing your (son/daughter/child/infant/adolescent youth) to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow him or her to participate in the study. If you later decide that you wish to withdraw your permission for your (son/daughter/child/infant/adolescent youth) to participate in the study, simply tell me.

You may discontinue his or her participation at any time. *This will not affect in any way your future treatment in this hospital.*

Printed Name of (son/daughter/child/infant/adolescent youth)

Kindly check the box whichever is applicable to you:

☐ My child is in the age group of >7 to 12 years and the researcher has obtained verbal consent from my child in my presence

☐ My child is in the age group of >12 to 18 years and the researcher has obtained written consent from my child in my presence

Signature of Parent(s) or Legal Guardian with Date Signature of Investigator with Date

SOP 03-V 4 / ANX 10 -V 1.1

PSG Institute of Medical Science and Research, Coimbatore

Institutional Human Ethics Committee

INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

(strike off items that are not applicable)

I / We (write name of the investigator(s) here), _____, am / are carrying out a study on the topic:

as part of my / our research project being carried out under the aegis of the Department of:

(*Applicable to students only*): My / our research guide is:

The justification for this study is:

Introduction:

Purpose :

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview (specify approximate duration):_____ minutes.

Data collected will be stored for a period of _____ years. We will / will not use the data as part of another study.

Health education sessions: Number of sessions: _____. Approximate **duration** of each session: ___ minutes.

Clinical examination (Specify details and purpose):

Blood sample collection: Specify quantity of blood being drawn: _____ml.

No. of times it will be collected: _____.

Whether blood sample collection is part of routine procedure or for research (study) purpose:

1. Routine procedure 2. Research purpose

Specify **purpose**, discomfort likely to be felt and side effects, if any: _____

Whether blood sample collected will be stored after study period: Yes / No, it will be destroyed

Whether blood sample collected will be sold: Yes / No

Whether blood sample collected will be shared with persons from another institution: Yes / No

Medication given, if any, duration, side effects, purpose, benefits:

Whether medication given is part of routine procedure: Yes / No (If not, state reasons for giving this medication)

Whether alternatives are available for medication given: Yes / No (If not, state reasons for giving this particular medication)

Final interview (specify approximate duration):_____ mts. If **photograph** is taken, purpose:

Benefits from this study:

Risks involved by participating in this study:

Reimbursement or compensation for the inconvenience: Yes/No

If yes describe the plan

Emergency Medical Treatment: If applicable, add here along with available medical treatment in case of complications.

Compensation for protocol Related Injury: Yes /No

If yes describe the details of compensation or insurance for protocol related injury to the study participant. Explain who will bear the cost in case of trial related injury?

How the **results** will be used:

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, **you have the right to withdraw from the interview / study at anytime.** You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will **NOT** be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings - including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date: Witness:

Contact number of PI:

Contact number of Ethics Committee Office: 0422 4345818

SOP 03-V 4 / ANX 11 -V 1.0

COVERING LETTER

From

_____

_____

_____

_____

_____

To
Member-Secretary
Institutional Human Ethics Committee
PSG Institute of Medical Sciences & Research
Coimbatore

Madam,

Sub: Ethical review of study proposal by IHEC – request for – reg.

I hereby request you to kindly place the enclosed application-cum-study proposal for ethical review before the IHEC of PSG IMS & R.

Title of the proposed study:

Name of the Principal Investigator:

Name(s) of Co-Investigator(s):

Thanking you,

_____ Date:_____
Principal Investigator

SOP 03-V 4 / ANX 12 -V 1.0

Guidelines for AV consenting

1. AV recording of the entire informed consent process is mandatory for all clinical trials.
2. AV recording for any re-consenting procedure that may follow must be done.
3. If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally acceptable representative (LAR) and the process recorded.
4. If the participant/LAR is illiterate then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.
5. AV recording should be done wherever applicable.
6. Ensure the following infrastructure is available prior to counseling of potential participant:
    a. The informed consent process should be carried out in the designated area (unless patient is on a bed) when the following conditions should be met, that is
        i. Free from disturbance
        ii. Well lit
        iii. Ensures privacy for the participant
        iv. Participant should be comfortable
    b. Camera having video facility with
        ✓ Good resolution
        ✓ Sufficient memory and battery back up
    c. Mike system
    d. Computer with CD/DVD writer
    e. External Hard disk to store the data
7. Before starting the informed consent process and the AV recording of the same Participant should be made comfortable first before starting the informed consent process.
    a. Consent for AV recording should be taken from the participant/LAR.
    b. Ensure that all the necessary equipments mentioned above are functional.
    c. The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that she/he has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and her/his rights for the purpose of documentation and the confidentiality of the same is assured.
    d. The potential participant/LAR/ impartial witness should be made aware that her/his recording may be shown to government agencies or members from the IEC.

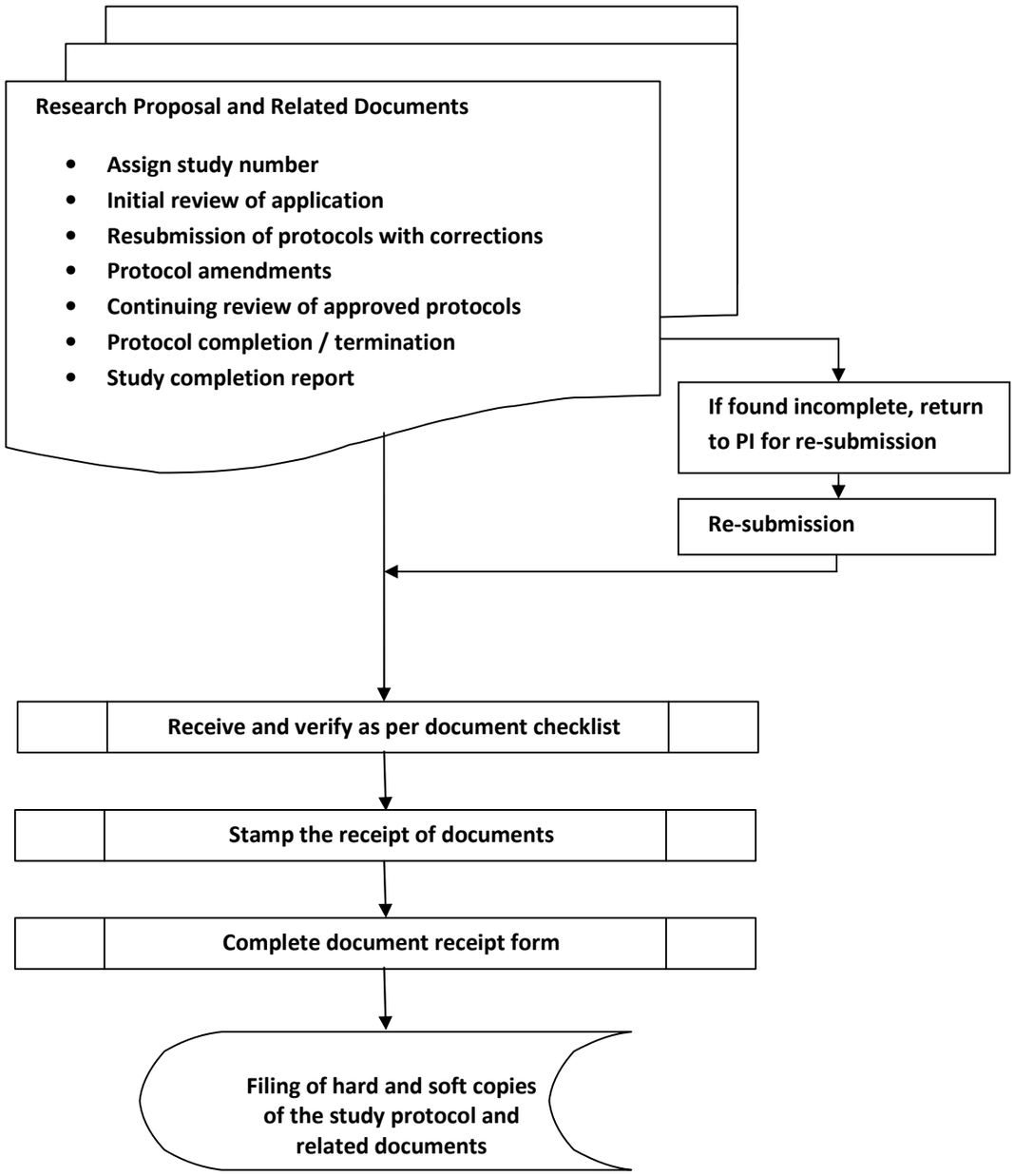
8. Actual AV recording process
    - The PI/Co-I and the participant/LAR should sit comfortably in such a way that their faces will be captured in the frame
    - The PI/Co-I should introduce herself/himself by name, designation and her/ his role in the research, and state the current date and time. Mention the title of the protocol and screening number of the participant.
    - Participant/LAR should be requested to introduce her/his name, age and address and in case of LAR, she/he should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language she/he understands best and is literate in. The PI/Co-I to ensure all above points are captured in the recording.
    - In case participant/LAR is illiterate then an impartial witness is needed, the impartial witness should be requested to introduce herself /himself, give her/his address and state the language that she/he is literate in.
    - The participant should be allowed to read the consent document

- The PI/Co-I should explain **all** the elements of the approved ICD in the language best understood by the potential participant
- Explanation or narration given by the PI/Co-I, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible and recorded.
- At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the time of stopping. When she/he returns, the recording from the point where it was stopped before shall be resumed as mentioned before stating clearly again the date and time of recording.
- If the participant/ LAR agrees to participate in the trial, she/he should be asked questions to assess her/his understanding of the informed consent process.
- The participant/LAR should be invited to sign or attest left hand thumb impression the consent form only after satisfactory answers have been given by the participant/ LAR to all the above mentioned questions.
- Participant/LAR should read out all the statements mentioned in ICF and state whether she/he agrees or not for each statement and affix signature/thumb print at the end
- The actual signing process or attesting left hand thumb impression should be recorded.
- The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.
- The PI/Co-I will also sign and date the consent form at the end of the process.
- The recording will be stopped after thanking the participant.

9. The recording should be checked the by PI/Co-I for completeness and clarity of both audio and video recording using a dedicated laptop / computer in which the original recording will be stored.
10. No editing should be done on the recording so as to maintain authenticity.
11. The laptop/ computer should be password protected. The password will be known only to the PI and members of the study team as designated by the PI.
12. The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings and archived in an external hard drive. The hard drive will remain with the PI which could be accessed by the study team members on request for transferring and storage The CD should be filed in the participant binder.

13. Archival
    a. One CD per participant will be archived with appropriate labeling in participant binder.
    b. The soft copies of the recordings will also be stored in a password protected hard drive.
    c. The original recording in the laptop will be deleted when study is closed out.

Flowchart: Management of Protocol Submission (SOP 03)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Submitted Protocol: Risk Based Categorization of Submitted Protocols	**SOP 04**
SOP Number: SOP 04 -V 3.1	**Effective Date: 01.01.21**	

The IHEC should review every research proposal on human participants and must approve the proposal before the research is initiated. The committee should evaluate the possible risks to the participants with proper justification, the expected benefits to participants/community and adequacy of documentation for ensuring privacy & confidentiality.

4.1 Purpose

The purpose of this SOP is to describe the procedure to categorize the submitted protocols to be eligible for exempt, expedited or full board review on risk basis.

4.2 Scope

This SOP applies to the administrative process concerning categorization of submitted protocols.

4.3 Responsibility

The Member-Secretary, IHEC, depending on the risk involved in the research proposals categorize them to be eligible for one of the three types of reviews (Exemption from review, Expedited review or Full Board review). The categorization will be done by the Member-Secretary and not the Investigator.

4.4 Categorization of Protocols

All proposals are categorized based on risk categorization (Table - Page No. 92, ICMR Guidelines 2017)

4.5.1 Exempt Review

The exemption from review may be considered under the following situations having less than minimal risk where there are no linked identifiers:

i. Research 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, educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods and consumer acceptance studies related to taste and food quality; and public health programmes by Govt agencies such as programme evaluation

Exceptions :

a. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm

b. When interviews involve direct approach or access to private papers

- The research proposals which do not involve human participants or data derived from them are exempt from ethics review. For example,
- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided such research reveals no identifying personal data

4.5.2 Expedited Review

An expedited review may be conducted, only if the protocols involve no more than minimal risk to the participants:

a. Revised proposal with minor modifications previously approved through full review by the IHEC.
b. Continuing review of approved proposals where there is no deviation from the original protocol approved by the IHEC
c. Anonymous surveys and retrospective study of medical records
d. Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers
e. Proposals involving previously banked biological materials and/or tissues without any identifiers
f. Research during emergencies and disasters
g. Research activities that involve only procedures listed in one or more of the following categories:

Clinical studies of drugs and medical devices only when –

i. Research is on already approved drugs except when,
   a. Study of drug interaction
   b. Conducting trial on vulnerable population
      OR
   c. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported
ii. Other documents which would be considered for expedited review are as follows but may not restrict to:
   a. Minor deviations from originally approved research during the period of approval (usually of one year duration) causing no risk or minimal risk;
   b. Change in the name, address of sponsor
   c. Change in contact details of PI and Member- Secretary, IHEC
   d. Request for change in PI, Co-I, change in any member involved in the research
   e. Minor amendments in the protocol, CRF
   f. Minor corrections in budget
   g. Other administrative changes in the IB, ICF.

4.5.3 Full Board Review

All research presenting with more than minimal risk, research protocols which do not qualify for exemption or expedited review and projects that involve vulnerable population (even if the risk is minimal) and special groups should be subjected to full board review by all the members.

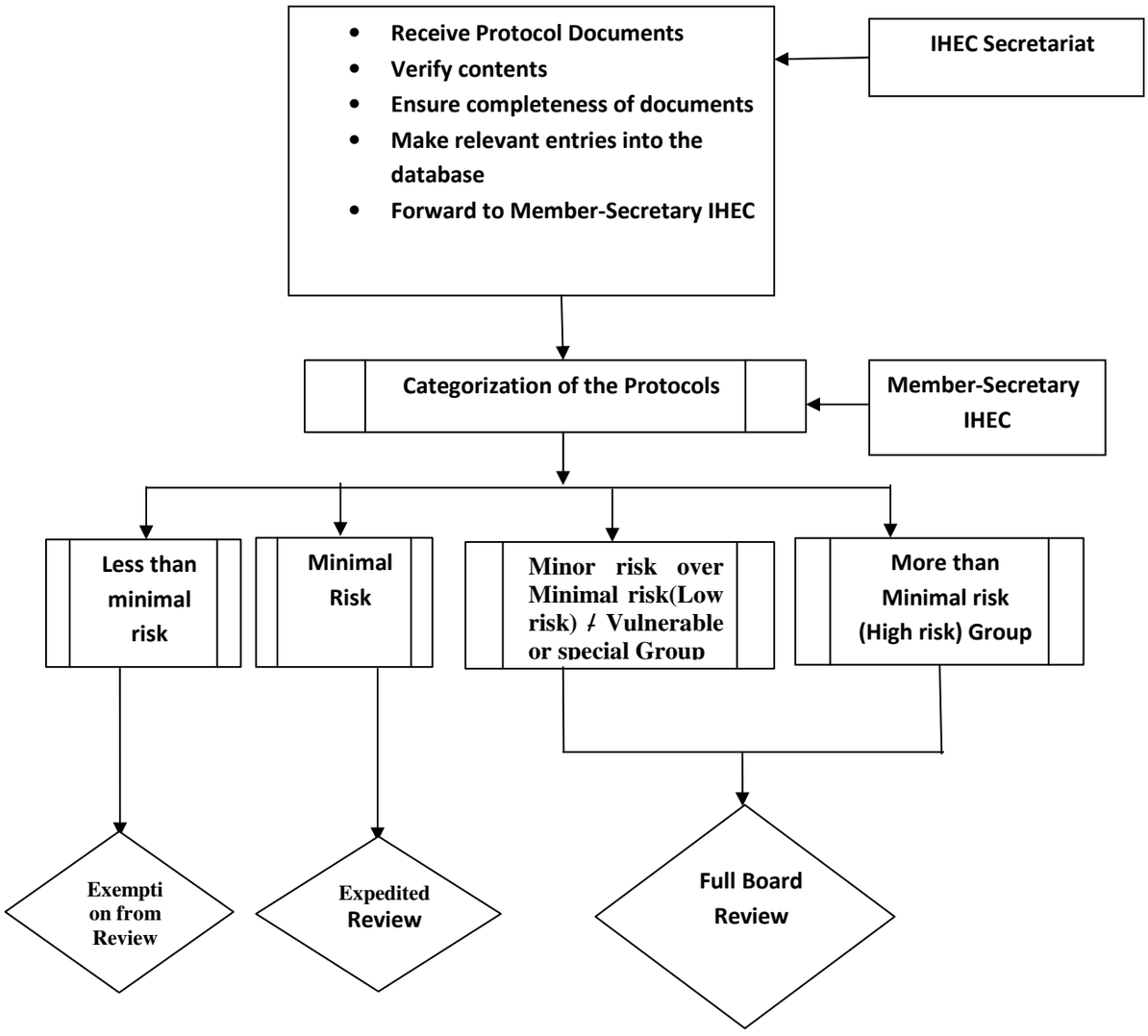
- research with minor increase over minimal risk
- studies involving deception of participants
- research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify 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

******

Categories of Risk

Types 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 situation such as routine research on children and adolescents; research on person 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.

Flowchart: Categorization of Protocols (SOP 04)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Exemption from Ethical Review	**SOP 05**
SOP Number: SOP 05-V 3.0	**Effective Date: 01.01.21**	

5.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe process of reviewing the projects categorized under exemption from review. This SOP is designed to standardize the process of exemption.

5.2 Scope

This SOP applies to the all protocols categorized as exemption from review. The final decision should be taken by the Member-Secretary in consultation with the Chairperson or during the Expedited review and should be informed to the members in the forthcoming IHEC full board meeting.

5.3 Responsibility

It is the responsibility of the Member-Secretary to record the decision in the Exemption from Review Form with reasons. (SOP 05-V 3.0 / ANX 01-V 1.0) The decision on approval will be given by the Member-Secretary. The Member-Secretary must sign and date the letter conveying the decision. The IHEC Secretariat is responsible for recording and filing the decision and communicating to the PI.

5.4 Exemption from review

Proposals which involve less than minimal risk fall under this category. Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of healthy individuals 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.

The exemption from review may be seen in following situations:

i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Exceptions:

a. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm
b. When interviews involve direct approach or access to private papers

c. When research is done in vulnerable population

ii. The research proposals which do not involve human participants or data derived from them are exempt from ethics review. For example,
   a. Audits of educational practices, quality control and quality assurance audits in the institution
   b. Research on microbes cultured in the laboratory
   c. Research on immortalized cell lines
   d. Research on cadavers or death certificates provided such research reveals no identifying personal data
   e. Analysis of data freely available in public domain
   f. consumer acceptance studies related to taste and food quality; and
   g. 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)

5.5. Exemption from review will not be considered if the research involves more than minimal risk such as:

i. Invasive physical procedures or potential for physical harm
ii. Procedures which might cause mental/emotional stress or distress, moral or cultural offence
iii. Personal or sensitive issues
iv. Vulnerable groups
v. Cross cultural research
vi. Investigation of illegal behavior(s)
vii. Invasion of privacy
viii. Collection of information that might be disadvantageous to the participant
ix. Use of information already collected that is not in the public arena which might be disadvantageous to the participant
x. Use of information already collected under agreement of confidentiality
xi. Participants who are unable to give informed consent
xii. Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
xiii. Deception
xiv. Audio or visual recording without consent
xv. Withholding benefits from “control” groups
xvi. Inducements
xvii. Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered on a case by case basis. Low risk research would involve the same risk as might be encountered in normal daily life.

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IHEC. This might be because of requirements of:

The publisher of the research

i. An organization which is providing funding resources, existing data and access to participants

5.6 Exemption Process:

5.6.1 Action by the Secretariat, IHEC

- Receive the application documents submitted by investigators as per the check list
- Complete the Database
- Acknowledge the submitted documents
- Hand over the received documents to the Member-Secretary, IHEC

5.6.2 Categorization of Protocols

Study protocols which are categorized under exemption from ethical review will be reviewed as per SOP 04 -V 3.1

5.6.3 Review Process

i. If the protocol and related documents satisfy the criteria as listed in 5.4, the Member-Secretary will fill the Exemption Form.
ii. The final decision will be taken by the Member-Secretary in consultation with the Chairperson.
iii. The Secretariat communicates the decision to the investigator.
iv. The Member-Secretary informs the IHEC members about the decision at the next full board meeting.
v. In case the protocol does not fit in any of the above stated criteria, the Member-Secretary / Chairperson may keep the application for review and discussion as expedited or full board.

5.7 Communication between the IHEC and the investigator

- The decision regarding Exemption from review will be signed by the Member-Secretary, IHEC and forwarded by the Secretariat to the PI within 7 days after the decision regarding the exemption.
- The Member-Secretary will inform the IHEC members of the decision at the forthcoming regular meeting and the same will be documented in the meeting minutes.

******

SOP 05 -V 3.0 / ANX 01-V 1.1

Exemption from Review Form

(To be filled in by the Member-Secretary IHEC)

PSG IMS&R IHEC Proposal No. :

1 Principal Investigator's Name:

2 Department:

3 Title of Project:

4. State reasons for exemption from ethics review

- ☐ Audits of educational practices
- ☐ Research on microbes cultured in the laboratory
- ☐ Research on immortalized cell lines
- ☐ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ☐ Analysis of data freely available in public domain
- ☐ Any other

This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the following:

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IHEC. This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources

Signature of the Member-Secretary: _____

Date

Final Decision:

☐ Exemption

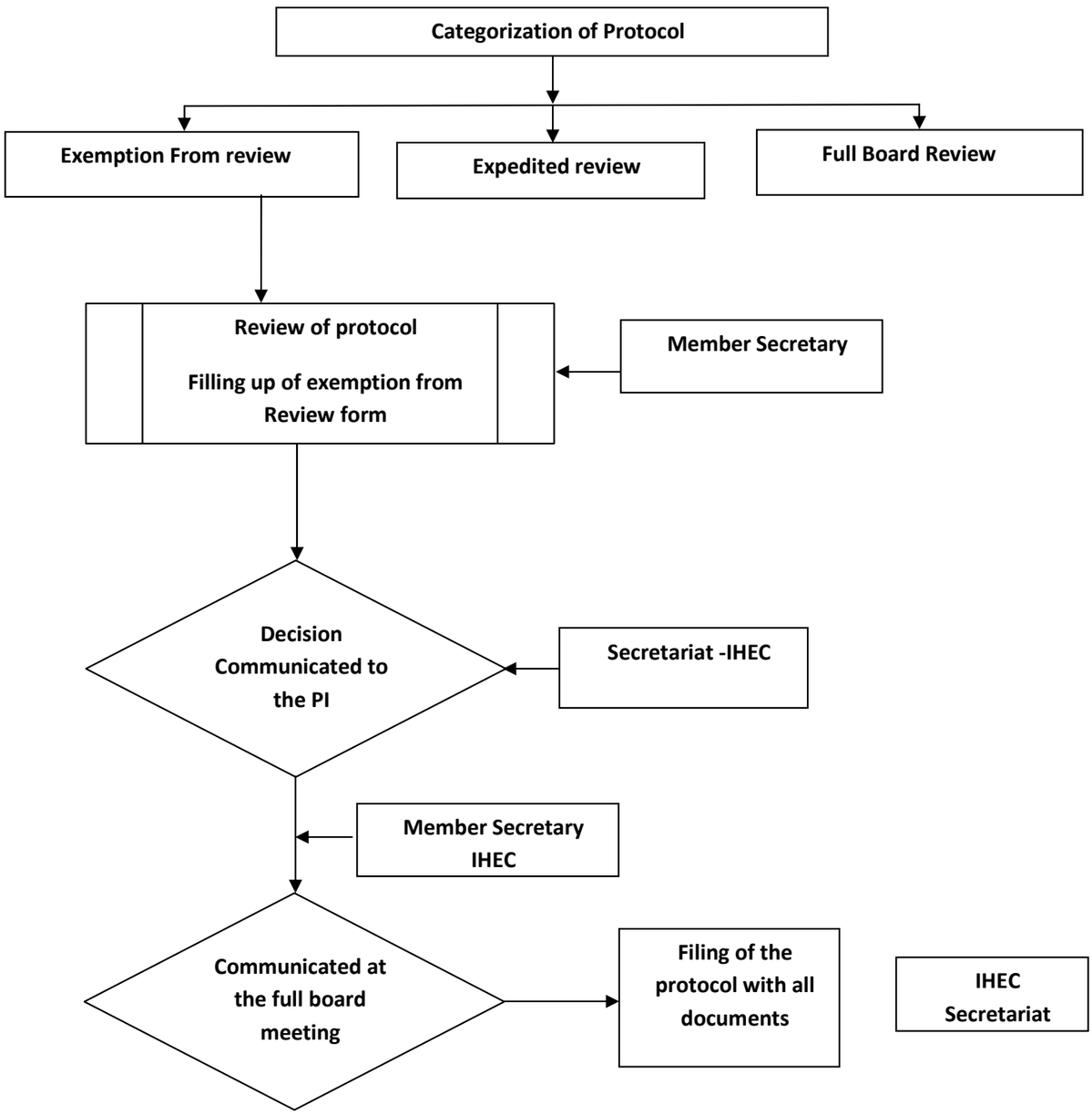
☐ Cannot be exempted

Reasons:

Signature of the Member-Secretary with date:

Flowchart

Exemption from Review (SOP 05)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Expedited Review	**SOP 06**
SOP Number: SOP 06 –V 3.0	**Effective Date: 01.01.21**	

6.1 Purpose

The purpose of this SOP is to describe the expedited review process.

6.2 Scope

This SOP applies to the review and approval of research protocols and documents with not more than minimal risk to participants which has been categorized as expedited review.

6.3 Responsibility

It is the responsibility of the Member-Secretary to identify (as per section **4.5.2**) which research protocols or documents should be reviewed through expedited process.

6.4 Expedited Review

The proposals involving no more than minimal risk to research participants may be subjected to expedited Review:

i. Revised proposal with minor modifications previously approved through full review by the IHEC.
ii. Continuing review of approved proposals in the expedited review where there is no deviation from the original protocol approved by the IHEC
iii. Anonymous surveys and retrospective study of medical records
iv. Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers
v. Proposals involving previously banked biological materials and/or tissues without any identifiers
vi. Research during emergencies and disaster

6.4.1 An expedited review may be conducted, only if the protocols involve –

6.4.1.1 Research activities that involve only procedures listed in one or more of the following categories:

a. Clinical studies of already approved drugs and medical devices which do not involve study of drug interaction or conducting trial on vulnerable population

OR

a. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported
b. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes

6.4.1.2 Other documents which would be considered for expedited review are as follows but may not be restricted to:

a. Minor deviations from originally approved research during the period of approval (usually of one year duration)
b. Change in the name, address of sponsor
c. Change in contact details of PI and Member-Secretary, IHEC
d. Change in PI or hand over of trials or projects
e. Inclusion or deletion of name/s of co-investigator/s
f. Request for change in PI , Co-I, change in any member involved in the research
g. Minor amendments in the protocol, CRF
h. Minor corrections in budget
i. Other administrative changes in the IB, ICF, etc.

6.5 Expedited Process

6.5.1 Action at the IHEC secretariat:

i. Receive the application documents submitted by investigators as per the check list
ii. Ensure the completeness of the documents
iii. Make relevant entries into the database
iv. Acknowledge the submitted documents
v. Hand over the received documents to the Member-Secretary, IHEC

6.6 Categorization of the protocols

Study protocols which are categorized under expedited review will be reviewed as per SOP 04 -V 3.1

6.7 Review Process

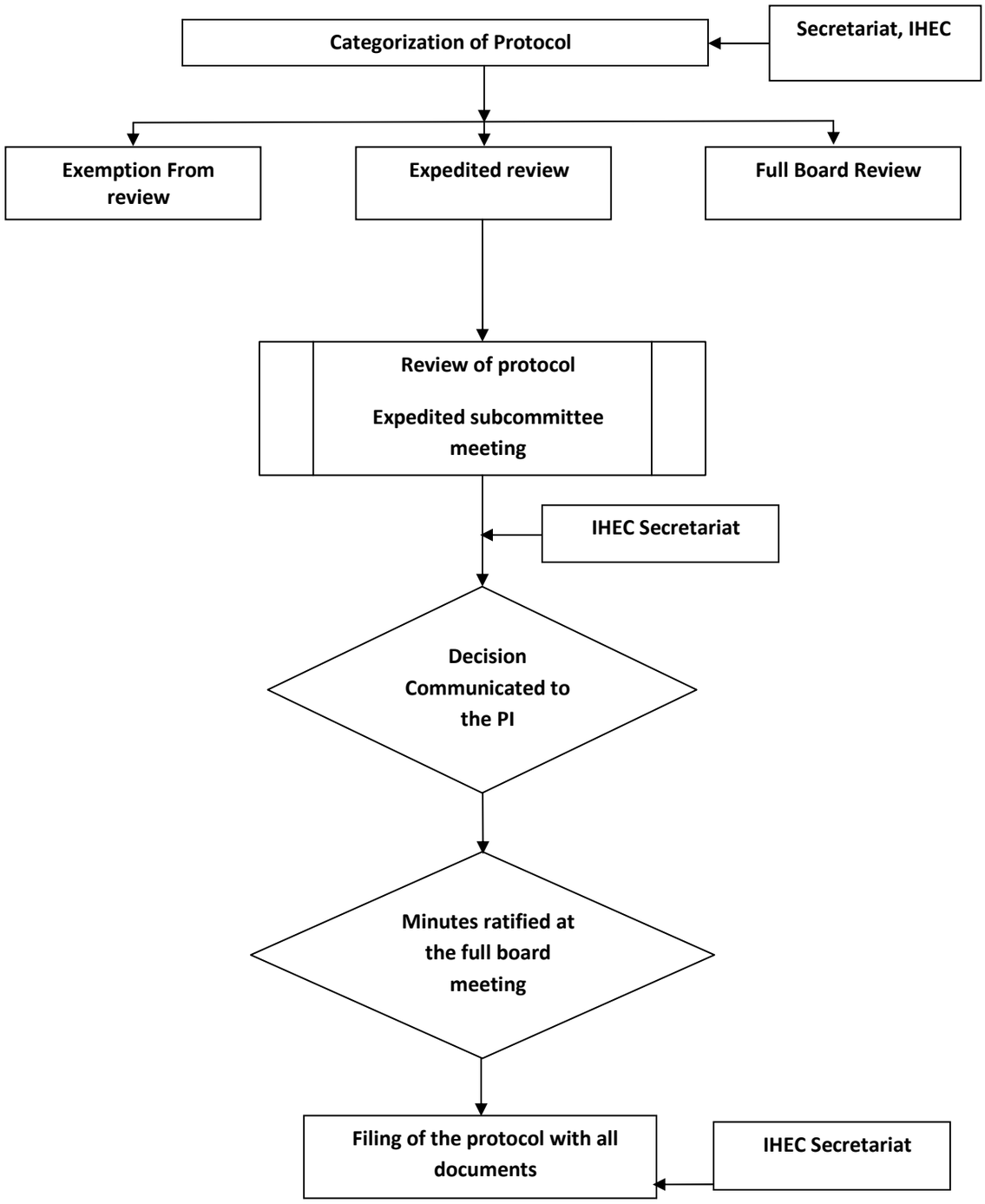
vi. Suitable IHEC member will be allotted as Primary reviewer by the Member Secretary.
vii. The Comments from the Primary reviewer will be received by IHEC secretariat.
viii. The subcommittee comprising of Chairperson, Member-Secretary and two to three identified members of the IHEC will review the documents which qualify for expedited review
ix. Review is done by the subcommittee meeting and decision regarding the protocol is taken. If a consensus is not reached during the expedited review subcommittee meeting, the proposal would be reviewed in the next full board meeting.
x. The expedited review should not take longer than 2 weeks, from the date of receipt of the research protocol.
xi. The minutes of the expedited review subcommittee meeting will be ratified in the next regular full board meeting.

6.8 Communication between the IHEC and the investigator

- The PI will be communicated within seven days once the decision is taken at the expedited subcommittee meeting.
- The minutes are then ratified in the subsequent full board review meeting. If, for any reason further clarifications are required by the full board, the decision is withdrawn and the project may be withheld until the final approval is given. This will be communicated to the PI.

******

Flowchart
Expedited Review (SOP 06)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Full Board Review	**SOP 07**
SOP Number: SOP 07 – V 3.2	**Effective Date: 01.01.21**	

7.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IHEC members will review a protocol during the full board review.

7.2 Scope

This SOP applies to the review and assessment of protocols submitted for approval from the IHEC in a full board review.

7.3 Responsibility

The IHEC Secretariat is responsible for receiving, verifying, and managing the hard copies (Three copies) and soft copy of the received protocols. In addition, the Secretariat should create a protocol specific file, distribute the soft copies of the protocols through an email to the IHEC members for review and communicate the decision to the investigators.

IHEC members are responsible for receiving, verifying, and reviewing the research protocols they receive.

7.4 Full Board Review

- Whenever review of ICD is involved, it should go to the Lay Person for review (proposal, amendment with changed ICD, etc.)
- All research presenting with more than minimal risk, research protocols which do not qualify for exemption or expedited review and projects that involve vulnerable population and special groups should be subjected to full board review by all the members.

7.5 Full Board Review Process

7.5.1 Action at the IHEC secretariat:

i. Receive the application documents submitted by investigators as per the check list
ii. Ensure the completeness of documents
iii. Make relevant entries into the database
iv. Acknowledge the submitted documents
v. Hand over the received documents to the Member-Secretary, IHEC

7.6 Categorization of Protocols

All research presenting with more than minimal risk (low risk and high risk), research protocols which do not qualify for exemption or expedited review and projects that involve vulnerable population and special groups should be subjected to full board review by all the members.

7.7 Assigning Primary Reviewer

- Member-Secretary, IHEC assigns two Primary reviewers from the IHEC to each research protocol. One primary reviewer will review the scientific aspects while the second reviewer looks into the ethical aspects of the protocol.
- The Primary Reviewers are informed preferably 10 days prior to the meeting through the agenda. In case, a Primary Reviewer is not in a position to review due to some reason; he/she should inform the Member-Secretary, IHEC at the earliest, so that the research protocols can be assigned to another member.
- It is the responsibility of the Primary Reviewers to review the research protocols assigned to them thoroughly, offer their observations, comments, and decisions in writing to the IHEC in the assessment form prior to the meeting and return all research protocols to the secretariat on the day of the meeting.
- In the event of his/her absence, the primary reviewers can send written comments on the research protocols to the Member-Secretary, which will be tabled and discussed during meeting. However, a final decision on the research protocol will be arrived at, by a broad consensus / voting at the end of discussion among attending members and not solely based on written comments.

7.8 Assigning Independent Consultants

An independent consultant is a subject expert in a specified field who is identified. A list of independent consultants is maintained at the IHEC. If a project requires additional expertise than those in the IHEC, an independent consultant of the related specialty is invited to review the project. However, an independent consultant cannot take part in the decision making process. For reviewing the proposals, a subject expert from the same field will be temporarily assigned as independent consultant.

7.9 Distribution of the project documents

The following documents (hard and / or soft copies) will be sent by email to the Chairperson, Member-Secretary, Primary Reviewers and members of the IHEC and the Independent Consultant, wherever, necessary:

i. Complete project proposal
ii. IHEC Project Submission form
iii. Informed Consent Documents
iv. Protocol review form
v. Other related documents

7.10 Responsibilities of IHEC members

i. Check the protocol documents received
ii. The Primary reviewers sign and date an acknowledgement form and the other IHEC members acknowledge by email
iii. Check the meeting date to see if he/she is available to attend the meeting.
iv. Identify the project assigned for review

v. Notify the IHEC Secretariat 5 days prior to the convened IHEC meeting regarding the missing documents, if any

7.11 Elements of Review

The primary task of the IHEC is to review the research proposals and their supporting documents with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol in addition to its scientific rigor and ethical soundness.

IHEC will also take into account prior scientific and ethical review by the Primary reviewers, and the requirements of applicable laws and regulations.

7.11.1 While reviewing the research protocols, the following situations should be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture
   i. Healthy adults and non-pregnant women who weigh normal for their age and not more than 450 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week
   ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg whichever is lesser, is drawn in an 8 week period and not more than 2 times per week.
   iii. From neonates depending on the hemodynamic, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion
   iv. Prospective collection of biological specimens for research purposes by noninvasive means.

   For instance:
   - skin appendages like hair and nail clippings in a non-disfiguring manner
   - dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth
   - excreta and external secretions (including sweat)
   - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue
   - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
   - sputum collected after saline mist nebulization and bronchial lavages

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing.

For instance:

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy
- Weighing or Testing Sensory Acuity
- Magnetic Resonance Imaging
- Electrocardiography, Echocardiography Electroencephalography, Thermography, detection of naturally occurring radioactivity, Electroretinography, Ultrasound, Diagnostic Infrared Imaging, Doppler Blood Flow and such alike
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes

d. Collection of data from voice, video, digital, or image recordings made for research purposes

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

f. Research involving collection and storage of genetic materials

The protocol will be reviewed under the following aspects:

7.11.2 Scientific Design and Conduct of the Study

- The appropriateness of the study design in relation to the objectives of the study.
- The statistical methodology (including sample size calculation), and the potential for reaching valid conclusions with the minimum number of research participants
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities
- The justification for the use of control arms
- Criteria for prematurely withdrawing research participants
- Criteria for suspending or terminating the research as a whole
- The adequacy of provisions made for monitoring and auditing the conduct of the
- Research including the constitution of a DSMB, the adequacy of the site, including the Supporting staff, available facilities, and emergency procedures
- The manner in which the results of the research will be reported and published

7.11.3 Recruitment of Research Participants

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, vulnerable population and ethnicity)

- The means by which initial contact and recruitment is to be conducted
- The means by which full information is to be conveyed to potential research participants or their representatives
- Inclusion criteria for research participants
- Exclusion criteria for research participants
- Students or staff recruitment in research

7.11.4 Community Considerations

- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
- Steps taken to consult with the concerned communities during the course of designing the research
- Influence of the community leaders on the consent of individuals
- Proposed community consultation during the course of the research
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs
- A description of the availability and affordability of any successful study product to the concerned communities following the research
- The manner in which the results of the research will be made available to the research participants and the concerned communities

7.11.5 Care and Protection of Research Participants

- Suitability of the investigators' qualifications and experience for the proposed study
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action
- Medical care to be provided to research participants during and after the course of the research
- Adequacy of medical supervision and psycho-social support for the research participants
- Steps to be taken if research participants voluntarily withdraw during the course of the research
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
- Description of any plans to make the study product available to the research participants following the research; a description of any financial costs to research participants
- Rewards and compensations for research participants (including money, services, and/or gifts).
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research
- Insurance and indemnity arrangements.

7.11.6 Protection of Confidentiality of Research Participants

A description of the persons who will have access to personal data of the research participants, including medical records and biological samples. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

7.11.7 Informed Consent Process

i. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
ii. Adequacy, completeness, and comprehension of written and oral information to be given to the research participants, and, when appropriate, their Legally Acceptable Representative(s) (LAR)
iii. Hospital employees/ Health care workers unrelated to the study participant cannot be accepted as an impartial witness who can sign the informed consent document.
iv. Clear justification for the intention to include research participants who cannot make informed decision making, and a full account of arrangements to obtain their consent / consent from the LAR. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being
v. Provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project

7.11.8 Use of protocol review forms

It is the responsibility of the IHEC members to use protocol review form as a checklist while reviewing each research protocol. The duly filled, signed and dated protocol review forms should be returned to the Secretariat at the end of the meeting. The protocol review form is designed to standardize the review process. The study protocol review form helps to ensure that all elements of research protocol are reviewed and are accordingly documented during the discussion / meeting Protocol Review Form Template (SOP 07 -V 3.2 / ANX 01 – V 4, SOP 07 -V 3.2 / ANX 02 – V 4 & SOP 07 -V 3.2 / ANX 03 – V 4).

7.11.9 IHEC meeting

The details of review procedures and communication of decision is described in detail in SOP 08-V 3.2/ANX 04-V 3.1 and SOP 08-V 3.2/ANX 05-V 3.1 In case an urgent approval is required by the investigators an emergency IHEC meeting will be convened as the need may be.

7.11.9.1 IHEC virtual meeting

During emergency / pandemic situations, review of research proposals will be done through virtual EC meeting ensuring appropriate scientific and ethical review and fulfilling the quorum requirements as per ICMR Guidelines for Ethics Committees (April 2020).

Measures such as virtual meetings will be attempted and face-to-face meetings will be avoided to observe social distancing norms. Suitable virtual software platform to enable face to face discussion will be used.

EC secretariat will schedule the virtual meeting thro' Zoom / Google meeting and forward the meeting link to EC members prior to the meeting.

EC members present during the virtual meeting will decide through consensus expressing their decision. Any disagreement will be recorded with reasons. Meeting will be digitally recorded (audio/video) with permission of members and secretariat will be responsible to note the attendance / participation in the virtual meeting.

******

SOP 07-V 3.2 / ANX 01-V 4.1

PSG Institute of Medical Sciences & Research
Peelamedu, Coimbatore 641 004, India

Institutional Human Ethics Committee

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Study Protocol Review Form (Regulatory trials)

(To be completed in full by the Reviewers)

1. IHEC PSG IMS&R Study Proposal No.		
2. Title of the Study:		
Principal Investigator:		
Project Status:	**New**	**Revised**
Name of the Reviewer:		

SCIENTIFIC / TECHNICAL

Sampling Methods and Sample Size

Sample size justified (our site)	Yes	No
Inclusion / Exclusion criteria	Acceptable	Inadequate
If inadequate, please specify		

ETHICAL

Risks

Is there physical / social / psychological risk / discomfort?	Yes	No
If yes, please mention the risks involved:		

Benefits

Direct	Reasonable	Undue	None
Indirect	Improvement in Science / Knowledge		Any other (specify)
Is the overall risk-benefit ratio:	Acceptable		Unacceptable

Participant Selection										
Are vulnerable population involved in this study? (tick all that are applicable)	Woman	Child	Mentally Challenged	Seriously Ill	Terminally Ill					
	Fetus	Economically Backward	Socially Backward	Healthy Volunteers	No					
If yes, are the vulnerable participants adequately protected?	Yes			No						
If special group participants are involved in the study, are they adequately protected?	Yes			No						
Is this a me-too drug?	**Yes**	**No**		**Does this address a common man's problem?**			**Yes**	**No**		
Post-trial access?				**Yes**	**No**					

ICF										
Patient information sheet	***In English:***						***In local languages:***			
	Yes			No			Yes			No
If yes	Adequate			Not Adequate			Adequate			Not Adequate
Informed consent form attached?	***In English:***						***In local languages:***			
	Yes			No			Yes			No
If yes	Adequate			Not Adequate			Adequate			Not Adequate
Assent form attached?	***In English:***						***In local languages:***			
	Yes	No	NA				Yes	No	NA	
If yes	Adequate			Not Adequate			Adequate			Not Adequate
Parental consent form attached?	***In English:***						***In local languages:***			
	Yes	No	NA				Yes	No	NA	
If yes	Adequate			Not Adequate			Adequate			Not Adequate
Facility for AV consent	Yes						No			
If yes	Adequate						Not adequate			

Therapeutic Misconception		
Does wordings in the informed consent form lead to Therapeutic Misconception?	Yes	No
If yes, please explain:		

Compensation			
Is compensation, if adequate, addressed appropriately?	Yes	No	NA
Is an appropriate and valid insurance certificate for the study participants attached?	Yes	No	NA

Conflict of Interest		
Is there a Conflict of Interest?	Yes	No

If yes	Acceptable	Unacceptable
	Appropriate	Inappropriate
OVERALL ASSESSMENT OF THE RESEARCH TOPIC		
Scientifically sound enough not to expose subjects to risk?	Yes	No
Relevant to contribute to further knowledge?	Yes	No
Of national importance?	Yes	No
To be filled by the Lay person		
Language of the Informed Consent Document	Clear	Unclear
Purpose of the study explained in a clear and simple language	Yes	No
Duration of Participation mentioned in the study	Yes	No
Procedures to be followed are clearly explained	Yes	No
Foreseeable risks and discomforts explained	Yes	No
Participant informed about compensation in case of regulatory trials	Yes	No
Participant has been explained about how the Confidentiality of data will be maintained	Yes	No
Participant has been explained about no loss of benefits including medical care	Yes	No
Contact details of IHEC/PI given	Yes	No
Please insert additional comments here :		
To be filled by the Legal Expert		
Compensation details	Adequate	Inadequate
Clinical Trial Agreement checked	Yes	No
Details of the Registration of the trial	Yes	No
Insurance policy	Adequate	Inadequate
Any other legal issues foreseen?	Yes	No
Please insert additional comments here :		

TYPES OF DECISION	
a. Approved	**b. Approval pending minor modifications**
c. Resubmission	**d. Disapproved**

Remarks / Suggestions by the reviewer:

Reviewer's Signature:

SOP 07-V 3.2 / ANX 02 –V 4.1

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Institutional Human Ethics Committee

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Study Protocol Review Form (other than regulatory trials)

(To be completed in full by the Reviewers)

IHEC PSG IMS&R Study Proposal No.	
Title of the Study:	
Principal Investigator:	

Project Status:	**New**		**Revised**
Categorization for review:	**Exempt**	**Expedited**	**Full-Board**
Name of the Reviewer:			

SCIENTIFIC / TECHNICAL

Sampling Methods and Sample Size

Sample size	Adequate	Inadequate
Sample size justification	Appropriate	Inappropriate
Inclusion / Exclusion criteria addressed?	Yes	No
If yes	Acceptable	Inadequate
If inadequate, please specify		

ETHICAL

Risks

Is there physical / social / psychological risk / discomfort?	Yes	No
If yes, please mention the risks involved:		

Benefits

Direct	Reasonable	Undue	None
Indirect	Improvement in Science / Knowledge	Any other (specify)	

Is the overall risk-benefit ratio:	Acceptable		Unacceptable		
Participant Selection					
Are vulnerable population involved in this study? (tick all that are applicable)	Woman	Child	Mentally Challenged	Seriously Ill	Terminally Ill
	Fetus	Economically Backward	Socially Backward	Healthy Volunteers	No
If yes, are the vulnerable participants adequately protected?	Yes		No		
If special group participants are involved in the study, are they adequately protected?	Yes		No		
Collaboration					
Is this a collaborative project?	Yes		No		
If yes, **a. are collaborators equally benefited?**	Yes		No		
b. is the study population benefited?	Yes		No		
c. who in your opinion benefits the most? (Tick all that you think are applicable)	a. Pharmaceutical company		b. Investigator (study the budget)		
	c. Institution		d. Study population:		

Privacy & Confidentiality			
Are privacy and confidentiality maintained?	Yes	No	Not Applicable
In case of use of stored samples / Case records:	Yes	No	Not Applicable
Non-Disclosure statement attached?	Yes	No	Not Applicable
Provision of anonymization explained?	Yes	No	Not Applicable

ICF

Patient information sheet	***In English:***		***In local languages:***	
	Yes	No	Yes	No
If yes	Adequate	Inadequate	Adequate	Inadequate
Informed consent form attached?	***In English:***		***In local languages:***	
	Yes	No	Yes	No
If yes	Adequate	Inadequate	Adequate	Inadequate
Assent form attached?	***In English:***		***In local languages:***	
	Yes	No	Yes	No
If yes	Adequate	Inadequate	Adequate	Inadequate
Parental consent form attached?	***In English:***		***In local languages:***	
	Yes	No	Yes	No
If yes	Adequate	Inadequate	Adequate	Inadequate

Therapeutic Misconception		
Does wordings in the informed consent form lead to Therapeutic Misconception?	Yes	No
If yes, please explain:		

Consent Waiver			
Is consent waiver enclosed	Yes	No	NA

Is confidentiality agreement enclosed	Yes	No	NA
Conflict of Interest			
Is there a Conflict of Interest?	Yes	No	
If yes:	Acceptable	Unacceptable	
	Appropriate	Inappropriate	
BUDGET			
Is budget statement attached with the application appropriate?	Yes	No	
OVERALL ASSESSMENT OF THE RESEARCH TOPIC			
Scientifically sound enough not to expose subjects to risk?	Yes	No	
Relevant to contribute to further knowledge?	Yes	No	
Of national importance?	Yes	No	
TYPES OF DECISION			
e. Approved	**f. Approval pending minor modifications**		
g. Resubmission	**h. Disapproved**		

Remarks / Suggestions by the reviewer:

Reviewer's Signature:

SOP 07-V 3.2 / ANX 03 -V 4.1

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Institutional Human Ethics Committee

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Case Report / Case Series Review Form

(To be completed in full by the Reviewers)

1. IHEC, PSG IMS&R Study Proposal No.	
2. Title of the Case Report / Case Series:	
Principal Investigator:	
Name of the Reviewer:	

SCIENTIFIC / TECHNICAL

Op Number/IP Number mentioned	Yes	No
Reason for submitting this case report / case series	Adequate	Inadequate

ETHICAL

Name and identifiers(DOB, Address, phone number) are not revealed in the case report / case series	Yes	No	NA
Face or any other body parts are camouflaged in photos	Yes	No	NA
Personal Identifiers are masked in all investigation reports / images	Yes	No	NA
Consent / consent waiver	Adequate	Inadequate	
Confidentiality agreement signed by all authors	Yes	No	NA

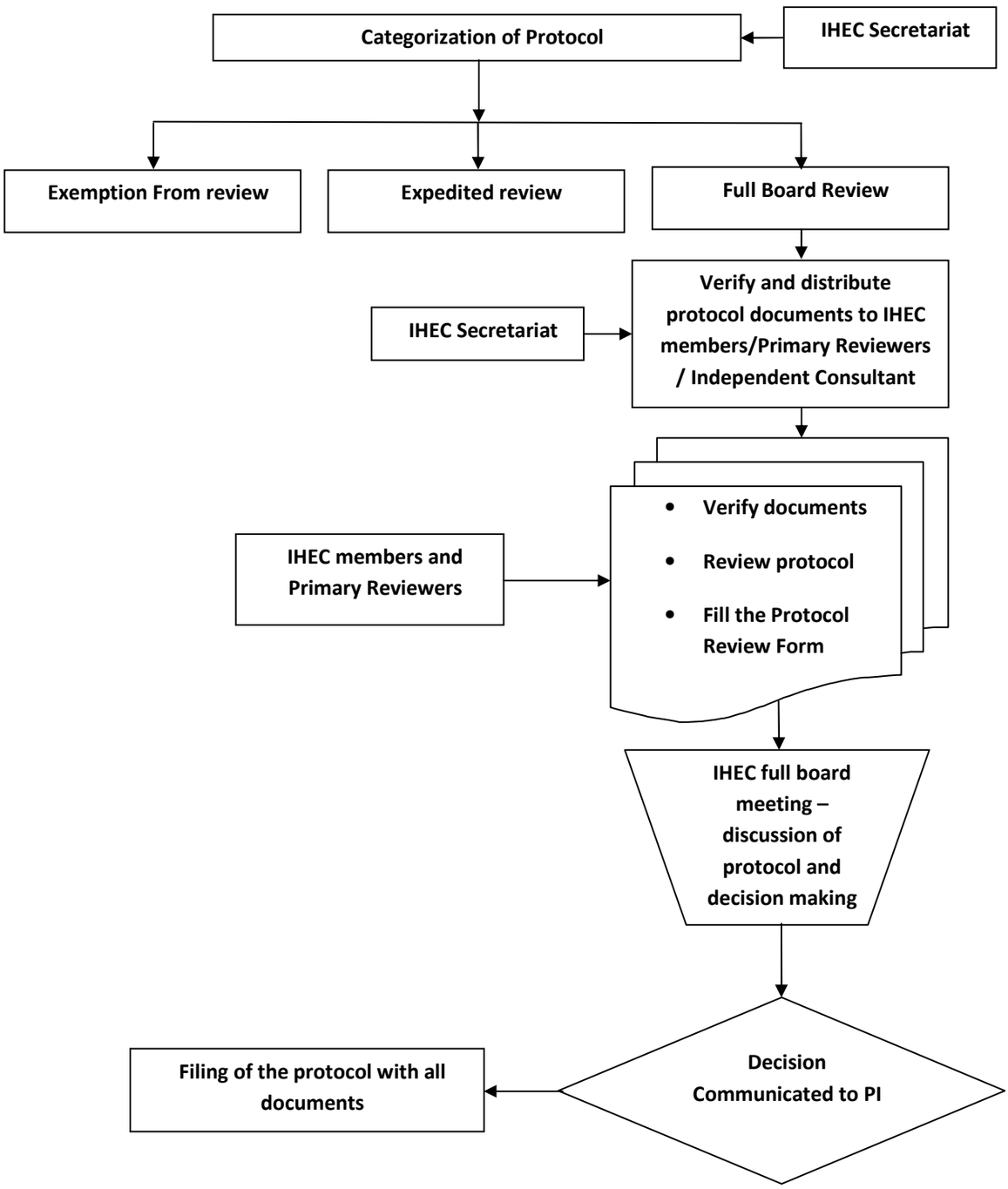
TYPES OF DECISION

a. Approved	**b. Resubmission**
c. Approval pending minor modifications	**d. Disapproved**

Remarks / Suggestions by the reviewer:

Reviewer's Signature:

Flowchart: Full Board Review (SOP 07)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Agenda Preparation, Meeting Procedures and Recording of Minutes	**SOP 08**
SOP Number: SOP 08 –V 3.2	**Effective Date: 01.01.21**	

8.1 Purpose

The purpose of this procedure is to elaborate the instructions for preparation, and distribution of meeting agenda, minutes, and notification letters of IHEC Full Board Review meetings.

8.2 Scope

This SOP applies to administrative processes concerning the conduct of the meeting and its follow-up actions.

8.3 Responsibility

The Member-Secretary, IHEC and IHEC secretariat staff are responsible for the smooth conduct of IHEC meeting.

8.4 Detailed instructions

8.4.1 Before the IHEC full board meeting

IHEC undertakes complete and adequate review of research proposals submitted to them. The committee will review new project proposals, amendments, annual progress of ongoing projects which were reviewed previously under full board review, SAE reports, and assess final reports of all research activities and ratification of expedited meeting minutes through a scheduled agenda.

The agenda of the IHEC meeting is prepared in the prescribed format (SOP 08 –V 3.2 / ANX 01-V 3.0) as per the different items to be discussed / reviewed. The Member-Secretary will prepare the agenda with the help of the IHEC staff and circulate it among the members of IHEC.

8.4.2 Distribution of Protocol/Documents to the IHEC Members

- The IHEC secretariat distributes copies of the protocols by electronic mail to members and hard copies to primary Reviewers 10 days in advance of the scheduled meeting with a request for acknowledgement by email.
- The IHEC secretariat confirms the receipt of the protocol documents with the members.
- It is the responsibility of the IHEC members to verify items of the protocol documents on receipt and in the event of any missing items, intimate the IHEC Secretariat at least 5 days before the meeting so that the relevant documents could be made available.

8.4.3 Preparation for the meeting

i. The Full Board Review Meeting of IHEC shall take place once in a month, on the third Friday from 2:30 pm onwards. Emergency IHEC full board meeting may be conducted on any other day if any protocol requires an urgent review.
ii. The meeting will be held at the College Council Room situated on the ground floor of

the PSG IMS&R (medical college building) near the Dean's Office Complex.

iii. The IHEC secretariat will reserve the College Council Room for the scheduled date and time for the IHEC meeting.

iv. The IHEC secretariat will ensure the availability of the room in good housekeeping condition, equipments (projector, mike, etc.,) and other facilities on the day of the meeting.

v. The secretariat will keep all the original files of protocols listed in the agenda in the meeting room for ready reference.

8.4.4 Conduction of Meeting

- The members will assemble in the IHEC meeting room at the scheduled time.
- The meeting proceeds in the sequential order of the agenda (SOP 08 –V 3.2 / ANX 01-V 3.0); however the Chairperson may change the order, if the situation so demands.
- The meeting will begin with a welcome note by the Member Secretary and remarks by the Chairperson
- The Chairperson should ensure that the quorum (SOP 02 –V 4 section no. 2.10) requirements are met.
- Independent consultants shall sign Confidentiality agreement.
- IHEC members shall register their presence in the attendance sheet.
- Representative of the patient groups or community can be invited during deliberations to offer their viewpoint and will sign confidentiality agreement.
- Observers, if any will also sign Confidentiality agreement.
- The Chairperson should ask for declaration of conflict of interest on any protocol to be discussed. If any IHEC member has conflict of interest involving a project then he / she should declare the same before the meeting commences and leave the meeting room before starting discussion on that project. This should be recorded in the minutes.
- The Member-Secretary should place the minutes of the previous meeting for ratification and present the agenda for discussion.
- The Member-Secretary should place the minutes of the expedited review committee meeting (SOP 08 –V 3.2 / ANX 02 –V 3.0) for discussion and ratification.
- The Member-Secretary should place the list of projects approved under exempt review for discussion and ratification.
- The IHEC will invite Primary Investigator (along with their guides in case of students) to attend the full board meeting.
- PI will present the proposal to the IHEC members.
- The Member-Secretary will request the Primary Reviewers to brief & discuss their views on the research protocol and the Informed Consent Document reviewed by them. This will be followed by discussion by other members.
- The Primary reviewers will submit the duly filled Protocol Review Form (SOP 07 -V 3.2 / ANX 01 – V 3.1, SOP 07 -V 3.2 / ANX 02 – V 3.1 & SOP 07 -V 3.2 / ANX 03 – V 3.1) at the end of the discussion or at the conclusion of IHEC meeting.
- In case the Primary Reviewers cannot attend the meeting, the Member-Secretary, IHEC or any other IHEC member may brief the IHEC about the research protocol and also discuss the written comments/duly filled protocol review form, provided by the Primary reviewer.
- The proceedings of the Full board meeting will be minuted / recorded by the Member-

Secretary as well as by the administrative staff.

8.4.5 Decision Making Process

i. Types of decisions will only be made at meetings where a quorum (SOP 02 - V4 section No. 2.8) is present.
ii. The documents required for a full board review of the application should be complete and the relevant elements shall be considered before a decision is made.
iii. Decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) with the exception of IHEC staff.
iv. Only IHEC members who attend the meeting will participate in the decision making process.
v. Decisions will be arrived at through a consensus / voting (50%+1). When a consensus is not possible voting process will be adopted.

The possible decisions may be

1. Approved
2. Approval pending for minor modifications
3. Resubmission
4. Disapproved

- If the full board approves a research proposal in principle subject to minor modifications i.e., Approval Pending for minor modifications, the revised project proposal submitted by the PI will be verified for modifications and approved by expedited review.
- In case of major changes, resubmission will be asked for and the revised documents will be discussed in full board meeting.
- IHEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
- The draft minutes of the IHEC meetings will be prepared by the Member-Secretary with the help of IHEC Staff.

8.4.6 After the IHEC meeting

8.4.6.1 Preparing the minutes

The Member-Secretary will compile and circulate the minutes of IHEC meeting within 5 (five) working days in the prescribed format (SOP 08 – V 3.2 / ANX 03-V3.0).

8.4.6.2 Approval of the minutes

The minutes of the IHEC meeting will be approved and signed by the Chairperson, IHEC and will be sent to all members by email within 7 (seven) working days from the date of meeting for comments, if any.

The minutes of the meeting will be ratified in the subsequent IHEC full board meeting.

8.4.6.3 Filing of the minutes of the meeting

The original version of the minutes will be placed in the minutes file and a copy of the relevant extract of the minutes will be filed in the corresponding protocol file.

8.4.7 Communication of the Decision

The decision will be communicated in writing to the PI by the Member-Secretary within a period of 9 (nine) working days of the IHEC meeting at which the decision was made (SOP 08-V 3.2 / ANX04-V3.1).

The communication of the decision will include, but is not limited to, the following,

- PSG IMS&R IHEC proposal number and Title of the research proposal reviewed.
- The names and specific identification number, version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form.
- The name and title of the Principal Investigator.
- The name of the site(s).
- IHEC members attended the meeting.
- The date and place of the decision.
- A clear statement of the decision reached.
- Suggestions by the IHEC if any.
- A conditional decision (i.e. approval with recommendations or modifications, suggestions for revision and the procedure, any other requirements by the IHEC), will be valid only for three months from the date of issue of letter. If the PI does not comply with the IHEC suggestions during these three months, a reminder will be issued

In the case of a negative decision, the reasons should be clearly stated in the communication to the PI. If the investigator wishes to appeal on the decision, he/she may do so by contacting the IHEC Secretariat. If not satisfied, may re-appeal to the Dean PSG IMS&R.

All decision letters will be signed & dated by the Member-Secretary.

8.4.8 Approval Letter

In the case of a positive decision, the PI is notified of the following requirements through an approval letter (SOP 08 –V 3.2 / ANX05-V3.1).

- a statement regarding the responsibilities of the PI; for example, confirmation of the acceptance of any requirements recommended by the IHEC
- Request for submission of date of commencement of the project
- Request for submission of status report(s) decided on case to case basis based on the risk involved for ongoing review /renewal of approval within the stipulated time (SOP 10-V 3.2).
- Request to notify the IHEC in case of amendment in protocol or related documents (SOP 09-V 3.2).
- Request to notify the IHEC in case of deviations / violations / non compliances/ waiver if any within the stipulated time (SOP 11 - V 1.2)
- Request to report serious , unexpected or expected adverse events related to the conduct of the study and any report by the DSMB regarding the ongoing study within the stipulated time (Refer SOP 12 - V 3.2)
- Request to report unforeseen circumstances, the termination of the study, or significant decision by other IHEC (SOP 14 –V 3.2).

- Request to submit the final report along with summary of findings and presentations/publications if any within the stipulated time (SOP 13 – V 3.2)

The approval letter will include the following

- The title and proposal number will appear on all pages of the approval letter
- The member secretary will attest on all pages of the approval letter

The PI will also be notified of the duration of the approval which is one year for all projects. Multiyear projects have to be reapproved after one year from the date of issue of letter (SOP 10 – V 3.2) on continuing review of study Protocols.

A copy of the decision as well as approval letters shall be placed in the relevant protocol file.

******

SOP 08 - V 3.2 / ANX 01-V 3.1
Template for Agenda of the Review Meeting of the Institutional Human Ethics Committee scheduled on Friday _____, at 2.30 pm in the College Council Room, PSG IMS&R

i. Welcome note by the Member-Secretary
ii. Introduction of members, when applicable
iii. Remarks by Chairperson
iv. Quorum requirement to be ensured
v. Confidentiality agreement to be signed by non-IHEC members, if present
vi. Appointment of new / resignation by IHEC members, if any
vii. Declaration of Conflict of Interest, if any, by the members

Items for discussion

1. Ratification of minutes of the meeting held on _____
2. Ratification of amendment to IHEC SOP Version ____, if any
3. Ratification of proposals reviewed in the expedited review meeting(s) held on _____ (Annexure I)
4. Ratification of proposals exempted from review (Annexure II)
5. Review of Serious Adverse Events (SAEs)
6. Projects for initial review:

Project No. ____

Date Received	Principal Investigator	Co-investigators	Primary Reviewers
Title:			

7. Proposals for Continuing review:

Project No. ____

Date Received	Co-investigators	Primary Reviewers	Co-investigators
Title:			

8. Deviations/Violations /Non Compliance

Project No.	***Principal Investigator***	***Patient ID***	***No of Deviations(D) / Violations(V) / Waivers (W)/ Non Compliance(NC)***	***Date of occurrence***	***Date of Deviations/Violations/ Waivers / Non Compliance(NC)submitted***

8. Amendments :

Date Received	Principal Investigator	Co-investigators	Primary Reviewers
Title:			
Discussion on:			

9. SAEs :

Proposal No.	*Principal Investigator*	*No. of SAES*		*Letter Date*	*Comments by the IC (SAEs)*
		On Site	Off Site		

10. Study Closures :

Project No. ____

Date Received	Principal Investigator
Title:	
PI's letter dated:	

11. Notifications :

a. Payment to Participants

Project No. ____

Date Received	Principal Investigator
Proposal:	
Payment list of travel allowance given to patients - PI's letter dated:	

b. Trial Status Report

Project No. ____

Date Received	Principal Investigator
Proposal:	
Status report of the study - PI's letter dated:	

c. DCGI Order

Project No. ____

Date Received	Principal Investigator
Proposal:	
Copy of order from DCGI - PI's letter dated:	

12. Additional documents for the study

Project No. ____

Date Received	Principal Investigator
Proposal:	
DCGI notification letter dated:	

13. Any other matter will be discussed with the permission of the Chair.

Member Secretary
Institutional Human Ethics Committee

SOP 08 –V 3.2/ANX 02 – V 3.0

Minutes Template for Expedited Committee Review Meeting

Minutes of the IHEC Expedited Committee Meeting of the Institutional Human Ethics Committee held on _____, at _____ in the College Council Room, PSG IMS&R.

The following members attended the meeting:

Sl. No.	Name	Qualification	Responsibility in IHEC	Sex	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1						
2						
3						
4						
5						

Conflict of Interest:

Item: 1 Projects for initial review:

The following projects were reviewed for scientific soundness and ethical (including ICF) considerations:

Proposal No.

Date Received	Principal Investigator	Primary reviewer

Title:
Suggestions:
Decision:

Item: 2 Proposals for Continuing review:
Project No.

Date Received	Principal Investigator	Primary reviewer

Title:
Suggestions:
Decision:

Item: 3 Deviations/Violations

Project No.	**Principal Investigator**	**Patient ID**	**No of Deviations(D) / Violations(V) / Waivers (W)**	**Date of occurrence**	**Date of Deviations/Violations/ Waivers submitted.**
Comments:					

Item: 4 Amendments:

Date Received	Principal Investigator
The project	
Discussions	
Decision:	

Item: 5 SAEs:

Proposal No.	***Principal Investigator***	***No. of SAES***		***Letter Date***	***Comments by the IC (SAEs)***
		On Site	Off Site		

Item: 6 Study Closures:
Project No.

Date Received	Principal Investigator	Primary reivewer
Proposal:		
Decision:		

Item: 7 Notifications:
Proposal No.

Date Received	Principal Investigator	Primary Reviewer

Title:
Decision: Suggestions:

The meeting came to an end at _____.

Date:

Member-Secretary **Chairperson**

SOP 08 – V 3.2 /ANX 03 - V 3.0

Minutes Template for Full Board Review Meeting

Minutes of the Full Board Review Meeting of the Institutional Human Ethics Committee held on ……..., ……., at …… in the College Council Room, PSG IMS&R.

The following members attended the meeting:

Name	Qualification	Responsibility in IHEC	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No

The Member-Secretary welcomed the members.

Remarks by Chairperson

Quorum

Apologies

Confidentiality agreement by non –IHEC members, if present

Conflict of Interest

Item- 1: Ratification of the last meeting's minutes as per Annexure __

Minutes of the Full Board Review meeting held on …….. were discussed and approved.

Item- 2: Ratification of the projects approved under Exempt Review as per Annexure __

Projects approved under Exempt Review were discussed and approved.

Item- 3: Ratification of the projects reviewed by the Expedited Review Committee as per Annexure __

Minutes of the Expedited Review meeting(s) held on ……, …….. were discussed and approved.

The following projects were reviewed for scientific soundness and ethical (including ICF) considerations:

Item- 4: Projects for initial review:

Project No.

Date Received	Principal Investigator	Co-investigators	Primary Reviewer
The Project			
Discussion:			
Decision:			

Item- 5: Projects for Continuing review:

Project No.

Date Received	Principal Investigator	Co-investigators
The project		
Discussion:		
Decision:		

Item- 6: Deviations/Violations

Project No.	***Principal Investigator***	***Patient ID***	***No of Deviations(D) / Violations(V) / Waivers (W)***	***Date of occurrence***	***Date of Deviations/Violations/ Waivers submitted.***

Item- 7: Amendments:

Project No.

Date Received	Principal Investigator	Co-investigators	Primary Reviewer
The project			
Decision:			

Item- 8: SAEs:

Proposal No.	***Principal Investigator***	***No. of SAES***		***Letter Date***	***Comments by the IC (SAEs)***
		On Site	Off Site		

Item- 9: Study Closures:

Project No.

Date Received	Principal Investigator	Co-investigators	Primary Reviewer
Decision:			

Item- 10: Notifications:

Project No.

Date Received	Principal Investigator	Co-investigators	Primary Reviewer
Decision:			

Item- 11: Other Points, if any.

The meeting ended with the vote of thanks.

Date: ……

Member-Secretary **Chairperson**

SOP 08 – V 3.2 / ANX 04 –V 3.2

Format for Types of Decision Letter for Approval with Minor/ Re-submission, Negative Decision of Protocols, Amendments & Renewal of Approval

Dr. ……

Principal Investigator,
Co-investigators
PSG IMS&R.

Ref: Project No.

Dear Dr…

The above referenced project was placed, reviewed and discussed in the Institutional Human Ethics Committee full board meeting held on date/time/place

List of documents reviewed.

The following members attended the meeting.

Decision Arrived: Approved / Approval pending for minor modifications/ Re-submission / Not Approved

Suggestions by the Committee / Reasons for Not Approval
a
b
c

The approval will be granted subject to the compliance with all the above suggestions of the IHEC

Kindly resubmit the two copies of revised proposal (version 2) or documents within three months for re-review before ----/…./).

The resubmission of projects decided as conditional approval is valid only for three months

Thanking you,

Yours sincerely,

Member-Secretary, IHEC

*Footer will have the title and proposal number in all the pages and member secretary will sign in all the pages

SOP 08 -V 3.2 / ANX 05 -V3.2

Format for Approval Letter

To,
Dr._____
Principal Investigator
Co-investigators
PSG IMS&R.

Ref: Project No.

Date

Dear Dr.

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application (dated) to conduct the research study entitled "_____" during the IHEC meeting held on (date).

The following documents were reviewed and approved:

1. Project Submission form.
2. Study protocol (including protocol amendments), dated_____, version no(s).
3. _____
4. Patient information sheet and informed consent form (including updates if any) in English and-Vernacular language.
5. Investigator's brochure, dated_____, version no._____
6. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for the purpose.
7. Current CVs of Principal investigator, Co-investigators
8. Insurance policy/compensation for participation and for serious adverse events occurring during the study participation.
9. Investigator's Agreement with the sponsor
10. Investigator's undertaking
11. DCGI/DGFT approval
12. Clinical Trial Agreement (CTA)/Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA), if applicable

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on Date _____Place _____

Name of member/Position on IHEC/Affiliation/Gender

_____Chairman of the Ethics committee

_____Member-Secretary of the ethics committee

_____Name of each member with designation

The trial is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/ New Drugs and Clinical Trials Rule 2019. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every ---------- months.
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time.
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors.
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence.
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
    a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
    b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
    c. If the amendments require a change in the consent form, the copy of revised Consent Form with version number and date should be submitted to Ethic Committee for approval.
    d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
    e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented.
    f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within

the stipulated period for review.

7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Thanking You,

Yours Sincerely,

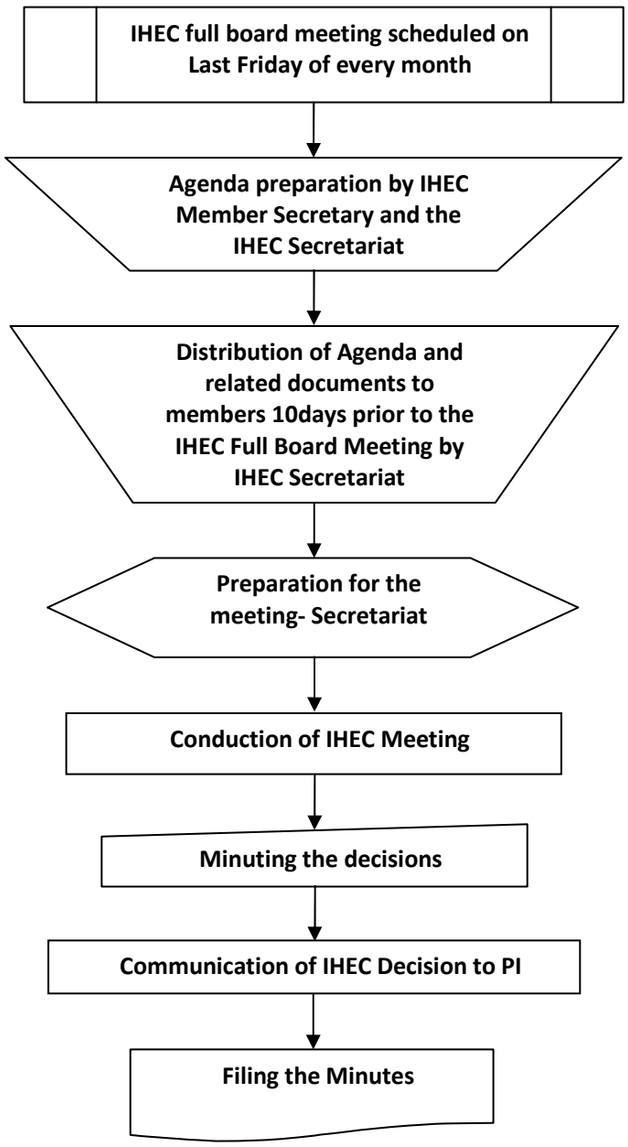
.

Member-Secretary,
Institutional Human Ethics Committee

*Footer will have the title and proposal number in all the pages and member secretary will sign in all the pages

Flowchart:

Agenda Preparation, Meeting Procedures and Recording of Minutes (SOP 08)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Protocol Amendments / Protocol Related Documents	**SOP 09**
SOP Number: SOP 09 – V 3.2	**Effective Date: 01.01.21**	

9.1 Purpose

The purpose of this SOP is to describe the procedure adopted to review a protocol amendments or any other amendments / letters after IHEC approval.

9.2 Scope

This SOP applies to amendments to study protocols / documents and letters that are submitted to IHEC approval after approval of the proposal. Amendments made to protocols or any other amendments related to the study should not be implemented until reviewed and approved by the IHEC.

9.3 Responsibility

It is the responsibility of the IHEC Secretariat to manage protocol amendments, documents and letters. The IHEC members are responsible for reviewing the amendments.

9.4 Review Process

9.4.1 Receipt of the Amendment documents

The amendment documents along with the covering letter and Amendment Reporting Form (SOP 09 – V 3.2 / ANX1-V1.1) forwarded by the PI will be received by the IHEC Secretariat.

The IHEC Secretariat should follow the procedures as in SOP 03 - V4.

9.4.2 Categorization

The Member-Secretary, IHEC classifies the amendments into minor or major (SOP 04 – V 3.1). Minor amendments and notifications will be placed for expedited review and major amendments for full board review. All major amendments will be sent to the originally assigned Primary Reviewer for comments.

9.4.3 Expedited Review

Minor amendments will be reviewed as per SOP 06 – V 3.0

9.4.4 Full Board Review

Major amendments will be reviewed as per SOP 07 – V 3.2

9.4.5 Decision and Communication to the PI

The IHEC members could arrive at any one of the following decisions at the IHEC meeting:

1. The amendment can be implemented without any modifications
2. The amendment can be implemented with recommendations.
   The PI should adopt the IHEC recommendations in the amendment and resubmit to

the IHEC within fifteen days for review. The amendment should not be implemented until the conditions set by the IHEC in the decision have been met.

3. Disapproved. The amendment should not be implemented.

This decision is recorded in the minutes and communicated to the PI in the prescribed format (SOP 09 – V 3.2 / ANX02-V 1.0) by the Member-Secretary.

9.4.6 Filing of Documents:

The amendment documents shall be placed in the corresponding research protocol file.

******

SOP 09-V 4 / ANX 01-V 1.2
Amendment Reporting Form

IHEC Study No with approval date:	
Title :	
Principal Investigator :	
Has the amended portion been highlighted?	
Does this amendment entail any changes in ICFs	Yes / No
If yes, whether amended ICFs are submitted pl. specify Version No. & Date	
Please mention version no and date of amended Protocol / Investigators brochure / Addendum,	
Is summary with list of original statement and changes with page numbers submitted?	
No. of active study participants	

Signature of the Principal Investigator & Date:

SOP 09 - V 3.2 / ANX 02 - V 1.2

Format for Project Amendment/Document Amendment Decision Letter

To XXXXX(PI)
Department

Ref: 1. IHEC Study No.
2. Full title of the Study (acronyms, if any in brackets) and study number assigned by the sponsor

Dear Dr. ——

We have received the following document/s on (date)

1.

At the IHEC meeting held on ——date/time/place, the above mentioned documents were reviewed. After deliberations, the committee came to the following decisions:

1. Approved
2. Minor or major amendments recommended requiring re-submission

Recommendations
1.
2.

The amendment should be modified and resubmitted to the IHEC within one month for re-review. The study should not proceed until the conditions set by the IHEC in the decision have been met.

3. Not approved

The members who attended this meeting held on —— date and place of meeting—— at which the above mentioned document was discussed, are listed below.

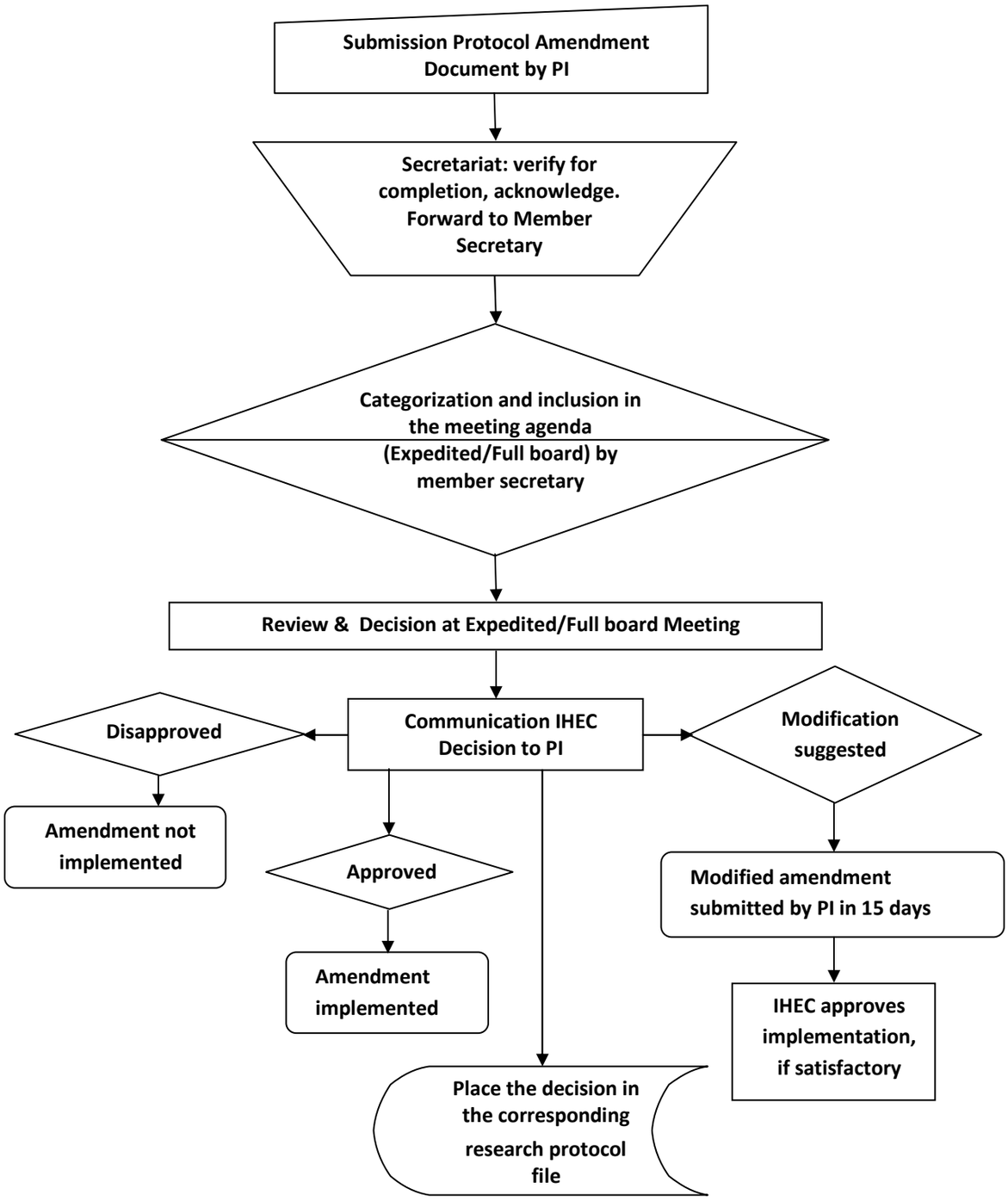
1.
2.
3.

Neither you nor any of your study team members were present during the decision-making process in the IHEC Expedited Review Meeting / Full Board Review Meeting.

Yours truly,

Signature with Date
Member-Secretary, IHEC

Flowchart: Review of Amendment to Protocol /Protocol Related Documents (SOP 09)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Continuing Review of Study Protocols	**SOP 10**
SOP Number: SOP 10 – V 3.2	**Effective Date: 01.01.21**	

10.1 Purpose

The purpose of this SOP is to review the status report of IHEC approved study and renewal of approval if required.

10.2 Scope

This SOP applies to review the status report of study protocols once a year. Depending upon the degree of risk to the participants, the nature of the studies and the vulnerability of the study participants and duration of the study, the IHEC may choose to review the studies more frequently. This SOP also includes the procedure to be adopted for renewing the approval for multiyear projects.

10.3 Responsibility

It is the responsibility of the IHEC Secretariat to check the scheduled date for status report review / status report with application for renewal of approval as applicable and send reminder to the PIs for submitting status reports (SOP 03 – V 4).

The IHEC is responsible for reviewing the progress made in the protocol.

10.4 Review Process

10.4.1 Submission of status report / renewal of approval

i. The Secretariat will plan two months ahead of the due date for review of status report (as scheduled) / renewal of approval (one year from the date of approval of the study) in the prescribed format (SOP 10 – V 3.2/ANX01-V2.0 & SOP 10-V 3.2/ ANX 02-V2.0 respectively). The secretariat will request the PI to submit 3 hard copies & a soft copy of the status report alone / status report with application for renewal of approval as applicable two months prior to the due date. If there is no response from the investigator, reminders will sent at 2 weeks intervals. If the investigator fails to respond to the final reminder, his/her future projects will be considered for IHEC review only on submission of the report.

ii. The Secretariat will verify for the following documents:
   - The Status Report / Application form for Renewal of approval (SOP 10 – V 3.2/ ANX 03-V2.0) duly signed by the PI
   - Inclusion of summary of the protocol results since last review in the status report.
   - Request letter for renewal of approval of the project, if applicable.

The IHEC Secretariat will acknowledge receipt of the application and forward it to the member secretary.

If the PI fails to submit the report for review within the stipulated time, the validity of the IHEC

approval given to the study ceases from due date.

10.4.2 Categorization

Based on the risk involved the Member-Secretary will categorize the status reports / renewal of approval applications for placing either in the expedited or full board review (SOP 04 – V 3.1).

10.4.3 Expedited Review

Continuing review of protocols categorized as expedited will be reviewed as per SOP 06-V 3.0 by the expedited review committee.

10.4.4 Full Board Review

Continuing review protocols categorized as full board will be reviewed as per SOP 07- V 3.2 in the forth coming full board meeting.

10.4.5 Decision and Communication to the PI

The IHEC members could arrive at any one of the following decisions at the IHEC meeting:

1. The project can be continued without any modifications
2. Approved with recommendations.
   Protocols should be amended as per IHEC recommendations and resubmitted to the IHEC within one month for IHEC review. The study should not proceed until the conditions set by the IHEC in the decision have been met.
3. Disapproved. The project has to be discontinued.

This decision is recorded in the minutes on SOP 10 – V 3.2/ANX 04-V 3.1 and communicated to the PI by the Member-Secretary.

10.4.6 Filing of Documents:

The IHEC Secretariat will place the decision form and minutes of the meeting relevant to the study in the corresponding research protocol file.

10.5 Post Review Activities:

Amended report to be submitted by the PI within the specified time period as decided by the IHEC. The IHEC Secretariat will keep track of the reports. Reminders will be sent if no reports are received.

IHEC will revoke the suspension if updated reports are satisfactory.

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SOP 10 – V 3.2 / ANX 01-V 2.0

Reminder to PI for Status / Progress Report

(To be filled by Member-Secretary)

PSG IMS&R IHEC Proposal No.
Protocol Title:
Name of the PI

From:

Member-Secretary
Institutional Human Ethics Committee
PSG IMS&R

To:

Dr.

Madam / Sir

Sub: Reminder for Status / Progress Report

This is to bring to your attention that a status / progress report of your study is due on ……

You are requested to send the same in the prescribed format to this office by ……..

Member-Secretary Date:
IHEC, PSG IMS&R

SOP 10 -V 3.2 / ANX 02-V 2.0

Reminder to PI for Renewal of Approval

(To be filled by Member-Secretary)

PSG IMS&R IHEC Proposal No.
Protocol Title:
Name of the PI

From:

Member-Secretary
Institutional Human Ethics Committee
PSG IMS&R

To:

Dr.

Madam / Sir

Sub: Intimation on expiry of IHEC approval to the study

This is to bring to your attention that IHEC approval given to your study expires on ……

If you propose to continue the study beyond this date, you are requested to send an application for renewal of approval for another year in the prescribed format along with a cumulative status / progress report to this office by ……..

Member-Secretary Date:
IHEC, PSG IMS&R

SOP 10-V3.0 / ANX 03-V 2.0

Status / Progress Report/Application for Renewal of IHEC Approval

(To be filled by PI)

PSG IMS&R IHEC Proposal No.	
Protocol Title:	
Name of the PI:	
* Abstract	
Date of Commencement of Study	
Number of participants recruited so far	
Number of participants withdrawn	
Change in investigators / co-investigators	
Protocol amendments, if any	
Protocol deviations, if any	
Protocol violations, if any	
Change in the informed consent, if any	
Serious adverse events	
** DSMB Reports	
** Statement on ongoing studies by the investigators **(Annexure – SOP 03- V 4 / ANX 05 – V 2.0- Pharma Sponsored Studies)**	
Renewal Requested	YES / No
Signature of the PI with date	

***** Extended abstract may be prepared under the following headings: Introduction (this section includes Review of Literature and justification), Objectives, Methods (Design, setting, participants, etc.,), Results and Conclusions. (Tables, if included, must be referred to in the report and attached as annexure.)

**Applies to clinical trials only

Acknowledgement by IHEC:

SOP 10 – V 3.2 / ANX 04 -V 3.0

IHEC Decision on Status / Progress Report and Renewal of Approval

Project Title:

PI:
Review
a) Status / Progress Report
b) Renewal of Approval

Date of IHEC meeting:

Further the review on status / progress report / renewal of approval of the submitted protocol was subjected to:

Full Board / Expedited Review meeting

Reviewers:

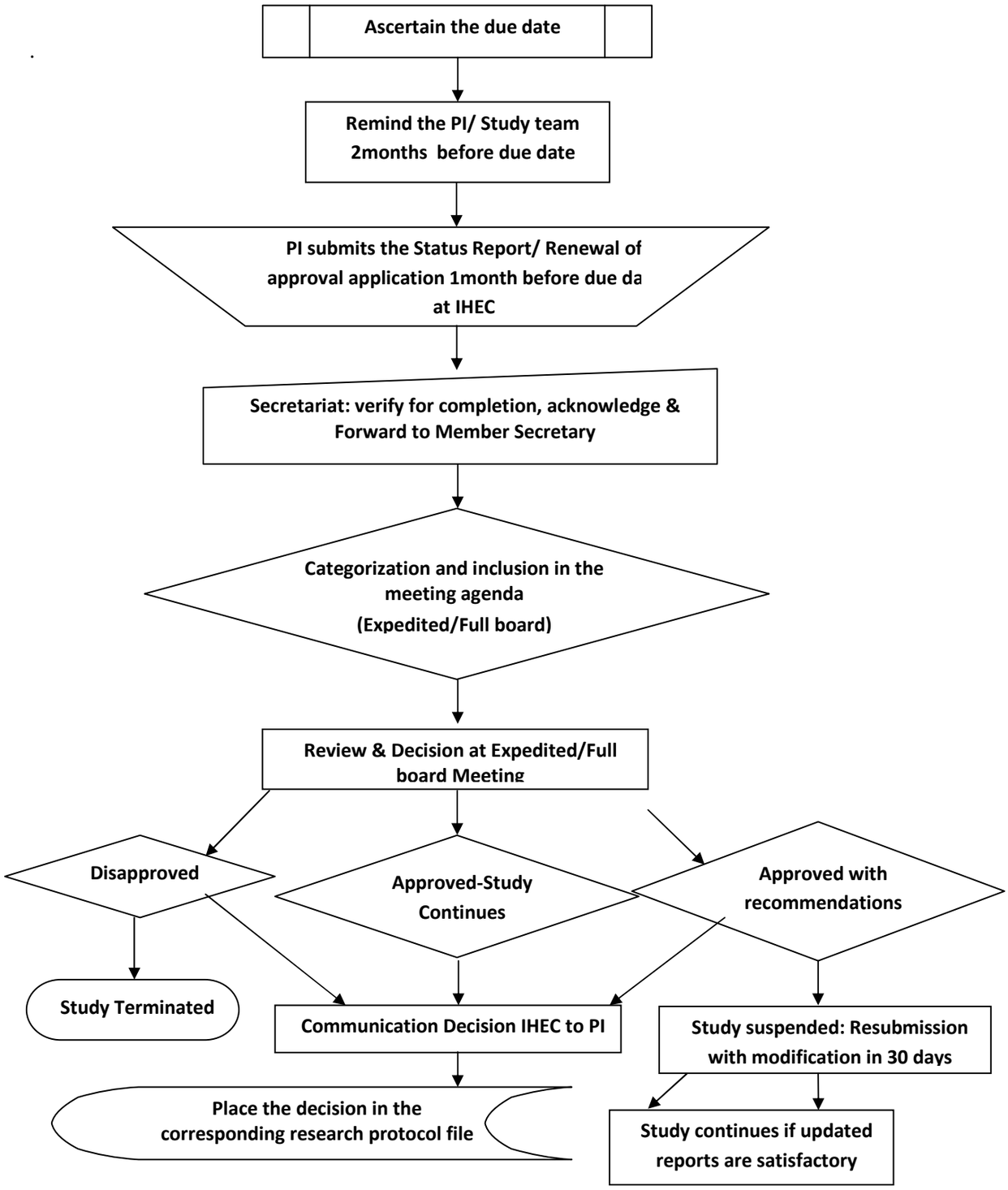
1.
2.

Decision

I. The status report is noted & approved
II. The project can be continued without any modifications
III. Modifications recommended, requiring protocol resubmission
Recommendations
1.
2.
3.
.
IV. Renewal not approved
Reasons
1.
2.
3.

Member-Secretary
Signature with date

Flowchart:
Continuing review of study Protocols (SOP 10)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Protocol Deviation /Non-Compliance / Violation	**SOP 11**
SOP Number: SOP 11 – V 1.2	**Effective Date: 01.01.21**	

11.1 Purpose

To provide directions for reviewing protocol deviations* / violations / non-compliance / reports reported either by the PI or identified during site monitoring visit.

11.2 Scope

This SOP applies to review of protocol deviations / violations / non-compliance reports of approved protocols.

11.3 Responsibility

1) IHEC secretariat is responsible for receiving deviations -Violations reports submitted by the PI and forwarding to Member-Secretary or the site monitoring team.
2) IHEC members review and act upon the reports.

11.4 Review Process

11.4.1 Detection of Protocol deviation/ non-compliance/ violation/waiver

11.4.1.1 The PI himself / herself may forward protocol deviation / non- compliance / violation reports to IHEC within 7 days of occurrence in the prescribed format (SOP 11 – V 1.2/ ANX 01–V1.0).

11.4.1.2 The Secretariat can detect protocol deviation / non-compliance / violation from:

- failure to comply with statutory requirements
- not responding to requests from IHEC within reasonable time limit
- not responding to communication made by IHEC

11.4.1.3 The IHEC members can detect protocol deviation/non-compliance / violation,

- During site monitoring if conduction of the project is not as per IHEC approved protocol study design / national / international regulations. The site monitoring team will inform the Secretariat in writing within 24 hours from the time of finding [one working day]
- when scrutinizing annual / periodic reports / SAE reports

11.4.1.4 Communication received from the Investigator / trial site / sponsor /study monitor / CRO

11.4.1.5 Communication / complaint / information received by IHEC Secretariat from research participant who has been enrolled or any individual who has been approached for enrollment.

11.4.2 Categorization

Based on the risk involved the Member-Secretary will categorize the protocol violation / non-compliance / protocol deviation report/s for placing either in the expedited or full board review (SOP 04 – V 3.1). Reports on deviations involving major risk will be sent to the primary reviewer for comments.

11.4.3 Expedited Review

Protocol violation / non-compliance / protocol deviation report/s categorized as expedited will be reviewed as per SOP 06 – V 3.0. During which "Root cause Analysis" will be done(RCA) and Corrective and Preventive Actions (CAPA) will be recommended.

11.4.4 Full Board Review

Protocol violation / non-compliance / protocol deviation report/s categorized as full board will be reviewed as per SOP 07 – V 3.2. During which "Root cause Analysis" will be done(RCA) and Corrective and Preventive Actions (CAPA) will be recommended.

11.4.5 Communication of Decision to the PI

The communication to the PI may include one or more of the following:

- IHEC has noted the violation / noncompliance / deviation and instruct the PI to avoid such deviations / noncompliance / violations in future.
- Enlist the measures the PI would carryout to avoid such deviations / noncompliance / violations in future.
- Call for additional information and suspend the study till recommendations made by the IHEC are implemented by the PI and found to be satisfactory by the IHEC.
- Suspend the study for a fixed duration of time.
- 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.

This decision is recorded and duly signed by the Member-Secretary on (SOP 11 - V1.2 / ANX 02–V1.0) and communicated to the PI within seven days of approval. In case of multicentre trials other sites will also receive a copy of the decision.

11.5 Filing of the Documents

Copies of the notification letter, protocol deviation / violation / non-compliance reports and the IHEC decision letter are placed in the protocol file and an additional copy of the notification letter in the "non-compliance' file.

11.6 Post-review activities

- Compliance report to be submitted by the PI within the specified time period as decided by the IHEC. The IHEC Secretariat will keep track of the reports. Reminders will be sent if no reports are received.
- In case of suspension, IHEC will revoke the suspension after receipt of satisfactory compliance report from the PI.
- In case a PI fails to respond to the IHEC letter, it will be discussed at the next full board meeting and a decision will be taken for specific action.

A separate file that identifies investigators who are found to be non-compliant with national /

international regulations or who fail to follow protocol approval stipulations or fail to respond to the IHEC request for information/action is maintained and reviewed by the IHEC periodically.

*** Protocol Deviation – explanation:**

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.

Examples:
• 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.

Examples:
• 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 participant protection regulations, policies, or procedures on the part of the investigator(s).

Examples:
• 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 participant protection regulations, policies, or procedures.

Examples:
• Working under an expired professional license or certification
• Failure to follow federal and/or local regulations, and intramural research or CC (Clinical Center) policies
• Repeated many minor deviations.

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles.

Examples:
• A breach of confidentiality.
• Inadequate or improper informed consent procedure.

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SOP 11 - V 1.2 / ANX 01–V 1.1

Deviation (D)/ Violation (V) / Non compliance Reporting Form

(to be filled by PI)

IHEC Proposal No: Project title:
Principal Investigator:
Specify if D/V/NC:
Reported by:
Nature: Minor Major (Tick whichever applicable) If other, please specify:
Date of occurrence: (Not applicable incase of Waiver)
No of similar D/V/NC occurred for the same trial:
Patient No.
Complete Details of D/V/NC:
Action taken by PI/Co-PI/Co-I :
Impact on study participant (if any) :
Name of PI: Sign of PI: Date:

SOP 11 – V 1.2 / ANX 02–V 1.1

IHEC Decision on of Protocol deviation/ non-compliance/ violation

Project Title:

PI Name:

- Protocol deviation
- Non-compliance
- Violation

Date of IHEC meeting:

IHEC has noted & reviewed the deviation/ non-compliance/ violation reported on your protocol in:

Full Board / Expedited Review meeting held on

Reviewers:

1
2

Decision

I Such deviations / noncompliance / violations in future should be avoided.

The IHEC recommends the following measures to be adopted to avoid deviations / noncompliance / violations in future

Recommendations

1.
2.

You are instructed to suspend the study till these recommendations IHEC are implemented and approved by the IHEC

II You are requested clarify the following suspend the study till your clarifications are approved by IHEC

1
2

III The IHEC has decided to revoke approval of the current study.
You are requested inform DCGI / Other relevant regulatory authorities.

IV The IHEC has decided suspend all studies under your guidance

V The IHEC has decided Review and / or inspect other studies undertaken by you

Member-Secretary
Signature with date

Flowchart: Reporting & Review of Protocol Deviation / Non-Compliance-Violation (SOP 11)

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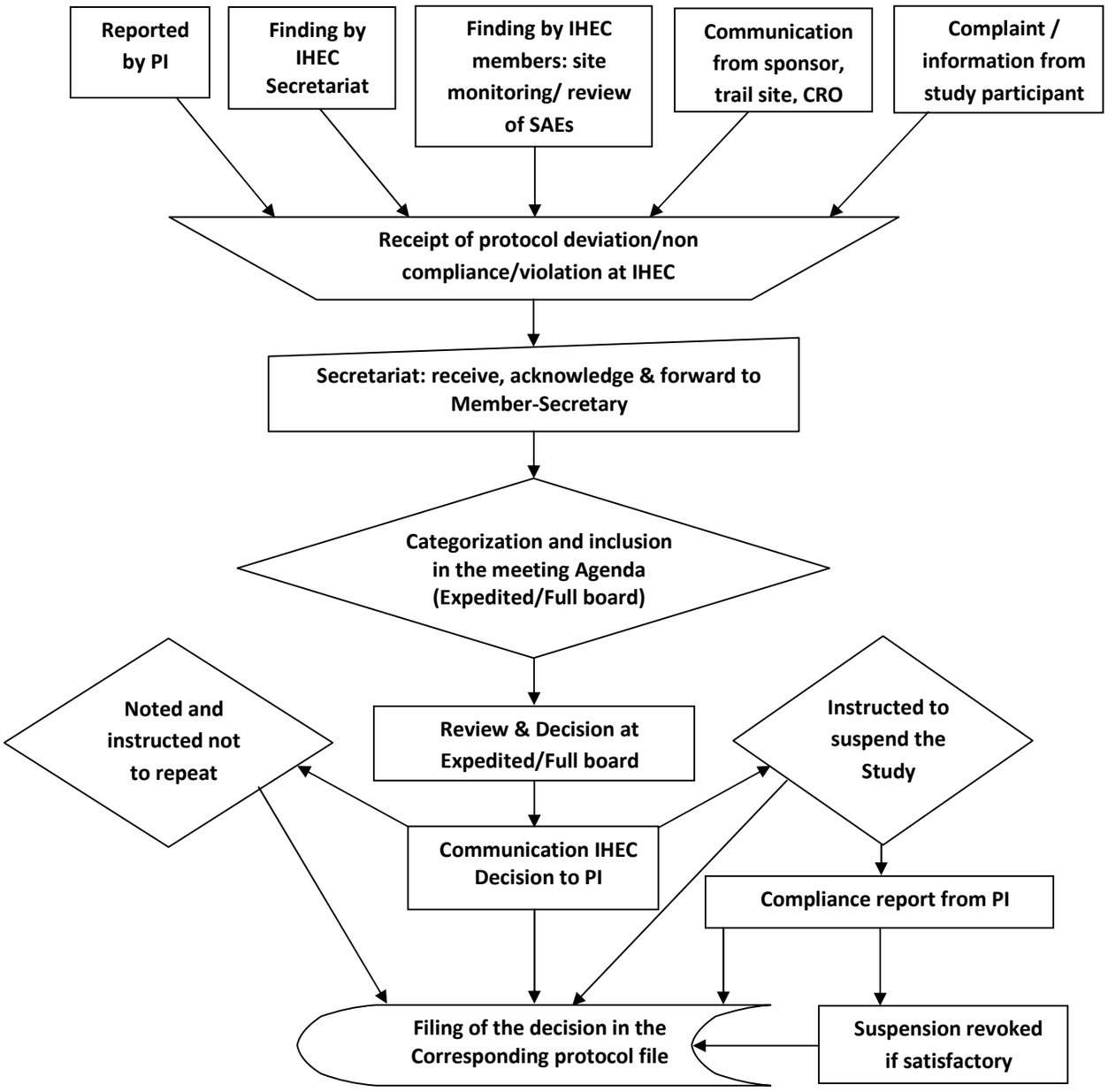


Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Serious Adverse Events (SAE) Reports	**SOP 12**
SOP Number: SOP 12 – V 3.3	**Effective Date: 01.01.21**	

12.1 Purpose

The purpose of this SOP is to describe the procedure for reviewing and follow-up actions to be taken on reports of Serious Adverse Events (SAEs) and unexpected events for any active study approved by the IHEC.

12.2 Scope

This SOP applies to the IHEC review of SAE and unexpected events reports, both on site and off site, including follow up reports submitted by investigators.

12.3 Responsibility

The IHEC Secretariat is responsible for receiving the complete SAE / unexpected events reports.

It is the primary responsibility of the IHEC through the primary reviewer(s) of the study and the independent consultant for SAE to review and address SAE and unexpected events involving risks to study participants.

IHEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

12.4. Review Process

12.4.1 On site SAEs

12.4.1.1 SAE related activities before IHEC meeting

The IHEC secretariat should receive the reports of SAEs occurred for IHEC approved studies within fourteen days of the occurrence of the SAE.

If the **SAE is 'Death'**, the PI shall report the SAE to the IHEC Secretariat in the SAE reporting form (SOP 12 – V 3.3 / ANX 01 – V 3.0) within 24 hours of the occurrence.

Reporting of SAE should be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days.

If the PI has not adhered to the above stipulated time period, the IHEC Secretariat will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

The IHEC Secretariat will receive and forward the SAE report to the Member-Secretary, IHEC immediately.

For clinical trials under the purview of CDSCO, the timeline and procedures as notified from time to time may be followed.

The Member-Secretary will verify the completeness of SAE report and the incomplete reports will be sent back to the PI for obtaining complete information.

12.4.1.2 Actions to be taken by IHEC

The Member-Secretary will forward all SAE Reports including reports of death to the Primary reviewer(s) of the study and the independent consultant for SAEs within one working day.

The Primary Reviewer(s) of the study and independent consultant for SAEs will review, prepare a report and submit to Member-Secretary, IHEC within 5 working days from the date of receipt of the SAE report from IHEC.

This review could be done through a meeting, teleconference, email or telephonic conversation.

The Member-Secretary will place the reports of the Primary Reviewer(s) of the study and independent consultant for SAEs at the next scheduled IHEC full board meeting as per section 9.5.

12.4.2 Off Site SAEs

12.4.2.1 SUSAR (Suspected Unexpected Serious Adverse Reaction)

Off Site SAEs where adverse event reports that are serious, unexpected and related (definitely, probably and possibly) to the drug need to be reported to the IHEC within seven days of PI receiving the report. However, SAE reports of deaths need be intimated within 24 hours from the time PI receiving the report. (SOP 12-V4 / ANX 02-V2.0)

The IHEC Secretariat will then forward the same to Member-Secretary, IHEC, Primary Reviewer(s) of the study and Independent Consultant for SAEs for further action.

12.4.2.2 The SAEs that are expected (if listed in the informed consent) or unexpected but unrelated to the drug (classified as per the Off Site Safety Report Classification form (SOP 12-V4 / ANX 02 V2.0) have to be logged (SOP 12-V4 / ANX 03 V2.0) by the PI and to be submitted every three months and/or submitted along with continuing review report. The log has to be maintained continuously until the end of the study. If the IHEC and Independent Consultant for SAEs need to review the logs of the offsite SAE reports, the committee will request copies of SAE reports at any time. If a trend is observed in SAEs by PI, such a trend will be reported to IHEC Secretariat, action on such reports will be taken by the Member-Secretary, IHEC and Independent Consultant for SAEs, as per 12.3-12.4.

12.5 Review and Decision

The IHEC full board will discuss the submitted reports of Independent Consultant and Primary Reviewers.

If appropriate, specific action or combination of actions will be taken, based on the consensus decision of the IHEC discussion, some of which are listed below:

- Terminate the study;
- Suspend the study till IHEC review of the same is completed;
- Suspend the study till additional information is obtained;
- Suspend the study for a fixed duration of time;
- Suspend the study till amendments requested for by the IHEC are accepted;
- Suspend enrolment of new research participants;

- Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
- Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
- Request additional details
- Request further follow up information
- Direct the PI to inform participants already enrolled in the study about the SAE and obtain re-consenting regarding continuation in the research trial, if necessary.
- Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
- Note the SAE report in the IHEC records if information submitted is found to be adequate
- Any other action

12.6 Assistance To Be Provided To The Participants

The IHEC full board will review the relatedness of the SAE to the research and determine the quantum and type of assistance to be provided to the participants as specified below;

- All research participants who suffer harm, whether related or not, should be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc. Medical management should be free if the harm is related to the research.
- Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.
- While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC should consider aspects including the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc.
- For other sponsored research, it is the responsibility of the sponsor (whether a pharmaceutical company, government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.
- All AEs should be recorded and reported to the EC according to a pre-planned timetable, depending on the level of risk and as recommended by the EC.
- In investigator initiated research/student research, the investigator/institution where the research is conducted becomes the sponsor.
    - It is the responsibility of the host institution to provide compensation and/or cover for insurance for research related injury or harm to be paid as decided by the EC.
    - The institution should create in-built mechanism to be able to provide for compensation, such as a corpus fund in the institution..
    - In the applications for research grants to funding agencies – national or international, government or non-government agencies – the researcher should keep a budgetary provision for insurance coverage and/or

compensation depending upon the type of research, anticipated risks and proposed number of participants.

- **Ancillary care**: Participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC.

12.7 After the review of SAE

- The IHEC secretariat will send a formal letter within 30 calendar days to the investigator/s and DCGI with instructions for specific actions as per the IHEC decision and instruct the PI regarding the compliance to actions recommended by the IHEC within 14 days of receipt of the IHEC letter.
- The IHEC Secretariat will send the letter and file a copy of the letter in the protocol file.

******

SOP 12 - V 4 / ANX 01-V 3.1

Serious Adverse Event Review Report (CIOMS format, with some modifications)

(To be filled by the PI)

I. REACTION INFORMATION

Name of the PI:	Proposal No.:	
Study Title:		
Please tick appropriately.	On-Site	Off-Site

1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL
(first, last)		Day	Month	Year	Years		Day	Month	Year	APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? □ YES □NO □NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-
17. INDICATION(S) FOR USE		DUCTION? □YES □NO □NA
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26-26a. NAME AND ADRESS OF REPORTER (INCLUDE ZIP CODE)
ORIGINAL REPORT NO.	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE □STUDY □LITERATURE □HEALTH PROFESSIONAL □REGULATORY AUTHORITY □OTHER	
DATE OF THIS REPORT	25a. REPORT TYPE □INITIAL □FOLLOW-UP	
Causality Assessment – The PI considers that the event is Certainly (b) Probably (c) Possibly (d) Unlikely - related to the study drug		
PI's Signature: Date:		

SOP 12 - V 4 / ANX 02-V 2.0

Off site Safety Reports Classification Form

NOTE to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Off-site Safety Reports.

If the answer to all three questions is "Yes", prompt reporting is required and such off site Safety Reports need to be reported to IHEC along with the log.

If any one answer is "No", it needs to be logged as prescribed format. (SOP 12 - V 3.3 /ANX 03-V 2.0). This log should be submitted to the IHEC Secretariat every 3 months and/or along with Continuing Review report.

Project No.

Project Title:

Questions	Yes	No
Is adverse event serious?		
Is adverse event related?		
Is adverse event unexpected?		

Date of reporting

Signature of PI

Name of PI

SOP 12 -V 4 / ANX 03 -V 2.0

Off Site Safety Reports Log

NOTE to PI:

1. Please log in details of Off Site Safety Report
2. The following log has to be maintained continuously until the end of the study.
3. This log should be submitted to the IHEC Secretariat every 3 months and/or along with
4. Status / progress report. The log must be submitted to the IHEC Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
5. Please note the complete set of Off-site Safety Reports need not be sent to IHEC Secretariat as and when received. If the IHEC needs to review the reports, they can request copies at any time.

Project No.:

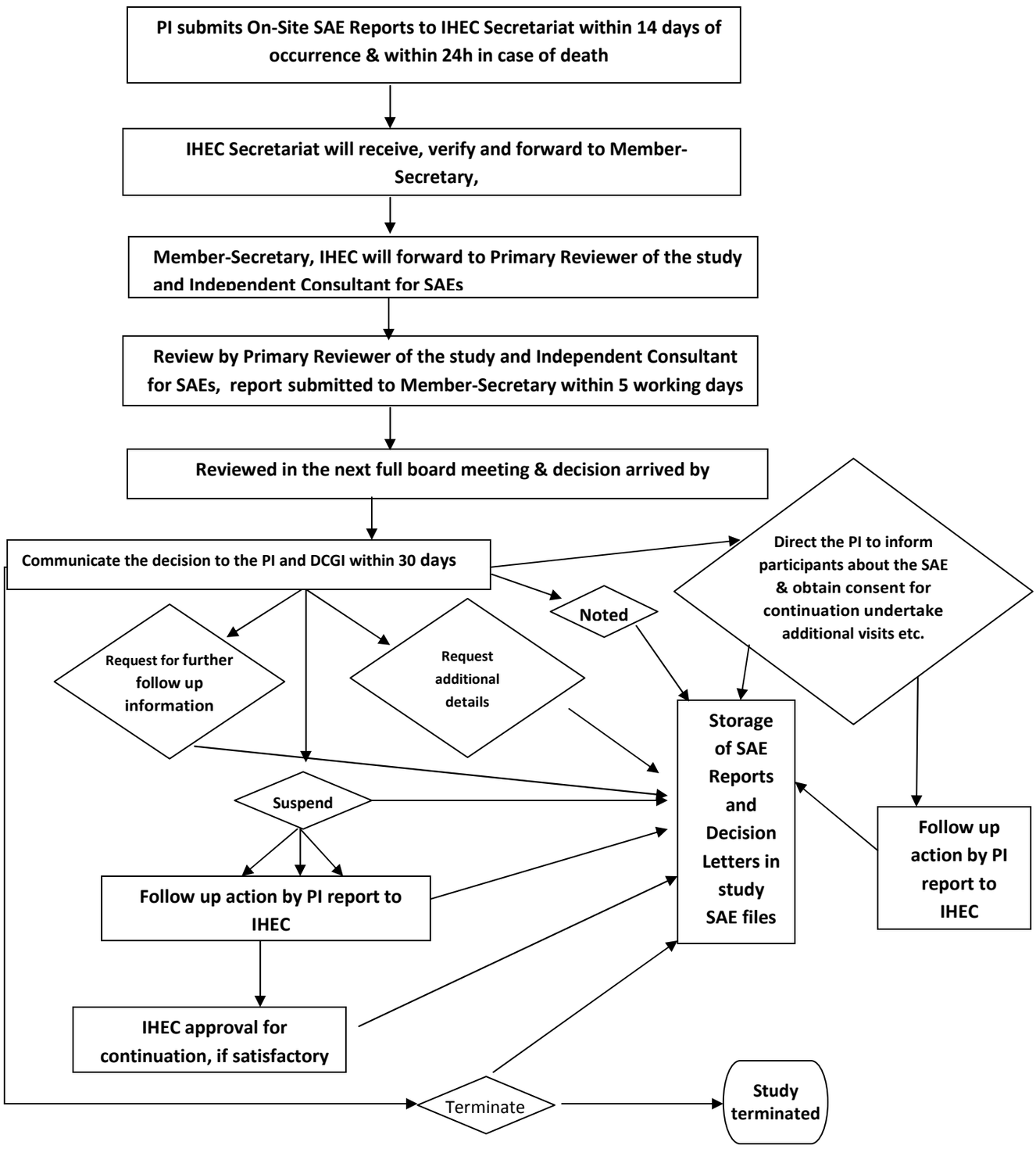
Project Title:

No. of Participants already enrolled in PSG IMS&R:

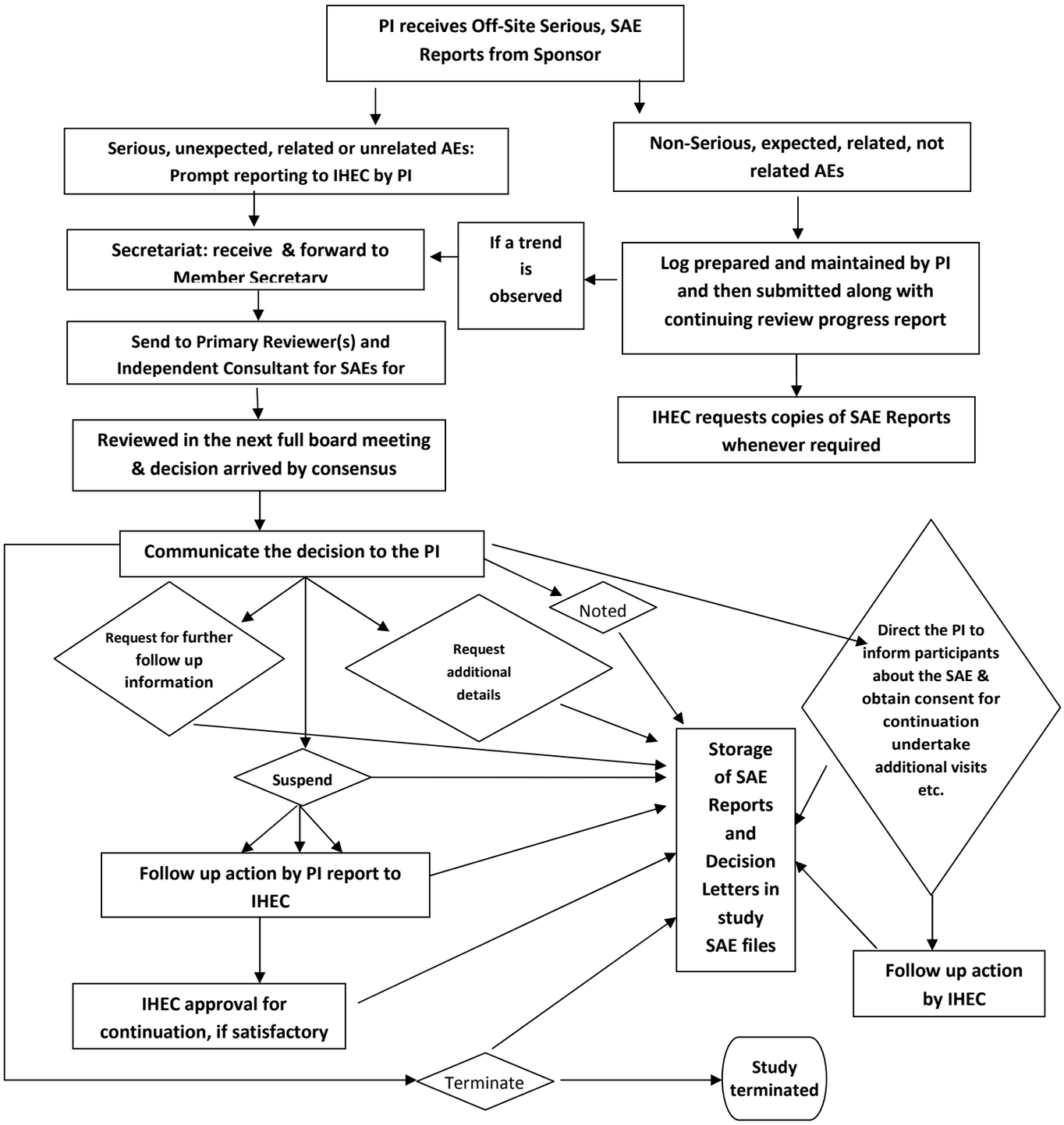
S. No.	Country	Date of Onset	Adverse event	Out Come	Remarks

Name and Signature of PI: Date:

Flowchart: Review of Serious Adverse Events (SAEs) Reports – On-Site SAEs (SOP 12)



Flowchart: Review of Serious Adverse Events (SAEs) Reports – Off-Site SAEs (SOP 12)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Study Completion Reports	**SOP 13**
SOP Number: SOP 13 – V 3.2	**Effective Date: 01.01.21**	

13.1 Purpose

The purpose of this SOP is to provide instructions on the review of Study Completion Report for study previously approved by the IHEC.

13.2 Scope

This SOP applies to the review of the Study Completion Report (SOP 13 – V 3.2 / ANX 01-V3.0) presented to the IHEC as written reports of study completed.

13.3 Responsibility

It is the responsibility of the IHEC members to review the study completion report which are mandated submissions by the PI at the completion of her/his study.

13.4 Detailed instructions

13.4.1 Before board meeting

- The secretariat will receive three hard copies and one soft copy each of Study Completion Report from the PI
- The Secretariat will follow instructions as in SOP 03 – V 4 for receiving and checking the reports
- Member-Secretary, IHEC will send hard copy to primary reviewer and soft copy to all the members
- The IHEC Secretariat should include the study completion reports in the agenda for IHEC meeting. (SOP 08 – V 3.2)

13.4.2 During the board meeting

- The members will discuss the report in the IHEC meeting.
- The Chairperson will call for consensus to accept it or request further information or take any other action as suggested by IHEC.

13.4.3 After the board meeting

- The Secretariat will note the decision in the meeting minutes and the study will be considered as closed if the documents are accepted.
- The IHEC decision is communicated to the investigator. In case further information / action is requested, the same should be provided by the PI and communicated to the IHEC Secretariat within 30 days. This update will be placed in the full board meeting of IHEC.
- The Secretariat will file the Final Report with requested details in the study file.
- All records must be archived for a period of at least 3 years after the completion/termination of the study
- Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations. Records may be archived for a longer period, if required by the sponsors/regulatory bodies

******

SOP 13 - V 3.2 / ANX 01-V 3.0

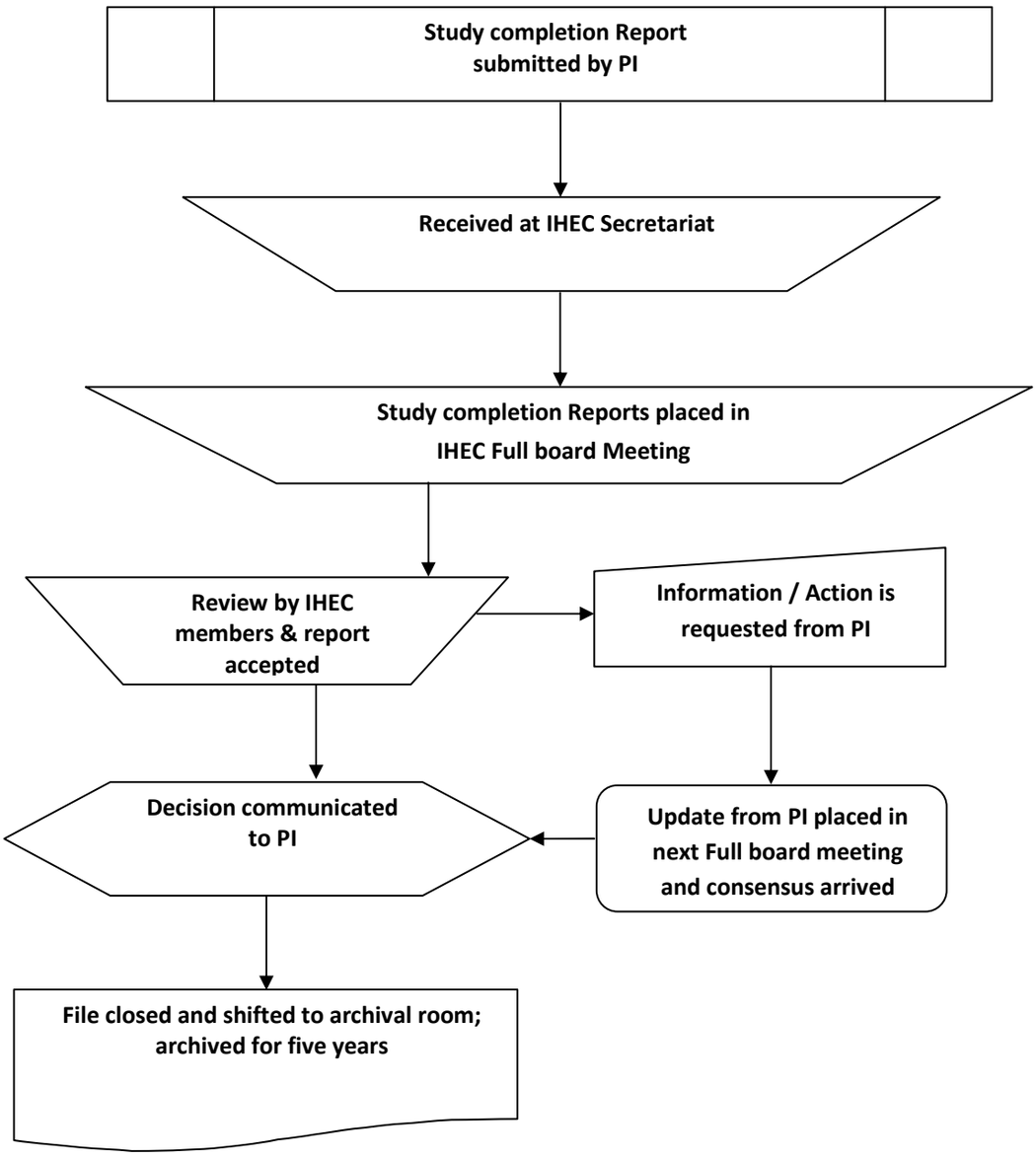
Study Completion Report Form

(To be filled by PI)

Proposal No. : Protocol Title: Principal Investigator:	
Phone number, email address	
Sponsor	
Address	
Phone, E mail	
Total no. of study participants recruited	
Study Initiation Date	
Total no. of study participants approved by the IHEC for recruitment	
*Abstract	
On site SAEs (Total number and type)	
Off site SAEs (Total number and type)	
Whether all SAEs intimated to the IHEC (Yes/No) If no give reason	
No. of participants withdrawn	
Reasons for withdrawal	
Protocol deviations-Violations (Number and nature)	
<u>Publications / presentations, if any</u>	
Any Ethical Issue encountered during the study	
<u>Undertaking</u>: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.	
Signature of PI Date:	

***** Extended abstract may be prepared under the following headings: Introduction (this section includes Review of Literature and justification), Objectives, Methods (Design, setting, participants, etc.,), Results and Conclusions. (Tables, if included, must be referred to in the report and attached as annexure.

Flowchart: Review of study completion reports (SOP 13)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Management of Premature Termination / Suspension / Discontinuation of the Study	**SOP 14**
SOP Number: SOP 14 – V 3.2	**Effective Date: 01.01.21**	

14.1 Purpose

The purpose of this SOP is to describe how the IHEC manages the premature termination / suspension / discontinuation of a research study.

14.2 Scope

This SOP applies to any study approved by IHEC that is being recommended for termination / suspension by IHEC / Regulatory bodies or discontinuation by sponsor / PI before its scheduled completion.

14.3 Responsibility

It is the responsibility of the IHEC to suspend /terminate any previously approved study when the safety or benefit of the study participants is doubtful or at risk.

14.4 Review Process

14.4.1 Receive recommendation for study Termination / Suspension / Discontinuation

- The Secretariat will receive recommendation and comments from the site monitoring team, PI, Sponsor or other authorized bodies for premature termination of study protocol.
- The IHEC can prematurely terminate the study if protocol non-compliance / violation is detected
- SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients as per the report given by the Independent Consultant for SAE.
- When IHEC decides to suspend / terminate a study, the decision will be informed to the PI requesting him to submit a protocol premature suspension/termination report in the prescribed format (SOP14 – V 3.2 / ANX 01- V3.0).
- If PI/Sponsor decides for discontinuation of the study, PI will submit the premature termination report in the prescribed format (SOP14 – V 3.2 / ANX 01- V3.0) to IHEC secretariat.
- The Secretariat will verify the contents of the documents for completion of Premature Termination/suspension/discontinuation Report (SOP 14 – V 3.2 / ANX 01- V3.0) signed and dated by the PI (three hard copies and one soft copy).
- The Secretariat will sign and date the report upon receipt and a copy is given to the PI.
- Member-Secretary, IHEC will send hard copies of the report to the Primary

reviewers and soft copies to other members for review.

14.4.2 At Full board meeting

- IHEC will review the study Termination / Suspension / Discontinuation report at full board meeting to discuss about the recommendation.

14.4.3 After the board meeting

- The study will be considered as terminated / suspended / discontinued , if the document is accepted and the Secretariat will note the decision in the meeting minutes
- In case further information / action is requested, the same should be followed by the PI and communicated to the IHEC Secretariat within 30 days. This update will be placed in the full board meeting of IHEC for ratification and final decision
- The IHEC decision is communicated to the investigator within 14 days of the meeting. In case of termination of the study intimation will include the reasons clearly stated .

14.5 Filing the documents

The Secretariat will place the corresponding report and decision letter in the study file.

14.6 Post-review activities:

14.6.1 Suspension:

- In case of suspension, IHEC will revoke the suspension after receipt of satisfactory compliance report from the PI.

14.6.2 Termination / Discontinuation:

- In case of termination / discontinuation, IHEC Secretariat will archive the entire study protocol and the report for a period of five years from the date of termination / discontinuation of the project.

******

SOP 14 – V 3.2 / ANX 01- V3.0

Premature Termination / Suspension / Discontinuation Report

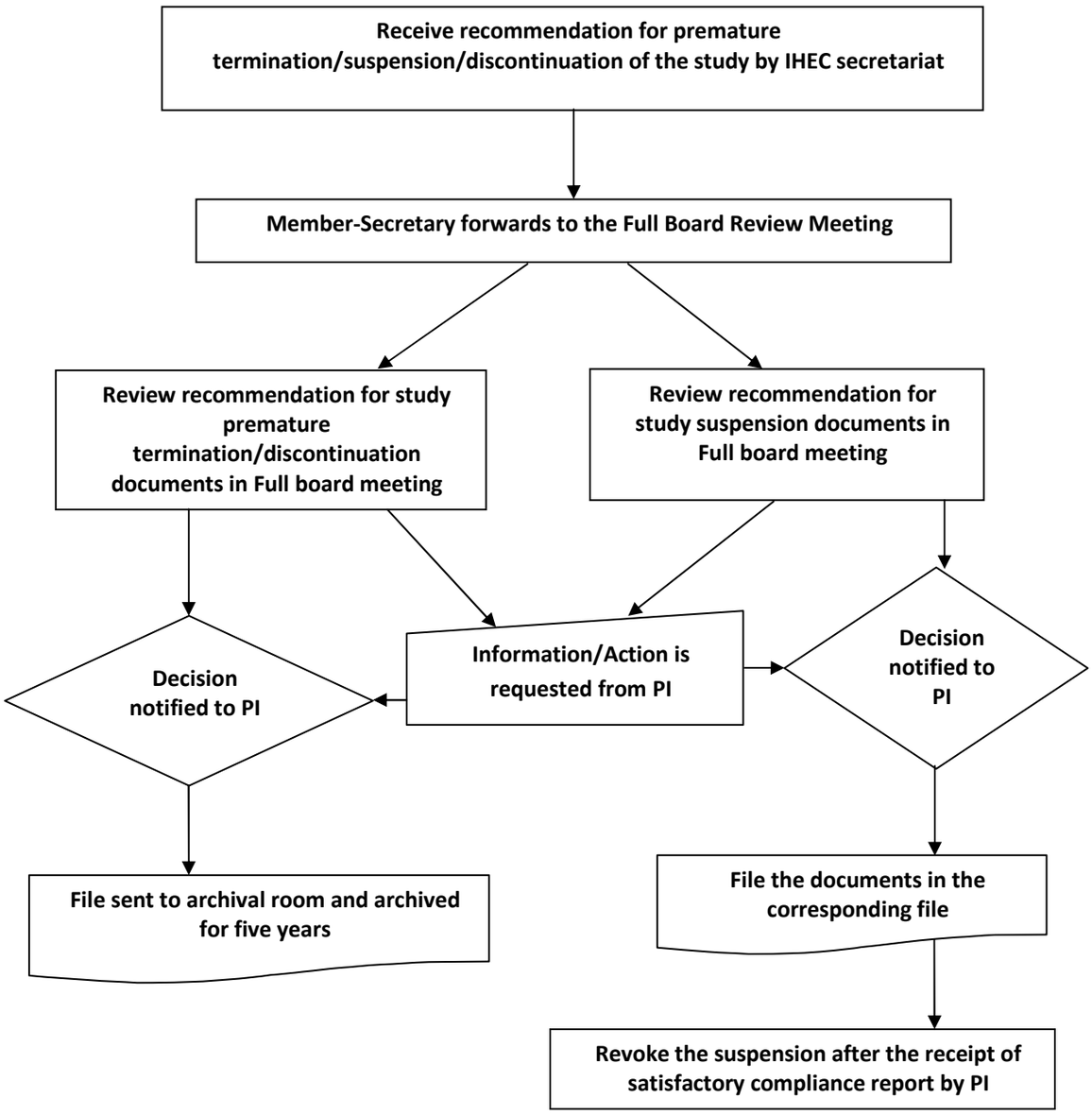
(To be filled by PI)

Proposal No.:	
Protocol Title:	
PI:	
Phone :	E-Mail:
Study Site:	
Sponsor:	
IHEC Approval Date:	Date on which Status Report Last Submitted to IHEC:

Starting Date:	Termination Date:
No. of Participants Enrolled:	No. of Participants Completed:
No. of Ongoing Participants:	No. of Drop Outs:
SAE (Total No.):	SAE Event:
Summary of Results:	
Reason for Premature Termination/Suspension/Discontinuation:	
Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.	
PI Signature:	Date:

Flowchart:

Management of Premature Termination / Suspension / Discontinuation of the Study (SOP 14)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Review of Request for Waiver of Written Informed Consent and Waiver of Consent	**SOP 15**
SOP Number: SOP 15 – V 1.2	**Effective Date: 01.01.21**	

15.1 Purpose

The purpose of this SOP is to describe the type of research projects for which the IHEC may grant waiver of written informed consent or waiver of consent itself.

15.2 Scope

This SOP applies to IHEC review of all protocols with a request for waiver of written informed consent or waiver of consent.

15.3 Responsibility

The decision can be taken by the IHEC at the expedited subcommittee meeting (the report is submitted for discussion in the full board meeting) or in some cases during full board meeting.

15.4 Waiver of Consent / Waiver of written Informed Consent Process

The IHEC Secretariat will check for completeness of the documents when a request for waiver of consent is submitted by the PI in the given format SOP 15 - V 1.2 / ANX 01-V 1.0.

The IHEC will review the request taking into consideration on conditions for which waiver of consent may be granted as per paragraph No. 15.5.

The IHEC 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, as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.

The decision whether to grant the waiver is taken in expedited subcommittee meeting (but it shall be reported to full board) or in some cases during full board meeting.

The decision regarding approval/disapproval of waiver is informed to the PI in writing.
If the waiver is not granted, the IHEC will provide reasons for the same.

15.5 Type of research projects which may qualify for consent waiver:

15.5.1 Retrospective studies, where participants are deidentified or cannot be contacted.
e.g., a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease.

15.5.2 When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be 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.

15.5.3 In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized.

The following points need to be considered.

a. The following documents need to be submitted for the IHEC review
   A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each participant 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. Investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. Since a specific number of study participants are to be recruited, it is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.

15.5.4 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.

15.5.5. 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.

15.5.6 In emergency situations the IHEC can allow waiver of consent for recruiting participant in a research study.

For example,

- When no surrogate consents can be taken,
- When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible,

However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

******

SOP 15 - V 1.2 / ANX 01-V1.0

Application form for requesting Waiver of Written Informed Consent/ waiver of consent

(To be filled by PI)

1. Proposal Number :
2. Principal Investigator's name:
3. Department:
4. Title of project:

5. Names of co-investigators:

6. Request for waiver of informed consent:

   Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IHEC to consider waiver of consent).

   1. Research involves 'less than minimal risk'
   2. There is no direct contact between the researcher and participant
   3. Emergency situations
   4. Any other (please specify)

   I hereby assure that the rights of the participants will not be violated.

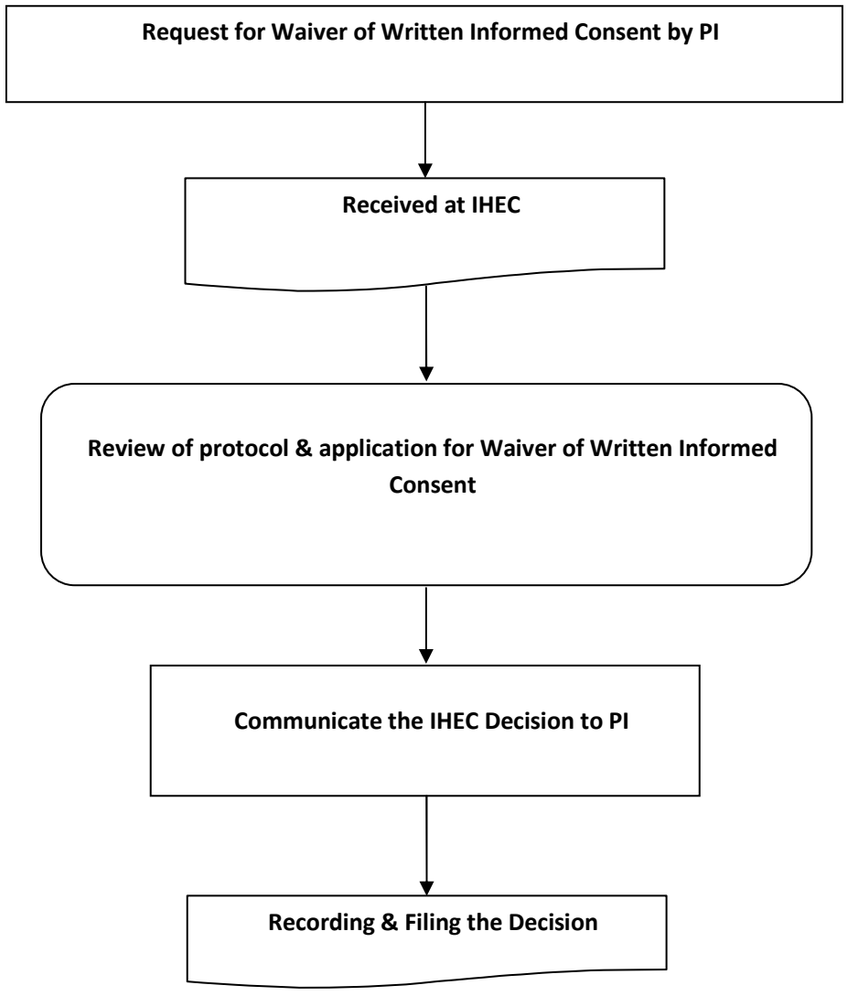
   Following are the measures described in the Protocol for protecting confidentiality of data and privacy of research participant
   1.
   2.
   3.

Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same.

Principal Investigator's signature with date:

Flowchart:

Waiver of Written Informed Consent and Waiver of Consent (SOP 15)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Site Monitoring and Post-Monitoring Activities	**SOP 16**
SOP Number: SOP 16 - V 1.2	**Effective Date: 01.01.21**	

16.1 Purpose

The purpose of this SOP is to provide the procedures for site monitoring of an IHEC approved protocol.

16.2 Scope

This SOP applies to selection and monitoring of sites where IHEC approved studies are conducted.

16.3 Responsibility

It is the responsibility of the IHEC or its nominees on its behalf to perform on-site inspection of selected sites of approved studies.

16.4 Site Monitoring Process

16.4.1 Selection of study sites

16.4.1.1 R**outine monitoring** sites may be identified at the time of approval of the project by the Full Board, which had been recorded in the minutes.

16.4.1.2 "For-cause" monitoring / "Root cause analysis" will be performed at sites for reasons identified by any member of IHEC, approved by Chairperson. For-cause monitoring could be initiated, in any of the following conditions: for high number of protocol violations, large number of studies carried out at the study sites, large number of SAE reports, high recruitment rate, Non-compliance or suspicious conduct and any other cause as decided by IHEC.

16.4.2 Before the visit

- In case of routine monitoring, the IHEC Secretariat will inform the IHEC members in the Full Board meeting, one month prior to the stipulated date of monitoring.
- For cause / routine monitoring of the project, the IHEC Chairperson will designate one or two IHEC members or its nominees to perform site monitoring.
- The IHEC Secretariat will inform the PI in writing about the date / time of monitoring visit and request for confirmation letter from the PI for his / her availability during the visit.
- The nominees will sign Confidentiality agreement to go through the protocol files.
- The IHEC members / nominees will review the IHEC project files for the study and site profile and make appropriate notes.
- The IHEC members / nominees may copy some parts of the IHEC project files for comparison with the site files.

16.4.3 During the visit

The IHEC members / nominees will brief the PI about site monitoring visit before starting:

i. Confidentiality agreement will be signed by site monitoring team at the study site
ii. The team will verify the informed consent document to make sure that the site is using the most recent version
iii. The participant files will be reviewed randomly to ensure that subjects are signing the correct informed consent.
iv. The informed consent process will be observed, if necessary SOP 16 - V 1.2/ ANX 02-V 1.0
v. Laboratory and other facilities necessary for the study at the site will be observed, if possible
vi. The project files for the study will be reviewed to ensure that documentation is appropriate
vii. The team will verify whether the investigator follows the approved protocol and all approved amendment(s), if any
viii. The team will ensure whether the investigator and the investigator's study staff are adequately informed about the study
ix. The team will verify that the investigator and the investigator's study staff are performing the specified study functions in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution and have not delegated these functions to unauthorized individuals
x. The team will verify whether the investigator is enrolling only eligible study participants
xi. The team will verify the source documents and other study records for completeness
xii. The team will check the accuracy and completeness of the CRF entries, source documents and other study -related records against each other
xiii. The team will verify whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IHEC, the sponsor, and the applicable regulatory requirement(s)
xiv. The team will collect views of the study participants if possible
xv. The team will fill the Site Monitoring Visit Report Form SOP 16 - V 1.2 /ANX 01-V 1.1
xvi. De-briefing will be done to the PI at the end of site monitoring process

16.4.4 After the visit

- The IHEC members / nominees will submit the report within 14 days to the IHEC Secretariat and the Member–Secretary will summarize the findings during the Full Board meeting for review.
- Full board recommendations of Corrective and Preventive Actions (CAPA) for continuation / change the study / premature termination of the project will be sent to the PI in writing within 14 days of the meeting. In case of termination of the study intimation will include the reasons clearly stated.
- The Secretariat will place the report and decision letter in the corresponding protocol files.

16.4.5 Post-review activities

Compliance report to be submitted by the PI within the specified time period as decided by the IHEC. The IHEC Secretariat will keep track of the reports. Reminders will be sent if no reports are received.

A separate file that identifies investigators who are found to be non-compliant with national / international regulations or who fail to follow protocol approval stipulations or fail to respond to the IHEC request for information/action is maintained and reviewed by the IHEC periodically.

In case a PI fails to respond to the IHEC letter, it will be discussed at the next full board meeting and a decision will be taken for specific action

******

SOP16 - V 1.2 / ANX 01-V 1.1

Site Monitoring Visit Report
(To be filled by site monitoring team)

Proposal Number:	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Site:
Sponsor:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs:
Are site facilities appropriate? Yes No	Comment:
Are Informed Consents of recent version used? Yes No	Comment:
Archives of AV consent available Yes No	Comment
Is it approved by the IHEC? Yes No	Comment:
Whether consent has been taken from all patients? Yes No	Comment:
Whether recruitment strategies (Inclusion/Exclusion criteria) followed as per protocol? Yes No	Comment:
Whether appropriate vernacular consent have been taken? Yes No	Comment:
Are Protocols of recent version used? Yes No	Comment:
Is it approved by the IHEC? Yes No	Comment:
Any adverse events found? Yes No	Comment:

Any SAEs found? Yes No	Comment:

Were the SAEs informed to IHEC within 7 working days & SAE death within 24 hrs.? Yes No	Comment:
Any protocol non-compliance / violation? Yes No If yes informed to IHEC 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 participants protected? Good Fair Not good	Comment:
Any outstanding tasks or results of visit? Yes No	Give details:
Is the documentation complete? Yes No	Comment:
Duration of visit: ……. hours	Starting from: Finish:
Name of IHEC/ representatives:	
Completed by: Signature:	Date:
Name of study team member (PI/Co-I): Sign & Date:	

SOP16-V 1.1 / ANX 02-V 1.0

Checklist for Informed Consent Process

1. Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
2. Is Assent form obtained from matured minor participants (if the study participants are between the age group 7 – 18 years) ☐ Yes ☐ No ☐ Not Applicable	Comment:
3. Is Parental consent obtained from matured minor participants (if the study participants are between the age group 7 – 18 years) ☐ Yes ☐ No ☐ Not Applicable	Comment:
4. Language of the Informed Consent process ☐ Clear ☐ Unclear	Comment:
5. Nature and purpose of the study explained clearly ☐ Yes ☐ No	Comment:
6. Is duration of Participation in the study communicated to participant ☐ Yes ☐ No	Comment:
7. Procedures to be followed clearly explained ☐ Yes ☐ No	Comment:
8. Investigations, if any to be performed, clearly explained ☐ Yes ☐ No	Comment:
9. Are foreseeable risks and discomforts adequately explained ☐ Yes ☐ No	Comment:
10. If the project involve more than minimal risk, is it explained to participant? ☐ Yes ☐ No	Comment:
11. Are benefits to participants / community / medical profession explained? ☐ Yes ☐ No	Comment:
12. Is the participant informed about compensation? ☐ Yes ☐ No ☐ Not applicable	Comment:

13. Is the participant informed regarding appropriate treatment for Study-Related Injuries? ☐ Yes ☐ No ☐ Not applicable	Comment:
14. Alternate treatment, if available, has been explained ? ☐ Yes ☐ No	Comment:
15. Is the participant's privacy maintained adequately? ☐ Yes ☐ No ☐ Not applicable	Comment:
16. Has the participant been explained about maintaining Confidentiality of data? ☐ Yes ☐ No ☐ Not applicable	Comment:
17. No loss of benefits on withdrawal. Is it explained? ☐ Yes ☐ No	Comment:
18. Did the PI inform her/his contact details to the study participant orally? • Name ☐ Yes ☐ No • Mobile ☐ Yes ☐ No • Email ID ☐ Yes ☐ No • Emergency Contact Nos. ☐ Yes ☐ No • Contact address ☐ Yes ☐ No	Comment:
19. Did the PI inform contact details of IHEC to the study participant orally? • Name ☐ Yes ☐ No • Mobile ☐ Yes ☐ No • Email ID ☐ Yes ☐ No • Emergency Contact Nos. ☐ Yes ☐ No • Contact address ☐ Yes ☐ No	Comment:
20. Did the PI inform contact details of other contact persons to the study participant orally? • Name ☐ Yes ☐ No • Mobile ☐ Yes ☐ No • Email ID ☐ Yes ☐ No • Emergency Contact Nos. ☐ Yes ☐ No • Contact address ☐ Yes ☐ No	Comment:
21. Is the recruitment of Participants Voluntary, Non-Coercive? ☐ Yes ☐ No	Comment:

22. If the participant needs to undergo HIV testing or diagnostic genetic testing or any other investigation requiring pre-test / post-test counseling, is information related to pre-test / post-test counseling described? ☐ Yes ☐ No ☐ Not applicable	Comment:
23.If there is storage of biological samples. Whether the following are obtained/explained? a. Participant's willingness to consent or otherwise for storage ☐ Yes ☐ No ☐ N A b. Period of storage ☐ Yes ☐ No ☐ N A c. Future use of sample ☐ Yes ☐ No ☐ N A d. Willingness of the participant to receive the results ☐ Yes ☐ No ☐ N A	Comment:
24. Is there inducement for Participation present? ☐ Unlikely ☐ Likely	Comment:
25. Is provision for Medical / Psychosocial Support explained? ☐ appropriate ☐ inappropriate	Comment:
26. Is provision for post-trial access explained? ☐ appropriate ☐ inappropriate	Comment:
27. Is sufficient time given to read Patient Information sheet ☐ Yes ☐ No	Comment:

Comments:		
Signature :		Date:

SOP16-V 1.1 / ANX 03-V 1.0

Research participant feedback form

Dear Research Participant,

We thank you for accepting to participate in the research study. We would be grateful if you could take a few moments to respond to this questionnaire so that we can ensure the research process being conducted in compliance with ethical guidelines. Please drop this form in the drop box facility or hand it over to the research team. Thank you.

Name of the Participant	**Contact Information**	**Date of the visit**
Name of the Research Doctor(Principal Investigator)	**Department**	**Study site**

Please tick ✓ the appropriate response

Please rate your overall experience as a research participant

Excellent ☐ Good ☐ Poor ☐ Average ☐

Give your feedback rating on Communication of the following :	Excellent	Good	Satisfactory	Poor	Very Poor
● Process of getting informed consent					
● Details of the research study					
● Benefits of the research study					
● Risks of the research study					
● Alternate treatment options					
● Medical management of study related injury					
● Compensation for study related injury*					

* For regulatory trials

When the research doctor was collecting data was privacy ensured?

Yes ☐ No ☐

Did the investigator assure of the confidentiality of the data?

Yes ☐ No ☐

Did the research doctor (Principal investigator) share his/ her contact information with you ?

Yes ☐ No ☐

Any suggestions to improve the research process?

……

……

Please note:

If you choose to remain anonymous you don't have to fill in your name

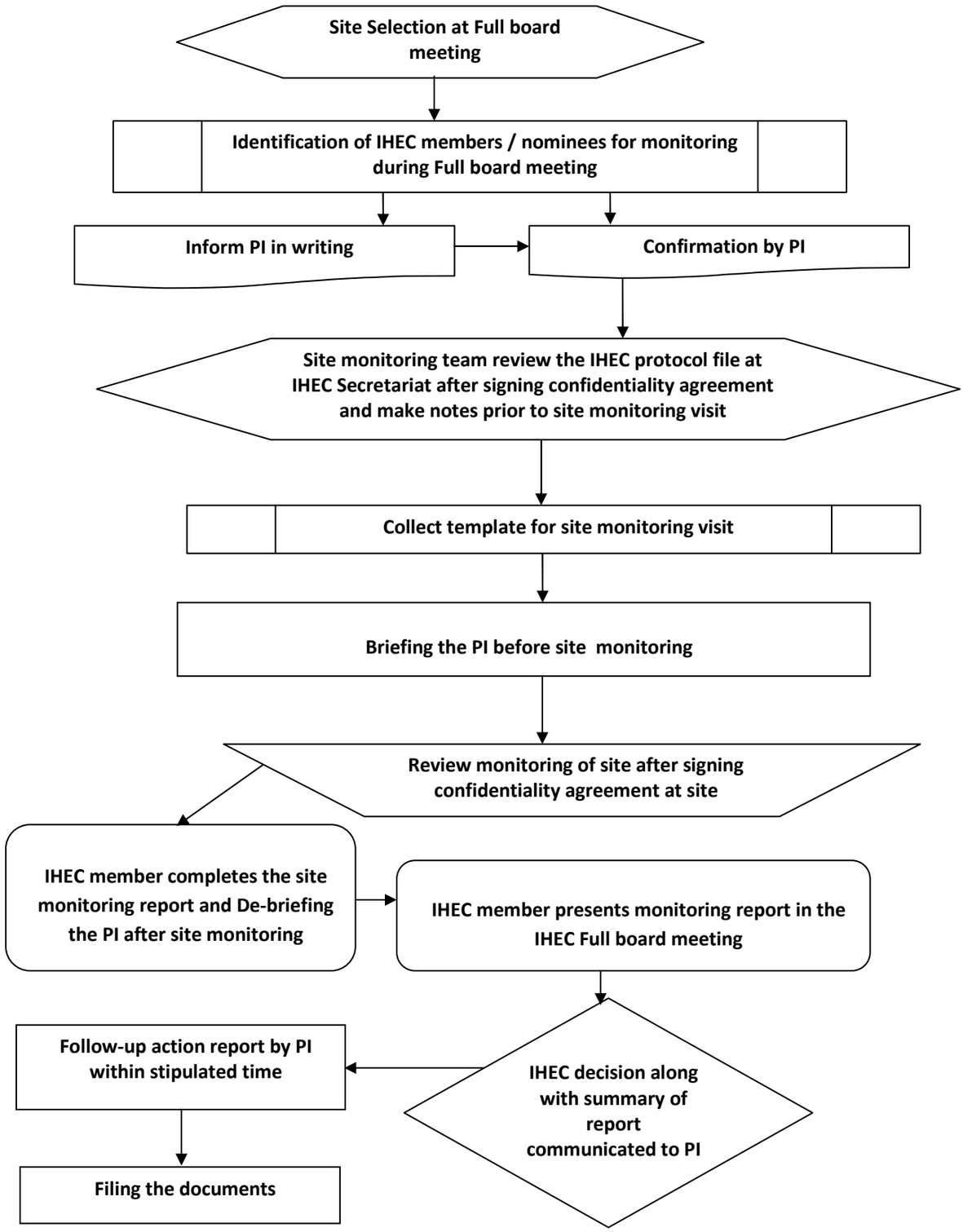
If you prefer to send this form by post please send it to the following address

To
The Chairperson/ Member Secretary
Institutional Human Ethics Committee
PSG Institute of Medical Sciences and Research
Coimbatore 641004

If you have any other suggestions please contact

Institutional Human Ethics Committee contact no: 0422-4345818

Flowchart: Site Monitoring (SOP 16)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Dealing with Participant's / Patients' Requests and Complaints that come to the IHEC	**SOP 17**
SOP Number: SOP 17 - V 2.1	**Effective Date: 01.01.21**	

17.1 Purpose

This procedure provides guidelines for dealing with requests by study participants regarding their rights as a participant or to resolve their complaints in any approved research study by IHEC.

17.2 Scope

This SOP applies to all requests concerning the rights and well-being of the study participants participating in studies approved by the IHEC.

17.3 Responsibility

It is the responsibility of the IHEC Secretariat for providing required information to the research participants in case of queries received from research participants.

17.4 Participant Request / Complaint Redressal Process

i. The IHEC member/ administrative staff receive an inquiry/request or feedback form from study participant. (SOP 17 –V 2.1 / ANX 01- V 1.0)
ii. The Secretariat will inform the Chairperson about the query / complaint received from the study participant.
iii. The Chairperson / Members designated by the Chairperson will provide information required by the study participant.
iv. In case of complaint received from a study participant, the Chairperson initiates a process to identify and address any injustice that may have occurred.
v. The Chairperson will direct the Member-Secretary to consider the matter for discussion at a full board meeting or to call an emergency meeting of 2 or more IHEC members for discussion or to appoint a subcommittee of 2 or more IHEC members for enquiry in order to resolve the matter.
vi. The Chairperson / Member-Secretary / designated IHEC members will assess the situation and mediate a dialogue between the study participant and the investigator in an attempt to resolve the matter.
vii. The IHEC will insist on factual details to determine reality between truth and individual perception. Based on this a root cause analysis (RCA) will be done.
viii. The IHEC will recommend Corrective and Preventive Actions (CAPA) based on the RCA.
ix. The final decision will be informed to the study participant by the Member-Secretary.
x. The information including any action taken or follow-up will be recorded in the form (SOP 17 –V 2.1 / ANX 01- V 1.0) and the form is signed and dated.
xi. The IHEC members are informed about the action taken and the outcomes in the Forthcoming IHEC meeting.

17.5 Filing the request document

The record form is placed in the "response" file by the Member-Secretary / administrative Staff and a copy of the same is kept in the study file.

17.6 Appellate authority for appeal

If the study participant is not satisfied with the decision of the IHEC, s/he may appeal to the Dean, PSG IMS&R for remedial action.

SOP 17 – V 2.1 / ANX 01-V 1.0

Form for filing of Complaint / Query
(To be filled by IHEC Member-Secretary)

Date Received:	
Received by :	
Request from :	Telephone No of the caller FAX No Letter / Date E-mail / Date Walk-in: Date / Time Others, specify
Participant's Name:	
Contact Address: Phone:	
Proposal number:	
Title of the Study:	
Date of enrollment in the study:	
What is requested?	
Action taken:	
Outcome:	

Name of the Chairperson / Member-Secretary _____

Signature of the Chairperson / Member-Secretary _____Date: _____

SOP 17 – V 4.2 / ANX 02-V 1.0

Rights and Responsibilities of the Research participants

Rights of the Research Participants

- Right to voluntary participation in research study.
- Right to informed consent and if necessary audio-video consenting before participation in any research study to ensure the following:
    - Right to information regarding investigational drug/ treatment/procedure, reason for study, benefits, risk, side effects, duration of study, treatment option available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation* in an understandable language
    - Right to have an interpreter if needed
    - Right to withdraw anytime from participation in the study
    - Right to have continued medical care irrespective of not consenting or withdrawal of consent
    - Right to privacy and confidentiality
    - Right to possess a copy of the informed consent document with the contact details of the Institutional Human Ethics Committee and Research Doctor (Principal Investigator)
- Right to be treated with dignity, respect and courtesy
- Right to be informed on how to voice a complaint and seek redressal
- Right to get 24 hours emergency care

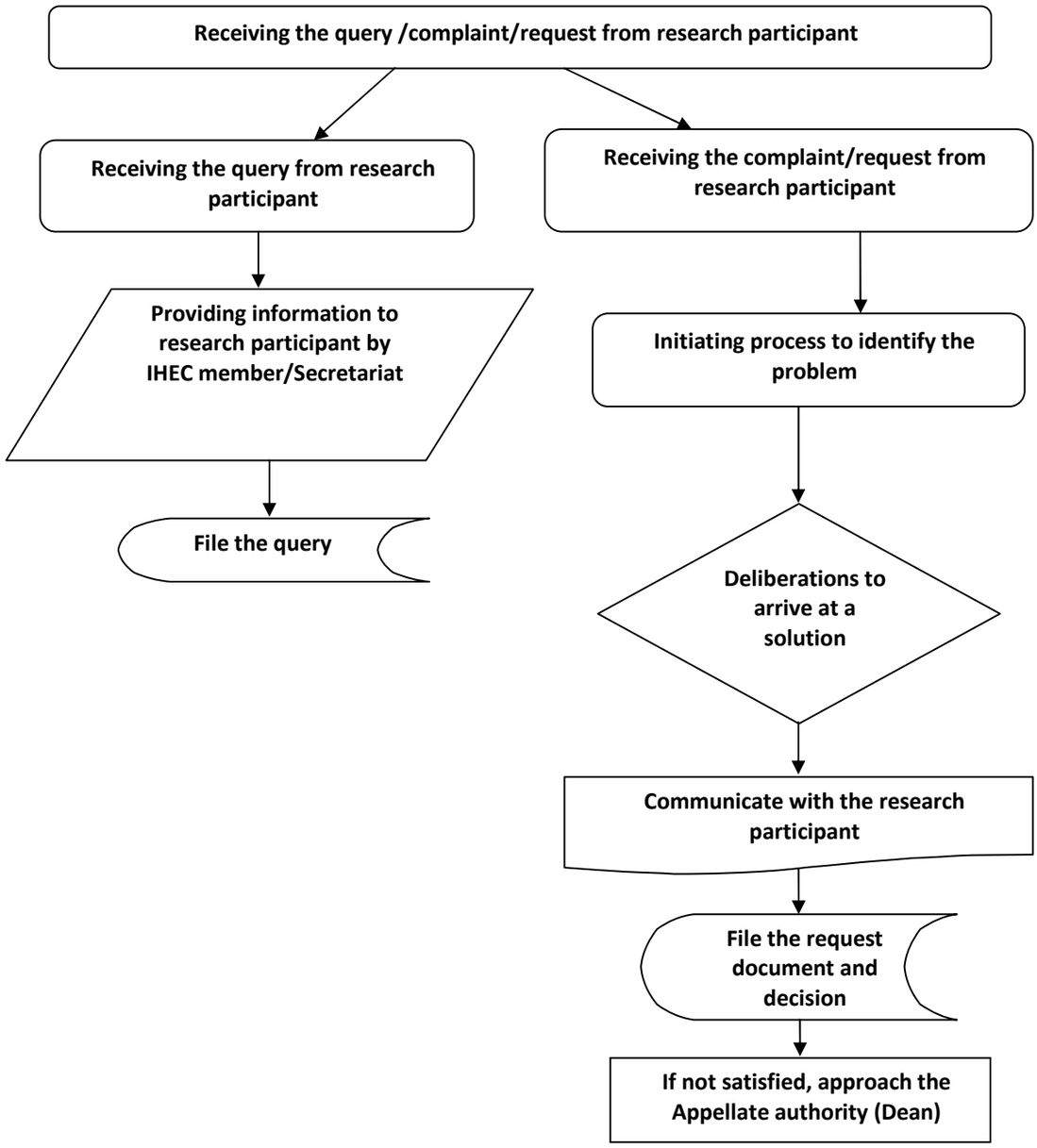
*Regulatory Trials

Responsibilities of the Research Participant

- To provide correct and complete information including full name, age, address, telephone number , complete information of previous medical history.
- To disclose to research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in the last one year
- To be compliant with research protocol and procedures
- To seek clarification when he/she does not understand what the research study team explains about the research process and or diagnosis and treatment
- To inform the research doctor (Principal Investigator) immediately in case of any injury or development of any new medical conditions/symptoms
- Not to take any medications without the knowledge of research doctor and research study team
- To adhere to instructions, advice and restrictions regarding treatment plan and visit schedules
- To treat hospital staff and study team with courtesy

IHEC PSGIMS&R Contact details Chairperson/Member Secretary 0422 4345818

Flowchart:
Dealing with participants requests and complaints that come to IHEC (SOP 17)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents	**SOP 18**
SOP Number: SOP 18 – V 3.2	**Effective Date: 01.01.21**	

18.1 Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the IHEC, PSG IMS & R, and storage and archival of closed files and retrieval of documents.

18.2 Scope

This SOP applies to all study files and their related documents that are maintained in the IHEC office and closed study files in the IHEC archival room.

18.3 Responsibility

It is the responsibility of IHEC staff to ensure that all study files are prepared, maintained during the study period and kept securely for a period of five years after the closure of the project.

18.4 Maintenance of the active study files

- Study file should be established on receipt of the proposal and should comprise all essential documents and correspondence related to the study / protocol. (SOP 18 - V 3.2/ANX 01-V2.0, SOP 18 - V 3.2/ANX 02-V2.0 & SOP 18-V 3.2/ANX 03-V2.0)
- The study files are assigned unique identifiers i.e. serial proposal No.
- A database of proposals received is maintained in an Excel format
- All related documents of the approved study are gathered, classified appropriately and placed in the study file.
- 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.

18.5 Maintenance of closed study files

- Once the study is closed, the related study files are shifted to the IHEC Archival room.
- All closed study files are archived in the IHEC archival room for a period of five years from the date of closure of the study.
- Files on SAE will be maintained lifelong or maximum of 21 years
- A log book for archival of study documents will be maintained.

18.6 Accessibility / Retrieval

Study files will be made available for inspection, copying or any other purposes (example,

research on SAEs) by authorized representatives of regulatory authorities or independent researchers after receiving the request in writing, clearly stating the purpose (SOP 18 - V 3.2/ANX 04 - V1.0)

The IHEC staff will furnish a copy of the required document within a week with IHEC Secretary's consent.

A log book of retrieval of documents will be maintained.

18.7 Disposal of closed files and copies of protocols and documents submitted for IHEC review

After completion of archival period the closed files will be shredded and disposed off by authorized IHEC personnel.

Copies of protocols and documents submitted for IHEC review and any other extra copies will be shredded off by the authorized IHEC personnel after the IHEC meeting without any notification to PI.

A formal disposal log (SOP 18 - V 3.2 /ANX 05-V1.0) will be maintained, providing details of documents that are being disposed.

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SOP 18 - V 3.2 / ANX 01 – V 2.1

Check list for Protocol File - Regulatory Trials

Protocol Title:

Proposal No.

S.No.	Description	Yes	No	NA
1	Covering Letter			
2	IHEC submission form			
3	Study Protocol			
4	Questionnaire / Proforma in English			
5	Questionnaire / Proforma in all relevant regional languages			
6	Investigator's Brochure (IB) for recruiting participants			
7	Patient Information Sheet in English			
8	Patient Information Sheet in all relevant regional languages			
9	Informed Consent form in English			
10	Informed Consent form in all relevant regional languages			
11	E Diary			
12	Insurance coverage certificate (for study participants)			
13	Indemnity insurance certificate (for the study team)			
14	HMSC/DCGI//BARC clearance if obtained			
15	CTRI Number			
16	Clinical Trial Agreement (CTA)			
17	Copy of advertisements/Information brochures			
18	Material Transfer Agreement (MTA)			
19	Other Institutional Ethics Committees' clearance, if applicable			
20	Institutional Animal Ethics Committee clearance, if applicable			
21	CV of all investigators			
22	Evidence of fee payment (DD/ Cheque/ online transfer)			
23	Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from those departments of PSG IMS & R			
24	Meeting intimation letter from IHEC			
25	Query letter from IHEC			
26	PI's reply to IHEC queries			

27	IHEC approval letter			
27	Study initiation letter			
28	Amendments to study documents			
29	IHEC approval for amendments			
30	Deviations / violations			
31	IHEC approval for deviation / violation			
32	SAEs			
33	IHEC approval for SAEs			
34	Site monitoring details			
35	Reminder for renewal			
36	Request for renewal of approval			
37	Renewal letter			
38	Study completion / close-out report			
39	IHEC approval for study completion / close-out			
40	Others, if any (Please specify):			

SOP 18 - V 3.2 / ANX 02-V 1.0
Check list for Protocol File – other than regulatory trials

Protocol Title:

Proposal No.

S.No.	Description	Yes	No	NA
1	Covering Letter			
2	IHEC submission form			
3	Study Protocol			
4	Questionnaire / Proforma in English			
5	Questionnaire / Proforma in all relevant regional languages			
6	Patient Information Sheet and informed consent form in English			
7	Patient Information Sheet and informed consent form in all relevant regional languages			
8	Confidentiality agreement (signed by all investigators)			
9	Application for waiver of consent			
10	CV of all investigators			
11	Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from those departments of PSG IMS & R			
12	Permission letter(s) from authorities / Heads of Institutions, if study is conducted outside PSG			
13	Other Institutional Ethics Committees' clearance			
14	Institutional Animal Ethics Committee clearance			
15	Meeting intimation letter from IHEC			
16	Query letter from IHEC			
17	PI's reply to IHEC queries			
18	IHEC approval letter			
19	Study initiation letter			
20	Amendments			
21	IHEC approval for amendments			
22	Deviations / violations			
23	IHEC approval for deviation / violation			

24	Site monitoring details			
25	Reminder for renewal			
26	Request for renewal of approval			
27	Renewal letter			
28	Study completion / close-out report			
29	IHEC approval for study completion / close-out report			
30	Others, if any (Please specify):			

SOP 18 - V 3.2 / ANX 03 – V 1.0
Check list for Case Report File

Protocol title:

Proposal No.:

S.No.	Description	Yes	No	NA
1	Covering Letter			
2	IHEC submission form			
3	Brief description of the case including photos and investigations, if any			
4	Informed Consent form in English, if applicable			
5	Informed Consent form in all relevant regional languages, if applicable			
6	Confidentiality agreement, if applicable			
7	Application for waiver of consent, if applicable			
8	CV of all investigators			
9	Others, if any (Please specify):			
10	Queries, if any			
11	Reply to queries			
12	IHEC approval letter			

SOP 18 - V 3.2 / ANX 04 –V 1.0

Document Request Form

Project No.:	Project Title :
Name of PI:	
Requested by:	
Documents requested:	
Purpose of the request:	
Principal Investigator's Signature:	
Signature of the requesting person:	
Comments by Member-Secretary, IHEC: Signature of Member-Secretary, IHEC with date:	
Decision by the Dean , PSG IMS&R: Signature of the Dean, PSG IMS&R with date:	

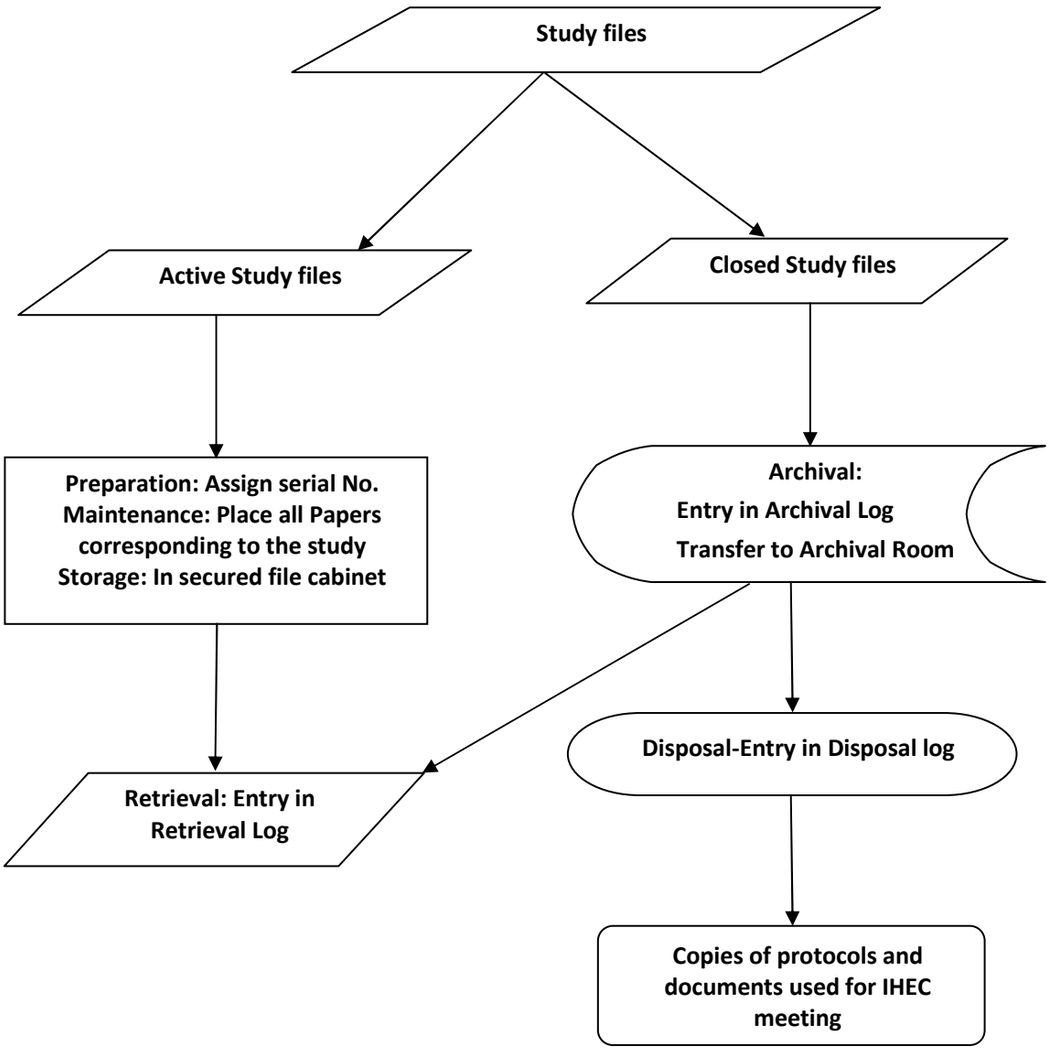
SOP 18 - V 3.2 / ANX 05 - V 1.0

Format for disposal of study documents log

Proposal No.	Title	PI	No of files	EC approval	Study Initiation Date	Study Closure Date	Disposed (Name & Sign) of Authorized Individual

Flowchart:

Maintenance of Active Project Files, Archival of Closed Files and Retrieval of Documents (SOP 18)



Institutional Human Ethics Committee, PSG Institute of Medical Sciences & Research		
	Title: Vulnerable Population	**SOP 19**
SOP Number: SOP 19 – V 1	**Effective Date: 01.01.21**	

19.1. Purpose

This SOP is designed to describe and act as a guideline for the IHEC to manage research protocol submissions related to vulnerable population.

19.2. Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IHEC.

19.3. Responsibility

- It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines
- IHEC Chairperson / Member Secretary are responsible for ensuring that IHEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes
- It is the responsibility of the IHEC Member-Secretary to review the protocols and appoint members of the IHEC to review protocols which are related to vulnerable subjects

19.3.1 Reviewing protocols with vulnerable participants

i) 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
- IHEC members dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study.

ii) The final version of the protocol will be approved at a full board meeting.

iii) Wherever necessary the IHEC 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.

19.4. Vulnerable participants

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens, social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so. It includes children, prisoners, pregnant women, handicapped or mentally differently-abled persons, refugees, displaced persons, students, staff and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

19.4.1 Characteristics of vulnerable individuals/populations/group

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
- 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.

19.5. Principles of research among vulnerable populations

- The key principle to be followed when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.
- Research using vulnerable participants is not prohibited by international ethical codes or regulations but their inclusion needs to be justified and special precautions need to be implemented for their protection
- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- If vulnerable populations are to be included in research, all stake holders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.
- Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group

19.5.1 Additional safeguards/protection mechanisms

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the

caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate

- Researchers must justify the inclusion of a vulnerable population in the research.
- ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.
- Additional safety measures should be strictly reviewed and approved by the ECs.
- The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured.
- ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.
- As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
- Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/AIDS, substance abuse, etc. may present special risks to research participants.
- Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
- Participants may be prone to stigma or discrimination, specifically when the participants enrolled as a normal control or is recruited from the general population in certain types of research.
- Efforts should be made to set up support systems to deal with associated medical and social problems.
- Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.
- Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counselling centre.

19.6 Obligations/duties of Researcher

- Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.
- Justify inclusion/exclusion of vulnerable populations in the study
- COI issues must be addressed.
- Ensure that prospective participants are competent to give informed consent.
- Take consent of the LAR when a prospective participant lacks the capacity to consent.
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.
- Research should be conducted within the purview of existing relevant Guidelines / regulations.

19.7. Obligations/duties of Ethical Committee

- During review, determine whether the prospective participants for a particular research are vulnerable.
- Examine whether inclusion/exclusion of the vulnerable population is justified.
- Ensure that COI do not increase harm or lessen benefits to the participants.
- Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
- Suggest additional safeguards, such as more frequent review and monitoring, including site visits.
- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.
- ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. ECs should have SOPs for handling proposals involving vulnerable populations.

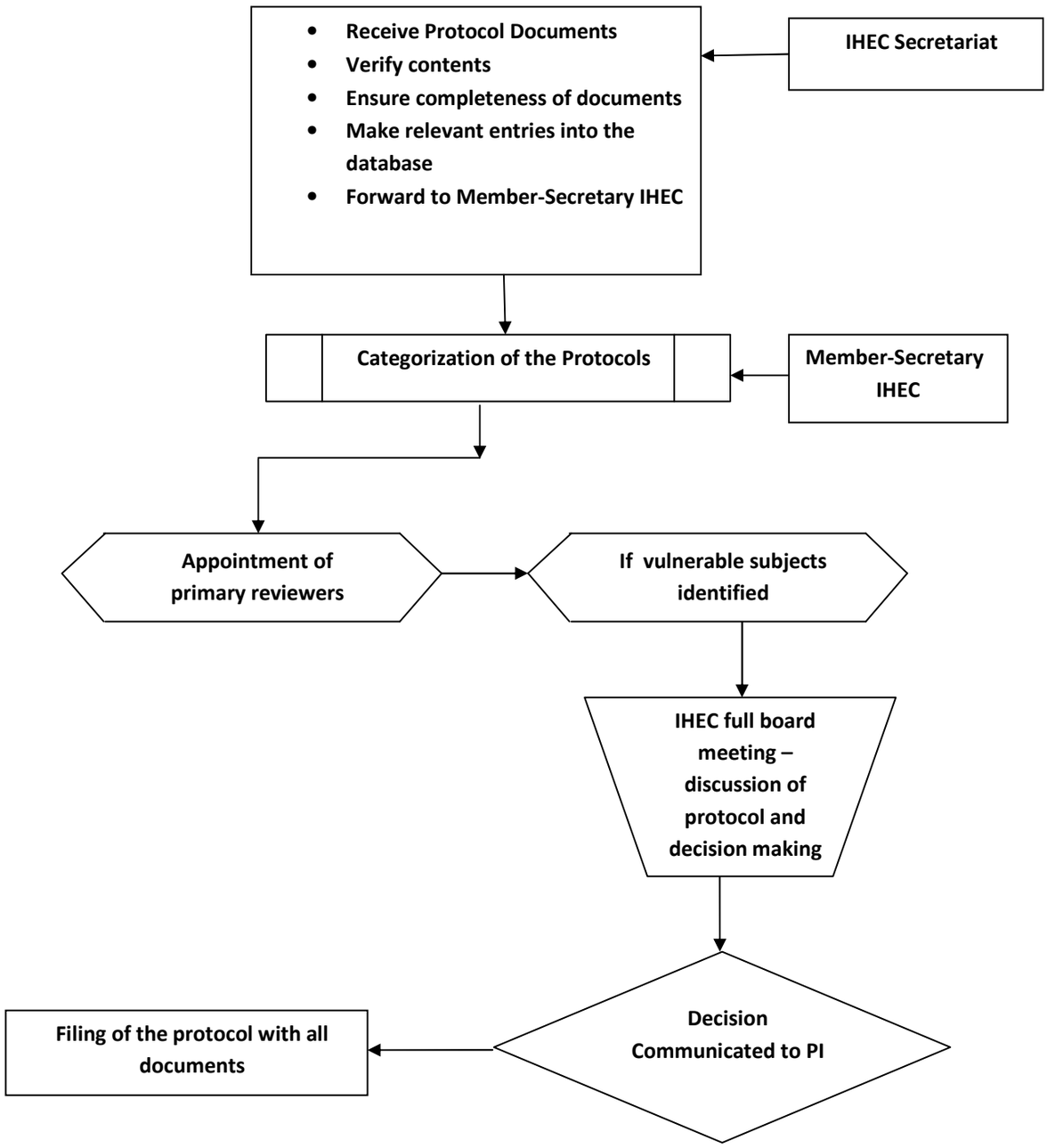
19.8 Obligations/duties of sponsor

- The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.
- The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC).
- The sponsor should ensure protection of the participants and research team if the research is on sensitive topics

19.9 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

Flowchart: Vulnerable Population SOP 19



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SOP Version 4.3	Effective Date: 16.01.19

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List of Annexes

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List of Flowcharts

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