PUSHPAGIRI
We care God cures
COLLEGE OF DENTAL SCIENCES

CODE OF ETHICS IN RESEARCH

Pushpagiri College of Dental Sciences
Tiruvalla.

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

INTRODUCTION

Pushpagiri College of Dental Sciences is committed to promoting and maintaining high standards of integrity and accountability in the conduct of academic research and is keen to embed and endorse a culture of honesty and transparency in all its institutional activities. In undertaking this commitment, the College emphasizes that academic freedom is a core value to be safeguarded and sustained. We are dedicated to ensure free academic environment to conduct research, to teach, to speak and to publish, subject to the norms and standards of scholarly inquiry. Research and developmental activities create and disseminate new knowledge, promote innovation and motivate better learning and teaching and this has been incorporated in our courses.

Research begins from the first year of admission in graduation and is a part of post graduate's curriculum. Faculty is also encouraged to participate and/or conduct research individually. As the research work is being conducted at all levels in this institute, the Code of Ethics in Research is an inseparable and integral part to set forth general principles of ethical conduct to guide scholars toward the highest ideals of scholarly research. Grants from various international and national agenies like ICMR, DBT, DST, SERB, NANOMISSION, KSCSTE, Bill & Melinda Gates Foundation etc. whose funding enables us to provide essential research resources to its scholarly community. The Institute abides by the highest standards of integrity in their conduct of academic research and/or support to academic research activities.

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PRINCIPLES AND ETHICAL VALUES IN RESEARCH

Academic integrity requires that academic research follows elevated professional standards, including:

i) Appropriate research design and frameworks

ii) Adheres to high levels of research ethics

iii) Abides by the requirements set out by professional and regulatory research guidance and research ethics frameworks issued in appropriate areas.

Academic integrity is defined in terms of the commitment to the values of honesty, trust, fairness, respect, responsibility, legality and dissemination.

Honesty: An academic community should advance the quest for truth, knowledge, scholarship and understanding by requiring intellectual and personal honesty in learning, teaching and research.

Trust: An academic community should foster a climate of mutual trust to encourage the free exchange of ideas and enable all to reach their highest potential.

Fairness: An academic community should seek to ensure fairness in institutional standards, practices and procedures as well as fairness in interactions between members of the community.

Respect: An academic community should promote respect among students, staff and faculty: respect for self, for others, for scholarship and research, for the educational process and intellectual heritage.

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Responsibility: An academic community should uphold high standards of conduct in learning, teaching and research by requiring shared responsibility for promoting academic integrity among all members of the community.

Legality: An academic community should observe valid legal norms related to the conduct and publication of research particularly in relations to copyright, the intellectual property rights of third parties, the terms and conditions regulating access to research resources and the laws of the land.

Communication: An academic community should seek to make the results of its research as widely and as freely available as possible.

INSTITUTIONAL RESPONSIBILITIES:

The Principal, the Vice Principals, the Head of Departments and Faculty members are responsible for promoting and endorsing a transparent academic environment conducive to the application of high professional and ethical criteria of good practice for academic research. Research guides are expected to create and sustain a climate of mutual co-operation that facilitates the open exchange of ideas and the development of academic research skills. They are also expected to ensure the provision of appropriate supervision and direction for researchers, in accordance with the nature of the individual academic discipline and associated mode of research. The institute is committed to provide appropriate direction to the research along with supervision for researchers. Guides are expected to adhere to the norms during the assessment of research progress, and procedures to resolve problems during research activity.

RESEARCH DATA MANAGEMENT:

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All original research data on which publications have been or will be based, in some cases samples or materials derived from the ongoing research, should be well-documented and safely archived to keep data from being manipulated, and to make data accessible for future reference for a period of time adequate for a given discipline.

RESEARCH PROCEDURES:

All research studies should be preceded by the risk and consequences analysis to foresee how research results may affect society and the environment. When applying for research funding, the researchers should formulate realistic goals and make every effort to accomplish them. Special care should be taken in case of research studies carried out on human subjects. Human dignity and an individual's autonomy must be respected at all cost. All research subjects, be they living organisms, the environment or cultural objects, should be handled with respect and care. The health, safety or welfare of a community or of collaborators should not be compromised. Researchers should be aware of the need for a balanced management of research funding. In special, justified cases, confidentiality of data or research findings should be respected by the researchers.

PUBLICATION PRACTICE AND AUTHORSHIP:

The Institute encourages the publication and dissemination of results of high quality research. It also expects that researchers will engage in the process of publishing and dissemination of their work responsibly and with an awareness of the consequences of any such dissemination in the wider media. Results should be published in a form appropriate to the academic discipline. The Institute requires that all individuals listed as authors accept responsibility for the contents of the publication and can identify their contribution to it. Authors should have

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participated sufficiently in the research to take public responsibility for the content. Authorship must be based solely on substantial intellectual contribution to the research. This includes: significant contribution in initiating scientific idea, formulating conceptions, designing research, significant share in data acquisition, in the analysis and interpretations of data and in drafting the article or revising it critically for intellectual content. Acquisition of funding, provision of technical assistance or materials, the collection of data, general supervision of the research group, by themselves, do not justify authorship. All authors are fully responsible for the content of the publication, unless it is specified they are responsible only for a specific part of the study within their speciality. When listing authors and their affiliations, it is appropriate to mention what was the nature of their contribution to the research. Sequence of authors should be consistent with the existing customs in a given scientific discipline and agreed by all, ideally at the start of the project. Intellectual contributions of others that have influenced the reported research should be appropriately acknowledged. Financial or other types of support for research should be properly mentioned and acknowledged. Publication of the same (or substantial parts of the same) work in different journals is acceptable only with the consent of the editors of the journals and where proper reference is made to the first publication.

THE ETHICS COMMITTEE

Tasks of Ethic Committee:

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i) To provide advice and guidance to the academic community on all matters pertaining to academic research ethics

ii) To advise the Academic Council on compliance with the 'Code of Ethics in Academic Research' of the various academic activities at the college.

iii) To provide guidance and academic support to scholars on ethical issues in respect of teaching, research and other academic activities.

iv) To advise the Academic Council of any policies that may be required in relation to accepting funds from particular sponsors of research.

v) To act as an investigative/consultative body for any disputed matter concerning research ethics and conduct

PEER REVIEW AND ASSESSMENT

Reviewers should not agree to peer review any research, scientific achievements or research concepts of other scientists, when the research falls outside their areas of expertise. Reviewers involved in the review process with regard to research projects, publications, scientific achievements, applications for faculty positions in scientific institutions and other forms of recognition, should withdraw from involvement in the review process, if there is any conflict of interests between them and evaluated individuals. Reviewers should provide accurate, objective, substantiated and justifiable assessments. Reviewers should maintain confidentiality until the manuscript is published. Reviewers and editors shall not make any use of the data or ideas presented in submitted manuscripts without the author's permission.

Training:

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The Academic Departments should ensure that all researchers undertake appropriate training in research design, methodology, regulatory and ethics approvals and consents, equipment use, confidentiality, data management, record keeping, data protection and publication, the appropriate use of licensed research resources and respect for the intellectual property rights of third parties.

Avoiding conflict of interest:

There are non-professional relationships between the evaluator and the evaluated, be that individual or institution. There is a connection between a member of the fund granting authority and a person or research unit to which these funds are granted.

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STANDARD OPERATING PROCEDURES

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INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

THIRUVALLA, KERALA-689101, INDIA

STANDARD OPERATING PROCEDURES

	Name	**Designation**	**Signature**	**Date**
Prepared by	Dr. Liya Roslin	Basic Medical Scientist		
	Dr. Philip Mathew	Clinician		
	Dr. Nibu Varghese	Scientific Member		
	Dr. Prasanth Rathinam	Supporting Staff		
Reviewed By	Dr. Nebu George Thomas	Member Secretary		
Approved By	Dr. Harikumar B Nair	Chairman		
Authorized By	Dr. T P Thankappan	Principal		

LIST OF ETHICS COMMITTEE MEMBERS

Sl No	Name	Gender	Qualification	Designation in the EC	Affiliation
1	Dr. Harikumar Bhaskaran Nair	M	BAMS (AYURVEDA PHYSICIAN)	Chairman	Not Affiliated
2	Dr. Nebu George Thomas	M	MDS (Periodontics)	Member Secretary	Affiliated
3	Dr. Vikram Gowda	M	MD (Physiology)	Basic Medical Scientist	Affiliated
4	Dr. T P Thankappan	M	MD (Dermatology,Venereology & Leprosy)	Clinician	Affiliated
5	Dr. Philip Mathew	M	MD - Community Medicine	Clinician	Affiliated
6	Adv. Minu Mathews	F	LLM	Legal Expert	Not Affiliated
7	Fr. Sibin Mathew	M	Bachelor in Theology	Social Scientist	Not Affiliated
8	Lijo George	M	B. COM	Lay Person	Not Affiliated
9	Dr. Tressia Alias Princy Paulose	F	DOCTORATE IN CHEMISTRY	Scientific Member	Not Affiliated
10	T M CHARRY	M	DOCTORATE IN BIOCHEMISTRY	Scientific Member	Not Affiliated
11	Dr. G SULOCHANA	F	MD - PATHOLOGY & MICROBIOLOGY	Basic Medical Scientist	Not Affiliated
12	Dr. NIBU VARGHESE	M	DOCTORATE IN PLANT BIOTECHNOLOGY	Scientific Member	Affiliated
13	STEPHEN JAMES	M	MTech CS-IT	Member	Not Affiliated
14	Dr. Athulya G Asokan	F	MD - General Medicine	Clinician	Affiliated

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LIST OF ETHICS COMMITTEE MEMBERS

15	Dr. LIYA ROSLIN JOSEPH	F	MD - Pharmacology	Basic Medical Scientist	Affiliated

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STANDARD OPERATING PROCEDURES

CHAPTER -1

PREPARATION AND IMPLEMENTATION OF STANDARD OPERATING PROCEDURE

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CHAPTER -1

PREPARATION AND IMPLEMENTATION OF STANDARD OPERATING PROCEDURES

1.0 Purpose

This Standard Operating Procedures (SOP) defines the process for writing, reviewing, distributing, and amending SOPs within the Institutional Ethics Committee (IEC). The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines Schedule _Y‖ and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

2.0 Scope

This SOP Chapter covers the procedures of writing, reviewing, distributing, and amending SOPs within the IEC.

Procedure and Responsibilities

The SOP shall be prepared according to the applicable regulatory requirements and it shall be approved by Chairperson of the Ethics Committee. SOP shall be revised time to time to meet the new regulatory requirements. The need of a revision of SOP shall be discussed in the IEC meeting and Chairperson shall appoint SOP writing team to revise the SOP.

The proposal for amendment shall be submitted to the Member Secretary. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting. Only regular members shall vote to accept or reject the proposed amendment. A proposed amendment will be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.

It is the responsibility of Chairperson of the IEC to appoint the SOP writing Team to formulate the SOPs. SOP writing team will consist of Member Secretary of IEC, administrative staff and one or two other IEC members

SOP writing team will prepare the draft SOP. The draft SOPs will be reviewed and approved by the IEC members. SOP writing team will be responsible to amend the SOPs as and when required.

SOPs will be reviewed by the members of IEC. The Chairpersons of IEC will approve the SOPs. The SOPs will then be approved by Head of Institution, as these are SOPs for Institutional Ethics Committee for Research Review.

Approved SOPs will be implemented from the effective date. The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly. Training on New SOP will be conducted for all members.

The EC Members will be trained on SOPs annually and whenever there is revision in the SOP. The training records will be maintained by EC

Old SOPs should be retained and clearly marked –superseded‖ and archived in a file by the secretariat. The process of evolution of previous SOPs of the IEC will be documented in a defined format.

ANNEXURES

1. Flow chart of SOP implementation
2. SOP Issue Log

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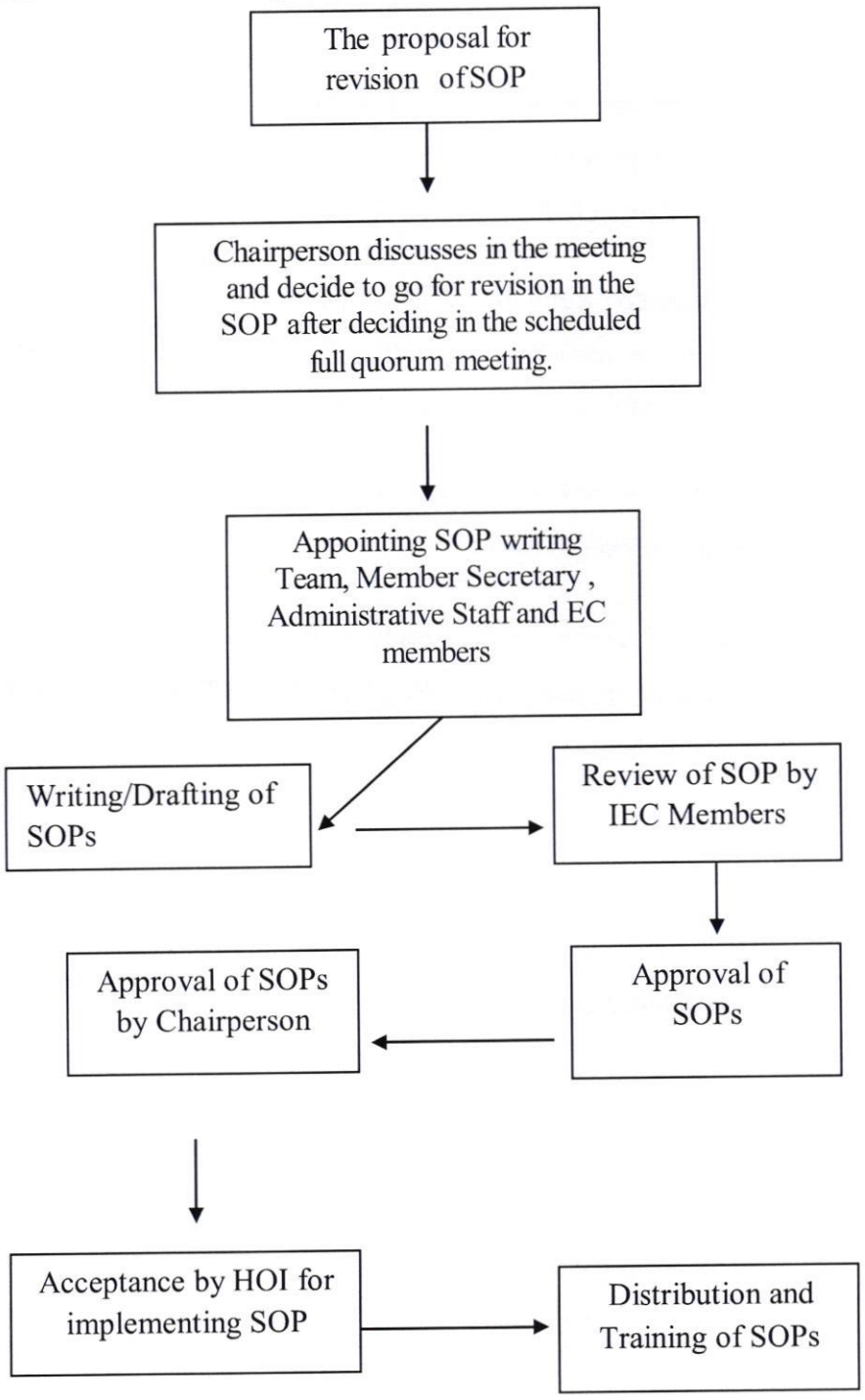
1. Flow chart of SOP implementation



2. SOP Issue Log

No	Name of the Recipient	Designation	SOP details	No. of Copies	Date Issued	Signature of the recipient

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STANDARD OPERATING PROCEDURES

Chapter 2

AUTHORITY AND PROCEDURE TO FORM ETHICS COMMITTEE

CHAPTER 2

AUTHORITY AND PROCEDURE TO FORM ETHICS COMMITTEE

1.0 Purpose

This SOP Chapter shall mention about the authority under which EC is constituted and its procedures for forming Ethics Committee.

2.0 Scope

The SOP Chapter applies to the formation of the EC.

3.0 Authority to constitute IEC

The Head of the institution or person who plays equivalent position from the Institution has the authority for constitution of Ethics Committee. The head of institution will select a Member Secretary from the institution to form Ethics Committee. The Head of Institution and Member Secretary will identify a Chairperson who is not affiliated to the institution by any means. The head of institution will have Memorandum of Understanding with Chairperson. All other EC members are appointed by the Head of the Institution in consultation with chairperson / Member Secretary.

Criteria for selection of members:

- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
- The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
- Directors, Head of Institution, Superintendents, Administrative officers who are responsible for business development will not serve as members of IEC.
- New members will be identified according to the requirement

All EC members will receive invitation letter from Head of Institution and all EC Members

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will sign acceptance to be part of the study and Confidentiality agreement. The office of Member secretary will act as the administrative office of EC. An updated CV will be collected from the invited members and Medical registration certificates will be collected for the members who are medically qualified.

The Ethics committee will maintain its independence from political, institutional, professional and market influences in the composition, procedures, and decision-making process. The head of Institution would ensure that its Members are competent enough to review a proposal submitted to them and at the same time they are free to express their thoughts and expressions in an unbiased manner.

EC would function in accordance with the Declaration of Helsinki, Good Clinical Practice, Schedule Y and all the applicable national and international guidelines for biomedical research.

The details of the Head of Institution, EC Chairperson and Member Secretary are given below:

Name of Head of the Institution:	**Dr. T P Thankappan**
Mailing address :	Head of the Institute, Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla - 689101
Contact No:	0469 2775518
Fax:	04692600020
Email:	tpthankappan@gmail.com
Name of the Chairman of EC:	Dr. HARIKUMAR BHASKARAN NAIR
Mailing address :	N.S.S. Ayurveda Hospital, Vallamkulam, Eraviperoor-689542 Kerala
Contact No:	+91 9447114492

Fax:	
Email:	doctorhari@gmail.com
Name of the Member Secretary:	Dr. Nebu George Thomas
Mailing address :	Pushpagiri Institute of Medical Science Pushpagiri Research Centre Mother and child block, Thiruvalla, Pathanamthitta, Kerala - 689101
Contact No:	9447044726
Fax:	04692600020
Email:	nebugt@gmail.com

ANNEXURES

a) Memorandum of Understanding with EC Chairperson
b) Format of invitation letter from Head of the institute to EC Members
c) Format for the acceptance letter/ Consent to be a member of IEC for IEC members
d) Name and Address of the member
e) Confidentiality agreement for members
f) Format for the Curriculum Vitae
g) Template for Conflict of Interest for members
h) Appointment letter

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a) Memorandum of Understanding with EC Chairperson

MEMORANDUM OF UNDERSTANDING (MOU)

This MOU made and entered into on -- <Date> (effective date) between Institutional Ethics Committee - <Name and address>(Here after represented as Institution) represented by its Head of the Institute <Name of the HOI>And <Name of the Chairman> having address < enter the address> (here after represented as EC Chairperson).

Institution and EC Chairman hereinafter are individually referred to as ―the Party‖ and are jointly referred to as ―the Parties‖.

Where as

- The Institution is involved in providing healthcare services
- The Ethics committee is the committee functioning in the hospital to review and oversee the biomedical research conducting in the hospital
- Institution appoints EC Chairperson to head the ethics committee and EC Chairman accepts the invitation
- In view of the above, the parties have entered into this MOU on the terms and conditions mentioned herein below:

ROLES AND RESPONSIBILITES OF THE PARTIES

The roles and responsibilities of the parties are as mention below. The parties agree that they shall abide by the roles and responsibilities described and defined hereafter.

EC Chairman

1. Conduct EC Meetings and be accountable for independent and efficient functioning of the committee
2. Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
3. Ratify minutes of the previous meetings

4. In case of anticipated absence of Chairman at a planned meeting, the Chairman should nominate a committee member as Acting Chairman or the members present may elect an Acting Chairman on the day of the meeting. The acting Chairman should be a non-affiliated person and will have all the powers of the Chairman for that meeting.

5. Seek Conflicts of Interest declaration from members and ensure quorum and fair decision making.

6. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

7. To protect the dignity, rights, safety and well-being of the potential research participants.
8. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
9. To assist in the development and education of a research community responsive to local health care requirements.
10. For this purpose, EC shall look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.

11. Provide documents pertains afflation, qualification and training.

12. Assessment of EC Members

INSTITUTION

1. Institution to provide an office for the EC.
2. The institution should provide space, infrastructure and staff to the EC for maintaining a full-time secretariat, safe archival of records and conduct of meeting.
3. Institution should allocate reasonable funds for smooth functioning of the EC
4. Receive and review the reports provided by the Chairperson as per standard Operating Procedure.
5. Approve Standard Operating Procedures
6. Provide administrative requirements for the EC
7. Provide adequate honorarium for the participants of the meeting.

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2. DURATION

The MOU shall be valid with effect from the effective date and shall continue to be in force for a period of Three years

3. TERMINATION

Either party may terminate this MOU by giving one month written notice to the other party

4. CONFIDENTIALITY

At all-time during the term of this MOU and thereafter each party shall hold in strictest confidence and shall not disclose, use, lecture upon or publish any of the other party's proprietary information, except as such disclosure, use or publication may be required in connection with such party's performance of its obligations under this MOU. The term "proprietary information" shall mean trade secrets, confidential knowledge, data or any other proprietary information of the party.

5. ARBITRATION

In the event of any dispute arising out of or in connection with this MOU, the parties wish to seek an amicable settlement as per the laws of India and Kerala.

Executed by their duly authorized representatives on the date(s) shown below.

Accepted and Signed by Hospital and EC Chairman

For INSTITUTION

Signature:_____

Name:_____

Date: _____

For EC CHAIRMAN

Signature:_____

Name:_____

Date: _____

b) Format of invitation letter from Head of the institute to EC Members

Invitation Letter

Date:

From,

Name and Address of the director

To,

Name and Address of the member

Sub: Invitation to join as a Member of Institutional Ethics Committee

Dear Sir / Madam,

On behalf of Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I request you to accept my invitation to be a member of Institutional Ethics committee. Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

Yours sincerely,

Signature:

Name of the director

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Pushpagiri College of Dental Sciences

c) Format for the acceptance letter/ Consent to be a member of IEC for IEC members

Acceptance Letter/ Consent to be a member of IEC

From

Name and Address of the member

To

Name and Address of director

Sub: Acceptance/Consent to be a member of IEC Regarding.

Ref: Your letter dated:

Dear Sir,

In response to your letter stated above, I accept the invitation to become a member of Institutional Ethics committee. I shall regularly participate in the Institutional Ethics committee meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing to publicize my full name, profession and affiliation.

I shall make available to the public on request, all reimbursement for work and expenses, if any, related to Institutional Ethics committee

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to any one other than project related personnel.

I herewith enclose my CV.

Thanking You,

Yours sincerely,

Signature ----------

Name of Member. ---------- Date:

Address

Telephone No: (Off)_____(Res)_____Email:

d) Format of the appointment letter from HOI to EC Members

Appointment Letter

Date:

From,

Name and Address of the HOI

To,

Name and Address of the member

Sub: Appointment letter as a Member of Institutional Ethics Committee

Dear Sir / Madam,

On behalf of Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I hereby appoint you as a member of Institutional Ethics Committee. You shall be designated the role of

……..

<<Terms of reference>>.

Your roles and responsibilities in the EC will be as follows: <<Roles and responsibilities>>

Yours sincerely,

Signature:

Name:

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e) Format for Confidentiality Agreement by the EC Members

Confidentiality agreement

To,

Institutional Ethics Committee

Pushpagiri Institute of Medical Sciences,
Pushpagiri Research Centre, Thiruvalla, Kerala – 689101

I understand that I being a member of Institutional Ethics Committee Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I may acquire or may have already acquired knowledge of or access to, information concerning with the various research studies from companies.

I understand that this confidential information is the exclusive property of the study sponsor / Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101. I understand to keep this information strictly confidential. I will not disclose to any third party the information and contents of the confidential documents without prior written consent from Institutional Ethics Committee.

Signature : _____

Name : _____

Date : _____

f) Format for the Curriculum Vitae

Curriculum Vitae

Name	:	

Educational Qualifications:

Qualification	Institution	Year of passing

Medical Reg. No. (If applicable)	:	
Residential Address	:	
Current Organization	:	
Nature of Current organization (Gov/Pvt/Aided/Autonomus)	:	
Official Address (With designation)	:	
Currently Affiliated/Not Affiliated with Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla		
Current Profession	:	

Professional Experience:

Designation/Role	Institute	Period

List of Publications (if any)	:	

Personal Details

Gender	:	
Date of Birth	:	
Nationality	:	
Phone No.	:	
Email Id	:	

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g) Template for Conflict of Interest for members

Agreement on Conflict of Interest

In accordance of the policy of the IEC, 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 IEC. The Undersigned will immediately disclose to the Chairperson of the IEC 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.

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

Signature Date

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: **0469 2775518**

STANDARD OPERATING PROCEDURES

Chapter 3

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES PUSHPAGIRI MEDICITY TIRUVALLA-7

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CHAPTER 3

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

1.0 Purpose

The IEC shall be established to formalize and specify Institution's commitment to the promotion of high scientific and ethical standards in patient care, professional education, clinical research, and community interests.

Ethical Basics for Constitution of EC

- The committee will consist of members who collectively have the qualifications & experience to review & evaluate the scientific, medical & ethical aspects of a proposed research project.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements & conditions of the various localities where proposed research is being considered.
- The IEC is guided in its reflection, advice & decision by the ethical principles expressed in WMA declaration of Helsinki- Ethical principles for medical research involving Human subjects.
- Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the :

  29th WMA General Assembly, Tokyo, Japan, October 1975

  35th WMA General Assembly, Venice, Italy, October 1983

  41st WMA General Assembly, Hong Kong, September 1989

  48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

  52nd WMA General Assembly, Edinburgh, Scotland, October 2000

  53rd WMA General Assembly, Washington 2002 (Note of clarification on paragraph 29 added)

  55th WMA General Assembly, Tokyo 2004 (Note of clarification on paragraph 30 added)

59th WMA General Assembly, Seoul, October 2008

- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code(1945), Belmont Report (1979), The council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research involving Human Subjects (Geneva 2002), and the European convention on Human rights & Biomedicine (1997).
- The IEC will ensure that the research protocols submitted by Clinical investigators are sound , scientifically designed, have statistical validity and are conducted according to the parameters of ICH-GCP, Indian GCP, Declaration of Helsinki, ICMR & Schedule Y as local regulatory requirements.
- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.

Terms of Reference of IEC

The terms of reference for the IEC are as follows:

- Ensure the highest scientific and ethical standards ofresearch
- Review and approve proposals for clinical, basic or translational research projects (Intra and Extra mural) for scientific and ethical content
- Improve ethical standards and issue guidelines
- To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public
- To maintain leadership as a national standard of reference in all fields
- To issue and periodically, update and revise SOP s and guidelines for effective functioning of IEC as and when necessary
- Continuing education in clinical research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for all categories of staff members including nursing and paramedical staff
- To initiate and commission research studies on ethical aspects of practice.

Responsibilities ofIEC

- To protect and safeguard the dignity, rights, safety and well-being of all actual or potential research participants.

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- To ensure that the research projects that are carried out are sound in design, have statistical validity and are conducted according to the ICMR, Schedule Y and ICH/GCP guidelines
- To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in societytaking into account age, gender, economic status, culture and ethics consideration.
- To provide advice to the researchers on all aspects of the welfare and safety of research participantsafter ensuring the scientific soundness of the proposed research.
- To ensure the research are conducted under the supervision of trained medical / bio medical persons with the required expertise
- To ensure that research will Include, solely, patients or participant who have given voluntary and informed consent
- It may be ensured that no research project shall be / can be started unless Ethics Clearance / Approval is obtained.
- It will review the proposals before start of the studies as well as monitor the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

5.0 Composition of IEC:

EC should be Multi-disciplinary and multi- sectorial. There should be adequate representation of age and gender. Preferably 50% Member will be non-affiliated or from the outside the organization. The number of Members in an EC should be between 7 and 15. The EC should have a balance between medical and non-medical members/ Technical and non-technical members depending up on the needs of the institution.

- The Ethics Committee shall have a minimum of sevenmembers from medical, non-medical, scientific and non-scientific areas with at least,_

  i. one lay person;

  ii. one woman member;

  iii. one legal expert;

iv. one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

- One member of the Ethics Committee who is not affiliated with the institute or organization shall be theChairperson, and shall be appointed by such institute or organisation.
- One member who is affiliated with the institute or organization shall be appointed as Member Secretary of theEthics Committee by such Institute or organization.
- The committee shall include at least one member whose primary area of interest or specialisation is nonscientificand at least one member who is independent of the institution.
- The members of the Ethics Committee shall follow the provisions of these rules, Good Clinical PracticesGuidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.
- Every member of the Ethics Committee shall be required to undergo such training and developmentprogrammes as may be specified by the Central Licencing Authority from time to time:Provided that any member, who has not successfully completed such training and developmentalprogrammes, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a memberof such committee.
- The members representing medical scientists and clinicians shall possess at least post graduate qualification intheir respective area of specialisation, adequate experience in the respective fields and requisite knowledge and clarityabout their role and responsibility as committee members.
- As far as possible, based on the requirement of research area such as Human Immunodeficiency Virus (HIV) orgenetic disorder, specific patient group may also be represented in the Ethics Committee.
- No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of theclinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign adeclaration to the effect that there is no conflict of interest.

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- While considering an application which involves a conflict of interest of any member of the Ethics Committee,such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same inwriting, to the Chairperson.
- The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of themeetings of the Ethics Committee.

Roles and Responsibilities of EC Members

Chairperson

Chairperson will be Non affiliated. A well respected person from any background with prior experience of having served/ serving in an EC.

Responsibilities

- Conduct EC Meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc

Member Secretary

Member Secretary will be affiliated with the institution. Should be a staff member of the institution, Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills, Should be able to devote adequate time to this activity which should be protected by the institution

Responsibilities

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review or full review
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist

Medical scientist can be Affiliated/ non-affiliated . He/she should be Non-medical or medical person with qualifications in basic medical sciences, In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. The representative of Medical scientist category should have postgraduate qualification & adequate experience in their respective fields.

Responsibilities

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

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Clinician

He should be affiliated/ non-affiliated Qualifications - Should be individual/s with recognized Post Graduate medical qualification, expertise and training

Responsibilities

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

Legal expert/s

He should be Affiliated/ non-affiliated with the institution .Should have a basic degree in Law from a recognized university, with experience.

Responsibilities

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

Social scientist/ philosopher/ ethicist/theologian

Non-affiliated persons with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

Responsibilities

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person(s)

Non-affiliated Literate person from the public or community , Has not pursued a medical science/ health related career in the last 5 years , May be a representative of the community from which the participants are to be drawn , Is aware of the local language, cultural and moral values of the community , Person involved in social and community welfare activities are desirable

Responsibilities

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

IEC Secretariat

The Secretariat is composed of the Member Secretary and the administrative supporting staff. The supporting staff consists of staff members of Asirvatham Hospital appointed by the Head of Institution.

The secretariat shall have the following functions:

- Organization of an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organization of regular IEC meetings. .
- Preparation of the agenda and the minutes of the meetings,
- Maintenance of the IEC records and archives.
- Communication with IEC members and Principal Investigators.
- Arrangement of training for personnel and IEC members.
- Provision of the necessary administrative support for IEC related activities to the Member Secretary, IEC.

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- Receipt of IEC processing fees for projects and the issue of official receipts for the same.

The IEC Administrative Staff Roles and Responsibilities

The administrative staff will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned as and when deemed necessary by the IEC. The administrative staff will be appointed by the Head of Institution by formal interview or direct appointment.

- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparing, maintaining and distributing study files.
- Organizing IEC meetings regularly
- Preparing the agenda and minutes of the meetings
- Maintaining IEC records and archives.
- Communicating with IEC members and PIs.
- Arranging training for personnel and IEC members
- Providing necessary administrative support for IEC related activities to the
- Member Secretary, IEC.
- Receiving IEC processing fees and issuing official receipts for the same.
- Corresponding with the IEC members, external experts and investigators.
- Making the pre and post arrangements of IEC meetings.
- Preparing the agenda and minutes of the IEC meetings.
- Answering queries of the investigators.
- Filing study related documents.
- Archiving and maintaining the study files.
- Preparation for accreditation, Registration and audits
- Training for investigators, key study personnel, IEC members, and IEC staff.
- Participate in the development and subsequent implementation of SOPs
- Developing an effective and efficient tracking procedure

Terms of Membership

- The members are drawn from different specialties to give a multi-sectorial, multidimensional structure. A one page current Curriculum Vitae (CV) will be collected from each member and filed in the administrative file.
- The duration of appointment is initially for a period of 3 years
- At the end of 3 years, the committee will be reconstituted, by the discretion of the Head of the institution
- A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.
- A member will also be removed if they fail to attend atleast three consecutive meetings unless proper reason for the absence is communicated in advance in writing.
- If a member is found acting code of conduct (or) objectives of the committee, he or she can be removed by $2/3^{rd}$ majority of the members subject to issue of notice seeking objection which is to be submitted within two weeks on receipt of the notice. On the expiry of two weeks the committees to consider the representation received from the members and decide the action of removal. If the committee is satisfied with the reply, it can drop the action of removal. If not satisfied, the committee can remove the member by passing a resolution to this effective in a meeting to be convened 21 days after sending notice to all the members.
- A member can tender resignation with proper reasons to do so, in writing to the Head of Institution and Chairperson of Ethics committee.
- All members should maintain absolute confidentiality of all discussions during the meeting. A confidentiality agreement will be signed from each member and filed with EC before joining in the EC

Meeting Procedures

- The IEC meetings are held trimonthly. Additional meetings may be held as and When considered necessary.
- The Investigator's team should submit the documents 2 weeks prior to the scheduled meeting to IEC. The applicant is required to submit 5 copies of his / her application letter and copies of the documents.
- The notice of each meeting with the agenda is sent out to the members at least one

week before the meeting.

- A quorum is required for all meetings. The project can be approved unanimously or by non-unanimously. When it is approved unanimously, an approval letter will be prepared and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- Member secretary will prepare the minutes of the meetings and circulated to all the members. The final minutes of the meeting will be kept in the minutes of the meetings file signed by the Chairman.

Quorum Requirement

- In a meeting, atleast five members should be present to meet the quorum requirements; to review and make a written decision on any application. None of the members present in the meeting must not have conflict of interest.

- Each Quorum (with a minimum of 5 members) should have following members
  - **a.** Clinician
  - **b.** Basic Medical Scientist (Preferably Pharmacologist)
  - **c.** Legal Expert
  - **d.** Social Scientist / Representative of Non-Governmental Voluntary Agency
  - **e.** Lay Person from Community
- If a quorum is not present during the course of the meeting, EC Meeting can be adjourned by Chairperson.
- Chairperson can nominate a member secretary during the absence of Member Secretary
- In the absence of Chairperson EC Members can select a Member as a Chairperson for that meeting. But the selected Member should not be affiliated to the institution
- All types of changes and situations should be documented in the Minutes of meeting of the EC

Policy to prevent conflict of interest

- The ultim ate interes t of Ethics comm ittee is to prevent conflict of interest.
- It has been recognized that the potential for conflict of interest will always exist, but Chairperson is capable to manage the conflict issues so that the ultimate outcome is the protection of human subjects.
- There should be no conflict of interest.
- The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review
- Chairperson can also ask the members to declare Conflict of interest during the meeting.
- All members shall sign a declaration on conflict of interest.
- All the declaration regarding conflict of interest should be mentioned in the minutes of Meeting.

Policy regarding Training and Updating IEC members

- All relevant new guidelines to be brought to the attention of the members.

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- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.
- All EC members must be conversant with ICMR Guidelines for Research involving Human Subjects, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
- All the members will be given training on the above-mentioned guidelines and rules yearly basis. A training record would be maintained for the same.
- Every new member will get trained on all of the above-mentioned guidelines and rules at the time of appointment.
- When a new rule/ guideline / sop revision has happened, all the members would be trained and training record would be maintained for the same.
- The Trainer will be invited from outside or from within the IEC and background and profile of the trainer will be documented
- All the training records which includes Agenda, Attendance, Pretest, Post test, Feedback forms training materials and Training logs will be maintained in the Training File

Independent Consultants

The IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson / Member secretary or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC 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 or subject experts cannot vote for a decision.

ANNEXURES

1. Confidentiality Agreement Form for Independent Consultant

Confidentiality Agreement

I, ... understand that I am allowed to attend the ethics committee meeting as a subject expert/independent consultant. In the course of the meeting of the IEC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as confidential.

_____ _____

Signature of the Guest or Observer Date

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INSTITUTIONAL ETHICS COMMITTEE PUSHPAGIRI

INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: **0469 2775518**

STANDARD OPERATING PROCEDURES

Chapter 4

MANAGEMENT OF SUBMISSION OF APPLICATIONS

CHAPTER 4

MANAGEMENT OF SUBMISSION OF APPLICATIONS

1.0 Purpose

This SOP is designed to describe and act as a guideline for the IEC Secretariat to manage research study submissions.

2.0 Types of research review by Ethics committee And Responsibility

The Ethics Committee will review Clinical Trials (Phase II, Phase III, Phase IV) epidemiological studies, retrospective studies, herbal studies and studies for devices.

It is the responsibility of the IEC secretariat to receive record and distribute the study documents for IEC review.

3.0Minimum required documents for submission of research project for approval

An application for review of the ethics of proposed biomedical research should be submitted by a qualified applicant responsible for the ethical and scientific conduct of the research. Principal Investigator can submit the documents for IEC for review and approval. All relevant documents should be enclosed with a covering letter and Submission Checklist.

Meeting Frequency of IEC

- The committee will hold regular meetings trimonthly. When there are no research proposals to review, the meeting may be hold less frequently, but no less than once every three months
- The Member Secretary will schedule the meeting either at the time of the previous scheduled meeting or within 2 weeks after new project submission and consult the Chairperson / IEC members to schedule and reconfirm the meeting date.

Submission Requirements

- The application should be submitted two weeks before the EC meeting date.
- 5 number of the hard copies of the proposal; along with the application and documents in prescribed format

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- Prescribed fee as per the Fee Structure should be remitted along with the application
- The following list of documents to be submitted by Applicant for review by EC
    - **a.** Trial Protocol: Submit the latest protocol along with all the amendments mentioning the version no. (s) and date(s).
    - **b.** Patient Information Sheet and Informed Consent Form: Submit the latest Patient Information Sheet(s) and Informed Consent Form (s) in English and all the applicable vernacular languages mentioning the version no . (s) and date(s).
    - **c.** AV consent form
    - **d.** Investigator's Brochure: Submit the latest Investigator' brochure mentioning the version no. (s) and date(s).
    - **e.** Proposed methods for patient accrual including advertisement if applicable (s) etc. proposed to be used for the purpose.
    - **f.** Principal Investigator's signed and dated current CV along with medical registration certificate.
    - **g.** Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
    - **h.** Investigator's Agreement with the Sponsor.
    - **i.** Investigator's undertaking, as per Schedule Y – Appendix VII format.
    - **j.** The Regulatory approval / submission status from sponsor for the conduct of study.
    - **k.** Description of site facilities using in the study including available emergency facilities
    - **l.** A description of the process to be used to obtain the informed consent.

Receive submission packages

For the initial review of study, investigators should submit all study related documents to the IEC, two weeks before the next scheduled meeting. The procedure for the receipt of documents are as follows :

- EC Secretariat will review the documents submitted.
- If any missing documents are there EC will inform the applicant to submit the required documents

- If the application is intact, the member secretary will give acknowledgement in the submission letter by signing and stamping for investigator use.
- Each Hard copy of the documents will be distributed to each of the members to their address and soft copy will be mailed to their official email id before 14 days before the EC meeting
- One copy will be stored at EC office which will be labeled as Master copy and this copy will be archived at EC office
- Agenda will be prepared by EC office and distributed to all EC members 7 days prior to the meeting.

ANNEXURES

1. Submission Checklist
2. Template for Submission letter
3. Dispatch Return Log

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1. Submission Checklist

S.No	Contents	Applicant Section		Ethics Committee Section		
		Yes	No	Yes	No	Comments
1.	Name of the applicant with designation	☐	☐	☐	☐	
2.	Name of the Institute/ Hospital / Field area where research will be conducted	☐	☐	☐	☐	
3.	Approval of the Head of the Department / Institution if applicable	☐	☐	☐	☐	
4.	Protocol of the proposed research	☐	☐	☐	☐	
5.	Ethical issues in the study and plans to address these issues.	☐	☐	☐	☐	
6.	Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.	☐	☐	☐	☐	
7.	Informed consent process, including patient information sheet and informed consent form in local language(s).	☐	☐	☐	☐	
8.	For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.	☐	☐	☐	☐	
9.	Current Curriculum vitae of all the investigators	☐	☐	☐	☐	
10.	Regulatory Approval/ Submission status	☐	☐	☐	☐	
11.	Source of funding and financial requirements for the project	☐	☐	☐	☐	
12.	Insurance and Indemnity arrangements	☐	☐	☐	☐	
13.	Description of site facilities using in the study including available emergency facilities	☐	☐	☐	☐	

S.No	Contents	Applicant Section		Ethics Committee Section		
		Yes	No	Yes	No	Comments
14.	Investigator Undertaking	☐	☐	☐	☐	
15.	Agreement to comply with the relevant national and applicable international guidelines.	☐	☐	☐	☐	
16.	All payment, reimbursement and medical services to be provided to the research subjects.	☐	☐	☐	☐	
17.	Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.	☐	☐	☐	☐	
18.	Information of other EC approval Status of the study if applicable	☐	☐	☐	☐	
19.	Details of the study Team	☐	☐	☐	☐	
20.	Any other information relevant to the study	☐	☐	☐	☐	

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2.0 Template for Submission letter

<< On PI/ Institution Letter Head>>>

Date:

To

The Member Secretary

Institutional Ethics Committee

<<Enter Address>>

Ref: <<<….. Protocol Name and Number……>>>

Sub: <<…..Submission of Study Documents to EC for review and Approval ……>>

Dear Sir/Madam,

Please find enclosed 5 copies of the follwing documents of the above mentioned project for forthcoming Institutional Ethics Committee (IEC).

<<<<……. List of Documents with version no. and date…….>>>>

I wish to assure you that the study would be initiated at the site only after approval of the Ethic Committee.

Please revert for additional information and clarifications.

Thanking you,

Yours Sincerely,

<<<…. Principal Investigator's Name, Designation …..>>>

Principal Investigator (Protocol Number)

TO WHOM IT MAY CONCERN

We here by confirm the receipt of the above referenced documents submitted to us

Signature , Date and Ethics Committee Seal

3.0 Dispatch Return Log

SI. No	Date of Issue	Document Given	Issued To	Signature of receiver	Issued by	Signature	Purpose	Due Date for Return	Returned on date	Received By	Signature

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INSTITUTIONAL ETHICS COMMITTEE PUSHPAGIRI

INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: 0469 2775518

STANDARD OPERATING PROCEDURES

Chapter 5

AGENDA PREPARATION, MEETING PROCEDURES ETHICAL REVIEW AND PREPARATION OF MINUTES OF MEETING

CHAPTER 5

AGENDA PREPARATION, MEETING PROCEDURES ETHICAL REVIEW AND PREPARATION OF MINUTES OF MEETING

1.0 Purpose

The purpose of this Chapter is to elaborate the administrative process and provide instructions on meeting agenda, review, approval, minutes, and communicating the decision to the Principal Investigator.

The IEC shall review and approve, every research study involving human participants and other forms of studies, before the research is initiated. The IEC shall evaluate the scientific rationale, scope, methodology, and the ethical aspects of the study. The committee shall evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality shall also be reviewed.

2.0 Scope

This Chapter applies to procedures to conduct the IEC meeting:

3.0 Responsibility

It shall be the responsibility of the respective Member Secretary of IEC and IEC staff to prepare for the IEC meeting.

4.0 Before full board IEC meeting

Prepare the agenda of the IEC meeting. Schedule studies on the agenda on first come first serve basis. No limit is placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and IEC workload.

Preparation of the meeting

- The meeting frequency of IEC will be trimonthly.

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- Reserve the meeting venue for the IEC meeting on the scheduled meeting date and time. The meeting will be held in the Board room of Hospital, unless otherwise specified. Ensure that the room, equipment (projectors, recorder, etc) and facilities are available in good working conditions
- All original files of studies on the agenda are kept in the meeting room for ready reference before the meeting
- Copies of SOPs, Schedule Y, ICMR guidelines are kept available for ready reference
- Secretariat informs the scheduled meeting date and time to the Principal Investigators.

Element of review

The Meeting will be organized in the institution or facility desired by institution. All the members will be signing the attendance sheet. The prepared Agenda will be followed during the meeting .The quorum requirement and conflict of interest will be ensured by the EC Chairperson before discussing the study by any investigator. The Investigator will present the study. Independent Consultants can also be invited to review and advice on a particular topic where EC doesn't have expertise.

The review and the decision will be done based on the below criteria.

- Scientific design and conduct of the study.
- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects: Exclusion/ Inclusion criteria
- Management of research related injuries, side effects, ADRs.
- Compensation provisions.
- Justification for placebo in control arm, if any.
- Availability of products after the study, ifapplicable.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary.
- Plans for data analysis and reporting
- Adherence to all regulatory requirements.

The prefilled Documents review checklists will be discussed with the Investigator by the respective EC members. All the queries will be discussed. EC can be go for two types

reviews based on the assessment of documents. The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into two types, namely expedited review, and full committee review

Expedited Review

Proposals that pose no more than minimal risk may undergo expedited review. Such meetings will be conducted by members meeting quorum including Member Secretary and Chairperson

- Research involving clinical documentation materials that are non-identifiable (data, documents, records)Modification or amendment to an approved protocol including administrative changes or correction of typographical errors
- Review of SAE and due analysis report preparation to be sent to CDSCO within 30 days of occurrence of SAE
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk
- Activity limited to data analysis.

Approval granted through expedited review and the decisions of the SAE must be ratified at the next full committee meeting.

Full Committee review

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

- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk
- Studies involving deception of participants
- 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.

Periodic Review

All the approved studies will be reviewed atleast once in 6 months from the day of initial approval of the study to understand the progress of the study. All the investigator will be notified the time frame of periodic review via initial approval letter of the study. Intimation notice will be issued by EC office to investigator. The following summary will be reviewed.

- Number of subjects screened
- Number of subjects randomized
- Number of subjects Drop outs
- Number of subjects withdrawn
- List of SAEs
- List of AE
- List of Protocol Deviation
- List of protocol violation
- Any new information relevant to the study

Annual Review

- Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study which will be conveyed to researcher at the time of initial review. The researcher should give annual report and request to continue the study with the documents available in the present form. The EC should review the annual report and if found satisfactory IEC will approve to continue the study.

- The first report shall be submitted within thirty (30) days of completion of the year following the date of the first approval. Subsequent reports will be submitted at one-Year intervals following the first report.
- An EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.

11.0 Review of Protocol Deviation/ Violation

All Protocol Deviation/Violation/ non-compliance/waiver will have to be notified. All such notifications shall be circulated to IEC members, reviewed & assessed by the committee during the meeting for the seriousness of the deviation / Non-Compliance / Violation with respect to the safety & health aspects of the subjects and the necessary actions shall be taken by the committee accordingly.

Review of Studies involves vulnerable population

The IEC of Pushpagiri Institute of Medical Sciences and Research Centre takes special consideration in protecting the welfare gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment. The IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects. The IEC may require additional safeguard measures to protect potentially vulnerable population. For instance, the IEC may require that the investigator submit each signed informed consent form to the IEC, that someone from the IEC oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time to allow the subject time for family discussion and query resolution, family discussion and questions. IEC expects to follow the principals laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participant.

RESPONSIBILITY:

It is the responsibility of the Chairperson and Member-Secretary of IEC to implement, amend and give training to other members of IEC of this SOP.

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PROTOCOL REVIEW PROCESS:

DETAILED INSTRUCTION

For Pregnant Women, Foetuses:

Research involving pregnant women and fetuses should involve the least possible risk. The IEC will document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent. The IEC will ensure that women are not encouraged to discontinue nursing for the sake of participation in research except in the cases where breast-feeding is harmful to the infant. IEC will also ensure that compensation in terms of supplying supplementary food such a milk formula will be considered in such circumstances. In the event of research related to pre-natal diagnostic techniques, IEC will ensure that such research is limited to detect foetal abnormalities or senetic disorders and not for sex determination.

Research involving Prisoners:

Prisoners may have a limited ability to make truly voluntary and un-coerced decisions about whether or not to participate as research subject.

Children involved as subjects/ participants in Research:

IEC requires special protections for research involving children. Under the regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable conducted. The proposed clinical research must fall within one of the four following categories: (i) Clinical Trial not involving Minimal Risk. (ii) Clinical trial involving greater than minimal risk, but presenting the prospect of direct benefits to the individual subjects. (iii) Clinical trial involving greater than minimal risk, yield knowledge that can be generalized about subject's disorder or condition. Clinical trial not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. Each category has specific conditions that must be included in their organization Standard Operating Procedures (SOPs) if the institution is involved in human research where children are in the subject population.

Parental/Legally acceptable representative Permission:

The IEC require that adequate provisions are made for solicit the permission of each child's parents or guardian/legally acceptable representative. Where parental permission is to be obtained, the IEC will determine whether permission of one parent is sufficient or whether permission must be obtained from both parents in order for the research to be conducted.

Assent of the Child:

(a) Provisions must also be made in the protocol to obtain the child's assent when the child is capable of giving assent. (b) IEC may determine that the assent of the child is not necessary if and only if all three of the following conditions are satisfied: (i) The research offers the child the possibility of direct benefit. (ii) The benefit is important to the health or well being of the child. (iii) The benefit is available only in the context of the research. IEC will take great care in approving research where the child is suffering from a life-threatening illness with little real chance of therapeutic benefit from the research. IEC will respect the child's refusal to participate in the research and will be cautious in allowing parents/ legally accepted representatives to overrule. IEC requires assent form is tailored for the child, with respect to his or her level of understanding.

Clinical trial involving Decisionally Impaired Subjects:

IEC will consider selection issues, privacy and confidentiality, coercion and undue influence, and risk-benefit analysis. Additional safeguards must be considered by the IEC to protect these subjects.

Decision-making

The committee will give its opinion on the project in writing in one of the following ways:

Members will discuss the various issues before arriving at a consensus decision.

- A meeting will be considered valid only if the quorum is fulfilled. This should be maintained throughout the meeting and at the time of decision making. Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- If a member has declared a Conflict of interest (COI) for a proposal then this

should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.

- The member who has declared COI should withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This should be minuted and the quorum rechecked.
- A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.
- Number of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal.
- Decision may be to approve, reject or modify the proposals. Specific suggestions should be given for modifications.
- Negative decisions should always be substantiated by appropriate reasons.
- The decision must be taken either by a broad consensus or majority vote and should be recorded. When it is approved unanimously, an approval letter in the prescribed template will be issued and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- The chairman / member secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made.
- This decision will be ratified at the next full committee meeting and minuted.

After the IEC meeting

Preparing the minutes and the decision letters

- The Member Secretary will compile the proceedings of IEC meeting in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes
- The minutes of the meeting will be compiled within 15 working days. The minutes will record whether the decision was unanimous, or whether a vote was taken for the decision. The number of members voting for, against, and abstaining will be recorded. The disclossure of the IEC member for conflict of interest is recorded in the IEC meeting minutes. The questions and answers

discussed in each meeting will also be discussed.

- The basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution must be recorded and filed.

Approval of the minutes and the decision

- The minutes of the IEC meeting will be prepared by Member Secretary, IEC or acting member secretary
- The minutes of the IEC meeting will be approved by Chairperson ratified in the subsequent IEC meeting
- The IEC decisions will be communicated to the PIs

Filing of the minutes of the meeting

Place the original version of the minutes in the minutes file and copy of the minutes are filed in the corresponding files of research protocol reviewed in the meeting.

Communicating the decision with the investigator

The decision will be communicated in writing to the PI, preferably within a period of 15 working days of the IEC meeting at which the decision was made. The decision will be communicated through written letter signed by EC member Secretary/ Chairperson. Original letter will be given to the applicant and copy will be maintained with the EC.

ANNEXURES

1. Template for Approval Letter
2. ICD Review Checklist
3. Protocol Review Checklist
4. CTA Review Checklist
5. IB Review Checklist

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6. Agenda Format
7. Application for Annual Review

a) Template for EC Approval

INSTITUTIONAL ETHICS COMMITTEE

Date

To,

<<PI Name and project code>>.

Ref: Study Protocol- <<protocol ID and Title>>

Sub: Ethics Committee approval

Dear <<PI Name>>,

The Institutional Ethics Committee, Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, reviewed and discussed your application dated <<Date of Submission>> to conduct the clinical trial entitled <<Title of the study>> on <<Date of EC meeting held>>.

The following documents were reviewed and approved:

<<List the documents which are reviewed and approved and reviewed only – separately>>

The following members of the Institutional Ethics Committee were present at the meeting held on <<date of EC meeting held>>.

<<List the members name and their role in the IEC in the box below>>

S#	Name	Role in the Ethics Committee
1		
2		
3		

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4		

5		
6		
7		
8		
9		

Case 1. <<In case study was unanimously approved follow the below pattern>>

The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study. One member was abstained from voting (<<write the name of the members who abstained from voting)

Case 2. <<In case study was non-unanimously approved - follow the below pattern>>

The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study as against <<Votes against - write here>> votes against the study. One member abstained from voting (<<write the name of the members who abstained from voting).

We confirm that principal investigator did not participate in the deliberations of the ethics committee for this study and did not vote on the proposal for this study.

Please submit the following documents before recruiting the patients in to the study.

<<List the documents which has to be submitted to the IEC before the study to be initiated at our center>>

Please note that you should follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by the IEC without the prior written approval of this ethics committee. Deviations/ changes to the approved protocol may be implemented without prior approval of this ethics

committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to the IEC:

- Any changes to or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial subjects.
- All serious adverse events.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit to the IEC, the status report of the study at every 6 months interval.

Please provide a close out report to the Ethics Committee on the completion of the study.

The IEC is organized and operates according to the requirements of ICH - GCP and requirements of the Indian Council of Medical Research (ICMR) and Schedule Y.

Thank you for your time and efforts.

Cordially,

Member Secretary
Institutional Ethics Committee
<<Enter Address>>.

<<Name of Chairman>>
Institutional Ethics Committee
<<Enter Address>>.

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b) ICD review Checklist

SI.No	Contents	Yes	No	Comments
1.	A statement that the study involves research	☐	☐	☐
2.	Explanation of the purposes of the research	☐	☐	☐
3.	Expected duration of subject's participation	☐	☐	☐
4.	Description of the procedures to be followed, including all invasive procedures	☐	☐	☐
5.	Description of any reasonably foreseeable risks or discomforts to the Subject	☐	☐	☐
6.	Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.	☐	☐	☐
7.	Disclosure of specific appropriate alternative procedures or therapies available to the Subject	☐	☐	☐
8.	Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records	☐	☐	☐
9.	Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)	☐	☐	☐
10.	Compensation and/or treatment(s) available to the	☐	☐	☐

	Subject in the event of a trial-related injury			
11.	An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury	☐	☐	☐
12.	The anticipated prorated payment, if any, to the Subject for participating in the trial	☐	☐	☐
13.	Subject's responsibilities on participation in the trial	☐	☐	☐
14.	Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled	☐	☐	☐
15.	Any other pertinent information	☐	☐	☐
16.	Additional elements, which may be required	☐	☐	☐
16.1	Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.	☐	☐	☐
16.2	Additional costs to the Subject that may result from participation in the study.	☐	☐	☐
16.3	The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.	☐	☐	☐
16.4	Statement that the Subject or Subject's representative will be notified in a timely manner	☐	☐	☐

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	if, significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.			
16.5	A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable	☐	☐	☐
16.6	Approximate number of Subjects enrolled in the study	☐	☐	☐
17	Details of Compensation or cost for medical management in case of any Serious Adverse event occurred	☐	☐	☐
18	Procedure for consenting AV recording if applicable.			
19	Section for details of Nominee,	☐	☐	☐
20	Section for Income and qualification of study subject	☐	☐	☐
21	Correctness of the contact details of Investigator and IEC mentioned	☐	☐	☐
22	Appropriateness of language used	☐	☐	☐

c) Protocol Review Checklist

Contents	Yes	No	Comments
General Information			
Protocol title	☐	☐	☐
Protocol identifying number and date	☐	☐	☐
Any amendment(s) number and date(s)	☐	☐	☐
Name & Address of the Sponsor	☐	☐	☐
Name & Address of the Monitor (If other than the Sponsor)	☐	☐	☐
Name & Title of the person(s) authorized to sign the protocol for the sponsor	☐	☐	☐
Name & Title of the person(s) authorized to sign the protocol amendment(s) for the sponsor	☐	☐	☐
Name, Title, Address and Telephone number of the sponsor's medical expert for the trial	☐	☐	☐
Name and title of the investigators	☐	☐	☐
Address and Telephone number of the trial site(s)	☐	☐	☐
Name, Title, Address, and Telephone Number of the qualified physician for all trial-site related medical decisions	☐	☐	☐
Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical departments and/or	☐	☐	☐

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institutions involved in the trial			
Background Information			
Name and description of the IP	☐	☐	☐
Summary of finding from nonclinical studies that potentially have clinical significance	☐	☐	☐
Summary of finding from Clinical studies that are relevant to the trial	☐	☐	☐
Description of and justification for the route of administration	☐	☐	☐
Description of and justification for the dosage	☐	☐	☐
Description of and justification for the dosage regimen	☐	☐	☐
Description of and justification for the Treatment period(s)	☐	☐	☐
A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s)	☐	☐	☐
Description of the population to be studied	☐	☐	☐
Reference to literature and data that are relevant to the trial	☐	☐	☐
Trial Objectives and Purpose			
Description about the trial objective	☐	☐	☐
Description about the trial purpose	☐	☐	☐
Trial Design			

A specific statement of the primary end points to be measured during the trial	☐	☐	☐
A specific statement of the secondary end points to be measured during the trial	☐	☐	☐
A description of the type/design of the trial to be conducted (e.g. double blind . placebo- controlled, parallel design)	☐	☐	☐
Schematic diagram of trial design	☐	☐	☐
Schematic diagram of trial procedures	☐	☐	☐
Schematic diagram of trial stages	☐	☐	☐
A description of the measures taken to minimize / avoid bias	☐	☐	☐
Blinding	☐	☐	☐
A description of the trial treatment(s)	☐	☐	☐
A description of the dosage& dosage regimen of IP	☐	☐	☐
A description of the dosage form	☐	☐	☐
A description of the packaging & labelling of the IP	☐	☐	☐
Expected duration of subject participation	☐	☐	☐
Description of the sequence and duration of all trial periods, including follow-up period	☐	☐	☐
Description of the -Stopping rules‖ or -discontinuation criteria‖ for individual subjects	☐	☐	☐
Accountability procedures for IP, Placebo(s) &	☐	☐	☐

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Comparator(s)			
Maintenance of trial treatment randomization codes	☐	☐	☐
Description of procedures for breaking codes	☐	☐	☐
The identification of any data to be recorded directly on the CRF's (i.e. no prior written or electronic record of data)	☐	☐	☐
Selection and Withdrawal of Subjects			
Subject inclusion criteria	☐	☐	☐
Subject exclusion criteria	☐	☐	☐
Subject withdrawal criteria (i.e. terminating IP treatment/trial treatment	☐	☐	☐
Description about when and how to withdraw subjects from the trial/IP treatment	☐	☐	☐
Description about the type and timing of the data to be collected for withdrawn subjects	☐	☐	☐
Follow up for subjects withdrawn from IP treatment/ trial treatment	☐	☐	☐
Treatment of Subjects			
Name of all the Product(s)	☐	☐	☐
The dose(s)	☐	☐	☐
The dosing schedule(s)	☐	☐	☐
Route/ Mode(s) of administration	☐	☐	☐

Treatment period(s) including follow up period(s)	☐	☐	☐
Description about Medication(s)/Treatment(s) permitted (including rescue medication) before and/or during the trial	☐	☐	☐
Description about Medication(s)/Treatment(s) not permitted before and/or during the trial	☐	☐	☐
Procedures for monitoring subject compliance	☐	☐	☐
Assessment of Efficacy			
Specification of efficacy parameters	☐	☐	☐
Methods and timing for assessing of efficacy parameters	☐	☐	☐
Methods and timing for recording of efficacy parameters	☐	☐	☐
Methods and timing for analyzing of efficacy parameters	☐	☐	☐
Assessment of Safety			
Specification of safety parameters	☐	☐	☐
Methods and timing for assessing of safety parameters	☐	☐	☐
Methods and timing for analyzing of safety parameters	☐	☐	☐
Procedures for eliciting reports of AE and Intercurrent illnesses	☐	☐	☐
Procedures for recording& reporting of AE and Intercurrent illnesses	☐	☐	☐

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Description about the type and duration of the follow-up of subjects after AE	☐	☐	☐
Statistics			
Description of the statistical methods to be employed, including timing of any planned interim analysis(ses)	☐	☐	☐
No of subjects planned to be enrolled in whole study	☐	☐	☐
In multicenter trials, no: of enrolled subjects projected for each trial site	☐	☐	☐
Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification	☐	☐	☐
The level of significance to be used	☐	☐	☐
Criteria for the termination of the trial	☐	☐	☐
Procedure for accounting for missing data	☐	☐	☐
Procedure for accounting for unused data	☐	☐	☐
Procedure for accounting for spurious data	☐	☐	☐
Procedure for reporting any deviation(s) from the original statistical plan	☐	☐	☐
Description about the selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects)	☐	☐	☐
Direct Access to Source Data/Documents			

Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related audits, providing direct access to source data/documents	☐	☐	☐
Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related IRB/IEC review, providing direct access to source data/documents	☐	☐	☐
Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related regulatory inspection(s), providing direct access to source data/documents	☐	☐	☐
Quality control and Quality Assurance	☐	☐	☐
Ethics			
Description of ethical considerations relating to the trial	☐	☐	☐
Data Handling and Record Keeping	☐	☐	☐
Financing and Insurance			
Details about Finance and insurance, if not addressed in a separated agreement	☐	☐	☐
Publication Policy			
Details about Publication Policy, if not addressed in a separated agreement	☐	☐	☐
Supplements	☐	☐	☐

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d) Clinical Trial Agreement Review Checklist

Sl No	Content	Yes	No	Comment
1	Sponsor's name	☐	☐	☐
2	Type of Agreement Tripartite or Quadripartite	☐	☐	☐
3	The venue of Jurisdiction mentioned?	☐	☐	☐
4	Insurance certificate reviewed?	☐	☐	☐
5	Indemnity clauses are favourable to the institution?	☐	☐	☐
6	Check for the compensation details	☐	☐	☐
7	Details of SAE management is mentioned?	☐	☐	☐
8	Financial funding for the project is mentioned?	☐	☐	☐
9	Any other legal implication for the institution and investigator	☐	☐	☐
10	Subjects rights will be protected?	☐	☐	☐

e) IB Review Checklist

SI.No	Contents	Yes	No	Comments
1.1	Sponsor's name	☐	☐	☐
1.2	The reference number allocated to the study	☐	☐	☐
1.3	The identity of investigational product (i.e. research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor)	☐	☐	☐
1.4	Edition number and date	☐	☐	☐
1.5	Reference to the number and date of the edition it supersedes	☐	☐	☐
2.	**Confidentiality statement**	☐	☐	☐
3.	**Table of Contents**	☐	☐	☐
4.	**Introduction**			
4.1	Information relevant to the stage of clinical development including the significant physical & chemical properties, pharmaceutical, pharmacological (pharmacological class, advantages over other substances in that class and rationale for performing the proposed study), toxicological, pharmacokinetic, metabolic, and clinical information (anticipated prophylactic/ therapeutic or diagnostic indication(s)) of all active ingredients	☐	☐	☐
4.2	The introductory statement - The general approach to be followed in evaluating the Investigational Product	☐	☐	☐
5	**Physical, Chemical, and Pharmaceutical Properties and Formulation parameters**			
5.1	A description about the Investigational Product substance(s), including the chemical and / or structural formula(e)	☐	☐	☐
5.2	A brief summary of the relevant physical, chemical and pharmaceutical properties.	☐	☐	☐
5.3	Information about the structural similarities to other known compounds	☐	☐	☐
5.4	Information about excipients	☐	☐	☐
5.5	Information about storage and dosage handling	☐	☐	☐

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6.1	Information about data relating to non-clinical pharmacology, pharmacokinetics, metabolism profile in animals and toxicology	☐	☐	☐
6.2	Summary ofall relevant non-clinical pharmacology, toxicology, pharmacokinetic, and the Investigational Product metabolism studies	☐	☐	☐
6.3	Summary of the methodology used,	☐	☐	☐
6.4	The result s and a discussion of the relevance of the findings to the investigated therapeutic effects besides the possible unfavourable effects in humans.	☐	☐	☐
6.5	Information about the species used	☐	☐	☐
6.6	Information about number and sex of animals in each group	☐	☐	☐
6.7	Information about Unit dose (mg/kg)	☐	☐	☐
6.8	Information about dose interval	☐	☐	☐
6.9	Information about route of administration	☐	☐	☐
6.10	Information about duration of dosing	☐	☐	☐
6.11	Information on systemic distribution	☐	☐	☐
6.12	Information about duration of post-exposure follow-up	☐	☐	☐
6.13	**Results**			
6.13.1	Nature and frequency of pharmacological or toxic effects	☐	☐	☐
6.13.2	Severity or intensity of pharmacological or toxic effects	☐	☐	☐
6.13.3	Time to onset of effects	☐	☐	☐
6.13.4	Reversibility of effects	☐	☐	☐
6.13.5	Duration of effects	☐	☐	☐
6.13.6	Dose response	☐	☐	☐
6.13.7	Dose response of observed effects	☐	☐	☐
6.13.8	The relevance to humans	☐	☐	☐
6.13.9	Any aspects to be studied in humans	☐	☐	☐
6.13.10	Comparison of the effective and non-toxic dose findings in the same animal species (i.e. The therapeutic index should be discussed)	☐	☐	☐
6.13.11	The relevance of this information to the proposed human dosing	☐	☐	☐
6.13.12	Comparisons made in terms of blood/tissue levels rather than on a mg/kg basis	☐	☐	☐
6.14	**Non-clinical Pharmacological (Pharmacodynamics)**			
6.14.1	A summary of the pharmacological aspects of the	☐	☐	☐

	investigational product and its metabolites studied in animals			
6.14.2	Potential therapeutic activity assessment (e.g. efficacy models, receptor binding, and specificity)	☐	☐	☐
6.14.3	Safety assessment (eg. special studies to assess pharmacological actions other than the intended therapeutic effect(s)).	☐	☐	☐
6.15	**Pharmacokinetics and Product Metabolism in Animals**			
6.15.1	A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species Studied	☐	☐	☐
6.15.2	Discussion of the findings about the absorption and the local and systemic bioavailability of the IP and its metabolites	☐	☐	☐
6.15.3	Investigational product and its metabolites relationship to the pharmacological and toxicological findings in animal species.	☐	☐	☐
6.16	**Toxicology**			
6.16.1	A summary of the toxicological effects of IP found in relevant studies conducted in different animal species	☐	☐	☐
6.16.2	Single dose	☐	☐	☐
6.16.3	Repeated dose	☐	☐	☐
6.16.4	Carcinogenicity	☐	☐	☐
6.16.5	Special studies (eg. irritancy and sensitisation)	☐	☐	☐
6.16.6	Reproductive toxicity	☐	☐	☐
6.16.7	Genotoxicity (Mutagenicity)	☐	☐	☐
7	**Effects in Humans**			
7.1	Discussion of the known effects of the investigational product(s) in humans	☐	☐	☐
7.2	Information on pharmacokinetics, metabolism, Pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities	☐	☐	☐
7.3	Brief summaries of other clinical studies conducted on the same product	☐	☐	☐
7.4	**Pharmacokinetics and Product Metabolism in Humans**			
7.4.1	A summary of information on the pharmacokinetics of the investigational product(s)	☐	☐	☐
7.4.2	Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination)	☐	☐	☐
7.4.3	Bioavailability of the investigational product	☐	☐	☐

	(absolute, where possible, and/or relative) using a reference dosage form			
7.4.4	Population subgroups (e.g. gender, age, and impaired organ function).	☐	☐	☐
7.4.5	Interactions (e.g. Product-product interactions and effects of food)	☐	☐	☐
7.4.6	Other pharmacokinetic data (e.g. results of population studies performed within clinical trial(s).	☐	☐	☐
7.5	**Safety and Efficacy**			
7.5.1	Information about the Investigational Product (s)' (including their metabolites, where appropriate) safety Pharmacodynamics	☐	☐	☐
7.5.2	Information about the Investigational Product(s)' (including their metabolites, where appropriate) efficacy and dose response(s) that were obtained from preceding trials in humans (healthy volunteers and/or patients)	☐	☐	☐
7.5.3	In cases where a number of clinical studies have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data.	☐	☐	☐
7.5.4	Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications)	☐	☐	☐
7.5.5	Important differences in adverse drug reaction patterns/incidences across indications or subgroups	☐	☐	☐
7.5.6	A description of the possible risks and adverse drug reactions to be anticipated based on prior experiences with the product under investigation and with related products.	☐	☐	☐
7.5.7	A description about the precautions or special monitoring to be done as part of the investigational use of the product(s).	☐	☐	☐
8	**Regulatory & Post-marketing Experiences**			
8.1	Countries where the investigational product has been marketed or approved.	☐	☐	☐
8.2	Any significant information arising from the marketed use should be summarised (eg. formulations, dosages, routes of administration, and adverse product reactions)	☐	☐	☐

8.3	Countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.	☐	☐	☐
9	**Summary of Data and Guidance for the Investigator**	☐	☐	☐
10	**Bibliography**	☐	☐	☐
10.1	Overall discussion of the non-clinical and clinical data	☐	☐	☐
10.2	The information from various sources on different aspects of the investigational product(s)	☐	☐	☐
10.3	Published reports on related products	☐	☐	☐
10.4	The information given in this section should provide the investigator with a clear understanding of the possible risks and adverse reactions.	☐	☐	☐
10.5	Guidance about recognition and treatment of possible overdose and adverse drug reactions.	☐	☐	☐

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f) Agenda Format

AGENDA OF IEC MEETING

Meeting No :

Location of IEC Meeting :

Meeting date:

Meeting Time:

The Board meeting will proceed in the following sequences:

Period1:

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

Period2:

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

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

C] Approve protocol amendment and related documents.

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

E] To review Protocol Deviations /Violations

F] To review other Letters related to projects to review Monitoring reports

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

H] To inform about the SAE Subcommittee meetings and to review SAE / Safety reports.

I] Other points for discussion_

Period3:

Issues reviewed and approved by the IEC member Secretary and Chairperson which are to be reported Secretary and Chairperson which are to be reported for Consideration

Period4:

Issues to be informed to the members at Full Board which are approved by the IEC member Secretary and Chairperson and letters already sent to the principal investigator

Period5:

Other issues based on the interest of members

g) Application For Renewal Of Approval

APPLICATION FOR RENEWAL OF APPROVAL

- IEC Reference number
- Title of the research proposal
- Name of the Principal Investigator (PI) with qualification and designation
- Approval date
- Date study initiated, if no, specify reason
- Has subject recruitment begun?
- If subject recruitment has not begun, give reasons
- How many subjects have been screened?
- How many subjects have been randomized?
- How many Screen failures and or drop outs? Reason
- Is subject recruitment continuing?
- Is the Subjects completed the study, if no number of pending visits.
- Expected date for study completion?
- Have there been any adverse events/ Serious Adverse Events? If yes, give details
- Any Protocol deviation/Violations?
- Have there been any unanticipated study-related problems? If yes, give details.
- List of attachments for review, if any
- Remarks, if any

Signature of the Principal Investigator with date.

NOTE

- Investigator can use own format, but all the information should be furnished.
- Investigator should attach the renewal fee along with the application.

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INSTITUTIONAL ETHICS COMMITTEE

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PUSHPAGIRI RESEARCH CENTRE,

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STANDARD OPERATING PROCEDURES

Chapter: 6

SITE MONITORING

Chapter : 6

SITE MONITORING

1.0 Purpose

The purpose of this chapter is to provide the procedures for site monitoring.

2.0 Scope

This Chapter applies to conducting monitoring of studies involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, IEC shall choose to monitor the study more frequently.

3.0 Responsibility

ECs shall follow mechanisms to monitor the approved study site until completion of the research to check for compliance or improve the function. Monitoring can be routine or -for causel and shall be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review shall suggest that routine monitoring may be conducted at more frequent intervals.

The frequency of monitoring shallbe decided during the initial review of the meeting among the EC Members. The monitoring will be done by the Monitoring committee nominated by Chairperson and Member Secretary.

Procedure

This includes review of the overall progress of each study to insure the safety of participants, validity of data, that the projected actual goals are met on a timely basis, eligibility and evaluability rates do not fall below minimum acceptable standards, risks are not excessive, adverse events are appropriately monitored and reported to the appropriate agencies. Inherent in this process is the goal of enhancing the quality of the research.

The Cause for monitoring will be performed based on the following criteria

- High number of protocol violations and deviations;
- Large number of proposals carried out at the study site or by the same researcher;
- Large number of SAE reports;
- Complaints received from participants;
- Non-compliance with EC directions;
- Misconduct by the researcher

5.0 Before the Visit

The EC Secretariat will inform the investigator about the monitoring visit date. The monitoring committee will inform the investigator about the agenda of the monitoring visit.

During the Visit

The monitoring will be done by using the checklist and report will be submitted to the EC Chairperson and member secretary. The report will be discussed in the next full quorum EC Meeting. Monitor should give special attention to right safety well-being of study subjects while reviewing the study documents.

The following objectives are followed while monitoring the study.

- Eligibility of subjects recruited
- Proper recording and reporting of AE and SAE
- Adequate Consent procedure are followed
- Ongoing informed consent procedure is in place
- Adherence to protocol and regulatory requirements
- Investigational Product storage and handling

7.0 After the Visit

Monitoring visit checklist will be filled and submit to the IEC secretariat within 14 days. The report will be discussed in the next full board meeting of IEC. The findings and recommendations from IEC will be communicated to the Principal investigator 14 days after the meeting

ANNEXURES

1. Monitoring checklist
2. Monitoring Visit report template

a) Monitoring Checklist

MONITORING CHECKLIST	
Monitoring Visit	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor:	Address:
Total number of expected subjects:	Total subjects Enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are Informed Consents recent? Check about the ongoing informed consent process.	Comment:
In case of AV consenting, are the video films taken and stored appropriately?	Comment:
Check all the subject has got ample time for consenting.	Comment:
Any Adverse Events found?	Comment:

Any protocol Non-Compliance /violation?	Comment:
Are all Case Record Forms up to date?	Comment:
Are storage of data and investigating products locked?	Comment:
How well are participants protected?	Comment:
Any outstanding tasks or results of visit?	Comment:
Duration of visit: …….hours	Starting from:_____Hrs Finish: _____Hrs
Name of IEC/member/ Representatives and Accompanying person:	
Completed by:	Date:

b) Template for Monitoring visit report

MONITORING VISIT REPORT	
Name of the Study:	
Name of sponsor:	
Study Drug:	
Protocol ID:	
Name of the Investigator:	

Site ID:	
Contact Details of Investigational Site	
Visit Date:	

Site personnel present	**Function**

S.No.	**Concerns / Issues/ Situations**	**Comments / Resolutions**	**Answer from the concerned personnel**	**Sign**	**Date**
1	**SMF Review**				
2	**ICD Review**				
3	**CRF Review**				
4	**Site Facility Inspection**				

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5	**Source Data Verification**				
6	**AE / SAE Review**				
7	**Other Issues**				

Comments from PI team:

Approvals / Signatures

This signature confirms that this report summarizes the actions and observations at the site audit visit.

Type of Monitoring Prepared By: Name : Designation: Sign & Date:	 Approved By: Name : Designation: Sign & Date:

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STANDARD OPERATING PROCEDURES

Chapter 7

PROTECTION OF SUBJECT RIGHT SAFETY AND WELL-BEING

CHAPTER 7

PROTECTION OF SUBJECT RIGHT SAFETY AND WELL-BEING

1.0 Purpose

This Chapter shall provide guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

2.0 Scope

This Chapter shall apply to all requests concerning the rights and well-being of the research participants participating in studies approved by the IEC.

Responsibility.

It shall the responsibility of the IEC Member Secretary to provide the required information to the research participants/ research participant's representatives/patient, in the case of queries received.

It shall the responsibility of the Member Secretary/Chairperson to initiate a process of giving information to the participants or identifying and addressing any injustice that has occurred, if complaints are received from research participants.

The IEC shall assess the adequacy of safeguarding of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application.

The IEC shall evaluate the involvement of human subjects and proposed protections according to the following review criteria:

- Risk to subjects.
- Adequacy of protection against risks.
- Potential benefits of the proposed research to the subjects and others.
- Importance of the knowledge to be gained.
- Required qualifications and experience of the Investigators for the proposed study

- Any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action.
- Plans to withdraw subjects from the study by the Investigator.
- Medical care to be provided to research participants during and after the course of the research.
- Adequacy of medical supervision and social support for the research participants.
- Steps to be taken if research participants voluntarily withdraw during the research.
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so.
- Description of any plans to make the study product available to the research participants following the research and description of any financial costs to the research participants.
- Compensations for research participants for attending the visits.
- 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.
- Translations for appropriateness of language, accuracy and completeness of information.

The adequacy of the above points shall be ensured by proper review and monitoring by the EC.

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

In addition to that IEC office shall have the complaint register forms (Annexure 1) available for subjects who can fill their complaint and furnish in the complaint box. The subjects can also call to the EC contact details provided in their complaint and register the complaint. The EC office shall keep a register (Annexure 2) for the same and communicate with the institution and investigator to resolve it. The resolution shall be discussed and communicated to the subject.

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ANNEXURES

1. Subject complaint form
2. Register template

1.0 **Subject complaint form**

SUBJECT COMPLAINT FORM	
Institutional Ethics Committee Address Contact person: Contact number : Email	
Name of the subject: Address : Contact Number: Email ID: Name of the Bystander: Contact Number:	
Name of the Principal Investigator: Name of the study:	
Brief Description of the complaint:	
Sign and Date:	
Received By	
Signature:	

2.0 **Subject Complaint Register**

SI No	Name of the subject	Name of the Study	Name of the Principal Investigator	Date of complaint registered	Nature of Complaint	Action Taken	Mode of resolution	Date of resolution

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STANDARD OPERATING PROCEDURES

Chapter 08

ADMINISTRATIVE SUPPORT FOR EC

CHAPTER 08

ADMINISTRATIVE SUPPORT FOR EC

1.0 Purpose

Purpose of this Chapter shall be to provide guidance for the administrative support for the functioning of IEC including financial support and resources.

2.0 Scope

This Chapter applies to the administrative support being received by IEC.

3.0 Administrative Support

The institution shall be responsible for establishing an EC to ensure an appropriate and sustainable system for quality ethical review and monitoring. The institution shallbe responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and time for the Member Secretary to run the EC functions.

The institution shall provide space, infrastructure and staff to the EC for maintaining a full-time secretariat, safe archival of records and conduct of meeting. The selection criteria for administrative support staff shall be based on the qualification and experience as decided by the institution.

Financial Operations

- Ethics committee can be financially supported by the Institution. Every institution shall allocate reasonable funds for smooth functioning of the EC
- A reasonable fee for review may also be charged by the EC to cover the expenses related to optimal functioning in accordance to Institutional policies.
- The income and expenditure of the ethics committee shall be documented in the Income Expense Ledger Book.

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- The income and expenditure shall be audited by audit committee of Ethics committee once in a year. The audit report shall be submitted to the Head of Institution and EC chairperson

- Member Secretary shall beresponsiblefor maintaining the finance records

- Member Secretary shall report to the Head of the Institution the income and expenditure report biannually.

- The fees charged by the EC for the review of applications as mentioned in the EC Fee SOP is mentioned in the Annexure. (Annexure 1)

Honorarium to EC Members

- It is recognized that all the Members of EC are busy individuals in their own positions. They, by all means, take time to review the protocol and attend the meeting.

- For balancing the sensitivity of their time on one hand & also not to be coercive in nature by furnishing undue amounts, it is decided that a nominal amount would be paid as compensation/reimbursement to each member who would attend a meeting.

- This amount would also serve as their travel allowance, to & from the meeting venue and other incidentals that the members may spend on account of the meeting.

- The Secretariat staff would be ready with the payments to be paid to the members by cheque/cash, after a meeting. (Annexure 2)

The Members who attended a meeting shall:

1. Sign the attendance sheet.

2. Return all the documents circulated to the members for preparation for the review for the meeting.

3. Sign the Dispatch and Return Log of Documents reflecting the above.

4. Sign the Payment Receipt Voucher for receipt of the compensation of the meeting held.

5. Receive the payment as per the Payment Receipt Voucher for their contribution in the meeting.

ANNEXURES

1. EC Fee Annexure
2. Payment receipt voucher

1.0 EC Fee Annexure

Bank Name	.....
Payee Name	.....
Pan No	.....
Account NO	.....
IFSC Code	.....
Initial Review Fees for Phase II, III & IV Clinical Trials	.....
Review fees for the amendment of approved documents	.....
SAE Review Fee	.....
Expedited review fee	.....
Annual Fee	.....

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2.0 **Payment Receipt Voucher**

Date: _____

	Rs	P
Paid To: _____		
Particulars: _____		
_____		
Rupees: _____		

Authorized by: _____

Passed by : _____

Paid cash/ Cheque drawn on: _____

Cheque No:_____ Date: _____

Receiver's Signature

INSTITUTIONAL ETHICS COMMITTEE

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STANDARD OPERATING PROCEDURES

CHAPTER 09

COMMUNICATION WITH STAKE HOLDERS

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CHAPTER 09

COMMUNICATION WITH STAKE HOLDERS

1.0 Purpose

Purpose of this chapter to give guidance on the communication process with the Head of Institution, Investigator and Regulatory.

2.0 Scope

This Chapter applies to the communication process for IEC with various stake holders.

Communication with Regulatory

The IEC is registered under Drug controller General of India.

IEC communicate with DCGI on the following topics

- In the contest of revision SOP and constitution of IEC members
- Reregistration process of IEC
- Communicating due analysis report of SAE occurred at the institution
- Any other relevant communication receive from DCGI

Communication with the investigator

IEC will communicate with investigator in writing and same will be documented. The IEC communicates with investigator in following contests

- Receipt acknowledgment for all communication from the investigators
- Reminder for the annual reports, annual review. periodic reports or any other relevant communication expect from investigator
- Deliberations of the meeting via approval letter, disapproval letter or query letter
- Monitoring intimations and monitoring findings
- Any additional information IEC requires regarding the study.

Communication with the Head of Institution

IEC is constituted under the HOI and report to the HOI timely manner. The communication will be through email or writing. Below are the common reporting procedures to HOI.

- Resignation and replacement of members
- Annual assessment of members
- Annual Audit report of EC functioning
- Biannual report from Member secretary regarding overall functioning and finance arrangements.
- Reconstitution and approval of revision of SOP
- Administrative requirements

Annexure

1. Reminder letter to investigator

Reminder letter to investigator	
Name of Principal Investigator: -	
Study Title	
The above-referenced project was approved by the IEC on_and is due for _____by the IEC. Kindly submit the continuing review application on or before_____. In case the projects have been completed/terminated, kindly complete the appropriate forms and submit to IEC on or before (date). Thanking you for your co-operation, Yours truly, Signature with date Member Secretary	

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STANDARD OPERATING PROCEDURES

Chapter : 10

REVIEW OF SERIOUS ADVERSE EVENT AND OTHER SAFETY REPORTS

CHAPTER 10

REVIEW OF SERIOUS ADVERSE EVENT AND OTHER SAFETY REPORTS

1.0 Purpose

Purpose of this chapter to shall be to give the guidance for the review and reconciliation of Serious Adverse events reporting to the IEC.

2.0 Scope

This SOP chapter shall apply to the IEC review of SAEs and unexpected events reports including follow up reports submitted by investigators.

3.0 Responsibility

The IEC shall be responsible for the review of all adverse events happening in the study. All AEs shall 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. EC shall give more attention while reporting and reviewing Serious Adverse Events (SAE). The EC shall be responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum of compensation and type of assistance to be provided to the participants.

4.0 Definition of Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

- results in death,

- is life-threatening,

- requires inpatient hospitalization or prolongation of existing hospitalization,

- results in persistent or significant disability/incapacity, or

- is a congenital anomaly/birth defect.

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All clinical trials under the purview of CDSCO, the timeline and procedures as notified from time to time shall be followed for SAE reporting. All research participants who suffer harm, whether related or not, shall be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc. Medical management shall be free if the harm is related to the research. Compensation shall be given to any participant when the injury is related to the research. This shall be applicable to participants in any of the arms of research, such as intervention, control and standard ofcare.

Procedure for reporting SAE

- Investigators who are participating in the clinical trial from the Institution shall be requested to strictly follow the reporting and review guidelines of the SAE as per the local regulations of the country.
- As per the regulation Investigator has to submit the initial report of SAE to EC within 24 hours of SAE occurrence. Investigator can submit the SAE report to EC via an email followed by hard copy. The reporting should make via Appendix XI form along with supportive documents.

Ethics committee E-mail ID for 24-hr SAE submission	
Ethics committee Email:	**pushpagiriirb@pushpagiri.in**
Ethics committee contact number	**0469 2775518**

- The investigator has to submit the initial report of SAE to the respective sponsor within 24 hours of SAE occurrence.
- The investigator has to submit the initial report of SAE to the Drug Controller General of India within 24 hours of SAE occurrence at the below mentioned Email ID/Fax No.

Higher Authority E-mail ID and Fax No. for 24-hr SAE submission	
Higher Authority Email:	**dci@nb.nic.in**
Higher Authority Fax No:	**01123236973**

- The Investigator and Sponsor have to submit the analyzed report of SAE to the EC Chairman, Head of the Institution and DCGI within 14 calendar days of SAE occurrence.
- On receipt of the analyzed report of SAE from the Investigator, the EC shallorganize a full quorum meeting and request the investigator to present about the event. The committee shall discuss about the relatedness of the event with the clinical trial and give opinion on financial compensation to be paid by the Sponsor/ his representative according to the formula published by DCGI.
- A detailed report of recommendation of compensation shall be submitted to the DCGI by EC within 30 calendar days of SAE occurrence.
- If the SAE is death the report shall be submitted to the Chairman of Expert Committee as well within the above-mentioned time frame.

Any injury or death due to the following reasons shall be considered as clinical trial related injury or death and subjects are entitled to receive the compensation.

a) Adverse effect of investigational product
b) Violation of approved protocol, scientific misconduct or negligence by sponsor or sponsor representative or investigator
c) Failure of investigational product to provide intended therapeutic effect
d) Use of placebo in placebo-controlled trial
e) Adverse effect due to concomitant medication excluding standard of care necessitated as part of approved protocol
f) For injury to child in utero due to parent's participation in clinical trial
g) Any trial related procedures involved in the study

While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC shall 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, shall be 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.

Compensation in case of injury or death during clinical trial:

- In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required or till it is established that the injury is not related to clinical trial whichever is earlier.

- In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the licensing authority defined under clause (b) of rule 21, and the financial compensation shall be over and above any expenses incurred on the medical management of the subject.

- In the case of clinical trial related death of the subject, his/her nominee(s) shall be entitled for financial compensation, as per the order of the licensing authority defined under clause (b) of rule 21, and the financial compensation shall be over and above any expenses incurred on the medical management of the subject.

- The expenses on medical management and the financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

- The financial compensation for clinical trial related injury or death could be in the form of

  - Payment for medical management;
  - Financial compensation for trial related injury;
  - Financial compensation to nominee(s) of the trial subject in case of death;
  - Financial compensation for the child injured in—utero because of the participation of parent in a clinical trial.

- Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her

nominee(s), as the case may be, shall be entitled for financial compensation for such injury or death:

- Adverse effect of investigational product(s);
- Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
- Failure of investigational product to provide intended therapeutic effect;
- Use of placebo in a placebo-controlled trial;
- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
- For injury to a child in-utero because of the participation of parent in clinical trial;
- Any clinical trial procedures involved in the study.

- The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for the conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the above reasons.
- The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the licensing authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.
- In case the sponsor fails to provide medical management for the injury to the subject and/or financial compensation to the trial subject for clinical trial related injury or financial compensation to the subject's nominee(s) in case of clinical trial related death of the subject, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons thereof, suspend or cancel the clinical trial and/ or restrict sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

Procedure for payment of financial compensation:

The Investigator shall report all serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the Clinical trial and the Ethics Committee that accorded approval to the study protocol, within twenty-four hours of their occurrence as per Appendix XI.

The cases of serious adverse events of death shall be examined as given below:

a. An independent Expert Committee shall be constituted by the Licensing Authority as defined under rule 21(b) to examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of death and quantum of compensation in case of clinical trial related death.

b. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on serious adverse event of death after due analysis to Chairman of the Ethics Committee and Chairman of the Expert Committee with a copy of the report to the Licensing Authority as defined under rule 21(b) and the Head of the Institution where the trial has been conducted, within ten calendar days of occurrence of the serious adverse event of death.

c. The Ethics Committee shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee with a copy of the report to the Licensing Authority within 30 days of the occurrence of the serious adverse event of death.

d. The Expert Committee shall examine the report of serious adverse event of death and give its recommendations to the Licensing Authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics Committee, and the Expert Committee while examining the event, may take into consideration, the reports of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Ethics Committee.

e. In the case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

f. The Licensing Authority shall consider the recommendations of the Expert Committee and shall determine the cause of death and pass orders as deemed necessary.

g. In case of clinical trial related death, the Licensing Authority, after considering there commendations of the Expert Committee, shall decide the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

Cases of serious adverse events, other than deaths, shall be examined as given below:

a. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Licensing Authority as defined under rule 21(b), Chairman of the Ethics

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Committee and Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

b. The Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his Representative, whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial, to the Licensing Authority within 30 calendar days of occurrence of the serious adverse event.

c. The Licensing Authority shall determine the cause of injury and pass order as deemed necessary. The Licensing Authority shall have the option to constitute an independent Expert Committee, wherever considered necessary, to examine such serious adverse events of injury, which will recommend to the Licensing Authority for arriving at the cause of the injury and also the quantum of compensation in case of clinical trial related injury, to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

d. In case of clinical trial related injury, the Licensing Authority, shall decide quantum of compensation to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

e. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, shall pay the compensation in case of clinical trial related injury or death as per the order of the Licensing Authority as defined under rule 21 (b) within thirty days of the receipt of such order.

Review of Suspected Unexpected Serious Adverse Reaction (SUSAR) / CIOMS

- All other sites SAEs, SUSARs, CIOMS and any other safety information pertaining to the trial have to be notified to IEC as per the timelines given in the guidelines or upon within 7 days of receipt.

- Safety Reports will be acknowledged by the Member Secretary and copy will be retained in the IEC study file/binder.

- All the Safety Reports or updates will be circulated to the members during the meeting
- IEC may ask to provide additional information related to SUSARs as required.

Annexures

1. Data Elements For Reporting Serious Adverse Events Occurring In A Clinical Trial (Table 5 Of New Drug And Clinical Trial Rule)
2. Due Analysis report template
3. Compensation formula

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a) DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL (Table 5 of New Drug and Clinical Trial Rule)

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

- Initials & other relevant identifier (hospital/OPD record number etc.):
- Gender:
- Age and/or date of birth:
- Weight:
- Height:

2. Suspected Drug(s)

- Generic name of the drug:
- Indication(s) for which suspect drug was prescribed or tested:
- Dosage form and strength:
- Daily dose and regimen (specify units - e.g., mg, ml, mg/kg):
- Route of administration:
- Starting date and time of day:
- Stopping date and time, or duration of treatment:

3. Other Treatment(s)

- Provide the same information for concomitant drugs (including non prescription /OTC drugs) and non-drug therapies, as for the suspected drug(s):

4. Details of Suspected Adverse Drug Reaction(s)

- Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction:
- Start date (and time) of onset of reaction:
- Stop date (and time) or duration of reaction:
- Dechallenge and rechallenge information:
- Setting (e.g., hospital, out-patient clinic, home, nursing home):

5. Outcome

- Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted:
- For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings:
- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc:

6. Details about the Investigator

- Name:
- Address:
- Telephone number:
- Email ID:
- Profession (Speciality):
- Site ID:

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- Date of reporting the event to Licensing Authority:
- Date of reporting the event to Ethics Committee overseeing the site:
- Signature of the Investigator:

7. Details about the Ethics Committee

- Name & Address
- Name of Chairman & Address
- Telephone/Mobile Number
- Email

8. Causality Assessment by Investigator with reasoning for Relatedness/Un-relatedness along with supporting investigational documents.

9. Socioeconomic background of subject/patient viz. Qualification, Occupation, Monthly income

b. Due Analysis report template

Due Analysis Report

Study Title	
CTRI Registration No	
Study ID	
CRO Address	

Type of Report	
Type of SAE	
DCGI Acknowledgement details of Initial Report	

1. Patient Details

Initials	
Subject No	
Date of Birth/Age	
Gender	
Weight	
Height	
Hospital OPD Record No	

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2. Suspected Drug(s)

Generic name of the drug	
Indication(s) for which suspect drug was prescribed or tested	
Dosage for and strength	
Daily dose and regimen	
Route of administration	
Starting date and time of day	
Stopping date and time, or duration of treatment	

3. Other Treatment(s)

Drug (Generic Name)	Dose/ Route/Frequency	Start date	Stop date	Indication

4. Details of Suspected Adverse Drug Reaction(s)

Event	
Start date	
Stop date	
Relationship to study drug	
Outcome	
Severity	
De challenging/ Re challenging	
Setting	

Description of the event/s

5. Outcome

6. Laboratory Reports:

7. Action Taken for the Serious Adverse Event:

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8. Details of Compensation:

9. Relatedness to Study Agent/ Study related procedure(s):

Investigator Causality	

10. Details about the Investigator & Ethics Committee

Details about the Investigator	
Site ID	
Investigator Name	
Specialty	
Address	
Telephone No:	
Email ID	
Details about the Ethics Committee	
Name & Address	
Name of the Chairman & Address	
Telephone/ Mobile Number	

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STANDARD OPERATING PROCEDURES

CHAPTER 11

SELF ASSESSMENT PROCESS

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Email	

Date if reporting the event to Licensing Authority	
Date of reporting the event to the Ethics Committee overseeing the site	
Sponsor (Address with contact no and Email)	
Investigator's signature & date	

CHAPTER 11

SELF ASSESSMENT PROCESS

1.0 Purpose

Purpose of this SOP chapter is to provide guidance for assessment of functioning of IEC.

2.0 Scope

This SOP Chapter applies the measures taken by IEC for the effective functioning.

3.0 Responsibility

The responsibility of self-evaluation of IEC functions shall lie with Chairperson and Member Secretary.

Process

IEC shall have a self-assessment system to ensure the effective functioning of IEC. Self-assessment shall be performed for each member. The self-evaluation shall be done annually. An Audit Committee shall be selected during the meeting which shall be approved by Chairperson.

One or more audit committees can be designated based on the requirement. All committees shall be approved in the full quorum meeting. The Audit Committee can be revised annually.

The Audit Committee shall be responsible for the assessment of functions and operations of IEC. The following areas shall be assessed by the Audit Committee once in a year.

- Functioning of IEC
- Attendance and Participation of Members
- Training and Certifications of Members
- Record Keeping and Archival
- Income and Expenditure of IEC
- Periodic Monitoring and Review
- SAE Management Process
- Documentation Management

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- Administrative Support
- Performance ofMembers

The Audit Committee shall share the report to Member Secretary. The Member Secretary shall share the report to the Chairman and Head of Institution. The audit report shall be discussed in the full quorum IEC meeting and Corrective Action and Preventive Actions (CAPA) will be preparedand implemented by the Audit Committee. The implementation of CAPA shall be verified by Member Secretary and the same shall be discussed in the next EC meeting.

Assessment of EC Members

IEC will do assessment of its functioning annually. The member secretary and Chairperson will do the self-assessment using the assessment form. Member Secretary will perform assessment the members and report to the Chairperson. Actions will be taken based on the assessment. The members may be retrained or removed based on the nonperformance in the EC functions.

Annexure

1. Audit Checklist
2. Assessment form for members

1. Audit Checklist

	Name of the Assessor: Period of Assessment:	
SI No	Assessment	Comments
1	No of meetings conducted	
2	Are IEC meetings held as per the timelines?	
3	Number of Protocols reviewed	
4	Number of Protocols approved	
5	Number of SAEs reported	
6	Number of SAEs reviewed	
7	Was SAE Management satisfactory	
8	Had effective compensation been paid to subjects	
9	Details of Trainings conducted by IEC	
10	Number of Monitoring's performed	
11	Number Complaints registered by subjects	
12	Details of action taken for the complaints	
13	Details of payment received and spent	
14	Details of reconstitution made in the IEC	
15	Were all the changes in the reconstitution reported to DCGI?	
16	Any revision in the SOP has been made	

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2. Assessment form for members

IEC Evaluation Form of Staff

	Mention () the individual who is performing the evaluation:	Self – evaluation: Member secretary IEC
	Name of the person who is evaluated:	
	Role in IEC:	
SI No	Assessment	Comments
1	Handles workload efficiently	Yes: No:
2	Number of protocols processed that were reviewed	
3	Completion of required checklists and documentation	Yes: No:
4	Maintains paper files efficiently andcorrectly	Yes: No:
5	Prepares agenda and minutes in timely manner	Yes: No:
6	Maintain IEC rosters efficiently and correctly	Yes: No:
7	Prepare IEC records efficiently and correctly	Yes: No:
8	Completion of Training requirement	Yes: No:
9	Attendance at Training sessions	Regular: Irregular:
10	Number of Training sessions Attended	
11	Preparedness for meetings	Good: Average: Poor:
12	Quality of pre-reviews	Good: Average: Poor:
13	Communication with IEC chair	Good: Average: Poor:

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STANDARD OPERATING PROCEDURES

CHAPTER 12

RECORD KEEPING AND ARCHIVAL

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CHAPTER 12

RECORD KEEPING AND ARCHIVAL

1.0 Purpose

Purpose of this SOP Chapter is to provide instructions for preparation and maintenance of active study files and other related documents approved by the IEC and storage/archival of closed study files and retrieval of documents.

2.0 Scope

This SOP chapter applies to all active protocol/study files, closed files and their related documents that are maintained in the IEC office and archival site

3.0 Detailed Procedure

All documentation and communication of an EC should be dated, filed, and archived with utmost confidentiality. The documents will be archived for a minimum period of 5 years following the completion of a study. The access is limited to the archived documents and tracked by a Register book for the entry and exit. EC Chairperson, Member Secretary and personnel delegated by Chairperson/Member Secretary only will have access to the archival area.

Documents that should be filed and archived include, but are not limited to:

Administrative Documents

- Constitution and composition of the EC
- Appointment letters
- Signed and dated copies of the most recent curriculum vitae of all EC members
- Signed confidentiality agreements
- COI declarations ofmembers
- Training records of EC members
- Financial records ofEC
- Registration/accreditation documents, as required

- A copy of national and international guidelines and applicable regulations
- Regulatory notifications
- Meeting-related documents
- Agenda and minutes
- All communications received or made by the EC
- SOPs

Study-related documents

- One hard copy and a soft copy of the initial research proposal and all related documents
- Decision letters
- Any amendments submitted for review and approval
- Regulatory approvals
- SAE, AE reports
- Protocol deviations/violations
- Progress reports, continuing review activities, site monitoring reports
- All correspondence between the EC and researchers
- Record of notification issued for premature termination of a study with a summary of the reasons
- Final report of the study
- Publications, if any

- Records can be maintained in hard copies as well as soft copies.
- For each project a separate file will be maintained.
- All the research related documents and communications of IEC will be dated and filed in the respective binders.
- All the Study related documents will be filed in the respective study specific binders.
- Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.
- The archival room will be provided with fire extinguisher and pest control to make sure the long term safety of the documents

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Retrieval Procedure

- The documents can be retrieved by Authorized personals by requesting via document request form to EC Member Secretary. Up on Permission copy of the requested documents will be shared which will be documented.
- If the investigator needs copy of the document. Investigator has to give document request form and the EC secretariat will issue the document within one week
- All the records shall be accessible for inspection and copying by authorized representatives of the regulatory at reasonable times and in a reasonable manner.

Final Disposal of documents

The files will be disposed off by the IEC secretariat after the archival period of 5 years. A formal document tracking register will be maintained, providing details of the documents being written off / disposed off after notification to IEC in IEC meeting. The disposal shall be performed by means of shredding.

ANNEXURE

1. Document Tracking register
2. Document request form

1. Document Tracking register

Project No.	Title of Project	IEC Approval Date	No of Files	Study Initiation date	Location of the storage	Study Closure Date	Location of the storage	Name of the authorized individual archived	Date of Destruction	Sign of the responsible person

2. Document Request Form

Name of Document requested:	Date:
Requested by:-	Study Title:-
☐ Principal investigator ☐ IEC/IRB Member ☐ Authority ☐ Others……..	
Purpose of the request:	
Retrieved by:	Date:
Returned by:	Date:
Archived by:	Date:
Approved by:	Date:

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STANDARD OPERATING PROCEDURES

Chapter 13

PREPARING FOR ETHICS COMMITTEE AUDIT/INSPECTION

CHAPTER 13

PREPARING FOR ETHICS COMMITTEE AUDIT/INSPECTION

1.0 Purpose

The purpose of this Chapter is to guide an Institutional Ethics Committee (IEC) to prepare for an audit or inspection of the IEC.

2.0 Scope

This chapter applies to all the IEC members and the Secretariat.

3.1 Responsibility

It is the responsibility of the Member Secretary, Chairperson, IEC Members and the IEC Secretariat to keep IEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

Detailed instructions

As per the provision of rule 122DD of Drugs And Cosmetic Rule 1945, _The Ethics Committee shall allow inspectors of officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of the trial. This SOP chapter is also applicable for the preparation of any audit or inspection from external regulatory bodies.

Receipt of notification of an Audit / Inspection

On receipt of written/ mailed communication regarding audit/ inspection visit, the Member Secretary will inform the Chairperson, IEC members and the Head of Institution, if applicable about the date and purpose of the audit/inspection.

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Preparing for the audit

- On receiving information about the audit /inspection, IEC Member Secretary and/ or IEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and / or designated IEC member/s will make arrangements in accordance with the steps mentioned in the checklist
- The studies with incomplete / missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

On the day/s of Visit

- Chairperson / Member Secretary / designated IEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.
- The IEC Chairperson / Member Secretary / IEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/ designated IEC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated IEC member/ Secretariat will review comments and recommendations of the auditor/inspector.

- On receipt of Audit/ Inspection Report the Chairperson should implement corrective and preventive measures and set the timeline for implementation of corrections as stated by the auditor/inspector.

- Action plan should be communicated by the Member Secretary/ designated IEC member to the auditor/inspector after seeking approval of the Chairperson.

- A review date for an internal follow-up audit will be decided by the Chairperson (if applicable).

The Member Secretary/ designated IEC member should report the outcome of the internal follow-up audit to the Chairperson.

Recording the Audit/Inspection Visit

- The Member Secretary/ designated IEC member/ Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.

- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.\

ANNEXURE

1. Check list

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES PUSHPAGIRI MEDICITY TIRUVALLA-7

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

ANNEXURE

- Check list

SI.No	Activity	Yes / NO
1.	Date of letter of communication regarding audit/inspection:	
2.	Date(s) on which the audit/inspection has been agreed on:	
3.	To ensure the IEC members and staff have been informed about the date/s and time.	
4	To ensure availability of IEC related information – mandate, terms of reference, organization chart (in the print form) in the IEC office.	
5	To make sure of availability of latest copy /copies of signed SOPs in print form in the office and/ or in electronic form on the IEC computer/s.	
6	To review the SOPs and note details of any omissions or deviations, with reasons.	
7	To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the IEC office.	
8	To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken. ➢ Records regarding applications of research studies for review including protocols and related documents ➢ Protocol Assessment Records – Comments of IEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records file) ➢ Communication records with investigator (documented in	

	individual study file) ➢ Amendment Approvals (documented in individual study file) ➢ SAE reports and SAE related communications with investigator and regulators ➢ Protocol deviation/violation/exception reports(documented in individual study file) ➢ Continuing and final completion/termination reports	
9	(documented in individual study file) To ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of IEC members	
10	To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.	
11	To ensure measures for maintaining security of electronic database and office records.	
12	To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as per the respective SOPs.	
13	To ascertain proper labelling and indexing of study files and storage cabinets.	
14	To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up audit(if applicable)	
15	To report about findings and report received regarding audit/inspection to IEC members at the full board IEC meeting.	

INSTITUTIONAL ETHICS COMMITTEE

Pushpagiri Institute of Medical Sciences,

Pushpagiri Research Centre,

Thiruvalla, Kerala – 689101

Ph: 0469 2775518

Email: pushpagiriirb@pushpagiri.in

STANDARD OPERATING PROCEDURES

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

THIRUVALLA, KERALA-689101, INDIA

STANDARD OPERATING PROCEDURES

	Name	**Designation**	**Signature**	**Date**
Prepared by	Dr. Liya Roslin	Basic Medical Scientist		
	Dr. Philip Mathew	Clinician		
	Dr. Nibu Varghese	Scientific Member		
	Dr. Prasanth Rathinam	Supporting Staff		
Reviewed By	Dr. Nebu George Thomas	Member Secretary		
Approved By	Dr. Harikumar B Nair	Chairman		
Authorized By	Dr. T P Thankappan	Principal		

LIST OF ETHICS COMMITTEE MEMBERS

Sl No	Name	Gender	Qualification	Designation in the EC	Affiliation
1	Dr. Harikumar Bhaskaran Nair	M	BAMS (AYURVEDA PHYSICIAN)	Chairman	Not Affiliated
2	Dr. Nebu George Thomas	M	MDS (Periodontics)	Member Secretary	Affiliated
3	Dr. Vikram Gowda	M	MD (Physiology)	Basic Medical Scientist	Affiliated
4	Dr. T P Thankappan	M	MD (Dermatology,Venereology & Leprosy)	Clinician	Affiliated
5	Dr. Philip Mathew	M	MD - Community Medicine	Clinician	Affiliated
6	Adv. Minu Mathews	F	LLM	Legal Expert	Not Affiliated
7	Fr. Sibin Mathew	M	Bachelor in Theology	Social Scientist	Not Affiliated
8	Lijo George	M	B. COM	Lay Person	Not Affiliated
9	Dr. Tressia Alias Princy Paulose	F	DOCTORATE IN CHEMISTRY	Scientific Member	Not Affiliated
10	T M CHARRY	M	DOCTORATE IN BIOCHEMISTRY	Scientific Member	Not Affiliated
11	Dr. G SULOCHANA	F	MD - PATHOLOGY & MICROBIOLOGY	Basic Medical Scientist	Not Affiliated
12	Dr. NIBU VARGHESE	M	DOCTORATE IN PLANT BIOTECHNOLOGY	Scientific Member	Affiliated
13	STEPHEN JAMES	M	MTech CS-IT	Member	Not Affiliated
14	Dr. Athulya G Asokan	F	MD - General Medicine	Clinician	Affiliated

LIST OF ETHICS COMMITTEE MEMBERS

15	Dr. LIYA ROSLIN JOSEPH	F	MD - Pharmacology	Basic Medical Scientist	Affiliated

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INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

THIRUVALLA, Kerala-689101, India

Ph: 0469 2775518

STANDARD OPERATING PROCEDURES

CHAPTER -1

PREPARATION AND IMPLEMENTATION OF STANDARD OPERATING PROCEDURE

CHAPTER -1

PREPARATION AND IMPLEMENTATION OF STANDARD OPERATING PROCEDURES

1.0 Purpose

This Standard Operating Procedures (SOP) defines the process for writing, reviewing, distributing, and amending SOPs within the Institutional Ethics Committee (IEC). The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines Schedule ‗Y‖ and ICH (International Conference on Harmonization) Good Clinical Practice (GCP).

2.0 Scope

This SOP Chapter covers the procedures of writing, reviewing, distributing, and amending SOPs within the IEC.

Procedure and Responsibilities

The SOP shall be prepared according to the applicable regulatory requirements and it shall be approved by Chairperson of the Ethics Committee. SOP shall be revised time to time to meet the new regulatory requirements. The need of a revision of SOP shall be discussed in the IEC meeting and Chairperson shall appoint SOP writing team to revise the SOP.

The proposal for amendment shall be submitted to the Member Secretary. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting. Only regular members shall vote to accept or reject the proposed amendment. A proposed amendment will be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.

It is the responsibility of Chairperson of the IEC to appoint the SOP writing Team to formulate the SOPs. SOP writing team will consist of Member Secretary of IEC, administrative staff and one or two other IEC members

SOP writing team will prepare the draft SOP. The draft SOPs will be reviewed and approved by the IEC members. SOP writing team will be responsible to amend the SOPs as and when required.

SOPs will be reviewed by the members of IEC. The Chairpersons of IEC will approve the SOPs. The SOPs will then be approved by Head of Institution, as these are SOPs for Institutional Ethics Committee for Research Review.

Approved SOPs will be implemented from the effective date. The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly. Training on New SOP will be conducted for all members.

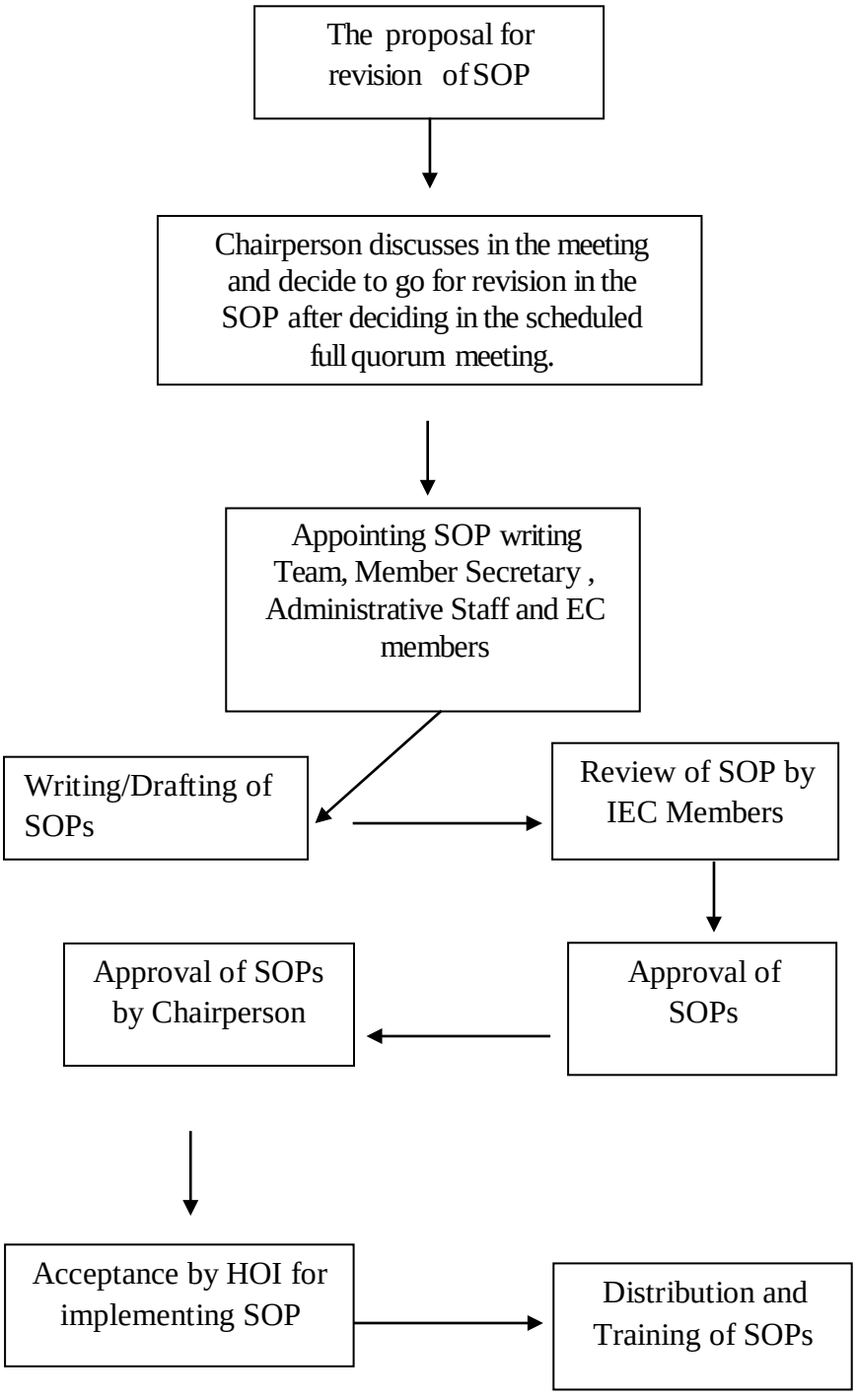
The EC Members will be trained on SOPs annually and whenever there is revision in the SOP. The training records will be maintained by EC

Old SOPs should be retained and clearly marked "superseded" and archived in a file by the secretariat. The process of evolution of previous SOPs of the IEC will be documented in a defined format.

ANNEXURES

1. Flow chart of SOP implementation
2. SOP Issue Log

1. Flow chart of SOP implementation



2. SOP Issue Log

No	Name of the Recipient	Designation	SOP details	No. of Copies	Date Issued	Signature of the recipient

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

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STANDARD OPERATING PROCEDURES

Chapter 2

AUTHORITY AND PROCEDURE TO FORM ETHICS COMMITTEE

CHAPTER 2

AUTHORITY AND PROCEDURE TO FORM ETHICS COMMITTEE

1.0 Purpose

This SOP Chapter shall mention about the authority under which EC is constituted and its procedures for forming Ethics Committee.

2.0 Scope

The SOP Chapter applies to the formation of the EC.

3.0 Authority to constitute IEC

The Head of the institution or person who plays equivalent position from the Institution has the authority for constitution of Ethics Committee. The head of institution will select a Member Secretary from the institution to form Ethics Committee. The Head of Institution and Member Secretary will identify a Chairperson who is not affiliated to the institution by any means. The head of institution will have Memorandum of Understanding with Chairperson. All other EC members are appointed by the Head of the Institution in consultation with chairperson / Member Secretary.

Criteria for selection of members:

- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
- The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
- Directors, Head of Institution, Superintendents, Administrative officers who are responsible for business development will not serve as members of IEC.
- New members will be identified according to the requirement

All EC members will receive invitation letter from Head of Institution and all EC Members

will sign acceptance to be part of the study and Confidentiality agreement. The office of Member secretary will act as the administrative office of EC. An updated CV will be collected from the invited members and Medical registration certificates will be collected for the members who are medically qualified.

The Ethics committee will maintain its independence from political, institutional, professional and market influences in the composition, procedures, and decision-making process. The head of Institution would ensure that its Members are competent enough to review a proposal submitted to them and at the same time they are free to express their thoughts and expressions in an unbiased manner.

EC would function in accordance with the Declaration of Helsinki, Good Clinical Practice, Schedule Y and all the applicable national and international guidelines for biomedical research.

The details of the Head of Institution, EC Chairperson and Member Secretary are given below:

Name of Head of the Institution:	**Dr. T P Thankappan**
Mailing address :	Head of the Institute, Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla - 689101
Contact No:	0469 2775518
Fax:	04692600020
Email:	tpthankappan@gmail.com
Name of the Chairman of EC:	Dr. HARIKUMAR BHASKARAN NAIR
Mailing address :	N.S.S. Ayurveda Hospital, Vallamkulam, Eraviperoor-689542 Kerala
Contact No:	+91 9447114492

Fax:	
Email:	doctorhari@gmail.com
Name of the Member Secretary:	Dr. Nebu George Thomas
Mailing address :	Pushpagiri Institute of Medical Science Pushpagiri Research Centre Mother and child block, Thiruvalla, Pathanamthitta, Kerala - 689101
Contact No:	9447044726
Fax:	04692600020
Email:	nebugt@gmail.com

ANNEXURES

a) Memorandum of Understanding with EC Chairperson
b) Format of invitation letter from Head of the institute to EC Members
c) Format for the acceptance letter/ Consent to be a member of IEC for IEC members
d) Name and Address of the member
e) Confidentiality agreement for members
f) Format for the Curriculum Vitae
g) Template for Conflict of Interest for members
h) Appointment letter

a) Memorandum of Understanding with EC Chairperson

MEMORANDUM OF UNDERSTANDING (MOU)

This MOU made and entered into on -- <Date> (effective date) between Institutional Ethics Committee - <Name and address>(Here after represented as Institution) represented by its Head of the Institute <Name of the HOI>And <Name of the Chairman> having address < enter the address> (here after represented as EC Chairperson).

Institution and EC Chairman hereinafter are individually referred to as –the Party‖ and are jointly referred to as –the Parties‖.

Where as

- The Institution is involved in providing healthcare services
- The Ethics committee is the committee functioning in the hospital to review and oversee the biomedical research conducting in the hospital
- Institution appoints EC Chairperson to head the ethics committee and EC Chairman accepts the invitation
- In view of the above, the parties have entered into this MOU on the terms and conditions mentioned herein below:

ROLES AND RESPONSIBILITES OF THE PARTIES

The roles and responsibilities of the parties are as mention below. The parties agree that they shall abide by the roles and responsibilities described and defined hereafter.

EC Chairman

1. Conduct EC Meetings and be accountable for independent and efficient functioning of the committee

2. Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations

3. Ratify minutes of the previous meetings

4. In case of anticipated absence of Chairman at a planned meeting, the Chairman should nominate a committee member as Acting Chairman or the members present may elect an Acting Chairman on the day of the meeting. The acting Chairman should be a non-affiliated person and will have all the powers of the Chairman for that meeting.

5. Seek Conflicts of Interest declaration from members and ensure quorum and fair decision making.

6. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

7. To protect the dignity, rights, safety and well-being of the potential research participants.
8. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
9. To assist in the development and education of a research community responsive to local health care requirements.
10. For this purpose, EC shall look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required.

11. Provide documents pertains afflation, qualification and training.

12. Assessment of EC Members

INSTITUTION

1. Institution to provide an office for the EC.
2. The institution should provide space, infrastructure and staff to the EC for maintaining a full-time secretariat, safe archival of records and conduct of meeting.
3. Institution should allocate reasonable funds for smooth functioning of the EC
4. Receive and review the reports provided by the Chairperson as per standard Operating Procedure.
5. Approve Standard Operating Procedures
6. Provide administrative requirements for the EC
7. Provide adequate honorarium for the participants of the meeting.

2. DURATION

The MOU shall be valid with effect from the effective date and shall continue to be in force for a period of Three years

3. TERMINATION

Either party may terminate this MOU by giving one month written notice to the other party

4. CONFIDENTIALITY

At all-time during the term of this MOU and thereafter each party shall hold in strictest confidence and shall not disclose, use, lecture upon or publish any of the other party's proprietary information, except as such disclosure, use or publication may be required in connection with such party's performance of its obligations under this MOU. The term –proprietary information‖ shall mean trade secrets, confidential knowledge, data or any other proprietary information of the party.

5. ARBITRATION

In the event of any dispute arising out of or in connection with this MOU, the parties wish to seek an amicable settlement as per the laws of India and Kerala.

Executed by their duly authorized representatives on the date(s) shown below.

Accepted and Signed by Hospital and EC Chairman

For INSTITUTION

Signature:_____

Name:_____

Date: _____

For EC CHAIRMAN

Signature:_____

Name:_____

Date: _____

b) Format of invitation letter from Head of the institute to EC Members

Invitation Letter

Date:

From,

Name and Address of the director

To,

Name and Address of the member

Sub: Invitation to join as a Member of Institutional Ethics Committee

Dear Sir / Madam,

On behalf of Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I request you to accept my invitation to be a member of Institutional Ethics committee. Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

Yours sincerely,

Signature:

Name of the director

c) Format for the acceptance letter/ Consent to be a member of IEC for IEC members

Acceptance Letter/ Consent to be a member of IEC

From

Name and Address of the member

To

Name and Address of director

Sub: Acceptance/Consent to be a member of IEC Regarding.

Ref: Your letter dated:

Dear Sir,

In response to your letter stated above, I accept the invitation to become a member of Institutional Ethics committee. I shall regularly participate in the Institutional Ethics committee meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing to publicize my full name, profession and affiliation.

I shall make available to the public on request, all reimbursement for work and expenses, if any, related to Institutional Ethics committee

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to any one other than project related personnel.

I herewith enclose my CV.

Thanking You,

Yours sincerely,

Signature ----------

Name of Member. ---------- Date:

Address

Telephone No: (Off)_____(Res)_____Email:

d) Format of the appointment letter from HOI to EC Members

Appointment Letter

Date:

From,

Name and Address of the HOI

To,

Name and Address of the member

Sub: Appointment letter as a Member of Institutional Ethics Committee

Dear Sir / Madam,

On behalf of Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I hereby appoint you as a member of Institutional Ethics Committee. You shall be designated the role of

……...

<<Terms of reference>>.

Your roles and responsibilities in the EC will be as follows: <<Roles and responsibilities>>

Yours sincerely,

Signature:

Name:

e) Format for Confidentiality Agreement by the EC Members

Confidentiality agreement

To,

Institutional Ethics Committee

Pushpagiri Institute of Medical Sciences,
Pushpagiri Research Centre, Thiruvalla, Kerala – 689101

I understand that I being a member of Institutional Ethics Committee Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101, I may acquire or may have already acquired knowledge of or access to, information concerning with the various research studies from companies.

I understand that this confidential information is the exclusive property of the study sponsor / Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, Kerala - 689101. I understand to keep this information strictly confidential. I will not disclose to any third party the information and contents of the confidential documents without prior written consent from Institutional Ethics Committee.

Signature : _____

Name : _____

Date : _____

f) Format for the Curriculum Vitae

Curriculum Vitae

Name	:	

Educational Qualifications:

Qualification	Institution	Year of passing

Medical Reg. No. (If applicable)	:	
Residential Address	:	
Current Organization	:	
Nature of Current organization (Gov/Pvt/Aided/Autonomus)	:	
Official Address (With designation)	:	
Currently Affiliated/Not Affiliated with Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla		
Current Profession	:	

Professional Experience:

Designation/Role	Institute	Period

List of Publications (if any)	:	

Personal Details

Gender	:	
Date of Birth	:	
Nationality	:	
Phone No.	:	
Email Id	:	

g) Template for Conflict of Interest for members

Agreement on Conflict of Interest

In accordance of the policy of the IEC, 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 IEC. The Undersigned will immediately disclose to the Chairperson of the IEC 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.

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

Signature Date

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: **0469 2775518**

STANDARD OPERATING PROCEDURES

Chapter 3

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

CHAPTER 3

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

1.0 Purpose

The IEC shall be established to formalize and specify Institution's commitment to the promotion of high scientific and ethical standards in patient care, professional education, clinical research, and community interests.

Ethical Basics for Constitution of EC

- The committee will consist of members who collectively have the qualifications & experience to review & evaluate the scientific, medical & ethical aspects of a proposed research project.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements & conditions of the various localities where proposed research is being considered.
- The IEC is guided in its reflection, advice & decision by the ethical principles expressed in WMA declaration of Helsinki- Ethical principles for medical research involving Human subjects.
- Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the :

  29th WMA General Assembly, Tokyo, Japan, October 1975

  35th WMA General Assembly, Venice, Italy, October 1983

  41st WMA General Assembly, Hong Kong, September 1989

  48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

  52nd WMA General Assembly, Edinburgh, Scotland, October 2000

  53rd WMA General Assembly, Washington 2002 (Note of clarification on paragraph 29 added)

  55th WMA General Assembly, Tokyo 2004 (Note of clarification on paragraph 30 added)

59th WMA General Assembly, Seoul, October 2008

- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code(1945), Belmont Report (1979), The council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research involving Human Subjects (Geneva 2002), and the European convention on Human rights & Biomedicine (1997).
- The IEC will ensure that the research protocols submitted by Clinical investigators are sound , scientifically designed, have statistical validity and are conducted according to the parameters of ICH-GCP, Indian GCP, Declaration of Helsinki, ICMR & Schedule Y as local regulatory requirements.
- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.

Terms of Reference of IEC

The terms of reference for the IEC are as follows:

- Ensure the highest scientific and ethical standards of research
- Review and approve proposals for clinical, basic or translational research projects (Intra and Extra mural) for scientific and ethical content
- Improve ethical standards and issue guidelines
- To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public
- To maintain leadership as a national standard of reference in all fields
- To issue and periodically, update and revise SOP s and guidelines for effective functioning of IEC as and when necessary
- Continuing education in clinical research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for all categories of staff members including nursing and paramedical staff
- To initiate and commission research studies on ethical aspects of practice.

Responsibilities of IEC

- To protect and safeguard the dignity, rights, safety and well-being of all actual or potential research participants.

- To ensure that the research projects that are carried out are sound in design, have statistical validity and are conducted according to the ICMR, Schedule Y and ICH/GCP guidelines
- To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in societytaking into account age, gender, economic status, culture and ethics consideration.
- To provide advice to the researchers on all aspects of the welfare and safety of research participantsafter ensuring the scientific soundness of the proposed research.
- To ensure the research are conducted under the supervision of trained medical / bio medical persons with the required expertise
- To ensure that research will Include, solely, patients or participant who have given voluntary and informed consent
- It may be ensured that no research project shall be / can be started unless Ethics Clearance / Approval is obtained.
- It will review the proposals before start of the studies as well as monitor the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

5.0 Composition of IEC:

EC should be Multi-disciplinary and multi- sectorial. There should be adequate representation of age and gender. Preferably 50% Member will be non-affiliated or from the outside the organization. The number of Members in an EC should be between 7 and 15. The EC should have a balance between medical and non-medical members/ Technical and non-technical members depending up on the needs of the institution.

- The Ethics Committee shall have a minimum of sevenmembers from medical, non-medical, scientific and non-scientific areas with at least,_

  i. one lay person;

  ii. one woman member;

  iii. one legal expert;

iv. one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

- One member of the Ethics Committee who is not affiliated with the institute or organization shall be theChairperson, and shall be appointed by such institute or organisation.
- One member who is affiliated with the institute or organization shall be appointed as Member Secretary of theEthics Committee by such Institute or organization.
- The committee shall include at least one member whose primary area of interest or specialisation is nonscientificand at least one member who is independent of the institution.
- The members of the Ethics Committee shall follow the provisions of these rules, Good Clinical PracticesGuidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.
- Every member of the Ethics Committee shall be required to undergo such training and developmentprogrammes as may be specified by the Central Licencing Authority from time to time:Provided that any member, who has not successfully completed such training and developmentalprogrammes, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a memberof such committee.
- The members representing medical scientists and clinicians shall possess at least post graduate qualification intheir respective area of specialisation, adequate experience in the respective fields and requisite knowledge and clarityabout their role and responsibility as committee members.
- As far as possible, based on the requirement of research area such as Human Immunodeficiency Virus (HIV) orgenetic disorder, specific patient group may also be represented in the Ethics Committee.
- No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of theclinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign adeclaration to the effect that there is no conflict of interest.

- While considering an application which involves a conflict of interest of any member of the Ethics Committee,such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same inwriting, to the Chairperson.
- The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of themeetings of the Ethics Committee.

Roles and Responsibilities of EC Members

Chairperson

Chairperson will be Non affiliated. A well respected person from any background with prior experience of having served/ serving in an EC.

Responsibilities

- Conduct EC Meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc

Member Secretary

Member Secretary will be affiliated with the institution. Should be a staff member of the institution, Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills, Should be able to devote adequate time to this activity which should be protected by the institution

Responsibilities

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC secretariat and EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review or full review
- Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist

Medical scientist can be Affiliated/ non-affiliated . He/she should be Non-medical or medical person with qualifications in basic medical sciences, In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. The representative of Medical scientist category should have postgraduate qualification & adequate experience in their respective fields.

Responsibilities

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

Clinician

He should be affiliated/ non-affiliated Qualifications - Should be individual/s with recognized Post Graduate medical qualification, expertise and training

Responsibilities

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

Legal expert/s

He should be Affiliated/ non-affiliated with the institution .Should have a basic degree in Law from a recognized university, with experience.

Responsibilities

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher‘s undertaking, protocol specific other permissions, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

Social scientist/ philosopher/ ethicist/theologian

Non-affiliated persons with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

Responsibilities

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person(s)

Non-affiliated Literate person from the public or community , Has not pursued a medical science/ health related career in the last 5 years , May be a representative of the community from which the participants are to be drawn , Is aware of the local language, cultural and moral values of the community , Person involved in social and community welfare activities are desirable

Responsibilities

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

IEC Secretariat

The Secretariat is composed of the Member Secretary and the administrative supporting staff. The supporting staff consists of staff members of Asirvatham Hospital appointed by the Head of Institution.

The secretariat shall have the following functions:

- Organization of an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organization of regular IEC meetings. .
- Preparation of the agenda and the minutes of the meetings,
- Maintenance of the IEC records and archives.
- Communication with IEC members and Principal Investigators.
- Arrangement of training for personnel and IEC members.
- Provision of the necessary administrative support for IEC related activities to the Member Secretary, IEC.

- Receipt of IEC processing fees for projects and the issue of official receipts for the same.

The IEC Administrative Staff Roles and Responsibilities

The administrative staff will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned as and when deemed necessary by the IEC. The administrative staff will be appointed by the Head of Institution by formal interview or direct appointment.

- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparing, maintaining and distributing study files.
- Organizing IEC meetings regularly
- Preparing the agenda and minutes of the meetings
- Maintaining IEC records and archives.
- Communicating with IEC members and PIs.
- Arranging training for personnel and IEC members
- Providing necessary administrative support for IEC related activities to the
- Member Secretary, IEC.
- Receiving IEC processing fees and issuing official receipts for the same.
- Corresponding with the IEC members, external experts and investigators.
- Making the pre and post arrangements of IEC meetings.
- Preparing the agenda and minutes of the IEC meetings.
- Answering queries of the investigators.
- Filing study related documents.
- Archiving and maintaining the study files.
- Preparation for accreditation, Registration and audits
- Training for investigators, key study personnel, IEC members, and IEC staff.
- Participate in the development and subsequent implementation of SOPs
- Developing an effective and efficient tracking procedure

Terms of Membership

- The members are drawn from different specialties to give a multi-sectorial, multidimensional structure. A one page current Curriculum Vitae (CV) will be collected from each member and filed in the administrative file.
- The duration of appointment is initially for a period of 3 years
- At the end of 3 years, the committee will be reconstituted, by the discretion of the Head of the institution
- A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.
- A member will also be removed if they fail to attend atleast three consecutive meetings unless proper reason for the absence is communicated in advance in writing.
- If a member is found acting code of conduct (or) objectives of the committee, he or she can be removed by 2/3rd majority of the members subject to issue of notice seeking objection which is to be submitted within two weeks on receipt of the notice. On the expiry of two weeks the committees to consider the representation received from the members and decide the action of removal. If the committee is satisfied with the reply, it can drop the action of removal. If not satisfied, the committee can remove the member by passing a resolution to this effective in a meeting to be convened 21 days after sending notice to all the members.
- A member can tender resignation with proper reasons to do so, in writing to the Head of Institution and Chairperson of Ethics committee.
- All members should maintain absolute confidentiality of all discussions during the meeting. A confidentiality agreement will be signed from each member and filed with EC before joining in the EC

Meeting Procedures

- The IEC meetings are held trimonthly. Additional meetings may be held as and When considered necessary.
- The Investigator‘s team should submit the documents 2 weeks prior to the scheduled meeting to IEC. The applicant is required to submit 5 copies of his / her application letter and copies of the documents.
- The notice of each meeting with the agenda is sent out to the members at least one

week before the meeting.

- A quorum is required for all meetings. The project can be approved unanimously or by non-unanimously. When it is approved unanimously, an approval letter will be prepared and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- Member secretary will prepare the minutes of the meetings and circulated to all the members. The final minutes of the meeting will be kept in the minutes of the meetings file signed by the Chairman.

Quorum Requirement

- In a meeting, atleast five members should be present to meet the quorum requirements; to review and make a written decision on any application. None of the members present in the meeting must not have conflict of interest.

- Each Quorum (with a minimum of 5 members) should have following members
    - **a.** Clinician
    - **b.** Basic Medical Scientist (Preferably Pharmacologist)
    - **c.** Legal Expert
    - **d.** Social Scientist / Representative of Non-Governmental Voluntary Agency
    - **e.** Lay Person from Community
- If a quorum is not present during the course of the meeting, EC Meeting can be adjourned by Chairperson.
- Chairperson can nominate a member secretary during the absence of Member Secretary
- In the absence of Chairperson EC Members can select a Member as a Chairperson for that meeting. But the selected Member should not be affiliated to the institution
- All types of changes and situations should be documented in the Minutes of meeting of the EC

Policy to prevent conflict of interest

- The ultim ate interes t of Ethics comm ittee is to prevent conflict of interest.
- It has been recognized that the potential for conflict of interest will always exist, but Chairperson is capable to manage the conflict issues so that the ultimate outcome is the protection of human subjects.
- There should be no conflict of interest.
- The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review
- Chairperson can also ask the members to declare Conflict of interest during the meeting.
- All members shall sign a declaration on conflict of interest.
- All the declaration regarding conflict of interest should be mentioned in the minutes of Meeting.

Policy regarding Training and Updating IEC members

- All relevant new guidelines to be brought to the attention of the members.

- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area.
- All EC members must be conversant with ICMR Guidelines for Research involving Human Subjects, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.
- All the members will be given training on the above-mentioned guidelines and rules yearly basis. A training record would be maintained for the same.
- Every new member will get trained on all of the above-mentioned guidelines and rules at the time of appointment.
- When a new rule/ guideline / sop revision has happened, all the members would be trained and training record would be maintained for the same.
- The Trainer will be invited from outside or from within the IEC and background and profile of the trainer will be documented
- All the training records which includes Agenda, Attendance, Pretest, Post test, Feedback forms training materials and Training logs will be maintained in the Training File

Independent Consultants

The IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson / Member secretary or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC 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 or subject experts cannot vote for a decision.

ANNEXURES

1. Confidentiality Agreement Form for Independent Consultant

Confidentiality Agreement

I, …….. understand that I am allowed to attend the ethics committee meeting as a subject expert/independent consultant. In the course of the meeting of the IEC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as confidential.

_____ _____

Signature of the Guest or Observer Date

INSTITUTIONAL ETHICS COMMITTEE PUSHPAGIRI

INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: **0469 2775518**

STANDARD OPERATING PROCEDURES

Chapter 4

MANAGEMENT OF SUBMISSION OF APPLICATIONS

CHAPTER 4

MANAGEMENT OF SUBMISSION OF APPLICATIONS

1.0 Purpose

This SOP is designed to describe and act as a guideline for the IEC Secretariat to manage research study submissions.

2.0 Types of research review by Ethics committee And Responsibility

The Ethics Committee will review Clinical Trials (Phase II, Phase III, Phase IV) epidemiological studies, retrospective studies, herbal studies and studies for devices.

It is the responsibility of the IEC secretariat to receive record and distribute the study documents for IEC review.

3.0Minimum required documents for submission of research project for approval

An application for review of the ethics of proposed biomedical research should be submitted by a qualified applicant responsible for the ethical and scientific conduct of the research. Principal Investigator can submit the documents for IEC for review and approval. All relevant documents should be enclosed with a covering letter and Submission Checklist.

Meeting Frequency of IEC

- The committee will hold regular meetings trimonthly. When there are no research proposals to review, the meeting may be hold less frequently, but no less than once every three months
- The Member Secretary will schedule the meeting either at the time of the previous scheduled meeting or within 2 weeks after new project submission and consult the Chairperson / IEC members to schedule and reconfirm the meeting date.

Submission Requirements

- The application should be submitted two weeks before the EC meeting date.
- 5 number of the hard copies of the proposal; along with the application and documents in prescribed format

- Prescribed fee as per the Fee Structure should be remitted along with the application
- The following list of documents to be submitted by Applicant for review by EC
    - **a.** Trial Protocol: Submit the latest protocol along with all the amendments mentioning the version no. (s) and date(s).
    - **b.** Patient Information Sheet and Informed Consent Form: Submit the latest Patient Information Sheet(s) and Informed Consent Form (s) in English and all the applicable vernacular languages mentioning the version no . (s) and date(s).
    - **c.** AV consent form
    - **d.** Investigator's Brochure: Submit the latest Investigator' brochure mentioning the version no. (s) and date(s).
    - **e.** Proposed methods for patient accrual including advertisement if applicable (s) etc. proposed to be used for the purpose.
    - **f.** Principal Investigator's signed and dated current CV along with medical registration certificate.
    - **g.** Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
    - **h.** Investigator's Agreement with the Sponsor.
    - **i.** Investigator's undertaking, as per Schedule Y – Appendix VII format.
    - **j.** The Regulatory approval / submission status from sponsor for the conduct of study.
    - **k.** Description of site facilities using in the study including available emergency facilities
    - **l.** A description of the process to be used to obtain the informed consent.

Receive submission packages

For the initial review of study, investigators should submit all study related documents to the IEC, two weeks before the next scheduled meeting. The procedure for the receipt of documents are as follows :

- EC Secretariat will review the documents submitted.
- If any missing documents are there EC will inform the applicant to submit the required documents

- If the application is intact, the member secretary will give acknowledgement in the submission letter by signing and stamping for investigator use.
- Each Hard copy of the documents will be distributed to each of the members to their address and soft copy will be mailed to their official email id before 14 days before the EC meeting
- One copy will be stored at EC office which will be labeled as Master copy and this copy will be archived at EC office
- Agenda will be prepared by EC office and distributed to all EC members 7 days prior to the meeting.

ANNEXURES

1. Submission Checklist
2. Template for Submission letter
3. Dispatch Return Log

1. Submission Checklist

S.No	Contents	Applicant Section		Ethics Committee Section		
		Yes	**No**	**Yes**	**No**	**Comments**
1.	Name of the applicant with designation	□	□	□	□	
2.	Name of the Institute/ Hospital / Field area where research will be conducted	□	□	□	□	
3.	Approval of the Head of the Department / Institution if applicable	□	□	□	□	
4.	Protocol of the proposed research	□	□	□	□	
5.	Ethical issues in the study and plans to address these issues.	□	□	□	□	
6.	Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.	□	□	□	□	
7.	Informed consent process, including patient information sheet and informed consent form in local language(s).	□	□	□	□	
8.	For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.	□	□	□	□	
9.	Current Curriculum vitae of all the investigators	□	□	□	□	
10.	Regulatory Approval/ Submission status	□	□	□	□	
11.	Source of funding and financial requirements for the project	□	□	□	□	
12.	Insurance and Indemnity arrangements	□	□	□	□	
13.	Description of site facilities using in the study including available emergency facilities	□	□	□	□	

S.No	Contents	Applicant Section		Ethics Committee Section		
		Yes	**No**	**Yes**	**No**	**Comments**
14.	Investigator Undertaking	□	□	□	□	
15.	Agreement to comply with the relevant national and applicable international guidelines.	□	□	□	□	
16.	All payment, reimbursement and medical services to be provided to the research subjects.	□	□	□	□	
17.	Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.	□	□	□	□	
18.	Information of other EC approval Status of the study if applicable	□	□	□	□	
19.	Details of the study Team	□	□	□	□	
20.	Any other information relevant to the study	□	□	□	□	

2.0 Template for Submission letter

<< On PI/ Institution Letter Head>>>

Date:

To

The Member Secretary

Institutional Ethics Committee

<<Enter Address>>

Ref: <<<….. Protocol Name and Number……>>>

Sub: <<…..Submission of Study Documents to EC for review and Approval ……>>

Dear Sir/Madam,

Please find enclosed 5 copies of the follwing documents of the above mentioned project for forthcoming Institutional Ethics Committee (IEC).

<<<<……. List of Documents with version no. and date…….>>>>

I wish to assure you that the study would be initiated at the site only after approval of the Ethic Committee.

Please revert for additional information and clarifications.

Thanking you,

Yours Sincerely,

<<<…. Principal Investigator's Name, Designation …..>>>

Principal Investigator (Protocol Number)

TO WHOM IT MAY CONCERN
We here by confirm the receipt of the above referenced documents submitted to us
Signature , Date and Ethics Committee Seal

3.0 Dispatch Return Log

SI. No	Date of Issue	Document Given	Issued To	Signature of receiver	Issued by	Signature	Purpose	Due Date for Return	Returned on date	Received By	Signature

INSTITUTIONAL ETHICS COMMITTEE PUSHPAGIRI

INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: 0469 2775518

STANDARD OPERATING PROCEDURES

Chapter 5

AGENDA PREPARATION, MEETING PROCEDURES ETHICAL REVIEW AND PREPARATION OF MINUTES OF MEETING

CHAPTER 5

AGENDA PREPARATION, MEETING PROCEDURES ETHICAL REVIEW AND PREPARATION OF MINUTES OF MEETING

1.0 Purpose

The purpose of this Chapter is to elaborate the administrative process and provide instructions on meeting agenda, review, approval, minutes, and communicating the decision to the Principal Investigator.

The IEC shall review and approve, every research study involving human participants and other forms of studies, before the research is initiated. The IEC shall evaluate the scientific rationale, scope, methodology, and the ethical aspects of the study. The committee shall evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality shall also be reviewed.

2.0 Scope

This Chapter applies to procedures to conduct the IEC meeting:

3.0 Responsibility

It shall be the responsibility of the respective Member Secretary of IEC and IEC staff to prepare for the IEC meeting.

4.0 Before full board IEC meeting

Prepare the agenda of the IEC meeting. Schedule studies on the agenda on first come first serve basis. No limit is placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and IEC workload.

Preparation of the meeting

- The meeting frequency of IEC will be trimonthly.

- Reserve the meeting venue for the IEC meeting on the scheduled meeting date and time. The meeting will be held in the Board room of Hospital, unless otherwise specified. Ensure that the room, equipment (projectors, recorder, etc) and facilities are available in good working conditions
- All original files of studies on the agenda are kept in the meeting room for ready reference before the meeting
- Copies of SOPs, Schedule Y, ICMR guidelines are kept available for ready reference
- Secretariat informs the scheduled meeting date and time to the Principal Investigators.

Element of review

The Meeting will be organized in the institution or facility desired by institution. All the members will be signing the attendance sheet. The prepared Agenda will be followed during the meeting .The quorum requirement and conflict of interest will be ensured by the EC Chairperson before discussing the study by any investigator. The Investigator will present the study. Independent Consultants can also be invited to review and advice on a particular topic where EC doesn‘t have expertise.

The review and the decision will be done based on the below criteria.

- Scientific design and conduct of the study.
- Examination of predictable risks/harms.
- Examination of potential benefits.
- Procedure for selection of subjects: Exclusion/ Inclusion criteria
- Management of research related injuries, side effects, ADRs.
- Compensation provisions.
- Justification for placebo in control arm, if any.
- Availability of products after the study, if applicable.
- Patient information sheet and informed consent form in local language.
- Protection of privacy and confidentiality.
- Involvement of the community, wherever necessary.
- Plans for data analysis and reporting
- Adherence to all regulatory requirements.

The prefilled Documents review checklists will be discussed with the Investigator by the respective EC members. All the queries will be discussed. EC can be go for two types

reviews based on the assessment of documents. The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into two types, namely expedited review, and full committee review

Expedited Review

Proposals that pose no more than minimal risk may undergo expedited review. Such meetings will be conducted by members meeting quorum including Member Secretary and Chairperson

- Research involving clinical documentation materials that are non-identifiable (data, documents, records)Modification or amendment to an approved protocol including administrative changes or correction of typographical errors
- Review of SAE and due analysis report preparation to be sent to CDSCO within 30 days of occurrence of SAE
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk
- Activity limited to data analysis.

Approval granted through expedited review and the decisions of the SAE must be ratified at the next full committee meeting.

Full Committee review

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

- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk
- Studies involving deception of participants
- 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.

Periodic Review

All the approved studies will be reviewed atleast once in 6 months from the day of initial approval of the study to understand the progress of the study. All the investigator will be notified the time frame of periodic review via initial approval letter of the study. Intimation notice will be issued by EC office to investigator. The following summary will be reviewed.

- Number of subjects screened
- Number of subjects randomized
- Number of subjects Drop outs
- Number of subjects withdrawn
- List of SAEs
- List of AE
- List of Protocol Deviation
- List of protocol violation
- Any new information relevant to the study

Annual Review

- Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study which will be conveyed to researcher at the time of initial review. The researcher should give annual report and request to continue the study with the documents available in the present form. The EC should review the annual report and if found satisfactory IEC will approve to continue the study.

- The first report shall be submitted within thirty (30) days of completion of the year following the date of the first approval. Subsequent reports will be submitted at one-Year intervals following the first report.
- An EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.

11.0 Review of Protocol Deviation/ Violation

All Protocol Deviation/Violation/ non-compliance/waiver will have to be notified. All such notifications shall be circulated to IEC members, reviewed & assessed by the committee during the meeting for the seriousness of the deviation / Non-Compliance / Violation with respect to the safety & health aspects of the subjects and the necessary actions shall be taken by the committee accordingly.

Review of Studies involves vulnerable population

The IEC of Pushpagiri Institute of Medical Sciences and Research Centre takes special consideration in protecting the welfare gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment. The IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects. The IEC may require additional safeguard measures to protect potentially vulnerable population. For instance, the IEC may require that the investigator submit each signed informed consent form to the IEC, that someone from the IEC oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time to allow the subject time for family discussion and query resolution, family discussion and questions. IEC expects to follow the principals laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participant.

RESPONSIBILITY:

It is the responsibility of the Chairperson and Member-Secretary of IEC to implement, amend and give training to other members of IEC of this SOP.

PROTOCOL REVIEW PROCESS:

DETAILED INSTRUCTION

For Pregnant Women, Foetuses:

Research involving pregnant women and fetuses should involve the least possible risk. The IEC will document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent. The IEC will ensure that women are not encouraged to discontinue nursing for the sake of participation in research except in the cases where breast-feeding is harmful to the infant. IEC will also ensure that compensation in terms of supplying supplementary food such a milk formula will be considered in such circumstances. In the event of research related to pre-natal diagnostic techniques, IEC will ensure that such research is limited to detect foetal abnormalities or senetic disorders and not for sex determination.

Research involving Prisoners:

Prisoners may have a limited ability to make truly voluntary and un-coerced decisions about whether or not to participate as research subject.

Children involved as subjects/ participants in Research:

IEC requires special protections for research involving children. Under the regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable conducted. The proposed clinical research must fall within one of the four following categories: (i) Clinical Trial not involving Minimal Risk. (ii) Clinical trial involving greater than minimal risk, but presenting the prospect of direct benefits to the individual subjects. (iii) Clinical trial involving greater than minimal risk, yield knowledge that can be generalized about subject's disorder or condition. Clinical trial not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. Each category has specific conditions that must be included in their organization Standard Operating Procedures (SOPs) if the institution is involved in human research where children are in the subject population.

Parental/Legally acceptable representative Permission:

The IEC require that adequate provisions are made for solicit the permission of each child's parents or guardian/legally acceptable representative. Where parental permission is to be obtained, the IEC will determine whether permission of one parent is sufficient or whether permission must be obtained from both parents in order for the research to be conducted.

Assent of the Child:

(a) Provisions must also be made in the protocol to obtain the child's assent when the child is capable of giving assent. (b) IEC may determine that the assent of the child is not necessary if and only if all three of the following conditions are satisfied: (i) The research offers the child the possibility of direct benefit. (ii) The benefit is important to the health or well being of the child. (iii) The benefit is available only in the context of the research. IEC will take great care in approving research where the child is suffering from a life-threatening illness with little real chance of therapeutic benefit from the research. IEC will respect the child's refusal to participate in the research and will be cautious in allowing parents/ legally accepted representatives to overrule. IEC requires assent form is tailored for the child, with respect to his or her level of understanding.

Clinical trial involving Decisionally Impaired Subjects:

IEC will consider selection issues, privacy and confidentiality, coercion and undue influence, and risk-benefit analysis. Additional safeguards must be considered by the IEC to protect these subjects.

Decision-making

The committee will give its opinion on the project in writing in one of the following ways:

Members will discuss the various issues before arriving at a consensus decision.

- A meeting will be considered valid only if the quorum is fulfilled. This should be maintained throughout the meeting and at the time of decision making. Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- If a member has declared a Conflict of interest (COI) for a proposal then this

should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.

- The member who has declared COI should withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This should be minuted and the quorum rechecked.
- A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.
- Number of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal.
- Decision may be to approve, reject or modify the proposals. Specific suggestions should be given for modifications.
- Negative decisions should always be substantiated by appropriate reasons.
- The decision must be taken either by a broad consensus or majority vote and should be recorded. When it is approved unanimously, an approval letter in the prescribed template will be issued and signed by chairman and member secretary. If some members are objecting the study to be approved, chairman will take the voting from the members to see the majority and if majority is there the project will be approved. In that case the voting status also will be mentioned in the approval letter.
- The chairman / member secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made.
- This decision will be ratified at the next full committee meeting and minuted.

After the IEC meeting

Preparing the minutes and the decision letters

- The Member Secretary will compile the proceedings of IEC meeting in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes
- The minutes of the meeting will be compiled within 15 working days. The minutes will record whether the decision was unanimous, or whether a vote was taken for the decision. The number of members voting for, against, and abstaining will be recorded. The disclossure of the IEC member for conflict of interest is recorded in the IEC meeting minutes. The questions and answers

discussed in each meeting will also be discussed.

- The basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution must be recorded and filed.

Approval of the minutes and the decision

- The minutes of the IEC meeting will be prepared by Member Secretary, IEC or acting member secretary
- The minutes of the IEC meeting will be approved by Chairperson ratified in the subsequent IEC meeting
- The IEC decisions will be communicated to the PIs

Filing of the minutes of the meeting

Place the original version of the minutes in the minutes file and copy of the minutes are filed in the corresponding files of research protocol reviewed in the meeting.

Communicating the decision with the investigator

The decision will be communicated in writing to the PI, preferably within a period of 15 working days of the IEC meeting at which the decision was made. The decision will be communicated through written letter signed by EC member Secretary/ Chairperson. Original letter will be given to the applicant and copy will be maintained with the EC.

ANNEXURES

1. Template for Approval Letter
2. ICD Review Checklist
3. Protocol Review Checklist
4. CTA Review Checklist
5. IB Review Checklist

6. Agenda Format
7. Application for Annual Review

a) Template for EC Approval

INSTITUTIONAL ETHICS COMMITTEE

Date

To,

<<PI Name and project code>>.

Ref: Study Protocol- <<protocol ID and Title>>

Sub: Ethics Committee approval

Dear <<PI Name>>,

The Institutional Ethics Committee, Pushpagiri Institute of Medical Sciences, Pushpagiri Research Centre, Thiruvalla, reviewed and discussed your application dated <<Date of Submission>> to conduct the clinical trial entitled <<Title of the study>> on <<Date of EC meeting held>>.

The following documents were reviewed and approved:

<<List the documents which are reviewed and approved and reviewed only – separately>>

The following members of the Institutional Ethics Committee were present at the meeting held on <<date of EC meeting held>>.

<<List the members name and their role in the IEC in the box below>>

S#	Name	Role in the Ethics Committee
1		
2		
3		

4		

5		
6		
7		
8		
9		

Case 1. <<In case study was unanimously approved follow the below pattern>>

The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study. One member was abstained from voting (<<write the name of the members who abstained from voting)

Case 2. <<In case study was non-unanimously approved - follow the below pattern>>

The study was unanimously approved with <<Votes in favour write here>> votes in favour of the study as against <<Votes against - write here>> votes against the study. One member abstained from voting (<<write the name of the members who abstained from voting).

We confirm that principal investigator did not participate in the deliberations of the ethics committee for this study and did not vote on the proposal for this study.

Please submit the following documents before recruiting the patients in to the study.

<<List the documents which has to be submitted to the IEC before the study to be initiated at our center>>

Please note that you should follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by the IEC without the prior written approval of this ethics committee. Deviations/ changes to the approved protocol may be implemented without prior approval of this ethics

committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to the IEC:

- Any changes to or deviations to the protocol approved by this ethics committee that you may implement to eliminate hazards to the trial subjects.
- All serious adverse events.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit to the IEC, the status report of the study at every 6 months interval.

Please provide a close out report to the Ethics Committee on the completion of the study.

The IEC is organized and operates according to the requirements of ICH - GCP and requirements of the Indian Council of Medical Research (ICMR) and Schedule Y.

Thank you for your time and efforts.

Cordially,

Member Secretary
Institutional Ethics Committee
<<Enter Address>>.

<<Name of Chairman>>
Institutional Ethics Committee
<<Enter Address>>.

b) ICD review Checklist

SI.No	Contents	Yes	No	Comments
1.	A statement that the study involves research	☐	☐	☐
2.	Explanation of the purposes of the research	☐	☐	☐
3.	Expected duration of subject‘s participation	☐	☐	☐
4.	Description of the procedures to be followed, including all invasive procedures	☐	☐	☐
5.	Description of any reasonably foreseeable risks or discomforts to the Subject	☐	☐	☐
6.	Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.	☐	☐	☐
7.	Disclosure of specific appropriate alternative procedures or therapies available to the Subject	☐	☐	☐
8.	Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject‘s medical records	☐	☐	☐
9.	Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)	☐	☐	☐
10.	Compensation and/or treatment(s) available to the	☐	☐	☐

	Subject in the event of a trial-related injury			
11.	An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury	☐	☐	☐
12.	The anticipated prorated payment, if any, to the Subject for participating in the trial	☐	☐	☐
13.	Subject's responsibilities on participation in the trial	☐	☐	☐
14.	Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled	☐	☐	☐
15.	Any other pertinent information	☐	☐	☐
16.	Additional elements, which may be required	☐	☐	☐
16.1	Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.	☐	☐	☐
16.2	Additional costs to the Subject that may result from participation in the study.	☐	☐	☐
16.3	The consequences of a Subject‘s decision to withdraw from the research and procedures for orderly termination of participation by Subject.	☐	☐	☐
16.4	Statement that the Subject or Subject's representative will be notified in a timely manner	☐	☐	☐

	if, significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.			
16.5	A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable	☐	☐	☐
16.6	Approximate number of Subjects enrolled in the study	☐	☐	☐
17	Details of Compensation or cost for medical management in case of any Serious Adverse event occurred	☐	☐	☐
18	Procedure for consenting AV recording if applicable.			
19	Section for details of Nominee,	☐	☐	☐
20	Section for Income and qualification of study subject	☐	☐	☐
21	Correctness of the contact details of Investigator and IEC mentioned	☐	☐	☐
22	Appropriateness of language used	☐	☐	☐

c) Protocol Review Checklist

Contents	**Yes**	**No**	**Comments**
General Information			
Protocol title	☐	☐	☐
Protocol identifying number and date	☐	☐	☐
Any amendment(s) number and date(s)	☐	☐	☐
Name & Address of the Sponsor	☐	☐	☐
Name & Address of the Monitor (If other than the Sponsor)	☐	☐	☐
Name & Title of the person(s) authorized to sign the protocol for the sponsor	☐	☐	☐
Name & Title of the person(s) authorized to sign the protocol amendment(s) for the sponsor	☐	☐	☐
Name, Title, Address and Telephone number of the sponsor‘s medical expert for the trial	☐	☐	☐
Name and title of the investigators	☐	☐	☐
Address and Telephone number of the trial site(s)	☐	☐	☐
Name, Title, Address, and Telephone Number of the qualified physician for all trial-site related medical decisions	☐	☐	☐
Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical departments and/or	☐	☐	☐

institutions involved in the trial			
Background Information			
Name and description of the IP	☐	☐	☐
Summary of finding from nonclinical studies that potentially have clinical significance	☐	☐	☐
Summary of finding from Clinical studies that are relevant to the trial	☐	☐	☐
Description of and justification for the route of administration	☐	☐	☐
Description of and justification for the dosage	☐	☐	☐
Description of and justification for the dosage regimen	☐	☐	☐
Description of and justification for the Treatment period(s)	☐	☐	☐
A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s)	☐	☐	☐
Description of the population to be studied	☐	☐	☐
Reference to literature and data that are relevant to the trial	☐	☐	☐
Trial Objectives and Purpose			
Description about the trial objective	☐	☐	☐
Description about the trial purpose	☐	☐	☐
Trial Design			

A specific statement of the primary end points to be measured during the trial	☐	☐	☐
A specific statement of the secondary end points to be measured during the trial	☐	☐	☐
A description of the type/design of the trial to be conducted (e.g. double blind . placebo- controlled, parallel design)	☐	☐	☐
Schematic diagram of trial design	☐	☐	☐
Schematic diagram of trial procedures	☐	☐	☐
Schematic diagram of trial stages	☐	☐	☐
A description of the measures taken to minimize / avoid bias	☐	☐	☐
Blinding	☐	☐	☐
A description of the trial treatment(s)	☐	☐	☐
A description of the dosage& dosage regimen of IP	☐	☐	☐
A description of the dosage form	☐	☐	☐
A description of the packaging & labelling of the IP	☐	☐	☐
Expected duration of subject participation	☐	☐	☐
Description of the sequence and duration of all trial periods, including follow-up period	☐	☐	☐
Description of the –Stopping rules‖ or –discontinuation criteria‖ for individual subjects	☐	☐	☐
Accountability procedures for IP, Placebo(s) &	☐	☐	☐

Comparator(s)			
Maintenance of trial treatment randomization codes	☐	☐	☐
Description of procedures for breaking codes	☐	☐	☐
The identification of any data to be recorded directly on the CRF's (i.e. no prior written or electronic record of data)	☐	☐	☐
Selection and Withdrawal of Subjects			
Subject inclusion criteria	☐	☐	☐
Subject exclusion criteria	☐	☐	☐
Subject withdrawal criteria (i.e. terminating IP treatment/trial treatment	☐	☐	☐
Description about when and how to withdraw subjects from the trial/IP treatment	☐	☐	☐
Description about the type and timing of the data to be collected for withdrawn subjects	☐	☐	☐
Follow up for subjects withdrawn from IP treatment/ trial treatment	☐	☐	☐
Treatment of Subjects			
Name of all the Product(s)	☐	☐	☐
The dose(s)	☐	☐	☐
The dosing schedule(s)	☐	☐	☐
Route/ Mode(s) of administration	☐	☐	☐

Treatment period(s) including follow up period(s)	☐	☐	☐
Description about Medication(s)/Treatment(s) permitted (including rescue medication) before and/or during the trial	☐	☐	☐
Description about Medication(s)/Treatment(s) not permitted before and/or during the trial	☐	☐	☐
Procedures for monitoring subject compliance	☐	☐	☐
Assessment of Efficacy			
Specification of efficacy parameters	☐	☐	☐
Methods and timing for assessing of efficacy parameters	☐	☐	☐
Methods and timing for recording of efficacy parameters	☐	☐	☐
Methods and timing for analyzing of efficacy parameters	☐	☐	☐
Assessment of Safety			
Specification of safety parameters	☐	☐	☐
Methods and timing for assessing of safety parameters	☐	☐	☐
Methods and timing for analyzing of safety parameters	☐	☐	☐
Procedures for eliciting reports of AE and Intercurrent illnesses	☐	☐	☐
Procedures for recording& reporting of AE and Intercurrent illnesses	☐	☐	☐

Description about the type and duration of the follow-up of subjects after AE	☐	☐	☐
Statistics			
Description of the statistical methods to be employed, including timing of any planned interim analysis(ses)	☐	☐	☐
No of subjects planned to be enrolled in whole study	☐	☐	☐
In multicenter trials, no: of enrolled subjects projected for each trial site	☐	☐	☐
Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification	☐	☐	☐
The level of significance to be used	☐	☐	☐
Criteria for the termination of the trial	☐	☐	☐
Procedure for accounting for missing data	☐	☐	☐
Procedure for accounting for unused data	☐	☐	☐
Procedure for accounting for spurious data	☐	☐	☐
Procedure for reporting any deviation(s) from the original statistical plan	☐	☐	☐
Description about the selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects)	☐	☐	☐
Direct Access to Source Data/Documents			

Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related audits, providing direct access to source data/documents	☐	☐	☐
Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related IRB/IEC review, providing direct access to source data/documents	☐	☐	☐
Surety from sponsor that it is specified in the protocol or other written agreement that the investigator(s) / Institution(s) will permit trial-related regulatory inspection(s), providing direct access to source data/documents	☐	☐	☐
Quality control and Quality Assurance	☐	☐	☐
Ethics			
Description of ethical considerations relating to the trial	☐	☐	☐
Data Handling and Record Keeping	☐	☐	☐
Financing and Insurance			
Details about Finance and insurance, if not addressed in a separated agreement	☐	☐	☐
Publication Policy			
Details about Publication Policy, if not addressed in a separated agreement	☐	☐	☐
Supplements	☐	☐	☐

d) Clinical Trial Agreement Review Checklist

Sl No	Content	Yes	No	Comment
1	Sponsor‘s name	☐	☐	☐
2	Type of Agreement Tripartite or Quadripartite	☐	☐	☐
3	The venue of Jurisdiction mentioned?	☐	☐	☐
4	Insurance certificate reviewed?	☐	☐	☐
5	Indemnity clauses are favourable to the institution?	☐	☐	☐
6	Check for the compensation details	☐	☐	☐
7	Details of SAE management is mentioned?	☐	☐	☐
8	Financial funding for the project is mentioned?	☐	☐	☐
9	Any other legal implication for the institution and investigator	☐	☐	☐
10	Subjects rights will be protected?	☐	☐	☐

e) IB Review Checklist

SI.No	Contents	Yes	No	Comments
1.1	Sponsor‘s name	☐	☐	☐
1.2	The reference number allocated to the study	☐	☐	☐
1.3	The identity of investigational product (i.e. research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor)	☐	☐	☐
1.4	Edition number and date	☐	☐	☐
1.5	Reference to the number and date of the edition it supersedes	☐	☐	☐
2.	**Confidentiality statement**	☐	☐	☐
3.	**Table of Contents**	☐	☐	☐
4.	**Introduction**			
4.1	Information relevant to the stage of clinical development including the significant physical & chemical properties, pharmaceutical, pharmacological (pharmacological class, advantages over other substances in that class and rationale for performing the proposed study), toxicological, pharmacokinetic, metabolic, and clinical information (anticipated prophylactic/ therapeutic or diagnostic indication(s)) of all active ingredients	☐	☐	☐
4.2	The introductory statement - The general approach to be followed in evaluating the Investigational Product	☐	☐	☐
5	**Physical, Chemical, and Pharmaceutical Properties and Formulation parameters**			
5.1	A description about the Investigational Product substance(s), including the chemical and / or structural formula(e)	☐	☐	☐
5.2	A brief summary of the relevant physical, chemical and pharmaceutical properties.	☐	☐	☐
5.3	Information about the structural similarities to other known compounds	☐	☐	☐
5.4	Information about excipients	☐	☐	☐
5.5	Information about storage and dosage handling	☐	☐	☐

6.1	Information about data relating to non-clinical pharmacology, pharmacokinetics, metabolism profile in animals and toxicology	☐	☐	☐
6.2	Summary ofall relevant non-clinical pharmacology, toxicology, pharmacokinetic, and the Investigational Product metabolism studies	☐	☐	☐
6.3	Summary of the methodology used,	☐	☐	☐
6.4	The result s and a discussion of the relevance of the findings to the investigated therapeutic effects besides the possible unfavourable effects in humans.	☐	☐	☐
6.5	Information about the species used	☐	☐	☐
6.6	Information about number and sex of animals in each group	☐	☐	☐
6.7	Information about Unit dose (mg/kg)	☐	☐	☐
6.8	Information about dose interval	☐	☐	☐
6.9	Information about route of administration	☐	☐	☐
6.10	Information about duration of dosing	☐	☐	☐
6.11	Information on systemic distribution	☐	☐	☐
6.12	Information about duration of post-exposure follow-up	☐	☐	☐
6.13	**Results**			
6.13.1	Nature and frequency of pharmacological or toxic effects	☐	☐	☐
6.13.2	Severity or intensity of pharmacological or toxic effects	☐	☐	☐
6.13.3	Time to onset of effects	☐	☐	☐
6.13.4	Reversibility of effects	☐	☐	☐
6.13.5	Duration of effects	☐	☐	☐
6.13.6	Dose response	☐	☐	☐
6.13.7	Dose response of observed effects	☐	☐	☐
6.13.8	The relevance to humans	☐	☐	☐
6.13.9	Any aspects to be studied in humans	☐	☐	☐
6.13.10	Comparison of the effective and non-toxic dose findings in the same animal species (i.e. The therapeutic index should be discussed)	☐	☐	☐
6.13.11	The relevance of this information to the proposed human dosing	☐	☐	☐
6.13.12	Comparisons made in terms of blood/tissue levels rather than on a mg/kg basis	☐	☐	☐
6.14	**Non-clinical Pharmacological (Pharmacodynamics)**			
6.14.1	A summary of the pharmacological aspects of the	☐	☐	☐

	investigational product and its metabolites studied in animals			
6.14.2	Potential therapeutic activity assessment (e.g. efficacy models, receptor binding, and specificity)	☐	☐	☐
6.14.3	Safety assessment (eg. special studies to assess pharmacological actions other than the intended therapeutic effect(s)).	☐	☐	☐
6.15	**Pharmacokinetics and Product Metabolism in Animals**			
6.15.1	A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species Studied	☐	☐	☐
6.15.2	Discussion of the findings about the absorption and the local and systemic bioavailability of the IP and its metabolites	☐	☐	☐
6.15.3	Investigational product and its metabolites relationship to the pharmacological and toxicological findings in animal species.	☐	☐	☐
6.16	**Toxicology**			
6.16.1	A summary of the toxicological effects of IP found in relevant studies conducted in different animal species	☐	☐	☐
6.16.2	Single dose	☐	☐	☐
6.16.3	Repeated dose	☐	☐	☐
6.16.4	Carcinogenicity	☐	☐	☐
6.16.5	Special studies (eg. irritancy and sensitisation)	☐	☐	☐
6.16.6	Reproductive toxicity	☐	☐	☐
6.16.7	Genotoxicity (Mutagenicity)	☐	☐	☐
7	**Effects in Humans**			
7.1	Discussion of the known effects of the investigational product(s) in humans	☐	☐	☐
7.2	Information on pharmacokinetics, metabolism, Pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities	☐	☐	☐
7.3	Brief summaries of other clinical studies conducted on the same product	☐	☐	☐
7.4	**Pharmacokinetics and Product Metabolism in Humans**			
7.4.1	A summary of information on the pharmacokinetics of the investigational product(s)	☐	☐	☐
7.4.2	Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination)	☐	☐	☐
7.4.3	Bioavailability of the investigational product	☐	☐	☐

	(absolute, where possible, and/or relative) using a reference dosage form			
7.4.4	Population subgroups (e.g. gender, age, and impaired organ function).	☐	☐	☐
7.4.5	Interactions (e.g. Product-product interactions and effects of food)	☐	☐	☐
7.4.6	Other pharmacokinetic data (e.g. results of population studies performed within clinical trial(s).	☐	☐	☐
7.5	**Safety and Efficacy**			
7.5.1	Information about the Investigational Product (s)' (including their metabolites, where appropriate) safety Pharmacodynamics	☐	☐	☐
7.5.2	Information about the Investigational Product(s)' (including their metabolites, where appropriate) efficacy and dose response(s) that were obtained from preceding trials in humans (healthy volunteers and/or patients)	☐	☐	☐
7.5.3	In cases where a number of clinical studies have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data.	☐	☐	☐
7.5.4	Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications)	☐	☐	☐
7.5.5	Important differences in adverse drug reaction patterns/incidences across indications or subgroups	☐	☐	☐
7.5.6	A description of the possible risks and adverse drug reactions to be anticipated based on prior experiences with the product under investigation and with related products.	☐	☐	☐
7.5.7	A description about the precautions or special monitoring to be done as part of the investigational use of the product(s).	☐	☐	☐
8	**Regulatory & Post-marketing Experiences**			
8.1	Countries where the investigational product has been marketed or approved.	☐	☐	☐
8.2	Any significant information arising from the marketed use should be summarised (eg. formulations, dosages, routes of administration, and adverse product reactions)	☐	☐	☐

8.3	Countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.	☐	☐	☐
9	**Summary of Data and Guidance for the Investigator**	☐	☐	☐
10	**Bibliography**	☐	☐	☐
10.1	Overall discussion of the non-clinical and clinical data	☐	☐	☐
10.2	The information from various sources on different aspects of the investigational product(s)	☐	☐	☐
10.3	Published reports on related products	☐	☐	☐
10.4	The information given in this section should provide the investigator with a clear understanding of the possible risks and adverse reactions.	☐	☐	☐
10.5	Guidance about recognition and treatment of possible overdose and adverse drug reactions.	☐	☐	☐

f) Agenda Format

AGENDA OF IEC MEETING

Meeting No :

Location of IEC Meeting :

Meeting date:

Meeting Time:

The Board meeting will proceed in the following sequences:

Period1:

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

Period2:

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

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

C] Approve protocol amendment and related documents.

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

E] To review Protocol Deviations /Violations

F] To review other Letters related to projects to review Monitoring reports

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

H] To inform about the SAE Subcommittee meetings and to review SAE / Safety reports.

I] Other points for discussion

Period3:

Issues reviewed and approved by the IEC member Secretary and Chairperson which are to be reported Secretary and Chairperson which are to be reported for Consideration

Period4:

Issues to be informed to the members at Full Board which are approved by the IEC member Secretary and Chairperson and letters already sent to the principal investigator

Period5:

Other issues based on the interest of members

g) Application For Renewal Of Approval

APPLICATION FOR RENEWAL OF APPROVAL

- IEC Reference number
- Title of the research proposal
- Name of the Principal Investigator (PI) with qualification and designation
- Approval date
- Date study initiated, if no, specify reason
- Has subject recruitment begun?
- If subject recruitment has not begun, give reasons
- How many subjects have been screened?
- How many subjects have been randomized?
- How many Screen failures and or drop outs? Reason
- Is subject recruitment continuing?
- Is the Subjects completed the study, if no number of pending visits.
- Expected date for study completion?
- Have there been any adverse events/ Serious Adverse Events? If yes, give details
- Any Protocol deviation/Violations?
- Have there been any unanticipated study-related problems? If yes, give details.
- List of attachments for review, if any
- Remarks, if any

Signature of the Principal Investigator with date.

NOTE

- Investigator can use own format, but all the information should be furnished.
- Investigator should attach the renewal fee along with the application.

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: **0469 2775518**

STANDARD OPERATING PROCEDURES

Chapter: 6

SITE MONITORING

Chapter : 6

SITE MONITORING

1.0 Purpose

The purpose of this chapter is to provide the procedures for site monitoring.

2.0 Scope

This Chapter applies to conducting monitoring of studies involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, IEC shall choose to monitor the study more frequently.

3.0 Responsibility

ECs shall follow mechanisms to monitor the approved study site until completion of the research to check for compliance or improve the function. Monitoring can be routine or ―for cause‖ and shall be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review shall suggest that routine monitoring may be conducted at more frequent intervals.

The frequency of monitoring shallbe decided during the initial review of the meeting among the EC Members. The monitoring will be done by the Monitoring committee nominated by Chairperson and Member Secretary.

Procedure

This includes review of the overall progress of each study to insure the safety of participants, validity of data, that the projected actual goals are met on a timely basis, eligibility and evaluability rates do not fall below minimum acceptable standards, risks are not excessive, adverse events are appropriately monitored and reported to the appropriate agencies. Inherent in this process is the goal of enhancing the quality of the research.

The Cause for monitoring will be performed based on the following criteria

- High number of protocol violations and deviations;
- Large number of proposals carried out at the study site or by the same researcher;
- Large number of SAE reports;
- Complaints received from participants;
- Non-compliance with EC directions;
- Misconduct by the researcher

5.0 Before the Visit

The EC Secretariat will inform the investigator about the monitoring visit date. The monitoring committee will inform the investigator about the agenda of the monitoring visit.

During the Visit

The monitoring will be done by using the checklist and report will be submitted to the EC Chairperson and member secretary. The report will be discussed in the next full quorum EC Meeting. Monitor should give special attention to right safety well-being of study subjects while reviewing the study documents.

The following objectives are followed while monitoring the study.

- Eligibility of subjects recruited
- Proper recording and reporting of AE and SAE
- Adequate Consent procedure are followed
- Ongoing informed consent procedure is in place
- Adherence to protocol and regulatory requirements
- Investigational Product storage and handling

7.0 After the Visit

Monitoring visit checklist will be filled and submit to the IEC secretariat within 14 days. The report will be discussed in the next full board meeting of IEC. The findings and recommendations from IEC will be communicated to the Principal investigator 14 days after the meeting

ANNEXURES

1. Monitoring checklist
2. Monitoring Visit report template

a) Monitoring Checklist

MONITORING CHECKLIST	
Monitoring Visit	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor:	Address:
Total number of expected subjects:	Total subjects Enrolled:
Are site facilities appropriate? □ Yes □ No	Comment:
Are Informed Consents recent? Check about the ongoing informed consent process.	Comment:
In case of AV consenting, are the video films taken and stored appropriately?	Comment:
Check all the subject has got ample time for consenting.	Comment:
Any Adverse Events found?	Comment:

Any protocol Non-Compliance /violation?	Comment:
Are all Case Record Forms up to date?	Comment:
Are storage of data and investigating products locked?	Comment:
How well are participants protected?	Comment:
Any outstanding tasks or results of visit?	Comment:
Duration of visit: …….hours	Starting from:_____Hrs Finish: _____Hrs
Name of IEC/member/ Representatives and Accompanying person:	
Completed by:	Date:

b) Template for Monitoring visit report

MONITORING VISIT REPORT	
Name of the Study:	
Name of sponsor:	
Study Drug:	
Protocol ID:	
Name of the Investigator:	

Site ID:	
Contact Details of Investigational Site	
Visit Date:	

Site personnel present	**Function**

S.No.	**Concerns / Issues/ Situations**	**Comments / Resolutions**	**Answer from the concerned personnel**	**Sign**	**Date**
1	**SMF Review**				
2	**ICD Review**				
3	**CRF Review**				
4	**Site Facility Inspection**				

5	**Source Data Verification**				
6	**AE / SAE Review**				
7	**Other Issues**				

Comments from PI team:

Approvals / Signatures

This signature confirms that this report summarizes the actions and observations at the site audit visit.

Type of Monitoring Prepared By: Name : Designation: Sign & Date:	 Approved By: Name : Designation: Sign & Date:

INSTITUTIONAL ETHICS COMMITTEE

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STANDARD OPERATING PROCEDURES

Chapter 7

PROTECTION OF SUBJECT RIGHT SAFETY AND WELL-BEING

CHAPTER 7

PROTECTION OF SUBJECT RIGHT SAFETY AND WELL-BEING

1.0 Purpose

This Chapter shall provide guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

2.0 Scope

This Chapter shall apply to all requests concerning the rights and well-being of the research participants participating in studies approved by the IEC.

Responsibility.

It shall the responsibility of the IEC Member Secretary to provide the required information to the research participants/ research participant‘s representatives/patient, in the case of queries received.

It shall the responsibility of the Member Secretary/Chairperson to initiate a process of giving information to the participants or identifying and addressing any injustice that has occurred, if complaints are received from research participants.

The IEC shall assess the adequacy of safeguarding of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application.

The IEC shall evaluate the involvement of human subjects and proposed protections according to the following review criteria:

- Risk to subjects.
- Adequacy of protection against risks.
- Potential benefits of the proposed research to the subjects and others.
- Importance of the knowledge to be gained.
- Required qualifications and experience of the Investigators for the proposed study

- Any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action.
- Plans to withdraw subjects from the study by the Investigator.
- Medical care to be provided to research participants during and after the course of the research.
- Adequacy of medical supervision and social support for the research participants.
- Steps to be taken if research participants voluntarily withdraw during the research.
- Arrangements, if appropriate, for informing the research participant‘s general practitioner or family doctor, including procedures for seeking the participant‘s consent to do so.
- Description of any plans to make the study product available to the research participants following the research and description of any financial costs to the research participants.
- Compensations for research participants for attending the visits.
- 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.
- Translations for appropriateness of language, accuracy and completeness of information.

The adequacy of the above points shall be ensured by proper review and monitoring by the EC.

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

In addition to that IEC office shall have the complaint register forms (Annexure 1) available for subjects who can fill their complaint and furnish in the complaint box. The subjects can also call to the EC contact details provided in their complaint and register the complaint. The EC office shall keep a register (Annexure 2) for the same and communicate with the institution and investigator to resolve it. The resolution shall be discussed and communicated to the subject.

ANNEXURES

1. Subject complaint form
2. Register template

1.0 **Subject complaint form**

SUBJECT COMPLAINT FORM	
Institutional Ethics Committee Address Contact person: Contact number : Email	
Name of the subject: Address : Contact Number: Email ID: Name of the Bystander: Contact Number:	
Name of the Principal Investigator: Name of the study:	
Brief Description of the complaint:	
Sign and Date:	
Received By	
Signature:	

2.0 **Subject Complaint Register**

SI No	**Name of the subject**	**Name of the Study**	**Name of the Principal Investigator**	**Date of complaint registered**	**Nature of Complaint**	**Action Taken**	**Mode of resolution**	**Date of resolution**

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STANDARD OPERATING PROCEDURES

Chapter 08

ADMINISTRATIVE SUPPORT FOR EC

CHAPTER 08

ADMINISTRATIVE SUPPORT FOR EC

1.0 Purpose

Purpose of this Chapter shall be to provide guidance for the administrative support for the functioning of IEC including financial support and resources.

2.0 Scope

This Chapter applies to the administrative support being received by IEC.

3.0 Administrative Support

The institution shall be responsible for establishing an EC to ensure an appropriate and sustainable system for quality ethical review and monitoring. The institution shallbe responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and time for the Member Secretary to run the EC functions.

The institution shall provide space, infrastructure and staff to the EC for maintaining a full-time secretariat, safe archival of records and conduct of meeting. The selection criteria for administrative support staff shall be based on the qualification and experience as decided by the institution.

Financial Operations

- Ethics committee can be financially supported by the Institution. Every institution shall allocate reasonable funds for smooth functioning of the EC
- A reasonable fee for review may also be charged by the EC to cover the expenses related to optimal functioning in accordance to Institutional policies.
- The income and expenditure of the ethics committee shall be documented in the Income Expense Ledger Book.

- The income and expenditure shall be audited by audit committee of Ethics committee once in a year. The audit report shall be submitted to the Head of Institution and EC chairperson

- Member Secretary shall beresponsiblefor maintaining the finance records

- Member Secretary shall report to the Head of the Institution the income and expenditure report biannually.

- The fees charged by the EC for the review of applications as mentioned in the EC Fee SOP is mentioned in the Annexure. (Annexure 1)

Honorarium to EC Members

- It is recognized that all the Members of EC are busy individuals in their own positions. They, by all means, take time to review the protocol and attend the meeting.

- For balancing the sensitivity of their time on one hand & also not to be coercive in nature by furnishing undue amounts, it is decided that a nominal amount would be paid as compensation/reimbursement to each member who would attend a meeting.

- This amount would also serve as their travel allowance, to & from the meeting venue and other incidentals that the members may spend on account of the meeting.

- The Secretariat staff would be ready with the payments to be paid to the members by cheque/cash, after a meeting. (Annexure 2)

The Members who attended a meeting shall:

1. Sign the attendance sheet.

2. Return all the documents circulated to the members for preparation for the review for the meeting.

3. Sign the Dispatch and Return Log of Documents reflecting the above.

4. Sign the Payment Receipt Voucher for receipt of the compensation of the meeting held.

5. Receive the payment as per the Payment Receipt Voucher for their contribution in the meeting.

ANNEXURES

1. EC Fee Annexure

2. Payment receipt voucher

1.0 EC Fee Annexure

Bank Name	……..
Payee Name	……..
Pan No	……..
Account NO	……..
IFSC Code	……..
Initial Review Fees for Phase II, III & IV Clinical Trials	……..
Review fees for the amendment of approved documents	……..
SAE Review Fee	……..
Expedited review fee	……..
Annual Fee	……..

2.0 **Payment Receipt Voucher**

Date: _____

	Rs	P
Paid To: _____		
Particulars: _____		
_____		
Rupees: _____		

Authorized by: _____

Passed by : _____

Paid cash/ Cheque drawn on: _____

Cheque No:_____ Date: _____

Receiver's Signature

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STANDARD OPERATING PROCEDURES

CHAPTER 09

COMMUNICATION WITH STAKE HOLDERS

CHAPTER 09

COMMUNICATION WITH STAKE HOLDERS

1.0 Purpose

Purpose of this chapter to give guidance on the communication process with the Head of Institution, Investigator and Regulatory.

2.0 Scope

This Chapter applies to the communication process for IEC with various stake holders.

Communication with Regulatory

The IEC is registered under Drug controller General of India.

IEC communicate with DCGI on the following topics

- In the contest of revision SOP and constitution of IEC members
- Reregistration process of IEC
- Communicating due analysis report of SAE occurred at the institution
- Any other relevant communication receive from DCGI

Communication with the investigator

IEC will communicate with investigator in writing and same will be documented. The IEC communicates with investigator in following contests

- Receipt acknowledgment for all communication from the investigators
- Reminder for the annual reports, annual review. periodic reports or any other relevant communication expect from investigator
- Deliberations of the meeting via approval letter, disapproval letter or query letter
- Monitoring intimations and monitoring findings
- Any additional information IEC requires regarding the study.

Communication with the Head of Institution

IEC is constituted under the HOI and report to the HOI timely manner. The communication will be through email or writing. Below are the common reporting procedures to HOI.

- Resignation and replacement of members
- Annual assessment of members
- Annual Audit report of EC functioning
- Biannual report from Member secretary regarding overall functioning and finance arrangements.
- Reconstitution and approval of revision of SOP
- Administrative requirements

Annexure

1. Reminder letter to investigator

Reminder letter to investigator	
Name of Principal Investigator: -	
Study Title	
The above-referenced project was approved by the IEC on and is due for _____by the IEC. Kindly submit the continuing review application on or before_____. In case the projects have been completed/terminated, kindly complete the appropriate forms and submit to IEC on or before (date). Thanking you for your co-operation, Yours truly, Signature with date Member Secretary	

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STANDARD OPERATING PROCEDURES

Chapter : 10

REVIEW OF SERIOUS ADVERSE EVENT AND OTHER SAFETY REPORTS

CHAPTER 10

REVIEW OF SERIOUS ADVERSE EVENT AND OTHER SAFETY REPORTS

1.0 Purpose

Purpose of this chapter to shall be to give the guidance for the review and reconciliation of Serious Adverse events reporting to the IEC.

2.0 Scope

This SOP chapter shall apply to the IEC review of SAEs and unexpected events reports including follow up reports submitted by investigators.

3.0 Responsibility

The IEC shall be responsible for the review of all adverse events happening in the study. All AEs shall 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. EC shall give more attention while reporting and reviewing Serious Adverse Events (SAE). The EC shall be responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum of compensation and type of assistance to be provided to the participants.

4.0 Definition of Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

- results in death,

- is life-threatening,

- requires inpatient hospitalization or prolongation of existing hospitalization,

- results in persistent or significant disability/incapacity, or

- is a congenital anomaly/birth defect.

All clinical trials under the purview of CDSCO, the timeline and procedures as notified from time to time shall be followed for SAE reporting. All research participants who suffer harm, whether related or not, shall be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc. Medical management shall be free if the harm is related to the research. Compensation shall be given to any participant when the injury is related to the research. This shall be applicable to participants in any of the arms of research, such as intervention, control and standard ofcare.

Procedure for reporting SAE

- Investigators who are participating in the clinical trial from the Institution shall be requested to strictly follow the reporting and review guidelines of the SAE as per the local regulations of the country.
- As per the regulation Investigator has to submit the initial report of SAE to EC within 24 hours of SAE occurrence. Investigator can submit the SAE report to EC via an email followed by hard copy. The reporting should make via Appendix XI form along with supportive documents.

Ethics committee E-mail ID for 24-hr SAE submission	
Ethics committee Email:	**pushpagiriirb@pushpagiri.in**
Ethics committee contact number	**0469 2775518**

- The investigator has to submit the initial report of SAE to the respective sponsor within 24 hours of SAE occurrence.
- The investigator has to submit the initial report of SAE to the Drug Controller General of India within 24 hours of SAE occurrence at the below mentioned Email ID/Fax No.

Higher Authority E-mail ID and Fax No. for 24-hr SAE submission	
Higher Authority Email:	**dci@nb.nic.in**
Higher Authority Fax No:	**01123236973**

- The Investigator and Sponsor have to submit the analyzed report of SAE to the EC Chairman, Head of the Institution and DCGI within 14 calendar days of SAE occurrence.
- On receipt of the analyzed report of SAE from the Investigator, the EC shallorganize a full quorum meeting and request the investigator to present about the event. The committee shall discuss about the relatedness of the event with the clinical trial and give opinion on financial compensation to be paid by the Sponsor/ his representative according to the formula published by DCGI.
- A detailed report of recommendation of compensation shall be submitted to the DCGI by EC within 30 calendar days of SAE occurrence.
- If the SAE is death the report shall be submitted to the Chairman of Expert Committee as well within the above-mentioned time frame.

Any injury or death due to the following reasons shall be considered as clinical trial related injury or death and subjects are entitled to receive the compensation.

a) Adverse effect of investigational product
b) Violation of approved protocol, scientific misconduct or negligence by sponsor or sponsor representative or investigator
c) Failure of investigational product to provide intended therapeutic effect
d) Use of placebo in placebo-controlled trial
e) Adverse effect due to concomitant medication excluding standard of care necessitated as part of approved protocol
f) For injury to child in utero due to parent's participation in clinical trial
g) Any trial related procedures involved in the study

While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC shall 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, shall be 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.

Compensation in case of injury or death during clinical trial:

- In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required or till it is established that the injury is not related to clinical trial whichever is earlier.

- In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the licensing authority defined under clause (b) of rule 21, and the financial compensation shall be over and above any expenses incurred on the medical management of the subject.

- In the case of clinical trial related death of the subject, his/her nominee(s) shall be entitled for financial compensation, as per the order of the licensing authority defined under clause (b) of rule 21, and the financial compensation shall be over and above any expenses incurred on the medical management of the subject.

- The expenses on medical management and the financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

- The financial compensation for clinical trial related injury or death could be in the form of

    - Payment for medical management;

    - Financial compensation for trial related injury;

    - Financial compensation to nominee(s) of the trial subject in case of death;

    - Financial compensation for the child injured in—utero because of the participation of parent in a clinical trial.

- Any injury or death of the subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her

nominee(s), as the case may be, shall be entitled for financial compensation for such injury or death:

- Adverse effect of investigational product(s);
- Violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator;
- Failure of investigational product to provide intended therapeutic effect;
- Use of placebo in a placebo-controlled trial;
- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
- For injury to a child in-utero because of the participation of parent in clinical trial;
- Any clinical trial procedures involved in the study.

- The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for the conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the above reasons.
- The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the licensing authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.
- In case the sponsor fails to provide medical management for the injury to the subject and/or financial compensation to the trial subject for clinical trial related injury or financial compensation to the subject‘s nominee(s) in case of clinical trial related death of the subject, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons thereof, suspend or cancel the clinical trial and/ or restrict sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

Procedure for payment of financial compensation:

The Investigator shall report all serious and unexpected adverse events to the, Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the Clinical trial and the Ethics Committee that accorded approval to the study protocol, within twenty-four hours of their occurrence as per Appendix XI.

The cases of serious adverse events of death shall be examined as given below:

a. An independent Expert Committee shall be constituted by the Licensing Authority as defined under rule 21(b) to examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of death and quantum of compensation in case of clinical trial related death.

b. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on serious adverse event of death after due analysis to Chairman of the Ethics Committee and Chairman of the Expert Committee with a copy of the report to the Licensing Authority as defined under rule 21(b) and the Head of the Institution where the trial has been conducted, within ten calendar days of occurrence of the serious adverse event of death.

c. The Ethics Committee shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee with a copy of the report to the Licensing Authority within 30 days of the occurrence of the serious adverse event of death.

d. The Expert Committee shall examine the report of serious adverse event of death and give its recommendations to the Licensing Authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics Committee, and the Expert Committee while examining the event, may take into consideration, the reports of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Ethics Committee.

e. In the case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

f. The Licensing Authority shall consider the recommendations of the Expert Committee and shall determine the cause of death and pass orders as deemed necessary.

g. In case of clinical trial related death, the Licensing Authority, after considering there commendations of the Expert Committee, shall decide the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

Cases of serious adverse events, other than deaths, shall be examined as given below:

a. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Licensing Authority as defined under rule 21(b), Chairman of the Ethics

Committee and Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

b. The Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his Representative, whosoever had obtained permission from the Licensing Authority as defined under Rule 21(b) for conducting the clinical trial, to the Licensing Authority within 30 calendar days of occurrence of the serious adverse event.

c. The Licensing Authority shall determine the cause of injury and pass order as deemed necessary. The Licensing Authority shall have the option to constitute an independent Expert Committee, wherever considered necessary, to examine such serious adverse events of injury, which will recommend to the Licensing Authority for arriving at the cause of the injury and also the quantum of compensation in case of clinical trial related injury, to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

d. In case of clinical trial related injury, the Licensing Authority, shall decide quantum of compensation to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

e. The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, shall pay the compensation in case of clinical trial related injury or death as per the order of the Licensing Authority as defined under rule 21 (b) within thirty days of the receipt of such order.

Review of Suspected Unexpected Serious Adverse Reaction (SUSAR) / CIOMS

- All other sites SAEs, SUSARs, CIOMS and any other safety information pertaining to the trial have to be notified to IEC as per the timelines given in the guidelines or upon within 7 days of receipt.

- Safety Reports will be acknowledged by the Member Secretary and copy will be retained in the IEC study file/binder.

- All the Safety Reports or updates will be circulated to the members during the meeting
- IEC may ask to provide additional information related to SUSARs as required.

Annexures

1. Data Elements For Reporting Serious Adverse Events Occurring In A Clinical Trial (Table 5 Of New Drug And Clinical Trial Rule)
2. Due Analysis report template
3. Compensation formula

a) DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL (Table 5 of New Drug and Clinical Trial Rule)

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

- Initials & other relevant identifier (hospital/OPD record number etc.):
- Gender:
- Age and/or date of birth:
- Weight:
- Height:

2. Suspected Drug(s)

- Generic name of the drug:
- Indication(s) for which suspect drug was prescribed or tested:
- Dosage form and strength:
- Daily dose and regimen (specify units - e.g., mg, ml, mg/kg):
- Route of administration:
- Starting date and time of day:
- Stopping date and time, or duration of treatment:

3. Other Treatment(s)

- Provide the same information for concomitant drugs (including non prescription /OTC drugs) and non-drug therapies, as for the suspected drug(s):

4. Details of Suspected Adverse Drug Reaction(s)

- Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction:
- Start date (and time) of onset of reaction:
- Stop date (and time) or duration of reaction:
- Dechallenge and rechallenge information:
- Setting (e.g., hospital, out-patient clinic, home, nursing home):

5. Outcome

- Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted:
- For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings:
- Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc:

6. Details about the Investigator

- Name:
- Address:
- Telephone number:
- Email ID:
- Profession (Speciality):
- Site ID:

- Date of reporting the event to Licensing Authority:
- Date of reporting the event to Ethics Committee overseeing the site:
- Signature of the Investigator:

7. Details about the Ethics Committee

- Name & Address
- Name of Chairman & Address
- Telephone/Mobile Number
- Email

8. Causality Assessment by Investigator with reasoning for Relatedness/Un-relatedness along with supporting investigational documents.

9. Socioeconomic background of subject/patient viz. Qualification, Occupation, Monthly income

b. Due Analysis report template

Due Analysis Report

Study Title	
CTRI Registration No	
Study ID	
CRO Address	

Type of Report	
Type of SAE	
DCGI Acknowledgement details of Initial Report	

1. Patient Details

Initials	
Subject No	
Date of Birth/Age	
Gender	
Weight	
Height	
Hospital OPD Record No	

2. Suspected Drug(s)

Generic name of the drug	
Indication(s) for which suspect drug was prescribed or tested	
Dosage for and strength	
Daily dose and regimen	
Route of administration	
Starting date and time of day	
Stopping date and time, or duration of treatment	

3. Other Treatment(s)

Drug (Generic Name)	Dose/ Route/Frequency	Start date	Stop date	Indication

4. Details of Suspected Adverse Drug Reaction(s)

Event	
Start date	
Stop date	
Relationship to study drug	
Outcome	
Severity	
De challenging/ Re challenging	
Setting	

Description of the event/s

5. Outcome

6. Laboratory Reports:

7. Action Taken for the Serious Adverse Event:

8. Details of Compensation:

9. Relatedness to Study Agent/ Study related procedure(s):

Investigator Causality	

10. Details about the Investigator & Ethics Committee

Details about the Investigator	
Site ID	
Investigator Name	
Specialty	
Address	
Telephone No:	
Email ID	
Details about the Ethics Committee	
Name & Address	
Name of the Chairman & Address	
Telephone/ Mobile Number	

Email	

Date if reporting the event to Licensing Authority	
Date of reporting the event to the Ethics Committee overseeing the site	
Sponsor (Address with contact no and Email)	
Investigator‘s signature & date	

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STANDARD OPERATING PROCEDURES

CHAPTER 11

SELF ASSESSMENT PROCESS

CHAPTER 11

SELF ASSESSMENT PROCESS

1.0 Purpose

Purpose of this SOP chapter is to provide guidance for assessment of functioning of IEC.

2.0 Scope

This SOP Chapter applies the measures taken by IEC for the effective functioning.

3.0 Responsibility

The responsibility of self-evaluation of IEC functions shall lie with Chairperson and Member Secretary.

Process

IEC shall have a self-assessment system to ensure the effective functioning of IEC. Self-assessment shall be performed for each member. The self-evaluation shall be done annually. An Audit Committee shall be selected during the meeting which shall be approved by Chairperson.

One or more audit committees can be designated based on the requirement. All committees shall be approved in the full quorum meeting. The Audit Committee can be revised annually.

The Audit Committee shall be responsible for the assessment of functions and operations of IEC. The following areas shall be assessed by the Audit Committee once in a year.

- Functioning of IEC
- Attendance and Participation of Members
- Training and Certifications of Members
- Record Keeping and Archival
- Income and Expenditure of IEC
- Periodic Monitoring and Review
- SAE Management Process
- Documentation Management

- Administrative Support
- Performance of Members

The Audit Committee shall share the report to Member Secretary. The Member Secretary shall share the report to the Chairman and Head of Institution. The audit report shall be discussed in the full quorum IEC meeting and Corrective Action and Preventive Actions (CAPA) will be preparedand implemented by the Audit Committee. The implementation of CAPA shall be verified by Member Secretary and the same shall be discussed in the next EC meeting.

Assessment of EC Members

IEC will do assessment of its functioning annually. The member secretary and Chairperson will do the self-assessment using the assessment form. Member Secretary will perform assessment the members and report to the Chairperson. Actions will be taken based on the assessment. The members may be retrained or removed based on the nonperformance in the EC functions.

Annexure

1. Audit Checklist
2. Assessment form for members

1. Audit Checklist

	Name of the Assessor: Period of Assessment:	
SI No	Assessment	Comments
1	No of meetings conducted	
2	Are IEC meetings held as per the timelines?	
3	Number of Protocols reviewed	
4	Number of Protocols approved	
5	Number of SAEs reported	
6	Number of SAEs reviewed	
7	Was SAE Management satisfactory	
8	Had effective compensation been paid to subjects	
9	Details of Trainings conducted by IEC	
10	Number of Monitoring's performed	
11	Number Complaints registered by subjects	
12	Details of action taken for the complaints	
13	Details of payment received and spent	
14	Details of reconstitution made in the IEC	
15	Were all the changes in the reconstitution reported to DCGI?	
16	Any revision in the SOP has been made	

2. Assessment form for members

IEC Evaluation Form of Staff

	Mention () the individual who is performing the evaluation:	Self – evaluation: Member secretary IEC
	Name of the person who is evaluated:	
	Role in IEC:	
SI No	Assessment	Comments
1	Handles workload efficiently	Yes: No:
2	Number of protocols processed that were reviewed	
3	Completion of required checklists and documentation	Yes: No:
4	Maintains paper files efficiently andcorrectly	Yes: No:
5	Prepares agenda and minutes in timely manner	Yes: No:
6	Maintain IEC rosters efficiently and correctly	Yes: No:
7	Prepare IEC records efficiently and correctly	Yes: No:
8	Completion of Training requirement	Yes: No:
9	Attendance at Training sessions	Regular: Irregular:
10	Number of Training sessions Attended	
11	Preparedness for meetings	Good: Average: Poor:
12	Quality of pre-reviews	Good: Average: Poor:
13	Communication with IEC chair	Good: Average: Poor:

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: 0469 2775518

STANDARD OPERATING PROCEDURES

CHAPTER 12

RECORD KEEPING AND ARCHIVAL

CHAPTER 12

RECORD KEEPING AND ARCHIVAL

1.0 Purpose

Purpose of this SOP Chapter is to provide instructions for preparation and maintenance of active study files and other related documents approved by the IEC and storage/archival of closed study files and retrieval of documents.

2.0 Scope

This SOP chapter applies to all active protocol/study files, closed files and their related documents that are maintained in the IEC office and archival site

3.0 Detailed Procedure

All documentation and communication of an EC should be dated, filed, and archived with utmost confidentiality. The documents will be archived for a minimum period of 5 years following the completion of a study. The access is limited to the archived documents and tracked by a Register book for the entry and exit. EC Chairperson, Member Secretary and personnel delegated by Chairperson/Member Secretary only will have access to the archival area.

Documents that should be filed and archived include, but are not limited to:

Administrative Documents

- Constitution and composition of the EC
- Appointment letters
- Signed and dated copies of the most recent curriculum vitae of all EC members
- Signed confidentiality agreements
- COI declarations of members
- Training records of EC members
- Financial records of EC
- Registration/accreditation documents, as required

- A copy of national and international guidelines and applicable regulations
- Regulatory notifications
- Meeting-related documents
- Agenda and minutes
- All communications received or made by the EC
- SOPs

Study-related documents

- One hard copy and a soft copy of the initial research proposal and all related documents
- Decision letters
- Any amendments submitted for review and approval
- Regulatory approvals
- SAE, AE reports
- Protocol deviations/violations
- Progress reports, continuing review activities, site monitoring reports
- All correspondence between the EC and researchers
- Record of notification issued for premature termination of a study with a summary of the reasons
- Final report of the study
- Publications, if any

- Records can be maintained in hard copies as well as soft copies.
- For each project a separate file will be maintained.
- All the research related documents and communications of IEC will be dated and filed in the respective binders.
- All the Study related documents will be filed in the respective study specific binders.
- Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.
- The archival room will be provided with fire extinguisher and pest control to make sure the long term safety of the documents

Retrieval Procedure

- The documents can be retrieved by Authorized personals by requesting via document request form to EC Member Secretary. Up on Permission copy of the requested documents will be shared which will be documented.
- If the investigator needs copy of the document. Investigator has to give document request form and the EC secretariat will issue the document within one week
- All the records shall be accessible for inspection and copying by authorized representatives of the regulatory at reasonable times and in a reasonable manner.

Final Disposal of documents

The files will be disposed off by the IEC secretariat after the archival period of 5 years. A formal document tracking register will be maintained, providing details of the documents being written off / disposed off after notification to IEC in IEC meeting. The disposal shall be performed by means of shredding.

ANNEXURE

1. Document Tracking register
2. Document request form

1. Document Tracking register

Project No.	Title of Project	IEC Approval Date	No of Files	Study Initiation date	Location of the storage	Study Closure Date	Location of the storage	Name of the authorized individual archived	Date of Destruction	Sign of the responsible person

2. Document Request Form

Name of Document requested:	Date:
Requested by:-	Study Title:-
□ Principal investigator □ IEC/IRB Member □ Authority □ Others……..	
Purpose of the request:	
Retrieved by:	Date:
Returned by:	Date:
Archived by:	Date:
Approved by:	Date:

INSTITUTIONAL ETHICS COMMITTEE

PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES,

PUSHPAGIRI RESEARCH CENTRE,

Thiruvalla, Kerala-689101, India

Ph: 0469 2775518

STANDARD OPERATING PROCEDURES

Chapter 13

PREPARING FOR ETHICS COMMITTEE AUDIT/INSPECTION

CHAPTER 13

PREPARING FOR ETHICS COMMITTEE AUDIT/INSPECTION

1.0 Purpose

The purpose of this Chapter is to guide an Institutional Ethics Committee (IEC) to prepare for an audit or inspection of the IEC.

2.0 Scope

This chapter applies to all the IEC members and the Secretariat.

3.1 Responsibility

It is the responsibility of the Member Secretary, Chairperson, IEC Members and the IEC Secretariat to keep IEC documents ready for audit and to be available to answer questions during audit or inspection by administrative and regulatory authorities.

Detailed instructions

As per the provision of rule 122DD of Drugs And Cosmetic Rule 1945, _The Ethics Committee shall allow inspectors of officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of the trial. This SOP chapter is also applicable for the preparation of any audit or inspection from external regulatory bodies.

Receipt of notification of an Audit / Inspection

On receipt of written/ mailed communication regarding audit/ inspection visit, the Member Secretary will inform the Chairperson, IEC members and the Head of Institution, if applicable about the date and purpose of the audit/inspection.

Preparing for the audit

- On receiving information about the audit /inspection, IEC Member Secretary and/ or IEC member/s are given the responsibility by the Chairperson to prepare for the visit with assistance of the Secretariat.
- The Member Secretary and / or designated IEC member/s will make arrangements in accordance with the steps mentioned in the checklist
- The studies with incomplete / missing documents will be dealt with separately and actions taken will be documented.
- Care should be taken to ensure that all documents are kept in the right order for easy and quick access.

On the day/s of Visit

- Chairperson / Member Secretary / designated IEC Member/s should welcome and accompany the auditors/inspectors to the reserved meeting room.
- Designated team members must be present in the meeting room.
- The conversation would start with the auditor/inspector stating the purpose of the visit and the type of information is needed.
- The IEC Chairperson / Member Secretary / IEC Members must answer questions of the auditors/inspectors clearly, politely, truthfully and straight to the point.
- The information and files requested by the auditors/inspectors should be made available by the Secretariat.
- The Member Secretary/ designated IEC member/ Secretariat will make note of the comments, recommendation of the auditors/inspectors.

Correction of deficiencies observed at audit/ inspection

- Member Secretary/ designated IEC member/ Secretariat will review comments and recommendations of the auditor/inspector.

- On receipt of Audit/ Inspection Report the Chairperson should implement corrective and preventive measures and set the timeline for implementation of corrections as stated by the auditor/inspector.

- Action plan should be communicated by the Member Secretary/ designated IEC member to the auditor/inspector after seeking approval of the Chairperson.

- A review date for an internal follow-up audit will be decided by the Chairperson (if applicable).

The Member Secretary/ designated IEC member should report the outcome of the internal follow-up audit to the Chairperson.

Recording the Audit/Inspection Visit

- The Member Secretary/ designated IEC member/ Secretariat must keep record of the audit/inspection visit reports and action plans in a separate audit/inspection file.

- The completed checklist and findings from the internal follow-up audit (if applicable) must also be maintained in the internal audit file.\

ANNEXURE

1. Check list

ANNEXURE

- Check list

SI.No	Activity	Yes / NO
1.	Date of letter of communication regarding audit/inspection:	
2.	Date(s) on which the audit/inspection has been agreed on:	
3.	To ensure the IEC members and staff have been informed about the date/s and time.	
4	To ensure availability of IEC related information – mandate, terms of reference, organization chart (in the print form) in the IEC office.	
5	To make sure of availability of latest copy /copies of signed SOPs in print form in the office and/ or in electronic form on the IEC computer/s.	
6	To review the SOPs and note details of any omissions or deviations, with reasons.	
7	To ascertain availability of all national and international ethics guidelines and regulations in print form and / or in electronic form in the IEC office.	
8	To check the files of ongoing and complete research study files for the presence of all signed documents as stated below and to note any missing/ incomplete documentation and actions taken. ➢ Records regarding applications of research studies for review including protocols and related documents ➢ Protocol Assessment Records – Comments of IEC members, Meeting Agenda, Minutes (documented in individual study file or separately in meeting records file) ➢ Communication records with investigator (documented in	

	individual study file) ➢ Amendment Approvals (documented in individual study file) ➢ SAE reports and SAE related communications with investigator and regulators ➢ Protocol deviation/violation/exception reports(documented in individual study file) ➢ Continuing and final completion/termination reports	
9	(documented in individual study file) To ensure availability of documents regarding list of members, tenure, appointment details, CVs, baseline and periodic training of IEC members	
10	To ensure availability of documents regarding appointment, CVs and training of staff of secretariat.	
11	To ensure measures for maintaining security of electronic database and office records.	
12	To make sure that maintenance, retrieval, storage, archival and tracking of the study files are done as per the respective SOPs.	
13	To ascertain proper labelling and indexing of study files and storage cabinets.	
14	To decide which members will communicate with auditors/ inspectors, be available for audit/inspection, prepare action plan and conduct follow-up audit(if applicable)	
15	To report about findings and report received regarding audit/inspection to IEC members at the full board IEC meeting.	

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES PUSHPAGIRI MEDICITY TIRUVALLA-7

File No. EC/19/000528

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 04-Mar-2020

To

The Chairman
Institutional Ethics Committee
Pushpagiri Institute of Medical Science
Pushpagiri Research Centre Mother and child block
Thiruvalla Pathanamthitta Kerala - 689101 India

Subject: Ethics Committee Re-Registration No. ECR/878/Inst/KL/2016/RR-19 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/6421 dated 11-Oct-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/878/Inst/KL/2016/RR-19. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

V G SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 15-Dec-2019 to 14-Dec-2024, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical,

File No. - EC/NEW/INST/2020/998

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Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 28-Oct-2020

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**Institutional Ethics Committee , Pushpagiri Institute of Medical Science Pushpagiri Research Centre**
Address :	**Pushpagiri Institute of Medical Science and Research Centre, Pathanamthitta, Kerala Thiruvalla, Pathanamthitta, Kerala - 689101**
Contact No:	**04692700755**
Fax :	**04692600020**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU NAGAR Digitally signed by ANU NAGAR Date: 2020.10.28 10:35:51 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research

(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bicavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall

such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

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Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 04-Mar-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Ms. Minu Mathews	LLB (Master of Laws (LL.M.))	Legal Expert
2	Dr. Tressia Alias Princy Paulose	Ph.D (Chemistry)	Scientific Member
3	Dr. Vikram Gowda	MBBS (MD-Physiology)	Basic Medical Scientist
4	Dr. Liya Roslin Joseph	MBBS (MD-Pharmacology)	Basic Medical Scientist
5	Dr. Athulya G Asokan	MBBS (MD-Medicine)	Clinician
6	Mr. Lijo George	B. COM (Not Applicable)	Lay Person
7	Dr. Harikumar B Nair	BAMS (MHSSA)	Chair Person
8	Dr. Nebu George Thomas	BDS (MDS)	Member Secretary
9	Dr. T P Thankappan	MBBS (MD-Dermatology and Venereology)	Clinician
10	Fr. Sibin Mathew	Bachelor in Theology	Social Scientist
11	Dr. Philip Mathew	MBBS (MD-Community Medicine)	Clinician
12	Dr. G. Sulochana	MBBS, MD-Pathology	Basic Medical Scientist
13	Dr. T.M Charry	MSc., Ph.D	Scientific member
14	Dr. Nibu Verghese	Ph.D (Plant Biotechnology)	Scientific member
15	Dr. Stephen James	M. Tech (CS & IT)	Member

V G SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES
PUSHPAGIRI
MEDICITY
TIRUVALLA-7

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

No: IRB: 01/2020 **26th MAY 2020**

Meeting Date: 19/05/2020

Minutes of the IRB committee on: 19/05/2020

1. Due to the COVID-19, the IRB members and the PIs' of the proposals were joined the meeting via. Online platform (ZOOM) and the chair welcomed the new IRB members and started the proceedings
2. The Member Secretary informed that the re-registration of the IRB with CDSCO was completed
3. Previous minutes of IRB meeting held on 19th November 2019 approved and seconded by Dr Liya Roslin Joseph

ATTENDANCE: the table below lists all members of the ethics committee, their role, and attendance

S.N.	Name	Primary Scientific or Non-scientific Specialty	Role in IEC
1	Dr Harikumar B Nair	Primary	Chairperson
2	Dr Nebu George Thomas	Primary	Member Secretary
3	Dr Nibu varghese	Primary	Member
4	Dr T M Chary	Primary	Member
5	Dr Vikram Gowda	Primary	Member
6	Dr Liya Roslin Joseph	Primary	Member
7	Dr Athulya G Asokan	Primary	Member
8	Dr Tressia Alias Princy Paulose	Primary	Member
9	Dr Philip Mathew	Primary	Member
10	Stephen James	Primary	Member
11	Mr Lijo George	Non- Scientific	Member
12	Adv. Minu Mathews	Non- Scientific	Member
13	Fr. Sibin Mathew	Non- Scientific	Member

Subject Expert: Nil
Members Absent with apologies: 2
Non Voting Member: NIL
Members alternating: NIL

Guests (Include Affiliation): NIL
Members attending via teleconference: 13
Total count: 13 out of 15

Quorum: The quorum was present.
> 50% members with 5 specified category as per ICMR guidelines/Schedule Y. The chair person called the meeting to order, after confirming the quorum was present

Attendance Notes:

- **Members in attendance who recused themselves:** None
- **Conflict of Interest of IRB Members**: None

Regulations followed for IRB Motion: Schedule Y, ICMR 13 principles

I. INITIAL REVIEW:

IRB study Ref No:01/2020

Protocol Title: "Clinical validation study of BIOCALCULUS V.1.0: A novel cardiac rhythm recorder**"**

Principal Investigator: Dr Rajan Joseph Manjuran

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. The outcome measure of the proposed study should be detailed
2. How the funding for the study gets met?
3. The IPR details regarding the proposed work should be clarified
4. Do the participants of the study face any adverse events? If yes, explain
5. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 02/2020

Protocol Title: "Simple technique to assess angiographic coronary artery dimensions: correlation with cadaver measurements"

Principal Investigator: Dr Rajan Joseph Manjuran

Primary reviewer of IRB**: Comments from IRB Member**
Motion:
Comments **:**
Detailed Research Plan

1. What is the novelty of the present study?
2. Is there any reference studies related to the present study?
3. The detailed budget of the study should be provided
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 03/2020

Protocol Title: "Depression, anxiety and their associated factors among general population during COVID 19 pandemic: a multi-centric study**"**

Principal Investigator: Dr. Roy Kallivayalil

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Please contact with the screening committee, ICMR since the present COVID-19 study involves multiple foreign study-centres
2. PI should clarify about the population under investigation
3. Does the follow-up will involve the same patients?
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 04/2020

Protocol Title: "Collaborative Outcomes study on Health and Functioning during Infection Times (COH-FIT)"

Principal Investigator: Dr. Roy Kallivayalil

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Budget details should be mentioned
2. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 05/2020

Protocol Title: "Bilirubin Levels in Patients with Schizophrenia and Bipolar Affective Disorder: A Comparative Study"

Principal Investigator: Dr. Sheena

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Rationale of the study should be clarified

2. Performa should include liver disorders as well
3. PI should include sample size calculation
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 06/2020

Protocol Title: "Mental health impact and associated factors of COVID 19 pandemic among general population in Central Kerala"

Principal Investigator: Dr.Sivin P Sam

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. The association between mental health and COVID-19 should be clarified
2. Is the bystanders are included in the study?
3. PI should evaluate the feasibility of attaining the sample size in the proposed study duration
4. PI should consider performing the study as a community based study
5. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 07/2020

Protocol Title: "Mental health impact and associated factors of COVID 19 pandemic among hospital staff in Central Kerala"

Principal Investigator: Dr.Soumya P Thomas

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Pi should clarify about the fact that all the hospital staff members are included in the study?
2. If yes, how they will be approached for the study?
3. How the mental state of the participants and the COVID-19 pandemic is associated?
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB study Ref No: 08/2020

Protocol Title: "Categorization of domestic injuries, during COVID-19 lockdown and comparison with injuries 6 weeks pre-lockdown, at tertiary care plastic surgery centre in a rural district of Kerala"

Principal Investigator: Dr. Cyril Joseph

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. How the sample size is calculated?
2. Pi should explain about the variables included in the study
3. The relevance of the study should be explained
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 9/2020

Protocol Title: "Influence of alcohol use disorders on complication in a tertiary care plastic and micro vascular surgery unit and psychiatry referral services"

Principal Investigator: Dr. Cyril Joseph

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Since the study uses the patient history from the documents, is there any bias included?
2. What is the significance of the study?
3. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 10/2020

Protocol Title: "A 5 year review of characteristics, management and outcome of upper extremity neurovascular injuries at a rural Plastic Surgery centre in Kerala"

Principal Investigator: Dr. Cyril Joseph

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. PI should consult a statistician before commencing the study
2. How the recall bias in the present study be avoided?
3. PI should clarify that whether the present study include follow up patients?
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 11/2020

Protocol Title: "Emotional problems of adolescence during COVID-19 lockdown and social media exposure"

Principal Investigator: Dr. Joice Geo

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. How do you establish the association between the emotional problems and COVID-19?
2. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 12/2020

Protocol Title: "Study on attitude, emotional disturbances and perceived mental healthcare need in women during COVID-19 pandemic in Kerala"

Principal Investigator: Dr. Joice Geo

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. What is the age group of women that involved in the study?
2. How the bias associated wide range of age group will be avoided?
3. How the sampling will be done?
4. PI should consult a statistician before commencing the study
5. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 13/2020

Protocol Title: "Appropriate use of personal protective equipment among healthcare workers during the COVID19 outbreak in India: A survey study"

Principal Investigator: Dr. Jebu

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Since the knowledge level of people about PPE vary, how the comparison will be done?
2. PI should clarify the term 'proper usage'
3. PI should include the study variables and sample size
4. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 14/2020

Protocol Title: "Locked versus unlocked cephalomedullary nails in the treatment of trochanteric fractures of femur- a comparative study."

Principal Investigator: Dr. Kiran

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. PI has asked for the waiver of consent
2. Will all the scores be used for the follow-up?
3. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 15/2020

Protocol Title: "Femoral head diameter in patients undergoing hemiarthroplasty – A clinical study"

Principal Investigator: Dr. Kiran

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. PI should have a clarification about the conduction of the study
2. What are the stastical tools be used in the study?
3. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 16/2020

Protocol Title: "Relevance of comparative in the diagnosis of traumatic extremity injuries in children"

Principal Investigator: Dr. Roney

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. PI should compare the residents in Department of Emergency and Orthopedic
2. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 17/2020

Protocol Title: "Demographic and Clinical profile of Acute Formic acid poisoning in a South Indian Tertiary Care Hospital: A Case Series Analysis"

Principal Investigator: Dr. Arjun

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :
Detailed Research Plan

1. Significance of the study should be clarified
2. Progress of the study has to be updated in every 3 months

*The PI will start the study only after the receipt of approval letter by the Committee

IRB study Ref No: 18/2020

Protocol Title: "ICMR–RUMC COVID 19 Study for the Assessment of Prophylaxis for Health Care Workers"

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments : Approved

*The PI will start the study only after the receipt of approval letter by the Committee

II. PROTOCOL CHANGES : Nil

III. RETROSPECTIVE REVIEW: Nil

IV. OTHER ISSUES DISCUSSED: Nil

The meeting ended at 5.15 pm.

MEMBER SECRETARY
Institutional review board
Pushpagiri group of institution
Tiruvalla - 689101, Kerala

.....
Member Secretary
Institutional Review Board

INSTITUTIONAL REVIEW BOARD

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES
PUSHPAGIRI
MEDICITY
TIRUVALLA-7

INSTITUTIONAL REVIEW BOARD
PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE

No: IRB/02/2020 29th SEP 2020

N O T I C E

This is to inform you that the meeting of the IRB will be held on 29th SEP 2020 **@ 10.00 am (Tuesday) through zoom meeting platform.** All members are requested to attend the meeting

SL NO	TITLE OF THE PROPOSAL	NAME OF PI	STARTING TIME
General Discussion: Previous Meeting Minutes Approval Considering the proposals submitted for expedited approval			10.05 am
1.	Pathways to Care for Eating Disorders	Dr. Roy Abraham Kallivayalil	10.20 am
2	Survival and functional status of chronic kidney disease patients initiated on hemodialysis after the age of 80 years	Dr Subhash Bhaskaran Pillai	10.40 am
3	An epidemiological and clinical analysis of covid-19 confirmed cases in a tertiary care hospital in central kerala	Dr. Sajit Varghese	11.00 am
4	Antibiotic prescriptions in dental implant surgery-An online questionnaire survey	Dr Annie Kitty George	11.20 am
5	Survival and morbidity of head neck cancers following multimodal therapy	Dr. Jency Mathews	11.40 am
6	Survival outcomes of breast cancer after tailored therapy	Dr. Jency Mathews	12.00 pm
7	An epidemiological and clinical analysis of patients presenting with delirium in the emergency department : a prospective single center observational study.	Dr. Lissa abraham	12.20 pm
LUNCH			12.25 pm to 1.00 pm

8	Clinical profile and efficacy of treatment strategies in COVID 19 patients in the intensive care of a tertiary care centre	Dr Manju Mathew	1.05 pm
9	Focused ultrasonography in COVID 19 patients – a pragmatic approach	Dr Manju Mathew	1.25 pm
10	Bipolar Cautery v/s Conventional Suture Ligation of Vascular Pedicles in Thyroidectomy- A comparative Study	Dr. Om Prakash	1.45 pm
11.	Prevalence, extent and severity of gingival recession among women belonging	Dr. Saumya John	2.05 pm
12.	An automated model for classification and prediction using pre-operative and post-operative mri	Ms. Divya	2.25 pm

IRB: 01/2021 **13th April, 2021**

Meeting Date: 13th April, 2021

Minutes of the IRB committee on: 13th April, 2021

1. Due to the prevailing Covid -19 pandemic situation, the IRB meeting was scheduled on an online platform (Zoom) on 13th April, 2021. The IRB Members and the Principal investigators were given the zoom link before head and were requested to join at 10am on 13th April, 2021. The IRB Chairman welcomed Dr. Melvin Associate Professor from SRM Medical College Hospital and Research Centre.

2. The previous minutes of the IRB Meeting was approved in this meeting.

ATTENDANCE: the table below lists all members of the ethics committee, their role, and attendance

S.No.	Name	Primary Scientific or Non-scientific Specialty	Role in IEC
1	Dr Harikumar B Nair	Primary	Chairperson
2	Dr Nebu George Thomas	Primary	Member Secretary
3	Rev Dr. Mathew Mazhavancheril	Primary	Member
4	Dr Vikram Gowda	Primary	Member
5	Dr Liya Roslin Joseph	Primary	Member
6	Dr Philip Mathew	Primary	Member
7	Dr Krishnan Namboodiri	Primary	Member
8	Dr Athulya G Asokan	Primary	Member
9	Dr Tressia Alias Princy Paulose	Primary	Member
10.	Dr. Melvin	Primary	Guest

Members Absent with apologies: NIL

Non Voting Member: NIL

Members alternating: NIL

Guests (Include Affiliation): Dr. Melvin, Associate Professor from SRM Medical College Hospital and Research Centre.

Total count: 11 out of 11

Quorum: The quorum was present. > 50% members with 5 specified category as per ICMR Guidelines/Schedule Y. The chair person called the meeting to order, after confirming the Quorum was present

Attendance Notes:

 Members in attendance who recused themselves: None

 Conflict of Interest of IRB Members: None

Regulations followed for IRB Motion: Schedule Y, ICMR 13 principles

I: INITIALREVIEW

IRB Study Reference No: 01/2021

Protocol Title: Estimation of COVID-19 IgG Antibodies post vaccination among health care workers in a tertiary care centre in South India.

Principal Investigator: Dr. Mathew Pulicken

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments :

1. Is antibody testing a part of routine hospital test or for study purpose?
2. What is the sample size?
3. Do samples selected have a bias selection?
4. Suggested for random sampling method
5. How will you handle the confidentially of the result
6. What is the budget proposal of the study
7. What type of antibody testing is followed in this study?
8. Publication has to be done as earlier as possible due to multiple studies already done in same topic.

Reply to the Comments:

1. Is antibody testing a part of routine hospital test or for study purpose?

We are trying to make antibody testing a part of the routine hospital test.

2. What is the sample size?

The minimum required sample size calculated is 168 with confidence level of 95% and relative precision of 10% of mean. To account for drop outs a total of 200 will be recruited.

3. Do samples selected have a bias selection?

Yes, because we are recruiting only those who are paying for the first testing there can be a bias. It is a limitation of the study.

4. Suggested for random sampling method

Random selection is not possible unless everything is paid for. At present we do not have the funds for random selection and we need to move rapidly to recruit for the study.

5. How will you handle the confidentially of the result

All data collected for this study will be kept confidential.

6. What is the budget proposal of the study

Attaching the budget for the study

7. What type of antibody testing is followed in this study?

HCW's recruited are tested for the total Immunoglobulin G (IgG) against spike protein. All samples will be tested for anti SARS-CoV-2 IgG antibodies by CLIA in the Abbott analyser

8. Publication has to be done as earlier as possible due to multiple studies already done in same topic.

I agree fully to the IRB's suggestion.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 02/2021

Protocol Title: Complications associated with Percutaneous Nephrolithotomy (PCNL) in a Tertiary Care Centre-a Retrospective Study

Principal Investigator: Dr. Anusha S Varghese

Primary reviewer of IRB: Comments from IRB Member

Motion:

Comments:

1. Apply for waiver of consent as there are challenges in getting consent.
2. When will patient come for PCNL
3. Will all patients included in the study come for follow up?
4. Clearly state the reason for why samples were lost from the study.

Reply to the Comment

1.We would like to apply for waiver of consent as, it is a retrospective study with no mention of patient details and due to difficulty in getting consent from all patients operated over a period of 5 years. We would get permission from Medical Director for accessing patient records from MRD.

2.Patients with renal calculus more than 2 cm in size, complex (staghorn calculus), extracorporeal shock wave lithotripsy (ESWL) refractory and lower pole calculi. Other indications are calyceal diverticular stone, associated with anatomical anomaly (horseshoe kidney, ectopic kidney). Patients posted for PCNL will get admitted one or two day prior to day of surgery.

3.Patients who undergo PCNL will get discharged within one week following Surgery. They are asked to follow up in the OPD after 2 weeks from surgery. We understand that a very small percentage would be lost to follow up and this is a limitation of the study. This Institution being a tertiary care centre, most of the people come from far off places and they tend to follow up near to their locality.

4.All the patients who underwent PCNL in the institution between 2016 and 2020 will be included in the study. The patients are asked for a follow up in two weeks post discharge for the stent removal. However, those who are lost to follow up (frequency) will be mentioned in the results.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 03/2021

Protocol Title: Retrospective study of patients with rhabdomyolysis in a tertiary care centre in South India

Principal Investigator: Dr. Manju Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:

Comments:

1. What is the sample size for the study?
2. Title of the study and objectives needs modification and has to be changed
3. If follow up of the patients is by telephone call then consent form is required or voice call can be recorded.
4. Modify the duration of the study
5. Why was this particular age group selected?

Reply to the Comment

1. Sample size: 75

2.Title

Clinical outcomes in rhabdomyolysis: a retrospective study in a South Indian centre

Objectives of the study

Primary objective:

1.To estimate the incidence of acute kidney injury in patients diagnosed with rhabdomyolysis admitted in a tertiary care centre over a 6 year period

Secondary objectives:

1. To determine the number of patients who required intensive care unit admission in this group
2. To determine the mortality
3. To validate a risk prediction score for requirement of renal replacement therapy and mo in this study group

3.**Informed consent**:If telephone calls are required for follow up, informed consent for the study will be ensured by recording the phone calls.

4. Duration of the study : 3 months

5. Why the age group of 15 and above was chosen?

Pushpagiri medical college hospital admits patients 15 years and above in the adult intensive care u and are under the care of physicians. Their clinical profile and aetiologies for rhabdomyolysis are similar, unlike patients less than 15 years. Hence, the age group of 15 years and above was chosen.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 04/2021

Protocol Title: Effect of Micro-osteoperforation with Lance Drill on rate of tooth movement during anterior en-masse retraction in Class I Malocclusion with bidental proclination.

Principal Investigator: Dr. Biju Sebastian

Motion:

Comments:

1. The patient information sheet is very brief and need to be in elaborate.
2. Is there any post operative complication expected after the procedure?
3. Is it the first time Lance Drill used for such procedures?

Reply to the Comment

Patient information sheet modified and sent again.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 05/2021

Protocol Title: Clinicoetiological profile of UTI in pediatric population in a teaching hospital in south India.

Principal Investigator: Dr. Poornima Venugopal

Motion:

Comments:

1. Duration of the study has to be changed and time needed for doing the study has to be added.
2. As you are including a wide population from 1 month – 15year will the micro organisms be the same in both population
3. How will you find which antibiotics are sensitive?
4. How will you know if samples are contaminated?
5. Is there similar studies published from Kerala?

Reply to the Comments:

1. Duration of the study has to be changed and time needed for doing the study has to be added.

   Duration of study- 4months, May 1st 2021 to August 30th 2021.

2. As you are including a wide population from 1 month – 15year will the microorganisms be the same in both population

UTI organism and treatment are same in all pediatric age group except newborn where it can be urosepsis. Stantard national and international guidelines for treatment are uniform in all pediatric age groups, only the incidence and sex prediliction and intensity of symptoms change in different age groups.

3. How will you find which antibiotics are sensitive?

We will collect the urine culture and sensitivity report , which will have the microorganisms and the antibiotic sensitive to those organisms. Sensitivity test will be done by Kirby-Bauer disk diffusion method and intepreted according to Clinical and Laboratory Stantard Institute Guidelines (CLSI).

4. How will you know if samples are contaminated?

If mixed fllora (2 or more microorganisms) are grown in urine, those samples will be contaminated.

5. Are there similar studies published from Kerala?
Yes

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 06/2021

Protocol Title: Impact of covid-19 pandemic on pediatric emergency care utilization in a teaching hospital in South Kerala

Principal Investigator: Dr Carol Sara Cherian

Motion:

Comments:

1. Will the information collected be adequate?
2. How are going to compare the samples?
3. There is a suggestion of comparing previous 2 or 3 years and get an average or observe the trend.

Reply to the Comments:

1. Will the information collected be adequate?

All the patients coming to our pediatric casualty , will be examined in detail by Pediatric PG and Pediatric Duty Medical Officer. And all the details will be entered in the patients outpatient record, including diagnoses. So all the details needed for this study, can be obtained from the op file of patients including summary from emergency departmment and we have a daily report book in department showing daily statistics and remarks about each patient.

2. How are you going to compare the samples?

a. We are planning to compare the number of patients who attended our pediatric emergency department prIor to COVID-19(March 2019- December 2019) and during COVID-19(March 2020 to December 2020) by collecting details from outpatient records during these years.
b. We will collect their details, including age, sex, pesenting complaint, time of presentation, system involvement , if they are refered case or did we refer them out, did they get admitted, number of mortatily and compare these parameters Pre COVID and Post COVID.

3. There is a suggestion of comparing the previous 2 or 3 years and get an average or observe the trend.

Since the average number of patients those have visited our pediatric emergency is almost equivalent during the previous 2 - 3 years, we have considered only previous 1 year. Moreover other studies done in different parts of world also has taken only previous 1 year.

But if the ethical committee suggest, we shall take 3 years average.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 07/2021

Protocol Title: Effectiveness of asynchronous versus synchronous teaching in forensic medicine for phase II MBBS students

Principal Investigator: Dr. Prince. M. Paul

Motion:

Comments:

1. Are you going to take same topics for both groups?
2. Are you giving a gap before the cross- over of students?
3. How are you going to evaluate after the class?

Reply to the Comments:

1. Are you going to take the same topics for both groups?

Both groups (1 & 2) will get the same topic at the same date and time.
group 1 - aynchronous

group 2- synchronous

2. Are you giving a gap before the cross- over of students?

After each topic, cross-over of students after a week for the next topic.

3. How are you going to evaluate after the class?

Soon after the class- test by MCQ/ Single precise answer for 15 min for both groups.
2 weeks later, test paper for both groups - to assess the retention of memory for each topic will be done.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 08/2021

Protocol Title: A Study of Central Venous Catheter-related Infections In Hemodialysis Patients.

Principal Investigator: Dr Subhash Chandran Bhaskaran Pillai

Motion:
Comments:

1. How long are follow-ups going to be done?
2. Are you expecting lost follow-ups?
3. Change the study type as retrospective cohort

Reply to the Comments:
1) Follow up will be continued as long as the patient uses the same catheter for hemodialysis (which in most cases is between 4- 8 weeks). Usually catheters are removed once patient has a surgically created AV fistula ready for use.
2) Not expecting many lost to follow ups.
3) The study will be changed to retrospective cohort study.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 09/2021

Protocol Title: Efficacy of an improvised endo-vascular thrombolytic technique for the treatment of thrombosed arterio-venous fistulas in Hemodialysis patients

Principal Investigator: Dr Subhash Chandran Bhaskaran Pillai

Motion:
Comments:

1. Suggested not to exclude lost follow up cases, include them in final diagnosis
2. Is the definition of stress mentioned in literature?

Reply to the Comments:
1) Shall include 'lost to follow up' cases in the final survival analysis.
2) The definitions used:

"According to the standard practice guidelines published by the Society of Interventional Radiology [14], technical success was defined as restoration of flow combined with less than 30% residual luminal diameter stenosis. Clinical success was defined as resumption of normal dialysis for at least one session."
Ref: 14. Aruny JE, Lewis CA, Cardella JF, et al. Quality improvement guidelines for percutaneous management of the thrombosed or dysfunctional dialysis access. J Vasc Interv Radiol. 2003;14:S247–53.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 10/2021

Protocol Title: Knowledge, Attitude and Behaviour Related to Evidence-Based Practice Among Health care Practitioners

Principal Investigator: Dr Sunu Alice Cherian

Motion:
Comments:

1. A suggestion was made to conduct a workshop after the study.

Reply to the Comments:
We are planning to conduct a workshop after the study.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 11/2021

Protocol Title: Predictors of recurrent febrile seizures in children in a tertiary care hospital in South Kerala

Principal Investigator: Dr Synu Elsa John

Motion:
Comments:

1. What is the sample size?
2. What are the risk factors?
3. A suggestion was given to include a larger population.

Reply to the Comments:

1. The sample size is 168. But since our study is from Jan 2011 to Dec 2016 we have around 400 cases to be included in the study.
2. The risk factors for recurrence of febrile seizure are
a) Age < 1 year
b) Duration of fever < 24 hours
c) Fever of 38-39℃ (100.4-102.2°F)
d) Family history of febrile seizures
e) Family history of epilepsy
f) Complex febrile seizures
g) Attending day care or school
h) Male gender
i) Low serum sodium level at the time of presentation.
3. Though the sample size is 168, since our study period is from Jan 2011 to Dec 2016 we have arounfd 400 cases to be included in the study. Kindly let me know if a further larger popululation needs to be included than this.

*The PI will start the study only after the receipt of approval letter by the Committee.

II. PROTOCOL CHANGES : Nil

III. RETROSPECTIVE REVIEW: 1

IV. OTHER ISSUES DISCUSSED: Nil

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES PUSHPAGIRI MEDICITY TIRUVALLA-7

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

The meeting ended at 1:00 pm.

Member Secretary
Institutional Review Board

.....

MEMBER SECRETARY
Institutional review board
Pushpagiri group of institution
Tiruvalla - 689101, Kerala

IRB: 02/2021 **7th September, 2021**

Meeting Date: 7th September, 2021

Minutes of the IRB committee on: 7th September

1. Due to the prevailing Covid -19 pandemic situation, the IRB meeting was scheduled on an online platform (Zoom) on 7th April, 2021. The IRB Members and the Principal investigators were given the zoom link before head and were requested to join at 12pm on 7th September, 2021. The IRB Chairman welcomed Dr. Melvin Associate Professor from SRM Medical College Hospital and Research Centre.

2. The previous minutes of the IRB Meeting was approved in this meeting.

ATTENDANCE: the table below lists all members of the ethics committee, their role, and attendance

S.No.	Name	Primary Scientific or Non-scientific Specialty	Role in IEC
1	Dr Harikumar B Nair	Primary	Chairperson
2	Dr Nebu George Thomas	Primary	Member Secretary
3	Rev Dr. Mathew Mazhavancheril	Primary	Member
4	Dr Vikram Gowda	Primary	Member
5	Dr Liya Roslin Joseph	Primary	Member
6	Dr Philip Mathew	Primary	Member
7	Dr Krishnan Namboodiri	Primary	Member
8	Dr Athulya G Asokan	Primary	Member
9	Dr Tressia Alias Princy Paulose	Primary	Member
10.	Dr T M Chary	Primary	Member
11.	Adv. Minu Mathews	Primary	Member
12.	Mr Lijo George	Primary	Member
13.	Fr. Sibin Mathew	Primary	Member
14.	Dr Nibu Varghese	Primary	Member
15.	Dr. Melvin	Primary	Guest – Subject Expert

Members Absent with apologies: NIL

Non-Voting Member: NIL

Members alternating: NIL

Guests (Include Affiliation): Dr. Melvin, Associate Professor from SRM Medical College Hospital and Research Centre.

Total count: 15 out of 15.

Quorum: The quorum was present. > 50% members with 5 specified category as per ICMR Guidelines/Schedule Y. The chair person called the meeting to order, after confirming the Quorum was present

Attendance Notes:

 Members in attendance who recused themselves: None

 Conflict of Interest of IRB Members: None

Regulations followed for IRB Motion: Schedule Y, ICMR 13 principles

I: INITIALREVIEW

IRB Study Reference No: 01/2021

Protocol Title: A comparative study on the effect of Calcium and Vitamin D supplements versus citicholine in fracture healing

Principal Investigator: Dr. John P S

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Choline is easily in our body so should there be a group with high protein and without citicholine?
2. A suggestion was given to consider protein intake factor.
3. Can a 4th group be considered supplementing only with Vitamin C, as Vit V increases the choline level in body?
4. Does this study require a CTRI registration?
5. Can we have randomization in methodology as the present study appears as a non –randomized trial?

6. The study title does not reflect tibial fracture.
7. Can we have a third group without Vitamin D- calcium/ citicholine supplementation?
8. Are you recording the other factors not responsible for healing of fracture?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 02/2021

Protocol Title: Mitral Annulus Calcifications: An Echocardiographic Study

Principal Investigator: Dr. Rajan Joseph Manjuran

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. As you are invited to participate in this study, will you be getting authorship for this study?
2. Patient doing echocardiography without doing lipid profile/ renal parameters, will that be a concern?
3. Will you be supporting any patients for doing the above said investigations?
4. By doing this study, are you expecting regional difference in the results?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 03/2021

Protocol Title: Perception and perspectives of Hospital Infection Control Committee (HICC) members regarding Infection Prevention and Control (IPC) Guidelines, 2020 and strategies to improve its adoption by healthcare facilities.

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Is this study a qualitative study?
2. How are you going to choose those 12 sample in your study and is it across Kerala?
3. The 12 sample selected sufficient for the study?
4. Is there any reason for restricting your study only to qualitative aspect?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 04/2021

Protocol Title: Shortage of specific antimicrobial agents affecting optimal drug procurement and dispensing in hospitals: A qualitative study from Kerala, India

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Suggestion: It would be better if you could distribute your study across the region.
2. Do you have a pre-defined questionnaire for collecting the data?
3. How will you be checking the shortage in your study?
4. How will you prevent the shortage?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 05/2021

Protocol Title: Identifying behavioral markers for mental wellbeing through digital phenotyping- Multicentric study

Principal Investigator: Dr. Roy Abraham

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Where can you access this application?
2. Who will do the data collection?
3. How will you ensure the confidentially of the data collected?
4. It would be better to include participants who are directly not reporting to you.
5. How do you prevent your data being taken by others as it's a public domain?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 06/2021

Protocol Title: Prevalance of Workplace violence in Kerala -It's Association with Clinical anger among Doctors

Principal Investigator: Dr. Roy Abraham

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is the sample size for the study decided?
2. Who all are included in the sample size?
3. Do you have any inclusion criteria?
4. It would be better if you can include a good sampling criteria.

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 07/2021

Protocol Title: Effectiveness of NiTi springs vs. elastomeric power chain force delivery systems with mini-implant assisted maxillary incisor intrusion in deep bite correction: A randomized controlled trial

Principal Investigator: Dr. Biju Sebastian

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. How do you prefer to randomize your sample?
2. Are you going to use a software for randomization?
3. How are you going to conceal the information?
4. Are both post delivering system regularly being used in the department?
5. How will you assess the root resorption?
6. Who will bear the expenses?
7. Are you going to include patients who have already started orthodontic treatment?
8. This study require a CTRI registration

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 08/2021

Protocol Title: Treatment effect evaluation of Facemask and 2×4 appliance on class lll patients of age 7-9 years: A randomized controlled trial

Principal Investigator: Dr. Biju Sebastian

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Patient information sheet have to be more elaborate.
2. What is Class III patients?
3. Is this Class III a complete term?
4. This study require a CTRI registration

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 09/2021

Protocol Title: Effect of online inquiry based learning versus lecture based learning in the academic performance of phase I MBBS students

Principal Investigator: Dr. Amrutha Mary

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Will the result lie on the topics been taken?
2. How are you going to assess the knowledge of the students?
3. Will you be informing the students that they are a part of this study?
4. What is your sample size?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 10/2021

Protocol Title: Effect of mnemonics in medical education- A perspective study on entertainment education in first year MBBS students for better memory

Principal Investigator: Dr. Meenu S

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is there a chance of sharing the same mnemonics between the groups?
2. How are you going to assess the students?
3. Will you conduct the test on the same day after class or an another day?

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 11/2021

Protocol Title: Incidence of Covid-19 infection and its associated oral manifestations among oral health care workers.

Principal Investigator: Dr. Lisa Elizabeth Jacob

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Who all are included in your study group?
2. Is this a Multi-centric study?
3. Do you think 213 will be adequate sample size if you are doing a multi-centric study?
4. How long after Covid-19 will you be checking for oral manifestations?
5. It is better to use the term frequency/ prevalence of COVID-19 instead of incidence.
6. It's better to have a clear strategy on how you are going to circulate the Google forms
7. Since there are no co-investigators from other region better to consider this study as a single centric study.
8. Please mention in your title as – A questionnaire Based Study

*The PI will start the study only after the receipt of approval letter by the Committee.

IRB Study Reference No: 12/2021

Protocol Title: Assessment of depression, anxiety and stress among the dental students during the Covid -19 pandemic.

Principal Investigator: Dr. Anju Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is there any study carried out in Kerala?
2. As students come under vulnerable population it is better to consider students who do not report to you.
3. It is better if the study is multi-institutional as it adds weightage while going for publication

4. It would be better if a study can be conducted among the faculties.

*The PI will start the study only after the receipt of approval letter by the Committee.

II. PROTOCOL CHANGES : Nil

III. RETROSPECTIVE REVIEW: Nil

IV. OTHER ISSUES DISCUSSED: Nil

The meeting ended at 3:45pm

MEMBER SECRETARY
Institutional review board
Pushpagiri group of institution
Tiruvalla - 689101, Kerala

.....

Member Secretary
Institutional Review Board

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES
PUSHPAGIRI MEDICITY TIRUVALLA-7

Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

Dental College | Pushpagiri <dentalcollege@pushpagiri.in>

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Dr. K. GEORGE VARGHESE
PRINCIPAL
Pushpagiri College of Dental Sciences

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