PES Institute of Medical Sciences & Research
Kuppam- 517 425, Chittoor Dist., Andhra Pradesh
Tel: 08570 - 277999, 277799, 277666
Email: principal@pesimsr.pes.edu Web: www.pesimsr.pes.edu

NAAC Criterion 3: Research, Innovations and Extension

3.3 Research Publications and Awards

3.3.1:The Institution ensures implementation of its stated Code of Ethics for research. The Institution has a stated Code of Ethics for research, and its implementation procedure

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The code of ethics of research clearly stating the claims of the institution duly signed by the Head of the Institution

3.3.1. Institutional Code of Ethics for Research

File No. - EC/NEW/INST/2024/4322

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 18-Apr-2024

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 :	**Human Ethics Committee**
Address :	**PES Institute of Medical Sciences and Research, National Highway 219, Kuppam, Chittoor, Andhra Pradesh - 517425**
Contact No:	**70332674333, 9391833752**
Fax :	**-NA-**

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.

Note: EC registration number provided by DHR should be displayed on every certificate of approval issued by the Ethics committee

ANU NAGAR
Digitally signed by ANU NAGAR
Date: 2024.04.18 15:00:37 +05'30'

(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairperson — Lokanatha Valluru, Dravidian University, Kuppam, Chittoor, Andhra Pradesh, India - 517426

2. Name and address of the office : of the Ethics Committee* — Human Ethics Committee, PES Institute of Medical Sciences and Research, National Highway 219 , , Kuppam, Chittoor, Andhra Pradesh - 517425 Contact No. : 70332674333, 9391833752 Fax No. :

3. Names, address, qualifications & designation of all the members of the Ethics Committee*

S.No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail and mailing address	Designation/ role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Lokanatha Valluru	BSc (MSc, PhD Zoology)	Dravidian University	Mobile: 9652840923, email: lokanath.valluru@gmail.com Add: Door No-6/225,Manjunath Layout,H.P Road, Kuppam, Chittoor, Andhra Pradesh-517425	Chair Person	No
2	Dr. Nagesh Raju G	MBBS (MD Pharmacology)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9845349793, email: nagpharma42@gmail.com Add: No.3,23 Cross, Rangaswamy Temple Street, Chikkapet Bangalore, Bengaluru (Bangalore) Urban, Karnataka-560053	Member Secretary - Basic Medical Scientist (Dual Role)	Yes
3	Dr. Sujatha K	MBBS (MD/MS - Anatomy)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9916287074, email: Sujathambbs@gmail.com Add: No 96, Eurosion Block, Marikuppam Post, K.G.F, Kolar Gold Fields, Kolar, Karnataka-563119	Basic Medical Scientist	Yes

4	Dr. Kumarguru B.N	MBBS (MD - Pathology & Microbiology)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9845813257, email: kumargurubn1978@gmail.com Add: 9th Cross, BEML Layout,1st Stage, Basaveswaranagara, Bangalore, Bengaluru (Bangalore) Urban, Karnataka-560079	Basic Medical Scientist - Alt Member Secretary (Dual Role)	Yes
5	Dr. Sreelatha P	MBBS (MD - Psychiatry)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9663399840, email: drsreelathakumar@gmail.com Add: F-101,KVR Residency,1st Stage,1 Block,HBR Layout, Bangalore, Bengaluru (Bangalore) Urban, Karnataka-560043	Clinician	Yes
6	Dr. Praveen Kumar B. A	MBBS (MD - Community Medicine)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9494071558, email: drpraveenba@pesimsr.pes.edu Add: Bhatrahalli, Shillenegere Post, Bethamanagala Road, Kolar, Kolar, Karnataka-563101	Clinician	Yes
7	Dr. Anil N.S.	MBBS (MD - Community Medicine)	ESIC MEDICAL COLLEGE AND HOSPITAL	Mobile: 9900165402, email: anilpsm@gmail.com Add: 2ndCross, 8thMain,ITILayout, Yellukunte, HSRExtension, Bangalore, Bengaluru (Bangalore) Urban, Karnataka-560068	Clinician - Vice Chair Person (Dual Role)	No
8	Dr. Nagakiran K.V.	MBBS (Diploma in Orthopedics)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 8331818330, email: drnagakiran@gmail.com Add: 1459, 6th Cross, Krishnamurthy Puram, Mysore, Mysuru (Mysore), Karnataka-570004	Clinician	Yes
9	Mr. Jagadeesh Babu D N	B. COM (M. COM, M.Phil)	Saimatha Seva Trust	Mobile: 9391833999, email: saimathasevatrust999@gmail.com Add: 14-25, Palace Road, Kuppam, Chittoor, Andhra Pradesh-517425	Social Scientist	No

10	Ms. Sarojini B. K.	BSc (Not Applicable)	Brahma Kumaris	Mobile: 9441653470, email: kuppam@bkivv.org Add: 13, 300, Ramachandra Rd, Kuppam, Chittoor, Andhra Pradesh-517425	Social Scientist	No
11	Dr. Amarnath B R	Other (LLB)	TDP Kuppam Constituency And Ms Heritage Foods India Pvt Ltd.	Mobile: 9949060181, email: bireddyamarnath@gmail.com Add: 11-16, Tapalraj Street, Kuppam Town, Post, Mdl, Kuppam, Chittoor, Andhra Pradesh-517425	Legal Expert	No
12	Mr. Venkatesh V.	B. COM (PhD)	Siddhartha Skill Development Centre	Mobile: 9440410510, email: venkatesh410510@gmail.com Add: 3-38, Munaswamy Puram Street, Kuppam Mandal Post, Kuppam, Chittoor, Andhra Pradesh-517425	Lay Person	No
13	Mr. Abhirami M	BSc (MSc, PhD Nursing)	PEOPLES EDUCATION SOCIETY(PES) INSTITUTE OF MEDICAL SCIENCES AND RESEARCH	Mobile: 9849581220, email: mani.abhirami@gmail.com Add: PES College Of Nursing, PESIMSR Campus, Gudupalli, Kuppam, Chittoor, Andhra Pradesh-517425	Scientific Member	Yes

4. Commitments:

(1) The Committee shall review and accord its approval to a biomedical research and also carry ongoing review of the study at appropriate intervals, as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants - ICMR for safeguarding the rights, safety and well- being of the research participants.

(2) In case of any serious adverse event occurring to research participants during the research study, the Committee shall analyze and forward its opinion as per procedures specified under National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

(3) The Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of

biomedical and health research.

(4) We agree to maintain adequate and accurate records after the completion or termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies).

(Signature of the Chairperson)

Date : 29/01/2024

Chairperson
Human Ethics Committee
PESIMSR,Kuppam-517425

(Signature of the Member secretary)

Date : 29/01/2024

Member Secretary
Human Ethics Committee
PESIMSR,Kuppam-517425

Standard Operating Procedures (S.O.P.)

for

Human Ethics Committee, PES Institute of Medical Sciences and Research, Kuppam.

Standard Operating Procedures (S.O.P.) for

Human Ethics Committee, PES Institute of Medical Sciences and Research, NH-219,KuppamAndhra Pradesh-517425.

Version - 01

Prepared by
Dr. Nagesh Raju,
Member Secretary

Dr. Praveen Kumar B A,
Member

Edited & Approved by

Dr. Lokanatha Valluru
Chairperson

Date of Implementation: 27/12/2023

PREAMBLE

The purpose of the Standard Operating Procedure (S.O.P.) for the Ethics Committee is to provide a standardized framework and guidelines for the functioning of the Ethics Committee. The Ethics Committee ensures that all research studies involving human subjects are conducted ethically and comply with relevant regulations and guidelines.

The S.O.P. outlines the procedures and processes the Ethics Committee will follow to ensure that ethical considerations are thoroughly evaluated and addressed in all research proposals. It also guides researchers and other stakeholders on interacting with the Ethics Committee and what to expect during the review process. The S.O.P. is intended to promote transparency, consistency, and accountability in the decision-making process of the Ethics Committee, ultimately protecting the rights, safety, dignity and welfare of research participants.

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LIST OF ANNEXURES

HUMAN ETHICS COMMITTEE, PES Institute of Medical Sciences & Research, Kuppam.

Standard Operating Procedures (S.O.P.) General.

1. Introduction

People's Education Soceity (PES) Institute of Medical Sciences and Research, Kuppam, was established on 11th of September 2001 with a mission to provide state-of-the-art, affordable health care to the poor and needy people in rural setup & to create globally competent, humane health care professionals through value-based education system and to offer scientific research opportunities.

Biomedical and health research involves several ethical issues that need to be addressed. The Human Ethics Committee (HEC) reviews the research proposals for scientific relevance. Also, it plays a vital role in guiding researchers in the ethical aspects of biomedical and health research. The HEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants-2017 (Indian Council of Medical Research), ICMR Ethical Guidelines for application of Artificial Intelligence in Biomedical research and healthcare-2023 and The New Drugs & Clinical Trial Rules 2019 (NDCT Rules-2019).

The following may be called Standard Operating Procedures (S.O.P.) of the Human Ethics Committee (HEC) of PES Institute of Medical Sciences & Research, Kuppam. The current S.O.P. covers the functioning of the Ethics Committee reviewing all Research on Human subjects done at PESIMSR and those done at other network hospitals/institutions of the Kuppam. S.O.P.s may also cover other than network hospitals/institutions within a location of the same city or a radius of 50 km distance from the headquarters with a memorandum of understanding (MoU) with the participating institution under the guidance of a principal investigator/ co-investigator employed at the participating institutions. The approving ethics committee for the research protocol shall be responsible for the study at the research site.

2. Objective:

The objective of this S.O.P. is to contribute to the effective functioning of the Human Ethics Committee (HEC) so that a quality and consistent ethical review mechanism for healthcare and biomedical research is put in place for all proposals dealt with by the committee as prescribed by the Ethical guidelines for biomedical research on human subjects by Indian Council of Medical Research (ICMR)

3. Authority for Constituting Ethics Committee:

3.1. The Principal & Dean of PES Institute of Medical Sciences & Research (PESIMSR) will propose the Chairperson & Member Secretary of HEC, PESIMSR, Kuppam.

3.2. The concurrence for Chairperson & Member Secretary will be obtained with all relevant information in accordance with the law, rules, values, and principles they serve.

3.3. The Principal & Dean, in consultation with Chairperson and Member Secretary, will propose the members of HEC with qualifications and experience as per ICMR ethical guidelines 2017 and NDCT Rules-2019.

3.4. The concurrence for members of HEC will be obtained with all relevant information in accordance with the law, rules, values, and principles they serve.

3.5. The Principal will direct the Member Secretary to conduct meetings of HEC quarterly and at regular intervals will monitor the functioning of HEC.

4. Role & Responsibilities of Ethics Committee:

4.1. To ensure that universal ethical values and international scientific and ethical standards are expressed in accordance with local community values and customs.

4.2. To ensure that research is designed and conducted in accordance with the ICMR and CDSCO rules and regulations.

4.3. To ensure fundamental principles of ethics, Autonomy, Beneficence, Non-maleficence, and Justice are incorporated during the planning, conduct, and reporting of the proposed research.

4.4. Review and approve research proposals involving human participants safeguarding all actual and potential research participants' dignity, rights, safety, and well-being.

4.5. To assist in developing and educating a research community responsive to local health care requirements.

4.6. Conflict of interest will have to be declared by all members of the HEC before every meeting.

4.7. Review the proposals before the start of the study and monitor the research throughout the study until and after completion through appropriate well-documented procedures.

4.8. Reviewing and approval of research protocols of medical, nursing paramedical and allied health sciences students and faculty of PES Institute of Medical Sciences & Research, Kuppam.

4.9. The HEC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

4.10. The EC should recommend appropriate compensation for research related injury, wherever required.

5. Composition of Ethics Committee:

5.1. The Ethics Committee will be multi-disciplinary and multi-sectorial in composition. Independence and competence will be the two hallmarks of the HEC.

5.2. The committee will be constituted as per the norms enabling reaching consensus opinions.

5.3. The Chairperson of the committee will be nominated from outside the institution, maintaining the independence of the committee.

5.4. The Member Secretary will be nominated, preferably from the parent institute, for the coordination and functioning of the committee.

5.5. The other committee members are a mix of medical / non-medical, scientific, and non-scientific persons, including the lay public, to reflect the different viewpoints.

5.6. **The composition, affiliations, and qualifications of HEC members**

Member	Number (minimum)	Qualification
Chairperson/ Vice-Chairperson	1	A well-respected person not affiliated with the institution, from any background, should have served or serving as a member of any human ethics committee elsewhere.
Member Secretary/ Alternate Member Secretary	1	A person should be a staff member of the institution, have knowledge and experience in research and ethics, be motivated, and have good

		communication skills.
Basic medical scientist	1 or 2	Either affiliated/not affiliated with the institution. Qualification in basic medical science and one person should have an educational qualification in Pharmacology.
Clinicians	1 or 2	Either affiliated or non-affiliated person. Qualified medical graduates.
Legal expert	1 or 2	Either affiliated or non-affiliated person. Basic degree in Law from a recognized university with experience. Desirable- training in medical law.
Social scientist	1 or 2	Either affiliated or non-affiliated person. Social/behavioral science qualification.
One philosopher/ ethicist/ theologian	1 or 2	Either affiliated or non-affiliated person. Possess philosophy/ religious qualification and training.
Layperson	1 or 2	Non-affiliated, Literate person from the public or community. Not pursued a medical science/health-related career in the last 5 years.

5.7. The committee members and individuals from other institutions or communities may be nominated as per ICMR guidelines.

5.8. Adequate representation of age, gender in the committee will be ensured to safeguard the interests and welfare of all sections of society.

5.9. Preferably 50% of the members should be non-affiliated or from outside the institution.

5.10. Members of the HEC will be aware of local, social, and cultural norms, as this is the most important social control mechanism. If required, subject experts will be invited to offer their views.

5.11. The membership of HEC may include Sociologist(s), Lawyer(s), Theologian, Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s), appointed by the Authority based on their

competencies and integrity as per the guidelines. It could be drawn from any public or private institute anywhere in the country.

6. Constitution of Ethics Committee:

The Principal & Dean (Head of the Institution) will constitute the Ethics Committee in the following pattern,

I. A Chairperson & Vice-chairperson
II. A Member Secretary & Alternate Member Secretary
III. As per the guidelines, 7-15 members from different Departments / Specialties / Disciplines or areas.
IV. HEC members will be reconstituted every three years or as per the terms and conditions of regulatory authorities from time to time.

7. Membership Requirements:

7.1. The number of members in an HEC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.

7.2. The HEC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

7.3. The tenure of membership will be for three years.

7.4. The membership tenure may be extended for another term depending on the appointing authority/or as per the regulatory body's terms and conditions.

7.5. At the end of 3 years, as the case may be, the committee will be reconstituted, and a defined procedure will replace 30%-50% of the members.

7.6. All members should maintain absolute confidentiality of all discussions during the meeting of HEC and sign a confidentiality form at the beginning of their tenure.

7.7. Conflict of interest will have to be declared by all members of the HEC before every meeting.

7.8. The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfill a role based on their qualifications

(such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

7.9. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

7.10. As far as possible a separate scientific committee should priory also review proposal before it is referred to EC.

8. Procedure for resignation/replacement/removal of members:

8.1. A member can be replaced in the event of death or long-term non-availability (for three continuous meetings) or for any action not commensurate with the responsibilities laid down in the guidelines deemed fit for a member.

8.2. A member can tender a resignation from the committee with valid reasons.

8.3. Chairperson shall investigate any complaint against members and may provide a resolution/redressal based on the response/explanation from the member or may remove the member in case of an unsatisfactory explanation/report and appraise the head of the institution. If the Chairperson cannot decide on a complaint against a member, he may forward it to the head of the institution. The authority to replace/remove the member shall be with the head of the institution (appointing authority).

9. Conditions of appointment and Quorum Requirements:

9.1. **Conditions of appointment**

9.1.1. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.

9.1.2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications.

Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

9.1.3. Every EC member must provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable.

9.1.4. They should either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy).

9.1.5. They must be willing to undergo training or update their skills/knowledge during their tenure as an EC member.

9.1.6. They must be aware of relevant guidelines and regulations.

9.1.7. They must read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time.

9.1.8. They must sign a confidentiality and conflict of interest agreement/s.

9.1.9. They must be willing to place her/his full name, profession and affiliation to the EC in the public domain and be committed and understanding to the need for research and for imparting protection.

9.2. **Quorum Requirements**

9.2.1. At least five members should be present in the meeting to review a proposal.

9.2.2. The quorum should include medical, non-medical or technical, or/and non-technical members.

9.2.3. A minimum of one non-affiliated member should be part of the quorum.

9.2.4. Preferably the layperson should be part of the quorum.

9.2.5. No decision is valid without fulfillment of the quorum.

10. Offices/ Functioning of Ethics Committee:

10.1. Regularly the Chairperson will conduct all meetings of the HEC. If, for reasons beyond control, the Chairperson is unavailable, the Vice-Chairperson or an alternate Chairperson will be elected from the members by the members present who will conduct the meeting.

10.2. The Member Secretary will organize the meetings, maintain the records, and communicate with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the researchers. If the member secretary is unavailable for reasons beyond control, then the alternate member secretary designated will carry out the responsibilities.

11. Subject experts/Independent Consultants:

11.1. HEC may call upon subject experts as independent consultants who may provide special reviews of selected research protocols if needed. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups, or special interest groups, e.g., Cancer patients, H.I.V./AIDS-positive persons, or ethnic minorities.

11.2. The subject experts/ Independent consultants are required to give their specialized views on selected proposals, but they will not be a part of the decision-making process.

11.3. Subject experts/ independent consultants must sign a confidentiality and conflict of interest form before an HEC meeting.

12. Application Procedures:

12.1. All proposals should be submitted in the prescribed application form provided by the HEC.

12.2. All relevant documents should be enclosed with the application form.

12.3. The required number of copies of the proposal, along with the application and documents in the prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators, should be forwarded by the Head of the Departments / Institution to the Ethics Committee.

12.4. The meeting date will be intimated to the researcher to be present, if necessary, to offer clarifications.

12.5. The decision will be communicated in writing. If a revision is to be made, the revised document in the required number of copies should be submitted within a stipulated time as specified in the communication or before the next meeting. A decision letter will be issued to the investigator within four weeks of a meeting or final decision.

13. Documentation:

For a thorough and complete review, all research proposals should be submitted along with the following documents:

13.1. Title of the Study

13.2. Clear research objectives and rationale for exploring human participants in the light of existing knowledge.

13.3. Name, affiliation, qualifications, address, principal investigator's (P.I.) contact information, and signature.

13.4. Name, affiliation, and qualifications of the co-research investigators, along with their signatures.

13.5. Name of the Institute/Hospital/Field area where research will be conducted.

13.6. Approval of the Head of the Department / Institution

13.7. Protocol of the proposed research - Introduction, literature review, objectives, the rationale for study, materials & methods describing the potential risks & benefits, outcome measures, statistical analysis, and whether it is of national significance with rationale.

13.8. Ethical issues in the study and plans to address these issues.

13.9. The type of participants, like vulnerable or specialized group involvement, should be specified.

13.10. The proposals with all the essential documents submitted to the ethics committee will be reviewed, and the decision will be based on the submitted documents.

13.11. An informed consent process in written/ verbal/ audio-visual should be specified. The consent form should include the patient information sheet in local/understandable language(s) with a statement that the study involves research, its purpose and procedures, risks and discomforts involved, and benefits and confidentiality of the records to be maintained. It should also ensure that the consent will be voluntary and that the participant has the right to withdraw.

13.12. For research involving Children, consent should be taken from Parents/ Legally Acceptable Representatives (L.A.R.). Assent of children below seven years is not needed; Verbal/ Oral assent must be obtained from children between 7 and 12 years; for children aged between 12 to 18 years, written assent must be obtained in the presence of parents/L.A.R.

13.13. In vulnerable populations, when potential participants lack the ability to give consent, a Legally Authorized Representative (L.A.R.) should be involved in decision-making. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give consent/ assent for participation.

13.14. For any drug/device trial, all relevant pre-clinical animal and clinical trial data from other centers within the country/countries should be enclosed.

13.15. The curriculum vitae of all the investigators with relevant publications in the last five years should be attached.

13.16. Any regulatory clearances required for the research proposals should be highlighted.

13.17. The source of funding and financial requirements for the project should be submitted.

13.18. Other financial issues, including those related to insurance, should be specified.

13.19. All protocol violations have to be reported to the ethics committee**.**

13.20. Investigators must comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.

13.21. A statement of conflicts of interest, if any, should be submitted.

13.22. Investigators must comply with the relevant national and applicable international guidelines. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the indemnity arrangements, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other HECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

13.23. Covenant to submit a half-yearly progress report and a final report at the end of the study. A progress report should also be submitted based on the seriousness//severity of the condition under study and the level of risk as per the protocol.

13.24. Plans for publication of study results, positive or negative, while maintaining the privacy and confidentiality of the study participants.

13.25. Any other information relevant to the study

14. Review Procedure:

14.1. The meeting of the HEC will be held at scheduled intervals (once in 3 months) as prescribed, and additional meetings may be held as and when the proposals are received for review.

14.2. The member secretary will screen the research proposals for their completeness and depending on the risk involved will categorize them into three types: exemption from review, expedited review, and full review.

14.3. Reviewing and approval of research protocols for the medical, paramedical, and allied sciences faculty and student projects may be done by a sub-committee formed by the members of the HEC. It will be apprised to the full board in the next meeting.

14.4. Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled/unscheduled full committee meetings, which may be decided by the Member Secretary on a case-to-case basis, depending on the urgency and need. If an expedited review is done, the full ethical review should follow as soon as possible. The review will be done per the ICMR National Ethical Guidelines for reviewing Biomedical and Health Research during the Covid-19 pandemic-April 2020.

14.5. The proposals for review will be sent to members at least a week in advance.

14.6. Decisions will be taken based on the consensus of members after discussions. If consensus is not reached, the chairperson can consult the member secretary before making a decision, but the chairperson/Vice-chairperson will make the final decision.

14.7. Researchers will be invited to offer clarifications if needed.

14.8. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

14.9. The decisions taken will be recorded in the meeting minutes, and the Chairperson's signature will be taken before the next meeting.

15. Types of review

1	**Exemption from review**	Proposals with less than minimal risk where there are no linked identifiers, for example; • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behavior, when information is recorded without any linked identifiers and disclosure, would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies, such as programme evaluation, where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	**Expedited review**	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimens and human tissue from sources like blood banks, tissue banks, and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol, including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review, or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress / annual reports where there is no additional risk, for example, activity limited to data analysis. An expedited review of S.A.E.s/unexpected A.E.s will be conducted by the S.A.E. subcommittee; and • for multicentre research where a designated main HEC among the participating sites has reviewed and approved the study, a local HEC may conduct only an expedited review for site-specific requirements in addition to the full committee common review. • Research during emergencies and disasters.
3	**Full committee review**	All research proposals presenting more than minimal risk that is not covered under exempt or expedited review should be subjected to full committee review. Some examples are; • research involving vulnerable populations, even if the risk is minimal; • research with a minor increase over minimal risk

		• studies involving the deception of participants • research proposals that have received an exemption from review or have undergone expedited review/undergone subcommittee review should be ratified by the full Committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited Committee; • amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • major deviations and violations in the protocol; • any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment; • Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

16. Element of review:

The review will be based on the following guidelines,

16.1. Scientific design and conduct of the study.

16.2. Protocol, proforma, and informed consent form for the study.

16.3. Approval of appropriate scientific review Committees.

16.4. Examination of predictable risks/harms.

16.5. Examination of potential benefits.

16.6. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria, and other issues like advertisement details.

16.7. Management of research-related injuries and adverse events.

16.8. Compensation provisions.

16.9. Justification for placebo in the control arm, if any.

16.10. Availability of products after the study, if applicable.

16.11. Patient information sheet and informed consent form in the local language.

16.12. Protection of privacy and confidentiality.

16.13. Involvement of the Community, wherever necessary.

16.14. Plans for data analysis and reporting.

16.15. Adherence to all regulatory requirements and applicable guidelines.

16.16. Competence of investigators, research, and supporting staff.

16.17. Facilities and infrastructure of study sites.

16.18. Criteria for withdrawal of patients, suspending or terminating the study.

17. Procedure for expedited review:

17.1. Unless specifically required to go to the main Committee, all revised proposals will be examined by a member of the sub-committee appointed by HEC for clearance and approved by the Chairperson.

17.2. The Member Secretary will report the approvals given for revised proposals in the next HEC.

17.3. Proposals requiring major revisions will be taken up in the next HEC.

17.4. All expedited approvals will be given in a meeting with a quorum of at least three members (nominated by the Chairperson) of HEC. The quorum must have one expert or scientist with scientific knowledge in the proposal field. It should also include either the Member Secretary, or the Chairperson, or both. However, decisions taken by the Committee on expedited approval will be brought to the notice of the full committee members for ratification.

18. Decision Making:

18.1. Members will discuss the various issues before arriving at a consensus decision in formal HEC meetings, and decisions through the circulation of research proposals will be outlawed.

18.2. Suppose a member has conflict-of-interest involving a project. In that case, s/he should submit this in writing to the Chairperson before the review meeting, which will also be recorded in the meeting minutes.

18.3. If one of the members has her/his proposal for review or has any Conflict of interest, then s/he should withdraw from the HEC while the decision on the project is being made.

18.4. Decisions will be made only in meetings where the quorum is complete.

18.5. Only members can make the decision, and the expert consultants will only offer their opinions.

18.6. A decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection will be given.

18.7. In conditional decisions, suggestions for revision and the procedure for re-reviewing the application will be specified.

18.8. An expedited review may review modified proposals through identified members.

18.9. Procedures for appeal by the researchers should be defined.

19. Communicating the decision:

19.1. The Member Secretary will communicate the decision in writing to P.I. within four weeks of the meeting or final decision date.

19.2. Suggestions for modifications, if any, should be sent to HEC. The principal investigator should highlight the changes made in the protocol / pro-forma / informed consent while sending the revised version to HEC.

19.3. Reasons for rejection will be informed to the researchers.

19.4. An HEC can make one of the following decisions:

- Approved
- Revision with minor modifications/ amendments
- Revision with major modifications for resubmission
- Not approved

20. Follow-up Procedures:

20.1. For all the approved proposals, the principal investigator should submit a half-yearly report on the progress in the prescribed format to the HEC.

20.2. The final report should be submitted to HEC at the end of the study in the prescribed format.

20.3. All S.A.E.s and the interventions undertaken should be intimated to HEC in the prescribed format.

20.4. Any Protocol deviation should be informed with adequate justifications to HEC.

20.5. Any amendment to the protocol should be resubmitted for renewed approval by HEC.

20.6. Any new information related to the study should be communicated to HEC.

20.7. Premature termination of study should be notified with reasons along with the summary of the data obtained until termination to HEC.

20.8. Change of investigators/sites should be informed to HEC

21. Record Keeping and Archiving:

21.1. All documentation and communication of an HEC should be dated, filed, and preserved according to written procedures.

21.2. Curriculum Vitae (CV) of all the members of HEC.

21.3. HEC will store copies of all study protocols with enclosed documents, progress reports, and S.A.E.s for a minimum of 5 years.

21.4. Minutes of all meetings duly signed by the Chairperson of HEC.

21.5. Copy of all existing relevant national and international guidelines on research ethics and laws, along with amendments.

21.6. Copy of all correspondence with members, researchers, and other regulatory bodies.

21.7. The final report of the approved projects will be stored for five years at HEC, and the principal investigator will be directed to preserve the documents for a minimum period of 10 years.

21.8. Records can be maintained in hard copies as well as soft copies.

21.9. All files should be appropriately labeled and archived separately in designated areas.

21.10. Confidentiality should be maintained during access and retrieval procedures by designated persons.

22. Terms of reference

Terms of reference will be maintained in the office of HEC. This includes

A. Membership Requirements
B. Roles and responsibilities of the member of the Committee
C. Conditions of appointment.
D. Terms of Appointment with reference to the duration of the term,
E. The policy for removal, replacement, and resignation procedure
F. Frequency of meetings (once in 3 months)

- The EC should refer to ICMR guidelines in preparing the SOPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority.
- A copy of the latest version of SOPs should be made available to each other and they should be trained on the SOPs.

- The SOPs must be made available in the secretariat of the EC as both hard and soft copies.
- The appointment letter issued to all members should specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following:
    - Role and responsibility of the member in the committee
    - Duration of appointment
    - Conditions of appointment
- The head of the institution should appoint all HEC members, including the Chairperson.
- The S.O.P.s will be updated periodically based on the changing requirements. The appointment of members could be extended for another term depending on appointing authority, and a defined percentage (30 to 50%) of members could be changed regularly. Preferably, HEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country.
- Types of research projects that will be reviewed are Academic Studies of Staff and Students including Dissertation Synopsis, Investigator - initiated studies and regulatory and non regulatory trails.
- Studies within a location of the same city or a radius of 50 km distance from the headquarters are done with a memorandum of understanding (MoU) with the participating institution under the guidance of a principal investigator/co-investigator employed at the participating institutions.
- **Fee for reviewing research proposals**

1.	*Academic/ Investigator-initiated proposals from inside (affiliated) the institution.*	*No review fee*
3.	*Academic/ Investigator-initiated proposals from outside (non-affiliated) the institution.*	*Rs.5000/-*

Honorarium

22.1. HEC members would be given an honorarium for their time spent reviewing a research protocol and participating in the decision-making process.

22.2. HEC fees will be included for the proposals submitted by other institutions as per the MoU.

23. Administration and management

23.1. PESIMSR, Kuppam should have an office for the IEC which have adequate space, infrastructure and staff to the EC for maintaining full-time secretariat, safe archival of records and conduct of meeting.

23.2. The HEC may charge a reasonable fee for review to cover the expenses related to optimal functioning in accordance with the Institutional policies. There should be a provision for allocating reasonable funds for the HEC's smooth functioning. The institute will pay an honorarium per sitting to the non-affiliated members attending the meeting.

24. Training/Updating HEC Members:

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

24.2. Members will be encouraged to attend national and international training programs in research ethics to maintain quality in ethical review and be aware of the latest developments in this area.

25. Standard Operating Procedures to be followed by HEC for vulnerable populations:

25.1. In case of any study involving vulnerable populations like the Handicapped, Pregnant women, Children, Socially backward, or special groups like students, nurses etc., an appropriate person from the vulnerable population/ special groups will be invited as a member to safeguard their interest.

25.2. The HEC will not review the research protocols involving vulnerable populations/ special groups through expedited review.

25.3. The HEC will ensure that adequate precautions are taken to safeguard the rights, safety, dignity and well-being of vulnerable populations/ special groups.

25.4. For research involving Children, consent should be taken from Parents/ Legally acceptable representatives (L.A.R.). Assent of children below 7 years is not needed; Verbal/ Oral assent must be obtained from children between 7 and 12 years; for children aged between 12 to 18 years, written assent must be obtained in the presence of parents/L.A.R.

25.5. In vulnerable populations, when potential participants lack the ability to give consent, a legally authorized representative (L.A.R.) should be involved in decision-making. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give consent/ assent for participation

26. Policy regarding training for new and existing Committee members along with Standard Operating Procedures:

26.1. All the newly constituted HEC members will be invited to attend and undergo a workshop to make them well-versed with the provisions of the Ethics Committee as well as, ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants-2017, Drugs & Cosmetic rule 1945, New Drugs and Clinical Trial Rules 2019, and other applicable regulations.

26.2. Member secretary will train a new member before attending a meeting after induction into the committee on SOPs and ethics review process.

26.3. An opinion letter/approval letter will be provided to the investigator within four weeks.

26.4. All the HEC members will be encouraged to attend regular training programs to keep abreast of all national and international developments in ethics.

26.5. All the members will be encouraged to attend workshops/ conferences focused on Institutional Ethics Committee roles and responsibilities involving human subject research.

26.6. All the Members will be invited to a workshop on Good Clinical Practice, Ethical and Regulatory guidelines.

26.7. The institute will extend support for members to attend training programs to fulfill the mandate of HEC in protecting the rights and welfare of research subjects.

27. Policy to monitor or prevent the conflict of interest along with Standard Operating Procedures:

27.1. All the members of the HEC should declare a conflict of interest before every meeting.

27.2. If a member has conflict-of-interest involving a project, then s/he should submit this in writing to the Chairperson before the review meeting, and it will also be recorded in the meeting minutes.

27.3. If one of the members has her/his proposal for review or has any Conflict of interest, then she/he should withdraw from the HEC while the decision on the project is being made.

28. Ethical Guidelines For Application Of Artificial Intelligence In Biomedical Research And Healthcare

- Artificial intelligence(AI) is defined as “a system’s ability to correctly interpret external data and to use those learnings to achieve specific goal and tasks through flexible adaption
- The field of AI is rapidly expanding and has made significant inroads in almost all aspects of human life, including healthcare.
- The incorporation of AI-based tools and techniques is expected to improve healthcare delivery by making healthcare accessible and affordable and improving the quality of care provided.
- An ethically sound policy frame work is essential to guide the AI technologies development and its application in healthcare

Scope- These guidelines apply to AI based tools created for all biomedical and health research and applications involving human participants and/or their biological data.Considering the far-reaching implications of AI-based technologies in healthcare, these guidelines are applicable to health professionals, technology developers, researchers, entrepreneurs, hospitals, research institutions, organization(s), and laypersons who want to utilize health data for biomedical research and healthcare delivery using AI technology and techniques.

- **Applications of AI in Healthcare**

a) Diagnostics and screening
b) Therapeutics, Drug discovery and development
c) Clinical care
d) Epidemiology and prevention of disease
e) Behavioural and Mental healthcare
f) Health management systems using AI

- **Ethical Principles for AI Technology in Healthcare**

1. Autonomy
2. Data Privacy
3. Accountability and Liability
4. Trustworthiness
5. Validity
6. Fairness and Non-discrimination
7. Optimization and Data quality
8. Accessibility and Equity
9. Safety and Risk Minimization
10. Collaboration

***Please refer to the ICMR Ethical Guidelines for application of AI in Biomedical research and healthcare-2023 for detailed information.**

References:

1. Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, New Delhi. 2006.
2. Ministry of Health & Family Welfare (Department of Health), Notification, Drugs & Cosmetics (Third Amendment) Rules 2013. New Delhi, 8th February 2013.
3. Drugs & Cosmetics (Second Amendment) Rules 2005. Ministry of Health & Family Welfare (Department of Health), Notification, New Delhi, 20th January 2005.
4. National Ethical Guidelines for Biomedical and health Research involving Human Participants, Indian Council of Medical Research, New Delhi. 2017. https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf
5. Ministry of Health & Family Welfare (Department of Health), Notification, New Drugs and Clinical Trails rules 2019. New Delhi, 19th March 2019. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
6. National Ethical Guidelines for Biomedical and health Research involving Children, Indian Council of Medical Research, New Delhi. 2017. https://main.icmr.nic.in/sites/default/files/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children_0.pdf
7. ICMR National Ethical Guidelines for reviewing Biomedical and Health Research during the Covid-19 pandemic,New Delhi-April 2020. https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf
8. ICMR National Ethical Guidelines for application of AI in Biomedical Research and healthcare, Indian Council of Medical Research, New Delhi. 2023. https://main.icmr.nic.in/sites/default/files/upload_documents/Ethical_Guidelines_AI_Healthcare_2023.pdf

1. Undertaking by Principal Investigator

Ref No: Date:

Name and

Address of the Investigator

To,

Chairperson/Member Secretary,

Human Ethics Committee,

PESIMSR,Kuppam- 563101

Sub: Ethical clearance for research project entitled "_"

UNDERTAKING

With respect to the above said research/clinical trial/thesis (Tick the relevant) protocol involving human subjects for whom the ethical clearance being sought, I hereby declare that I have read the Ethical Committee Guidelines of PESInstitute of Medical Sciences & Research and that I am aware of the regulations governing research with human participants. I am also aware that the above-mentioned research project involving human participants will strictly adhere to these rules.

Responsibilities- As the principal investigator, I will oversee the research team, ensure the quality of the research, and report on the progress of the research to the relevant stakeholders. I will ensure that the research team has the necessary resources, including funding, personnel, and equipment, to conduct the research project effectively.

Further, I also affirm that I will be responsible to keep the HEC informed of,

i) Any serious and unexpected adverse events and remedial steps taken to tackle them.
ii) Any new information that may influence the conduct of the study.
iii) Any changes made in the consent form.
iv) Results of the research accurately and objectively, and share data and findings in a timely and accessible manner.
iv) Under no circumstances I/we deviate from the original approval protocol without prior consent to that effect from the HEC In the event of need to

amend the original protocol approved by the HEC, the proposed amendment shall be brought to the notice of HEC for its consideration and approval.

Signatures- By signing below, I confirm that I have read and understood this undertaking by P.I., and I agree to comply with all the requirements outlined in this document.

Date:

Name and Signature of the Principal Investigator

2. Application for Ethical Review of Biomedical Research Proposal

Please Note that:
I. There are Separate Application forms for:

1. Academic Studies of Staff and Students (Applicable for Most of the Research Proposals of PESIMSR): Form 1& 2

2. P.G. Dissertation Synopsis: Form 3

II. The Researchers are requested to use the appropriate application form only.

III. Other Documents to be Submitted Along with the Registration form are made available in a Separate File (FORMATS). Please Submit these documents as applicable to the Type of Study.

IV. For all studies, prior approval of the PESIMSR HEC is mandatory before initiating the Study. Once you obtain approval for the study, Separate approval for publication/presentation is not required.

V. For case reports, approval of PESIMSR HEC has to be obtained after studying the case, for presentation /publication.

VI. Meeting: PESIMSR HEC meeting will be conducted once in 3 months. However, additional meetings may be held depending on the number of proposals awaiting approval.

VIII. PESIMSR HEC has every right to do continuous monitoring of the studies approved by it, and to verify the study documents.

I) Form 1-

Registration Form for Research project - *Faculty form*

(Both soft and Hard copy to be submitted)

Title of the Research project	
Name of the **Principal Investigator**	
Faculty: Designation: Department:	
Names of Co-Investigators, if any: (Name, Designation & Department).	
Proposal/Protocol form **of the research project:**	Enclosed / Not enclosed
Patient Information Sheet & Informed Consent Form	Enclosed / Not enclosed
Signature of the **Principal Investigator**	

For office use

Level of Risk to the study subjects: 1. No risk to Minimal risk 2. Greater than minimal risk
Level of Ethical clearance, applied for: 1. Expedited 2. Full Review

II) Form 2

Registration Form for Research project - *Student form*

(Both soft and Hard copy to be submitted)

Title of the Research project	
Name of the **Principal Investigator**	
Course: Under graduate / Post graduate: **Subject:** in which research is done	
Names of Co-Investigators, if any: (Names & Details) Applicable in group projects.	
Name of Guide: (Name, Designation & Department).	
Name of Co-guide (Other Dept. if any): (Name, Designation & Department).	
Level of Risk to the study subjects: 1. No risk to Minimal risk 2. Greater than minimal risk	
Level of Ethical clearance, applied for: 1. Expedited 2. Full Review	
Proposal/Protocol form **of the research project:**	
Signature of the **Principal Investigator**	

Proposal/Protocol form of the research project – Faculty/Student Form

(Should be written in the following format)

I. Title page: Title of the research project (with the names of the investigators)
II. Introduction: (including the Need for the study/ Justification of the study):
III. Research Question(s):
IV. Objectives of the study:
V. Methodology (Materials & Methods):
   1. Study design:
   2. Study setting:
   3. Study period:
   4. Study population:
   5. Sampling method:
   6. Sample size:
   7. Inclusion & Exclusion Criteria:
   8. Study tools:
   9. Method of collection of data:
   10. Statistical Analysis of data:

VI. Approximate time for each of the following activities:

S.No.	Activity	From	To
1	Pre-study preparation		
2	Study tools development/ arrangement		
3	Data collection		
4	Statistical Analysis of data		
5	Report writing		
6	Journal article preparation		

VII. What are the expected outcomes of the study?
VIII. What is the impact of the study in the population or in science?
IX. Funding: by Self / Any other source: Specify.
X. Conflict of Interest (if any) in the project:
XI. How is the confidentiality of participants ensured?
XII. References:
XIII. Interview Questionnaire (if any) in English & Local language:
XIV. Informed consent form, in English & Local language

III) Form 3-

Registration of subject of Dissertation

Name of the student	M. X. XXXXXXXXXXXX
PG course	(subject XXXXXXX)
Name of Institute	PES Institute of Medical Sciences & Research, Kuppam, AP.
Title (topic) of the **Dissertation subject**	
Name of the Guide	Dr. X. XXXXXXXXXXXX
Name of the Co-guide (if any)	--------
Date of joining the course	
Date of commencement of the course	
Date of submission for Registration of subject of Dissertation	

Signature of student :	**Institutional Research Committee (I.R.C.), PESIMSR,Kuppam.**
Signature of Co-Guide: (if any) **Seal**	**Signature of IRC member:** **Seal**
Signature of Guide: **Seal**	**Signature of IRC member:** **Seal**
Signature of H.O.D.: **Seal**	**Signature of IRC member:** **Seal**
Signature of the Dean/D.S./Coordinator: **Seal**	

Synopsis of Dissertation Research (Protocol / Proposal form)

I. Title page: Title of Research project (with name of Principal investigator)
II. Introduction: (including the Need / Justification for the study):
III. Objectives of the study:
IV. Review of Literature:
V. Materials & Methods (Methodology):
1. Study design:
2. Study setting:
3. Study period:
4. Study population:
5. Sampling method:
6. Sample size:
7. Inclusion & Exclusion Criteria:
8. Tools to be used in the study:
9. Procedure for data collection:
10. Statistical Analysis of data:

VI. Approximate time for each of the following activities:

S.No.	Activity	From	To
1	Pre-research preparation		
2	Writing & submitting the proposal to I.R.C.		
3	Getting feed-back from I.R.C. & modifying the proposal		
4	Getting approval for modified proposal from HEC		
5	Collecting the Data		
6	Statistical Analysis of data		
7	Dissertation writing		

VII. What are the expected outcome(s) of the study?
VIII. What is the impact of the study in the population or in science:
IX. Funding: by Self / Institute / Any other source: Specify……
X. Conflict of Interest (if any) in the project:
XI. How is the confidentiality of participants ensured?
XII. Ethical clearance & approval:
XIII. References:
XIV. Interview Questionnaire in English & Local language:
XV. Informed consent form, in English & Local language:

3. Serious Adverse event format for Biomedical Health research

Title of the study: HEC proposal no:

P.I. – Name, Designation and Department:

Date of HEC approval: Date of Start of study:

Participant details:

a) Initials/ID:
b) Age at the time of event
c) Gender: Male/Female
d) Weight (Kgs) :
e) Height (cms) :

- Suspected S.A.E. diagnosis:
- Date of onset of S.A.E.:
- Describe the event:
- Date of reporting S.A.E.:
- Details of suspected intervention causing S.A.E.:
- Report type: Initial/Follow-up/Final
- If Follow-up report, state date initial report
- Have any similar S.A.E. occurred previously in this study? Yes/No
  If yes, please provide details.
- In case of a multi-centric study, have any of the other study sites reported similar S.A.E.s? (Please list number of cases with details if available)

Tick whichever is applicable for the S.A.E.:(Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event/ Unexpected event
B. Hospitalization □
   Increased Hospital Stay □

Death □
Congenital anomaly/birth defects □
Persistent or significant disability/incapacity□
Event requiring intervention (surgical or medical) to prevent S.A.E. □
Event which poses threat to life□
Others□

- In case of death, state probable cause of death _____

- No permanent/significant functional/cosmetic impairment □
  Permanent/significant functional/cosmetic impairment □
  Not Applicable □
- Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

- Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom)

- Outcome of S.A.E.
  Fatal □ Recovered □
  Continuing □ Unknown □
  Recovering □ Other *(specify)* □

- Provide any other relevant information that can facilitate assessment of the case such as medical history.

- Provide details about P.I.'s final assessment of S.A.E. relatedness to research.

Signature of P.I. with date

4. Informed Consent

Study Volunteer ID: Study Volunteer Name:

Title:

Purpose of the study

We would like to ask you to take part in this research project being carried out at the department of ……., P.E.S. Institute of Medical Sciences & Research.

The Aim of this study is to know about
……
……
……

Procedures

If you agree to join this study, you will agree to these things:

1. To answer some simple questions about yourself – such as age, education, occupation etc. followed by set of questions regarding ……...The questions will not take more than …..... minutes of your time.
2. We will collect your ……samples of ……...Quantity at ……intervals for ……..duration.
3. You will be given the following intervention:
    - Drug/Procedure/Education/Others (Specify): ……...
    - Details of Intervention: (Eg: Dose, form, route, duration & schedule of administration)
      ……
      …..

Risks to you

The procedure may cause minimal pain and discomfort. It may rarely cause complications such as……..

However, necessary precautions will be taken to ensure your safety and care.

Benefits to you

The intervention might improve your symptoms or cure your disease. The information collected from you will help us to decide the better alternatives. The results got from the study may be helpful to give better care & education to you and your community.

Alternatives

Even if you don't participate in this study, you will still get the standard benefits/treatment/care & education.

Compensation/Institutional Policy

No incentives shall be provided to you for participating in the study. However, any untoward incidents shall be managed by the investigator/institute.

Privacy &Confidentiality

All answers that you give will be kept private& anonymous. We will not reveal your name and identity at any time.

Your right to withdraw

We would like you to take part in this study voluntarily. However, you have the right to withdraw from the study any time for any reasons. You will continue to get the standard benefits/treatment/care & education from the institute.

Authorization to Publish Results

The results will be used to benefit the patients/community care. The results may also be presented/published in conferences/journals which contribute to scientific knowledge.

Problems or questions

If you have any questions about the study you may contact any member of the study team. Contact details are provided below:

Dr._____ Designation: Contact No:
(Principal Investigator/Student)
Dr._____ Designation: Contact No:
(Co-Principal Investigator/ Guide)
Human Ethics Committee **Contact No 7032674333**

Informed Consent Form

I voluntarily agree to the take part in the study of **"……"**

I have been informed, in written form, about the study plan.

The possible harms and discomforts and the possible benefits of this study have been explained to me.

All my questions have been answered.

I am aware that I can withdraw at any time and for any reason from this study.

Signature or left thumb print of participant or legally authorized representative:

_____ Participant's name _____ Participant's signature/thumb print

_____ Parent/Guardian name _____ Parent/Guardian signature

_____ Witness' name _____ Witness' signature

_____ Date

(**Note:** If the participants are Minors (under 18), the parents sign the form, rather than the participants

5. Premature termination/discontinuation of study report format

Title of the study:-

HEC Approval no: - Date of HEC approval:-

P.I. – Name, Designation and Department:-

Date of Start of study:-

Date of termination/ discontinuation: -

Date of last progress report submitted to HEC:-

Reason for Termination /Discontinuation:-

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

Details of study participants

- Total number of participants recruited for study-
- Total no of Screened -
- Screen failures -
- Consent withdrawn: reason_____
- With drawn by P.I.: reason _____
- Active on treatment / Completed treatment/ Participants on follow-up:
- Participants lost to follow up:
- Number of drop outs:
- Reasons for each drop-out:
- Any other reason: Specify_____

Have any unexpected adverse events or outcomes observed in the study been reported to the HEC? **Yes/No**

Have there been participant complaints or feedback about the study?
Yes/No
If yes provide details _____

Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes □ No□
(e.g., making arrangements for medical care of research participants):
If yes, provide details

Summary of results:

Signature of P.I. with date:

6. Study completion /Final report

- **Title of study**:-
- P.I. (Name, Designation and Department):-
- Date of HEC Approval:-
- Date of Start of Study:-
- Total no. of study participants recruited:-
- Total no. of study participants approved by the HEC for recruitment:-
- Total number of participants withdrawn from the study (if any):-
- Reasons for Withdrawal of Patients:-
  _____
- Duration of the study:-
- Results (summary) with Conclusion: (use extra blank paper, if more space is required).
  _____
  *Note: If the final report is not available from sponsor, it may be submitted later to the HEC once it is ready.
- Number of S.A.E.s at our center:-
- Whether all S.A.E.s intimated to the HEC:- Yes No
- Medical management or compensation for SAE provided to the participants_____

Signature of Principal Investigator:- **Date:**

- Action taken: Noted/ Requires more information/ action as follows:
  _____
- HEC Meeting date (If reviewed in the meeting):
- Final decision:_____

Signature of Member Secretary with date: _____

7. Waiver of informed consent

- Name of Principal Investigator :
- Department :
- Title of the project :
- Please Tick the Reasons for Requesting Waiver of Consent :
    - Research involves "not more than minimal risk":
    - There is no direct contact between the researcher and participant (Retrospective studies) :
    - Emergency situations as described in ICMR Guidelines : Any other (please specify)
- Statement assuring that the rights of the participants are not violated :
- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:

Principal Investigator's signature with date:

8. Declaration of Conflict of Interest Template

To,

The Chairperson,

Human Ethics Committee,

PES Institute of Medical Sciences

& Research, Kuppam- 517425

I,_____Member/Member-Secretary of the Human Ethics Committee, PES Institute of Medical Sciences & Research, Kuppam, declare conflict of interest for the following New/Ongoing protocols submitted to the committee. I voluntarily restrain while taking decision on my protocol.

Proposal Reference No.	Research Proposal Title

Yours sincerely,

(Signature)