

Policy Guidelines for Interdisciplinary Healthcare Research

1. Introduction

At PES University, we are committed to promoting quality interdisciplinary healthcare research that adheres to ethical, scientific, and regulatory standards. These policy guidelines are aimed at a structured process for researchers to navigate collaborations, approvals and ethical clearances aligned with national and institutional mandates.

2. Regulatory Framework and References

All healthcare related research activities must comply with the following foundational guidelines and regulations by the **Indian Council for Medical Research (ICMR)** outlined at <https://www.icmr.gov.in/guidelines>:

1. ICMR National Ethics Guidelines (2017):
https://ethics.ncdirindia.org//asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pdf
2. ICMR AI Guidelines (2023):
https://ethics.ncdirindia.org//asset/pdf/Ethical_Guidelines_Application_Artificial_Intelligence_Biomed_Rsrch.pdf
3. Medical Devices Rules (2017) and National Medical Devices Policy (2023):
<https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/>

3. Scope and Applicability

These guidelines apply to all departments including engineering, science, pharmacy etc. undertaking interdisciplinary healthcare-related research at PES University with the University Medical College PESUIMSR that require;

- ❖ Research involving human participants
- ❖ Use of human biological samples or health-related data
- ❖ Development/validation of software, AI models, and medical devices
- ❖ Access and use of any other hospital data

4. Institutional Oversight and Approval Pathways

Institutional Scientific Research Committee (ISRC) and Institutional Ethics Committee (IEC) will ensure scientific and ethical integrity of proposed healthcare research projects through appropriate review and approval process.

Any faculty member or student from Medicine, Engineering, Pharmacy, Nursing or Science interested in interdisciplinary healthcare studies must consult and discuss their research ideas with a subject expert from the relevant department before proceeding with their proposal.

The initial points of contact for any assistance are:

PESU RR Campus: Dr. Manikandan J, Dean Research dean.research@pes.edu

PESU EC Campus: Prof. Deepa S, Director PESU RF deepa.s@pes.edu

PESU IMSR: Dr. N Nagendra Prasad, Chairperson ISRC & Vice Principal (Academics) PESU IMSR vice.principal@pesuimsr.pes.edu

A. Preparation of Research Proposal

For research collaborations with PESU IMSR, researchers must work with a subject expert in fully developing the research proposal. The Chairperson ISRC (currently Dr. N Nagendra Prasad, Vice Principal, PESUIMSRS) will facilitate the association with the expert based on the specific requirements of the research topic. The subject expert must be included as co-investigator / co-author in the study to ensure their continuous involvement and to uphold ethical standards and compliance with stipulated guidelines for patient care.

The finalized research proposal must be duly signed and sealed by the subject expert and the Heads of the departments of the primary investigator before submission to the ISRC approval.

B. Institutional Scientific Research Committee (ISRC)

ISRC is responsible for;

- Collaboration with domain experts
- Evaluation of project proposals for scientific merit
- Required approvals for projects requiring human participation or data

Project proposals to be submitted before 15th of the month for a review meeting in the subsequent month

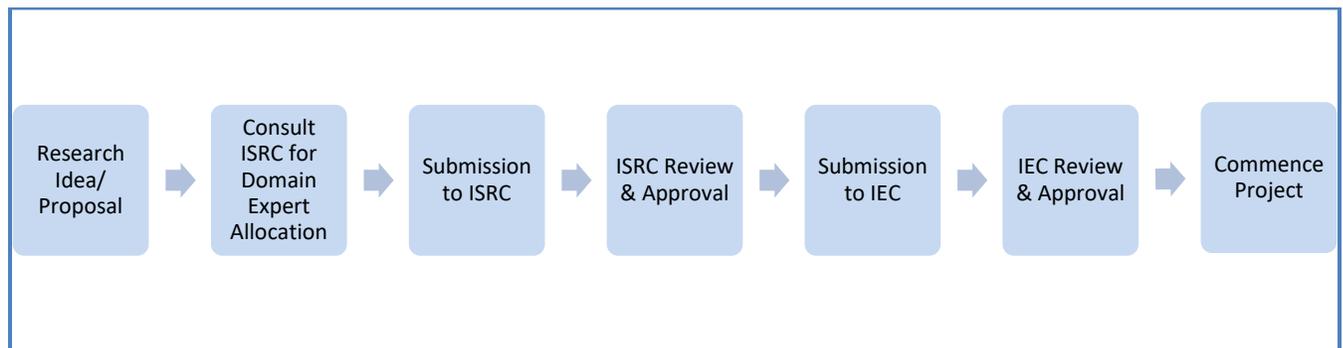
- Contact for further details and formats for submissions:
 - Dr. N Nagendra Prasad, Chairperson ISRC & Vice Principal, PESUIMSRS
 - Dr. Shyma P, Coordinator ISRC, Dept. of Physiology, PESUIMSRSEmail: src@pesuimsr.pes.edu

C. Institutional Ethics Committee (IEC)

- Provides ethical clearance to initiate research for projects approved for scientific merit
- Mandatory for projects involving human subjects or their data/samples
- IEC Meeting is scheduled in the last week of every alternate month
- Contact for further details and formats for submissions:
 - a. Dr. Rita Christopher, Director, Dept. of Integrative Medical Research, PESUIMSR
Email: iec@pesuimsr.pes.edu

5. Approval Pathway Flowchart

Faculty and students interested in interdisciplinary research collaborations with PESU IMSR are expected to follow the process as in the flowchart given below:



6. Hospital Data Access

Researchers must work closely with ISRC and designated medical experts for permissions, data protocols, and compliance.

7. Compliance and Research Integrity

All researchers must ensure compliance with institutional guidelines and medical data protocols to ensure quality research:

- Abide by ICMR ethical frameworks
- Maintain confidentiality and data protection
- Follow PES University's internal research conduct protocols

Non-compliance may result in withdrawal of approval, disciplinary action, or funding implications.

For More Information

- ISRC Queries: src@pesuimsr.pes.edu
- IEC Queries: iec@pesuimsr.pes.edu
- PESU Research Policy related Queries: dean.research@pes.edu

APPENDIX: Detailed Guidelines

Responsible and ethical principles are mandated in Health Research through guidelines from the Indian Council of Medical Research (ICMR) and the same is applicable to all healthcare related projects in PES University. (<https://www.icmr.gov.in/guidelines>)

Guidelines Reference:

1. **National Ethics Guidelines for Biomedical and Health Research involving human participants'**, Indian Council of Medical Research, 2017
https://ethics.ncdirindia.org//asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pdf
2. **Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare**, ICMR 2023
https://ethics.ncdirindia.org//asset/pdf/Ethical_Guidelines_Application_Artificial_Intelligence_Biomed_Rsrch.pdf
3. **Research and development of medical devices guidelines:**
Medical Devices Rule 2017 by Ministry of Health and Family Welfare, India and
National Medical Devices Policy 2023 by The Department of Pharmaceuticals, Government of India
<https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/>
4. **PES University Guidelines and Process for Hospital Data Access:**
Mandatory approvals are required from designated Institutional bodies. Assistance will be provided through the Institutional Scientific Research Committee (ISRC) ensuring integrity through collaboration with appropriate domain experts in the proposed research.

For research involving human participants, researchers must note that:

- a. The **safety and well-being of human participants** in a research study should prevail over the interest of science and society. Research studies and clinical trials cannot be initiated before all the foreseeable risks and inconveniences are weighed against the anticipated benefits for the trial subjects or society. Therefore, the study/trial needs to be conducted under certain ethical principles through proper and fair subject selection, risk-benefit evaluation, utmost respect for the enrolled subjects, independent review procedures, proper and valid methodology and informed consent.

- b. The researcher and the team are **responsible for** protecting the dignity, rights, safety and well-being of all participants enrolled in the study. They should have the appropriate qualifications and competence in research methodology and should be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal.
- c. **Partnership** between the researcher(s) and a representative of the department from where data is sourced is encouraged to avoid misinterpretation of the data, violations of terms and conditions for which data was allowed access thus compromising data security, confidentiality of information, inappropriate and unauthorized use of the data, and unethical publication.
- For Clinical trials or research conducted as part of a student dissertation/project, the Principal Investigator should always be a faculty/guide. However, during publication, students can be given authorship, including the first author based on their contribution to the work.
 - Voluntary written informed consent must be obtained from the prospective participant for any biomedical and health research involving human participants.
 - It is mandatory for a researcher to administer consent before initiating any study related procedures involving the participant. In the case of an individual who is not capable of giving voluntary informed consent, the consent of a legally acceptable/ authorized representative (LAR) must be obtained.
 - It is necessary to maintain privacy and confidentiality of participants at all stages
 - Participants in the research study should not be made to pay for any expenses incurred beyond routine clinical care. If any additional investigations, patients work up, any interventions or associated treatment are done for the patient outside the purview of the standard treatment protocol, the expenses should be met with research funding or the same may be waived off by a competent authority (Supporting documents to be provided).
 - The researcher is responsible for reporting all serious adverse events (SAEs) to the IEC within 24 hours of knowledge. Reporting of SAE may be done through email

communication to iec@pesuimsr.pes.edu (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days.

- Research participants who suffer direct physical, psychological, social, legal or economic harm because of their participation are entitled, after due assessment, to financial or other assistance to compensate them fairly, for any temporary or permanent impairment or disability. In the unfortunate event of death of a participant, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research-related harm.
- The details of compensation or responsibility of further treatment in case of any adverse events/effects on account of the study protocol/drug, should be clearly mentioned in the Patient Information Sheet.
- All clinical research involving human participants and including any intervention such as drugs, surgical procedures, devices, biomedical, educational or behavioral research, public health intervention studies, observational studies, implementation research and preclinical studies of experimental therapeutics and preventives or AYUSH studies may be registered prospectively with the Clinical Trials Registry – India (CTRI).
- The research proposal should be evaluated first for its scientific merit by the Institute Scientific Research Committee (ISRC), or any scientific funding agency. Research proposals which have been scientifically approved may be submitted to the Institutional Ethics Committee (IEC), PESUIMSR, for ethical clearance.

Proposal Submission and Approval Process at PESU

For all healthcare related research and projects, the faculty in charge or the Principal Investigator of the proposed research should ensure the following:

1. **Drafting the Proposal:** The researcher must consult and discuss their research idea with a subject expert from the relevant department in drafting their final proposal. The initial point of contact for interdisciplinary research collaborations at PESUIMSR will be the Vice Principal (Academics), Dr. N Nagendra Prasad. He will facilitate the process by guiding the researchers to the appropriate subject experts based on the specific

requirements of the topic. **The subject expert must be included as a co-author/co-investigator in the study to ensure their continuous involvement.** This will uphold ethical standards and ensure compliance with stipulated guidelines for patient care.

2. **Proposal Format:** Study protocol should be prepared in the word document as per IMRAD style [Introduction (I), Methods (M), Results (R), and Discussion (D)].
3. **Proposal Submission:** Research proposals with the study protocol must be first submitted to Dr. Shyma P, Coordinator of the ISRC, Associate Professor, Department of Physiology, for an initial review. Email: src@pesuimsr.pes.edu
4. **ISRC Review and Approval:** The ISRC members will conduct a detailed evaluation of the submitted proposal. Upon preliminary approval, the researcher must present the study to the ISRC for final approval.
 - The ISRC presentation must be conducted in the presence of the Subject expert, guide or co-guide
 - If students are presenting, it is mandatory for the faculty-in-charge to be present along with the subject expert
 - The allotted time for presentation is 8+2 minutes. Prepare less than 10 slides with title of the study, rationale and methodology including analysis.
 - ISRC Meeting is scheduled every alternate month for review and approval of proposals.
5. **IEC Clearance:** Research proposals that are approved by ISRC may be submitted to the Institutional Ethics Committee (IEC), PESUIMSR, for ethical clearance. The IEC, PESUIMSR, is provisionally registered with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR), Government of India. The IEC is mandated to observe all the conditions as stipulated in Chapter-IV of 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).

The guidelines for submission of research proposals for IEC clearance are as follows:

- Study protocol should be submitted in the format provided by the IEC, PESUIMSR. The soft copy of the format may be obtained by sending a request to iec@pesuimsr.pes.edu

- All fields in the proforma should be filled. Incomplete protocols will not be accepted.
- The Patient Information Sheet and Informed Consent should be prepared in simple language that can be easily understood by the participants.
- The details of the Principal Investigator (PI) including contact details should be provided in the Patient Information Sheet so that the patient or his relatives can contact the concerned, in case of any emergency.
- The details of compensation or responsibility of further treatment in case of any adverse events/effects on account of the study protocol/drug, should be clearly mentioned in the Patient Information Sheet.
- The signed hard copy of protocol along with
 - Covering letter addressed to 'The Chairperson, IEC, PESUIMSR, Bengaluru 560100'
 - The protocol approval letter from ISRC or scientific/technical approval letter from the funding agency may be submitted to Dr Rita Christopher, Member-Secretary, IEC, IMR, 2nd Floor, PESU Hospital, Bengaluru.
- A signed and scanned soft copy of the documents, as a single merged PDF with all attachments, should be sent to the following email: iec@pesuimsr.pes.edu
- IEC meetings will be held in the last week of every alternate month. Protocols submitted on or before the 10th of the month will be considered for review in the ensuing IEC meeting.
- The PI should be available to make a 5-7 min power point presentation to the IEC members during the meeting.
- After reviewing the research protocol, comments of IEC, if any, will be sent to the Principal Investigator. PI may provide point-by-point answers to the queries raised by the IEC. The required clarifications/documents (1 hard copy and a soft copy as merged PDF, with covering letter) should be submitted within 10 days from the date of receipt of the comments. Final Approval letter will be given subject to fulfillment of IEC requirements.

- For clinical trials or research requiring CTRI registration, the PI must submit the CTRI registration details without fail, following which the final approval letter will be issued. The letter issued by the IEC, prior to this, is 'in principle' only.
- After receiving the IEC approval letter the PI should send yearly progress reports to the following email: iec@pesuimsr.pes.edu. A short final report should be submitted after completion of the project.

Please contact **Dr. Rita Christopher, Member-Secretary, IEC, Integrative Medical Research** for further details. Email: iec@pesuimsr.pes.edu

Tentative schedule of IEC meetings

| Month | Jan | March | May | July | Sept | Nov |
|--|---------------|---------------|---------------|---------------|---------------|---------------|
| Proposed date of meeting* | Last Thursday |
| Last date for protocol submission | Jan 10 | Mar 10 | May 10 | July 10 | Sept 10 | Nov 10 |

*Actual date will be finalized after approval of the Chairperson, IEC PESUIMSR

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Approved Signatories: 1. Dr. Suryaprasad J, Vice Chancellor, PES University

2. Dr. Suresh Krishnamurthy, Medical Director, PESUIMSR

Acknowledgement: Dr. Shyma P (ISRC) and Dr. Rita Christopher (IEC)

Related Document: PESU Research Policy (<https://research.pes.edu/research-policy/>)