St. Andrews Education Foundation's
(An ISO 9001: 2015 Certified Minority Institution)
St. Andrews College of Physiotherapy
(Christian Minority Institution)
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Standard Operating Procedure (SOP) for Institutional Ethics Committee

Introduction:

St. Andrews College of physiotherapy is a Christian minority institution established under St. Andrews Education Foundation, Pune. Vision of the institution is to produce the best possible environment for the future physiotherapist with international recognition who shall lend a hand to the prosperity & betterment of mankind and social settings to provide the best quality of life for them. Mission Statement of the institution is to equip their graduates with the necessary physiotherapy knowledge, service-orientation, self-assurance, reflective practitioners who, by virtue of critical and integrative thinking along with clinical reasoning, lifelong learning, and ethical values, render independent judgments concerning patient /person needs by having patient-centered approach considering the cultural values and socioeconomic status of the client with patient-centered practice.

Physiotherapy research involves a number of ethical issues that need to be addressed. The Institutional Human Ethics Committee (IHEC)/IEC plays an important role in guiding physiotherapy researchers/ students in the ethical aspects associated with the physiotherapy research. Apart from ethical issues, IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines and MUHS Guidelines for Biomedical and Health Research involving Human Participant.

Objectives:

The objective of this SOP is to maintain and ensure quality, technical excellence and consistent ethical review of all submitted Physiotherapy research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and MUHS Guidelines.

Composition:

This IEC will be multidisciplinary in composition and independent. As per the ICMR National Ethical Guidelines2017, IEC, SACOP have the following categories of members

- Chairperson – Affiliated
- Member Secretary- Affiliated
- Basic medical scientist-Non-affiliated/affiliated
- Clinicians -Non-affiliated/affiliated

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- Legal expert -Non-affiliated/affiliated
- Social Scientist /representative of NGO/Philosopher/ethicist/theologian-Nonaffiliated/affiliated
- Lay person from the community -Non-affiliated/affiliated

Conduct of IEC meetings

The Chairperson will conduct all meetings of the IEC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. All proposals will be received at least 6 days before the meeting and after initial scrutiny by Member Secretary the proposals will be circulated to the IEC members. The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals. If required additional review meetings can also be conducted with a short notice period.

Application procedures

All proposals should be submitted to IEC on any working day 1 week in advance of scheduled meeting in the prescribed application form along with relevant documents. The proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators /should be submitted to IEC. Two hard copies (with sign and seal) and a soft copy (without sign and seal) have to be submitted. Principle Investigators should send their application to Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting. All research proposals/clinical trials funded/sponsored by Companies, Agencies, and Trusts Multinationals etc. will be charged an administrative fee/ processing fee of () of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, MoHFW, Govt of India, Non Profitable Organizations etc.

Details of documents to be submitted for EC review

a) Project of students
b) Permission from the Data collection setting
c) Approval from Guide
d) Synopsis of Research Proposal (5 slides) with emphasis on ethical considerations
e) A complete protocol
f) List of ongoing research studies undertaken by the principal investigator (if applicable)

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Review procedures

a) The meeting of the IEC will be held periodically as specified by the Member Secretary.
b) The proposals should be sent to the IEC at least 1 week in advance of scheduled meeting.
c) The Member-Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved
d) The review discussions/ decisions will be charted down and the final minutes will be approved by the Chairperson.
e) After the IEC meeting, the decision of the IEC members regarding the discussed proposals to obtained on the same day of the meeting.
f) The type of EC review based on risk involved in the research, is categorized as follows

Type of risk	Definition/description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not Expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, Physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than The minimal risk threshold. • Routine research on children and adolescents; Research on persons incapable of giving consent • Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; • Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; • Trying a new diagnostic technique in pregnant and breastfeeding Women etc. • Research should have a social value. Use of personal identifiable data in research also imposes indirect risks. • Social risks, psychological harm and discomfort may also fall in this Category
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

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Record keeping and archiving of documents

All Research proposals (2 hard copies along with soft copy) along with the information and documents submitted will be dated and filed

The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study.

IEC members should not retain any documents with them after the meeting is over.

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