ज्ञानं सविज्ञानम्
DPES
Dhole Patil Education Society

DHOLE PATIL COLLEGE OF PHYSIOTHERAPY
Approved by Govt. of Maharashtra,
Affiliated to Maharashtra University of Health Science, (MUHS) Nashik

Campus - Near EON IT Park, Kharadi, Dhole Patil College Road, Wagholi,Pune - 412207., India. Tel. : +91-20-66059900 Email : dholepatilphysiotherapy@gmail.com Web. : www.dpcop.in

Ref. No.: DPCOP/A.Y 2023-24/IEC/004 Date : 12/01/2024

Standard Operating Procedures (SOP)

Institutional Ethics Committee (IEC)

1. Objectives:

The objective of this SOP is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019.

2 .Authority under which IEC is constituted

Dhole Patil College of Physiotherapy IEC (DPCOP-IEC) is an Institutional standing ethics committee which functions independently. The Dean of Faculty in consultation with the Executive Director, DPCOP-will appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of IEC members will be for 3 years or till further orders.

3. Responsibilities of DPCOP-IEC:

The main responsibility of DPCOP- IEC is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals. It should ascertain that all the ethical principles of research such as Autonomy, Beneficence, Non –maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research.IEC will review each study proposal for its both scientific and ethical review.

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Ref. No.: Dpcop/A.Y IE committee/ 2023-24/0040

Date : 12/01/2024

Institutional Ethics Committee members for the Academic Year **2024-25** of Dhole Patil College of Physiotherapy, Pune are,

S. N.	Name	Department	Designation
1	Dr. N. Gunasekaran	Principal cum Professor	**Chairperson**
2	Dr. Dinesh Chavan	Professor	**Coordinator**
3	Dr. P. Senthil	Professor	**Coordinator**
3	Dr. Lokesh R	Associate Professor	**Asst. Coordinator**
4	Dr. Sneha L Joy	Associate Professor	**Member**
5	Dr. Snehal Khalegaonkar	Asst. Professor	**Member**
6	Dr. O. S. Rajenkar	Professor, DPCOE	**Invitee Member**
7	Dr. A. Dandavate	Professor	**External Member**
8	All Concerned Department HOD's		**Member**
9	Adv. Unmesh Dindore		**Legal Advisor**
10	Mr. Lakhan Mandlik		**General Public/Lay man**

Prof. Dr. N. Gunasekaran (PT)

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Members of IEC are expected to attended all IEC meetings and prior information should be provided if a member is unable to attend meeting.

3.1 Responsibilities of each member is mentioned below

Chairperson:

Conduct EC meetings and ensure active participation of all members during Meeting. Ratify minutes of the previous meetings. Seek COI declaration from members and ensure quorum and fair decision making. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, et.

Member Secretary

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

Basic scientist

Scientific and ethical review - emphasis on intervention, benefit- risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmaco-dynamics in case of clinical trials

Clinician

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

Legal expert

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Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc) compliance with guidelines etc.

Social scientist/ philosopher/ethicist/theologian

Ethical review of the proposal,ICD along with the translations. Assess impact on community involvement, socio–cultural context, religious orphilosophical context, if any Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns

Lay person

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

Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences.

All IEC members must be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines.

When there is any change in SOP the same will be communicated to the members and

Necessary training will be imparted. Record will be maintained regarding the training of members and change in the SOP/guidelines.

Members are expected to declare conflicts of interest, if any, before commencement of the meeting.IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest.

The IEC has the rights to revoke its approval accorded to scientific study/clinical study protocol, and further, it has to record the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders.

IEC may review progress of the approved studies periodically till the completion of the study through periodic study progress report /internal audit reports.

The investigator is responsible for reporting all SAEs including hospitalization or prolongation of hospitalization, clinical trial related injury or death, regardless of causal relationship to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the

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Research must also be submitted within 14 days. SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days).

The IEC shall forward the report on any SAE(including, death), after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority. The copy of the report has to be submitted the Licensing Authority within twenty one calendar days of the occurrence of the SAE.

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