

**Standard Operating Procedure – SOP**

**INSTITUTIONAL ETHICS COMMITTEE  
SCHOOL OF PHYSIOTHERAPY, RK UNIVERSITY**

**Dr.Devang Mandaliya**  
Chairperson

**Dr. Priyanhsu Rathod**  
Institutional Head

**Dr. Ankur Parekh**  
Member Secretary

**STANDARD OPERATING PROCEDURE (SOP)**

Complete Name of the Ethics Committee	Institutional Ethics Committee, School of Physiotherapy, RK University, Rajkot (SOPTIEC)
Complete address of the Ethics Committee	School of physiotherapy, RK University, Rajkot-Bhavnagar Highway, Tramba, Rajkot – 360020, Gujarat, India
Frequency of Ethics Committee Meeting	As per the requirement usually 3 in a year
Date of Next immediate Ethics Committee meeting	As decided by the Chairperson/member secretary
Lead time required by the Ethics Committee before which they discuss documents submitted to them	15 days
Complete home and contact number of Ethics Committee member whose details will appear on the informed consent form	As applicable

#	Name	Designation in Ethic committee	Qualification	Residential Address	contact number
1	Dr. Devang Mandaliya	Chairperson/clinician	MS, Orthopaedic	"shree" , Everest park street no 2, near McDonald restaurant, Kalawad road, Rajkot - 360005	09727719706
2	Dr. Divyesh Sondarva	Pharmacologist/Bsic medical scientist	MD Pharmacologist	Geeta nagar -2, Airport road, Keshod : 362220	09712953340
3	Dr. Sunil Shah	Clinician	MD(internal Medicine)	Kinjal nursing home, Kinjal, 14- Sardar nagar , Rajkot - 360001	09712375850
4	Dr. Priyanshu Rathod	Clinician	MPT, PhD	"Vandana", 6-shri Ram Park, Kalawad Road, Rajkot - 360005	09426803108
5	Dr. Ankur Khant	Clinician	MPT	11/B - Aalap avenue, opp. Royal hall, university road, Rajkot -360005	9727681829
6	Dr. Ankur Parekh	Member secretary	MPT	'Vraj Kamal', 11/2 Rani park, Near Nadanvan- 3, Mavdi bypass, Rajkot - 360004	9925966373
7	Mr. Shabbir Lokhandawala	Legal expert	B.com , LLB	Burhani Patnakar society, main road ,Airport Road, Rajkot - 360001	07383182354
8	Dr. Alka Mankad	Social scientist/Philosopher	MA , PhD, Psychology	49,"Tarak Street", 8- Janta Society, Opp. LIC office, Rajkot - 360001	09825555343
9	Mr. Arvind Sorathiya	Lay person from community	B.A.	"Pitru Krupa", Amarnath Park ,Main Road, Kothariya Ring road, Rajkot, Gujarat, India.	09979012854

➤ **Objective:**

Institutional Ethics Committee (SOPTIEC) is intended to ensure a competent review of scientific and ethical aspects of the project proposal received.

➤ **Role:**

The Institutional Ethics Committee (SOPTIEC) will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, right, safety and well-being of all actual and potential research participants. The goals

of research, however important, would never be permitted to override the health and well-being of the research subjects.

The Institutional Ethics Committee (SOPTIEC) will take care that all the cardinal principles of research viz. Autonomy, Beneficence, Non-maleficence and justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, the Institutional Ethics Committee (SOPTIEC) will look into the aspects of informed consent process, risk benefit ratio whenever required. The Ethics committee will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study. The Institutional Ethics Committee (SOPTIEC) will also examine compliance with all regulatory requirements, applicable guidelines and laws.

➤ **Composition:**

The Institutional Ethics Committee (SOPTIEC) will comprise of 8-10 members. As per the rule 122DD for review of each protocol the quorum of Ethics Committee shall be at least following five members 1. Basic Medical scientist, 2. Clinician, 3. Legal expert, 4. Social scientist/philosopher, 5. Lay person from community in order to provide collective expertise ensuring a comprehensive review (scientific and ethical) of the projects submitted to it.

The Chairperson of the Institutional Ethics Committee (SOPTIEC) would be from outside the institution and not head of the same institution to maintain the independence of the committee. The member secretary would generally, belong to the same institution and would conduct the business of the committee. The members including the member secretary will be nominated & appointed by the Dean & Institutional Head in office who would be a mix of

Medical, non-medical scientific and non-scientific persons including lay public to reflect different viewpoints. The members may be replaced at the discretion of the committee members when a majority vote is obtained.

➤ ***Removal procedure:***

A member may be relieved of his/her membership in case of a conduct unbecoming for a member of the Ethics Committee or inability to participate in the meetings on any ground

➤ **Responsibility:**

The Institutional Ethics Committee (SOPTIEC) is setup to ensure that the clinical research as well as intramural studies that are carried out at School of Physiotherapy, RK University.

- Are sound in scientific design, have statistical validity and are conducted according to the parameters of ICH-GCP as well as local regulatory requirements.
- Do not compromise the safety, rights and well-being of the patients participating in the research study.
- Are conducted under the supervision of medical persons with the required experience / expertise.
- Include safely, patients who, through their legally acceptable representative have given informed consent for participation in the research study.

All members should maintain in absolute confidentiality of all discussions during the meeting. They have no rights to participate if they are principal investigator.

The member secretary / designee / Institutional Ethics Committee (SOPTIEC) coordinator will record the minutes during each meeting

Correspondence between the Institutional Ethics Committee (SOPTIEC) and the principal investigator / study team and other relevant records (response letter, minutes of meetings, membership list composition etc) will be retained for minimum period of 3 years after completion of the trial.

The Institutional Ethics Committee (SOPTIEC) will review all research projects and also the ongoing research projects at intervals appropriate to the degree of risk to the study subjects.

The committee will maintain a list of projects submitted, approved / disapproved and the outcome of each project including subject information, relevant correspondence and all study related documents.

In one academic year, beginning from June of each year, any principal investigator shall be allowed to handle between 2-3 clinical researches trials in his field of work in the institution.

The Institutional Ethics Committee (SOPTIEC) expects from the principal investigator to be informed about:

- The initiation of the study/randomization of the first patient,
- The progress of the study at interval of every three months,[If period of the study is short then at the interval of every one month],

- Any Serious Adverse Events occurring in the course of the study within 1-2 calendar day/s of their occurring.
- Any changes in the protocol and patient information /informed consent documents, prior to their implementation.
- Amendments/revisions to any study-related document as well as patient safety related information
- Study completion and discontinuation with reasons
- Justification for approval to restart studies discontinued earlier. The final report of the study shall be submitted to the Institutional Ethics Committee (SOPTIEC) in all cases, even when the study abandoned for any reason (s).

➤ **Procedure:**

The applicant of the proposal generally the principal investigator is required to submit his/her application letter and 10 copies of the following documents, 15 days before a scheduled meeting:

- A letter of intent or proposal by the Investigator [1 copy only]
- Research protocol.
- Protocol Amendment, if any.
- Investigator's Brochure.
- Case Report Form / assessment form
- Informed consent form, [English]
- Informed consent form, [English to Gujarati translation].
- Informed consent form, [Gujarati to English back translation].
  - including translation certificate [1 copy]
- Informed consent form, [English to Hindi translation].
- Informed consent form, [Hindi to English back translation].
  - including translation certificate [1 copy]
- Patient/ volunteer information Leaflet [English]
- Patient/ volunteer information Leaflet [English to Gujarati translation].
- Patient/ volunteer information Leaflet [Gujarati to English back translation].
  - including translation certificate [1 copy]
- Patient/ volunteer information Leaflet [English to Hindi translation].
- Patient/ volunteer information Leaflet [Hindi to English back translation].
  - including translation certificate [1 copy]
- Safety Reports where applicable
- DCGI - (Drug Controller General of India) Approval Letter [1 copy] where applicable

- Insurance Policy [1 copy] where applicable
- Import license, where applicable[1 copy]
- Investigator's undertaking[1 copy]
- The fees for the consideration of the protocol/clinical study in question will be as applicable
- Ethics Committee Members Conveyance Allowance as and when applicable. The member secretary shall be aware of the amount decided by the Institutional Head.
- The Institutional Ethics Committee (SOPTIEC) is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.

The Institutional Ethics Committee (SOPTIEC) will meet as and when required. Advance notice, 07 days before each meeting will be sent out to the (SOPTIEC) members, along with the agenda.

The requisite quorum of 5 members is required to be present at each review meeting. Decisions will be made only in meetings where quorum is complete. All nominated members including the member secretary have the right to vote. It is preferable that at least one of the Institutional Ethics Committee (SOPTIEC) members who are not affiliated to the Institute be present during each review meeting as per Schedule-Y. The Member secretary, designated by the Chairperson, will record the Minutes of the meeting and circulate the same to the members within two weeks of the meeting.

The Investigator/Co-investigator is called to the meeting to present the study or answer specific queries. However, he / she will not participate in the decision making / voting process of that study even if he / she is a regular member of the SOPTIEC.

A Study Team member including the Principal Investigator will be deemed an interested party with regard to the review.

The Study Team Member's non participation in the decision making / voting process will be recorded in the response letter from the EC.

The Institutional Ethics Committee (SOPTIEC) may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. 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, HIV/AIDS positive person or ethnic minorities. They are required to give their specialized views but do not take part in the

decision making process which will be made by the members of the Institutional Ethics Committee (SOPTIEC) The decision of the committee will take by a majority vote after the quorum requirements are fulfilled to recommend / reject / suggest modifications for a repeat review or advise appropriate steps.

If subject experts are invited to offer their views, they will not take part in the voting process.

The Institutional Ethics Committee (SOPTIEC) will give its opinion on the project in one of the following ways:

- Approval
- Disapproval
- Modification before Approval
- Discontinuation of a previously Approved project

In case an Institutional Ethics Committee (SOPTIEC) revokes its approval accorded to a trial protocol, it must record the reasons for doing so and at once communicate such a decision to the Investigator.

In all cases, the study will be unambiguously identified by protocol title and number. All documents reviewed will be listed in the response letter, which will also state the list of members present and date of the meeting at which the study was reviewed. The member-secretary will convey the decision of the committee to the Principal Investigator in writing. The response letter will include the signature and date by the Institutional Ethics Committee (SOPTIEC) member-secretary.

The decision letter must contain following information:

- Date and time of EC meeting
- Place of the meeting
- Names and designation of the Chairperson and members who attend the meeting.
- Title of the Research proposal
- Name of the Chief investigator
- List of documents (with date and version number wherever possible) reviewed by the Institutional Ethics Committee (SOPTIEC)
- A clear Statement of the Decision Reached. Any advice (non-binding) by the Institutional Ethics Committee (SOPTIEC)

- In the case of Negative decision, reasons for not approving the proposal must be mentioned
- In the case of "approval" decision, the responsibilities of the chief investigator must be communicated

Should an amendment to a study related document be administrative in nature and not involving study design or safety criteria, it may be provisionally approved in writing, by the

Chairperson/member-secretary of the Institutional Ethics Committee (SOPTIEC) without calling a full meeting.

The Chairperson/member-secretary will inform other members of the Institutional Ethics Committee (SOPTIEC) of amendment and his / her decision during the subsequent regular meeting of the committee. The decision will be ratified and committed.