

STANDARD OPERATING PROCEDURE [SOP] REVISION I [January 2022]

**Amendment 2 [January 2022] INSTITUTIONAL ETHICS COMMITTEE
- CHARUSAT, Changa**

Amendment 2 - 14th January, 2022

**Institutional Ethics Committee-CHARUSAT CHARUSAT Campus,
Nadiad-Petlad off Highway, Changa Ta. Petlad, Dist. Anand, Gujarat -
388421**

STANDARD OPERATING PROCEDURE [SOP] Revision - 1, January 2022, Amendment 2, 14/01/2022

In view of strengthening clinical trials, certain amendments are mandated in the current IEC-CHARUSAT SOPs. The contents of the amendments below were circulated to all the members with permission of the Chairperson and finalized following inputs, if any, from the members. The amendments were prepared by Member Secretary and reviewed by all the members before finalization. Final Amendments were approved by Chairperson and final copy was released by Registrar, CHARUSAT.

These amendments would be effective from 27th January, 2022.

SOP-1: Authority for Information of Institutional Ethics Committee – No Change

SOP-2: Development, Review and Revision of Sops – No Change

SOP-3: Ethics Committee Composition – No Change

SOP-4: Review of Research Project – No Change

SOP-5: Review of Research Proposals/Process of Review – No Change

SOP-6: Decision Making and Post Review Activities – No Change

SOP-7: Monitoring of Research Projects – No Change

SOP-8: Administrative Support

4. Financial dealings of Ethics Committee activities and functioning Incomes and Expenditures towards functioning of the committee

1. Standard fee will be charged for the review of research proposals submitted by the investigators of CHARUSAT for review in case of Industry Sponsored Clinical Trials.

To be added:

- a. IEC-CHARUSAT fees for Clinical Trials: Fees for review of sponsored clinical trials shall be Rs. 50000/- (Rupees Fifty Thousand only) per proposal.
- b. In case of SAE review the charges will be Rs. 15000/- (Rupees Fifteen Thousand Only) per SAE review
- c. IEC-CHARUSAT fees for Academic Proposals: Fees for review of Academic Proposals shall be Rs. 2000/- (Rupees Two Thousand only) per proposal.

All the clinical trials will be monitored by IEC-CHARUSAT every three months and as needed till it completed.

2. Research projects initiated and submitted by investigators outside CHARUSAT but to be conducted within CHARUSAT will be accepted only after written permission granted by CHARUSAT Research Cell [on hard copy of the research proposal]

3. Research projects initiated and submitted by investigators outside CHARUSAT for research to be conducted outside CHARUSAT will not be accepted for review EXCEPT when there is a research collaborator from CHARUSAT as a co-principal investigator (Co-PI).

To be added:

With reference to SOP-4, line 23, page number 2, proposal/project for clinical trial submitted by investigators outside CHARUSAT and CHRF will be accepted for review by having MOU between the site hospital and Charusat Health Care and Research Foundation (CHRF) or by signing formal agreement between the principal investigator and IEC-CHARUSAT on Rs.300/- stamp paper with legal notarization.

4. Research proposal review fees should be deposited in favour of “Charotar University of Science and Technology, payable at Changa, Gujarat.

SOP-9: Record Keeping and Archival – No Change.

SOP-10: Training & Self-Assessment – No Change.

Sr.No	Role in Amendment	Signature
01	Approved Amendment by Dr. Swapnil Agarwal, Chairperson	Sd/-
02	Prepared the amendment by Mr. Siddaram Sarate, Member Secretary	Sd/-
03	Reviewed the amendment by 1. Ms. L Surbala, Member/Joint Secretary 2. Mr. Mayur Khunti, Member/Legal Expert 3. Dr. Bhavtosh A Kikani, Member	Sd/-
04	Released the final amendment by Dr. Devang Joshi, Registrar, CHARUSAT	Sd/-