

**STANDARD OPERATING PROCEDURE [SOP] REVISION I [April 2021]
Amendment 1 [April 2021] INSTITUTIONAL ETHICS COMMITTEE –
CHARUSAT, Changa**

Amendment 1 – 1st April, 2021

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

STANDARD OPERATING PROCEDURE [SOP] Revision – I, April 2021 Amendment 1 01/04/2021

In view of current pandemic, 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 1st May 2021.

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

(Page 2 of 11)

3. Review by conducting a formal Meeting

All proposals that are submitted to the Institutional Ethics Committee for the review will be thoroughly and critically evaluated and the decision about the proposal will be taken during the Meeting. The Meeting will be considered valid, only if the quorum is maintained throughout the Meeting and at the time of decision making process as well. If the IEC Member has declared a conflict of interest for any research proposal, then a written statement stating the same will be submitted to the Chairperson of the IEC, before beginning of the meeting and shall be recorded in the minutes of the meeting. The member who has declared conflict of interest will be asked to withdraw from the IEC Meeting, i.e. vacating the Meeting venue, while the research proposal is being discussed upon, if he/ she is not an investigator. If the IEC Member is an investigator, he/ she shall be present for review process only. At the time of discussion amongst members and final decision, the concerned member shall

Page 2 of 4

leave the meeting. This will be recorded officially and the quorum rechecked. A list of absentee members as well as members leaving or entering in-between the meeting will also be recorded. Proposals will be taken up item-wise, as given in the agenda. Number of proposals reviewed in a meeting will justify that there is ample time devoted for review of each proposal. If there is more number of proposals for consideration per meeting, the meetings will be arranged frequently to review them. The time allotted for the meeting will be reasonable to allow ample discussion on each agenda item. The minutes of the previous meeting and list of protocols that underwent expedited review will be ratified. The contents of the patient/participation information sheet including the local language translations, back translations of the informed consent document in English, wherever required; provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and if consent waiver or verbal/oral consent request has been asked for, this will be specifically reviewed.

Apart from research proposals taken for Full Committee/ Board Meeting, investigator[s] can submit their research projects any time to the IEC, in the same way as mentioned above, with justification as to why their research project should be considered for an expedited review.

To be added:

*All the proposal should be submitted via online portal available at <https://www.charusat.ac.in/EthicalCommittee.php>, upon receiving a hardcopy of all the document submitted online via portal to the office of member secretary, proposal will be consider for the review.

*Keeping current pandemic COVID-19 into consideration, the ethics committee shall consider online participation of IEC members to complete the quorum or to have review, and

needs to take the prior permission of Chairperson. No Principal Investigator or presenter were permitted for online presentation, If any co-investigator or PI more than one or from other institution in case of multicentric biomedical and health research proposals, may join the meeting virtually with prior permission from chairperson through member secretary only if necessary. EC would ensure availability of adequate infrastructure and facilities for effective participation and discussions of external members joining via online mode, online platform can be decided as per the feasibility such as Zoom, Microsoft team, Google meet etc. All meeting proceedings must be recorded and archived for at least 3 years.

A list of absentee members as well as members leaving or entering in-between the meeting will also be recorded.

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

SOP-7: Monitoring of Research Projects – No Change

SOP-8: Administrative Support – No Change

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	Sd/-
04	Released the final amendment by Dr. Devang Joshi, Registrar, CHARUSAT	Sd/-