

STANDARD OPERATING PROCEDURE [SOP-1]

AUTHORITY FOR FORMATION OF INSTITUTIONAL ETHICS COMMITTEE

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1. Purpose

To define the authority who will establish and govern the formation of Institutional Ethics Committee-CHARUSAT, Charotar University of Science and Technology, Changa, GUJARAT - 388421

2. Scope

It covers the procedure for establishment of an independent and competent Institutional Ethics Committee and laying down its functioning as per applicable rules and regulations of ICMR guidelines 2017.

3. The authority under which the Ethics Committee is established and administratively governed

The Registrar, Charotar University of Science and Technology, Changa, will be the appointing authority under which Institutional Ethics Committee-CHARUSAT [IEC-CHARUSAT] is constituted. Currently, IEC-CHARUSAT, needs to be registered with ***Department of Health Research & Central Drugs Standard Control Organization [CDSCO]***

The formation letter from Registrar, Charotar University of Science and Technology, Changa will clearly specify the independence and competence of the formed Ethics

Institutional Ethics Committee – CHARUSAT
Charotar University of Science and Technology, Changa -388421

Committee. Composition will be as such that conflicts of interest[s] are adequately addressed so that it exhibits an independent decision.

4. Functioning as per applicable rules and regulations

The formation letter from Registrar, Charotar University of Science and Technology, Changa will clearly specify the terms of reference for functioning of the independent Institutional Ethics Committee, taking care of existing regulations.

The terms of reference shall include:

- Statement on Independence of the IEC
- Core value of the IEC
- Scope of the IEC
- Appointment of Chairperson, Member Secretary and other members; including subject experts, when required
- Communication with regulatory authorities
- Preparation of Standard Operating Procedure for effective functioning of the committee

[Annexure1]