

STANDARD OPERATING PROCEDURE [SOP]

AUTHORITY FOR FORMATION OF ETHICS COMMITTEE

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1. Purpose

To define the authority who will establish and govern the Institutional Ethics Committee, HM Patel Centre for Medical Care and Education, Karamsad.

2. Scope

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

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

The Chief Executive Officer (CEO), Charutar Arogya Mandal, will be the appointing authority under which Institutional Ethics Committee [IEC], HM Patel Centre for Medical Care and Education is constituted [HMPCMCE]. Currently, IEC, HMPCMCE is registered with **Central Drugs Standard Control Organization [CDSCO] with registration no. ECR/ 331/ Inst/ GJ/ 2013/ RR-16, valid till 22nd May 2019** and **Office of Human Research Protections [OHRP], US Department of Health and Human Services [HHS] – Registration of an Institutional Review Board [IRB] with registration no. IORG0006830, valid till 31st March 2020.**

4. Policy to ensure the independence of the Ethics Committee in its functioning and decision making

The formation letter from CEO, Charutar Arogya Mandal will clearly specify the independence and competence of the formed Ethics Committee. Composition will be as such that conflict of interest [s] are adequately addressed so that it exhibits an independent decision.

5. Functioning as per applicable rules and regulations

The formation letter from CEO, Charutar Arogya Mandal will clearly specify the terms of reference

INSTITUTIONAL ETHICS COMMITTEE
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KARAMSAD, GUJARAT -388325

[Reg. No. ECR/ 331/ Inst/ GJ/ 2013/ RR-16]

for functioning of the independent Institutional Ethics Committee, which will be done taking care of existing regulations.

The terms of reference would include:

- Statement on Independence of the committee
- Core value of the committee
- Scope of the committee
- 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

[Annexure 1]