

Format of Approval of Institutional Ethics Committee
[As per Schedule Y, Appendix VIII (2)]
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD

To
Dr.

Dear Dr. _____

The Institutional Ethics Committee reviewed and discussed your application to conduct the clinical trial/ research project entitled “” on (date).

The following documents were reviewed:

- a. Trial Protocol (including protocol amendments), dated _____ Version no (s). _____
- b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language
- c. Investigator’s Brochure, dated _____, Version no. _____
- d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose
- e. Principal Investigator’s current CV
- f. Insurance Policy/ Compensation for participation and for serious adverse events occurring during the study participation
- g. Investigator’s Agreement with the Sponsor
- h. Investigator’s Undertaking (Appendix VII)

The following members of the ethics committee were present at the meeting held on (date, time, and place).

_____ Chairman of the Ethics Committee
_____ Member secretary of the Ethics Committee
_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee, functions as per the requirements of the ICH-GCP, ICMR, Revised Schedule Y and their SOP’s. The Registration Number of IEC is ECR/331/Inst/GJ/2013/RR-16.

The IEC expects to be informed about the progress of the study, any serious adverse event [SAE] occurring in the course of the study, any changes in the protocol and participant information sheet/ informed consent document and asks to be provided a copy of final report.

Member Secretary,
Institutional Ethics Committee, HMPCMCE