

Annexure XI  
**Format for Approval of 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 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 expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee.