Annexure 9

# Format of Approval of Institutional EthicsCommittee [As per Schedule Y, Appendix VIII (2)] INSTITUTIONAL ETHICSCOMMITTEE- CHARUSAT

To Dr

DearDr.

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

The following documents were reviewed:

1. Protocol (including protocol amendments), Dated Version no (s).
2. Patient/ParticipantInformation Sheet and Informed Consent Form (including updates if any) in English and/or vernacularlanguage
3. Investigator’sBrochure,Dated , Versionno.\_
4. Proposed methods for patient accrual including advertisement(s) etc. proposed to be used for thepurpose
5. Principal Investigator’s updated/ recentCV
6. Insurance Policy and/ or Compensation for participation in the research study as wellfor occurrence of adverse events (AE) orserious adverse events (SAE) or deathto the Patient/ Participant or nominees (in case of death) during the study.
7. Investigator’s Agreement with theSponsor
8. Investigator’s Undertaking (AppendixVII)

The following members of the ethics committee were present at the meeting held on (Date, Time, andPlace).

 Chairman of the EthicsCommittee

 Member secretary of the EthicsCommittee

 Name of each member withDesignation

We approve the research 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 **DHR: EC/NEW/INST/2020/875, CDSCO: ECR/1507/Inst/GJ/2021, HHS (US):RB00012931**.

The IEC must be informed timelyabout the progress of the study, immediatelyaboutany adverse event [AE] and/ orserious adverse event [SAE] occurring during 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 - CHARUSAT