

# Institutional Human Ethics Committee

CDSCO Registration No. ECR/28/Inst./GJ/2013/RR-19 Approved upto 15 / April / 2024  
NECRBHR Provisional Registration No. ECINEWIINST/2019/261 Approved upto 12 / November / 2021  
GMERS Medical College & Hospital, Gotri, Vadodara – 390021, Gujarat, India  
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## Annexure – 3

### Investigator's Undertaking

#### Study Title:

1. We certify that, we have determined that the proposal herein is not unnecessarily duplicative of previously reported research.
2. We certify that, we are qualified by education, training and have enough experience to do such a study.
3. For procedures listed under proposal, we certify that we have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress to the patient.
4. We certified that, study will be initiated only upon review and approval of scientific intent by IHEC GMERS Medical College and Hospital Gotri, Vadodara and getting a certificate from IHEC.
5. We will do necessary changes in our study protocol as per the suggestions given by respected IHEC members during meeting before getting approval letter and bound to submit the changes to IHEC. We will obtain approval from the IHEC GMERS Medical College and Hospital Gotri, Vadodara, before making any significant changes in this study. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
6. We will do our study according to ICH-GCP guidelines and maintain all the study related records. Whenever asked, we are bound to produce to IHEC GMERS Medical College and Hospital Gotri, Vadodara.
7. We will report adverse drug reaction to Pharmacovigilance Cell & IHEC whenever, we come across the adverse drug reaction while doing research work. (If Applicable)
8. We certify that, we will follow the recommendations of IHEC and Govt. of Gujarat rules and regulation issued from time to time.
9. We certify that, record of all premature termination of a study with a summary of the reasons/final report after completion of the study including microfilms, CDs and Video recordings, will submit to the IHEC GMERS Medical College and Hospital Gotri, Vadodara.

Name, Signature & Date of All Investigators