GUIDELINES FOR SUBMISSION OF CLINICAL/DRUG TRIAL PROTOCOL INVOLVING RESEARCH IN HUMAN PARTICIPANTS FOR CLEARANCE BY INSTITUTIONAL REVIEW BOARD OF GMC, SURAT

Submit fourteen (14) copies of the Research Project along with Covering letter to the Chairman/Member Secretary, Human Research Ethics Committee from the Departmental log-in through GMC Surat website. **The documents should also be submitted in a soft copy in word and pdf formats as specified online from GMCS website.**

1. Covering letter (through the Head of Department)
2. Undertakings as specified
3. All relevant Permissions –MS, Dean, Collaborator, Resource site, Higher authority
4. Duly filled format of Ethics Committee
5. Hard Copy of the Research Protocol
6. All relevant Participant Information Sheets in Gujarati, English and Hindi
7. All relevant Participant Informed Consent Forms in Gujarati, English and Hindi
8. Detailed budget
9. CTRI registration number and details
10. Permission from Drug Controller General of India (DCGI)
11. Insurance Policy with extent of coverage and validity period
12. Any other relevant annexures

The Principal Investigator must submit protocol **ONLINE** and in Hard Copy who ensures that the project has been wetted both from the scientific and ethical point of view. The link for the submission is given on GMCS website. It also has a link for the help and guideline for the submission process.

No Clinical Trial shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to Clinical Trials which were neither submitted nor wetted by the Institution Ethics Committee.

**Protocol Submission:** All the necessary documents and letters to be prepared for submission are given on College website as ready formats. Please use those formats to fill in your specific details before taking a print out. Covering letter, Undertakings, Permissions, Registration at CTRI and Insurance Policy are administrative and ethics committee requirements. Your research protocol is the main document, which needs to be written with all the numbered headings. If not applicable for your research, you can write as NA or NOT APPLICABLE. Proformas, scales, questionnaires or assessment tools must be attached, and if copyrighted, their permissions must be obtained prior to use. The submission must be accompanied with *Participant Informed Consent Form* (PICF)and *Participant Information Sheet* (PIS), in English as well as Gujarati and Hindi if required, **in a simple layman’s language in a narrative form, directed to Participant /LAR, covering all the points given on the website of ICMR (Link available on GMCS website).**  Also ensure that all the pages of the protocol are numbered. The Clinical Trial must be registered at CTRI and permission from DCGI must be attached.

**Review Process:** Submissions will be received on all days. SRC/EC reviewers will be reviewing the protocol in 30 working days. Proposals received will be processed in the coming monthly Ethics Committee after it has been duly cleared by the Scientific Review Committee (SRC). HREC can process only 15 protocols at the last in-person meeting, which will be taken on first come first served basis.

**Resubmission with Reply:** While submitting replies to queries/issues raised by the Ethics Committee/Scientific Review Committee, the PI is advised to upload corrected copy of the changed document in the relevant tabs. Review comments must be acted upon in 3 working days if minor and 7 working days if major. All changes must be done in liaison with the sponsors.

**Amendment Submission:** While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.