GUIDELINES FOR SUBMISSION OF PROTOCOL INVOLVING RESEARCH IN HUMAN PARTICIPANTS FOR CLEARANCE BY INSTITUTIONAL REVIEW BOARD OF GMC, SURAT FOR MCh / MD / MS / MBBS / PhD STUDENTS (FOR THESIS OR DISSERTATION) OR ANY OTHER RESEARCH PROJECT

Submit **ONE** (1) copy of the all documents 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. Departmental Protocol discussion meeting minutes – dated and signed
5. Duly filled Title page of Protocol with signatures of student and guide/co-guides
6. Protocol in the format of HREC, GMCS
7. Proforma and Assessment tools/ scales/ questionnaires
8. Participant Information Sheet in English (must), Gujarati and Hindi (where required)
9. Participant Informed Consent Form in English (must), Gujarati and Hindi (where required)
10. References: at least 2 main relevant National and International references
11. Budget (if applicable)
12. Any other relevant Annexures

The Investigator must submit protocol **ONLINE** through PG Guide and Head of Department 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 thesis work shall be / can be started unless ethics approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the 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 and Departmental meeting minutes 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.

**Review Process:** Submissions will be received on all days. SRC/EC reviewers will be reviewing the protocol in 10 working days. Proposals received will be processed in the coming 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 candidates are advised to upload corrected copy of the changed document in the relevant tab. Review comments must be acted upon in 3 working days if minor and 7 working days if major. All changes must be done under the guidance of the PG Guide.

**It is desirable that topics pertaining to Interventional clinical/drug trials/RCT should be avoided as research topics to D.M./ M.Ch. / MD / MS and MBBS students.**