FORMAT FOR SUBMISSION OF RESEARCH PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY SCIENTIFIC REVIEW COMMITTEE/INSTITUTIONAL ETHICS COMMITTEE OF GMERS MEDICAL COLLEGE & HOSPITAL, VADNAGAR

- All the research projects shall be / can be started following ethics clearance/approval only. No retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

- An original hard copy of the research proposal and a photocopy of the same along with covering letter addressed to Member Secretary (SRC/IEC-HR, GMERS Medical College, Vadnagar) have to be submitted. The hard copy should be typed using both sides of A4 size paper, in 11 font size with 1.5 spacing and page numbering.

- Scanned copy of the proposal (with all required signatures) in ".pdf format" and Microsoft word file of the proposal in ".docx format" (2 attachments) should be mailed to iechrvadmed@gmail.com with subject as "Submission of Initial / Revised proposal by <<Name of Principal Investigator>> for First Scientific Review Committee (SRC) meeting on DD/MM/YYYY". Ensure that all the pages are numbered.

- The proposals submitted beyond the last date of submission will be taken up for the next meeting.

- Research proposals deviating from the format will not be accepted. No subsequent modification of the proposals will be accepted unless specified by the SRC/IEC.

- Only citing and listing of references as per ICMJE (International Committee of Medical Journal Editors) style will be accepted.

- Only the proposals approved by Scientific Review Committee shall be considered for the approval in subsequent IEC-HR meeting.

- All submissions should be made in the prescribed Format of the Institution Ethics Committee with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), in English, Gujarati and Hindi, in a simple layman's language, in a narrative form, directed to Participant, covering all the points, before it can be considered for placing before the Institution Ethics Committee.

- 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.

- The research projects / proposal submitted should be as follows:

GMERSMCH, VADNAGAR

Performa to be submitted to the Institutional Ethics Committee (Human Research), GMERSMC, VADNAGAR (For MD / MS / Ph.D (Thesis or Dissertation) / MBBS student / Faculty projects)

IEC(HR)/SRC Form:

For Office use only	
Inward No. VADMED/SRC/IEC(HR)/IN/	
Date	
Type of proposal	Research Project/ Dissertation
Sign of Member Secretary	

1. Full Title of Study:			
2. Names of Investigators / coinvestigators with designation and departments (Please write the details of Principle Investigator first)	Signatures	Contact Number	Email ID
2.1			
2.2			
2.3			
2.4			
2.5			
2.6			
3. Name of Guide (If Applicable)	Signatures	Contact Number	Email ID
3.1			
4. Proposal	☐ Research Project	☐ Dissertation/ Thesis	
4. Aim/Objectives of the study			
4. Introduction / Background / Rationale (250 words)			
5. Methodology			
5.1 Number of Patients/Subjects/Participants			
5.2 Inclusion Criteria			
5.3. Exclusion criteria			
5.4. Control(s)			

GMERSMCH, VADNAGAR

5.5. Study design	
5.6. Data Collection Method / Tool (Setting / Periodicity)	
5.7. Whether permission of Head of Department/Institute taken for data collection	1. Yes 2. No
5.8. Type of Data (Tick the appropriate)	1. Quantitative 2. Qualitative 3. Both
5.9. Duration of Study	
5.10. Investigation specifically related to projects	
5.11. Permission to use copyrighted Questionnaire/ proforma	
5.12. Demographic Variables to be studied	
5.13. Research Variables to be studied	
5.14. Analysis Required	1. Descriptive 2. Inferential
5.15. Others	
6. Permission from Drug Controller General of India (DCGI)	1. Required 2. Not required 3. Received 4. Applied when:
7. Permission from DGFT if applicable	1. Required 2. Not required 3. Received 4. Applied when:
8. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human	
9. Plans to withdraw standard therapy during conduct of research	1. Yes 2. No
10. Plan for provision of coverage for medical risk (s) during the study period	
11. How you will maintain confidentiality of subject?	
12. **Total Budget (Approx. in Rs.)** Who will bear the cost of investigation / implants drugs / contrasts? (Provide details as a separate annexure)	
12.1 Funding Agency	
13. Participant Information Sheet	1. Attached English version 2. Attached Gujarati version 3. Attached Hindi version

GMERSMCH, VADNAGAR

(mark √ if yes)	*(Certified that Hindi/Gujarati version is a true translation of English version)*
14. Participant Informed Consent Form *(mark √ if yes)*	1. Attached English version 2. Attached Gujarati version 3. Attached Hindi version *(Certified that Hindi/Gujarati version is a true translation of English version)*
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief)	
16. Whether any work on this project has started or not?	1. Yes 2. No
17.Attached documents	17.1 Covering letter, through proper channel. 17.2 Copy of the detailed protocol is mandatory. 17.3 Brief CV of Investigators (including No. of projects with Principal Investigator) 17.4 Investigator's Brochure 17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines 17.6 In case of multicentric study, IEC clearance of other centres must be provided 17.7 Definite undertaking as to who will bear the expenditure of injury related to the project 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines) 17.9 Permission as mentioned in point 5.10 17.10 Certificate/undertaking as mentioned in point 6 & 7 17.11 Investigator should provide undertaking what they will do with the leftover sample tissue 17.12 Details of Total Budget mentioned in point 12 17.13 Any other
To be decided by IECSRC Subcommittee	
Risk & Benefits of Research	
a. Risks	
b. Benefits	
Ethical Issues (enlist)	
Level of Risk (Encircle the appropriate)	1. < MR 2. = MR 3. > MR 4. >> MR

Self-Declaration: I/We undersigned investigator(s), am/are abide by relevant law of the land and exiting ICMR guidelines for biomedical research involving human participants. I give assurance that the same data have not been used for the same or related topic(s) previously.

Date:

_____ _____ _____

Signature of Principle Investigator Signature of Guide (If applicable) Signature of Head of Department

GMERS-MCH, VADNAGAR