GMERS MEDICAL COLLEGE, PANCHMAHAL GODHRA

GOVERNMENT ENGINEERING COLLEGE CAMPUS, CHABANPUR
LUNAWADA ROAD, GODHRA, PANCHMAHAL, GUJARAT
Email: dean.health.panchmahal@gmail.Com
Letter of permission: No. NMC/UG/2022/000222 dt 18.08.2022

Guidelines for Initiating a Research Project at GMERS Medical College Panchmahal Godhra

Submission of Proposal

The Principal Investigator (PI) must submit the clinical research proposal to the Member Secretary of the Scientific Research Committee at GMERS Medical College Panchmahal Godhra via email (src.gmersmcpg@gmail.com). This submission should include:

1. **Application for Approval**: Complete the prescribed format (Annexure 1) in soft copy. The signature page must be printed, signed by the Head of Department (HOD) and all investigators, scanned, and attached to the protocol's soft copy.
2. **Investigator Undertaking**: Complete the prescribed format (Annexure 2) in soft copy, print, sign, and attach the scanned signature page.
3. **Protocol Template**: Follow the provided **protocol template** without deleting any headings. If a section does not apply, indicate "**NOT APPLICABLE**."
4. **No Physical Copy Required**: Submit only a soft copy of the protocol with the application and undertaking via email.

Protocol Template Content:

- Title of the Study
- Background/Introduction (up to 1500 words with relevant references)
- Aims and Objectives
- Materials and Methods, including:
    - Study Design
    - Study Population and Subjects
    - Inclusion and Exclusion Criteria
    - Sample Size and Randomization Details
    - Blinding Procedures
    - Data Collection Methods
    - Statistical Analysis Plan
    - Operational Definitions
    - References
    - Proposed Deadlines

Ethical Justification:

Include specific ethical challenges and measures to address them in your protocol. Adhere to guidelines from ICMR (2017) and the Helsinki Declaration (2000). Ensure informed consent and respect for participant's privacy and confidentiality.

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Presentation in Scientific Committee

Submit a PowerPoint presentation (max. 10 slides) of the research proposal to src.gmersmcpg@gmail.com before the submission deadline. Include:

- Project Title and Investigator Details
- Aims and Objectives
- Brief Methodology
- Study Design and Population
- Inclusion/Exclusion Criteria
- Sample Size and Randomization Details
- Case Record Form (CRF) Proforma
- Ethical Considerations
- Risks and Benefits
- Subject Selection Procedures

The PI or a Co-investigator must present the proposal at the scheduled Scientific Research Committee (SRC) meeting.

Forwarding Approved Proposals

Projects approved by Scientific Research Committee are forwarded to the Institutional Ethical Committee (IEC) for further approval.

Presentation in Institutional Ethics Committee (IEC)

Revise the proposal per SRC amendments and submit it via same email. Present the revised proposal at the IEC meeting. Highlight any edits in the PowerPoint presentation submitted two days prior to the IEC meeting.

IEC Approval

The IEC will issue an approval letter within 15 days of the IEC meeting. Only upon receipt of this letter can the PI commence the clinical research.

Completion Notification

Upon study completion, notify the IEC in writing or via email (src.gmersmcpg@gmail.com).

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Annexure 1: Application for Approval

Submit a duly filled application to the Member Secretary of SRC/IEC at GMERS Medical College. Ensure all required signatures and details are provided.

N.B.: Application should be duly filled; INCOMPLET APPLICATIONS WILL BE REJECTED

To,
The Member Secretary,
SRC/Institutional ethical committee
GMERS Medical College, Panchmahal, Godhra.

Sir,

I/We herewith submit a research proposal for approval by the Institutional ethical committee, GMERS Medical College, Panchmahal, Godhra and request you to do the needful for the same. The details of the projects are as follows:

1. Nature of submitted proposal: Clinical Research/Dissertation
2. Title of the research project :
3. Name and designation of principal investigator/s (Name of PG student in case of Dissertation):
4. Name and designation of investigator/s responsible to comply in the absence of PI :
5. Name and Designation of Co-investigators (Name of PG teacher in case of Dissertation):
6. Whether the project is approved by the funding agency : Yes/Pending
   (If yes, please attach a copy of the sanction letter or provide it as and when available)
7. Is it a collaborative study? Yes/No. If yes, please provide name and address of co-sponsoring agency with name and address of the person responsible for the work.
8. Any specific remarks for Ethics Committee:

I have noted all above mentioned points and all the information is true to the best of my knowledge and belief.

Signature of Principal Investigator/PG student (for PG dissertation) :

Signature of the co-Investigator/PG teacher:

Signature of the HOD:

Date : **Place:**

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Annexure 2: Investigator Details

Provide detailed information about the Principal Investigator and Co-investigators, including contact details and medical council registration numbers.

Title of the project:

Detail of Principal investigator:

Name:

Designation:

Affiliation:

Medical council registration number (additional registration if working as specialist)

Contact Number:

Email id:

(Note: in case of multi-centric study or collaborative study mention name of PI from all the sites with their designation and qualification. In case of multicentric or collaborative study short CV of investigators from other site with no objection certificate from their respective head of institute is necessary at the time of submission of proposal to SRC).

Details of Co-Investigators (PG guide in case of PG dissertation)

Name:

Designation:

Affiliation:

Medical council registration number (additional registration if working as specialist)

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Annexure 3: Informed Consent Form

Include a template for obtaining informed consent from participants, ensuring all ethical guidelines are followed.

Sample of Informed consent form

I, Mr./Ms._____aged :_____ years, mother/father/guardian of _____Bearing Registration number: have beeninformed that_____ _____has been enrolled in the above mentioned research project. If needed, I shall be required to provide –_ml of blood & / or _____ sample during diagnostic/treatment procedures and for further follow-up intensive research. I am fully explained the procedure and probable effects and results of the above research project by the doctors concerned. I hereby of my own free will and give consent for the same.

Signature of the Participant: Signature of the Witness:

Signature of Doctor:

Date : Place :

N.B: To be used as a sample only; submission of this same format will render the concerned proposal rejected.