

**INSTITUTIONAL ETHICS COMMITTEE
GULBARGA INSTITUTE OF MEDICAL SCIENCES
KALABURAGI.**

(Autonomous Medical Institution , Government of Karnataka)

**STANDARD OPERATING
PROCEDURES**

**INITIAL RESEARCH STUDY PROPOSAL
PROCEDURES**



All proposals should be submitted on any working day three weeks in advance of scheduled meeting. Copy of SOP of GIMS IEC will be given to PI / Co-PI if he/she has applied for review for the 1st time. All relevant documents should be enclosed with application form.

Required number of copies (**5 copies**) of the proposal along with the application and documents in **prescribed format** duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators / Research Scholars shall be guided to the Chairperson GIMS IEC, through member secretary. In his absence via any person nominated by chairperson. Receipt of the application will be acknowledged by the IEC office.

All research proposals/clinical trials funded/sponsored by Pharmaceutical companies/ Agencies/ Multinationals etc. will be charged an administrative fee/ processing fee of ***Rupees Twenty Five Thousand for fresh proposals and Rupees Twenty Five Thousand for annual follow-ups/renewal review proposals.***

All non funded/ funded (funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc) research proposals by Undergraduate students are charged an administrative fee/ processing fee of ***Rupees One Thousand for fresh proposals.*** Post graduate students and staffs of GIMS, Kalaburagi are charged an administrative fee/ processing fee of ***Rupees One Thousand five hundred for fresh proposals.***

Waiver of these fees is permissible for Post Graduate Synopsis of RGUHS and Under Graduate Students of GIMS, Kalaburagi for ICMR-STS projects. **Waiver of fees is at the discretion of Chairman-IEC and Member secretary-IEC, GIMS, Kalaburagi.**

Method of payment: The payment will be taken by cash or can be paid by cheque drawn in favour of “ **Director, Gulbarga Institute of Medical sciences**”. The review fee for pharmaceutical and government sponsored study will always be accepted through cheque.

Required documents submitted for Research Proposal:

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Institution / Guide.
6. Protocol of the proposed research:
 - Research objectives,
 - Rationale for undertaking the investigations in human participants in the light of existing knowledge
 - Brief review of literature which include all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available and usefulness of the project / trial
 - Precise description of methodology of the proposed research, including
 - Inclusion and exclusion criteria for entry of participants,
 - Sample size (with justification),
 - Type of study design (observational, experimental, pilot, randomized, blinded etc.)
 - Intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any,
 - Plan to withdraw or withhold standard therapies in the course of research.
 - Plan for statistical analysis of the study.
 - Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant enclosures like
 - Proforma,
 - Case report forms,
 - Questionnaires,
 - Informed consent process, including patient information sheet and informed consent form in english and local language(s).
 - Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.
 - Source of funding and financial requirements for the project.

Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period.

Resubmission of study with corrections as per IEC suggestions

- For resubmission- the PI will submit 3 copies of the amended study related documents along with justification for amendment or modification, and clearly highlighted/demarcated sections which have undergone change
- The IEC Secretariat will verify the completeness and reconfirm that the copies contains the modification highlighted with respect to the earlier submission
- The IEC Secretariat will perform the analysis. The unchanged study related documents need not be submitted.