Application procedures and Review

1. For initial review of study, the Principal investigator will require to submit 1 hard and 1 soft copy (email: iec@pimsj.com) of the Research Project along with all study related documents as specified in Annexure 5, 6, 10, 11 to the Members Secretary, Institutional Ethics Committee at least 14 days before the next scheduled meeting. The Principle Investigator (PI) must submit protocol (duly signed by all the Investigators) through Head of Department.
2. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.
3. If revision is to be made, hardcopy of revised protocol must be submitted with corrections as per IEC suggestions clearly highlighting changed sections along with required documents within 10 days of meeting.
4. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of total budget.
5. All non sponsored research proposal from within the institute will be charged 1000 Rs per project
6. All non sponsored research proposals from outside the institute will be charged 3000 Rs per project.
7. Waiver of the fees is permissible for studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc.

8. No research project will be allowed to start unless IEC clearance is obtained. No retrospective/ post facto ethical clearance can be provided to research projects.

Communicating the decision

- Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified format.

Follow up procedures for approved proposals by PI / Sponsor

- IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
- Progress of all the research proposals will be followed at a regular interval of at least quarterly or midway in project. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
- Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents (as specified in Annexure 9) based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
- Final report should be submitted at the end of study. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary/ Publication of study completed from the applicant.
- Following instances and events will require the follow-up review/ Renewed Approval (Annexure 7,8)

- Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
- Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority (Annexure 12).
- Any event or information that may affect the benefit/risk ratio of the study.
    - ✓ Protocol deviation, if any, should be informed with adequate justifications.
    - ✓ Any new information related to the study should be communicated.
    - ✓ Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
    - ✓ Change of investigators/sites must be informed to the office of IEC.
    - ✓ Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project.