ETHICAL REVIEW COMMITTEE

HMC/KGMC

The institutional review board of KGMC primarily protects the rights, safety and wellbeing of human subjects involved in biomedical research. It foresees the risks involved in conducting any biomedical research. In addition, it safeguards the clinical trial subjects to meet the International Conference on Harmonization of Good Clinical Practice.

Terms of Reference of Ethical Committee

- To prepare, monitor, and review the MTI KGMC/HMC ethics policy concerning ethical issues which may arise from teaching and research activities within the KGMC and its allied institutes to ensure they are in line with international ethical standards
- To provide advice and make recommendations to Research Advisory Board to respond to the emergence of ethical issues (external or internal).
- To scrutinize each research proposal for ethical rights of patients and institutional esteem before conduction
- To review and monitor ethical issues associated with undergraduate and postgraduate research projects and staff research
- Ensure compliance with the set standards during the research conduction process at all levels.
- To advise on any issues of an ethical nature referred to it by the Dean, faculty, or any department

- To receive and evaluate relevant papers/manuscripts from external bodies for ethical consideration under the set standards of MTI HMC/KGMC.
- To strive for the accreditation of the institutional board with the national regulatory authority, drug regulatory authority
- To provide guidance and training to faculty and students on ethical principles/issues to ensure that research is undertaken in accordance with the ethical Policies.
- Adhering to agreed arrangements, with adequate consent and privacy safeguards, on time after the research has finished

Membership

- Chairman
- Layman from society
- Legal person
- Social worker
- Religious Scholar
- Two medical specialists
- Two surgical specialists
- Tow faculty members from basic sciences
- Student representative
- Nursing representative

GUIDELINES

- Educational research, testing and survey procedures where no identifying information will be recorded that can link subjects to the data and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation. Such results must be subjected to inform written consent
- Every medical research project involving human subjects should be preceded by a careful assessment of predictable risks and burdens compared to foreseeable benefits to the subject or others.
- The human subjects in your project must participate willingly, having been informed about the research. Therefore, provide all information likely to affect the person irrespective of age, sex, or literacy level of the subjects. For example, suppose the human subjects in your research are part of a vulnerable population, such as prisoners, children or the mentally disabled. In that case, the researcher should clearly state why it is necessary to have such groups as their

research subjects and how they plan to administer the informed consent.

- The informed consent is taken from the research subject directly
- The information gathered is relevant/beneficial to the research subject and their community.
- The proposal includes plans to share study findings with the research subject/s and the relevant communities.
- Analysis of data, documents, and specimens not linked to individual subjects.
- Evaluation studies of intervention programs/projects, especially by those partners in planning the intervention.
- All researchers must give the subject participants the option of sharing the results and specify how this will be done.

Frequency of Meeting

Every fortnight

Reporting Structure

The ethical committee will submit the report to the office of Associate Dean Research quarterly

List of documents to be submitted to an ethical committee for review

1. Clinical trial protocol
2. Informed consent
3. Patient recruitment procedure
4. Study subjects' information
5. Clinical trial agreement
6. ASRB approval
7. Co-opted member (as when required/invited)

Quoracy

The Ethics Committee is considered quorate when at least 50% of members are present.