INSTITUTIONAL ETHICS COMMITTEE (IEC)

GUIDELINES FOR INVESTIGATORS

1. All the studies qualifying as 'clinical research' need to be submitted for the Ethics Committees permission. Any study involving direct or indirect participation of healthy human volunteers/patients or their data qualifies as clinical research.

2. Proposals for all the interventional as well as observational clinical/preclinical studies as well as community based studies proposed by the students and/or faculties of GMERS medical college, Gandhinagar as well as studies conducted in the civil hospital and/or GMERS medical college, Gandhinagar by students and/or faculties of other institutes should be submitted to the ethical committee for its approval before initiation of study.

3. Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy [ICH-GCP]) should be registered with the Clinical Trial Registry of India or any other WHO platform registry and a copy of the documentation of registration should be provided at the time of submission of a new study proposal for review.

4. For clinical study planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2006 guidelines.

5. Submission of Report of Protocol Deviations/ Violations in the study protocol, please use the protocol Deviation / Non-Compliance / Violation Record Annexure 24 for submitting report of Protocol Deviations/ Non-Compliance / Violations.

6. Submission of Report of Serious Adverse Events (SAEs) All Serious Adverse Events (SAEs) at our site occurring during the study should be submitted to the IEC within 7 working days of their occurrence. If the SAE is 'death', it should be reported to the IEC within 24 hours of its occurrence via an e-mail.

7. Any new information that may adversely affect the safety of the subjects or conduct of the trial should be informed to the IEC.

8. For studies which will continue for more than a year, a continuing review report need to be submitted for review

9. Once a study is over:
    - Submission of Study Completion Report: For studies which are completed within the

IEC approval period, a study completion report as per the format given in should be submitted to the IEC, by the investigator. The study completion report is expected for review within 1 month of completion of the study at the site. A brief study report containing data analysis from all centers should be submitted once available from the sponsor.

- In case a study is not initiated or terminated, the same should be communicated to the IEC stating reasons for the same.
- The IEC archives all the study related documents for a period of 3 years after the study is completed / terminated/ reported as not initiated at our site. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same using the form1- Document Request Form *Annexure 31*

Appendix I: Regulatory permissions

- **DCGI approval:** Studies which plan to use a "new drug" (as defined in section 122-E of the Drugs and Cosmetics Act, 1945) require DCGI permission. According to section 122-E any drug is considered as "new drug" if-
  Any new drug which has not been approved before by DCGI for safe and effective use for the given condition OR already approved drug but with modified indication/dosage/dosage form/route of administration OR a fixed dose combination of two or more drugs which are individually approved earlier for certain claims but which are now proposed to be combined for the first time in a fixed ratio OR already approved fixed dose combination but ratio of individual drugs in fixed dose combination is changed or indication/dosage/dosage form/ route of administration has been changed.
  For such studies, a copy of the permission letter issued by the DCGI to the pharmaceutical company/investigator also needs to be submitted to the IEC. If the DCGI permission is awaited, a letter of conditional approval will be given by the IEC and the final IEC approval will be given after a copy of DCGI permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.
- **Director General of Foreign Trade (DGFT)** approval in case study samples are to be sent abroad for analysis
- **FDA marketing/manufacturing license** for Ayurvedic/ herbal formulations/ nutraceutics Health Ministry Screening Committee (**HMSC**) **approval** in case a study involves collaboration with any foreign laboratory/clinic/institution
- Bhabha Atomic Research Centre **(BARC) approval** in case a study involves use of radioisotopes/ ionizing radiations
- Genetic Engineering Advisory Committee **(GEAC) approval** in case a study involves use of gene therapy
- **Administrative sanction** from the Dean of the Institution should be sought by investigators for studies involving collaboration with other Indian or foreign Laboratory/ Clinic/ Institution.

Submission of Projects for IEC Review (IEC procedure plan)