Annexure 7

AX 07/SOP 05-A/V7.1

Guidelines for Investigators

1. All the studies satisfying the following definitions as per NDCT Rules 2019 need to be submitted for the Institutional Ethics Committees review:
   - Clinical Trial: (Regulatory trial).
   - Academic clinical trial
   - Bio medical and health research (Non-regulatory trial).

   As per the above definitions an Investigator planning to conduct a research study involving human participants; **funded by Government agencies and Pharmaceutical companies** at Seth G.S. Medical College & K.E.M. Hospital will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.
   Research studies which are undertaken as **dissertation projects** (postgraduate students: MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), **research projects of undergraduate students** (Indian Council for Medical research studentship) and **investigator initiated** research studies which are **self funded / intra or extra mural funded** will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.

2. Those research protocols which fulfill the definition of clinical trial and academic clinical trial as per NDCT Rules 2019 (GSR 227-E) will be managed by the committee/s registered with CLA (IEC-I).

3. Those research protocols which fulfill the definition of Biomedical and Health Research as per GSR 227-E will be managed by the committee registered with DHR (IEC-II & IEC-III).

4. Criteria for Principal investigator of regulatory and non regulatory trials:

   - **Criteria for Principal Investigator (PI) of regulatory and academic clinical trials:**

   Principal Investigator for regulatory studies **will ALWAYS be regular/permanent faculty** of Seth GSMC & KEMH and have relevant qualification approved by Maharashtra Medical Council (except in case as mentioned below).

   Principal investigator (**regular/permanent faculty** of Seth GSMC & KEMH) will have **ONLY** eight (8) regulatory trials approved by the IEC as PI and **ONLY** eight (8) regulatory trials approved by the IEC as Co-I.

   With regards to exceeding this cap (applicable **ONLY for PI belonging to super specialty departments)**, contractual faculty may be made the PI as per clauses stated below:

   - should have completed ONE YEAR of service in this institute and this needs to be endorsed in writing by the HOD.
   - HOD / regular/permanent faculty will be the CO-PI for such projects to support the contractual faculty working as PI for the given regulatory study.
   - HOD / regular/permanent faculty to provide an undertaking stating that if the contractual faculty who is working as PI of the regulatory study leaves the institute then the regulatory study will be taken up by the HOD / regular/permanent faculty as PI.

- Duly signed undertaking from the contractual faculty which is forwarded or countersigned by permanent faculty stating that if he/she leaves the institute he/she ceases to be the PI of the project and the project cannot be transferred outside the institute.
- The contractual faculty of super specialty department can have **ONLY** four (4) regulatory trials approved by IEC as PI and **ONLY** four (4) regulatory trials approved by the IEC as Co-I.

Responsibility of the Principal Investigator (PI): In regard to clinical research trials (regulatory trials and academic clinical trials), if an IEC approved affiliated study team member leaves the institute (anybody who resigns from KEMH, is transferred out of KEMH, or is affiliated to KEMH in some way but not on regular biometric attendance system or death of the study team member) he/she ceases to be part of the trial.
It is the responsibility of the Principal Investigator (PI) to ensure that the said person is removed from duty delegation log with immediate effect. This is to be informed to the sponsor (if applicable) and IEC. IEC will review and accord approval for the revised duty delegation. The last working day would be the end date in the duty delegation log.
All PIs should make appropriate changes in departmental clinical research SOPs pertaining to the above matter.

In case the PI leaves the department, It is duty of Head of the Department / Institution to remove the concern person's name from duty delegation log with immediate effect. If the PI is not head of the department, an undertaking from HOD would be taken. The same needs to be notified to Head of the Institution by PI and Head of the Department. IEC would like to ensure that at no point of time any trial participant is unsupervised by the study team/ Department.

- **Criteria for Principal Investigator (PI) of non-regulatory trials:**

Principal Investigator for other studies/ non-regulatory studies can be regular / permanent faculty, Emeritus professor, or contractual faculty of Seth GSMC & KEMH. If the Principal investigator is an Emeritus professor or a contractual faculty of Seth GSMC & KEMH, then the Co-Principal Investigator or Co-Investigator HAS to be a regular / permanent faculty of Seth GSMC & KEMH and who will be responsible for the study oversight.

a. For resident / post graduate students, Ph.D students, MSc students, nursing students, M.Sc. Pharma Medicine (MUHS) projects, PI will be his / her guide / teacher and should be a permanent faculty of Seth GSMC & KEMH.

b. Thesis / Dissertation of Wadia Maternity and Paediatrics
Faculty from the Wadia hospital are also considered as faculty **from** Seth GSMC & KEMH. Hence faculties from Wadia can be PI for the thesis submitted by the postgraduate students of Wadia hospital, however the recruitment of patient should be from only Wadia and not from the Seth GSMC & KEMH. For dissertations from BJJWHC must be forwarded by HOD (Pediatrics) Seth GSMC.

c. For collaborative studies with NIRRH, NIIH, TMH, IIT Bombay or for studies of nursing students from the colleges other than GSMC & KEMH, PI should be a regular / permanent faculty from Seth GSMC& KEMH.

d. If request received 'to become a Principal Investigator' by contractual Assistant Professors (speciality / super speciality)

e. IEC will accept the research proposals with less than minimal risk projects /retrospective/web based study/audits with contractual Assistant Professors as PI and in each protocol will need a permanent faculty as a co-investigator. It was by consensus decided that the contractual Assistant Professors should be allowed to be PI for such studies by all six members Hence the Board will have to revise the SOP as per the change.

- **Case report and Case series should be submitted by the faculty** (as per criteria for Principal Investigator mentioned above) **of Seth GSMC & KEMH only.**

For all types of studies and for both permanent and contractual faculty as PI or Co-I to note that the study belongs to the institution and will stay with the institution whenever the contractual or permanent faculty leaves the institution. When the permanent or contractual faculty as PI or Co-I leaves the institute he / she ceases to be PI or Co-I in the project.

5. **Location and Office Address:**
   Institutional Ethics Committee (IEC),
   New UG/PG Hostel, 20 Storey hostel building, ground floor, KEM Hospital Campus, near main boy's hostel, Parel, Mumbai 400 012. Telephone no. (GSMC and KEMH): 91 22 410 7000 Ext. 7515, 24107515, 24122188, Email: iec-1@kem.edu iec-2@kem.edu and iec-3@kem.edu
   The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC staff are as follows:
   Monday to Friday - 1.30 p.m. to 4.30 p.m.
   Saturday - 10.30 a.m. to 01.00 p.m.
   The office will remain closed on Sundays, all public holidays and last working day of every month.

6. There will be no meetings held in the month of May and November (during college vacations) except during emergency and epidemics/pandemics. In case a meeting is to be held during vacation due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.

7. The clinical trial (Any investigation in human research participants 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]) must be registered with the Clinical Trial Registry of India (CTRI) or any other WHO platform registry and a copy of the documentation of registration must be provided at the time of submission of a new study proposal for review.

8. General responsibilities of PI and Co-PI
   - **MMC/State Medical Registration council:**
     Investigators involved in the trial are competent having a valid medical degree registered with the Medical Council of India (MCI) / State Medical Council or a dental degree registered with the Dental Council of India / State Dental Councils or OTPT COUNCIL
   - **Updated and signed CVs:**
     Investigators responsible for conduct of clinical trials are adequately qualified, experience.
   - **GCP:**
     Investigators should have knowledge about clinical trial process, ethical issue and applicable rules and regulation ensuring data integrity and protection of subject rights, safety and wellbeing.

Investigators should be GCP trained regularly at the interval of three years and GCP training certificate should be provided to the IEC at the time of submission of a new study proposal / prior to initiation as applicable.

- **SOPs of IECs:**
  Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention, archival and destruction.
- **Trial site specific SOPs for regulatory studies:**
  Investigator should prepare site specific SOPs which should be approved by the IEC and one copy should be handed over to the IEC for its records. Site specific SOPs should also cover the following elements related to the conduct of the clinical trial.
  - Updated investigators Brochure and clinical trial oversight plan
  - Work delegation log signed by the PI
  - SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
  - Clinical trial site shall have a policy of investigators handling over the trial case he /she to leave investigator will continue to be responsible for the trial until such time another investigator takes over the trial. Authorized person from the site shall communicate with the sponsor and ethics committee if needed. There should be back up research staff to ensure that recruited subject's rights safety and wellbeing is not compromised.

9. The IEC is currently following version 7.1 dated 09th April 2026 of the Standard Operating Procedures (SOPs), which are individual activity based and are 25 in number. The updated SOPs are available at our website **www.kem.edu- Department – Committees and Societies - Institutional Ethics committee**

10. Project proposals submitted **on or before 20th of every month will** be taken up for discussion at the next month's IEC meeting. All proposals (all documents need to be typed on A4 size paper) need to be submitted as soft copy and one hard copy set (sponsored study preferably filed in Box File & non sponsored study in card board file) documents appropriately labelled and arranged in the file in orderly manner. The list of documents to be submitted as per SOP5-A Section 5.3.1. Incompletely filled forms / forms without signatures / proposals will not be accepted and same will be conveyed to the PI.

11. The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the Indian Council for Medical research 2017 Guidelines. The section should include the following aspects:
    - A statement saying that the study will be conducted in adherence to relevant national/international laws.
    - Policy regarding autonomy (voluntariness, right to withdraw).
    - Confidentiality
    - Recruitment policy ensuring equitable enrollment.
    - Protection of vulnerable participants.
    - Process of obtaining informed consent.
    - Policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.
    - Policy regarding dissemination of data, presentation of data, publication.

12. **Decision on type of review:**
    Member secretary will review the protocol and related documents and will take the decision regarding the type of the review required for the particular protocol as follows:
    - Full Board Review (refer SOP 05-B)
    - Expedited Review (refer SOP 05-C)
    - Exempt from Review (refer SOP 05-D)

    Note: For management of initial protocol submission during epidemics/lockdown periods refer to SOP 22/V7.1

13. An investigator may refer to the SOP. No. 19 for 'Request for Waiver of Written Informed Consent' whenever necessary.
14. An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable *AX 10/SOP 05-A/*V7*.1*

15. **The processing fees Details:**
    Institutional Ethics Committee (IEC)shall charge an application fee for review of research projects. The Institute shall not charge an EC application fee.

    15.1) **Fee Structure:**
    - The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
    - Payment should be done to DJST's Bank of Maharashtra only. DJST has strictly prohibited IEC transactions to their SBI account.
    - The protocol review processing fees for all types of studies will always be accepted through cheque / online.
    - If any transaction made by mistake to SBI, IEC will not be responsible for consequences.
    - No cash payment will be entertained. Don't pay cash via bank also.
    - For non-sponsored projects, detailed screen shot for payment details need to submitted to IEC and if required to DJST for cross verification (transaction ID/Reference no. etc.)
    - Transaction details (screen shot)
    - The protocol review processing fees of all types of projects will be taken by online only through following details:

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	60236880148
Account Type:	Saving
Name of Bank:	Bank of Maharashtra, Branch Parel
Add of Bank:	Vikas Apartment, Dr. Ambedkar Road, Parel, Mumbai, 400012.
IFSC Code:	MAHB0000079
MICR Code:	400014011
PAN No:	AABTS5336G

    - For sponsored projects fees, please note the following requirements:

- ✓ The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the TDS, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College & KEM Hospital'.
- ✓ Please note a letter from sponsor is required (on sponsors letterhead) mentioning the following details: Gross amount, TDS amount deducted and the net amount to be paid as IEC review processing fees.

1.	Payer / remitter's reference no.	
2.	Payer PAN number	
3.	Beneficiary details	
4.	Payment date	
5.	Trans currency	
6.	Payment method	
7.	Transaction reference number	
8.	Net amount	
9.	TDS	
10.	Gross amount	

- ✓ Please note if sponsor / investigator is not deducting any TDS then they have to provide a letter stating that no TDS has been deducted and actual fees of i.e. Rs. 85,000/- is being paid.

- TDS certificate should be provided quarterly.

- Protocol review processing fees:

	Project Types	**Initial review processing fees in INR**		**Periodic review processing fees in INR Six monthly Review**		**Annual review processing fees in INR**	
		Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**
1	Pharmaceuticals sponsored project	94,445/- Less 9,444.50/-	**85,000.50/-**	11,112/- Less 1,111.20/-	**10,000.80/-**	22,223/- Less 2,222.30/-	**20,000.70/-**
2	Government sponsored projects	11,112/- Less 1,111.20/-	**10,000.80/-**	2778/- Less 277.80/-	**2,500.20/-**	5,556/- Less 555.60/-	**5,000.40/-**
3	Thesis / Dissertation	Rs. 1,500/-		NA	NA	NA	NA
4	All academic non- sponsored projects (Including DNB, DM, Nursing, PhD Research)	Rs. 2,500/-		NA	NA	NA	NA

5	Funded studies	Budget ranging from 5,00,000/- to 25,00,000/- IEC charge- Rs. 10,000/- per project Above 25 lakhs for every 5,00,000/- in addition – charges are Rs.1,000/- + TDS 10%)	NA	NA	NA	NA

- Initial submission process will be completed subject to payment of initial review fees and submission of all mandatory documents.
- Processing fees for periodic review report need to be submitted at the time of submission of periodic review report.

16. The research study may be self funded / intra or extra mural funded. The PI should distinguished between funding agency and sponsor. Sponsor is defined as a person, a funding agency or an institution or an organisation responsible for initiation and management of a clinical trial / clinical study.

    Funding agency is defined as a person, a funding agency or an institution or an organisation who provides bulk of the funding for the trial. Money is usually like a grant for the advancement of science or for public good.

    Thus, in a PI-initiated trial that is funded it is important to ensure that:
    - The funding is not to obtain and / or use the data for commercial gain for the funding agency
    - The funding is not to promote the product of the funding agency
    - The funding agency would receive only a summary report of the trial
    - The report of the trial cannot be used by the pharmaceutical industry if it is a funding agency for commercial gain; or to obtain licenses or permissions, etc.
    - The funding agency will not have access to participant (anonymized) data, CRF, reports, or will not be sent samples for testing, storage, etc.
    - The funding agency will not provide compensation or insurance for the trial participants or the trial. The PI will be responsible for free medical management and providing financial compensation for any trial related injury.
    - The funding agency has no control on the publication of the trial by the PIs, and the PIs are not obliged to inform or share their drafts or publications with the funding agency
    - If the PI discovers or invents something new with the product of the funding agency, the intellectual property rights would be with the PI and/or the institute and not the funding agency
    - Funding agency may at most do a financial audit of the funding provided to the PI. But, funding agency cannot do an audit of or monitor the trial.
    - Registering the trial on the CTRI website would be the responsibility of the PI or the institution, but not the funding agency.

    CTA / MOU between Funder and Department conducting the study in particular should address the following clauses:

- The title must mention through whom the Institutes are a party i.e. the Head of the Institutes, and their names, and the Departments in the institutes that are involved, and the name of the PI or Co-PI, designation, etc. Please mention addresses of all the parties too.
- The MoU/CTA must state the purpose of the project/ trial, and if there are any financial transactions or payments to be made by one party to the other for the purpose of the project/ trial.
- The roles and responsibilities of each party to the MoU should be stated. It also needs to be stated who will be responsible for taking the informed consent, conduct of the trial, final report writing, etc.
- Material Transfer Agreement or clauses need to be added to the MoU/CTA or a separate agreement to be made for MTA, where samples collected by one party will be transported to another party (who will be responsible for the transport, how will it be done, who will ensure that the samples will not be adulterated or tampered with, at what temperature will they be transferred, etc.).
- It also needs to be stated that the samples sent will be anonymized by KEMH, to maintain the confidentiality of the participants.
- It needs to be stated that the tests conducted by one party on the samples shared, whether the results will be shared with KEMH. The results will be shared also needs to stated in the MoU/CTA and process of result sharing need to be specified.
- It needs to be stated in the MoU/CTA which party will take the trial insurance policy and/or pay compensation to the participants in case of any injury or adverse or serious adverse event.
- The study should be registered on the CTRI website, and which party will be responsible for the same should also be mentioned. If DCGI Permission is required for the study, it needs to be stated, and which party will be responsible for the same should be stated in the MoU/CTA.
- The parties that can publish and report the study/ trial/ project should be stated clearly in the MoU/CTA. If permission from another party is required, then that also should be stated.
- The MoU/CTA should mention the clauses on confidentiality, not only of the product or project, but also of the data generated, and the personal information of the participants of the trial/ research/ project.
- The MoU /CTA must state that qualifications of the persons involved in the trial/ project, and that they would follow the law, rules, guidelines, etc. in relation to conducting research trials.
- There should be a clause on arbitration or amicable settlement of any disputes that may arise between the parties. The parties must try to amicably settle the dispute, however, if it remains unresolved, then a common arbitrator could be involved to resolve the dispute. If the dispute does not still get resolved, then each party to appoint an arbitrator, and agree upon a common arbitrator to resolve the disputes under the Arbitration Act, 1996. The jurisdiction of the arbitration should be Mumbai.

17. If funding is awaited: PI to notify the IEC regarding sanction and receipt of funding subsequently IEC will issue approval letter.

18. Duplicate copy of any document (for e.g. Permission letter, certificate, query letter) will be charged Rs. 250/-).

19. An investigator may be invited (telephonically/ through written communication) to the IEC meeting to discuss issues related to the study proposal.

20. 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. This is in accordance with the Indian Council of Medical Research 2017 guidelines.

21. **For full board review** an investigator is expected to submit a reply to the 1st query sent by the IEC within 180 days of date of receipt of the letter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter.

    For expedited review and exemption from review, investigator is expected to submit a reply to the 1st query sent by the IEC within 90 days of date of receipt of the letter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter.

    For case report / case series review, investigator is expected to submit a reply to the 1st query sent by the IEC within 90 days of date of receipt of the letter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter.

    In the absence of any response specified above, the project will be declared closed for the IEC office records. In case of any valid reason IEC must be communicated within the said period to increase the validity period. The documents for these projects will be shredded by IEC staff and same will be recorded in the log book for shredded documents as well as the master register book. The project can not be revived if the documents are shredded.

22.1 For regulatory Trial If PI fails to submit the reply to 1st query letter for the new project which is under review with IEC **within 180 days for regulatory trials:**

- Before the expiration / termination of validity of the query letter, an extension request should be submitted to IEC before the end of 180 days (are counter from the date mentioned on the query letter). If an extension request is not received in the timeline, then the project file will be shredded and declared closed for IEC records.
- If PI wishes to reply to the queries or re-opening of the trial file AFTER 180 days but within one year from the date of receipt of query letter, PI should re-submit the entire project and related documents (day 181 to day 365 from the date of the receipt of the query letter) along with 50% of the prevailing protocol review processing fees with TDS 10%. (project registration number will continue to be the same).
- If PI wishes to reply to the queries or re-opening of the trial file after 365 days, PI should re-submit the entire project and related documents along with 100% of the prevailing protocol review processing fees with TDS 10%. On resubmission the project will receive a new registration number.

22.2 For regulatory Trial If PI fails to submit the reply to 2nd / subsequent query letter within 60 days then the project will be closed and shredded off for the IEC records. If PI wishes to reply to the queries or re-opening of the trial file after 60 days, PI should re-submit the entire project and related documents along with 100% of the prevailing protocol review processing fees with TDS 10%. On resubmission the project will receive a new registration number.

23. Reply **to the query letter as provided by the PI will be subjected to review as per IEC Decision form (AX 06/ SOP 05-B/V7.1). If found satisfactory IEC will issue final approval for the study.** An approval will be granted for the entire duration of the study. *(***AX 07/SOP 05-B/V7.1),** (**AX 08/ SOP 05-B/V7.1**) & (**AX 09/SOP 05-B/V7.1**)

24. For all regulatory clinical trials it is the responsibility of the principal investigator to submit a periodic review report / continuing review report (within 1 month of the due date i.e. 5 months from the date of approval for studies which will continue beyond six months). Such periodic reports have to be submitted to IEC at six monthly intervals till the completion of the study.

25. It is the responsibility of the principal investigator / study coordinator to ensure the periodic review processing fees along with the periodic review report need to be submitted within the timelines for all regulatory and sponsored trials. The coordinators should make the appropriate invoices as per AX 07/05-A/V7.1 section 15.1 regarding review fees.
26. For academic / non-regulatory trials it is the responsibility of the principal investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval)
    For submission of continuing review report Refer to SOP 7 /V 7.1

27. For submission of **Study Completion Report r**efer to SOP 8 /V7.1

28. **In case a study is not initiated or terminated** Refer to SOP 9 V 7.1

29. Agenda for the IEC meeting is prepared 3 working days in advance before the date of meeting and is sent to the IEC members at least 1-2 working days in advance. Hence, all study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received seven days before and other types of documents received 3 days before the preceding date of the meeting will be considered for the meeting. It will be deferred to the next month's meeting for discussion (**Exception -** any matter which in the opinion of the IEC secretariat has direct bearing on the safety of the research participants such as SAE report, major protocol violation).

30. **Submission of Amended Protocol and Protocol Related Documents**
    All amendments to the approved research proposal (only one set) should be submitted to the committee for its review no later than 7 seven days prior to the date of forthcoming meeting.
    No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).
    A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents along with the Annexure 1 SOP6 Amendment request form.

31. **Submission of Report of Protocol Deviations / Violations in the study protocol.** PDs should be reported quarterly (not exceeding three months from the detection of the deviation). Please use Annexure 1 SOP 10 Deviation / Non-Compliance / Violation Record AX 01/SOP 10/V 7.1 for submitting report of Protocol Deviations / Non-Compliance / Violations.

32. Submission of Report of Serious Adverse Events (SAEs) Refer to SOP 11B V7.1 Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

33. If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/ objections raised by the committee within twelve (12) weeks of the receipt of the committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.

34. **The following regulatory permissions will be required prior to issue of IEC approval letter.**

- **DC(I) approval**
  Studies which plan to use a new drug (as defined in NDCT Rule 2019 (GSR-227 -E) require DC(I) permission. For such studies, a copy of the permission letter issued by the DC(I) to the sponsor also needs to be submitted to the IEC. If the DC(I) permission is awaited, a letter of provisional 'approval will be issued by the IEC and the final IEC approval will be given after a copy of DC(I) permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.
- 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 head of the Institution should be sought by investigators
  - for studies involving collaboration with other Indian or foreign Laboratory/ Clinic/Institution.
  - For conducting the study
  - For sending the samples to laboratories outside KEM Hospital.
- to register clinical trial / academic clinical trial at www.ctri.gov.in before enrolling first patient in the study.

35. For regulatory trials PI to collect participant feedback (as per Annexure 10, AX 10/SOP 05-B/V7.1) from all enrolled participants during any scheduled visits (preferably this feed back may be collected during any of the initial three visits) and this duly filled feedback form to be kept in the participant file.

36. For regulatory trials PI to display patient Charter reflecting rights of the research participant in patient recruitment areas.

37. **List of forms / annexures required for submission of study related documents**
    The following forms / annexures are available on the website www.kem.edu and should be used for submission of study protocol and other study related documents as per revised SOPs of the IEC:
    - Project Submission Application Form for Initial Review and any additional forms as per your Research Project
    - Serious Adverse Event Report Assessment Form for SAE at our site *AX 01/SOP 11-B/V7.1*
    - Deviation/Non-Compliance/Violation Record *AX 01/SOP 10/V7.1*
    - Continuing Review Report Form *AX 01/SOP 07/V7.1*
    - Study Completion Report *AX 01/SOP 08/V7.1*
    - Premature Termination Report *AX 01/SOP 09/V7.1*
    - Document Request Form *AX 01/SOP 16/V7.1*
    - Guidance document for Department Review Boards (*AX 11/SOP 05-A/V7.1)*
    - AV consent checklist for participants (SOP 12, AX02/SOP12/V*7.1*)
    - Common Ethic Review of Multicentre Research (SOP 21)