Annexure 7
AX 07/SOP 05/V6.1

Guidelines for Investigators

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

1. All the studies qualifying as 'clinical research' need to be submitted for the Institutional Ethics Committees review.
2. 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 **selffunded** and those funded by Research Society of KEM Hospital, Diamond jubilee Society trust will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.
3. Location and Office Address (current):
   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.eduiec-2@kem.eduand 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 4.00 p.m.
   Saturday - 10.30 a.m. to 12.00 noon

   The office will remain closed on Sundays, all public holidays and last working day of every month.
4. 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.
5. 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.
6. General responsibilities of PI and Co-PI
   - **MMC/MCI :**

   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: (As per ICMR Annexure 13, kem.edu,** http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx)

   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.
   - **Investigators 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.

a. Updated investigators Brochure and clinical trial oversight plan
b. Work delegation log signed by the PI
c. SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
d. 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.

6. The IEC is currently following the version 6.1dated 29th June 2020 of the Standard Operating Procedures (SOPs), which are individual activity based and are 22 in number. The updated SOPs are available at our website **www.kem.edu- Department -Institutional Ethics committee-Initial submission & other submission**
7. The following steps need to be followed by investigators while **submission of a New study proposal to** the IEC:

I. Prior to approval of a research study

a) **e-EC software registration for the Principal Investigator:**

- **PI should keep ready following information and documents (in PDF versions) at the time of registration:**

1. Employee / Student ID Numbers of study team
2. Current Medical Council Registration certificate
3. Passport size photo
4. Biodata /CV
5. GCP training Certificate (within the preceding three years)

- **Follow the link as http://iecmanager.org**

1. Select institution as **Seth GS Medical College and KEM Hospital, Mumbai**.
2. Register
3. Submit the required information (registration) to get associated with institution for the project submission under following heads.
    a. Basic information
    b. Professional information
    c. Certifications
    d. Trainings
    e. Submit (Request)
    - Principal Investigator registration request will for IEC Admin verification. After IEC admin approval, user will get the account activation link to his/her email. Through this he/she can set their own password to login to system as Principal Investigator(PI).

Note: Only PI can forward the Project to IEC Admin.

Project proposals submitted via e-EC **on or before 20th of every month will** be taken up for discussion at the next month's IEC meeting.

b) The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the ICMR 2017 Guidelines. The section should include the following aspects which may be stated in the Ethics Section or elsewhere in the protocol:

- 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.

c) Incompletely filled forms / forms without signatures / proposals will not be accepted and same will be conveyed to the PI.

d) 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:

a) Full Board Review (refer SOP 05-A)
b) Expedited Review (refer SOP 05-B)
c) Exempt from Review (refer SOP 05-C)

Note: For management of initial protocol submission during epidemics/lockdown periods refer to SOP 22/V1.0

e) An investigator may refer to the SOP. No. 19 for 'Request for Waiver of Written Informed Consent' whenever necessary.

f) An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable AX 09/SOP 05/V6.1

g) The processing fees Details:

Projects Types	**The processing fees**
*Pharmaceuticals sponsored project	Rs. 85,000/ project +TDS (10%)
*Government sponsored projects	Rs. 10,000/- + TDS (10%)
Thesis/ Dissertation	Rs. 1,500/- (in hard cash/NEFT)
All academic non- sponsored projects (**Including DNB, DM, Nursing, PhD Research**)	Rs. 2,500/-project (in hard cash/NEFT)

The processing fees shall be collected only once at the time of submission of the project. The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the tax, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College'. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.

Note: * For Pharmaceutical Industry and Government Sponsored projects Annual Review Fee is applicable as mentioned under clause II f).

Online payment details for thesis and investigator initiated studies during epidemics and pandemics:

Name of Account: **Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust**
Name of Bank: **State Bank of India**
Add of Bank: **PO Bag No. 6034, Mitra Dham Bldg, Elphinston Road, JB Road, Parel T.T., Mumbai 400 012.**
Account No: **32127685176**
IFSC Code: **SBIN0001884**
MICR Code: **400002064**
PAN No: **AABTS5336G**

Online payment details for funded/ sponsored studies:

Name of Account: **Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust**
Name of Bank: **Bank of Maharashtra Parel Branch**
Add of Bank: **Vikas Apartment ,Dr.Ambedkar Road, Parel, Mumbai 400 012.**
Account No: **60236880148**
IFSC Code: **MAHB0000079**
MICR Code: **-**
PAN No: **AABTS5336G**

For international transaction as per DJST Rule

- **If funding is awaited:**

  1. **PI to notify the IEC regarding sanction and receipt of funding.**
  2. **Failure to do so will result in disciplinary action.**
  3. **Upon on receipt of funding PI must follow the procedures prescribed for Sponsored or Govt. studies.**

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

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

h) Investigator will be able to track the status of the submitted project and respective meetings dates on PI's dashboard of e-EC software or *via* email.

i) 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 2017 guidelines.

j) An investigator is expected to submit reply to the 1st query sent by the IEC within 180 days of date of receipt of theletter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter. In the absence of any response, 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.

II . Once approval for a study is granted

a) An approval will be granted for the entire duration of the study.

b) For all regulatory and pharmaceutical sponsored clinical trials it is the responsibility of the principle investigator that for studies which will continue for more than six months, a periodic review report / continuing review report needs to be submitted (within 1 month of the due date i.e. 6 months from the date of approval).

c) Annual status report for regulatory and pharmaceutical sponsored clinical trials should be submitted one month before end of validity along with annual review fees.

d) For studies approved during epidemics status update should be submitted at 45 days after approval (continuation review fees not applicable).

e) For BHR it is the responsibility of the principle 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)

f) For all projects sponsored by pharmaceuticals, the annual review fees will be Rs. **20,000/**project + TDS (10%) (Administrative sanction obtained on 17th July,2020), for the Government sponsored projects, the processing fees will be Rs. **5,000** /project (Administrative sanction obtained on 17th July,2020). The Annual review fee should be paid Rs.10000/- every six monthly for pharmaceuticals sponsored projects and Rs.2500/- for Government Sponsored projects.

For academic (non- sponsored) projects (in hard cash) no continuing review fee will be charged (Administrative sanction obtained on 17th July,2020). The continuing review fees shall be collected annually from the date of approval (unless specified otherwise). The sponsored continuing review fees will be accepted by cheque / demand draft which will include the tax, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College'. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.

g) Submission of Study Related Documents for IEC review

Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations, termination) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review.

Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting and is sent to the IEC members at least 1-2 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 within seven days and other types of documents within3 days preceding the date of meeting will not 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).

h) 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 assessment form.

i) Submission of Report of Protocol Deviations/ Violations in the study protocol

Please use Annexure 1 SOP 10 Deviation /Non-Compliance/Violation Record AX 01/SOP 10/V 6.1 for submitting report of Protocol Deviations/ Non-Compliance / Violations.

j) Submission of Report of Serious Adverse Events (SAEs)

Refer to SOP 11B V6.1

k) Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

l) 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.

m) Submission of continuing review report
Refer to SOP 7 V 6.1

III. Upon completion of study

Submission of Study Completion Report
Refer to SOP 8 V6.1

IV. In case a study is not initiated or terminated
Refer to SOP 9 V 6.1

Appendix I: Regulatory permissions

- **DC(I) approval**
  Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945 & GSR-227 -E) require DC(I) permission. For such studies, a copy of the permission letter issued by the DC(I)to the pharmaceutical company/investigator 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, Stem cell research committee
- **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.
- **Administration sanction** from the head of the Institution for sending the samples to laboratories outside KEM Hospital.
- It is mandatory as per the directive by the DC(I) (w.e.f.15th June 2009, which is applicable for clinical trials initiated after 15th June 2009) to register clinical trial at ICMR clinical trial registry at www.ctri.gov.in before enrolling first patient in the study. (Registration is mandatory for interventional clinical trials).

Appendix II: List of forms required for submission of study related documents

The following formsare 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/V6.1*
- Deviation/Non-Compliance/Violation Record *AX 01/SOP 10/V6.1*
- Continuing Review Report Form *AX 01/SOP 07/V6.1*
- Study Completion Report *AX 01/SOP 08/V6.1*
- Premature Termination Report *AX 01/SOP 09/V6.1*
- Document Request Form *AX 01/SOP 16/V6.1*
- Guidance document for Department Review Boards (*AX 11/SOP 05/V6.1)*
- AV consent checklist for participants (SOP 12, AX02/SOP12/V*6.1*)
- Common Ethic Review of Multicentre Research (SOP 21)

Initial submission of protocol
Sample format of covering letter by Principal Investigator (PI)
for review of pharmaceutical & GOVT sponsored / Funded studies.

1) Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for pharmaceutical & GOVT sponsored / Funded studies.

The Member Secretary,
IEC.
Sub: Submission of clinical trial / trial documents for Ethics Committee review and approval.
Ref: Protocol number XXX Version XX dated XXX entitled, "XXXXXXX".
Sir / Madam,
We are conducting a study in our department. XXX sponsor has approached us for the conduct of the abovementioned study. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019.

Please find enclosed the following documents for review and approval:

Sr. No.	Document title	Version no. and date
1		
2		

Also kindly note the following:

1	Co-Investigators: 1)_____ 2)_____ Clinical Research Coordinator: 1)_____ 2)_____	Signature of co-investigator	
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute(during study period) who will take over the responsibility of PI		
3	Recruitment Strategy	1. _____ 2. _____	
4	Collaboration department signature of HOD required if applicable		
5	Study conduct – Sponsor / CRO		
6	Funding agency		
6.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status		
6.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)		
7	Approximate budget per patient and overall budget		
8	Name & number of the Indian sites		
9	Local laboratory address (if applicable)		
10	Outside KEMH laboratory address (if applicable)		
11	Reprimanding letters from IEC in last five years inclusive all type studies(PHARMA, GOVT, OA & Thesis)		

Note : * Any funding from outside will not be treated as intramural funded studies.

Ongoing trial status as PI and as Co-I

Sr. No.	Project no.	Title	Recruited participants	Time given by PI for the project each day

Status of trials which are under process as PI and as Co-I

Sr. No.	Project no.	Title	Participants to be enrolled	Time to be given by PI for the project each day

With this I would like to request you to review this project and consider for approval.
Thanking you,
Sincerely yours,

Dr. XXXXXXX
Principal Investigator

Forwarded by Head of the Department
Seal

[Definition of Principal investigator (PI): (as per policy decision 13 March 2014): PI must be a faculty / employee of Seth G. S. Medical College and KEM Hospital, Mumbai and have appropriate graduate/post graduate qualification approved by respective statutory council.]

2) Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for thesis/dissertations & investigator initiated/ Other Academic(OA) studies.

Date:
To,
The Member Secretary,
IEC.
Sub: Submission of trial documents for Ethics Committee review and approval.
Ref: Protocol number XXX Version XX dated XXX entitled, "XXXXXXX".
Sir / Madam,
I'm submitting the study entitled, "xxxxxxx". This is a dissertation topic for my post graduate student / an investigator initiated study. Requesting for review and approval as per IEC SOPs. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019 whichever is applicable.

Please find enclosed the following documents for review and approval:

Sr. No.	Document title	Version no. and date
1		
2		

Also kindly note the following:

1.	Co-Investigator (if applicable): 1)_____ 2)_____	Signature of Co-I	
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute who will take over the responsibility of PI		
3	Recruitment Strategy	1_____ 2_____	
4	Collaboration department signature of HOD required if applicable		
5	Funding agency		
5.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status		
5.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)		
6	Approximate budget per patient and overall budget		
7	Name & number of the Indian sites (if applicable)		
9	Local laboratory address (if applicable)		
10	Outside KEMH laboratory address (if applicable)		
11	Reprimanding letters from IEC in last five years inclusive all type studies **(**PHARMA, GOVT, OA & Thesis**)**		

Note: * Any funding from outside will not be treated as intramural funded studies.

Ongoing trial status as PI and as Co-I (PHARMA, GOVT, OA & Thesis)

Sr. No.	Project no.	Title	Recruited participants	Time given by PI for the project each day

Status of trials which are in under process as PI and as Co-I (PHARMA, GOVT, OA & Thesis)

Sr. No.	Project no.	Title	Participants to be enrolled	Time to be given by PI for the project each day

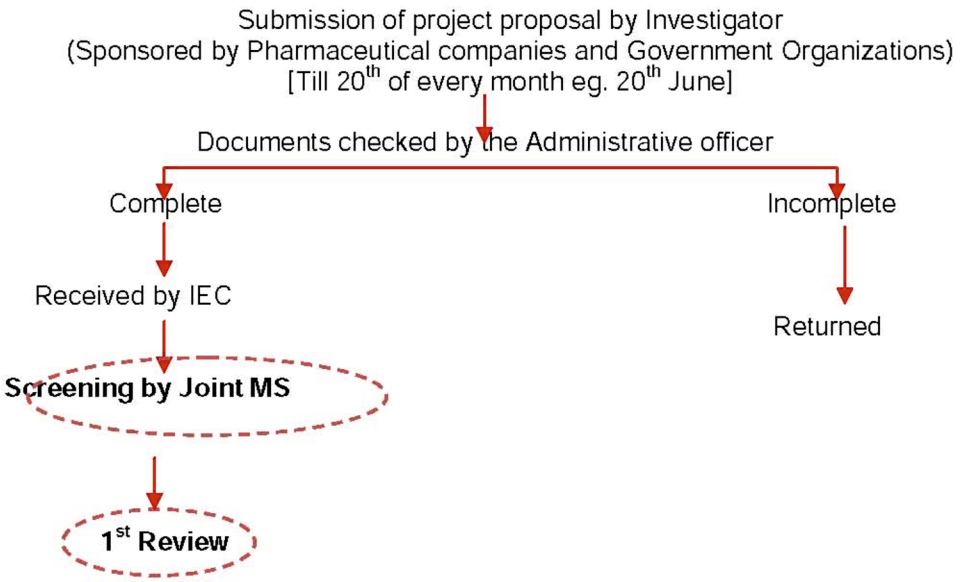
With this I would like to request you to review this project and consider for approval.
Thanking you,
Sincerely yours,

Dr. XXXXXXXx
Principal Investigator

Forwarded by Head of the Department
Seal

[Definition of Principal investigator (PI): (as per policy decision 13 March 2014): PI must be a faculty / employee of Seth G. S. Medical College and KEM Hospital, Mumbai and have appropriate graduate/post graduate qualification approved by respective statutory council.]

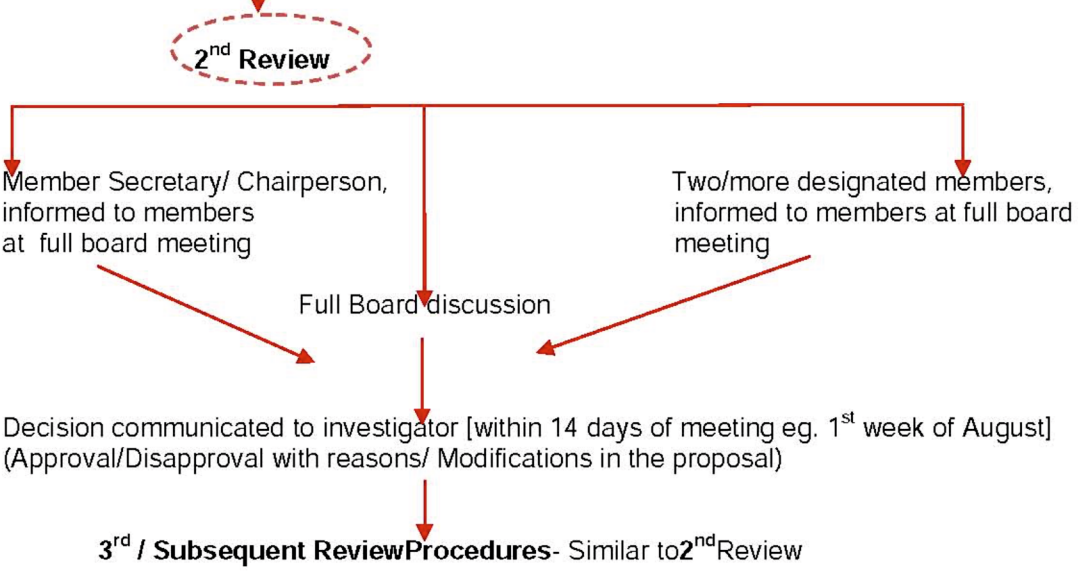
Submission of Projects for IEC Review



Review by the IEC members by circulation of projects [about 4 weeks] and
Discussion at full board meeting [3rd/ 4th week of the next month eg. 3rd week of July]

Decision communicated to investigator [within 14 days of meeting eg. 1st week of August]
(Approval/Disapproval with reasons/ Modifications in the proposal)

Submission of response to IEC queries/modified project documents
[to be submitted within 180 days after the IEC query letter is sent]



Decision communicated to investigator [within 14 days of meeting eg. 1st week of August]
(Approval/Disapproval with reasons/ Modifications in the proposal)

3rd / Subsequent ReviewProcedures- Similar to**2nd**Review