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**Institutional Animal Ethics Committee
(IAEC)**

MGM Medical College, Navi Mumbai.

Standard Operating Procedures (SOPs)

**Version 1
March 2022**



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Institutional Animal Ethics Committee

Standard Operating Procedures (SOPs) for Institutional Animal Ethics Committee (IAEC) of MGM Medical College, Navi Mumbai.

MGM Medical College, Navi Mumbai, a teaching and research institution with many postgraduate students performing research on animals. As per the CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) norms, Institutional Animal Ethics Committee (IAEC) has been constituted to supervise and evaluate all aspects of the animal care and use program in the institution under Rule 5(a) of the breeding and Experiment on Animals (Control and Supervision) rules 1998.

CPCSEA Registration No.: 303/PO/Re/S/2000/CPCSEA

Objective:

The objective of this SOP is to contribute to the effective functioning of the IAEC MGM Medical College, Navi Mumbai, so that a quality and consistent ethical review mechanism for biomedical research in animal is put in place for all proposals dealt by the Committee. IAEC is also responsible for reviewing Form-B, Form-C and Form-D, inspecting animal facilities and uphold 5R's principles of (Replacement, Reduction, Refinement, Rehabilitation and Responsibility) ensuring adherence to CPCSEA guidelines. Before research involving animal can be undertaken, the project will have to be reviewed and approved by the IAEC.

Function:

The functions of the Institutional Animal Ethics Committee (IAEC) are as follows:

- Review proposed use of animals in research and require any modifications necessary for approval, or withhold approval prior to use of animals
- Approve research involving animals which conform to the various guidelines for use of animals in research
- Review periodically the Institute's animal facility
- Review and investigate legitimate concerns involving the care and use of animals during research
- Ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities

Composition of Institutional Animal Ethics Committee (IAEC):

Composition of Institutional Animal Ethics Committee (IAEC) shall include members as follows-

1. A biological scientist
2. Two scientists from different biological disciplines preferably involved in animal experiments, out of two, one from the non-clinical discipline.
3. One veterinarian involved in the care of animals
4. A scientist in charge animal House
5. A scientist from outside the institute
6. One non-scientific socially aware person
7. One nominee of CPCSEA

One specialist may be co-opted while reviewing special projects using hazardous agents such as radio-active substance and deadly micro - organisms The Chairperson of the committee and member secretary shall be nominated by the institution from amongst

the eight members. Members against serial no. 5, 6 & 7 will be nominated by CPCSEA with a provision of a link nominee for CPCSEA nominee.

Authority under which IAEC is constituted and duration:

Five names against serial numbers 1- 4 will be sent from the institute to CPCSEA. The duration of IAEC will be for a period of 5 years. The IAEC will be reconstituted at the time of renewal of registration to CPCSEA. Changes can be made in deserving cases with the approval of CPCSEA.

Membership duration and responsibilities:

The duration of membership will be 5 years (coinciding with renewal of registration). The committee will be reconstituted at the time of renewal of registration and at least half of the members will be replaced. A member can be replaced in the event of long-term non-availability (three consecutive meetings) or death.

Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period. Conflict of interest should be declared by members of IAEC. A member can tender resignation from the committee.

Quorum requirements:

A minimum of 6 members are required to compose a quorum. All decisions should be taken in meeting and not by circulation of proposals. Presence of CPCSEA nominee, Scientist from outside Institute and Socially aware member's is must. Link nominee can attend in case main nominee conveys his unavailability in writing. However member's presence of Link Nominee is compulsory for at least one meeting in a calendar year.

Conduct of the meetings:

The Chairperson will conduct all meetings of the IAEC. If, for reasons beyond control, the Chairperson is not available, or has conflict of interest, an alternate Chairperson will be elected from the members by the members present. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson & nominee of CPCSEA before communicating to the Principal Investigator. In any case the meeting should not be held without the presence of CPCSEA member or nominee.

Participation of by Investigators / Experts in IAEC:

If needed, IAEC may call upon subject experts for offering special opinion for selected research projects. They will give specialized view but not take part in the decision making. Investigators whose proposals are to be discussed can be called to present their case to IAEC.

Application procedure:

All proposals should be submitted in the prescribed application form, copies of which will be available from the Member Secretary. All relevant documents with check list should be enclosed with application form. Eight copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator and Co-investigators/Collaborators should be forwarded by the Head of the Department to the IAEC. A fee of Rs 5000/- will be charged for sponsored project from out side the institution. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

Review procedure:

- Meetings of IAEC shall be held every 6 months, for which the month will be decided at the end of previous meeting. Additional meetings will be held as and when necessary.
- Even if there are no projects, it is mandatory to call for an IAEC meeting at least once in a year to discuss matters related with maintenance of the animals in the animal house. The member secretary must be present with all available records at every IAEC meeting.
- The copy of the application/ proposals will be sent to CPCSEA nominee and to all the members 15 days before the meeting.
- The date of meeting will be intimated to the Principal Investigator who should be available to offer clarifications if necessary.
- The decision will be taken by consensus after discussion. Negative view point will be recorded in the minutes. If consensus is not reached, the case will be referred to CPCSEA.
- Independent Consultants/Expert will be invited to offer their opinion on specific proposals if needed.
- The decisions will be recorded in minutes, approved by chairman and will be signed by all the IAEC members present.

Decision making:

Decision will be taken by discussion before arriving at consensus.

- A member having conflict of interest should inform the chair person and withdraw during the decision procedure of concerned application. It should be recorded in minutes.
- The quorum of the meeting should be complete at the time of decision making.
- Only members shall take decision. Experts/ invitees/ investigators will only offer their opinion.

- Decision may be to approve, reject or revise the proposal. Specific suggestions for modification and reasons for rejection should be given. □ In case of conditional decisions, clear suggestions for revision and procedure for re-review the application should be specified.
- Modified proposal's review may be expedited through identified members.

Communication of the decision:

- The decision of IAEC will be communicated by Member Secretary in writing.
- Suggestions for modification will be communicated by IAEC. If revision is to be made, the revised document in required number of copies should be submitted within a fortnight.
- Reasons for rejection will be informed to the researchers.
- Schedule/ plan of ongoing review will be informed to the Principal investigator.

Follow up procedures:

- Reports of ongoing research projects should be submitted every 6 months, before next IAEC meeting.
- Final report should be submitted at the end of the study.
- All serious Adverse Events (SAEs) & the interventions should be intimated.
- Protocol deviation, if any should be informed with adequate justification.
- Any amendment to the protocol should be resubmitted to IAEC for renewed approval. Premature termination of the study should be notified with reasons along with summary of the data obtained so far.
- Change of Investigators / sites should be informed for approval of IAEC.
- Any new information related to the study should be communicated.
- Record keeping and archiving:

All of the following documents must be stored for a period of five years.

- Curriculum Vitae (CV) of all members of IAEC including training programmes in animal ethics.
- Minutes of all meetings duly signed by the Chairperson and CPCSEA nominee, copy of all correspondence with members, researchers and other regulatory bodies.
- Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
- All study related documents (study projects with enclosed documents) should be archived for minimum of five years after the completion of study. A copy of filled proforma related to the projects shall remain with the Principal Investigator for minimum of five years.

Updating IAEC members:

Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research related to the animal ethics to help in improving the quality of research projects/animal ethics committee submissions and review.

Reporting to CPCSEA:

IAEC will send a copy of minutes of IAEC meeting within 15 days. Inspection report of animal house by IAEC members will be sent once in a calendar year. If action is required, the ATR should be provided in stipulated time.

Reimbursement to CPCSEA representative:

CPCSEA representatives on IAEC or authorized persons sent for inspection of the establishment are required to be paid Rs 5000/- each as sitting fees and 1500/- as travelling allowance

Performance of experiments:

Experiments shall be performed under supervision of a qualified person (Veterinarian/ Post graduates in life sciences/ trained laboratory technician) and under the responsibility of the person performing the experiment.

Experiment shall be performed with due care and humanity. Animals intended for the performance of experiments shall be properly looked after both before and after experiments.

Personnel using experimental animal(s) shall be responsible for the welfare of animal(s) during their use in experiments.

Investigators shall be responsible for the aftercare and rehabilitation of animal(s) after experimentation, and shall not euthanize animal(s) except in situations as defined.

The following parameters shall be adopted for application of euthanasia, namely;

(a) When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner.

(b) If during the course of anaesthesia /experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.

(c) Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence. It is mandatory that the cost of after care and rehabilitation should be met from the contingency of the project.

Experiments involving operative procedures shall be performed under anaesthesia to be administered by a veterinary surgeon/scientist/technician so trained for the purpose. Experiments shall not be performed by way of an illustration/ as a public demonstration.

No experiment the result of which is already conclusively known shall be repeated without justification.

Laboratory animal ethics:

All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view it is important that such considerations are taken care of at the individual level, institutional level and finally at the national level.

Documentation:

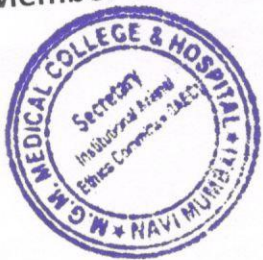
- All research proposals should be submitted with the following documents:
- Title of the project
- Names of the Principal Investigator and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Endorsement of the name of Head of the Department.
- Protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant annexure like proforma, Curriculum Vitae of outside members, undertaking etc. to be used in the study.
- Any other information relevant to the study.
- Agreement to submit six monthly progress report and final report at the end of study.
- The Principal Investigator should provide the details of other ongoing research projects related to the Animal studies (Title of the project, Date of starting and duration, source and amount of funding).

Elements of review:

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies if applicable.
- Assessment of predictable risks/harms to the animals.
- Protocol and proforma of the study.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure in the animal house.

Ray 10/3/22

Member Secretary



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10.3.22

Chairperson



[Signature]

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Dean
MGM Medical College & Hospital
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