

Standard Operating Procedures (SOP) Institutional Animal Ethics Committee

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Standard Operating Procedures (SOP) for IAEC

The guidelines and policies regarding the operation of the IAEC are adopted by following the “act 1960 of prevention of cruelty to animals - Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)”

1. Objective:

The motto of the Prevention of Cruelty to Animals (PCA) Act 1960 as amended in 1982, is to prevent the infliction of unnecessary pain or suffering on animals. The Central Government as enumerated under PCA Act 1960 has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) which is duty-bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. For this purpose, the Government has made the “Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998” as amended in 2001 and 2006, to regulate the experimentation on animals. The objective of this SOP is to prevent unethical use of animals in research and contribute to the effective functioning of the Institutional Animals Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt with by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation (Control and Supervision) Rules 1998, as amended in 2001 and 2006.

2. IAEC has been designed to secure the following specific objectives:

- (1) Every experiment shall be performed by or under the supervision of a person duly qualified on that behalf, that is, Degree holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognized by the Government for the purpose and under the responsibility of the person performing the experiment.
- (2) That experiments are performed with due care and humanity and as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals from feeling pain.
- (3) That animals who, in the course of experiments under the influence of anaesthetics are so injured that their recovery would involve serious suffering, are ordinarily medically allowed to die while still under influence of the anaesthetic.
- (4) That experiments on animals are avoided wherever it is possible to do so.
- (5) That experiments on larger animals are avoided when it is possible to achieve the same results by experiments on small laboratory animals like guinea pigs, rabbits, mice, rats etc.

(6) That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skills.

(7) Animals intended for the performance of experiments are properly looked after before, during, and after experiments

(8) That suitable records are maintained with respect to experiments performed on animals

3. Functions of IAEC:

As defined in “Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998”. "Institutional Animals Ethics Committee (IAEC)" means a body comprising of a group of persons recognized and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment that is constituted and operated in accordance with procedures specified for the purpose by the Committee; The primary duty of IAEC is to work for the achievement of the objectives as mentioned above. IAEC should focus mainly on ensuring ethical and methodical handling of animals during and after experiments so that they have less suffering. IAEC will review and approve all types of protocols for research involving small animal experimentation before the start of the study. For the approval of experimentation on large animals, the case is required to be forwarded to CPCSEA in a prescribed manner with the recommendation of IAEC. IAEC is required to monitor the research throughout the study and after completion of the study, IAEC shall obtain the periodic reports on research development and shall ensure a visit to the animal house facility and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

4. Composition of IAEC:

1. One veterinarian involved in the care of animals.
2. One scientist in charge of animal facility.
3. One Caretaker of the animal house.

The minimum qualification for the IAEC Members is as below B.V.Sc. or M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or M.Sc. / M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/ Biomedical Engineering) with experience in animal handling and animal research or M. Pharm with experience in animal handling and animal research.

5. Participation by Investigators/experts in IAEC:

IAEC may call upon subject experts who may provide special inputs of selected research protocols if needed. They are required to give their specialized views but not to take part in the decisions making process which will be made by the members of the IAEC only. Investigators whose proposals are to be discussed can also be called to present their cases to the IAEC.

6. Application Procedures:

1. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation.
2. All relevant documents as per the checklist should be enclosed with the application form.
3. The Required number of copies of the proposal along with the application and documents in the prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be submitted to IAEC.

7. Review procedures:

1. The meeting of the IAEC should be held on scheduled intervals as prescribed in the SOP of the IAEC and additional meetings may be held if there are reasons to do so.
2. The proposals/ applications will be sent to members at least 15 days in advance.
3. Decisions will be taken by consensus after discussions. Negative view points should be recorded in the minutes. CPCSEA shall consider only those decisions which are arrived with consensus. In case of consensus is not arrived and the case merits special attention of CPCSEA, such cases may be forwarded to CPCSEA with approval of the chairman of the IAEC of the establishment along with the detailed reason for forwarding the matter to CPCSEA and points of consideration for CPCSEA.
4. Researchers will be invited to offer clarifications if needed.
5. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
6. The decisions of the IAEC will be minuted and Chairperson's approval shall be taken in writing with the signature of all the IAEC members present.

8. Guidelines to be followed for use of animals

1. Any experiment on animals is performed only after the approval of the protocol by IAEC.
2. Approval of IAEC is also necessary for any change in protocol in an already IAEC-approved project.
3. Staff/Person involved in animal experimentation should be suitably trained and certified.
4. Experimental procedures on animals are performed under the supervision of a qualified person (scientist or veterinarian).
5. Humane practices are to be followed.
6. Regular monitoring of experimental animals is to be done throughout the course of the experiment.

For more information regarding guidelines on the use of laboratory animals in experimentation/research please go through the **CPCSEA Guidelines**.

9. Submission/approval of protocols to IAEC:

For animal usage in research, application form in an appropriate format needs to be submitted to IAEC.

1. While submitting the protocols the following should be ensured:
 - Completely filled.
 - Date of submission and duration of the experiment should be clearly specified.
 - Name of individuals allowed to conduct the experiments should be mentioned (only authorized persons will be allowed to enter the animal facility).
 - The details of animals required for the experiments should indicate:
 - Species
 - Strain
 - Age and /or weight range
 - No. of animals required
 - Sex
 - Number of days animals will be housed
 - Justification regarding the use of particular species and sex is essential.
 - In case animal experiments require **potential human pathogens, radio nuclides, biological agents, hazardous chemicals, recombinant DNA agent, etc** then prior approval from Institutional Biosafety Committee (IBC) is a must requirement.
 - Complete experimental design pertaining to break up of number of animals (preferably in tabular form) to be used in different groups and total number of experiments need to be conducted over the period of time should be specified.
 - If any change is desired in the already approved protocols it should be indicated by filling up the Protocol amendment form which needs to be approved in IAEC meeting.
2. Animal requirements will be executed at short notice for small numbers of animals but it is desirable to give advance notice of a minimum of 2 months regarding the requirement for animals. This will ensure better planning of the breeding program and supply of animals according to the specifications and on the date required.
3. Animals will be maintained in SAFE or may be collected from SAFE for experimentation in the respective laboratory.
