

III. Standard Operating Procedures (SOP) for IAEC

1. Objective:

To contribute to the effective functioning of the Institutional Animal Ethics Committee (IAEC) so that a standard and consistent ethical review procedure for animal research is practised for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation Rules 1998.

2. Functions of IAEC

As defined in "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" "Institutional Animals Ethics Committee" means a body comprising of a group of persons recognized and registered by CPCSEA in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee. The primary duty of IAEC is to work for achievement of the objectives as mentioned above. IAEC will review and approve all types of research proposals involving small animals before the start of the study. IAEC is required to monitor the research throughout the study and after completion of study through periodic reports and visit animal house and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

For experimentation on large animals, the application is required to be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.

3. Composition of IAEC (as prescribed by CPCSEA)

Institutional Animals Ethics committee shall include eight members as follows.

1. A biological scientist,
2. Two scientists from different biological disciplines,
3. A veterinarian involved in the care of animal,
4. Scientist in charge of animals facility of the establishment concerned,

5. A scientist from outside the institute,
6. A non scientific socially aware member
7. A nominee of CPCSEA /link nominee

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from among the eight members. Members against Serial number 1-4 will be nominated by the institute and approved by CPCSEA where as members 5,6 and 7 will be nominated by CPCSEA, with a provision of a Link nominee for CPCSEA nominee.

4. Authority under which IAEC is constituted and duration

The duration of IAEC is for a period of 5 years and is required to be reconstituted at the time of renewal of registration. However, changes may be made in deserving cases with the approval of CPCSEA.

5. IAEC requirements

The duration of appointment is for a period of 5 years (coterminous with registration).

- b. The committee is required to be reconstituted at the time of renewal of registration, and at least half of the members will be replaced.
- c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- f. Conflict of interest should be declared by members of the IAEC.

6. Quorum requirements:

The minimum of 6 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. Presence of CPCSEA nominee is a must. Link nominee can attend in case main nominee conveys his

unavailability in writing to the Chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a calendar year.

7. Conduct of business:

1. IAEC meeting will be conducted once in 3 months.
2. Intimation regarding the dates of meeting will be communicated to all the departments one month prior to the scheduled date.
3. The copies of the proposals will be sent to the members 2 weeks prior to the meeting
4. The Chairperson will conduct all meetings of the IAEC. If the Chairperson is not available an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting.
5. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.
6. A copy of minutes will be sent to Member Secretary CPCSEA within 15 days of the meeting
7. Approval letters will be issued not later than 15 days of the meeting
8. To revised and resubmitted proposals approval will be issued not later than 7 days of re submission.

8. Participation by Investigators / experts in IAEC

IAEC may call upon subject experts who may provide special review of selected research protocols, if need be. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the

IAEC. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

9. Application Procedures:

All proposals should be submitted in the prescribed application form B, which can be downloaded from the website of IAEC

10 copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators attested by the Head of the departments should be submitted to IAEC.

11. Review procedures:

Each proposal will be carefully reviewed for the following

1. The need of the proposed research work based on existing information available
2. The type and the reason for the animal chosen
3. Number of animals required
4. The detailed procedure involved - grouping of animals, handling, feeding, blood withdrawal, anaesthetics used and their dose, route of administration of the investigational agents, the dose, duration and monitoring of animals and how the samples will be used
5. The safety data available for the investigational agent
6. Post study plan - rehabilitation / euthanasia
7. Details of euthanasia
8. Method of disposal of carcass

Decisions will be taken by consensus after discussions. Negative view points should be recorded in the minutes. In case consensus is not reached, the case should be referred to CPCSEA.

Researchers will be invited to offer clarifications if need be.

Independent consultants/Experts will be invited to offer their opinion on specific Research proposals if needed.

The decisions will be minuted and Chairperson's approval taken in writing with signature of all the IAEC members present.

14. Decision-making

- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- c. Decisions will be made only in meetings where quorum is complete.
- d. Only members can make the decision. The experts / investigators / invitees will only offer their opinions.
- e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- g. Modified proposals may be reviewed by an expedited review through identified members.

15. Communicating the decision

- a. Decision will be communicated by the Member Secretary in writing.
- b. Suggestions for modifications, if any, should be sent by IAEC.
- c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by IAEC should be communicated to the PI.

16. Follow up procedures

a. Study report should be submitted by PI at prescribed intervals for review.

b. Final report should be submitted at the end of study.

c. All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted to IAEC for renewed approval.

f. Any new information related to the study should be communicated

g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

h. Change of investigators / site should be informed and approval of IAEC should be taken.

17. Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.

b. Copy of all study protocols with enclosed documents, progress reports.

c. Minutes of all meetings duly signed by the Chairperson and the members.

d. Copy of all existing relevant national and international guidelines on animal ethics and laws along with amendments.

e. Copy of all correspondence with members, researchers and other regulatory bodies.

- f. Final report of the approved projects.
- g. Record of Breeding of animals, supply etc, if breeding of animals is undertaken.
- h. Record of import of animals with species, source, quantity, usage etc.
- i. Record of all Contract research, if conducted at the institute.
- j. All documents should be archived for period as prescribed in the concerned SOP of the IAEC. However, this should not be less than one year.

18. Updating IAEC members

- a. All relevant new guidelines and amendments to the Rules and Act should be brought to the attention of the members.
- b. Members should be encouraged to attend national and international training programs / workshops / conferences in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

19. Reporting to CPCSEA

- a. IAEC is required to send a copy of minutes of IAEC meeting to CPCSEA within 15 days.
- b. Inspection report of animal house with photographs by IAEC members is required to be sent once in a calendar year. If action is required, the facility must provide ATR within 30days.

20. Reimbursement to CPCSEA representative

CPCSEA representative(s) on the IAEC or authorized person(s) sent for inspection of the establishment(s) are required to be paid Rs. 2000/- each as sitting fees and reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

21. Fees Payable to CPCSEA

Registration fee of Rs. 10,000/- and renewal fee of Rs. 2,500/- is to be paid by Demand Draft in favor of CPCSEA payable at New Delhi (as applicable).