



**DEEN DAYAL UPADHYAYA
GORAKHPUR UNIVERSITY
GORAKHPUR**

**POLICY
DOCUMENT**

Internal Quality Assurance Cell (IQAC)

INSTITUTIONAL ANIMAL ETHICAL POLICY AND COMMITTEE (IAEC)

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Institutional Animal Ethical committee (IAEC) is important in organizations that perform research on animals in order to maintain ethics in animal research and governance. This necessitates the development of appropriate research guidelines, as well as the public release of scientific/technical/biomedical data and findings and their use in scientific administration at all levels. IAEC of DDU Gorakhpur University will be constituted as per the guidelines of CPCSEA and will follow the standard operating procedures laid by CPCSEA.

OBJECTIVE

The motto of Prevention of Cruelty to Animals (PCA) Act 1960 as amended in 1982, is to prevent infliction of unnecessary pain or suffering on animals. The Central Government 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 “Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998” as amended during 2001 and 2006, to regulate the experimentation on animals.

The objective of the Standard Operating Procedure(SOP) is to contribute to the effective functioning of the Institutional Animal Ethics Committee (IAEC) so that a quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation Rules 1998.

STANDARD OPERATING PROCEDURE FOR INSTITUTIONAL ANIMAL ETHIC COMMITTEE:

- The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been constituted under the provisions of the Prevention of Cruelty to Animals (PCA) Act, 1960. It gives the guidelines for the conduct of animal experiments.
- Animals are maintained in a proper and healthy manner.
- Animals are not subjected to unnecessary pain or suffering before, during and after performance of experiments on them.
- There is no unnecessary sacrifice of animals for the sake of science. There should be no duplication of research.
- Animals are kept in disease free condition to ensure proper data collection.
- Animals are procured from registered breeders.
- Experiments on large animals are to be avoided whenever it is possible to achieve the same results by experiments on small laboratory animals.

- For effective implementation of these rules and guidelines, the Institutional Animal Ethics Committees (IAEC) has been constituted in institutions conducting experiments on animals. This is a scientific body nominated by the Head of the Institution. The IAEC is required to examine proposals for conducting experiments on small animals, which would chiefly examine the necessity of performing the experiment, and ensure that experiments are not performed in a routine manner. All decisions are to be taken with the approval of the Committee. The Standard Operating Procedures (SOP) for Institutional Animal Ethics Committee for experimentations on animals will help the Principal Investigators, Animal Ethics Committee members and scientific researchers, for better understanding of the ethical procedures involved in animal experimentations.

FUNCTION OF IAEC:

- IAEC should provide independent, competent and timely review of the ethics of a proposed study before the commencement of the same and regularly monitor the ongoing studies.
- IAEC will review and approve all research proposals involving animal experiments with a view to assure quality maintenance and welfare of animals used in laboratory studies while conducting research.

COMPOSITION OF IAEC:

Institutional Animal Ethics Committee shall include members as follows:

1. A scientist from different biological discipline cum chairperson
2. A scientist from different biological discipline
3. A Biological Scientist
4. One veterinarian involved in the care of animals
5. A scientist in charge of animal House facility cum member secretary
6. A scientist from outside the institute
7. One non-scientific socially aware person
8. One main nominee of CPCSEA
9. One link nominee of CPCSEA

Specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substance and deadly microorganisms. The Chairperson of the committee and member secretary shall be nominated by the institution from amongst the nine members. Members against serial no. 6, 7, 8&9 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 1-5 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

IAEC REQUIREMENTS:

- The duration of appointment 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 longterm nonavailability (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 REQUIREMENT:

The minimum of six members shall be required to form quorum of the IAEC meetings. All decisions shall be required to be undertaken in the meetings of IAEC and not by the method of circulation of project proposals. Presence of main nominee of CPCSEA nominee is a must. It shall be a must for the establishment to invite all nominees of IAEC for attending the meeting and the meeting notice shall invariably be issued by Registered Post at least 15 days before the date of the meeting. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairperson of IAEC. Socially aware member's presence is compulsory in all cases referred to CPCSEA and their presence is mandatory at least in one meeting of IAEC of the establishment in a calendar year. It shall be the duty of establishment to inform to CPCSEA about the continuous absence of nominees of CPCSEA in a calendar year.

CONDUCT OF MEETING:

The Chairperson of the IAEC shall be responsible for conducting at least two meeting of IAEC in a calendar year with the help of the Member Secretary of IAEC. If, for reasons beyond control, the Chairperson is not available, or has conflict of interest, an ad-hoc Chairperson will be elected from amongst 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. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

PARTICIPATION OF INVESTIGATORS/EXPERTS IN IAEC:

IAEC may call upon subject experts who may provide special inputs of selected research protocols, if need be. 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 case to the IAEC.

APPLICATION PROCEDURE:

- All proposals should be submitted in the prescribed application form.
- All relevant documents with checklist should be enclosed with application form.
- Required number of copies of the proposal along with application and documents in prescribed format duly signed by Principal Investigator (PI) and Co- investigators/ Collaborators should be submitted to IAEC.

REVIEW PROCEDURE:

- The meeting of the IAEC should be held on scheduled intervals as prescribed in the concerned SOP of the IAEC and additional meetings may be held if there are reasons to do so.
- 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 proposals may be reviewed by an expedited through identified members
- Procedures for appeal by the researchers should be clearly defined.

COMMUNICATION:

- 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 by the IAEC should be communicated to the Principal Investigator.

FOLLOW UP PROCEDURE:

- 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 ARCHIVAL:

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

- Curriculum Vitae (CV) of all members of IAEC including training programs 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:

- All relevant information on Animal ethics will be brought to the attention of the members of IAEC by the Member Secretary.
- 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 15days.
- 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 REPRESENTATIVES:

CPCSEA representatives on IAEC or authorized persons sent for inspection of the establishment are required to be paid Rs 1000/- each as sitting fees per day along with reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

FEE PAYABLE TO CPCSEA:

Registration fee of Rs. 1,000/- and renewal fee of Rs. 500/- is to be paid by Demand Draft in favor of CPCSEA payable at New Delhi (as applicable).

EXECUTION 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;
 - 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.
 - If during the course of anesthesia /experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.
 - 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 anesthesia 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:

1. Title of the project
2. Names of the Principal Investigator and Co investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Endorsement of the name of Head of the Department
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma,
8. Curriculum Vitae of outside members, undertaking etc. to be used in the study.

9. Any other information relevant to the study.
10. Agreement to submit six monthly progress report and final report at the end of Study.
11. 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.
- 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.

ALL COMMUNICATIONS MUST BE ADDRESSED TO:

Deputy Secretary (AW) and Member Secretary (CPCSEA)

Ministry of Environment, Forest and Climate Change,

Government of India (Animal Welfare Division)

5th Floor, Vayu Wing,

Indira Paryavaran Bhawan, JorBagh Road, New Delhi – 110003.

Telephone No. 011-24695424

Email: cpcsea-mef@gov.in

INSTITUTIONAL ANIMAL ETHICS COMMITTEE, DDU GORAKHPUR UNIVERSITY, GORAKHPUR

As defined in “Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 1998’ which were amended in 2001 and then in 2006, to regulate the experimentation on animals”, 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 (CPCSEA) in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee.

IAEC shall accord quality and consistency in review of research proposals and to prevent infliction of unnecessary pain & sufferings before, during and after experiments on animals, to follow the CPCSEA guidelines.

IAEC shall provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies. IAEC shall review and approve all research proposals involving small laboratory animals with an objective to assure quality maintenance and welfare of animals used in research. For experiments on higher animals, the IAEC shall forward its recommendation to the CPCSEA, New Delhi, for its approval process.

IAEC shall ensure that experiments shall be performed in every case by or under the supervision of a qualified person (Minimum qualification- Bachelor of Veterinary Science/ Human Medicine or Post graduate in life sciences/ Pharmaceutical sciences/Lab animal science) and under the responsibility of the Principle Investigator.

Every researcher must be trained enough in animal experimentation either during education or by training provided by competent trainers. IAEC shall review the proposals before start of the study as well as monitor the research throughout the study and after completion of the study through annual reports and final report.

The committee shall also ensure compliance with all regulatory requirements, to adhere to all applicable guidelines, to ensure the principles of Replacement, Reduction and Refinement. Simulation models, meta-analysis and in-vitro experimentation shall be promoted.

IAEC in association with Department of Zoology, DDU Gorakhpur University will organize in-house training programs for fresh animal experimenters, without any previous experience of animal experimentation, before execution of any animal experiment to ensure the welfare and quality research.

Minor invasive procedures required as the part of the experimentation on feeding trials, breeding experiments and livestock management studies which require blood collection from the experimental animals to further study the clinical parameters may be approved by the IAEC, keeping in view the nature of experimentation, volume of blood to be collected, its frequency and general health conditions of the experimental animals. The other protocols related to the large animals requiring major invasive techniques shall be sent to CPCSEA with recommendations of IAEC.

REFERENCE:

<http://cpcsea.nic.in/Auth/index.aspx>

MEMBERS OF INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

IAEC includes eight members of whom three are nominated by CPCSEA and remaining five members by the institute. The chairperson and member secretary of the committee are nominated by the institute from the existing members. The term of appointment of the committee will be for a period of 5 years. The committee will meet at regular intervals to review new proposals, requests and existing policies. The committee will also regularly monitor the procedures and practices related to animal experiments to ensure that animal welfare and ethics are strictly followed at every point of research.

