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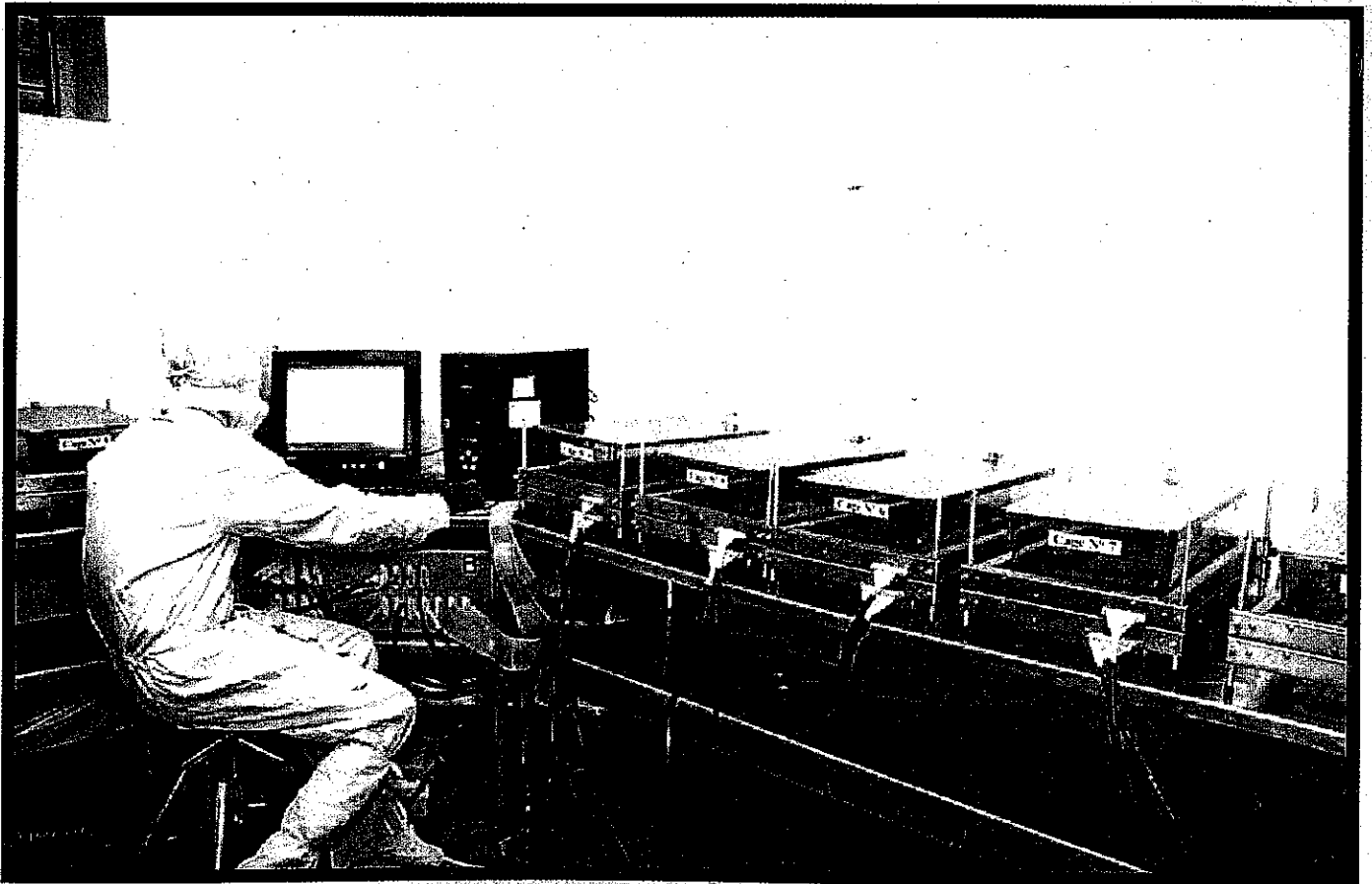
CPCSEA

Committee for the Purpose of Control and Supervision of Experiments on Animals

STANDARD OPERATING PROCEDURES

FOR

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)



Animal Welfare Division
Ministry of Environment and Forests

जहाँ है हरियाली ।
वहाँ है खुशहाली ॥

January, 2010

जयराम रमेश
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NEW DELHI - 110 003

7th January 2010

MESSAGE

I extend my best wishes, on the occasion of the Animal welfare fortnight, to all the members of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Institutional Animal Ethics Committee (IAEC) and to everyone who is actively associated with Animal welfare activities.

I am pleased to know that CPCSEA has put together a comprehensive manual on the 'Standard Operating Procedure' to be followed for the Institutional Animal Ethics Committee with the objective of ensuring uniformity in methods among all such committees in the country. Such a work has been long overdue and it is my sincere hope that it will go a long way in preventing the infliction of unnecessary pain or suffering on animals.

The guiding legislation in this regard is the Prevention of Cruelty to Animal (PCA) Act 1960 which provides for performance of experiments on animals for the purpose of advancement of knowledge or of knowledge which will be useful for saving lives and/or alleviating the suffering of human beings, animals or plants. However, the Act intends for such experiments to be performed with due care so as to minimize the pain inflicted on the animals.

I am glad to note that CPCSEA has made commendable strides since the Rules for Experimentation on Animals (Control and Supervision) were first notified in 1968 under the above legislation. It is also heartening to note that CPCSEA guidelines are being implemented effectively in more than 1300 establishments/institutions across the country.

I am sure that this manual will encourage IAEC members including researchers and animal facility managers to upgrade and improve their capacity for the welfare of research animals.

I wish all the individuals and groups involved, great success in their objectives and commend them on their work in furtherance of animal welfare.


(Jairam Ramesh)



सत्यमेव जयते

मु. फ़ै. फारूकी

अपर सचिव

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नई दिल्ली-110 003
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6th January, 2010

MESSAGE

The Prevention of Cruelty to Animal (PCA) Act 1960 provide for performance of experiments on animals for the purpose mitigation of sufferings and saving the lives of human beings and animals.

The Central Government has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) as per clause 15 of PCA Act, 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, to regulate the experimentation on animals.

This **Standard Operating Procedure (SOP) for Institutional Animal Ethics Committee (IAEC)** has been designed to bring out uniformity in the working IAEC so that consistent views are taken while reviewing the proposals entailing use of animals for experimentation. This manual explains in clear and simple terms, the CPCSEA approved procedure and rules position.

I would like to thank all the members of CPCSEA and Member Secretary for their sincere and dedicated effort in preparing the SOP. I hope that this would be a useful document for the IAEC members, principal investigators, researchers. Any suggestions to improve the SOP are most welcome.

I also take this opportunity to wish you all a very happy new year.

(M. F. Farooqui)

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FOREWORD

Experimentation on animals in course of medical research and education is covered by provisions of the **Prevention of Cruelty to Animals Act, 1960** and *Breeding of and Experiments on Animals (Control & Supervision) Rules of 1998, 2001 and 2006* framed under the Act. These are enforced by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960. Under these provisions, the concerned establishments are required to get themselves registered with CPCSEA, form IAEC, get their Animal House Facilities inspected, and also get specific projects for research cleared by CPCSEA before commencing the research on animals. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

In an amendment brought out in 2006 in the Rules for Breeding of and Experiments on Animals (Control & Supervision), powers to permit experiments on small animals were given to Institutional Animal Ethics Committee (IAEC) of the establishments. Only proposals for conducting experiments on large animals are required to be sent to CPCSEA for approval. Accordingly, it is important that all the IAEC members are fully aware of the extant rules and guidelines. It may be noted that approvals given by IAEC's which are not in accordance with the extant rules are invalid.

This document is a step to apprise the IAEC members about the rules and guidelines and provides a compilation of the same and would serve as an important document for all IAEC's. It also describes the objectives, role of IAEC, formation, procedure in which the meeting are to be conducted and other relevant information like decision making, reporting, record keeping etc.

ANJANI KUMAR
Member Secretary

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CPCSEA Standard Operating Procedures (SOP) for IAEC

1. 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 this 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..

IAEC has been designed to secure the following objectives:

- (a) experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in Veterinary Science or Medicine or Laboratory Animal Science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment;
- (b) that experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anesthetic of sufficient power to prevent the animals feeling pain;
- (c) that animals which, in the course of experiments under the influence of anesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible;
- (d) that experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
- (e) that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, mice, rats etc;

- (f) that, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
- (g) that animals intended for the performance of experiments are properly looked after both before and after experiments;
- (h) that suitable records are maintained with respect to experiments performed on animals

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 the Committee for the purpose of control and supervision of experiments on animals performed 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 animal experimentation before the start of the study. For experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.

IAEC is required to monitor the research throughout the study and after completion of study through periodic reports and visit to animal house and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

3. Composition of IAEC

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 and
7. A nominee of CPCSEA

Specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from amongst the eight members. Members against Serial number 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:

CPCSEA constitutes the IAEC on receipt of five (5) names against serial numbers 1-4 from the institute. The duration of IAEC is for a period of 3 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:

- a. The duration of appointment is for a period of 3 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.
- g. IAEC is required to formulate a SOP for its working requirements and follow it in all the meetings.

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 atleast in one meeting in a calendar year.

7. Conduct of business:

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, who will conduct the meeting. 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. 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.

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:

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

11. Review procedures:

- a. 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 expedited review.
- b. The proposals will be sent to members at least 15 days in advance.
- c. 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.
- d. Researchers will be invited to offer clarifications if need be.
- e. Independent consultants/Experts will be invited to offer their opinion on specific Research proposals if needed.
- f. 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.
- h. Procedures for appeal by the researchers should be clearly defined.

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 the IAEC should be communicated to the PI.

16. Follow up procedures

- a. Reports should be submitted 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 / sites 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. Record of rehabilitation of large animals if done.
- k. 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. 1000/- 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. 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).

22. All communications must be addressed to:

Member Secretary, CPCSEA,
Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001
Phone : 011-23318553
Email: cpcsea@rediffmail.com