

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

3. Functions of IAEC of AIMS R

- a. The primary duty of IAEC is to work for achievement of the objectives as mentioned above.
- b. IAEC will review and approve all types of research proposals involving small animal experimentation before the start of the study.
- c. As the AIMS R Animal house is not approved for 'large animal facilities', so no proposal for experiments on large animals will be undertaken by the IAEC.
- d. 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.

4. IAEC requirements

- a. 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. Proposal for renewal must be submitted with O/o CPCSEA at least 3 months prior to the expiry of registration.
- 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 (Annexure 1).

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- f. As per the 'mandatory actions for all establishments registered with CPCSEA as specified by Ministry of environment, forests and climate change", no person other than member of IAEC, as approved by CPCSEA, is allowed to attend the IAEC meeting; unless called upon subject experts for providing special review of selected research protocols, if need be, by the IAEC or as investigator of submitted proposal called for clarifications by the IAEC.
- g. All members will submit their brief, one page signed CV (Annexure 2).
- h. Conflict of interest should be declared by members of the IAEC.
- i. At least one meeting of IAEC will be conducted every six months.

5. Quorum requirements

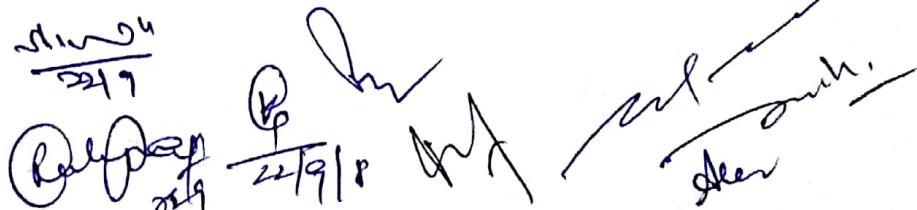
- a. The minimum of 6 members are required to compose a quorum.
- b. All decisions will be taken in meetings and not by circulation of project proposals.
- c. Presence of CPCSEA nominee is a must. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairman IAEC.
- d. Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a calendar year.

6. Conduct of business

- a. 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.
- b. 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.
- c. 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.

7. Participation by Investigators / experts in IAEC

- a. 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.



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

8. Application Procedures

- a. All proposals should be submitted in the prescribed application form (Form B)
- b. Approval of the 'AIMSR Research Committee', after considering the scientific content of the proposal must be enclosed with application form
- c. A 'No Objection Certificate' from the Principal AIMSR, specifying no objection for the use of Animal House facilities must be enclosed with the application form.
- d. Declaration as specified in Form B must be submitted by the investigator with the application form.
- e. In addition, researchers will submit an undertaking as per Annexure A.
- f. Form D as specified in the declaration form must also be submitted by the investigator with the application form.
- g. Details of laboratory facilities where experiments will be conducted, specifying facilities available etc must also be submitted by the investigator along with application form.
- h. Nine hard 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 the Chairperson, IAEC.
- i. A soft copy of the research proposal must be submitted to drrajvmahajan01@gmail.com with a copy to drkapilgupta02@gmail.com

9. Review procedures

- a. The meeting of the IAEC should be held once every six month. 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 will be recorded in the minutes. In case consensus is not reached, the case will 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.

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

10. Decision-making

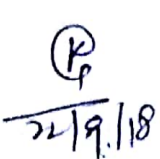
- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application 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 will be given.
- f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.
- g. Modified proposals may be reviewed by an expedited review.
- h. In case researchers are not satisfied with the decision of the IAEC, they can submit an appeal, citing reasons and clarifications, to the Member Secretary, IAEC in writing. Appeal will be discussed in the next scheduled meeting and if need be, case may be referred to the CPCSEA.


11. Communicating the decision

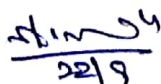
- a. Decision will be communicated by the Member Secretary in writing.
- b. Suggestions for modifications, if any, will be sent by IAEC.
- c. Reasons for rejection will be informed to the researchers.
- d. The schedule / plan of ongoing review by the IAEC will be communicated to the PI.

12. Follow up procedures

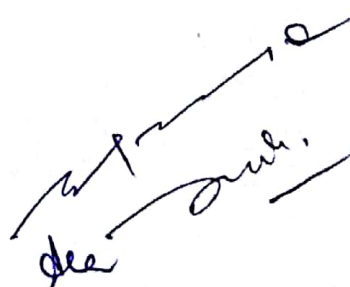
- a. Reports will be submitted by researchers/proposers every month for a study lasting less than one year and at interval of two months for study lasting more than one year from the date of approval of project by IAEC, to the member Secretary IAEC for review.
- b. Final report will be submitted by the researcher at the end of study to Member Secretary, IAEC.


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- c. All Serious Adverse Events (SAE's) and the interventions undertaken must be intimated by the researcher to Member Secretary, IAEC.
- d. Protocol deviation, if any, must be informed with adequate justifications by the researcher to Member Secretary, IAEC.
- e. Any amendment to the protocol must 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.

13. Record keeping and Archiving

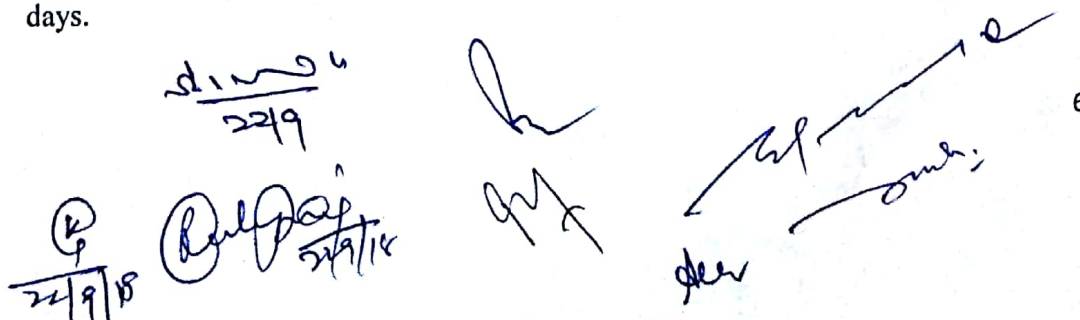
- a. Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.
- b. Copy of all study protocols with enclosed documents, progress reports.
- c. Minutes of all meetings duly signed by the Chairperson and the members.
- d. Copy of all existing relevant national 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 of two years.

14. 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.

15. Reporting to CPCSEA


- a. IAEC is required to send a copy of minutes of IAEC meeting to CPCSEA within 15 days.



 The bottom of the page contains several handwritten signatures and dates. On the left, there is a signature with the date '22/9/18' below it. Next to it is another signature with the date '22/9/18' below it. In the center, there is a signature with the date '22/9' below it. To the right of that is a signature with the date '22/9' below it. Further right is a signature with the date '22/9' below it. On the far right, there is a signature with the date '22/9' below it.

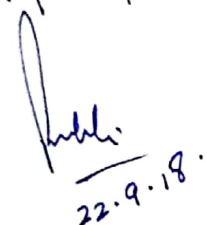
- b. Inspection report of animal house with photographs by IAEC members is required to be sent once in a calendar year. If action is required, the facility must provide ATR within 30 days.


16. Reimbursement to CPCSEA representative

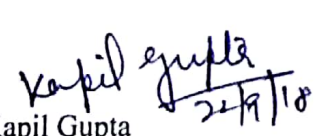
- a. CPCSEA representative(s) on the IAEC or authorized person(s) sent for inspection of the establishment(s) are required to be paid Rs. 2000/- each as sitting fees and reimbursement of actual expenditure incurred in this regard.

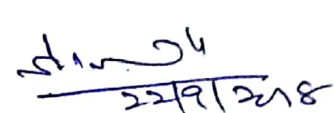

Dr Rajiv Mahajan
Chairperson



Dr Rajesh Kumar Goel
Link Nominee



Dr Preet Mohinder Singh Bedi
Member (Scientist from outside the institute)

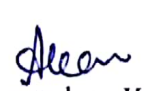

Mr Rajveer Singh Sethi
Member (In-charge Animal House)


Dr Kapil Gupta
Member Secretary, IAEC


Dr Lachhman Das Singla
Main Nominee


Dr Sandeep K Jain
Socially Aware Nominee


Dr Surinder Kumar Chaudhary
Member (Veterinarian)


Dr Amandeep Kaur
Member

Form B (per rule 8(a))*

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

Part A

1. Name and address of establishment
2. Registration number and date of registration.
3. Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C
4. Place where the animals are presently kept (or proposed to be kept).
5. Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)
6. Date on which the experiment is to commence and duration of experiment.
7. Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)

Signature

Name and Designation of
Investigator

Date:

Place:

*The filled in Form B having above information / details / supporting documents (1 original + 14 copies and 1 soft copy in CD) should be sent to: -

The Member Secretary,
CPCSEA, Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001

PART B

Protocol form for research proposals to be submitted to the committee / Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

- 1. Project / Dissertation / Thesis Title:**
- 2. Principal Investigator / Research Scholar / Research Guide / Advisor:**
 - a. Name
 - b. Designation
 - c. Dept / Div/ Lab
 - d. Telephone No.
 - e. Experience
- 3. List of names of all individuals authorized to conduct procedures under this proposal.**

Co-guides

 - a. Name
 - b. Address
 - c. Experience
- 4. Funding source with complete address (Please attach the proof)**
- 5. Duration of the project**
 - a. Number of months
 - b. Date of initiation (Proposed)
 - c. Date of completion (Proposed)
- 6. Detailed study plan may be given (Not more than one page)**

12. Will survival surgery be done?

If Yes, the following to be described.

- a. List and description of all such surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of operators
- c. Description of post-operative care
- d. Justification in major survival surgery is to be performed more than once on a single individual animals.

13. Methods of disposal post-experimentation

a. Euthanasia (Specific method):

b. Method of carcass disposal :

c. Rehabilitation :

14. Animal transportation methods if extra-institutional transport is envisaged.

15. Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified)

- (a) Radionuclides
- (b) Microorganisms / Biological infectious Agents
- (c) Hazardous chemicals or drugs
- (d) Recombinant DNA
- (e) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.

7. Animals required

- a. Species / Common name
- b. Age/ weight/ size
- c. Gender
- d. Number to be used (Year-wise breakups and total figures needed to be given)
- e. Number of days each animal will be housed.
- f. Proposed source of animals.

8. Rationale for animal usage

- a. Why is animals usage necessary for these studies?
- b. Why are the particular species selected required?
- c. Why is the estimated number of animals essential?
- d. Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.
- e. If yes, why new experiment is required?
- f. Have similar experiments been made by any other organization agency ? If so, their results in your knowledge.

9. Description the procedures to be used.

List and describe all invasive and potentially stress full non-invasive procedures that animals will be subjected to in the course of the experiments.

Furnish details of injections schedule

Substances	:
Doses	:
Sites	:
Volumes	:
Blood withdrawal	:
Volumes	:
Sites	:
Radiation (dosage and schedules)	:

- 10. Please provide brief descriptions of similar studies from invitro / invivo (from other animal models) on same / similar test component or line of research. If, enough information is available, justify the proposed reasons.**

- 11. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification.**

INVESTIGATOR'S DECLARATION.

1. I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previously reported research.
2. I certify that, I am qualified and have experience in the experimentation on animals.
3. For procedures listed under item 11, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
4. I will obtain approval from the IAEC/ CPCSEA before initiating any significant changes in this study.
5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body (to be named)).
6. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
7. I shall maintain all the records as per format (Form D)
8. I certify that, I will not initiate the study unless approval from CPCSEA received in writing. Further, I certify that I will follow the recommendations of CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted.

Signature

Name of Investigator

Date:

CERTIFICATE

This is certify that the project title

.....

has been approved by the IAEC.

Name of Chairman/ Member Secretary IAEC:

Name of CPCSEA nominee:

Signature with date

Chairman/ Member Secretary of IAEC:

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

FORM C

Record of Animals bred / acquired: (to be maintained by the Breeder/Establishment)

Date of entry	No. of Animals (Specify species, sex and age)	No. of Animals acquired (Specify date of acquisition species, sex and age)	Name, Address and date & from whom acquired	No. of animals transferred (specify date, species, sex and voucher/bill no.)	Name, address and registration No. of the Establishment to whom transferred	Signature
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FORM D

Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator)

Date of entry	No. of animals acquired (specify species, sex and age)	Name, address and registration No. of the breeder from whom acquired with voucher/bill no.	Date and particulars of order of grant of permission by the committee	Date/period of experiment	Name and address of the person authorizing the experiment	Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied with (Signature)

Annexure A

Undertaking by the Principal Investigator/Proposer

I, _____ working as _____ at
_____ and Principal Investigator of
research protocol titled _____

being submitted for review of IAEC of AIMS do hereby state that:

1. I will submit a report every month (for a study lasting less than one year) / at interval of two months (for study lasting more than one year) from the date of approval of project by IAEC, to the member Secretary IAEC for review.
2. Final report will be submitted by me at the end of study to the Member Secretary, IAEC.
3. All Serious Adverse Events (SAE's) and the interventions undertaken will be intimated by me to the Member Secretary, IAEC.
4. Protocol deviation, if any, will be informed with adequate justifications by me to Member Secretary, IAEC.
5. Any amendment to the protocol will be resubmitted to IAEC for renewed approval.
6. Any new information related to the study will also be communicated
7. If the study is terminated prematurely, the same will be notified with reasons along with summary of the data obtained till that time by me to the Member Secretary, IAEC.
8. Change of investigators / sites will be informed and approval of IAEC will be taken.

Signature of the Principal Investigator: _____

Date: _____ Place: _____