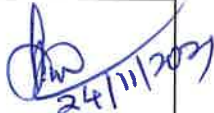





SRIHER – IAEC- Institutional Animal Ethics Committee		
SOP No.: CEFT/ACAD/001	Author: Dr. R. Siva	IAEC
Revision No.: 01	Date of Issue: 24//112021	Effective Date: 24/11/2021

Name	Designation	Responsibility	Signature with date
Dr. R. Siva	Member Secretary, IAEC	Author	 24/11/2021
Dr. Solomon F.D. Paul	Chairman- IAEC	Approval	 24/11/2021

Distribution
SRIHER Website and CEFTE

Revision Summary
Revised as per CPCSEA instruction letter dated 01.02.2019 and 07.09.2019

Confidential

Sharing this information in any mode is strictly forbidden

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1. Introduction

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 as defined in “Breeding of and Experiments on Animals (Control and Supervision) rules, 1998”.

2. Scope

This standard operating procedure outlines the objective, responsibilities, duty and functions and system to be followed in all the meetings by Institutional Animal Ethics Committee of Sri Ramachandra Institute of Higher Education and Research.

3. Objective

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

4. Responsibility

IAEC members –SRIHER

5. Procedure

5.1. Composition of IAEC

1. Institutional Animals Ethics committee of establishment should comprise eight members.
2. CPCSEA constitutes the IAEC on receipt of five (5) scientist names from the institute/establishment.
 - A biological scientist
 - Two scientist from different biological disciplines
 - A Veterinarian involved in the care of animal
 - Scientist in charge of animals facility of the establishment concerned
3. Chairperson of the Committee and Member Secretary would be nominated by the Institution/Establishment from amongst the eight members.
4. In addition, CPCSEA nominates three external members
 - A scientist from, outside the institute
 - A non scientific socially aware member and

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- A Main nominee of CPCSEA with a provision of a Link nominee for CPCSEA nominee.
5. Specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms.
 6. The duration of IAEC is for a period of 5 years and is required to be reconstituted at the time of renewal of registration, at least with the replacement of 50% of existing members. Renewal process has to be submitted to CPCSEA before 40 days of renewal expiry date.
 7. However, changes of members shall be made by submitting justification to CPCSEA and their approval through online.
 8. 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.
 - IAEC will 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 will ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.
 9. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
 10. Conflict of interest should be declared by members of the IAEC.

5.2. Quorum requirement

1. Minimum of 6 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.
2. Presence of CPCSEA nominee and socially aware member's is a must. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairman IAEC and at least in one meeting in a calendar year and update him /her about the activities of IAEC.

5.3. General Requirements

1. As per CPCSEA instruction, CCTV camera shall be installed in the animal house facility to ensure that the animals are being looked after and maintained as per guidelines of CPCSEA. The recorded footage of CCTV camera should be reviewed

Signature of Member Secretary



Signature of Chairman



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once in a fortnight and observations recorded and the document to be available at the time of inspection for Nominee / representative of CPCSEA.

2. Establishment should have a permanent /full time Veterinarian for ensuring proper care and well being of laboratory animals.
3. Health check up of animal attendants shall also be ensured regularly and the health records retained in the facility.
4. As per CPCSEA, experiments to be conducted at the facility, with Do's and Don'ts as follows:

Do's

- 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 and under the responsibility of the person performing the experiment
- Experiments shall be performed 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 recognized by the Government
- Experiments involving operations are performed with due care and humanity under the influence of some anesthetic of sufficient to prevent the animals feeling pain
- Animals which, in the course of experiments under the influence of anesthetics, are so injured that their recovery would involve serious suffering, are ordinarily euthanized while still insensible
- Animals intended for the performance of experiments are properly looked after both before and after experiments.
- Suitable records are maintained with respect to experiments performed on animals

Don'ts

- Experiments on animals are avoided in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice;
- Experiments are not performed merely for the purpose of acquiring manual skill.
- 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;

5.4. Conduct of the Meeting

1. The meeting of the IAEC should be four times a year or three months once intervals as applicable.
2. Additional meetings may be held, if there are reasons to do expedited review.

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3. In addition, establishment where more than 40 proposals are conducted annually should mandatorily convene the IAEC meeting once in three months to ensure proper scrutiny of research protocols, proper functioning of IAEC and checking the status of research proposal and health status of laboratory animals.
4. 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.
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. IAEC meetings will be organized by member secretary based on the number of proposals available (First cum first serve basis, minimum 10) with the due concurrence of all members.
7. Meeting dates notification will be sent via circular through university portal
8. Attendance of members and investigator need to be documented and maintained for each meeting.
9. 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.

5.5. Participation by Investigators / experts in IAEC.

1. 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.
2. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.
3. Specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly micro organisms. They may provide special review of selected research protocols, if required. 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.

Signature of Member Secretary



Signature of Chairman



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5.6. Application procedures

1. All proposals should be submitted in the prescribed application form (Form B which as Part A and Part B). All relevant documents with checklist should be enclosed with application form by researcher. Documents are available in SRIHER website under Authorities – Committee – IAEC.
2. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Researcher /Principal Investigator (PI) and Co-investigators / Collaborators should be submitted to IAEC with declaration of Head of Department. Soft copy of proposal shall be submitted via email -sruiacc@gmail.com.
3. PhD students shall submit the proposal with Guide declaration and provide the details of registration and name co-guide as applicable in Form B.
4. Proposal submitted for the purpose of provisional clearance for funding agency or PhD clearance, it should be mentioned appropriately by researcher.
5. Proposals submitted for the projects funded from government agency or any other source, photocopy of the sanctioned letter received need to be submitted along with proposal.
6. In case of emergency, project proposals may be circulated to all the members either hard / soft copy by member secretary and chairman discretion.

5.7. Review procedures:

1. The process of review proposals will be done as follows
 - Proposal will be sent to members at least 15 days in advance.
 - 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 make presentation and offer clarifications.
2. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
3. The decisions will be recorded as minutes and Chairperson's approval will be received along with signature of all the IAEC members present.
4. Decisions will be made only in meetings where quorum is complete.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
6. Modified proposals may be reviewed by an expedited review through identified members.

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5.8. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision.
2. 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.
3. Decisions will be made only in meetings where quorum is complete.
4. Only members can make the decision. The experts / investigators / invitees will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
7. Modified proposals may be reviewed by an expedited review through identified members.
8. Procedures for appeal by the researchers should be clearly defined.

5.9. Communicating the decision

1. Decision will be communicated by the Member Secretary in writing.
2. Suggestions for modifications, if any, should be sent by IAEC to researcher.
3. IAEC Approval certificate for each proposal/experiments will be issued by IAEC with chairperson and CPCSEA nominee approval.
4. For PhD students who appear for provisional ethical clearance, member secretary will directly send the approval clearance letter to controller of examination.
5. Reasons for rejection should be informed to the researchers.
6. The schedule / plan of ongoing review by the IAEC should be communicated to the PI.
7. IAEC approval for experiments will be valid for one year from the date of approval. For extension of period, investigator has to seek the permission from IAEC.

5.10. Follow up procedures

1. After experiments are approved by IAEC, the investigators have to follow up the following procedures:
2. Investigators have to submit the experiment initiation form to Veterinarian to initiate the experiment as per approved proposal

Signature of Member Secretary



Signature of Chairman



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3. Once experiment completed, Form D shall be submitted by the investigator for the usage and return of animals as applicable
4. Reports should be submitted at prescribed intervals for review as applicable or Final Experiment completion report should be submitted at the end of study as applicable.
5. All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any amendment to the protocol should be resubmitted to IAEC for renewed approval.
8. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
9. Change of investigators / sites should be informed and approval of IAEC should be taken.

6. Record keeping and Archiving

- Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics attended.
- Copy of all study protocols with enclosed documents, progress reports.
- Minutes of all meetings duly signed by the Chairperson and the members.
- Copy of all existing relevant national and international guidelines on animal ethics and laws along with amendments.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Record of Breeding of animals, supply etc, if breeding of animals is undertaken.
- Record of import of animals with species, source, quantity, usage etc.
- Record of all Contract research, if conducted at the institute.
- All documents should be archived for a period of 5 years

7. Updating IAEC members

- All relevant new guidelines and amendments to the Rules and Act should be brought to the attention of the members.
- 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.

8. Reporting to CPCSEA

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

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- Inspection report of animal house with photographs by IAEC members is required to be sent once in a calendar year by 7 nominee. If action is required, the facility must provide ATR within 30 days.

9. IAEC related Formats

- Bio data and Consent form for Members of IAEC
- Form B – Application for permission for Animal Experiments
- Form C- Record of Animals bred / acquired: (to be maintained by the Breeder/Establishment)
- Form D - Record of Animals Acquired and Experiments performed: (to be maintained by the Investigator and submitted to Animal House)
- Experiment Completion Report
- IAEC Application processing fee

10. Reference

- CPCSEA Standard Operating Procedures (SOP) for IAEC under PCA Act 1960 and Breeding and Experimentation Rules 1998
- CPCSEA Compendium -2018
- F.No. 25/28/2017-CPCSEA - Instruction for animal house facilities registered with CPCSEA.
- www.cpcsea.nic.in


Signature of Member Secretary


Signature of Chairman