

Standard operating procedure (SOP), IAEC, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh, India

As defined in “Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998” "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) performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee¹.

Objective: This SOP provides guidelines to IAEC for effective functioning 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 of and Experimentation (Control and Supervision) Rules 1998, as amended in 2001 and 2006¹.

Function of IAEC: The functions of IAEC as per the compendium of CPCSEA, 2018 are as follows¹.

1. The primary duty of IAEC is to work for achievement of the objectives.
 - Every experiment shall be performed by or under the supervision of a person duly qualified in that behalf, that is, Degree 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;
 - That experiments are performed with due care and humanity and as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals from feeling pain;
 - That animals who, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily medically allowed to death while still under influence of anaesthetic;
 - That experiment on animals is avoided wherever it is possible to do so.
 - That experiments on larger animals are avoided when it is possible to achieve the same results by experiments on small laboratory animals like guinea-pigs, rabbits, mice, rats etc;
 - That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill;
 - That animals intended for the performance of experiments are properly looked after before, during and after experiments;
 - That suitable records are maintained with respect to experiments performed on animals
2. IAEC should focus mainly on ensuring ethical and methodical handling of animals during and after experiments, so that they have less suffering.

3. IAEC will review and approve all types of protocols for research involving small animal experimentation before the start of the study.
4. For approval of experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.
5. IAEC is required to monitor the research throughout the study and after completion of study, IAEC shall obtain the periodic reports on research development and shall ensure visit to animal house facility and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

IAEC members

S. No.	Name of IAEC Members	Designation in IAEC	Designation in GITAM (Deemed to be University)
1	Prof. Subrat Kumar Bhattamisra	Biological Scientist, Chairperson	Professor, GITAM School of Pharmacy, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh
2	Dr. G. Suhasin	Scientist In charge of Animal House Facility, Member Secretary	Assistant Professor, GITAM School of Pharmacy, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh
3	Dr. K. Padma Dorothy	Scientist from different biological discipline	Assistant professor, Department of Biotechnology, GITAM School of Technology, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh
4	Dr. Avijit Banik	Scientist from different biological discipline	Associate Professor, GITAM School of Sciences, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh
5	Dr. B. Santosh Kumar	Veterinarian	Veterinary Doctor, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh
6	Dr. K. Eswar Kumar	CPCSEA nominated Main Nominee	Associate Professor, Department of Pharmacology, A.V College of Pharmaceutical Sciences, Andhra University, Visakhapatnam, Andhra Pradesh
7	Dr. Nama Sreekanth	CPCSEA nominated Link Nominee	Principal and Professor, Koringa College of Pharmacy, Korangi (V), Tallavevu (M), East Godavari, Andhra Pradesh
8	Dr. Bhavani Boddeda	CPCSEA nominated Scientist from outside the Institute	Professor, Koringa College of Pharmacy, Korangi (V), Tallavevu (M), East Godavari, Andhra Pradesh
9	Mr. Satyanarayan Murthy	CPCSEA nominated Socially Aware Nominee	Chitoory Venky Residency, Jawahar Street, Kakinada, East Godavari, Andhra Pradesh

Conduct of IAEC meetings:

- IAEC meeting will be conducted as prescribed in the compendium of CPCSEA, 2018.
- Meetings of IAEC, GITAM will be convened once in every 3 months subjected to the availability of minimum three applications. Additional meetings can be convened as and when necessary. Meetings are convened in **3rd or 4th week** of March, June, September, and December. (Date will be decided at the end of previous meeting).
- Proposal should be submitted on or before **15th** of February, May, August, and November for upcoming IAEC meeting in the month of March, June, September, and December.
- Any proposal submitted after the deadline will be considered for the next scheduled IAEC meeting.

Activity	Jan	Feb	March	April	May	June	July	August	September	October	November	December
Proposal Submission deadline		15th			15th			15th			15th	
IAEC Meeting												

Quorum requirements as per CPCSEA:

- 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.

Application procedure

- All the Investigators planning to submit the research proposal for IAEC approval need to mandatorily refer the Investigators guideline of GITAM (Deemed to be University), Visakhapatnam.

- Principal Investigators initially need to submit the soft copy of the proposal to iaec_gitam@gitam.edu before the deadline. The proposals will be screened by designated members using a checklist. The screening report will be sent to the PI to submit the final copy (after corrections if any) within TWO days.
- PI has to submit four copies of research proposals hard copy with the relevant documents to member secretary, IAEC.
- The procedures as follow

For New proposals:

- a. Covering letter from the PI addressing to The Chairperson, IAEC
- b. Form B
- c. Sanction letter from external funding agency (if applicable/available)

Amendment of approved proposal

- a. Covering letter from PI with justification for the proposed amendment.
- b. Revised Form B (with modified parts highlighted)
- c. IAEC approval letter

Progress reports

- a. Covering letter from the PI
- b. Progress Report
- c. IAEC approval letter
- d. Form-D

Study completion Final reports

- a. Covering letter from the PI
- b. End of project report
- c. Original IAEC approval letter
- d. Form D

- Where the PI requires IAEC approval copy for research proposal submission to external funding agencies, a provisional IAEC approval of such proposals may be given after due consideration. However, there shall not be any allotment of animals and the PI has to obtain the full approval if research proposal is successful in obtaining research fund. The PI has to follow the procedure of new proposal submission for IAEC approval and initiation of the study.
- On the day of IAEC meeting, the investigator/co-researcher has to present the research proposal before the IAEC members using a PowerPoint presentation as described in Form-B. The schedule of the presentation will be intimated by the member secretary one week before the commencement of meeting.
- The decisions of IAEC shall be considered final.

Post-IAEC meeting

- The minutes of the meeting of IAEC will be communicated to the PI by the Member Secretary in writing. If revision is necessary, the revised document in required number of copies to be submitted within a stipulated period as specified in the communication.

- Suggestions for modifications and reasons for rejection will be communicated to the PI.
- The species and number of animals as approved need to be procured by the PI from a CPCSEA registered breeder in accordance to rule ten of the breeding and experiments on animals' control and supervision, rules 1998, as amended.
- Record of Animals Acquired and Experiments performed should be maintained (Form-D).
- Reports should be submitted by PI at prescribed intervals for the review, and it should not exceed the timeline of the research as mentioned in the Form B.
- The final report should be submitted by PI.
- All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated to IAEC.
- During the experimentation if any Protocol deviations are adopted should be communicated by the PI with adequate justification to IAEC.
- Any amendment(S) to the protocol should be resubmitted to IAEC for renewed approval.
- Any additional information obtained related to the study will be communicated to IAEC by PI.
- Premature termination of the study by the PI will be communicated with reasons along with the summary of data obtained so far.
- Change of investigators /sites should be, and communicated of IAEC should be taken.
- You must quote the proposal number in your future correspondence.
- Abide by the conditions stipulated in the investigators' declaration as submitted by you to IAEC.
- Any other regulations/stipulations as may be notified from time to time by CPCSEA shall also be applicable.
- Follow the guidelines furnished in the CPCSEA standard operating procedures for the Institutional animal ethics committee, as framed from time to time.
- Documents /registers as may be applicable need to be maintained by the investigator properly.
- In the case of the funded project, the principal investigator also needs to abide by the funding agency's guidelines.

References

1. Compendium of CPCSEA 2018, Ministry of Environment, Forest and Climate Change, Animal welfare division, Government of India. (<https://cpcsea.nic.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf>) (<https://cpcsea.nic.in>)