

Standard Operating Procedures (SOPs) for Institutional Animal Ethics Committee (IAEC) of MKCG Medical College, Berhampur.

MKCG Medical College, Berhampur, a teaching and research institution with many post-graduates students performing research on animals. As per the CPCSEA (Committee for the Purpose of Control And Supervision of Experiments on Animals) norms, Institutional Animal Ethics Committee (IAEC) has been constituted to supervise and evaluate all aspects of the animal care and use program in the institution under Rule 5(a) of the breeding and Experiment on Animals (Control and Supervision) rules 1998.

CPCSEA Registration No.: 472

Objective:

The objective of this SOP is to contribute to the effective functioning of the IAEC MKCG Medical College, Berhampur, so that a quality and consistent ethical review mechanism for biomedical research in animal is put in place for all proposals dealt by the Committee. IAEC is also responsible for reviewing Form-B, Form-C and Form-D, inspecting animal facilities and uphold 3R's principles of (Replacement, Reduction and Refinement) ensuring adherence to CPCSEA guidelines. Before research involving animal can be undertaken, the project will have to be reviewed and approved by the IAEC.

Function:

The functions of the Institutional Animal Ethics Committee (IAEC) are as follows:

- Review proposed use of animals in research and require any modifications necessary for approval, or withhold approval prior to use of animals
- Approve research involving animals which conform to the various guidelines for use of animals in research
- Review periodically the Institute's animal facility
- Review and investigate legitimate concerns involving the care and use of animals during research
- Ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities

Composition of Institutional Animal Ethics Committee (IAEC):

Composition of Institutional Animal Ethics Committee (IAEC) shall include members as follows-

1. A biological scientist
2. Two scientists from different biological disciplines preferably involved in animal experiments, out of two, one from the non-clinical discipline.
3. One veterinarian involved in the care of animals
4. A scientist in charge animal House
5. A scientist from outside the institute
6. One non-scientific socially aware person
7. One nominee of CPCSEA

One specialist may be co-opted while reviewing special projects using hazardous agents such as radio-active substance and deadly micro - organisms The Chairperson of the committee and member secretary shall be nominated by the institution from amongst the eight members. Members against serial no. 5, 6 & 7 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- 4 will be sent from the institute to CPCSEA.
- The duration of IAEC will be for a period of 3 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. 5.

Membership duration and responsibilities:

- The duration of membership will be 3 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 long-term non-availability (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 requirements:

- A minimum of 6 members are required to compose a quorum.
- All decisions should be taken in meeting and not by circulation of proposals.
- Presence of CPCSEA nominee is must.
- Link nominee can attend in case main nominee conveys his unavailability in writing.
- Socially aware member's presence is compulsory in proposals referred to CPCSEA and at least one meeting in a calendar year.

Conduct of the meetings:

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. 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. In any case the meeting should not be held without the presence of CPCSEA member or nominee.

Participation of by Investigators / Experts in IAEC:

- If needed, IAEC may call upon subject experts for offering special opinion for selected research projects.
- They will give specialized view but not take part in the decision making.
- Investigators whose proposals are to be discussed can be called to present their case to IAEC.

Application procedure:

- All proposals should be submitted in the prescribed application form, copies of which will be available from the Member Secretary.
- All relevant documents with check list should be enclosed with application form.
- Fifteen copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator and Co-investigators/Collaborators should be forwarded by the Head of the Department to the IAEC. Sixteen additional copies for proposals for experiment on large animals will be required for forwarding it to CPCSEA.
- A fee of Rs 20000/- will be charged for sponsored project from outside the institution.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

Review procedure:

- Meetings of IAEC shall be held every 6 months, for which the month will be decided at the end of previous meeting. Additional meetings will be held as and when necessary.
- 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 proposal's review may be expedited through identified members.

Communication of the decision:

- 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 will be informed to the Principal investigator.

Follow up procedures:

- 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 archiving:

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

- Curriculum Vitae (CV) of all members of IAEC including training programmes 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 15 days. 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 representative:

CPCSEA representatives on IAEC or authorized persons sent for inspection of the establishment 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).

Performance 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;
 - (a) 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.
 - (b) If during the course of anaesthesia /experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.
 - (c) 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 anaesthesia 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:

- Title of the project
- Names of the Principal Investigator and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Endorsement of the name of Head of the Department.
- Protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant annexure like proforma, Curriculum Vitae of outside members, undertaking etc. to be used in the study.
- Any other information relevant to the study.
- Agreement to submit six monthly progress report and final report at the end of study.
- 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.

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)

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 animal 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.

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.

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 of MKCG Medical College, Brahmapur on _____.

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)

CHECK-LIST (To be submitted for consideration of CPCSEA)

1. Title of the protocol
2. Name and address of the Institute submitting proposal, with Ref No. If any
3. CPCSEA Registration No. And valid upto
4. Status of Institute and its accreditation, if any DST/ICMR/DBT/CSIR/Public funded Institution/ State/ Central University/ College/ ISO-NABL certified lab/ GLP certified lab/ others
5. Type of research work
 - a. Academic
 - b. Research
6. Composition of IAEC as per approved guidelines, names and addresses of establishment / members to which they represent
7. Detailed signed minutes of IAEC by members attached with the protocol.
8. Recommendations of IAEC
9. The date of last inspection of Animal House Facility and approval details conveyed by CPCSEA
10. Name of the Principal Investigator with designation, qualification and work experience with animals
11. Name of the Co- Principal Investigator with designation, qualification and work experience with Animals
12. Source of procurement of animals, types, number, age & sex
13. Information regarding import / export of animals / material before and after experimentation
14. A signed declaration by Principal Investigator is attached with proposal?

Signature of Chairman IAEC	Principal Investigator
For official use only Date of receipt of the protocol and number of copies / CD	
CPCSEA Reference number	
New proposal / revised proposal	
Signature of Expert Consultant, CPC	

N.B. These forms are to be maintained by the Investigator

Form C: Record or animal bred/acquired: (to be maintained by the breeder/Establishment)

Date of entry	No. of animals (specify species, sex and age.)	No. of the bred (specify date, Species & Sex)	No. of animals acquired (specify date, species, sex and age.)	Name, address & Date of acquirement	No. of the animals transferred (specify date, Species & Sex)	Name, address & regd. No. to whom transferred	Signature

Form D: Record or animal acquired and experiments performed : (to be maintained by the investigator)

Date of Entry	No. of animals (specify species, sex and age.)	Name, address and registration No. of the bidder from whom acquired with voucher / bill No.	Date and Particulars of order of Grand of permission by the committee	Date / Period of experiment	Name and Address of the person authoring the experiment	Certification of the investigator authorizing the experiment that all conditions specified for such an experiment have been complied with (signature)

REVIEW OF PROJECTS IN THE IAEC MEETING

1. Date of IAEC meeting:
2. Name of the projects:

3. Name of the PI:
4. Duration of the project:
5. No. of animals approved in the IAEC:
6. No. of animals used till date:
7. Project status : completed/ongoing
8. Brief progress report:

9. Remarks:

Signature of the PI & date

**One Page CV for Members of the Institutional
Animal Ethics Committee**

Last Name	First Name	Middle Initial
Date of Birth (mm/dd/yy):		Sex
Professional Mailing Address (Include institutional name)		
Telephone (Office) :		Mobile Number :
Telephone (Residence):		E-Mail:
Academic Qualifications (Most current qualification first)		
Degree / Certificate	Year	Institution, Country
Professional Experience		
Month and Year	Title	Institution / Company, Country
Signature: (Signature Required)		

**CONSENT LETTER BY MEMBER OF INSTITUTIONAL ANIMAL ETHICS
COMMITTEE**

To,

CPCSEA,
New Delhi.

Subject: Consent to act as an IEAC member.

I, _____, hereby give my consent to be a member of IEAC, MKCG Medical College, Berhampur.

Date:

Place: Berhampur

Signature:.....

Designation:.....

Composition of IAEC

SL. NO.	NAME OF THE IAEC MEMBER	DESIGNATION IN IAEC
1	Professor Arun Kumar Dandapat, Dean & Principal, MKCG Medical College, Brahmapur.	Chairman
2	Professor Chandra Sekhar Maharana, Prof. & HOD of Pharmacology, MKCG Medical College, Brahmapur.	Member Secretary
3	Professor Radha Madhab Tripathy, Prof. & HOD of Community Medicine, MKCG Medical College, Brahmapur.	Scientist from different discipline
4	Dr. Arabinda Behera, Specialist (Veterinarian), Department of Pharmacology, MKCG Medical College, Brahmapur.	Veterinarian
5	Dr. Supriya Pradhan, Associate Professor, Department of Pharmacology, MKCG Medical College, Brahmapur.	Scientist In charge of the animal house Facility
6	Dr M Mohanty, Khandagiri, BBSR.	Biological Scientist
7	Mr. Biswajit Lahiri	Non- Scientific Member (Social Worker)