

**Standard Operating Procedure (SOP) for Institutional animal ethics committee (IAEC).
Maharaja Sriram Chandra Bhanja Deo University, Takatpur, Baripada**

1. Purpose

The use of animals in research is widely practiced in various laboratories across the world. Animals have an intrinsic value and they have the sense organ to feel pain. Besides animals have a moral status, and that our treatment of them should be subject to ethical considerations. Therefore, researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Research and experimentation on animals are covered by provisions of the Prevention of Cruelty to Animals Act, 1960 (amended in 1982) and Rules of Breeding of and Experiments on Animals (Control & Supervision) 1998 (amended in 2001 and 2006) framed under the PCA 1960. Government has constituted a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) under the provision of Section 15 of PCA Act 1960. In this regard the ethical issues involving animal experimentation at Maharaja Sriram Chandra Bhanja Deo University will be monitored, controlled and regulated by Institutional animal ethics committee (IAEC).

2. Objectives

Institutional Animal Ethics Committee is a local body, approved by CPCSEA, which has been empowered to permit experiments on small animals through an amendment in Rules for Breeding and Experiments on Animals (Control and Supervision) in year 2006. The objective of this Standard Operating Procedure (SOP) is to ensure the effective and responsible functioning of IAEC.

3. Functions of Institutional Animal Ethics Committee (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 CPCSEA performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the Committee. IAEC accords quality and consistency in review of research proposals and to prevent infliction of unnecessary pain & sufferings before, during and after experiments on animals, to follow the CPCSEA guidelines. IAEC is providing independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies. IAEC reviews and approves all research proposals involving small laboratory animal experiments, up to phylogenetic level of rodents and lagomorphs only, with a view to assure quality maintenance and welfare of animals used in pre-clinical research. For experiments on higher animals, the IAEC will forward its recommendation to the CPCSEA, New Delhi, for its approval process. IAEC ensures that experiments shall be performed in every case by or under the supervision of a qualified person (Minimum qualification- Bachelor of Veterinary Science/ Human Medicine or Post graduate in life sciences/Pharmaceutical sciences/Lab animal science) and under the responsibility of the Principal Investigator. Every experimenter must be trained enough in animal experimentation either during education or by training. IAEC reviews the proposals before start of the study as well as monitor the research throughout the study and after completion of the study through annual reports, final report. IAEC team will visit of the laboratory in the animal house/respective department where the experiments are conducted. The committee also ensures compliance with all regulatory requirements, applicable guidelines and laws.

IAEC will also:

- Monitor and inspect the housing of animals and ensure that it is as per specified standards.
- Grant permission to MSCBDU for conducting experiments on small animals. Regulate experiments on animals as per stipulated conditions and standards.

- Ensure the human end point for animals which in course of the experiments are so deeply anesthetized / injured / suffering from severe pain with poor prognosis / recovery would involve serious sufferings and are euthanized as per specified norms. 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 and where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals it will be euthanized.
- Ensure that experiments on animals are avoided whenever it is possible to do so and propagate the principles of 3Rs (Replacement, Reduction and Refinement). Simulation models, meta-analysis and in-vitro experimentation will be promoted. Power analysis (and related software) will be used to calculate the minimum possible number of animals required for every study. Up gradation of procedure and skill enhancement & regular training for experimenter will be promoted.
- Ensure that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon smaller animals viz. guinea-pigs, rabbits, rats, mice, frogs, zebra fish, drosophila etc.
- Ensure that required records are maintained with respect to experiments performed on animals.
- Ensure that as far as possible experiments are not performed merely for the purpose of acquiring manual skill.
- Ensure that animals intended for the performance of experiments are properly cared before and after experiments.
- Organize in-house training programs for fresher animal experimenters, without any previous experience of animal experimentation, before execution of any animal experiment to ensure the welfare and quality research.

4. Composition and Constitution of IAEC

IAEC includes following members as described below:

1. Chairman of the committee: Preferably Head of the Dept.
2. A Biological Scientist
3. Two Scientists from Different Biological Disciplines
4. A Veterinarian Involved in The Care of Animal
5. A Scientist in Charge of Animals Facility
6. A CPCSEA Main Nominee & A CPCSEA Link Nominee
7. A Scientist from Outside the Institute
8. A Socially Aware Nominee

A member secretary would be nominated by the institution from amongst the nine members.

CPCSEA constitutes the IAEC after receiving 5 names (Section A) along with their CV, secrecy undertaking from MSCBDU and demand draft of prescribed fee. CPCSEA nominates the members for Section B from its office. IAEC will be reconstituted for 5 years (or as per latest notification of CPCSEA) at the time of CPCSEA Registration renewal. Midterm reconstitution may be requested to CPCSEA in special cases viz. event of death, long time non-availability or violation in responsibilities of IAEC with details (CV and secrecy undertaking) of replacing member along with bank demand draft of prescribed fee by CPCSEA. Request for renewal of registration and reconstitution of IAEC will be uploaded to CPCSEA website, along with above described documents. A hard copy will also be sent to CPCSEA.

1. Membership Duration & Replacements in Committee

1. The duration of membership is 5 years or as per latest notification of CPCSEA (coterminous with registration renewal).
2. At the time of renewal of registration new IAEC will be formed and at least half of the members will be replaced. MSCBDU will introduce at least two new members during this process.
3. Any replacement in IAEC members can be made only with the prior approval of CPCSEA.
4. CPCSEA may be requested to replace a member in special cases viz. event of death, long time non-availability or violation in responsibilities of IAEC. Long time non-availability is defined as absence in three consecutive meetings.

Note:

- A. In case of any delay in registration renewal process the old committee will be in existence and function as of normal routine with the permission from CPCSEA till registration renewal and formation of new IAEC by CPCSEA.
- B. Application for animal house registration renewal will be forwarded to CPCSEA before three months from expiration.
- C. Animal House In Charge will initiate the process of registration renewal of animal house by preparing Bank Demand Draft of prescribed fee by CPCSEA and proposing the Institutional members for IAEC. Amount of the Draft shall be paid from the research endowment fund of the research cell.
- D. Bank demand draft will be prepared in favour of CPCSEA, payable at NEW DELHI.

5. Rights and Responsibility of Members

1. Every member of committee has equal rights to raise any relevant issue.
2. Conflict of interest should be declared by members of the IAEC to the chair.
3. It is cumulative responsibility of members to facilitate the smooth functioning of IAEC.
4. Members should maintain confidentiality of all discussions during the meeting and sign a secrecy undertaking 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 and after their membership period.
5. Member can tender resignation from the committee with proper reasons to do so.
6. Members should promote principle of 4Rs with active involvement, guidance and suggestions.
7. Any member who has any current information in field of animal welfare and ethics, during his/her visit to any conference or during latest literature review, must share with other members.
8. Members should not raise any discussion on his/her gut feeling. Reference material, if any, must be carried to meeting for easy sharing and decision making.

6. Role of CPCSEA Nominee

Nominee should be familiar with the CPCSEA guidelines, the concept of 3 Rs and other animal welfare issues. He/She must keep liaison with CPCSEA and also browse the CPCSEA MoEF website for any update of information or draft guidelines or rules and regulation, placed for comment. He/She should be familiar with animal experimentation procedures, husbandry conditions, supplies, humane way of dealing with animals, handling procedures etc. and other requirements as published in the CPCSEA/INSA guidelines for GLP methods. He/she must learn/be familiar with alternatives, reduction and refinement procedure available in biomedical research studies/programmes.

Nominee attached to educational institution should be thorough with the syllabus prescribed by the University/college for a particular course. Nominee attached with research institutions should learn about the overall goal/mandate of the institute and keep himself/herself abreast with the current and past work done by the institute in animal studies and thus be able to link the new studies proposed. Nominees

attached with institutions undertaking regulatory toxicology work should read and be familiar with various guidelines for registration of products such as pesticide, drugs and pharma, biotechnology and etc. For any clarifications on the protocols, methods, either they should see more details with the investigator when the agenda is circulated or seek comments from CPCSEA.

Nominee must read the proposal attached with Agenda thoroughly and come prepared to attend the IAEC meeting. He/she should aim for humane/ethical issues and compliance to GLP principles, avoid repetitions of animal studies, expected outcome and its impact, number and sex of animals used, source, health status, alternatives, reduction without losing scientific conclusion etc.

Nominee should not indulge in arguments and heated debate but understand the merit of a study based on above principles. Nominee is expected to sign the necessary forms of each protocol and maintain a copy/list in his/her records. In case of proposals dealing with large animal, nominees should note that IAEC is only a recommending authority for such studies. Nominee should ascertain the capability of institution to perform studies on large animals and make sure his/her recommendations find place in the minutes attached to CPCSEA.

Nominees should forward a copy of the minutes to CPCSEA office within 15 days from the date of meeting/inspection of animal house.

If no meetings are held for 6 months in a row because of lack of projects or due to other reasons, nominee should notify to CPCSEA about "no meetings" after confirmation/verification with the organization. Nominee should visit animal house at least once in a calendar year and submit the report in the prescribed form to CPCSEA office within a month from the date of inspection. Follow up may be taken up and reports also submitted to CPCSEA with ATR.

If nominee requires assistance of any other expert to review a protocol he/she can do so by consulting CPCSEA.

Nominee not supposed to do

Nominee is not permitted to make any campaign/publicity about his/her role and solicit any sponsorship from any organization falling under his/her jurisdiction.

Nominee should not sign the minutes of the meeting/Forms/Register without attending the meeting in person.

Further, nominees should not allow any tele/audio conference with a non participating member during the IAEC meeting.

Nominee should not allow any outside member to attend the IAEC meeting.

The nominees must keep themselves away from the media and press and will not disclose the confidential information related to the CPCSEA.

7. Quorum Requirements

A minimum of 6 members is required for quorum. The presence of CPCSEA main/link nominee is mandatory for every meeting. Link nominee will attend in case main nominee conveys his unavailability in writing (hard copy or email) to the Chairman IAEC. Socially aware member's presence is compulsory in cases referred to CPCSEA and at least in one meeting in a calendar year.

8. Frequency of IAEC Meetings

1. Meetings of IAEC shall be held on scheduled intervals. Minimum 2 meetings will be held in 1 year. Additional meetings will be held as and when necessary.
2. Regular meeting will be called in month of March and September.
3. As and when 5 or more than 5 study protocols will be submitted to office of Member Secretary, meeting will be organized as earliest possible to expedite the process of IAEC discussion and decision.
4. Even if there are no projects, mandatory frequency of meeting will be maintained; to discuss the animal welfare and well being issues in the animal houses. The Animal House In-Charge will maintain and provide all relevant record to the committee members.

9. Offices/Conduct of the Meeting

The Chairperson will conduct all meetings of the IAEC. If, for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves, who will conduct the meeting. 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 signed by every member present in meeting for record purpose and further communication. Copy of minutes will be uploaded to CPCSEA website as well as hard copy will be sent to Member Secretary, CPCSEA within 15 days of meeting, if no genuine cause of delay is in existence.

Note: In every meeting visit to animal house will be mandatory agenda.

10. Independent Consultants

IAEC may call upon subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific subjects or methodologies, or representative of CPCSEA. They will not take part in the decision making process.

11. Animal Experimentation Application Procedure

1. Application procedure is open round the year. It is advised to submit animal study protocols without waiting for notification of IAEC meeting that will avoid the last minute hurry.
2. Animal Research projects will be submitted to the Research Cell, MSCBDU and to the office of Member secretary, IAEC, MSCBDU through the proper proceedings as per Institutes' rules and regulations (**SOP for Animal Experimenters**) and in prescribed application format.
3. PI will attach the bank demand draft of CPCSEA prescribed fee for animal experimentation.
4. The Member Secretary will acknowledge the receipt of study protocol and indicate any lacunae. Missing information should be supplied within one week.
5. PI need to prepare small power point presentation, **consisting not more than 7 slides**, to be presented during IAEC meeting.

12. Animal Experimentation Related Documentation and Formats

1. Office, Member Secretary, IAEC will maintain the application, review, modification/cancellation of animal experimentation related documents.
2. Office, Member Secretary, IAEC will maintain the communication to PI.
3. Different formats are available in office of member secretary as well as institute's website.
4. Animal experimentation related formats are available in **SOP for Animal Experimenters**.

13. Animal Experimentation Review Procedure

1. The proposals will be sent to members at least 2 weeks in advance.
2. Every member will be provided a separate assessment sheet of predictable risks/harms to the animals vs. advantage of research outcome to record his/her opinion with every study protocol. Member must fill this format before hand to expedite the discussion during meeting. Assessment sheet will be mandatorily handed over to Member Secretary, IAEC, MSCBDU.
3. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
4. The decision will be made by consensus after discussion.
5. The decisions of the meeting shall be recorded in the minutes' book and approval of Chair Person will be taken along with signature of all members present in meeting. Minutes will be confirmed during the next meeting.
6. The minutes of each meeting will be stored at Office, Member Secretary, IAEC.

14. Element of Review

Protocol will be reviewed ensuring following criteria:

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms to the animal vs advantage of research outcome.
4. Protocol and proforma of the study.
5. Judicious number of animal allotment and usage in the study.
6. Plans for data analysis and reporting.
7. Adherence to all regulatory requirements and applicable guidelines.
8. Competence of investigators, research and supporting staff.
9. Facilities and infrastructure in the animal house/respective department

15. Discussion on Animal Experimentation Study Protocols and Decisions Making

- I. The date of meeting will be intimated to the PI. PI or Co-PI must be available during meeting for presentation and to offer clarifications. He/she will take the note of suggested modification/corrections discussed in meeting for further improvisation and submission of final copy to the office of Member Secretary, IAEC.
- II. Every member will initiate his/her discussion as per points captured in sheet of predictable risks/harms to the animals vs. advantage of research outcome.
- III. Decision of IAEC would normally be taken by consensus after discussion on various aspects of study proposal. If divergent views are expressed by the members, these may be recorded in the minutes and a broad consensus be recorded as per understanding of the Chair. Welfare of animal, by various means, must be promoted during decision making.
- IV. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- V. Decisions will be made only in meetings where quorum is complete.
- VI. Only members will make the decision. The decisions shall be taken in the absence of investigators & consultants.
- VII. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- VIII. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- IX. Modified proposals must be submitted to the office of Member Secretary, IAEC, MSCBDU within 1 week from the date of notification.
- X. Modified proposals may be reviewed by an expedited review through identified member/s. Member/s

will be nominated for review of modified proposal in meeting. Chairman, IAEC and CPCSEA Nominee will sign on study protocol certificate after clearance of identified members. In case appointed reviewer is not available; Chairman, IAEC will do the process.

- XI. Study proposals on large animals will be discussed and forwarded to CPCSEA with recommendation of IAEC for further discussion and decision.

16. Communicating the Decision on Animal Experimentation

- I. Decision will be communicated to PI by the Member Secretary in writing.
- II. Suggestions for modifications and reasons for rejection will be communicated to the PI.
- III. Once IAEC study protocol will be approved for experimentation then Protocol Approval Certificate will be released to PI with sign of Member Secretary and Chairman IAEC.

17. Follow up Procedures of Animal Experimentation

- a. Without fail annual progress report will be submitted to IAEC by PI.
- b. Final report will be submitted to the IAEC by PI.
- c. Deviations from the project is not allowed without the permission from IAEC.
- d. Any new information related to the study will be communicated to IAEC by PI.
- e. Premature termination of study will be notified with reasons along with summary of the data obtained so far. The un-used animals may be surrendered to Animal House.
- f. All serious adverse effect (SAEs) and unexpected animal welfare concerns must be intimated to IAEC as soon as possible.
- g. Change of investigators will be done with the approval of IAEC.
- h. Note: For any collaborative animal experimentation, with ethical clearance from other institution and part of work at MSCBDU, PI must submit the relevant documents to protocol approving IAEC. Experimenter at MSCBDU will send the copy of approved protocol/IAEC certificate for information and record purpose to the Office of Member Secretary, IAEC, MSCBDU before start of animal experimentation.

18. Contract Animal Experiments

Amendment of Rule-12, in the breeding and experiments on animal Rule 1998, this rule has been amended to allow to establishment to undertake contract research as per provision of PCA-Act 1980, and the rules made their under. If any proposal will requested to MSCBDU then with permission of IAEC it may start the research.

19. Record Keeping and Archiving

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

- i. Curriculum Vitae (CV) and secrecy undertaking of all members of IAEC.
- ii. Minutes of all meetings duly signed by all members present in meeting. Copy of all correspondence with members, researchers and other regulatory bodies.
- iii. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
- iv. All study related documents (study projects/protocol with enclosed documents, progress reports) will 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 PI for minimum of five years.
- v. Record of animal breeding and animal import.
- vi. Record of Animal rehabilitation.

20. Updating IAECmembers

- i. All relevant information on Animal ethics will be brought to the attention of the members of IAEC cumulatively by every member.
- ii. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research related to the animal and animal ethics & welfare to help in improving the quality of research projects/animal ethics committee submissions and review.

21. Reporting to CPCSEA

- a. Member Secretary, IAEC will upload the minutes of meeting to CPCSEA website through user (establishment) login. Also a hard copy will be sent to CPCSEA.
- b. Once in a year animal house inspection report along with photographs of animal facility will be uploaded by CPCSEA nominee (or Link nominee in absence of main nominee). ATR, if required, will be submitted to CPCSEA nominee by Member Secretary, IAEC within 30 days of inspection. Further CPCSEA Nominee will upload the ATR to CPCSEA website using nominee login. CPCSEA nominee will also send hard copies to CPCSEA as required.
- c. Large animal study proposal, with other required documents, will be uploaded to CPCSEA website using user (establishment) login. A hard copy will be sent to CPCSEA.
- d. New website of CPCSEA will be used to check any recent development. Web address is as follows: <http://cpcsea.nic.in/>
- e. Preferred mode of communication to CPCSEA will be emailing. CPCSEA email is as follows: cpcsea.moef@gmail.com
- f. CPCSEA is promoting the paperless working through its website. Once the process will be fully operational then the practice of sending hard copies may be stopped.
- g. All communication will be sent at following address of CPCSEA:
Member Secretary, CPCSEA
Ministry of Environment, Forests and Climate Change
(Animal Welfare Division)
5th Floor, Vayu Block
Indira Paryawaran
Bhawan
Zorbagh Road, New Delhi-110 003

21. Reimbursement to CPCSEA representative

CPCSEA representative(s) of the IAEC or authorized person(s) sent for inspection of the establishment(s) will be paid

Rs.2000/- each as sitting fees (Honorarium) and reimbursement of actual expenditure incurred in this regard (if not provided by the MSCBDU), or as per latest notification of CPCSEA.

Format: #1

ONE PAGE CV: FOR MEMBERS OF THE INSTITUTIONAL ANIMAL ETHICS COMMITTEE MAHARAJA SRIRAM
CHANDRA BHANJA DEO UNIVERSITY, BARIPADA

Last Name	First Name	Middle Initial
Date of Birth (mm/dd/yy):		Sex
Professional Mailing Address (Include institution 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:		Date:

Format: #2

**SECRECY UNDERTAKING BY MEMBER OF INSTITUTIONAL ANIMAL ETHICS COMMITTEE MAHARAJA SRIRAM
CHANDRA BHANJA DEO UNIVERSITY, BARIPADA**

Name:

Designation:

Address:

I understand that as a Member of the Institutional Animal Ethics Committee I may receive documents containing confidential or privileged information about research activities related to the study.

I agree not to disclose or discuss such information or minutes of the meeting with persons not entitled to have them. I also agree either to return all documents marked CONFIDENTIAL/PRIVILEGED to Member Secretary or destroy them after perusal.

Date

Signature

IAEC PROTOCOL APPROVAL CERTIFICATE

Dispatch#:
IAEC PROTOCOL#:
IAEC PROTOCOL TITLE:

Date:

Dear Prof. / Dr. /Mr. /Ms.

This is to certify that above mentioned animal study protocol has been approved in....
IAEC meeting held on with following conditions:

PI : Prof/Dr/Mr/Ms.....

Other Experimenters :

1. Prof/Dr/Mr/Ms.....
2. Prof/Dr/Mr/Ms.....
3. Prof/Dr/Mr/Ms.....
4. Prof/Dr/Mr/Ms.....

Duration of Study : months/years(From..... to)
Animal Sanctioned :
Species :
Strain :
Sex/Age :
Total No. :

It is requested to get prior approval of IAEC in case of any deviation/changes in submitted protocol.
Please maintain the Form D & provide the photocopy to IAEC along with project report at defined interval.

Member Secretary
IAEC, MSCBDU

Chairman
IAEC, MSCBDU

**Assessment of Predictable risk/harm to the animals vs.
Advantage of research outcome**

Name of IAEC Member

Details of IAEC Meeting Title

of Study Protocol

Predictable risk/harm to animals:

Advantage of research outcome

Member's Opinion

Signature of IAEC Member

Standard Operating Procedure (SOP) for Animal Experimenters

Objectives

Constant evolution in animal ethics is the guiding force for this SOP. This SOP is a detailed guideline describing the procedure for investigators/researchers to design an animal experimentation according to national and international norms to avoid the unnecessary sufferings and pain to animals for proposed research. This SOP has clear guidelines for animal experimenters of MSCBDU (and collaborative) regarding the application procedure, its review system, communication of decision, start of experimentation, closure of experimentation and reporting of projects. Various formats are included to make the process streamline and user friendly.

1. Animal Experimentation

Due to intrinsic worth of animals as sentient beings, defined ethical principles and clear objectives of scientific experiments are mandatory which would justify the use of animals in the cause of scientific advancement and promoting human welfare while ensuring humane treatment of such animals.

Definition of experiment In terms of Rule 2 (e) of the Breeding of and Experiments on Animals Control and Supervision) Rules, 1998, as amended, "Experiments" means any programme or project involving use of animal(s) for the acquisition of knowledge of a biological, physiological, ethological, physical or chemical nature; and includes the use of animals(s) in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or alleviating suffering, or significant gains in the well-being for people of the country or for combating any disease, whether of human beings, animals or plants.

CPCSEA has defined the relative sentience of different species of animals as follows: Invertebrates (e.g., cockroaches) <Birds <Rodents <Canines/Felines <Bovine/Equines <Primates (e.g., Rhesus Macaque)<More evolved Primates (e.g., chimpanzee)

Anything higher than invertebrates in terms of level of sentience requires regulation. Thus rats, mice, birds, and farm animals are also subject to regulation.

For an all-new animal experimentation the small pilot study will be advisable to confirm the readability of end points, feasibility of experiment at large scale and assess the real connect between proposed outcomes and real results.

Ethical principles adopted by CPCSEA for use of animals in scientific experiments

Principle 1

"Experiments on animals" (including experiments involving operations on animals) may be carried out for the purposes of advancement by new discovery of physiological knowledge; or of knowledge which is expected to be useful for saving or prolonging human life or alleviating suffering; or for significant gains in the wellbeing for the people of the country; or for combating any disease, whether of human being, animals or plants.

Principle 2

Animals lowest on the phylogenetic scale (i.e., with the least degree of sentience), which may give scientifically valid results, should be used for any Experimental procedure. Experiments should be designed with the minimum number of animals to give statistically valid results at 95% level of confidence. Alternatives not involving animal testing should be given due and full consideration and sound justification provided, if alternative, when available, are not used.

Principle 3

Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anaesthesia.

Principle 4

Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. Investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation, and may be permitted to euthanize animals only in the following situations:

- (a) When the animal is paralyzed and is not able to perform its natural functions; it becomes incapable of independent locomotion; and/or can no longer perceive the environment in an intelligible manner.
- (b) During the course of experimental procedure the animal has been left with a severe recurring pain and the animal exhibits obvious signs of long term extreme pain and suffering.
- (c) In situations where non-termination of the animal experimented upon would be life threatening to human beings or other animals.

Costs of aftercare and/or rehabilitation of animals post-experimentation are to be part of research costs and should be scaled per animal in positive correlation with the level of sentience of the animals.

Principle 5

The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.

2. 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 at the individual level, at institutional level and finally at the national level.

3. Eligibility, Role and Responsibility of Animal Experimenters

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.

Persons engaged in conducting scientific experiments on animals must act in conformity with the provisions of the Prevention of Cruelty to Animals Act, 1960, and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended.

Experimenter must ensure:

- 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 anaesthetic of sufficient power to prevent the animals feeling pain
- 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.
- 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.
- 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 both before and after experiments
- that suitable records are maintained with respect to experiments performed on animals
- that general and experiment specific human end points will be well defined and followed
- that adverse effects, if any, during experiment is reported properly

4. Procedure of Application for Animal Experimentation

All proposals should be submitted in the prescribed application formats (see formats).

During application for **small animal** experimentation following documents will be required (kindly arrange the formats in the below mentioned order):

1. Checklist for IAEC, MSCBDU	(Format# 1)	1 Original Copy
2. Protocol Receiving	(Format# 2)	1 Original Copy
3. PI Undertaking	(Format# 3)	1 Original Copy
4. DRC Minutes	(Format# 4)	1 Original Copy
5. CPCSEA Form B	(Format# 5)	10 Copies (1 original + 9xerox)
6. CV of Every Experimenter	(Format# 6)	10 Copies (1 original + 9xerox)
7. Soft Copy in CD of above documents		1 Original Copy

Note:

1. Attach IBSC clearance certificate along with copy of the minutes of IBSC granting approval, if required. Total 10 Copies (1 original + 9xerox) will be required to submit. Find this format in **SOP IBSC functioning**.
2. During application for **large animal** experiment 15 copies (1 original + 14 xerox) of CPCSEA Form B (Format# 5) will be required. Also 1 original copy of Checklist for CPCSEA (Format# 7) will be required to submit.
3. These documents will be submitted to the Office, Member Secretary, IAEC, MSCBDU.

In terms of Rule 9 (bb) of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended, animals lowest on the phylogenetic scale which may give scientifically valid results should be first considered for any experimental procedure, and the experiment should be designed with

the minimum number of animals to give statistically valid results at **95% degree of confidence**.

Replacement alternatives, not involving experiments on animals, should be given due and full consideration and sound justification must be provided, in case alternatives, though available, are not used.

Food and water must be provided *ad libitum*. If any restriction is required then proper references and animal welfare must be ensured.

Unisex animal requirement must be avoided. Proper justification and references must be provided in CPCSEA form B, if unisex animals are specially required for experiment.

5. Review, Discussion and Decision Process

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 will be forwarded to CPCSEA in prescribed manner with recommendation of IAEC.

The proposals will be sent to members at least 15 days in advance for their proper review and comments.

During IAEC meeting, power point presentation by PI, Co-PI will be done. Other than PI/Co-PI only PhD students will be allowed for presentation of their animal experimentation protocols as part of their PhD program. No JRF/SRF candidate will defend the study protocols. PI, CO-PI will jot down the points of discussions with IAECmembers.

Decisions will be taken by consensus after discussions otherwise it will be referred to CPCSEA. If it is decided to refer the CPCSEA then Format# 7 (Check list for CPCSEA) will be submitted for small animal experimentation as well, by PI within 7 days after communication of IAEC Meeting decisions from office of Member Secretary, IAEC.

Note: In absence of PI/Co-PI/PhD student in the IAEC meeting the submitted protocol (CPCSEA Form B) will not be discussed. PI/Co-PI/PhD student may again submit the protocol to be considered in next meeting.

6. Communication between IAEC andExperimenter

Office, Member Secretary, IAEC, MSCBDU will communicate the following to experimenter (PI):

1. Any major lacunae viz. printing error, blank pages, missing signature, inprotocol.
2. Date of IAECmeeting.
3. Decision of IAEC for protocol modification for re-reviewprocess.
4. Decision of IAEC for protocol rejection, if occurred, with IAECreasoning.
5. Decision of IAEC regarding referring the animal study protocol to CPCSEA for final discussion anddecision.
6. Protocol approvalcertificate.

PI will communicate the following to the Office, Member Secretary, IAEC, MSCBDU:

1. Submission of fresh documents, if major lacunae reported, as described in procedure of application.
2. Submission of modified protocol document (for re-review process). Three (1 original + 2 Xerox) modified copy will be required tosubmit.
3. Submission of check list for CPCSEA in case animal study protocol referred toCPCSEA.
4. Submission of Form D (Format# 8) along with annual progress report (Format#9).
5. Submission of Serious Adverse Effect report (Format# 10), asrequired.

6. Submission of final report of project (Format#11) along with Form D (Format #8).

7. Procurement of animals

In terms of Rule 10 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, as amended,

1. An establishment shall acquire animals for experiments from registered breeders only.
2. In case of non-availability of animals from registered breeders, the animals may be procured from alternative legal sources.
3. In case the animal is procured from alternative legal sources, the same shall be procured after taking written permission from the authority competent under the law for the time being in force, to give such permission; and Replacement alternatives, not involving experiments on animals, should be given due and full consideration, and sound justification must be provided, in case alternatives, though available, are not used.
4. For procuring animal from Animal House, MSCBDU; experimenters need to fill animal requisition form (Format# 12) and to submit to office, Animal House. Based on availability and approval of Animal House-in-charge, animals will be provided to the experimenters. For experimentation purpose no animal will be provided without approved IAEC/CPCSEA study protocol.
5. Animal House, MSCBDU will charge the cost of animal as well as cost of maintenance, as per institute approved rate list. Accountant, Animal House will receive the money and provide the receipt of the same.
6. For procuring animal from overseas vendors, import licence will be mandatory. PI will manage for getting import licence for the respective project.
7. Animals may be procured from other CPCSEA registered breeders in India (Baripada or other station).
8. For out station transportation courier service experienced in animal transportation must be employed.
9. For city transportation animals will be carried in designated cages, with feed and water, in air conditioned van.

9. Welfare of animal during use in experiments

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, personnel using the experimental animals shall be responsible for the welfare of the animals during their use in experiments. The CPCSEA Guidelines for Laboratory Animal Facility also spell out the baseline procedures to be followed when using animals in the course of scientific experimentation, including quarantine and animal care.

10. After care and rehabilitation of animals after use in scientific experiments

In terms of Rule 9 (cc) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, as amended, Investigators shall be responsible for the aftercare and rehabilitation of the animals after experimentation.

Costs of aftercare and rehabilitation of the animals after experimentation shall be made part of research costs and shall be scaled in positive correlation with the level of costs involved in such aftercare and rehabilitation of the animals.

Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence by providing a lump-sum amount as costs for rehabilitation and care of such animal to cover its entire statistical expected life span; and the establishment undertaking experiments or duly licensed and authorized animal welfare organizations under the control of the Committee may, on payment of lump-sum amount, undertake rehabilitation of animals.

11. Transportation of animals

The transport of animals from one place to another is very important and must be undertaken with care. The main considerations for transport of animals are mode of transport, containers, animal density in cages, food and water during transit, protection from transit infections, injuries and stress.

For out station transportation courier service experienced in animal transportation must be employed. For city transportation animals will be carried in designated cages, with feed and water, in air conditioned van.

The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable, free movement and protection from possible injuries. The food and water should be provided in suitable containers or in suitable form so as to ensure that they get adequate food and more particularly water during transit. The transport containers (cages or crates) should be of appropriate size and only a permissible number of animals should only be accommodated in each container to avoid overcrowding and infighting (**Annexure – 4, From SOP CPCSEA**)

12. Anesthesia and Euthanasia

The investigators should ensure that the procedures, which are considered painful, are conducted under appropriate anaesthesia as recommended for each species of animals. It must also be ensured that the anaesthesia is given for the full duration of experiment and at no stage the animal is conscious to perceive pain during the procedure. If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irreparable injury, the animal should be humanely sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia (**Annexure – 5, From SOP CPCSEA**).

In the event of a decision to sacrifice an animal or termination of an experiment or otherwise an approved method of euthanasia should be adopted (**Annexure – 6, From SOP CPCSEA**) and the investigator must ensure that the animal is clinically dead before it is sent for disposal. The data of all the animals, that have been euthanized, should be maintained.

Anaesthesia

Unless contrary to the achievement of the results of study, sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment. Anaesthetic agents generally affect cardiovascular, respiratory and thermo-regulatory mechanism in addition to central nervous system.

Before using actual anaesthetics the animals are prepared for anaesthesia by long time fasting (as required) and using pre-anaesthetics, which block parasympathetic stimulation of cardio-pulmonary system and reduce salivary secretion. Atropine is most commonly used anti-cholinergic agent. Local or general anaesthesia may be used, depending on the type of surgical procedure.

Local anaesthetics are used to block the nerve supply to a limited area and are used only for minor and rapid procedures. This should be carried out under an expert supervision for regional infiltration of surgical site, nerve blocks and for epidural and spinal anaesthesia.

A number of general anaesthetic agents are used in the form of inhalants. General anaesthetics are also used in the form of intravenous or intra-muscular injections such as

barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side-effects such as excess salivation, convulsions, excitement and disorientation should be suitably prevented and controlled. The animal should remain under veterinary care till it completely recovers from anaesthesia and postoperative stress.

Euthanasia

Euthanasia is resorted to events where an animal is required to be sacrificed or termination of an experiment or otherwise for ethical reasons (human end point). The procedure should be carried out quickly and painlessly in an atmosphere free from fear or anxiety. For accepting an euthanasia method as humane it should have an initial depressive action on the central nervous system for immediate insensitivity to pain. The choice of a method will depend on the nature of study, the species of animal to be killed (**Annexure – 6, From SOP CPCSEA**). The method should in all cases meet the following requirements:

- (a) Death, without causing anxiety, pain or distress with minimum time lagphase.
- (b) Minimum physiological and psychological disturbances.
- (c) Compatibility with the purpose of study and minimum emotional effect on the operator.
- (d) Location should be separate from animal rooms and free from environmental contaminants.

Tranquilizers have to be administered to larger species such as monkeys, dogs and cats before an euthanasia procedure.

13. Project Reporting and Archiving System

Reports should be submitted at prescribed intervals (annual) for review. Protocol deviation, if any, should be informed with adequate justifications. Any amendment to the protocol should be resubmitted to IAEC for renewed approval. Any new information related to the study should be communicated

Premature termination of study should be notified with reasons along with summary of the data obtained so far. Change of investigators / sites should be informed and approval of IAEC should be taken.

Final report / project closure report should be submitted at the end of study.

All Serious Adverse Events (SAE's) and the interventions undertaken should be intimated

All study related documents (study projects/protocol with enclosed documents, progress reports) will be archived for minimum of five years after the completion of study by PI.

14. Contract Animal Experiments

Amendment of Rule-12, in the breeding and experiments on animal Rule 1998, this rule has been amended to allow to establishment to undertake contract research as per provision of PCA-Act 1980, and the rules made thereunder. Any proposal of contract research will be discussed in IAEC and after approval such studies may be initiated.

Format #1

To,

Date:

**Prof./Dr/Mr./Ms.
Designation
Department MSCBDU,
Baripada**

Sir/Madam,

Your Animal study protocol with a title “ **to be filled by PI** ” has been received.

This protocol will be shared with IAEC members in upcoming IAEC meeting for discussion and decision.

Date and venue of upcoming IAEC meeting will be informed to you for power point presentation and clarifications, if any, to the IAEC members.

Thanks and Regards.

Sincerely yours,

)

Format #3

Maharaja Sriram Chandra Bhanja Deo University, Takatpur, Baripada

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

- 1. TITLE OF THE PROJECT**
- 2. NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**
- 3. OTHER MEMBERS OF THE RESEARCH TEAM Co-PIs:**

Experimenters: (JRF/SRF etc.)

- 4. NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

1. I confirm that I will initiate the study only after obtaining all regulatory clearances.
2. I will not implement any deviation from the approved project without prior consent of the IAEC.
3. I confirm that the Co-PI and other experimenters of the study team have been informed about their obligations and are qualified to meet them. I will arrangement for training of laboratory animal practices to the experimenter of my team, to whom it will be required, before involvement in actual animal experimentation.
4. I will personally supervise the study and ensure that all the requirements related to the study are fulfilled and will follow the CPCSEA guidelines as well as gazette of India time to time.
5. I will submit the progress report/final report on regular basis.

Signature of Principal Investigator

Date

Format #4

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

Date:
Place:

Name: Prof./Dr./Mr.
Designation:

*Submit 1 Original + 9 Photocopy + 1 Soft copy in CD

[#] For large animal study

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. TelephoneNo.
 - e. Experience
3. List of names of all individuals authorized to conduct procedures under this proposal.
 - ☐ Co-guides (1,2 etc.)
 - a. Name
 - b. Address
 - c. Experience
 - ☐ Authorized Experimenter (1, 2 etc.)
 - 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 (IBSC). 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 (given name)

If, your project involved use of any of the above, attach copy of the minutes of IBSC 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 Principal Investigator

Date:

Format #5

Certificate

This is certify that the projecttitle:.....

.....:..... has been

approved by the IAEC.:.....

Name of Chairman/ MemberSecretary IAEC:

Name of CPCSEA nominee:

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

Format #6

**One Page CV: PI/Co-PI/Experimenter IAEC Study
Protocol, MSCBDU**

Affiliation to Animal Study Protocol: PI / Co-PI / Experimenter		
IAEC Protocol Title:		
Personal Details:		
Title: Dr <input type="checkbox"/> , Mr <input type="checkbox"/> , Ms <input type="checkbox"/>		
Last Name	First Name	Middle Name
DOB: DD / MM / YYYY	Sex: M <input type="checkbox"/> , F <input type="checkbox"/>	Marital Status:
Contact Details:		
Mobile:	Email:	
Tel (Office):	Tel (Res):	Fax:
Professional Details:		
Designation:		
Work Place:		
Professional Address:	Address of Working Site:	
	<input type="checkbox"/> Same as professional address	
Experience in Animal Research:		
Other Relevant Research Experience:		
Academic Qualifications (Current to Previous)		
Degree / Certificate	Year	Institution, University, Place

Place:	Date:	Signature:
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Format #7**CHECK-LIST: CPCSEA**

(To be submitted for consideration of CPCSEA)

Title of the protocol	
Name and address of the Institute submitting proposal, with Ref No. if any	
CPCSEA Registration No. and valid upto	
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
Type of research work	<ol style="list-style-type: none"> 1. Academic Research 2. In-house R&D 3. Drug Development & Research 4. Preclinical toxicity study 5. Multicenter research collaborative study 6. Education 7. Contract Research
Name & Address of CPCSEA Nominee and Link Nominee and date of appointment [Date of change of Nominee (if any)]	
Composition of IAEC as per approved guidelines and the names and addresses of the establishment/member to which they represent	
Whether detailed signed minutes of IAEC by members including nominee attached with the protocol.	
Recommendations of IAEC	
Recommendation of Institutional Bio Safety Committee (IBSC)	
Recommendations of Review Committee on Genetic Manipulation (RCGM)	
The date of last inspection of Animal House Facility and approval details conveyed by CPCSEA.	
Name of the PI with designation, qualification and work experience with animals.	
Name of the Co-PI with designation, qualification and work experience with Large Animals.	
Source of procurement of animals, types, number, age & sex.	
Information regarding import / export of animals / material before and after experimentation.	
A signed declaration by PI 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

Format #8

Form D: Record of Acquired and Experiment Performed
(to be maintained by the Investigator)

PI:

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)

Format #9

Annual PROGRESS REPORT

1. Project CodeNumber
2. Title of theproject/study
3. Principal Investigator (Name &Department)
4. Date of project approval byIAEC
5. Type of IAEC Approval:
 - Approved for animal experimentation
 - Approved for submission to funding agency (whether fund sanctioned?)
6. Date of start ofstudy
7. Approved duration of studyprotocol
8. Duration of thisreport
9. Whether previous year reportssubmitted
10. Name of FundingAgency
11. Animalsapproved
 - Species
 - Age/Sex
 - Numbers
12. Number of animals utilized in this duration (attach the Xerox of FormD)
13. Objectives of the study
14. Progress report as per objectives (attach separatesheet)
15. Report/publications/conference presentation, ifany

Name of Principal Investigator

Department

Signature & Date

Format# 10

Report of Serious Adverse Events (SAE)

1. Project CodeNumber
2. Title of theproject/study
3. Principal Investigator (Name &Department)
4. Description ofSAEs

Serious Adverse Event	Suspected/ Non suspected	No. of animal affected	Start Date	End Date	Severity	Action taken	Result of action	Effect on study

Severity: * Mild, ** Moderate, *** Severe

5. PI's summery on SAE and furtherrecommendations

Name of Principal Investigator
Department
Signature & Date

Format #11

FINAL REPORT /PROJECT CLOSURE REPORT

1. Project CodeNumber
2. Title of theproject/study
3. Principal Investigator (Name &Department)
4. Date of project approval byIAEC
5. Date of start ofstudy
6. Approved duration of studyprotocol
7. Whether previous year reportssubmitted
8. Name of FundingAgency
9. Animalsapproved
 - Species
 - Age/Sex
 - Numbers
10. Number of animals utilized (attach the Xerox of FormD)
11. Whether lesser than approved number of animals used? If yes, describe the rationalebehind
12. Whether study terminated before approved duration? If yes, describe the rationalebehind
13. Objectives of thestudy
14. Progress report as per objectives (attach separatesheet)
15. Report/publications/conference presentation, ifany
16. Whether any SAE observed and reported
17. Outcome of theProject

Name of Principal Investigator
Department
Signature & Date