



VNSGU Institutional Human Ethics Committee (IHES)

Scope

Veer Narmad South Gujarat University has three Post graduate Departments and few other affiliated colleges who are educating different areas of biological sciences and inculcating in research. The departments/ Colleges offers M.Sc. and Ph. D. courses in Biological sciences with specialization in subjects of Botany, Zoology, Microbiology, Aquatic Biology, Biotechnology, Biochemistry, genetics and other allied areas of biological sciences. In all these subjects experimentation involving human/human samples and other biomedical research and education is being imparting.

In October 2017, the Indian Council of Medical Research issued the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The guidelines are applicable to all biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material and data. The purpose of these guidelines is to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research. These guidelines must be followed by all stakeholders including institutions, ethics committees (ECs), researchers and sponsors/funding agencies.

Purpose of Institutional Human Ethics Committee (IHES)) is to provide ethical guidelines for researchers and other people who are considering experiments involving humans. The committee will be useful when planning projects, assessing them, and when reporting and publishing findings and results. They are also intended to contribute to reflection on research ethics and the use of animals in research in research communities.

VNSGU Institutional Human Ethics Committee (IHES)

IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and wellbeing of the research subjects/participants.

The IHEC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc.

The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

Composition of VNSGU-IHEC

The VNSGU Human Ethics Committee comprises a panel of distinguished luminaries in various professional and social fields.

1.	1	Chairperson	
2.		Vice Chairperson/ Clinician	
3.		Clinician	
4.		Medical Scientist	
5.		Pharmacological expert	
6.		Social Scientist	
7.		Legal expert	
8.		Lay person	
9.		Affiliated Scientific members-I	
10.		Affiliated Scientific members-II	
11.		Affiliated Scientific members-III	
12.		Member Secretary	
13.		Coordinator	

Address of the office of the VNSGU- IHEC

Standard Operating Procedures (SOP) for Institutional Human Ethics Committee (IHEC) of VNSGU

1. Objective

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health and biomedical research for all proposals submitted by the faculty and students of VNSGU as prescribed by the Ethical guidelines for biomedical research on human participants of ICMR (2006).

2. The Terms of Reference of the Committee

IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects/participants. The IHEC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHECs will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

3. Composition of IHEC

IHECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IHEC. The number of persons in an ethical committee will be around 8-12 members. The Chairperson of the Committee should be from outside the Institute with a legal background and not head of the Institute to maintain the independence of the Committee. The Member Secretary will be a faculty member from the Institute to conduct the business of the Committee. Other members will be a mix of medical / nonmedical, scientific and non-scientific persons including lay public to reflect different viewpoints.

The composition will be as follows: -

1. Chairperson
2. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If

required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The members will be appointed by the Director of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country

IHEC should be constituted in the following pattern:

- i) A Chairperson
- ii) A Deputy Chairman if need be,
- iii) A Member Secretary,
- iv) 7 – 9 members from different Departments / Specialties / disciplines or areas etc.

4. Authority under which IHEC is constituted:

Drugs Controller of India, Central Drugs Standard Control Organization, Drugs and cosmetics (Third Amendment) Rule, 2013, Ministry of Health and Family Welfare (Dept. of Health), Govt. of India The VC of VNSGU constitutes the IHEC.

5. Membership requirements:

- a. The duration of appointment will be initially for a period of 3 years
- b. At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced by a defined procedure.
- c. A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting.
- f. Conflict of interest should be declared by members of the IHEC

6. Quorum requirements:

The minimum of 5 members + Chairperson are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. This quorum must include at least one non-scientific member that may either be a lawyer, philosopher or a lay person from the community.

7. Procedure for resignation, replacement or removal of members

The members who have resigned may be replaced at the discretion of the appointing authority for the same. VNSGU IHEC members who decide to resign must provide the Director, VNSGU and Chairman, IHEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Director, VNSGU would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative. The recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairman

A member may be relieved or terminated of his/her membership in case of

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds
- If a regular member fails to attend more than 3 meetings of IHEC. The membership shall be reviewed by the IHEC if the member is a regular defaulter. If deemed necessary, the IHEC may decide to

terminate the membership and recommend to the Director, VNSGU, by the Chairman IHEC for necessary action

- Relocate to another city or any such matter In all such situations/circumstances, Director, VNSGU will serve a letter of termination to the member. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IHEC meeting and IHEC membership circular/ roster will be revised.

7. Offices

The Chairperson will conduct all meetings of the IHEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority.

8. Independent consultants

IHEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IHEC.

9. Application Procedures:

- a. All proposals should be submitted in the prescribed application form.
- b. All relevant documents should be enclosed with application form.
- c. A soft copy of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the member secretary.
- d. The date of meeting will be intimated to the researcher to be present for clarification.
- e. The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

10. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Forwarded by the Head of the Institution /Head of the Department. (should be there)
4. Protocol of the proposed research
5. List of Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like Proforma, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.

11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance
13. An agreement to report all Serious Adverse events (SAEs)
14. Statement of Conflict of interests, if any
15. An agreement to comply with all national and international guidelines
16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable;
17. All significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
18. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
19. Any other information relevant to the study



VNSGU Institutional Animal Ethics Committee (IAEC)

Scope

Veer Narmad South Gujarat University has three Post graduate Departments and few other affiliated colleges are educating different areas of biological sciences and inculcating in research. The departments/ Colleges offers M.Sc. and Ph. D. courses in Biological sciences with specialization in subjects of Botany, Zoology, Microbiology, Aquatic Biology, Biotechnology, Biochemistry, genetics and other allied areas of biological sciences. In all these subjects experimentation on animals in course of animal research/ medical research and education is being imparting. Research involving animal use and biomedical samples are covered by provisions of the Prevention of Cruelty to Animals Act, 1960 and Breeding of and Experiments on Animals (Control & Supervision) Rules of 1998, 2001 and 2006 framed under the Act. These are enforced by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960. Under these provisions, the concerned establishments are required to get themselves registered with CPCSEA, form IAEC to perform research involving animal model and get specific projects for research cleared by IACE before commencing the research on animals. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

Purpose of Institutional Animal Ethical Committee (IAEC) is to provide ethical guidelines for researchers and other people who are considering experiments on animals. The committee will be useful when planning projects, assessing them, and when reporting and publishing findings and results. They are also intended to contribute to reflection on research ethics and the use of animals in research in research communities.

Institutional Animal Ethics Committee (IAEC)

The primary duty of IAEC is to review and approve all types of research proposals involving small animal experimentation before the start of the study.

The Committee also monitors research throughout the study and after completion of the study through periodic reports besides regular visits to the research faculty animal house and laboratories where the experiments are conducted. It also ensures compliance with all regulatory requirements, rules, guidelines and laws related to animal experiments.

IAEC includes eight members of which three are nominated by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and remaining five members by the institute. The chairperson and member secretary of the committee are nominated by the institute from the existing members. The term of appointment of the committee is for a period of 3 years. The committee meets at regular intervals to review new proposals, requests and existing policies. The committee also regularly monitors the procedures and practices related to animal experiments to ensure that animal welfare and ethics are strictly followed at every point of research.

1	A Biological Scientist	
2	Scientists from different biological Disciplines-I (preferably involved in animal experiments)	

3	Scientists from different biological Disciplines-II (from the non-clinical discipline)	
4	A Veterinarian involved in the care of Animals.	
5	Scientist In-Charge of Animal House Facility.	
Nominated by CPCSEA on receipt of the above composition of IAEC for the establishment.		
6	Main Nominee,	
7	Link Nominee	
8	Scientist from outside the Institute and Socially Aware Nominee	

Standard Operating Procedure for Institutional Animal Ethic Committee:

- The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been constituted under the provisions of the Prevention of Cruelty to Animals (PCA) Act, 1960. It gives the guidelines for the conduct of animal experiments.
- Animals are maintained in a proper and healthy manner.
- Animals are not subjected to unnecessary pain or suffering before, during and after performance of experiments on them.
- There is no unnecessary sacrifice of animals for the sake of science. There should be no duplication of research.
- Animals are kept in disease free condition to ensure proper data collection.
- Animals are procured from registered breeders.
- Experiments on large animals are to be avoided whenever it is possible to achieve the same results by experiments on small laboratory animals.
- For effective implementation of these rules and guidelines, the Institutional Animal Ethics Committees (IAEC) has been constituted in institutions conducting experiments on animals. This is a scientific body nominated by the Head of the Institution. The IAEC is required to examine proposals for conducting experiments on small animals, which would chiefly examine the necessity of performing the experiment, and ensure that experiments are not performed in a routine manner. All decisions are to be taken with the approval of the Committee. The Standard Operating Procedures (SOP) for Institutional Animal Ethics Committee for experimentations on animals will help the Principal Investigators, Animal Ethics Committee members and scientific researchers, for better understanding of the ethical procedures involved in animal experimentations.

Function of IAEC:

- IAEC should provide independent, competent and timely review of the ethics of a proposed study before the commencement of the same and regularly monitor the ongoing studies.
- IAEC will review and approve all research proposals involving animal experiments with a view to assure quality maintenance and welfare of animals used in laboratory studies while conducting research.

Composition of IAEC:

Institutional Animal Ethics Committee shall include members as follows:

- A scientist from different biological discipline cum chairperson
- A scientist from different biological discipline
- A Biological Scientist
- One veterinarian involved in the care of animals
- A scientist in charge of animal House facility cum member secretary
- A scientist from outside the institute
- One non-scientific socially aware person
- One main nominee of CPCSEA
- One link nominee of CPCSEA

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 nine members. Members against serial no. 6, 7, 8&9 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 1-5 will be sent from the institute to CPCSEA.
- The duration of IAEC will be for a period of 5years.
- 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

IAEC Requirements:

- The duration of appointment will be 5 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 Requirement:

The 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.

Conduct of meeting:

The Chairperson of the IAEC shall be responsible for conducting at least two meeting of IAEC in a calendar year with the help of the Member Secretary of IAEC. If, for reasons beyond control, the Chairperson is not available, or has conflict of interest, an ad-hoc Chairperson will be elected from amongst 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. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

Participation of Investigators/Experts in IAEC:

IAEC may call upon subject experts who may provide special inputs of selected research protocols, if need be. They are required to give their specialized views but not to take part in the decisions making process which will be made by the members of the IAEC only. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

Application Procedure:

- All proposals should be submitted in the prescribed application form
- All relevant documents with checklist should be enclosed with application form.
- Required number of copies of the proposal along with application and documents in prescribed format duly signed by Principal Investigator (PI) and Co-investigators/ Collaborators should be submitted to IAEC.

Review Procedure:

- The meeting of the IAEC should be held on scheduled intervals as prescribed in the concerned SOP of the IAEC and additional meetings may be held if there are reasons to do so.
- 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 proposals may be reviewed by an expedited through identified members
- Procedures for appeal by the researchers should be clearly defined.

Communication:

- 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 by the IAEC should be communicated to the Principal Investigator.

Follow Up Procedure:

- 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 Archival:

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

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

CPCSEA representatives on IAEC or authorized persons sent for inspection of the establishment are required to be paid Rs 5000/- each as sitting fees per day along with reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

Renewal Fees Payable to CPCSEA:

Renewal fees for the purpose of Research for education and commercial are as follows:

- For small or large animals for education research : Rs. 2500 each
- For small or large animals for commercial research : Rs. 2500 each

Execution 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;
 - 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.
 - If during the course of anesthesia /experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.
 - 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 anesthesia 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:

1.	Title of the project
2.	Names of the Principal Investigator and Co-investigators with designation.
3.	Name of any other Institute/Hospital/Field area where research will be Conducted.
4.	Endorsement of the name of Head of the Department
5.	Protocol of the proposed research.
6.	Ethical issues in the study and plans to address these issues.
7.	Proposal should be submitted with all relevant annexure like proforma, Curriculum Vitae of outside members, undertaking etc. to be used in the study.
8.	Any other information relevant to the study.
9.	Agreement to submit six monthly progress report and final report at the end of Study.
10.	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.

All communications must be addressed to:

Member Secretary, CPCSEA,

Ministry of Environment & Forests,

8th floor, Jeevan Prakash Building,

25, Kasturba Gandhi Marg,

New Delhi-110 001

Phone : 011-23318553

Email : cpcsea@rediffmail.com

Biodata and consent format for
Members of the Institutional Animal Ethics Committee

Name		Sex:	
Date of Birth (dd/mm/yy):			
Professional Mailing Address (Include institutional name)			
Telephone (Office) :		Mobile Number:	
Telephone (Residence):		E-Mail:	
Academic Qualifications (Most current qualification first) :			
Degree / Certificate	Subject	Year	Institution, Country
Professional Experience:			
Month and Year	Title	Institution / Company, Country	
Experience in animal handling research:			
Month and Year	Area of Specialization	Institution / Company, Country	
<p>Consent:</p> <p>I hereby give my consent to be the member of the IAEC of (Name of the establishment)</p> <p>I undertake to follow all the rules and guidelines of the CPCSEA.</p>			
Signature:			
Date:			