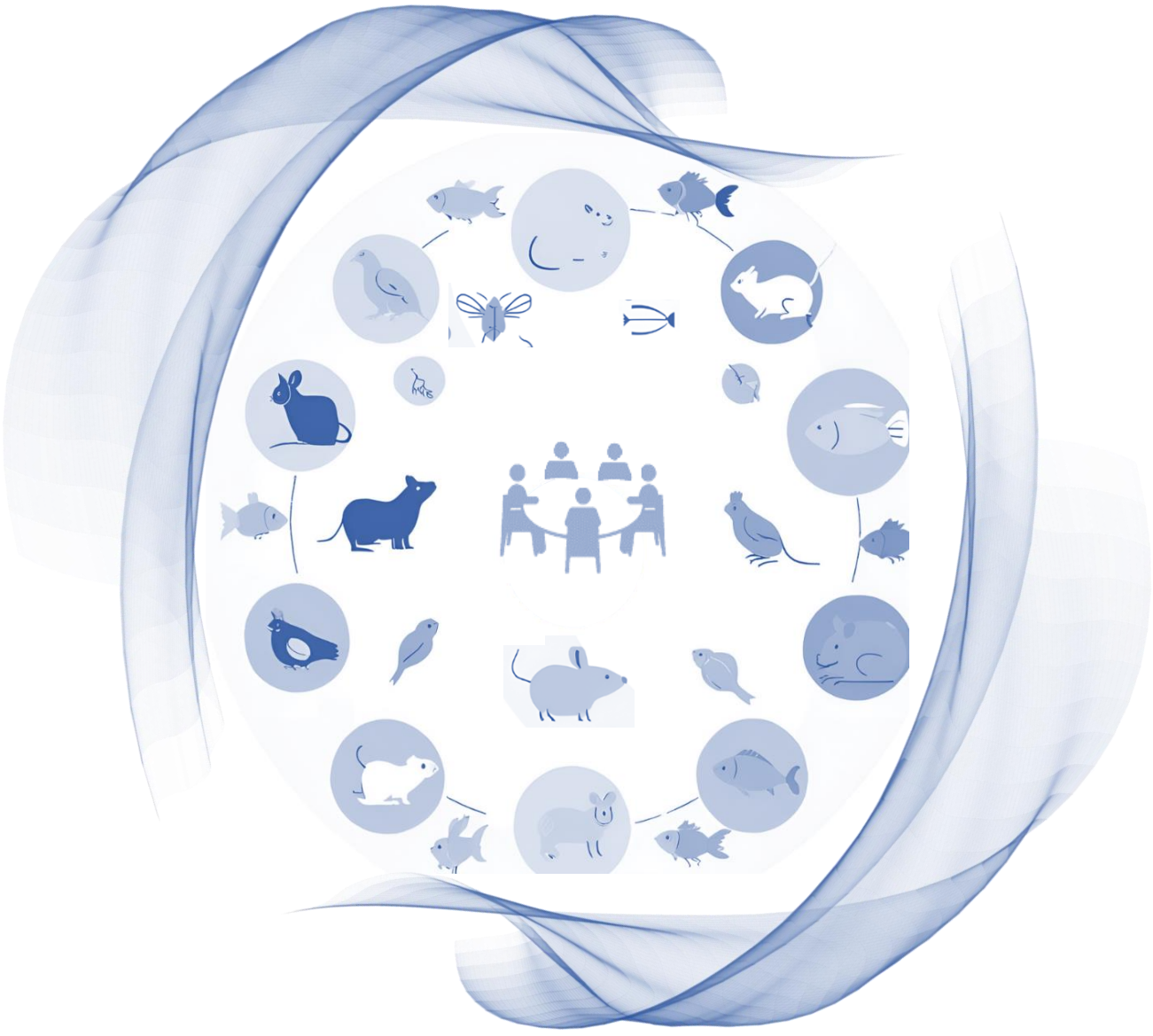
FREQUENTLY ASKED QUESTIONS

INSTITUTIONAL ANIMAL ETHICS COMMITTEES

(IAEC)



INDIAN COUNCIL OF MEDICAL RESEARCH

2025

FREQUENTLY ASKED QUESTIONS

FOR INSTITUTIONAL ANIMAL ETHICS COMMITTEES

Q.1 What is the Committee for Control and Supervision of Experiments on Animals (CCSEA)?

A.1 The Committee for Control and Supervision of Experiments on Animals (CCSEA) previously known as Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), is a statutory Committee of Department of Animal Husbandry and Dairying (DAHD), Ministry of Fisheries, Animal Husbandry and Dairying (MoFAH&D) constituted under the Prevention of Cruelty to Animals (PCA) Act, 1960.

Q.2 What is the objective of the CCSEA?

A.2 The objective of CCSEA is to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them.

Q.3 What is an Institutional Animal Ethics Committee (IAEC)?

A.3 IAEC means a body comprising of a group of persons recognized and registered by the CCSEA for the purpose of control and supervision of experiments on animals performed in an establishment that is constituted and operated in accordance with procedures specified for the purpose by the CCSEA.

Q.4 What is the composition of IAEC?

A.4 The IAEC must be constituted as per the CCSEA guidelines and duly registered with the CCSEA. IAEC is composed of a Biological Scientist, two Scientists from different biological disciplines, a veterinarian involved in the care of animals (mandatory), and the Scientist in charge of the Animal House Facility. The Chairman of the committee (preferably the Head of the Institution/Department) and Member Secretary are nominated by the establishment from the aforementioned five IAEC members. Additionally, the Main Nominee, Link Nominee, Scientist from outside the Institute, and Socially Aware Nominee are nominated by CCSEA. The IAEC of an establishment is constituted by CPCSEA at the time of registration for a period of 5 years. To ensure periodic renewal and compliance, at least half of the IAEC members must be replaced during its reconstitution. Please refer to **Annexure-1** for the Constitution/Re-constitution of the Institutional Animal Ethics Committee, CCSEA.

Q.5 Define "animal".

A.5. As per the Prevention of Cruelty to Animals Act, 1960, "animal" means any living creature other than a human being.

Q.6 Which animal studies experiments do not need regulation?

A.6 Animals that do not require regulation include invertebrates. While obtaining IAEC approval for research involving invertebrates is not mandatory, it is still desirable, as some journals may require ethics approval during the submission process.

Q.7 Which animal studies experiments require IAEC approval?

A.7 Any experimental study involving animals with a higher level of sentience than invertebrates require regulation. IAEC is authorized to approve experiments involving animals up to the phylogenetic level of rodents. Thus rats, mice, birds, and rabbits are also subject to IAEC approval. However, for research involving animals higher on the phylogenetic scale than rodents, IAEC can provide recommendations and forward the proposal to the CCSEA for approval. Please refer to **Annexure-2** for the IAEC approval format.

Q.8 How to obtain an IAEC ethics approval?

A.8 Ethics approval has to be obtained from the IAEC of the institute/organization where animal experiments will be conducted. The Principal Investigator should submit the experimental protocols in a prescribed format (Form B) to the CCSEA-registered IAEC of their institute/ organization, who shall call for an IAEC meeting and issue an IAEC certificate as per their Standard Operating Procedure. The period of approval by the IAEC would be for one year. However, the IAECs may grant in-principle approval for more than one year (wherever required as per specific case) after reviewing the progress report every year for further continuation of the protocol. Please refer to **Annexure-3** for format or designated signatories for issuing IAEC approval.

Q.9 What is the process to obtain a CCSEA Certificate for experiments on large animals such as dogs?

A.9 For approval of experimentation on animals greater than the phylogenetic level of rodents such as dogs, goats, pigs, cattle, monkeys, etc the experimental protocol must be forwarded to CCSEA in a prescribed manner with the recommendation of IAEC. Such studies using mammals of higher sentience may also be required to submit Rodent Study data in a specified format along with the application. Please see the CCSEA website (URL: https://ccsea.gov.in/) for the formats.

Q.10 Are there additional regulatory clearances required when conducting research involving wild animals, beyond standard IAEC approval?

A.10 Working on wild animals may additionally require clearance from the Chief Wild Life Warden of the respective state and/or Ministry of Forest, Environment and Climate Change, depending on their scheduled status under the Wildlife (Protection) Act, 1972.

Q.11 Do you require IAEC/CCSEA approval to work on slaughterhouse samples?

A.11 IAECs and CCSEA have no objection to studies conducted on slaughterhouse samples.

Q.12 Does chicken chorioallantoic membrane (CAM) assay or working with live chicken eggs/embryos require approval from IAEC?

A.12 Yes, studies conducted on live chicken embryos may be placed before the IAECs for decision.

Q.13 Does research involving the collection of small amounts of blood from animals in institutions such as ICMR/ ICAR/ Veterinary or Agriculture University require approval from IAEC?

A.13 The research protocols dealing with withdrawal of up to or below 0.6 ml/kg body weight of blood from large animals on a weekly basis for the purposes of the experimentation on feeding trials, breeding experiments and livestock management studies, which require blood collection from the experimental animals to further study the clinical parameters and for the purpose of clinical disease diagnosis, field studies or thesis studies, may be approved by the IAEC. This will be applicable for ICMR, ICAR, Veterinary and Agriculture Universities and Government-funded institutions that handle large animals.

Q.14 Are research establishments allowed to conduct contract animal experiments for other institutions?

A.14 Yes, registered establishments may undertake contract research on behalf of other agencies, provided they are registered with the CCSEA for contract research and they comply with the Prevention of Cruelty to Animals Act, 1960, and the relevant rules.

Q.15 What approvals are required for conducting research on genetically engineered (GE) insects?

A.15 Institutional Biosafety Committee (IBSC) approval is required for all Phase 1 and Phase 2 studies on GE insects. It reviews and approves Phase I- Category I experiments and forwards Category II and III in Phase I and Phase II to RCGM. IBSC ensures compliance with biosafety rules and submits recommendations for further approvals. Please refer to **Annexure 3** for the composition of IBSC. Additionally, the State Biotechnology Coordination Committee (SBCC) and the District Level Committee (DLC) inspect, investigate, and monitor safety measures in industries and institutions handling genetically engineered or hazardous organisms, ensuring compliance with safety protocols at the state and district levels, respectively. Also, at both national and international levels Recombinant DNA Advisory Committee (RDAC) reviews biotechnology developments to recommend safety regulations for recombinant research, use, and applications.

Q.16 Which studies require Review Committee on Genetic Manipulation (RCGM) approvals?

A.16 RCGM approval is required for Category II and III experiments in Phase 1 involving higher-risk genetic modifications, all Phase 2 studies conducted in semi-field conditions, and any import, export, or transfer of GE insects.

Q.17 When does research on GE insects require Genetic Engineering Appraisal Committee (GEAC) approval?

A.17 GEAC approval is required when GE insects are released into natural environments, specifically during Phase3 confined field trials, where their behaviour is tested under real-world conditions, and Phase4 post-release monitoring, which assesses their long-term interaction with the environment. Since these stages involve environmental release, they fall outside the regulatory scope of IBSC and RCGM. GEAC ensures that the introduction of GE insects does not pose risks to ecosystems or public health.

Q.18 Where can a researcher or establishment procure animals for research purposes?

A.18 An establishment must acquire laboratory animals only from CCSEA-registered breeders. However, if animals are unavailable from registered breeders, they may be procured from alternate legal sources with written permission from the competent authority.

Q.19 Can genetically defined animals be imported for experiments?

A.19 Yes, genetically defined animals may be imported with permission from the Directorate General of Foreign Trade (DGFT), but only if they are not available from registered breeders or alternative legal sources within the country. However, this condition does not apply to laboratory-bred rats and mice of genetically defined strains.

Q.20 Under what conditions can model organisms like *Drosophila* be imported for research purposes?

A.20 Model organisms, including commonly used ones like *Drosophila*, can be imported if they are handled in BL-1N/BL-1P/BL-1 containment facilities. IBSC must certify that these organisms carry only routine and standard experimental mutations/insertions and do not contain foreign gene insertions from non-model organisms.

Q.21 Are there any penalties for conducting animal experiments without ethical clearance?

A.21 Conducting animal experiments without approval can result in penalties, including suspension of research activities, legal action under the Prevention of Cruelty to Animals Act, and blacklisting of the institution or investigator by regulatory authorities.

Please refer to **Table 1** for an overview of the approvals required to conduct animal experiments:

Table 1: Approvals Required for Different Animal Categories

Research Category	Primary Approval	Secondary Approval	Additional Approvals	Special Cases
Microorganisms	IBSC	EC	-	-
*Genetically Engineered Organisms/ Hazardous Microorganisms	IBSC (Phase 1 -Category I)	IBSC+ RCGM (Phase 1 -Category II &III & Phase 2)	GEAC (Phase 3&4)	-
Animals - Invertebrates	Not Mandatory	-	-	IAEC may be required if results are to be published
Animals - Vertebrates (Small)	IAEC	-	-	-
Animals - Vertebrates (Large)	IAEC (recommendation)	CCSEA	-	-
Wild Animals	IAEC	CCSEA	CWLW	-
Schedule-I Endangered Species (protected under Wildlife Protection Act 1972)	IAEC	CCSEA	CWLW + MoEFCC	-
Import of Laboratory Animals	DGFT Import License	NOC from the regional quarantine officer	IAEC/CCSEA/ CWLW/ MoEFCC, as applicable	Category I: Not allowed Category II: Allowed for specific purpose Category III: Lab-bred for specific research purposes only
Slaughterhouse-derived samples	IAEC or CCSEA has no objection			

CCSEA: Committee for Control and Supervision of Experiments on Animals, CWLW: Chief Wildlife Warden, DGFT: Directorate General of Foreign Trade, EC: Ethics Committee, GEAC: Genetic Engineering Appraisal Committee, IBSC: Institutional Biosafety Committee, IAEC: Institutional Animal Ethics Committee, MoEFCC: Ministry of Forest, Environment and Climate Change, NOC: No Objection Certificate, and RCGM: Review Committee on Genetic Manipulation.

*Ref:

- Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023, Department of Biotechnology, Government of India. Available at: https://dbtindia.gov.in/sites/default/files/Final%20guideline_GE%20Insects.pdf (Accessed on 11 March 2025)
- Handbook for Institutional Biosafety Committee (2020), Available at https://ibkp.dbtindia.gov.in/Content/FlashPDF/IBSC%20Handbook.pdf (Accessed on 11 March 2025)

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13. Review Committee on Genetic Manipulation (RCGM), Department of Biotechnology, Ministry of Science and Technology. Available at: https://ibkp.dbtindia.gov.in/ (Accessed on 11 March 2025)
14. Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989 under the Environment (Protection) Act 1986. Available at: https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115121526033_Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf (Accessed on 11 March 2025)
15. The Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006, CCSEA. Available at: https://ccsea.gov.in/WriteReadData/userfiles/file/2006.pdf (Accessed on 11 March 2025)

Disclaimer

This document is intended for informational purposes only.

Annexure-1: Constitution/Re-constitution of Institutional Animal Ethics Committee, CCSEA.

CONSTITUTION/ RE-CONSTITUTION OF INSTITUTIONAL ANIMAL ETHICS COMMITTEE, CCSEA.

1. CCSEA Constitutes/Re-constitutes the LAEC on the receipt of 5 (Five) names (all from science background including one Veterinarian) from the establishment.

2. IAEC must be reconstituted after every five years as per extant guidelines of CPCSEA.

3. The revised minimum qualification for the Internal IAEC Members is as below:
   i. B.V.Sc. or
   ii. M.Sc. (Zoology/ Animal Sciences/ Animal Biotechnology), or
   iii.M.Sc./M.Tech (Life Sciences, Biological Sciences/ Biochemistry/ Biotechnology/Biomedical Engineering) with experience in animal handling and animal research, or
   iv. M. Pharm. with experience in animal handling and animal research, or
   v. MDV MS with research experience in laboratory animal handling.

4. The composition of IAEC should be as under.
   i. A Biological Scientist.
   ii. Two Scientists from different biological disciplines.
   iii. A Veterinarian involved in the care of Animals.
   iv. Scientist In-Charge of Animal House Facility.

5. The establishments are required to upload the biodata with consent of proposed IAEC members in a single PDF file in the format (Annexure-1).

6. The Chairman of the Committee (preferably Head of the Institution/ Department) and Member Secretary would be nominated by the establishment from the above five IAEC members.

7. Further, having a Veterinarian in IAEC is mandatory. However, if no Veterinarian (full-time/ part-time) is available, the establishment may engage the Veterinarian on outsource basis.

8. At least half of the members are required to be replaced at the time of Reconstitution of IAEC.

9. Other members of the IAEC viz. Main Nominee, Link Nominee, Scientist from outside the Institute and Socially Aware Nominee will be nominated by CPCSEA on receipt of the above composition of IAEC for the establishment.

Ref: Constitution/Re-constitution of Institutional Animal Ethics Committee, CCSEA. Available at : https://ccsea.gov.in/WriteReadData/userfiles/file/IAEC_Constitution.pdf (Accessed on 11 March 2025)

Annexure-2: Format for IAEC Certificate

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC) APPROVAL CERTIFICATE

This is to certify that the project proposal no. _____ entitled "_____" submitted by Dr./ Mr./ Ms. _____ has been approved/recommended by the Institutional Animal Ethics Committee (IAEC) of _____ (Organization) in its meeting held on _____ (Date) and _____ (Number and Species of animals) have been sanctioned under this proposal for a duration of the next _____ months.

Authorized by	***Name***	***Signature***	***Date***
Chairman:	…….	……	……..
Member Secretary:	…….	……	……..
Main Nominee of CCSEA:	…….	……	……..

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

Ref: Form B (per rule 8(a) for Submission of Research Protocol(s), CCSEA. Available at*:* *https://ccsea.gov.in/WriteReadData/userfiles/file/New%20Form%20BFeb_2022.pdf* (Accessed on 11 March 2025)

Annexure-3: Composition of Institutional Biosafety Committee

COMPOSITION OF INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)

The IBSC shall be constituted by all institutions handling hazardous microorganisms and/or GE organisms. This committee shall comprise of a Chairperson, Member Secretary, Biosafety Officer, a DBT nominee and at least four scientists engaged in rDNA work (at least one each from within and outside the organization) as members.

Composition	Criteria
Chairperson	The Head of the organisation or his/her designate (suitable senior officer) shall be the Chairperson (utmost authority) of the IBSC. The Chairperson should preferably have knowledge and experience in scientific research pertaining to GE organisms, latest technological developments in the area & handling of hazardous microorganisms.
Member Secretary	One of the internal members should be designated as Member Secretary.
Biosafety Officer	Each IBSC shall have a member with medical qualifications designated as Biosafety Officer. The Biosafety Officer should be adequately trained with good lab practice in handling RG3 & RG4 pathogenic agents that require special containment conditions (Biosafety Level 3 or 4 facilities) and be able to offer advice on specialized containment requirements.
DBT Nominee	Each IBSC shall have an outside expert nominated by DBT who oversees the activities to ensure that biosafety aspects are being fully adhered by the organisation. While seeking registration of IBSC, the organization shall suggest 3 outside experts working in the areas preferably from nearby institutions. DBT may nominate one among them as DBT nominee or may nominate any other suitable expert as DBT nominee.
Internal and External members	IBSC shall have at least four members with at least one internal and one external member, preferably scientists engaged in rDNA work & non-GE hazardous microorganisms.

IBSC may associate/ invite qualified experts/ consultants from within or outside organisation as and when required to seek advice on specific scientific/ technical matters. Participation of such external experts/consultants in meeting should be recorded in the minutes. The opinion of the expert along with rational of the recommendation should be submitted along with the application.

Ref: Handbook for Institutional Biosafety Committee (2020), Available at https://ibkp.dbtindia.gov.in/Content/FlashPDF/IBSC%20Handbook.pdf (Accessed on 11 March 2025)

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