

4.1 CPCSEA: the statutory framework

The **Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)** is the statutory body constituted under the Prevention of Cruelty to Animals Act, 1960, working under the Ministry of Fisheries, Animal Husbandry and Dairying, Government of India. It exists to ensure that animals used in experiments are not subjected to avoidable pain or suffering, before, during or after the experiment. Its instruments are the Breeding of and Experiments on Animals (Control and Supervision) Rules framed under the Act, and its guidelines for laboratory animal facilities, which this unit follows. The working machinery has two tiers. Every establishment that breeds or uses animals must be **registered with CPCSEA** and must constitute an **Institutional Animal Ethics Committee (IAEC)**, which includes a CPCSEA nominee, to approve and oversee animal experiments. Experiments on small animals are approved by the IAEC; experiments on large animals are referred to CPCSEA itself. For the M.Pharm student, this unit together with the ethics of Unit 3 completes the regulatory frame of pharmacology research: human work answers to the ethics committee and the Declaration of Helsinki, animal work to the IAEC and CPCSEA.

4.2 Getting approval: the IAEC route

No animal experiment in a registered establishment begins without prospective approval, on this path:

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Investigator writes the protocol: species, numbers, procedures,
anaesthesia, endpoints, euthanasia method, justification
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    v
IAEC reviews: scientific need, the 3Rs, animal numbers,
housing and care arrangements, investigator competence
    |
    v
Small animals: IAEC approval is final, experiment may begin
Large animals: protocol referred to CPCSEA for approval
    |
    v
During the work: IAEC oversight, records open to inspection,
CPCSEA inspection of the facility at any time
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The protocol must justify the species and the number of animals (the sample size logic of Unit 2 applies to animal work with full force: an underpowered animal study wastes lives), state the humane endpoints at which suffering ends the animal's participation, and name the anaesthesia and euthanasia arrangements of sections 4.9 and 4.10.

4.3 Veterinary care

Veterinary care is the professional core of the facility. A qualified veterinarian, experienced in laboratory animal medicine, must be available to the establishment, with authority over animal health decisions. The duties run from advising investigators on species choice, anaesthesia and endpoints, through routine health monitoring of colonies, diagnosis and treatment of disease, supervision of quarantine and acclimatisation, to certifying animals fit for experiment and ensuring euthanasia is performed humanely. Veterinary oversight is what converts the guidelines from paper into practice: an establishment whose veterinarian is

nominal has a paper facility, whatever its buildings contain.

4.4 Quarantine, stabilisation and separation

Newly arrived animals are **quarantined**: housed separately from established colonies for a defined period, observed for signs of illness, and examined before release, so that an infected shipment cannot seed the whole facility. **Stabilisation** (acclimatisation) is the companion rule for experiments: animals need a settling period after transport before any procedure, because transport stress distorts physiology and therefore data; readings taken on a transported, unsettled animal measure the journey as much as the drug.

Separation continues inside the facility: animals of different species are housed apart, sick animals are isolated from healthy ones, and animals undergoing different experiments are kept identifiable and distinct. The three rules together protect both the animals and the validity of the research, a pairing that recurs in every section of this unit.

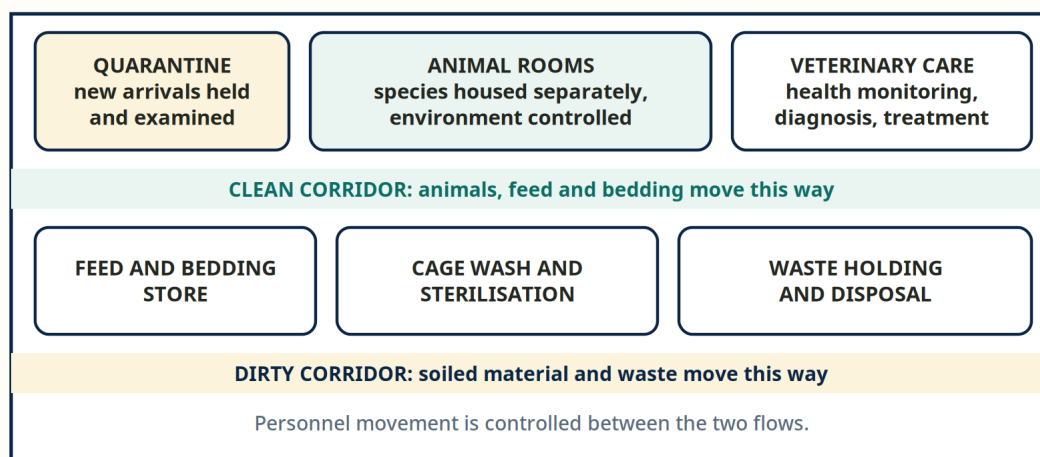
4.5 Surveillance, diagnosis, treatment and control of laboratory animal diseases

The facility runs a continuous **surveillance** programme for laboratory animal diseases: routine observation of every animal, sentinel animals and periodic health screening where the programme requires it, post mortem examination of unexplained deaths, and records that make an outbreak traceable. **Diagnosis** follows the ordinary veterinary path of clinical examination supported by microbiological, parasitological and pathological investigation. **Treatment** is given where compatible with the animal's experimental status, and an animal whose treatment would compromise either its welfare or the study is removed and, where necessary, humanely killed rather than left to suffer for data. **Control** combines the quarantine of section 4.4 with sanitation, pest control, controlled access and, where the species programme uses it, vaccination. The scientific stake is direct: an undiagnosed infection sweeping a colony alters baselines, inflates variability (the sigma of Unit 2), and can invalidate months of experiments, besides being a welfare failure in itself.

4.6 Location of the animal facility, and animal housing systems

Location. The animal facility should be located away from public ways, noise, vibration and pollution, and separated from general institutional traffic, while remaining connected to the laboratories it serves. It is planned with **barrier and corridor systems** that separate clean and dirty flows: animals, feed and bedding move one way, waste and soiled material another, and personnel movement is controlled so that hands and clothing do not carry contamination between rooms. The building is designed for washdown, drainage and pest proofing, with service areas (feed and bedding stores, cage washing, waste holding, post mortem) distinct from animal rooms. The layout also protects the neighbourhood: noise, odour and waste from the facility are contained by design, not by apology.

Anatomy of a Laboratory Animal Facility



Design contains noise, odour and waste, and keeps sick animals isolated.

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Figure: The facility in plan. Separate clean and dirty corridors, species separation, quarantine at the receiving end and service areas at the working end are the design facts CPCSEA inspection looks for.

Environment. Animal rooms are held within the comfort range of the species, with temperature, humidity, ventilation, light and noise controlled and monitored: for common rodent rooms, temperatures near 22 degrees Celsius, relative humidity roughly 30 to 70 percent, ventilation of the order of 10 to 15 air changes per hour, and a regular light cycle, typically 12 hours light and 12 dark, are the usual working values. Alarms and backup for power and ventilation failures are welfare equipment, because a failed ventilator in a closed room kills quietly and quickly.

Animal housing systems. Animals are housed in systems suited to the species: ventilated or conventional **cages** for rodents (with solid floors and bedding, or grid floors only where justified), **pens and runs** for larger animals, and tanks or racks for aquatic species, each with space, bedding, nesting material and environmental enrichment appropriate to natural behaviour. Stocking density follows the guideline space allowances per animal by species and weight; overcrowding is a welfare breach and a data breach together, since stressed animals are physiologically abnormal animals. Cages and housing are identified by cards recording strain, sex, number, experiment and investigator, the paper trail that links every animal to its protocol.

4.7 Maintenance and husbandry

Husbandry is the daily routine of care: feeding with nutritionally adequate, uncontaminated diet of known composition (the diet is itself an experimental variable and is standardised and recorded), clean water always available, bedding changed at intervals that keep cages dry and ammonia low, cages and rooms cleaned and sanitised on schedule, and every animal observed daily, with the observation recorded. Feeding and cleaning routines are timed so they do not collide with experiments, and weekend and holiday care is rostered like any other day: animals do not observe the academic calendar. Enrichment (nesting material, shelters, gnawing material, social housing for social species) is part of husbandry, not decoration, because barren housing produces abnormal behaviour and abnormal physiology.

4.8 Personal hygiene

Personal hygiene protects staff, animals and experiments in one system. Personnel wear facility clothing (changed or covered before entering animal rooms), gloves, masks and head covers as the barrier level

requires; hands are washed on entry, between species and rooms, and on exit. Eating, drinking and cosmetics are barred from animal areas. Health of personnel is monitored, because staff can carry infections to animals (and, with zoonoses, receive them); injuries and bites follow a written first aid and reporting procedure, and shower and change facilities separate the animal areas from the outside. Hygiene discipline is also a data discipline: most colony contamination arrives on people.

4.9 Anaesthesia

Anaesthesia is required wherever a procedure would cause pain beyond the momentary: the governing principle is that an animal must not be allowed to experience pain the investigator would not accept untreated in a patient. The choice of agent and regimen follows the species and the procedure, under veterinary guidance: inhalant agents such as isoflurane for controllable depth and recovery, injectable combinations such as ketamine with xylazine for rodents where inhalation is impractical, chosen and dosed by trained persons. Anaesthetic depth is monitored throughout (reflexes, respiration, heart rate), the animal is kept warm, and recovery is supervised until the animal is conscious and stable; analgesia continues into the post operative period, because anaesthesia ending does not end pain. Neuromuscular blocking agents are never used alone: they paralyse without removing sensation, and their use without adequate anaesthesia is among the gravest welfare breaches in experimental work.

4.10 Euthanasia

Euthanasia, the humane killing of an animal, is required at the end of experiments whose design needs tissue or terminal measurements, at humane endpoints where suffering cannot be relieved, and for animals surplus to breeding or suffering incurable disease. The method must produce rapid unconsciousness and death without pain or distress, be reliable and irreversible, suit the species and the scientific needs (some methods contaminate tissues or distort measurements), and be performed by trained persons, out of the sight and smell of other animals where possible. Physical and chemical methods each have their accepted place by species in the CPCSEA framework (an overdose of an anaesthetic agent is the standard chemical route for most laboratory species); death is confirmed before disposal, carcasses are disposed of hygienically, and the record of every euthanasia closes the animal's file. The investigator's duty is to design the experiment so that the endpoint, and the manner of meeting it, was decided in the protocol, not improvised at the cage side.

4.11 Record keeping and SOPs

The facility runs on its records. **Record keeping** covers the registers of animals received, bred, issued, experimented on and disposed of; IAEC approvals and minutes; veterinary and health monitoring records; environmental monitoring; training records; and incident reports. Every animal must be traceable from arrival to end point against a protocol number. **Standard operating procedures (SOPs)** are the written, version controlled instructions for every routine activity: receiving and quarantine, cleaning schedules, feeding, cage changing, anaesthesia, euthanasia, waste disposal, emergency response. New personnel work from the SOPs, audits check practice against them, and deviations are recorded and explained. In CPCSEA inspection, the records and SOPs are the evidence that the guidelines are a living system rather than a framed certificate.

4.12 Personnel, training and transport of laboratory animals

Personnel. The facility is staffed by people competent for their roles: a veterinarian (section 4.3), trained animal care staff, technicians and supervisory personnel, in numbers sufficient that no duty of this unit depends on goodwill and overtime. **Training** is mandatory and continuing: animal handlers are trained in handling, restraint, recognition of pain and illness, and the procedures they perform; investigators in the

ethics, regulations and techniques of their protocols; and training is recorded, because CPCSEA inspection asks for the record, not the assurance. Handling technique is itself a welfare and data issue: a frightened animal roughly handled arrives at the experiment stressed, and its readings say so.

Transport of laboratory animals follows the same care logic outside the building. Animals travel in suitable, labelled containers with adequate ventilation, space, bedding, and food and water for the journey's length, protected from extremes of temperature, noise and public exposure, by the shortest reasonable route, with the consignment documented (species, number, sender, receiver, health status). Transport between institutions moves animals through the quarantine of section 4.4 at the receiving end. The rules complete the circle of the unit: the animal is protected at arrival, in housing, in experiment and in transit, which is the whole content of the CPCSEA approach.

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