

Topic - The Study of CPCSEA Guideline And The Requirement Modification In Research Area

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GOAL- *The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal well- being, quality in the pursuit of advancement of biological knowledge that is relevant to humans and Animals.*

I. INTRODUCTION

CPCSEA is a statutory Committee, which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pains or suffering before, during or after performance of experiments on them.

Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The cost of late stage development has meant it is usually done by the larger pharmaceutical companies.

The introduction sets the stage for your research area, providing context and highlighting its significance. By clearly framing your research objective and problem statement, you can capture the attention of readers and create a solid foundation for your study.

Animal welfare

DEFINITION

Animal welfare is defined as the well-being of animals. The well-being of animals is again defined by many people, organisations and societies in different ways. The indicators of animal welfare are the longevity, health, behaviour, physiology, immunity, reproduction, expressions etc. The concerns of animal welfare are that non-human animals are sentient like human beings and care should be given for their need, health and well-being.

Principles of Animal Welfare

The principles of animal welfare may be best understood by the five freedoms of animals. The World Health Organization for Animal Health (OIE) recognises the

following five internationally recognized freedoms for animals:

1. freedom from thirst and hunger by ready access to fresh water and a diet to maintain full health and vigour
2. Freedom from discomfort by providing an appropriate environment including shelter and a comfortable resting area
3. Freedom from pain, injury, and disease by prevention or rapid diagnosis and treatment Freedom to express most normal behaviour by providing sufficient space, proper.
4. facilities, and company of the animal's own
5. Freedom from fear and distress by ensuring conditions and treatment which avoid mental suffering

An animal's primary welfare needs can be met by safeguarding the above mentioned five freedoms. The animals can live a natural life, fit and healthy by advocating these five freedoms.

CPCSEA guideline

[Committee for the Purpose of Control and Supervision on Experiments on Animals]

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) was established under Section 15(1) of the Prevention of Cruelty to Animals Act 1960. CPCSEA is a statutory Committee, which is duty bound to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pains or suffering before, during or after performance of experiments on them. For this purpose, the Committee formulated the "Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998" (amended in 2001 & 2006) to regulate the experimentation on animals. Under the provisions of the above rules, establishments who are engaged in Bio-medical research are required to get themselves registered with CPCSEA, constitute Institutional Animal Ethics Committee (IAEC), get their Animal House Facilities inspected, and also get specific projects for research cleared by IAEC (in case of small laboratory animals) or CPCSEA (in

case of large animals) before commencing them. Further, breeding and trade of animals for such experimentation are also regulated under these Rules.

The present CPCSEA at Animal Welfare Division, Ministry of Environment, Forest and Climate Change, New Delhi consists of the Special Secretary (MoEF&CC) as Chairman, Joint Secretary (Animal Welfare) as Vice Chairman and Deputy Secretary (Animal Welfare) as Member Secretary. The other members include Director, National Institute of Animal Welfare (NIAW), Drug Controller General of India, experts/ officials from Medical Council of India (MCI), Veterinary Council of India (VCI), Pharmacy Council of India (PCI), University Grant Commission (UGC), Wildlife Institute of India, Institutes under Department of Biotechnology (DBT), experts from Medical and Pharmacy Colleges, experts from Universities (Biotech, Zoology, Life sciences etc.).

Mandates of CPCSEA

- Registration of establishments conducting experiments on animals. Registration of establishments engaged in Breeding of Laboratory animals.
- Constitution of Institutional Animals Ethics Committees (IAECs) in the establishments registered.
- Approval of Animal House Facilities for Small and Large animals. Permission for conducting experiments on large animals.
- Recommendation for import of animals for experimentations and breeding.

Function of CPCSEA

All establishments engaged in research and education involving animals, are required to comply with the various guidelines, norms and stipulations set out by CPCSEA.

The main functions of CPCSEA are:

- Registration of establishments conducting animal experimentation or breeding of animals for this purpose.
- 8am • Selection and appointment of nominees in the Institutional Animal Ethics Committees of registered establishments.
- Approval of Animal House Facilities on the basis of reports of inspections conducted by CPCSEA.
- Permission for conducting experiments involving use of animals.

- Recommendation for import of animals for use in experiments.
- Action against establishments in case of violation of any legal norm/stipulation

Website of CPCSEA

(<http://cpcsea.nic.in>)

The Website of CPCSEA has been launched on 24th April, 2015 by the Hon'ble MEF&CC on the occasion of 'World Laboratory Animal Day' for timely disposal of work and to maintain a database for easy retrieval and exchange. It will help to provide online facilities to the Bio-medical research Organizations who are involved in the animal experimentation. The Website marks yet another step in ushering in more transparency in the functioning of the CPCSEA. This initiative will impact in the Digital India Programme of the Government of India with a vision to transform India into a digitally empowered society.

Objectives of the Website of CPCSEA:

- To provide 'online' facilities to the establishments for registration, renewal, revision and submission of Research Protocols on Large Animals.
- Make it easy to use for the registered establishments by providing latest updates of CPCSEA and to function as the two way communication mode.
- To maintain the database for easy retrieval and exchange.
- To facilitate quick and easy communication with CPCSEA by Nominees of CPCSEA and the establishments registered with CPCSEA.

CPCSEA Guidelines for laboratory Animal Facility

The CPCSEA brought the 8guidelines for laboratory animal facility in 2003 (aiming the implementation of Good Laboratory Practices) for animal facilities which are intended to assure quality maintenance and safety of animals used in laboratory studies while conducting biomedical and behavioural research and testing of products. The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal wellbeing, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

Ethical Principles of 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 (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.

CONDUCT OF ANIMAL EXPERIMENTS

Definition of Experiment

As per rule 2(e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 "Experiment" 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 animal(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

Why are animals being used in experiments and research?

The animals are used in research because very limited number of studies can be done on humans, their physiology/anatomy can be matched to humans, animals are mostly susceptible to the diseases that affect humans, the short life span allows animals to be studied throughout their entire life in a limited period, it also allows controlled experiments and environmental variables can be minimized. The dosage/route of exposures can be controlled/ varied and the experiments can be replicated. Animal experimentation is used in several areas of biomedical research and product testing, developing new treatments for diseases, or ways of preventing diseases, fundamental biological and medical research, safety testing of non- medical products used in the household, agriculture and industry, developing new methods of diagnosis.

Points to be taken care off while using animals in Research:

The drug substance to be tested for the first time in animals should be for specific purpose. The detailed literature review and comparison of data available on previous studies should be done. Wherever possible, computational modelling, simulations or in silico analysis should be carried out. The in

in vitro assays with cell lines/ tissue culture should support the desired activity/ experiment to be conducted in animals. The ex vivo studies with organs collected from slaughter houses or culling animals may be used, wherever feasible avoiding live animal experiment. All the animal experiments need the approval of IAEC or CPCSEA as the case may be. Required training and education on the handling care, and use of animals is mandatory. All research using animals must adhere to scientific, institutional, and governmental principles, policies, laws, regulations and guidelines. It is ethical and moral responsibility of each researcher for the lives of animals. Researchers are responsible for quality of animal care, appropriateness of animal use and minimization or relief of pain and distress

Why to use animals in Education?

The path to quality research is via excellence in higher education. Primarily due to generous funding from the Govt. of India, last two decades have witnessed a surge in high quality research in the field of life sciences, emanating from various state and central universities. With a view to build on this foundation, India will need a strong force of talented students capable of facing the challenges in basic as well as applied biology. On the global scenario, India is rapidly emerging as a hub of intense activity in the field of

- (a) contract research for drug discovery,
 - (b) preclinical screening of potential drugs for life-style and neurodegenerative diseases,
 - (c) drug toxicology, and
 - (d) generation of transgenic animal models for use in research.
- In all these studies, application of in vivo animal models is indispensable, and there is a pressing need for personnel trained to handle live animals and perform complicated surgical procedures. To this end, the use of laboratory bred rodents is a basic necessity that must be met with in the institutions of higher learning, as practiced in renowned universities across the world. The students need to be sensitized to the moral and ethical issues in the use of the animals, and also be trained to work in strict compliance of CPCSEA norms.

Which are the experimental animals subject to regulations?

Most of the animals that are being used for experimentation are under the purview of CPCSEA. Anything higher than invertebrates in terms of level of sentience requires regulation. Thus rats, mice, birds, fishes and farm animals are all subjected to regulation. The relative sentience of different species of animals is as follows: Invertebrates (eg.

cockroaches) < Birds < Rodents < Canines/Felines Bovine/Equines < Primates (eg. Rhesus Macaque) < More evolved Primates (e.g. Chimpanzee) The 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.

The 3Rs (Replacement, Reduction and Refinement)

The Three Rs (3Rs) in relation to science are guiding principles for more ethical use of animals in testing. They were first described by W. M. S. Russell and R. L. Burch in 1959. The 3Rs are-

- (1) Replacement: methods which avoid or replace the use of animals in research,
- (2) Reduction: use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals
- (3) Refinement: use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

The concept of the 3Rs- Reduction, Refinement and Replacement has paved way to the concept of "Science of Alternatives" which brings finest discoveries in in vitro technologies.

The 4 R (Reuse and Rehabilitation)

The concept of Rehabilitation has been recognised in India as the 4th R and evolved as an official policy of the CPCSEA in 2004. It is defined as "the aftercare rendered to animals that have been

- (i) bred for the purpose of experimentation
- (ii) subject to any form of experimentation.
- (iii) retained in laboratory animal houses or breeding houses for the purpose of experimentation, both for education and research, with the sole intention of alleviating the pain/distress or suffering due to the physical, physiological and psychological trauma that the animals have been exposed to and to provide the animal a life distinctly different from laboratory housing and care, until the point of natural death". "Reuse" of laboratory animals is a term used where in, after completion of an experiment (experiment as defined in

Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 and as amended in 2004) an animal is used again in the same or a different protocol, where an unused animal would have equally sufficed to meet the objectives of the second/or subsequent use.

EDUCATION AND TRAINING ON ANIMAL WELFARE IN INDIA

National Institute of Animal Welfare (NIAW), Ballabgarh

National Institute of Animal Welfare (NIAW) is a premier training institute of the Government of India under the Animal Welfare Division in the Ministry of Environment, Forest & Climate Change functioning with the mandate of organizing and imparting training on diversified subjects in animal welfare. The main objective is to create a pool of qualified and technical personnel at each level to ensure proper implementation of the welfare of animal scheme and for fulfilment of the requirements and rules framed under the "Prevention of Cruelty to Animals Act, 1960. The trainings enable strict enforcement of the PCA Act at every level, be it in animal welfare or in animal experimentation in bio-medical field. Different training programmes are generally conducted for CPCSEA nominees/ socially aware nominees/ LAEC members, pool of scientists, CPCSEA nominee's refresher courses, Honorary Animal Welfare Officers, 8. Pharmacy and Veterinary students/interns, Gaushala workers, farmers, NGO workers etc. Besides these, trainings are also conducted for zoo keepers across the country and volunteers of Wild Life Crime Control Bureau. Apart from NIAW the various courses on laboratory animal welfare are being run at different institutes at different levels of expertise like Tamil Nadu Veterinary & Animal Sciences University (TANUVAS), National Centre for Laboratory Animal Science, Hyderabad, CSIR-Mysore.

Required Modification in Research Area

I will guide you through the essential steps to meet the requirements and make necessary modifications in your research area. From understanding the requirements to evaluating the modified research, you'll gain the knowledge and skills to enhance your research.

Understanding the Requirements

Thoroughly understanding the requirements of your research area is crucial for success. By analyzing existing literature, conducting surveys, and engaging with experts, you can identify the key components, constraints, and expectations that shape your research.

Analysis of the Research Area

Research Gaps

Identify the existing gaps in your research area. By critically analyzing the current body of knowledge, you can discover opportunities to contribute new insights and address unanswered questions.

Trends and Emerging Technologies

Stay updated with the latest trends and emerging technologies relevant to your research area. This awareness will help you align your study with the cutting-edge developments and ensure its relevance in a rapidly evolving field.

Identifying the Modifications Needed

Incremental Improvements

Identify the areas in your research that can be enhanced through incremental improvements. Small adjustments and fine-tuning can make a significant difference in the overall quality and impact of your study.

Revolutionary Changes

Explore the possibility of implementing revolutionary changes in your research area. By challenging established norms and adopting innovative approaches, you can push the boundaries of knowledge and drive transformative progress.

Implementation of Necessary Changes

1. Developing Prototypes

Create prototypes to test and validate the modifications you plan to implement in your research area. Prototyping allows you to assess the feasibility and effectiveness of your proposed changes before fully committing to them.

2. Collaborative Efforts

Engage with peers, mentors, and domain experts to gather valuable insights and perspectives on your modifications. Collaborative efforts can provide diverse viewpoints and enhance the robustness of your research.

Evaluation of the Modified Research Area

Data Analysis

Perform a comprehensive analysis of the data collected after implementing the modifications in your research area. This analysis will enable you to assess the impact and effectiveness of the changes made.

Comparison with Baseline

Compare the results and outcomes of the modified research area with the baseline or previous state. This comparison will provide a clear understanding of the improvements achieved and the value added by the modifications.

II. CONCLUSION

Reflect on the significance of the **CPCSEA guidelines** in fostering ethical and responsible animal research practices. Emphasize the importance of upholding animal welfare standards and ethical considerations to ensure the credibility and validity of scientific investigations.

Summarize the key findings, lessons learned, and the overall impact of the modifications in your **Research Area**. Emphasize the significance of continuous improvement and adaptation in the ever-evolving landscape of research.

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