

Global Journal of Novel Pharma and Paramedical Research

Research Article

Use of Animals

2022 Volume 1 Number 2 July-Dec

Brief Overview of the Laws and Rules Governing The Use of Animals in Research

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DOI: https://doi.org/10.58260/j.ppmr.2202.0107

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More emphasis has been laid on the welfare of animals and the morality of this approach as its use in research projects has increased. Dissemination of knowledge regarding current ethical issues and alternatives in animal experimentation serves two crucial purposes: first, it makes researchers more aware of potential ways to use animals in experiments, and second, it makes sure that potential users are aware of the available alternatives. It is not a privilege to be able to utilise animals in research labs. Certain members of the scientific community have been granted this privilege by society, and it comes with the need to abide by the relevant laws, regulations, policies, and standards as well as work to improve them. For instance, laws passed in many nations throughout the 1980s mandate that applications using laboratory animals should be minimised, improved, and replaced whenever possible in accordance with the 3Rs. As a result, experts from around the world worked to put the 3Rs into practise to safeguard the wellbeing of laboratory animals used in scientific research. This review article covers a collection of articles that examine how animal laws, regulations, and standards operate in various nations.

Keywords: Laws, Animal, Research, Experiments, Regulations

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How to Cite this Article

Shanmugarathinam Alagarsamy, Saravanan Ravindran, Ruckmani Kandasamy, Dhayabaran Daniel, Dharshana Karthikeyan, Vidhyaa Ganesh Karthikeyan, Brief Overview of the Laws and Rules Governing The Use of Animals in Research . Glo.Jou.of.pharma.par.of.ADSRS.Edu.Res.

2022;1(2):7-14.

Available From

http://ppmr.adsrs.net/index.php/ppmr/article/view/7

To Browse



Manuscript Received 2022-12-04

Review Round 1 2022-11-23

Review Round 2 2022-12-06

Review Round 3 2022-12-23 Accepted 2022-12-30

Conflict of Interest

Funding

Ethical Approval

Plagiarism X-checker

Note



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Introduction

The scientific community largely agrees that anyone who utilizes, cares for, or seems to use animals in a laboratory environment must at the very least be responsible for their wellbeing. The rules governing using laboratory animals are pondered in societal legal guidelines, cultures, and traditions, further being expressed by using the establishments of law and culture that broaden and uphold those restrictions. Scientists are required to abide by the applicable legal guidelines, policies, regulations, and pointers of the jurisdictions wherein they're based totally. Refinement, substitute, and discount, or the 3Rs, are essential to animal welfare programmes across the globe. The 3Rs can be followed and used explicitly in laws and regulations, or they are probably implied. Even in international locations wherein laboratories have no longer been set up for animal welfare laws, the 3Rs are recognised and practised.

Animal Regulatory Rules Across the World: An Overview

Within the north american area, both canada and the US have large, long-standing laboratory animal programmes that are the end result of several legal guidelines, regulations, guidelines, and processes. The Animal Welfare Act(AWA) and the fitness research extension act are two countrywide laws that the US has exceeded which have an effect on laboratory animal studies. The united states department of agriculture is allowed by the AWA to issue regulations, check out facilities, and penalise noncompliance. Any group that gets investment from the public fitness service is subject to the health research extension act, that's an amendment to the public health services act. The primary way of handling oversight is via issuing guidelines and guarantees that the research organisation has to observe. The essential obligation for ensuring animal welfare at the part of the institutional animal care and use committee, the attending veterinarian, and the institutional reputable is at the core of each of those policies.

The management of animals in Canada is decentralised, and behavior is ruled by means of practice and custom. The Canadian infrastructure does not consist of regulation that especially controls the remedy and use of animals in studies, in contrast to the hierarchical

Laws enacted in the US system. The Canadian council on animal care is important to Canada's oversight of studies using animals and performs an extensive position in programme self-governance1.

All European union member states are required to abide by means of the European directive (directive three/european), as 2010/sixty revised september 22, 2010. The provisions of the directive were to be adopted and posted in countrywide law via the member states with the aid of january 1, 2013. The amendments to the directive had been made for you to harmonise the requirements for regulation, training, and the housing and care of animals throughout all of the member countries and to grow uniformity in their transposition. Three regions of awareness for the examination of the transposition encompass minimal standards for laboratory animal housing and care, regulations on using specific animal species, and task evaluation and authorization 2.

Economic factors affect the laws and regulations formed in Latin America. Their laboratory animal regulations and regimes reflect political stability and cultural variety. The countries with the most advanced infrastructures include Brazil, Mexico, and Uruguay, all of which have particular laws governing the use and care of research animals. Other Latin American nations' political structures and legislative frameworks for the regulation of research animals are weak or non-existent. In a research article by Rivera et.al (2016) it become stated that the advancement of laboratory animal sciences thru the involvement of institutions plays a crucial element in forming an animal studies network that brings the nations of Latin America together3.

In the countries like China, Japan, and Korea, there are many distinct types of state control over animal testing. In 1983, China passed legislation governing the use and care of animals, and the Ministry of Health also published guidelines at that time. Currently, this is the responsibility of the Ministry of Science and Technology, which is in charge of the Administration of Laboratory Animals Act. The treatment of experimental animals and all other aspects of experimentation are covered by this law. Neighbourhood governments bolstered this statute with the aid of developing their own laws that establish central, regional, and levels of control. The law for the humane treatment and control of animals in japan gives a regulatory

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Framework in assessment to this hierarchical structure. Establishments self-modify and hold an eye on themselves, and the law does not limit this. Institutions are required by means of the ministry of education to establish institutional animal care and use committees, and ministry standards call for that issues like humane endpoints, pain management, euthanasia, and safety to be addressed inside the development of an experimental protocol. It isn't always necessary for the authorities to conduct formal inspections or submit reviews 4.

The improvement of the financial system, subculture, and faith has an effect on other pacific rim nations like Singapore, Thailand, Indonesia, and Malaysia, that have the differing infrastructure and regulatory norms. The countrywide advisory committee for laboratory animal research prepared and implemented guidelines on the care and use of animals for medical functions, which have been published on October 20, 2004, due to Singapore's dynamic research surroundings. The regulations, which are based on the 3Rs, set forth what organisations, researchers, and others responsible for animal care are expected to do while utilising animals in research.

The indian parliament passed the prevention of cruelty to animals act in 1960. The committee for the management and supervision of experiments on animals changed into created according to this law to make certain the welfare of studies animals and to set up appropriate requirements. The committee for the purpose of manage and supervision experiments on animals advanced the "tips for laboratory animal facility" to deal with all elements of animal care and use packages, which encompass appropriate veterinary care, quarantine, sickness surveillance, animal procurement, physical plant issues, animal husbandry, and training 5.

An animal welfare board was also established by the cruelty to animals act to reduce the useless struggle for animals. India focuses its moral assessment of medical animal checking out on five guiding standards. Principle 1 creates the idea that experiments on animals can best be done if they improve information, which includes retaining or extending human lifestyles, gaining knowledge of new physiological information, or eradicating sickness in animals, humans, or vegetation. Precept 2 covers both species choice (the usage of the fewest animals with the lowest

Phylogenetic scale and least sensibility to get valid outcomes) and animal variety (using the fewest animals to supply results with a ninety-five% confidence interval which is statistically legitimate). In step with precept 3, it's far crucial to prevent and limit pain and suffering in animals and to expect that any procedure that might be uncomfortable for a human could additionally be uncomfortable for an animal. All techniques that motivate greater pain have to be achieved under an appropriate anaesthetic, sedation, and/or analgesia. In precept four, those worried about animal experimentation are reminded that they have got an ethical duty to take care of and rehabilitate the animals used in their research. There are just a few truly described instances wherein euthanasia is acceptable. Regarding animal living situations, precept 5 states that they ought to be suitable for the species and guide the welfare of the animals. A veterinarian or other expert ought to oversee dealing with and housing and ensure that the right care is given. Research establishments need to be registered with the government and establish an institutional animal ethics committee6.

In Japan, there is a single major statute that governs the use of animals in testing, teaching, and research, as well as other ministry directives that offer administrative direction. The "Act on Humane Treatment and Management of Animals," which requires a self-regulatory framework for animal testing, is the major piece of legislation. Below is a summary of the development of the law and its history.

Animals Protection and Management Act

Originally known as the "Act on Protection and Management of Animals," the law was adopted in 1973. Because there was no rules or policies governing animal welfare, inclusive of the usage of animals in research, trying out, and training, japan turned into receiving grievance from other, industrialised international locations earlier than enacting this law. The regulation from 1973 covers domesticated animals, birds, and reptiles but not amphibians or fish. Only one article—Article 11—of this regulation, which largely dealt with pets, set forth the procedures to be followed when employing animals for scientific research. In Article 11, the principal measures were equivalent to "refinement," one of the 3Rs, with no reference to the other two R's, replacement and reduction.

Human Treatment and Management of Animals act

"Act on Humane Treatment and Management of Animals" was the new name given to the original law after it was amended in 1999 (Law No. 105, revised 2000). The preamble of this amendment, which distinguished animals from human property and rethought them as living beings, was particularly notable. The sanctions for animal cruelty have also increased significantly as a result of this. Additionally, Article 11, "Measures When Using Animals for Scientific Means," was modified to Article 24 due to the addition of other articles pertaining to companion animals. The following change took place in 2005. (Law No. 105, revised 2005). Because there were many other articles about companion animals added before this one, Article 24 was modified to Article 41 in this version. Furthermore, the 3Rs ideas were included to Article 41. This amendment imposed penal servitude and also increased the amount of penalty for breaking the law. The most recent change, which became the current statute, took place in 2012. Despite substantial pleas from organisations participating in the movement against animal research to make the law harsher, Article 41 was not altered at all in this modification. However, in part to placate these groups, the severity of fines and prison time for infractions did increase. Despite numerous modifications, Japanese legislation still does not mandate the registration of establishments using experimental animals, staff training, or regulatory inspections.7.

The main laws governing the treatment and use of laboratory animals in Malaysia are the Animal Welfare Act 2015 and the Animal (Amendment) Act 2013. The Animal Act, which was passed into law in 1953, served as the model for the 2013 Animal (Amendment) Act. The Wildlife Conservation Act of 2010 regulates the use of non-domesticated species, such as non-human primates and other wildlife species, for research purposes. The Malaysian fishery act of 1985 governs the upkeep of aquatic and fishery species. The legislative outline that resulted in the introduction of the federation of Malaysia in 1963 lays out the prison machine's purview and geographic attain. Whilst in comparison to the Malay Peninsula states and the three federal territories (Kuala Lumpur, Putrajaya, and Labuan), the eastern Malaysian states of Sabah and Sarawak had legal guidelines that handiest

Treated the extraction, conservation, and use of natural world and fisheries of their respective states, together with the flora and fauna conservation enactment 1997 in Sabah and the wildlife protection ordinance 1998 in Sarawak. Sabah and Sarawak, on the other hand, are free to do so and have the option to do so when it is appropriate or necessary. It was difficult to create a consistent set of laboratory animal care laws across Malaysia due to these legal autonomies. A realistic set of guidelines for the control and use of laboratory animals in Malaysian establishments ought for you to go beyond and unite present prison frameworks because of the delegation of electricity provided through the federation system government. Additionally, it was observed that the animal welfare act of 2015 no longer alters the use of animals in different faculties and handiest applies to institutions of better schooling (as defined via the Malaysian training act 1996). The education ministry's lengthy-time period purpose is to increase using pc-aided mastering generation in Malaysian classrooms, which lessens or, in some cases, completely removes the need to use animals. The Animal Welfare Act of 2015 must be implemented in elementary and secondary schools, and major financial and human resources are required for that. But a regulation governing the handling and application of animals for educational purposes in Malaysian schools is now being developed8.

Significant Laws and Acts for Protection of Animal

When you come across someone behaving cruelly or when you file a FIR with the police to report cruelty, it is essential to be aware of the rights granted to animals 9.

These are the most powerful laws to protect animals:

- 1. Section 428of the Indian Penal Code
- 2. Section 429of the Indian Penal Code

Animal Welfare Act

The US Congress approved the Animal Welfare Act, which guarantees that animals employed as test subjects, pets, or for exhibitions receive humane treatment and complete respect. Care for an animal's bodily and psychological well-being is included in animal welfare.

The regulation of the treatment and use of animals in biomedical research is the responsibility of numerous organizations. The Animal and Plant Health Inspection Service enforces the Animal Welfare Act under the direction of the United States Department of Agriculture. The treatment of animals used in biomedical research in the United States is governed by the Public Health Service policy and the Animal Welfare Act regulations, depending on the animal species and the funding source. Rodents, specifically rats and mice bred for research purposes, are the subject of discussion in this appendix. Rats and mice are now excluded from the Animal Welfare Act Regulations, however "all vertebrate animals" are covered in the Public Health Service policy guidelines. The Health Research Extension Act, a federal law implemented in 1985 that established standards for the right handling and care of animals used in biomedical and behavioural research, is enforced by the Public Health Service. Prior to receiving financing for research involving such subjects, institutions receiving Public Health Service funding are required to submit a written Animal Welfare Assurance to the Office of Laboratory Animal Welfare 10.

The Wildlife Protection Act (1972)

Section 39 prohibits harm to any wild animal or tree.

All "animals," including birds, reptiles, mammals, and their progeny, are included in this definition. In the case of birds and reptiles, this includes even their eggs. The exceptions are the "vermin." Each state maintains a list of non-human animals that are considered vermin.

If found guilty of an offence under this Act, the punishment is either three years in jail, a fine of \$25,000, or both. You will be sentenced to seven years in jail and must pay a \$10,000 fine if this is your second offence.

The Prevention of Cruelty to Animals Act, 1960

Sections 11(a)–(o) of the Act define cruelty. The perpetrator will have to pay a first-rate a good way to extend to fifty rupees. Within the occasion of a second offence, the culprit faces a first-class of as a minimum 25 rupees however up to a hundred rupees, up to 3 months in prison, or a combination of each. Any illegal killing or cruelty in the direction of an animal should be reported to the local

Police station, and a F. I. R. Need to be filed against the perpetrator. Consult with sections 428 or 429 of the indian penal code and the prevention of cruelty to animals act of 1960 if the killing or cruelty is dedicated on an animal no longer owned by the culprit. Discuss with the prevention of cruelty to animal act 1960 if the killing or cruelty is inflicted on an animal owned by means of the wrongdoer. If the animal is a wild animal now not described as "vermin" with the aid of the nation, or if the individual is killing or injuring an animal defined as vermin in an unlawful or inhumane manner, check with the flora and fauna safety act of 1972 and the prevention of cruelty to animals act of 1960.

Institutional Animal Care and Use Committee - IACUC

Each university has an IACUC in place to examine every suggested animal experimentation. The following information must be included in every animal protocol: (1) the justification for using animals, the number of animals to be used, and the species chosen; (2) the methods or medications to be used to eliminate or minimise pain and discomfort; (3) a description of the methods and sources used to search for alternatives to painful procedures; and (4) a description of the search used to ensure that the experiment does not unnecessarily duplicate prior research.

An IACUC normally comprises five or more members, one of whom must be the institution's veterinarian who oversees animal care. professional whose main interests are not scientific (such as an ethicist, clergyperson, or lawyer) and a member who is not connected to the institution in any way and is intended to represent the interests of the community at large must also be included on the committee. This includes at least one scientist with experience in animal research. Additionally, the IACUC conducts twice-yearly inspections of the institution's animal facilities to make sure that it complies with federal regulatory guidelines. In cooperation with the Office for Laboratory Animal Welfare at the NIH, the Applied Research Ethics National Association (ARENA) has published guidelines to assist institutions in setting up and sustaining IACUCs and to assist IACUCs in effectively monitoring the welfare of animals at their facility. Public Responsibility in Medicine and Research, a sister organisation of ARENA, often hosts training sessions for new IACUC members as well as annual meetings for IACUC members 11.

CPCSEA- The Committee for the Purpose of Control and Supervision of Experiments on Animals

The Central Government of India established the CPCSEA as a statutory body in accordance with Section 15(1) of Chapter IV of the Prevention of Cruelty to Animals Act, 1960. The committee's goal is to prevent unnecessary suffering or abuse of animals. The laws on breeding and experimenting were further implemented in 1998 to promote this goal, and they have since been changed to maintain the provisions current with changing times and to address loopholes. The committee can carry out its functions according to its protocol. Grants from the government would occasionally be used to fund the Committee. Anyone can send a gift, donation, contribution, bequest, or other similar contribution to the Committee's funds. Certain ethical criteria have been listed in the rules on the regulation of scientific research on animals issued by the Ministry of Environment and Forests in June 2007 and are expected to be followed by the CPCSEA 12-13. These principles are:

1st Principle: The purpose at the back of sporting out the experiments

The experiments are carried for

- To progress the field of physiology through discovery
- To acquire knowledge that will be useful for enhancing, preserving, or extending human life
- To significantly contribute to assuring the welfare of the people and
- To discover a treatment for a disease. The sickness may affect humans, animals, or plants.

2nd Principle: Evade animal investigation if an alternate exists

Animal experiments should only be conducted on the least sentient animals—those incapable of feeling emotions other than pain. There needs to be sufficient justification provided for why utilising animals for experiments was chosen in cases when there was an alternative but the experiment was nonetheless carried out.

3rd Principle: Appropriate sedation and anaesthesia

The objective of inflicting the animal with the least

Amount of discomfort possible during an experiment must be prioritized. When choosing whether to cause suffering to an animal, it must be considered equally to humans. Researchers must take a humane approach; if an experiment's discomfort would endure longer than a brief period of time, the animal must be given anesthesia or the proper level of sedation. Animals should always be handled with the utmost kindness and compassion.

4thPrinciple: Euthanasia, when allowed?

Animal welfare and post-experiment protocols must be provided for the animal once the experiment is completed on it. The animal's recovery and posttreatment are the responsibility of the investigator. Only in the following circumstances can the researcher decide to administer euthanasia:

- When the animal is concentrated physically or psychologically unable of functioning, inept of perceiving its environment, or when it loses its sentience
- When the animal is experiencing excruciatingly long pangs of pain as a result of an experimental procedure
- When human lives are put in danger as a result of failing to kill animals that have undergone an experiment.

Rule 9(cc) of the Breeding of and Experimentation on Animals (Control and Supervision) Rules, 1998 incorporates this idea.

5thPrinciple: Suitable living conditions

Animals should live in habitats that are appropriate for their species. The animals must be handled by a qualified scientist or veterinarian for biomedical objectives.

Activities of CPCSEA

- The CPCSEA should register any facilities that use or breed animals for experiments.
- The selection of candidates for the registered institutions' Institutional Animal Ethics Committee.
- On the basis of findings from CPCSEA inspections, approving animal facilities that the report deemed suitable for harbouring animals.
- approving approval for animal experimentation.
- Endorsing the importation of animals for use in research.

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 CPCSEA has the power to take any action in the event that establishments violate the rules.

Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (Enforced IN 1982)

The guidelines embody the principles and make registration with CPCSEA a necessity among other necessities. The important guidelines were discussed below:

The animals can also be used in the following ways:

- To create reagents (a substance or mixture used in other reactions).
- To produce antibodies or antigens.
- To conduct diagnostic and testing procedures.
- To establish transgenic stock.
- To save and improve lives.
- To significantly improve the nation's population's well-being and
- To find a cure for a disease associated with h. Pylori.

Any endeavour undertaken to accomplish one of the aforementioned goals would be considered a "experiment."

10thRule: Procurement of Animals

It states that:

- In the event that "registered" breeders are not available.
- Alternative legal sources must be sought to obtain animals for experiments.
- It was necessary to obtain formal authorization from the relevant authority before purchasing anything from lawful sources. Priority should be given to a replacement approach if it allows for the avoidance of using animals. In circumstances where an animal is used for an experiment despite the availability of a substitute method, the choice to proceed with the use of the animal must be strongly justified.

14thRule: Holdup of Registration of an Establishment by CPCSEA

According to the Rules, the CPCSEA may suspend or revoke an establishment's registration when:

 If the Member Secretary's or authorised officer's report demonstrates that the establishment or a

- breeder is not abiding by the rules and that the Committee's instructions to correct the violation have not been followed, the Committee may decide to suspend or revoke the establishment's registration.
- It is important to give the establishment or the breeder a voice.
- There should be no revocation or suspension for a minor infraction. A minor infraction is one that doesn't directly affect an animal's health or that doesn't cause the animal to feel agony, develop another health condition, or pass away.

Institutional Animal Ethics Committee (IAEC)

According to Rule 13 of the Breeding of and Experiments on Animals (Control and Supervision) Rules 1998, this committee was established. The committee is made up of a group of persons whose primary responsibility is to keep an eye on how the establishment runs an experiment. The case is sent to CPCSEA for large animal experimentation. The committee has been established for three years. The registration is intended to be recreated when it is renewed. Six people make up the quorum.

IAEC should include a socially conscious member in addition to scientists from other fields, as well as a nomination from CPCSEA. During meetings, a CPCSEA nominee is required to be present. Meetings are led by the Chairperson, with an alternate chairperson sometimes selected in special circumstances.

The minutes of the meeting must be prepared by the committee member secretary, and a copy must be forwarded to the member secretary of CPCSEA within 15 days in order for the meeting to be considered valid.15.

A Few Legal Rights and Provisions to Protect Animals

Article 51A(g), Rules 135B and 148C 1945, Section 11(1)(h) of the PCA Act, Section 9 of the Wild Life (Protection) Act, 1972, all of these regulations and laws were put into place years ago, but they weren't applied with serious repercussions until recently, which was also following the 1999 PETA scandal. It is regrettable that India still conducts business with nations and funds corporations where such egregious abuses persist despite the existence of such regulations. Even though there have been fewer instances of these infractions since 2015,

The system still lacks transparency because a research indicated that 90% of the animals were left out of the records kept by labs for assembling data on the animal subjects because they were brought into the labs illegally.15

Conclusion

The usage of animals in laboratory studies isn't a right but a privilege granted through society to a few participants of the clinical community. Analysing contemporary criminal structures, just like the ones mentioned above, clearly indicates that worldwide laboratory animal legal guidelines, guidelines, and rules will remain essential social troubles. The adoption of the 3Rs into diverse regulatory outlines, as mentioned in this article, demonstrates a global commitment to advancing splendid technological know-how and animal welfare via the moral use of animals in studies and affirms the fundamental idea that society will retain to responsibly alter using animals in laboratory technological know-how as a controlled possibility via its regulations.

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