

ISSN: 2582-6433



INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed 6th Edition

VOLUME 2 ISSUE 7

www.ijlra.com

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LEGAL ASPECTS OF ANIMAL TESTING UNDER CLINICAL TRIALS

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LLM II, Semester III.

(2022-2023)

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Abstract:

Clinical trials are a series of procedures necessary to guarantee that a medicinal product is both safe and effective for the populace. Drugs must initially be tested on animals for this reason to confirm that they are safe for human use. But by causing physical pain, psychological discomfort, and suffering to a huge number of sentient beings, this was cruel to animals and violated their rights. So new laws were passed to protect animals and enhance their welfare during research. In this article, we will examine the historical context of animal research in clinical trials, current legal protections for animals, and whether new rules have had any impact.

Keywords: Clinical Trials, Animal testing, Animal protection rights and laws.

Introduction:

Clinical trials are research studies that are carried out on individuals (healthy volunteers or patients with a particular health concern) or animals to explore and evaluate novel medical treatments, such as medications, vaccines, medical devices (like spinal cord stimulators), medical procedures (like surgeries), and diagnostic tests. Clinical trials may also be carried out to compare treatments, investigate novel therapy combinations, or investigate an already available medicine for a novel use.¹ The term "animal testing" refers to procedures carried out on living animals for research into basic

¹ Introduction to Clinical Trials – What are they? What Happens? Who is Involved?

<https://genesisresearchservices.com/introduction-to-clinical-trials-what-are-they-what-happens-who-is-involved/>, last seen on 02/12/2022.

biology and diseases, evaluating the efficacy of new pharmaceuticals, and testing the safety of consumer and industry products for human health and/or the environment. The operations frequently lead to a lot of pain. Most animals are killed at the conclusion of an experiment, although some might be used again.²

However, doing so put the rights of animals in jeopardy. For the benefit of humanity, they had to suffer intense pain and psychological trauma. Prior to Independence, there were few regulations pertaining to animal safety and little knowledge. Later, as public awareness grew, laws were passed that favored animals to safeguard their rights and spare them from suffering. These rules and regulations have now been put into effect. As in the present situation, prior authorization from the law is required to begin the procedure to test and experiment on animals.

Objectives:

1. To study animal testing and its types in clinical trial
2. To study the historical context of clinical trials.
3. To study the animal protection laws and rights.
4. To assess whether the situation of animals in trials has improved as a result of the new regulations.

Animal testing under clinical trials:

The pharmacological and clinical profile of a novel drug in humans, including its pharmacodynamic and pharmacokinetic effects, are studied methodically in clinical trials. It precedes animal trials in which the effectiveness and side effects of the medicine are demonstrated in animals and an estimated drug dose is established. This is the only way to determine a medication's efficacy and safety before it is sold for use by humans.³

Some treatments and goods may be developed by researchers through non-animal research projects. Animal testing is permitted to determine whether the experimental therapy appears to be safe only if

² About Animal testing, Humane Society International, <https://www.hsi.org/news-media/about/>.

³ Pikee Saxena and Rohit Saxena, Clinical trials: Changing Regulations in India, National Library of Medicine, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4215498/>, last seen on 02/12/2022.

it appears to be a promising treatment.⁴

It is crucial to understand why animal testing began in the first place.

A permanent mascara known as Lash Lure caused the blindness of more than a dozen people and the death of one other in 1933. P-phenylenediamine, an unproven substance, was in Lash Lure. There were no rules in place to guarantee product safety at the time. The p-phenylenediamine rendered some Lash Lure users completely blind and produced horrifying boils, abscesses, and ulcers on their faces, eyelids, and eyes. In one instance, the ulcers were so bad that a woman died from a bacterial infection.⁵ It has always been common practice to conduct scientific research using animals as models. Animals were initially used in scientific experiments around 500 B.C. in ancient Greece. Vivisection of animals were common during that time to learn more about the workings of living things.⁶

Following are some examples of tests conducted on animals:

- **The Draize Test**

A substance's toxicity can be evaluated using the Draize test. The substance to be evaluated is applied to the skin or eye of a restrained animal.

- **Acute toxicity**

Animals are made to undergo repeated chemical exposure for up to three months while testing for acute toxicity. This can be done to examine how the chemical affects various organs, including the heart, lungs, liver, and neurological system.

- **Skin corrosion and irritation**

In tests, rabbits are used to determine how corrosive or irritative compounds are.

⁴ S. Bhambri & Associates, <https://www.sbhambriadvocates.com/post/a-critical-study-on-clinical-trials-and-rights-of-animals>, last seen 02/12/2022.

⁵ Safety Testing, Science, Medicine, and Animals, National Academic Press, Washington, DC, <https://nap.nationalacademies.org/read/10733/chapter/10>.

⁶By Beonchip, Animal-free testig, History of animal experimentation and animal rights, Jun 8, 2021, <https://beonchip.com/animal-rights-history>, last seen on 03/12/2022.

- **Skin sensitization**

To determine whether a substance has the potential to trigger an allergic reaction, skin sensitization studies are conducted. 5 The substance may be injected beneath the skin or used topically.

- **Toxicokinetic**

These tests are performed to find out how quickly harmful compounds pass through the body. As the body breaks down some compounds, their toxicity increases. Force feeding, inhaling, or injecting an animal with a chemical dose are three possible methods.

- **Carcinogenicity**

Carcinogens are substances that either promote the growth of cancerous cells or raise the risk of it happening. These experiments employ drugs that cause test animals' tumors to grow.

- **Reproductive & developmental toxicity**

These experiments, which frequently include rats, mice, and rabbits, are intended to look at how a substance impacts an animal's reproductive system and capacity for reproduction.⁷

Current animal protection laws and committees against clinical trials (CPCSEA):

Today's scenario is vastly superior than that during the time of British Indian control. It has been accepted that employing animals in research is vital because India has not yet created an artificial human simulator as a substitute; However, the Committee for the Purpose of Control and Supervision of Experiments on Animals has established specific guidelines (CPCSEA).

1. Prevention of Cruelty to Animals Act, 1960

The Prevention of Cruelty Act, 1960 was created with the intention of severely punishing individuals who harm animals. Additionally, it created an animal welfare board and specified the actions that meet the criteria.⁸

⁷ Experimentation of cosmetics and household products, Animals Ethics, <https://www.animal-ethics.org/experimentation-cosmetics-household-products/>, last seen on 03/12/2022.

⁸ Draft Prevention of Cruelty to Animal (Amendment) Bill-2022, 24 Nov 2022, <https://www.drishtias.com/daily-updates/daily-news-analysis/draft-prevention-of-cruelty-to-animal-amendment-bill>

Now a new amendment draft is prepared to amend the Prevention of Cruelty to Animals Act, 1960.

In order to alter the six-decade-old Prevention of Cruelty to Animal Act, 1960, the government has created a draught bill titled Prevention of Cruelty to Animal (Amendment) Bill-2022. The Ministry of Fisheries, Animal Husbandry, and Dairy has drafted the draught.⁹

2. The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) formed in 1964:

As a statutory committee, CPCSEA is obligated to take any and all steps required to prevent undue pain or suffering for animals before, during, or after performing research on them. In order to control animal experiments, the Committee created the "Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998" (amended in 2001 & 2006).

3. PETA:

Since its founding in 1980, 'People for the Ethical Treatment of Animals (PETA)' has worked to uphold and protect the rights of all animals. PETA educates the public about animal mistreatment and promotes for the humane treatment of animals. Regardless of whether they are helpful to humans, PETA believes that animals have rights and should have their best interests considered. They have the same capacity for pain as you do, and they want to live their own lives.¹⁰

4. No cosmetics shall be tested on animals:

The Ministry of Health & Family Welfare has now published the cosmetic testing ban, which adds the new rule "148-C. prohibition of testing of cosmetics on animals - No person shall use any animal for testing of cosmetics" to the existing Drugs and Cosmetics Rules, 1945. This follows the removal of animal tests from the cosmetics testing standards by the PCD 19 Cosmetics Sectional Committee of the Bureau of Indian Standards (BIS) last year.

2022#:~:text=Recently%2C%20the%20Government%20has%20introduced,Fisheries%2C%20Animal%20Husbandry%20and%20Dairying. last seen on 03/12/2022.

⁹ Draft for amendment to Prevention of Cruelty to Animal Act ready, public comments sought: 3-year jail for gruesome cruelty, 5 for killing, Updated on November 24, 2022, The Free Press Journal, <https://www.freepressjournal.in/india/draft-for-amendment-to-prevention-of-cruelty-to-animal-act-ready-public-comments-sought-3-year-jail-for-gruesome-cruelty-5-for-killing> , last seen on 03/12/2022.

¹⁰Animals are not ours, Peta, <https://www.peta.org/about-peta/learn-about-peta/>, last seen on 03/12/2022.

The Drugs and Cosmetics Rules, 1945 have recently been amended, and the Ministry of Health & Family Welfare recently released a cosmetic testing ban that, if approved, will prohibit the import of cosmetics from any country that have undergone animal testing. The revised regulation, if it is adopted, may read "135-B. Import of cosmetics barred from animal testing. - No cosmetic tested on animals shall be imported."¹¹

5. Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (as amended in 2001 and 2006)

These regulations, which were first published on November 15, 1998, and were later updated in 2001 and 2006, place a strong emphasis on registering businesses before conducting experimentation and breeding, inspecting animal house facilities, maintaining informational registers there, providing home for animals there, obtaining authorization from the IAECs and CPCSEA to perform experiments, and setting up breeding facilities under the right conditions.

6. Institutional Animal Ethics Committee (IAEC)

The Standard Operating Procedures for Institutional Animal Ethics Committees were published by the CPCSEA in January 2010 and are known as SOP for IAECs. The Institutional Animal Ethics Committee (IAEC) of the establishments is permitted to approve experiments on small animals under the Rules for Breeding of Animals and Experiments on Animals (Control & Supervision).¹²

The situation of animals in trials has improved as a result of the new regulations.

Over the last decade, there have also been significant landmarks in the legal protection of animals. Based on these achievements, it is obvious that, while the animal rights movement still has a long way to go, it is far past its infancy and well into adolescence. However, in order for the movement to truly fulfil its objectives, systematic institution development and the passage of tougher protection laws are required.

While these rules may seem extensive there is a major issue with implementation. And the reasons for this range from public apathy to a vested or commercial interest in exploiting animals. Despite

¹¹ Cosmetics Testing Ban on Animals Now Permanent, May 24,2014, Peta, <https://www.petaindia.com/blog/cosmetics-testing-banned-on-animals/>.

¹² Regarding CPCSEA Guidelines, Chapter on Animal Welfare, <https://www.pci.nic.in/pdf/15.pdf>.

rules being passed in 2001 for each district to have an SPCA, hardly any states have them. The state of Maharashtra, for instance, only began issuing notices to set up SPCAs in 2018—seven years after the mandate was issued. Similarly, rules regulating shops that sell animals for pets and breeders have not been implemented in any state completely. Even if one is able to push for better implementation, there is still the issue of penalties, which are often not commensurate with the offense.¹³

Some of the most horrific animal experiments in history:

1. Charles River employees force animals to breathe harmful gases

Millions of animals, including mice, rats, gerbils, rabbits, and monkeys, are bred and sold by Charles River Laboratories to research facilities all over the world. Additionally, it performs animal testing for businesses that make medications, insecticides, food additives, and industrial chemicals. In addition to being forced to breathe harmful chemicals, employees also smear experimental chemicals onto animals' shaved skin. Before they eventually die or are murdered, they experience excruciating abdominal pain, diarrhea, convulsions, seizures, paralysis, and bleeding from the nose, mouth, and genitalia.

2. For experiments involving Huggies baby products, researchers covered mice in faeces and urine.

Huggies baby product manufacturer Kimberly-Clark paid researchers at the University of Iowa to cover mouse skin with human baby urine and excrement. For up to 48 hours, the feces were attached to the animals. After the mice were killed, their skin was removed for analysis to examine diaper dermatitis.

3. Coca-Cola forced-fed chemicals to rodents while slicing the faces of chimps.

The Coca-Cola business forced-fed rodents chemicals to test "caramel color" and performed "taste experiments" in which chimpanzees had their faces sliced open. In 2007, the company stopped using animals in its testing.

¹³Ambika Hiranandani, Animal rights: Legislation is not enough, September 3, 2019, idr, <https://idronline.org/animal-rights-legislation-is-not-enough/>.

4. Puppy blindness experiments and acid drips through injured eyes

Six beagle puppies from the University of Missouri were divided into two groups after having their left eye blinded. To investigate if topical hyaluronic acid had any therapeutic effects, researchers dripped it into the injured eyes of the puppies in one group. The six beagles were murdered once the experiment was over since none of them were able to regain their vision.¹⁴

Case Laws:

1. Kennel Club of India (KCI) v. Union of India (2013)¹⁵

The petitioner informed the Indian Veterinary Council that the Animal Welfare Association Board of India had informed them that puppies of breeds of dogs such as Doberman, Cocker Spaniel, Great Dane, Boxer, etc. were all subjected to avoidable and unneeded cosmetic procedures. As a result, they performed procedures like docking tails. According to Section 11 of the 1960 Prevention of Cruelty to Animals Act, the owners' sole discretion does not apply when a dog's ears are cropped or its tail is docked; rather, the court made this ruling.¹⁶

2. Animal Welfare Board of India v. Nagaraja and Others (2014)¹⁷

According to Article 21, everyone has the right to life and personal liberty, neither of which may be taken away from them without a court order. The Supreme Court explicitly ruled in favour of animals in the 2014 case of Animal Welfare Board of India v. Nagaraja and Others.¹⁸

3. Ozair Hussain vs. Union of India, (2001)¹⁹

In this case, the Petitioner filed a writ petition asking the respondents to protect the rights of those who are strongly opposed to the use of animals and animal products by requiring manufacturers to print a list of the contents that go into manufacturing a product on their packaging, as 60% of Indians

¹⁴ History of Animal Testing in new PETA Exhibit, 'Without Consent', PETA, <https://withoutconsent.peta.org/>, last seen on 03/12/2022.

¹⁵ <https://indiankanoon.org/doc/159107874/>.

¹⁶ Kakoli8 Nath, Landmark Cases and Laws, Finology Blog, <https://blog.finology.in/Legal-news/animal-rights-india>, last seen on 03/12/2022.

¹⁷ <https://indiankanoon.org/doc/39696860/>

¹⁸ Jis John Sebastian, Protection of Animals: Important Laws in India, last updated on September 24, 2022, ClearIAS, <https://www.clearias.com/protection-of-animals/>.

¹⁹ <https://indiankanoon.org/doc/295123/>.

are vegetarians. As a result, the Delhi High Court's decision in this case enabled citizens to make educated decisions about the things they buy or consume.

Suggestions:

1. Proper Facilities under which trials are conducted should be developed to provide better facilities for animals.
2. Everyone should feel the responsibility towards wellbeing of animals.
3. Which laws are created should be implemented properly in practical way.
4. Law makers should work on loopholes through which illegal animal testing is still carried out.

Conclusion:

Sadly, despite the existence of laws protecting animals' rights and interests, authorities continue to abuse and mistreat the animals used as test subjects. This is done by taking advantage of severe flaws in the legal system. Despite India's ban on animal testing for cosmetics and soaps, import regulations for cruelty-free goods are not strictly enforced in that country. And animals are still harmed for the sake of experimentations.

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