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## Ethical dilemmas faced by veterinarians in translational research and clinical practice

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### Abstract

Veterinary research stands at a crossroads where innovation meets responsibility, demanding that every step forward honors the life it touches. Veterinarians are duly qualified to minimize animal suffering through the application of scientific knowledge and to safeguard animal welfare. Yet, when contributing to healthcare through research, veterinarians must conduct studies in compliance with ethical frameworks that govern research planning and implementation. While discoveries from *in vivo* research have advanced medicine, they often come at the cost of animal lives. These lives, though not directly benefited, deserve humane treatment, reminding us that every creature is entitled to dignity in life and in death. Implementing the 3Rs principles of reduction, refinement and replacement, alongside the growing importance of translational research in companion animal oncology, provides a pathway to balance innovation with ethics. Furthermore, addressing ethical challenges in preclinical trials and clinical practice requires veterinarians to align practice with regulatory education, welfare and consent.

**Keywords:** Clinical practice, Companion animals, Ethics, In vivo trials, Veterinarian, 3Rs principle.

## Introduction:

The primary role of a veterinarian is to safeguard the health of animals for the well-being of humans. For centuries, numerous pieces of evidence including the smallpox vaccine (Riedel, 2005), antibiotic effects of penicillin (Gaynes, 2017) from in vivo animal testing have made significant contributions towards the scientific advancement in the field of health care. Hence, the fact that every mankind is benefited from a greater to a lesser extent from such animal findings cannot be denied. Despite its numerous advantages, there is always a group of individuals or organisations protesting either to limit or stop such in vivo research. So, understanding the concept of ethics is needed to assess the ethical concerns of in vivo research.

Ethics deals with moral duty considered either as morally right or wrong. It can also be viewed as one's personal beliefs, whether an action is right or wrong, good or bad (Fischer, 2004). Hence, all animal experiments in preclinical trials require the knowledge and skills of a qualified veterinarian who is legally authorised to assess the health of research animals in accordance with ethical

principles (Kiraga & Dzikowski, 2023). This article addresses the ethical challenges veterinarians face in balancing innovation with welfare, focusing on the 3R principle, translational research, clinical practice, informed consent, persistent dilemmas of preclinical and clinical trials.

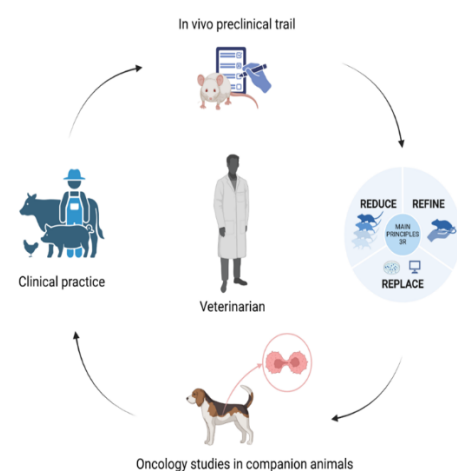
## The 3Rs principle (Refinement, Reduction, Replacement):

Every animal experiment planning undergoes the implementation of the 3Rs principle (Russell & Burch, 1959). The 3Rs principle includes “reduction”, “replacement” and “refinement” while the concept of “rehabilitation” is included in the 4Rs principle. “Reduction” involves the minimal usage of animals that can produce appropriate statistical strength as per the regulatory requirements for the approval of the test compound. “Replacement” implements the use of alternatives to animals such as in vitro studies, in silico computer modelling, epidemiological, microbiological and clinical studies that can train machine learning deep network algorithms. “Refinement” is generally concerned with minimizing animal suffering during experimentation by

administering anesthesia, analgesia, inhalation instead of injection (minimize pain due to needle injection), humane animal restraint that prevents repetition of experiment that might occur due to wound licking, restricting use of painful inflammatory substances such as Complete Freund's Adjuvant in immunological studies, alternatives to Draize tests such as Corrositex, EpiOcular tests (Ibrahim, 2006).

Instead of leaving suffering animals alive, it is morally correct to kill the animals under proper anaesthesia after the end of the experiment. But it is still controversial when certain research experiments that cannot avoid pain raise many ethical concerns. Besides providing insights into mechanisms, efficacy and safety, drug testing in animals faces significant constraints. It should be clearly justified for the harm caused to animals against the benefit of better innovations. But the high failure rate of anticancer therapies due to their poor clinical effectiveness, rather than the drug safety issues, questions the present in vivo efficacy studies (Regan et al., 2018). The use of standardized laboratory conditions, inbred strains and artificial disease

models limits translational relevance. Moreover, such models cannot replicate the long-term dynamics of human tumor growth, the features of minimal residual disease or the complex heterogeneity of the macro and microenvironment characteristic of spontaneously arising human cancers (Paoloni & Khanna, 2008).



### Role of veterinarian in clinical research and practice (Created in Biorender)

Though it is ethically concerning to use animals from the lower order species for animal research, some experiments necessitate the use of primates as they are the evolutionarily closest to humans. This is because the use of rodent models in many diseases with idiopathic pathogenesis and ineffective treatments, leads to poor clinical translation. Despite the ethical dilemma, such conditions mandate the use of sentient animals, the primates

to arrive at effective prevention and treatment of diseases (Kiraga & Dzikowski, 2023).

### Importance of translational research:

The concept of use of naturally occurring animal diseases as human disease models was first proposed by Nobel laureate August Krogh in 1929. He stated that “for a large number of problems there will be some animal of choice on which it can be most conveniently studied” (Krogh, 1929). Natural disease models overlap with human diseases in terms of the underlying pathophysiology, exposed environment and therapeutic responses. The American Veterinary Medical Association (AVMA) maintains an Animal Health Studies Database [website](https://ebusiness.avma.org/aahsd/study_search.aspx) [https://ebusiness.avma.org/aahsd/study\\_search.aspx](https://ebusiness.avma.org/aahsd/study_search.aspx) listing details of companion animal clinical trials about diseases of translational importance including mesenchymal stem cell therapy for cats with chronic kidney disease and dogs with osteoarthritis, to immunotherapy for equine skin tumors and gene therapy for canine degenerative myelopathy.

Pets as natural disease models make veterinary research a valuable contributor to human health outcomes (Quigley et al., 2024). In canine models, tumorigenesis occurs within a biologically relevant chronology under an intact immune system, enabling progressive emergence of immune escape mechanisms, therapeutic resistance and metastatic progression (Regan et al., 2018). Oncology trials are more frequently conducted in animals because veterinary drug approval can proceed on the strength of animal data alone, whereas human drug approval requires independent human clinical data and cannot rely solely on veterinary findings (Füüdös et al., 2015). Further, the shorter lifespan of dogs in comparison to humans enables faster efficacy data. Generally, the effectiveness of oncology therapies requires accurate identification of tumor biology and the patient cohorts most responsive for therapeutic benefit. Thus, a collaborative initiative for an Oncology-Pathology Working Group can enhance communication between oncologists and pathologists to ensure excellence in pathology reporting within veterinary oncology (Regan et al., 2018).

### **Ethical challenges in translational research:**

Best-practice guidelines for veterinary oncology trials support rigorous evidence generation, while attention to patient welfare and owner advocacy ensure ethical integrity and trust in the research team (Page et al., 2016). Thus, effective strategies for veterinary clinical trial recruitment should adopt a holistic perspective, encompassing protocol development and coordination, inclusive recruitment, incentive structures, workforce allocation, promotional efforts and participant continuity. While human clinical trial evidence and frameworks provide valuable benchmarks, it is equally important to evaluate current veterinary methodologies and identify opportunities for refinement within this discipline (Quigley et al., 2024). Regulatory frameworks do not allow authorities to assess whether consumer product tests are unnecessary or ethically imbalanced against animal welfare.

In practice, this means that toxicity testing continues even when it imposes considerable suffering on animals yet produces only superficial human benefits, such as “new and

improved” household cleaners (Ibrahim, 2006). Ethics committee submissions are also bound only by laboratory animal regulations, yet these do not fully apply to companion animals. Housing standards, for instance, cannot be standardized for pet dogs and essential elements such as predefined quality standards for owner consent forms are not addressed (Füüdös et al., 2015). Stem cell research, cloning technology and xenotransplantation viewed as an alternative to animal experimentation actually involves countless animals in experiments throughout its development.

### **Ethical challenges in clinical practice:**

Early efforts to teach ethics in veterinary practice were centered on “professional etiquette” (Rollin, 2013), rather than addressing deeper ethical dilemmas such as those involved in euthanasia decisions. A key ethical challenge in veterinary practice is the divergence between safeguarding animal welfare and client expectations. Ethical dilemmas in veterinary practice are often settled in favour of the client rather than the animal. This is accomplished through legislation that treats animals as

property, denying them comparable legal and moral recognition to humans. If such standing were equal, practices like using animals for food or fibre would be hard to defend. Thus, even in production-based industries, veterinarians often struggle to align ethical duties to animals with the expectations of the corporation. Hence, veterinarians emphasize the importance of ethical oversight in companion animal practice where the interests of animals, owners, practitioners and sponsors may conflict (Clutton et al., 2017). Veterinarians in clinical practice also face greater difficulty with ethics oversight than laboratory animal specialists, particularly when procedures fall outside the framework of randomized controlled trials (Quain et al., 2021).

To avoid blame or paternalism, some veterinarians present treatment options without guidance, a “vending machine medicine” approach (Hartnack et al., 2016) that prioritizes client autonomy but neglects responsibility for the animal’s welfare. Though clients make the final decision, they often depend on veterinarians for counsel during difficult choices. However, poor food

animal transportation decisions, veterinarian’s contribution to ongoing animal negligence, economic decisions impacting animal welfare, failure of the client to follow up on timely veterinary care, owner’s nonacceptance of their animal’s poor quality of life and owner’s denial of end-of-life realities are some of the reasons animal welfare needs often go unmet (Hernandez et al., 2018).

### **Veterinary consent in clinical trials:**

Although clinical trials are an old concept, the FDA did not mandate them until the thalidomide crisis of 1962 revealed the dangers of unregulated prescribing, thereby prompting the FDA to strengthen trial requirements (Junod, 2008). In September 2023, FDA also issued draft guidance on informed client consent in companion animal clinical trials. By reshaping veterinary informed consent through defined procedures, timelines and formats, this guidance imposes compliance responsibilities yet simultaneously enhances owner engagement and clinical trial enrolment (Frederick, 2024). Veterinarians sometimes extend their work beyond the laboratory, studying rare conditions in donated pets or monitoring

vaccination trials in dogs and cats. Such nontraditional uses of companion animals in research have driven the establishment of regulations to guarantee that these animals' benefit from clinical veterinary innovations and practices (Hampshire, 2003). Unlike medical informed consent, which protects the patient's rights, veterinary consent primarily secures the owner's property rights. As a result, a veterinarian acting without consent is liable for property damage, whereas a physician would face charges of assault (Flemming & Scott, 2004).

**Conclusion:** Navigating the ethical dilemmas at the intersection of translational

research and clinical practice is thus essential for the continued advancement of both human and

clinical medicine. Translational research, particularly through comparative oncology in companion animals, provides a vital bridge for accelerating drug development that benefits multiple species including humans. However, this progress must be guided by a strong commitment to the 3Rs principles, ensuring that the experimental techniques remain as humane as possible. Furthermore, the ethical integrity of clinical trials depends on strong informed consent, protecting animal and owner interests while maintaining public trust in research process. Ultimately, veterinarians must balance science and advanced care, keeping medical innovation rooted in patient welfare.

#### References:

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