

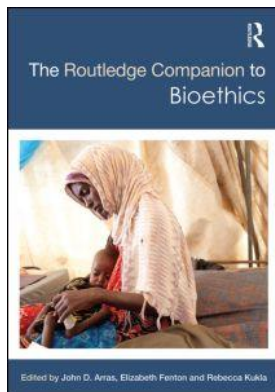
This article was downloaded by: 10.2.97.136

On: 30 Sep 2023

Access details: *subscription number*

Publisher: *Routledge*

Informa Ltd Registered in England and Wales Registered Number: 1072954 Registered office: 5 Howick Place, London SW1P 1WG, UK



## **The Routledge Companion to Bioethics**

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### **The Ethics Of Biomedical Research Involving Animals**

Publication details

<https://test.routledgehandbooks.com/doi/10.4324/9780203804971.ch20>

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**Published online on: 12 Dec 2014**

**How to cite :-** Tom L. Beauchamp. 12 Dec 2014, *The Ethics Of Biomedical Research Involving Animals from: The Routledge Companion to Bioethics* Routledge

Accessed on: 30 Sep 2023

<https://test.routledgehandbooks.com/doi/10.4324/9780203804971.ch20>

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# THE ETHICS OF BIOMEDICAL RESEARCH INVOLVING ANIMALS

*Tom L. Beauchamp*

Approximately 50–100 million vertebrate animals<sup>1</sup> are used, worldwide, in biomedical and behavioral experiments each year (House of Lords 2002; Taylor et al. 2008). The research occurs in universities, hospitals, laboratories, government facilities, and corporations. Animals are used to study disease and injury and to assess the risks posed by drugs, chemicals, pesticides, cosmetics, and the like. Some of the research produces useful generalizable knowledge for the treatment of human disease, injury, and discomfort, but much of it fails to yield medical applications and presents moral problems about scientific uses of animals.

Claims of human preeminence and just dominion over animals have been at work for centuries (Sorabji 1993). In the first book of the Bible, God is reported to have given humans such dominion (*Genesis* 1: 26; Regan 1986). Guided by such views, animals have often been treated as without moral or legal *status*, but many writers in ethics, scientists involved in animal research, and members of the public find themselves unsatisfied by these views about our uses of animals. When it comes to scientific research, many people are perplexed and undecided.

In some cases, though, people are not perplexed. We all tend to be angry in the face of abuses of companion animals in biomedical research. In 1965 an article appeared in *Sports Illustrated* about a dog stolen from a Pennsylvania home, later to die in a laboratory in a New York hospital (Phinizy 1965), and in 1966 a story in *Life* magazine (Silva and Wayman 1966) showed some seriously mistreated and dead dogs at a breeding facility for research animals. The ensuing public outcry from these stories galvanized the American public against such uses of “pets” in biomedical research, which eventuated in the 1966 *Laboratory Animal Welfare Act*. However, this legislation itself would show how confused and scattered our thoughts and actions have been, and no doubt remain, on problems of animal research. For at least 20 years after passage of the 1966 law, the U.S. Congress did virtually nothing to protect animals in research laboratories. The law functioned only to protect companion animals from being rounded up for or sold to research laboratories. It failed to affect how the animals were used once they were in the laboratories.

Our sympathies extend deeply to companion animals, but when we read almost identical reports about research animals who have never been companion animals, especially

if they are of a despised species such as rats, these creatures are commonly framed as merely “animals.” Companion animals are typically accorded more moral significance than are research animals, but can that view be morally justified? In the end, do we have a set of coherent views about research animals, or do most of us live in an incoherent world in which some animals are admired and adored friends; others are merely pests; and some just dumb beasts—but all of which may be research subjects?

I start this chapter with a short sketch of the history of human thought about animals and then turn to a recent case that has had an extraordinary impact on public policy in the United States and has reversed that country’s public policy in one area.

## Two Histories of Conceptions of Animals and Their Welfare

There are several largely independent histories of *animal research ethics*, a recently coined term. Various strands of history have focused on animal minds and animal welfare, and two such strands will be discussed here: (1) Moral and psychological theories, and (2) government codes, guidelines, and regulations.

### *The History of Moral and Psychological Theories*

Many writers have been interested in questions about animal minds and animal ethics since ancient times. Cultural and philosophical diversity was extensive in the ancient world, and there was no one canonical view. The two most influential, which is not to say justified, perspectives on the use of animals descending from the ancient world to the modern were that (1) plants are for animals and animals are for use by humans, and (2) animals have minds driven by motives, but lack the rational souls possessed by humans (Sorabji 1993). These theories have had remarkable persistence.

Early modern philosophy saw some impressive work on the nature of animals, produced by, among others, René Descartes, Pierre Bayle, Francis Hutcheson, David Hume, and Immanuel Kant. They disagreed among themselves about the nature of non-human animal minds and about the moral importance of our treatment of animals, but here, for the first time, we find major philosophers thinking at a deep level about animal minds and, to a lesser extent, animal ethics.

Jeremy Bentham would become the most influential of these early modern philosophers on subsequent animal ethics literature. Bentham focused on the capacity of animals to experience pleasure, pain, and suffering—a capacity itself sufficient, he thought, to make animals morally important beings—just as these capacities make humans morally considerable. Bentham asked, “Is there any reason why we should be suffered to torment them [e.g., research animals]? Not any that I can see. Are there any why we should *not* be suffered to torment them? Yes, several.” This reasoning underlies Bentham’s famous rhetorical questions, “The question is not, Can they [nonhuman animals] *reason*? nor, Can they *talk*? but, Can they *suffer*?” (Bentham 1996: ch. 17, sec. 1).

Finally, Charles Darwin’s theory of evolution and philosophical reflections on animal minds and their moral significance have been more influential in intellectual history than any figure before or since. In *The Descent of Man*, Darwin catalogued many similarities in mental ability between humans and apes, observing that “it is a significant fact, that the more the habits of any particular animal are studied by a naturalist, the more he ascribes to *reason* and the less to *unlearned instincts*” (Darwin 1989: 107–10). He

saw ample empirical evidence that many animals have powers of deliberation and decision making, excellent memories, fertile imaginations, and even moral emotions.

Darwin looked for similarities across multiple species. He pointed out that numerous levels of mental activity are shared by many species close to humans, from basic pain receptors to intentionality. He argued that the moral, physical, and mental qualities of humans evolved through processes similar to those that occur elsewhere in nature. The faculties of reason and speech are comparable in their evolutionary origin to snake fangs, shark fins, and eagles' feet. Moreover,

The difference in mind between man and the higher animals, great as it is, certainly is one of degree and not of kind . . . If it could be proved that certain high mental powers, such as the formation of general concepts, self-consciousness, etc. were absolutely peculiar to man, which seems extremely doubtful, it is not improbable that these qualities are merely the incidental results of other highly advanced intellectual faculties . . . The half-art, half-instinct of language still bears the stamp of its gradual evolution.

(Darwin 1989: 107–10)

Darwin's theory of evolution challenged the traditional idea that human beings have capacities that give them natural dominance over to the rest of the animal world. He thought we are but one species of rational creature.

### *The History of Government Codes, Guidelines, and Regulations*

Dozens of editions of guidelines and principles of animal care and use for research animal facilities have been issued by governments in the last century or so. As this chapter was being written, the National Health and Medical Research Council of the Australian Government released its eighth edition of its code for the use of animals for scientific purposes, which presents an "ethical framework" whose principles obligate all researchers and teachers in Australia who use animals for scientific purposes (National Health and Medical Research Council 2013).

The history of concentrated attempts at animal welfare protections in the United States can be dated to the previously mentioned 1966 *Animal Welfare Act* legislation. However, the history in some other countries, notably the U.K. among western nations, is much older than either the U.S. or Australia. The British *Animal Welfare Act 2006* is an Act of the Parliament of the U.K. that dates back to the *Protection of Animals Act 1911*, which it largely replaced. Even earlier, the *Cruelty to Animals Act* of 1876 was passed by Parliament, creating a licensing system for animal experimentation that amended the *Cruelty to Animals Act* of 1849. The U.K.'s history is one of the few truly rich histories of animal research laws and guidelines, and since 1951 significant laws and regulations have continued to be passed in the U.K. almost every decade.

In the U.S. it was not until 1985, when the U.S. Congress enacted the *Improved Standards for Laboratory Animals Act* (Public Law 99-198 1985), that a major stride was taken toward government-supported animal research guidelines. This Act came in response to scandals in the use of primates at esteemed research laboratories, one at the University of Pennsylvania and the other at the Institute of Behavioral Research in Maryland. In effect these laboratories had no rules of ethics in place and no knowledge of moral requirements of animal care. Physical treatment of animals was brutal, and

behavioral pathologies such as self-injurious behavior were caused during the course of the research.

The 1985 law and subsequent regulations had a profound effect. Suddenly, formal committee review of animal research was a requirement. These review committees had to include non-scientist members, which exposed the work, to a limited extent, to public awareness. Investigators now had to explain, and sometimes defend—as never before—their pain-producing procedures and to reduce the number of animals involved, if possible. Most disturbing to some investigators were new requirements of providing “for a physical environment adequate to promote the psychological well-being of primates” (United States Code (USC), Title 7 § 2143, 2.a.B). This requirement to protect “psychological well-being” was immediately contested by research institutions as too onerous. Struggles over proper criteria of ethologically appropriate conditions and psychological wellbeing have continued from that time to the present (see the section below on “Moral Requirements of Psychological Wellbeing”).

In the century-old history of government struggles with animal research guidelines, a key fact is that the responsibilities of research investigators put into effect by governments are matters of both legal and professional *obligations to animals*; they are not merely optional, charitable ideals. However, it would be wide of the mark to regard government guidelines and regulations as merely matters of history. To get a sense of how underdeveloped some of our moral frameworks remain still today, I turn to an uncommon and influential case of government policy that developed between 2011 and 2013.

### A Landmark Case in Chimpanzee Research

This case originates in efforts by the U.S. National Institutes of Health (NIH) in 2010 to move 176 NIH-owned chimpanzees from semi-retirement as research subjects at the Alamogordo Primate Facility in New Mexico to a larger, private research facility that engages in invasive research. A public protest erupted over NIH's plan, which was criticized by many animal welfare advocates and by New Mexico Governor Bill Richardson as well as Jeff Bingaman and Tom Udall, the two U.S. Senators from New Mexico. Protesters were concerned about the welfare of chimpanzees in research, and issues were also raised about the risks associated with shipping chimpanzees because some had died in the course of previous transfers (Gray 2011). Virtually all interested parties raised questions about the need for chimpanzees in research, now and in the future. Because most (over 600 of the approximately 950) chimpanzees in U.S. research were owned or financially supported by NIH, its policies had the effect of determining how chimpanzees could be used in about 65 percent of the research population in the U.S.

The two New Mexico senators wrote a letter to NIH Director Francis Collins calling for critical scrutiny by the U.S. National Academy of Sciences of the necessity of chimpanzee research. The NIH then commissioned an Institute of Medicine (IOM) study of the problem (National Institutes of Health Statement on the Alamogordo Primate Facility Chimpanzees 2011). An IOM Committee was formed immediately, almost entirely composed of research scientists. It ultimately released its report in December 2011 (Committee on the Use of Chimpanzees in Biomedical and Behavioral Research 2011: 2).

This striking report surprised almost everyone. The Committee had been expected to endorse NIH's traditionally uncompromising claims of the necessity of animal research, but instead it recommended what are, from an historical perspective, quite demanding guidelines for federally funded research with animal subjects. The

Committee proposed three conditions that must be met for biomedical research on chimpanzees to be justified:

1. The knowledge gained must be necessary to advance the public's health.
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects.
3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments or in natural habitats.

(Committee on the Use of Chimpanzees in Biomedical and Behavioral Research 2011: 4)

These *principles*, as the Committee designates them, form a framework in the report for ethically permissible use of chimpanzees in research.

These conclusions came as a surprise to most observers because *ethics* had never been an intended target of the investigation by either NIH or IOM. For weeks IOM resisted the idea that the Committee could even discuss the ethics of animal research. Such discussion had never occurred in a policy context at NIH (though conferences on ethics had been held there). However, this committee had a mind of its own and stated firmly that ethics is a significant consideration:

The committee . . . recognizes that any assessment of necessity for using chimpanzees as an animal model in research raises ethical issues, and any analysis must take these ethical issues into account . . . For the committee, this ethical context is reflected in its assessment of when, if ever, the use of chimpanzees in biomedical research is necessary.

(Committee on the Use of Chimpanzees in Biomedical and Behavioral Research 2011: 4)

The IOM had not taken the term “scientific necessity,” in “scientific necessity for using chimpanzees,” as a moral notion. The IOM thought the issue was only whether it is, in any given research situation, scientifically necessary to use chimpanzees to achieve desired research results. However, the Committee that IOM had appointed did not see the situation as free of moral considerations. It determined that the term “necessity” (as in “scientific necessity of using chimpanzees”) should be analyzed as a necessary condition of *morally justified* use of chimpanzees in research; that is, scientific necessity was analyzed as a *morally necessary*—but *not a morally sufficient*—condition of justified scientific research involving chimpanzees. Put another way, it must be scientifically necessary to use this species to achieve valid scientific results, but this fact does not render the research morally justified because other conditions besides scientific necessity must be met (see the three principles above). What IOM and NIH had viewed as exclusively a scientific question thus became both a scientific and a moral question.

The Committee also recommended that research animals should be allowed to “acquiesce” to participation in research. Here the Committee is expressing its confidence that chimpanzees can act voluntarily to accept or to reject research procedures. The Committee did not conclude that chimpanzees can give an autonomous informed *consent*—an absurdly high-level task. It is revolutionary enough that the Committee judges that chimpanzees have cognitive capacities of voluntary agreement and refusal, not merely submission, fear, and the like. This conclusion acknowledges decision-making capacity, voluntariness, and moral status; it appears to exceed criteria of animal minds and ethics that the NIH had ever contemplated.



Finally, the Committee recommended that chimpanzees be maintained in “ethologically appropriate environments.” This recommendation constitutes a demanding requirement in many research settings, requiring in effect that chimpanzees be housed under conditions fundamentally similar to the conditions under which the species is known to flourish—ideally their natural environments.

Unlike virtually all previous federal-level reports regarding the protection of research subjects, this report was immediately accepted as federal policy. The Director of NIH, Francis Collins, stated that “I have . . . decided to accept the IOM Committee recommendations. NIH is in the process of developing a complete plan for implementation of the IOM’s guiding principles and criteria.” Collins stated that chimpanzees, as our closest relatives, deserve “special consideration and respect” (National Institutes of Health, Office of the Director 2011). NIH had never previously taken a position even approximating this one, and had never before for ethical reasons phased out invasive research on any species, including dogs and cats. These facts alone make this report a landmark that turned NIH policy in a decidedly different direction. But this policy applies only to chimpanzees, not to other species.

In January 2013, a year after the committee submitted its report, an NIH Working Group appointed by Director Collins presented an independent evaluation of the IOM Committee’s recommendations (Council of Councils (NIH) 2013). This report heavily supported the original IOM committee’s recommendations, principles, and criteria. The Working Group determined that the need (or necessity) for chimpanzee subjects is effectively non-existent for contemporary research on human diseases. It recommended that NIH maintain a population of 50 animals in case an emergency need for chimpanzees should arise, but it also recommended a ban on breeding, which entails that the population would be gradually decreased to zero. As chimpanzees die off, even a small-sized research population will not be available. A later NIH statement endorsed the conclusions of the Working Group (National Institutes of Health 2013).

### Animal Minds

The IOM Committee’s conclusion that chimpanzees have cognitive capacities of voluntary decision-making, and Darwin’s theory of evolution and animal minds, raise ethical and public policy issues as well as questions about the nature of animal minds, including the psychological complexity, cognitive gifts, and social lives of animals.

Close observers of animal behavior today agree that many animals have capacities to understand and have elaborate forms of social interaction and communication. Chimpanzees, for example, have a rich psychology of beliefs, intentional actions, cognitive understandings, structured social organization—and apparently self-awareness as well. Intelligence and adaptation in animal behavior, as explored by ethologists and psychologists, are often inexplicable without acknowledging that animals exhibit understanding, intention, thought, imaginativeness, and forms of communication. These animals therefore have at least some mental properties similar to those of humans.

However, scientists still understand much less about the inner lives of animals than they hope to learn. For example, we have difficulty understanding how to analyze *intention* and *choice* in animals. The behavioral and life sciences together with the philosophy of mind may shed only limited light on animal mental states, but the light increases every year as we learn more about how animals do what they do.

## Moral Status

Many writers in animal ethics in the last 35 years have viewed the *moral status* of animals as the major philosophical moral problem of animal ethics. However, it is generally agreed today that many species of animals have some form of moral status. The critical questions are now about what *level* of status they have.

Over the course of human history, vulnerable groups of humans have been refused a significant social status in many countries. Slaves, women, minority groups, and others have been declared to lack some property relevant to their political, legal, or moral status and so have been declared to not qualify for full moral status; but these social norms have also been reconceived in many societies, even though the relevant properties of people in these groups had not changed at all. In this way, slaves, women, and minority groups came to have a full, or at least fuller, moral status in many cultures (Lindsay 2005).

Research animals may be poised for an analogous reconsideration of status, though most species still fail to satisfy reigning criteria of legal status, and confusion persists about their moral status. Traditionally the dominant perspective in animal research laboratories was that protections for research animals are not necessary because they do not have *interests* that carry moral significance, but this thesis is clearly mistaken. Animals certainly have interests. The term “interest” refers to that which is in an animal’s interest—that is, what is to the animal’s welfare advantage in a given circumstance. Research animals have welfare interests in liberty of action, not suffering physical and psychological harms, a social life, good health, and familiar and clean environments and housing. These interests are the basis of their moral status and of the obligations researchers have to treat animals appropriately, as expressed in the codes and regulations previously discussed.

The cutting edge issues about moral status today are about the level of moral status, the protections that must be provided at that level, and how many interests of animals must be protected. For example, one issue is whether primates must be given a natural habitat free of cages as a basic condition of research involvement. Even among persons who feel strongly that chimpanzees, monkeys, dogs, and even rats deserve moral protections in biomedical research, many regard the interests of these animals as far less significant than the interests of humans. These moral issues will occupy us for the remainder of this essay.

## Moral Requirements of Psychological Wellbeing

I start with how animals experience psychological suffering and distress in research, including the semi-hidden suffering that results from maternal separation, captivity, cage confinement and other restraints, social isolation, handling and transportation, and sleep deprivation. Following the *Animal Welfare Act’s* standards for a physical environment sufficient to promote the “psychological well-being of primates” (Committee on Well-Being of Nonhuman Primates 1998), the U.S. Department of Agriculture regulations require use of indices of psychological well-being for primates (U.S. Department of Agriculture 1999). A similar view is endorsed by the American Psychological Association (APA) in its “Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research” (American Psychological Association 2013).

However, as the APA forthrightly acknowledges in these guidelines, the Association does not attempt to define “psychological well-being” or to provide “specific guidelines



for the maintenance of psychological well-being of research animals.” It does not even analyze the meaning of “well-being.” The reason, it says, is that “procedures that are appropriate for a particular species may not be for others.” This default position is disappointing, though fairly typical of literature and guidelines on this subject. A persistent vagueness and absence of adequately specified guidelines has created a lack of understanding of what is ethically required, especially when it comes to the assessment of particular research protocols and housing standards.

Although criteria have been upgraded in recent years—as illustrated by the IOM chimpanzee case—most countries still lack an adequate body of protections of the psychological wellbeing of research animals. In only a few countries are there legal requirements that compel investigators to categorize the invasiveness of their proposed work as to pain, suffering, social deprivation, confinement, and overall social wellbeing.

### The Justification of Human Uses of Animals

The single most difficult and the most intractable moral problem about biomedical research with animals is its *justification*. This problem is also the most important, the least carefully investigated, and the most ignored moral issue. When asked to justify their practices with, and beliefs about, the use of animal subjects, investigators have typically not provided a justification. Instead, they note that many examples of successful research show that animals are essential to achieving human health benefits and that many contributions have been made to biological and medical knowledge, even when no direct human medical welfare benefit occurred (cf. Council for the International Organizations of Medical Sciences 2012).

Many of the vaccines, medicines, and other products on the market have been tested on animals and approved by governments on the basis of this testing. However, little investigation has been devoted to the question “How much new knowledge stands to be gained, and does the value of this new knowledge *justify* the harms caused to the animals involved?” It is more assumed than demonstrated or argued that the potential knowledge is sufficient to justify the research. This response begs the critical questions and evades problems confronting an adequate answer to the question.

It becomes increasingly difficult to justify using animals in research as the likelihood of human benefits decreases, as risks of harm increase for animals, and as alternatives to the use of animals become available. Many justificatory appeals are made every week in animal research centers to investigators’ conformity to professional ethics and government regulations as a source of justification, but these rules are virtually never themselves the subject of careful ethical scrutiny for adequacy. The IOM Chimpanzee report was a rare case of an exacting, analytical examination of the need to revise traditional rules, regulations, and assumptions. Members of this Committee accepted the fact that there is a possibility that animal research might be necessary and justified under some conditions in order to find a prophylactic vaccine for hepatitis C, but the Committee did not think that this possibility was sufficiently strong to recommend continuing to use chimpanzees (Committee on the Use of Chimpanzees in Biomedical and Behavioral Research 2011: 67). This example is particularly striking because committee members were divided on the scientific promise of the research, but even those who thought chimpanzee use might be justified in the future did not support or recommend new research at the present time.

Every scientific protocol requires a carefully reasoned justification, but there also are troubling problems about how to justify claims regarding what is necessary to medical progress. Despite the many medical success stories in the past, these successes may not be a good predictor of whether continued animal use in any given area of research still shows promise of creating human health benefits. It is widely believed that great discoveries about neurological disorders, heart and blood diseases, pulmonary diseases, infectious diseases, and cancer can now be made if and only if investigators are able to use animals. This claim could be correct; but the promise has to be demonstrated, as must the need for animal research rather than alternative research that does not use animals. When the IOM chimpanzee committee looked closely at claims about past examples of advances made in conquering disease by using research chimpanzees, it found that human subjects could have been ethically used as subjects in many cases and that alternative research models are often available. It appeared that better scientific data could often have been collected if chimpanzees were *not used*. Past examples had been a poor basis on which to justify new protocols with chimpanzees.

The likelihood of human benefits in the future is often either low or uncertain in animal research. Data suggest that the probabilities of a good medical product such as a drug that is approved and marketed resulting from studies *using humans* (starting with phase 1 studies) are somewhere around 8 percent (Wendler 2014). Former Health and Human Services Secretary Mike Leavitt reported that “Currently, nine out of ten experimental drugs fail in clinical studies because we cannot accurately predict how they will behave in people based on laboratory and animal studies” (Food and Drug Administration 2006). Because testing in humans occurs *after* promising animal research has been conducted, the probabilities of successful human medical applications in animal testing prior to use of humans is certainly decreased (even in primate studies), and will be below 1 percent in the use of some species and some forms of research.

There is virtually no way to know whether findings from animal research are applicable to humans until testing has occurred in humans. Interventions that are successful with animals are unsuccessful in many human trials because of high toxicity levels or inefficacy. It seems a prudent principle that the higher the probability of harm to both animals and humans and the lower the probability of health benefits, the more difficult it is to justify use of animals in research. However, practical implementation of such a principle is but a distant hope at the present time.

### Committee Review to Control Pain, Suffering, and Distress

The dominant model in most countries of a procedural process to justify, as well as to approve or disapprove, animal research protocols is to establish review committees to examine the protocols to see if they can be improved in various ways, including by reducing or refining animal use. These committees—called Institutional Animal Care and Use Committees (IACUCs) in the U.S. and by different names in other countries—are mandated oversight committees intended to be impartial in their assessments (Whitney 1987). Public Health Service policy in the U.S. requires them for ongoing review of animal care and use, facilities inspection, review and approval or disapproval of research protocols, and the like. Committee review also considers whether immobilization for the animals is necessary and whether tumor burden in cancer research can be reduced. Universities, government facilities, and many corporations in the pharmaceutical, chemical, and cosmetics industries have such committees.

However, the objectives of these committees have proved difficult to achieve in many institutions. Different empirical assumptions are often made about the degree to which animals feel pain or suffer in research; about how to measure pain, distress, discomfort, and suffering; about whether an anesthetic, analgesic, or tranquilizer is adequate for the intended effect; and about whether the animal conceives the experience as agony or torment. In the scientific literature, some assert that animals have different forms of pain reception and many cannot anticipate or remember pain, and therefore suffer less than humans. A contrasting view is that animals suffer more, not less, because they have less understanding of the origin, nature, and meaning of pain. An animal may be a captive of the momentary experience of pain and without the capacity to deal with danger, injury, and the like (Akhtar 2011; Dresser 1988, 1990; Graham 2002).

Review committees are generally given extensive data about proposed *scientific* investigations. The data show intricate planning, probing scientific hypotheses, and familiarity with the relevant literature. Rarely are the committees given comparable detail about *ethics* problems, arguments, and justification issues. Yet, for an adequate ethics review, the ethical problems and reasoning would have to be spelled out, just as the scientific problems and reasoning must be presented. The absence of searching moral examination by these committees has led to widespread suspicion about the quality and worth of the committees' deliberations and conclusions. Many members of these committees would say that framing the issues in this way holds researchers to an unrealistically high ethical standard, but these committees are *ethics* committees, not *scientific* committees, so ethical reasoning needs to be taken with great seriousness.

### **Should the Ethics of Research with Animals Follow the Example of the Ethics of Research with Humans?**

A perspective that may help handle some problems raised in the various sections above is to ask whether animal research ethics should be modeled on human research ethics. Their histories are very different, with markedly dissimilar assumptions about acceptable risk, proper facilities, permission giving, and the like. But why should animal research subjects be governed by rules so unlike those governing human research? An attempt at modeling animal research ethics on human research ethics has never, to my knowledge, been attempted in any country, but as an ideal it makes a great deal of sense. If the two pillars of research ethics (human and non-human) are (1) protection from harm and (2) ethical oversight by committee review, then the human model, which is far more protective of subjects, would seem a good starting model for animal research.

As things now stand, animal subjects have significantly more pain and suffering visited on them than do human research subjects, and pain can also be substantially increased in level with animal subjects far beyond a point that we would allow with human subjects. But human interests and animal interests are relevantly similar in that their welfare is contingent on not being constrained and coerced, not being deprived of basic needs, not experiencing pain and terror, etc. Why, then, are animal interests not treated with similar respect and concern to human interests?

Federal regulations in the U.S. have stringent rules governing use of human research subjects who do not have the ability to consent (for example, children), but no comparable regulations exist for animals. It would be possible to restructure regulations for animal research so that they closely follow regulations for human research with those unable to consent, especially regarding risk of harm. For animals, as for humans, a line

of unacceptable risk could be drawn at the point where biomedical research is expected to exceed a threshold or upper limit of pain, suffering, anxiety, fear, and distress. In research with human subjects, it is conventional to insist on thresholds of risk, pain, and discomfort. For such a threshold to be meaningful in research involving animals, careful guidelines would have to be prepared for investigators and review committees, including a grading of research procedures as to their noxious, aversive, and painful properties.

The argument against a firm threshold in our use of animals is that any criterion proposed will be too restrictive and will bring productive research on injury, disease, toxic agents, etc. to a halt. In the end, however, the main problem is less *whether* we should require a threshold in research with animals (it seems clear that we should) than *how and where* to draw the threshold line. The threshold may need to be drawn in different places for different species, but having no threshold at all seems more a case of moral blindness than a morally justified approach.

Finally, human research subjects who cannot give permission for involvement in research not designed to benefit them are heavily protected by mechanisms of informed consent given by parents, guardians, or family members. Requirements of surrogate consent are universally accepted in human research. Animal research could be similarly structured using guardian consent where impartial individuals are charged, as guardians, with protecting the interests of the animals.

### Conclusion

We know from excellent data that if human subjects could be substituted for animal subjects in biomedical research, results would be significantly improved. But the painful, invasive, and often lethal character of testing in animal research has long been assessed as presenting insurmountable moral problems for the use of human subjects. The burden of this essay has been to show that, despite scientific and moral advances in recent years, traditional systems that place enormous burdens on research animals are morally flawed and still in need of watchful reform.

### Related Topic

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Chapter 14, "Biomedical Research Ethics: Landmark Cases, Scandals, and Conceptual Shifts," Jonathan D. Moreno and Dominic Sisti

### Note

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- 1 In this chapter the term "animals" refers exclusively to non-human vertebrates, but no assumption is made that questions of research involving invertebrates do not deserve ethical analysis.

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