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EDITED BY STEPHEN G. POST

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Stephen G. Post Editor in Chief

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Front cover photos (from left to right): Custom Medical Stock; Photo Researchers; Photodisc; Photodisc; AP/Worldwide Photos. indication of continuing public uneasiness over the morality of animal experimentation (Welsh).

JAMES C. WHORTON (1995) Revised by Author

SEE ALSO: Cloning: Scientific Background; Harm; Hinduism, Bioethics in; Jainism, Bioethics in; Moral Status; Pain and Suffering; Veterinary Ethics; Xenotransplantation; and other Animal Research subentries

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II. PHILOSOPHICAL ISSUES

Ethical problems related to research on nonhuman animals are grounded in the assertion that animals have conscious experiences and that their lives can go well or badly. Central to this issue is the belief that nonhuman animals can experience pain and other unpleasant or distressing mental states. The seventeenth-century philosopher René Descartes denied this (Regan and Singer), and one or two contemporary philosophers continue to deny it (Carruthers). On the whole, however, popular opinion and the overwhelming majority of contemporary scientists and philosophers agree that animals, especially vertebrate animals, can suffer (Smith and Boyd; DeGrazia, 1996, 2002). To take a contrary view, one must refute not just the experience of everyday owners of animal companions but also the increasing body of empirical evidence, both physiological and behavioral, suggesting close parallels between animal behavior and human behavior (Dawkins, 1980, 1993; Rollin; Griffin). Moreover, these behavioral parallels are supported by the known similarities among the nervous systems of all vertebrate animals

and by the fact of common animal and human evolutionary origin (Rachels).

It is difficult to believe that despite all these similarities the nervous systems of human and nonhuman animals operate in radically different ways. Many codes regulating animal experimentation instruct regulating committees to assume that procedures that would cause pain in humans also will cause pain in vertebrate animals unless there is evidence to the contrary. From this point, therefore, the existence of animal suffering will be taken for granted.

Before considering the ethical questions that arise from the existence of animal suffering, however, it is necessary to provide some further information.

Nature and Extent of Animal Experimentation

Some governments provide detailed information on the number of animal experiments carried out each year. In the United Kingdom, for instance, the annual report on scientific procedures performed on living animals under the Animals (Scientific Procedures) Act 1986 for the year 2000 showed that 2.71 million animals were used in that year, a significant decrease from the 1980s, when the figure topped 5 million, although the decline appears to have leveled out. An estimated 12 million animals are used in the fifteen member nations of the European Union, which includes the United Kingdom. An incomplete Japanese survey published in 1988 reported a total in excess of 8 million. There are no accurate figures for the United States because the official figures compiled by the U.S. Department of Agriculture do not include rats, mice, and birds, the species used most commonly in research. In 1986 the U.S. Congress, Office of Technology Assessment, estimated that "at least 17 million to 22 million" animals are used in research annually (U.S. Congress, Office of Technology Assessment). Many think that this figure is very conservative, and several unofficial estimates indicate a higher figure. In addition to rats and mice, dogs, cats, primates, guinea pigs, and rabbits are used widely (Singer, 1990 [1975]; Orlans).

Opponents of animal experiments have focused on examples such as those discussed below (Singer, 1990 [1975]).

TOXICITY TESTING. From about 1950 until the late 1980s the standard method for assessing the toxicity of any product was the LD_{50} (lethal dose 50%) test. The object of this test is to find the dose level that will fatally poison 50 percent of a sample of animals. Often more than one species of animal is

used. In the process of stepping up the dose until half the experimental animals die, all of them are likely to become ill, experiencing symptoms such as nausea, thirst, diarrhea, stomach cramps, and fever. The LD_{50} test was carried out routinely on most household products, including food colorings, household cleaners, shampoos, and cosmetics.

After campaigns against the test by the animal rights movement, most U.S. government agencies began to discourage the use of the classical LD₅₀ test, and the Center for Laboratory Animal Welfare estimates that its use has fallen by as much as 90 percent (Center for Laboratory Animal Welfare). In 2000 the Organization for Economic Cooperation and Development announced that it was planning to delete the LD₅₀ test from its testing guidelines in favor of three alternative methods. Nevertheless, the LD₅₀ test still is used in some circumstances, and even if only 10 percent as many animals are subjected to it, that still amounts to hundreds of thousands of animals every year. The replacement for that test, the limit test, still uses animals but does not require doses sufficient to kill them. Instead, other signs of toxicity are used. In addition to undergoing toxicity testing, many products, especially cosmetics and shampoos, used to be placed in the eyes of conscious, unanesthetized rabbits in what is known as the Draize eye test, which was designed to assess the likelihood that a product would cause eye damage. In the late 1980s, after a decade of campaigning against that test, some leading cosmetic companies developed an alternative to the Draize test and stopped conducting tests on animals.

MILITARY TESTING. It is often difficult to find out exactly what happens to animals who undergo military experimentation, but in the United States, in experiments carried out in 1984, monkeys were trained with electric shock to run for hours on a treadmill and then were exposed to lethal doses of radiation to see how long the sick and dying animals could keep running (when they stopped, they received more electric shocks). At Brooks Air Force Base, in Texas, research that involves observation of the effect of radiation on the behavior of monkeys is, according to the most recent information available, still being funded. So too is research in which monkeys are trained to "fly" a device called a "primate equilibrium platform" which simulates some of the tasks that a pilot has to perform when flying a plane. They are then exposed to radiation, to see how this affects their ability to perform. This research was first carried out in the 1960s by Donald Barnes, a psychologist who later came to consider it cruel and pointless (Barnes). Nevertheless, the U.S. Department of Defense continues to fund the training of monkeys to operate the primate equilibrium platform before being exposed to "degradation in the functioning of the central nervous system."

PSYCHOLOGY EXPERIMENTS. In a psychology experiment performed at the University of Pennsylvania in 1968 dogs were placed in cages with wire floors that could be electrified. Subjected to repeated, inescapable electric shock, the dogs at first jumped, ran, attacked the cage, howled, defecated, and urinated, but the shocks continued until the dogs stopped attempting to escape. The experiment was designed to demonstrate the existence of a state known as "learned helplessness" in the belief that such research might throw light on some forms of depression in human beings. From 1984 to 1986 researchers at Temple University used rats in similar experiments with inescapable electric shock; at the same time researchers at the University of Tennessee at Martin were trying to apply inescapable electric shock to goldfish. Learned helplessness experiments on animals are continuing at various centers in the United States, including the University of Colorado at Boulder, where research of this kind has been carried out since 1993 (National Institutes of Health). Experiments in maternal deprivation in monkeys and other animals have been going on in American universities since the 1960s and are continuing. In research at the University of California, Davis, published in 2000, researchers carried out experiments over a five-year period to discover whether there are differences in the problem-solving abilities of monkeys reared with inanimate "surrogate mothers," as compared with the problem-solving abilities of monkeys reared by dogs (Capitanio and Mason).

STUDENT USE OF ANIMALS. Although it has been estimated that more than 5 million animals are used for dissection annually in the United States alone, there has been a move away from the use of living animals for practice surgery in medical schools. Only a minority of U.S. and Canadian medical schools still require the use of live animals, and in almost all those schools students may choose not to participate. In 2000 the Tufts University School of Veterinary Medicine became the first veterinary school in the United States to eliminate the use of healthy dogs for surgical training (Tufts). A number of valuable alternatives to the use of live animals in education have been developed (Smith and Boyd).

Guidelines and Codes

Many countries have national, legally enforceable guidelines, for the protection of animals in research. Among the more advanced are those developed by the Australian National

Health and Medical Research Council and the Swedish regulations. Both require experiments to be approved by ethics committees. In Australia the ethics committee must include a lay member and, in addition, a person from an animal welfare organization (National Health and Medical Research Council). In Sweden the ethics committees consist of six scientists and six lay members and are chaired by a judge (European Science Foundation). Both the European Union and the Council of Europe have their own codes, dating from the mid-1980s. From the same period comes the most frequently cited international code, the International Guiding Principles for Biomedical Research Involving Animals developed by the Council for International Organizations of Medical Sciences (CIOMS). The CIOMS code is, however, much weaker than the relatively more advanced codes in specific countries, such as the European nations and Australia. Instead of mandatory review by committees that include lay members, for example, the CIOMS code allows "voluntary self-regulation by the biomedical community."

In Defense of Current Animal Experimentation

Defenders of animal experimentation emphasize the use of animals in medical experimentation, particularly in areas such as diabetes and hypertension research, where the use of animals is claimed to have led to important medical breakthroughs (Paton; U.S. Congress, Office of Technology Assessment). They assert that statistics on the large numbers of animals used can be misleading because a great deal of animal experimentation is of a relatively harmless nature, for example, running a rat through a maze with a reward of food as encouragement for good performance rather than an electric shock as punishment for poor performance. They argue that animal experimentation is the only way to advance basic knowledge of human anatomy and physiology and that it offers the best hope of finding cures for diseases such as cancer and AIDS. They also may point out that a considerable amount of animal experimentation is carried out in schools of veterinary medicine to find ways to treat diseases that affect animals. The majority of this work is concerned with farm animals, but some is directed toward companion animals and wild animals.

If experiments now being carried out inflict substantial suffering on animals, how can this practice be defended? The usual justification offered is that the suffering of animals is outweighed by the benefits to humans of discoveries that can be made only through the use of animals. Sometimes, however, it is said that the goal of increasing scientific knowledge is an overriding one and thus provides sufficient justification for whatever suffering might be inflicted on animals in the process of advancing toward that goal. Because this goal is not said to justify inflicting substantial suffering on nonconsenting human experimental subjects, however, further justification is needed to account for the alleged difference in moral status of human beings and other animals.

Behind such arguments lie a variety of philosophical positions. For instance, it may be said that, as related in Genesis 1:26, God has given human beings "dominion" over the other animals, to use them as we please. Combined with other theological notions, such as the idea that humans, alone of all animals, have immortal souls, this idea has been influential throughout the Christian world. But it can be turned the other way: As long ago as 1713 Alexander Pope argued against cruel experiments on the grounds that dominion requires us to play the role of the good shepherd, caring for our flock (Turner). More recently a number of Christians have suggested that the gift of dominion should be interpreted as one of "stewardship," which makes us responsible for the care of the nonhuman creation (Attfield; Linzey). It remains unclear, however, precisely what follows from this reinterpretation. In particular, does it imply that humans are not entitled to use animals in harmful experiments or only that there must be a strong reason for doing so?

It also has been said by writers as diverse as Thomas Aquinas and Immanuel Kant that animals are not "ends in themselves" or that they have no rights (Regan and Singer). In support of this idea it is alleged that the status of a being who is an "end in itself" or has rights belongs only to a being who is rational, is capable of autonomous action, or is a moral agent. This position attempts to equate the universe of moral agents-those to whom moral judgments or prescriptions can sensibly be addressed-with the universe of moral patients-those about whom it matters, morally, what people do. One possible justification for this equation would be a social contract model of ethics: We have a moral obligation to respect the rights or interests only of those who can reciprocate respect for their rights or interests (Gauthier; Carruthers). This position, however, does not provide any grounds for distinguishing between nonhuman animals, on the one hand, and infants and the profoundly intellectually disabled, on the other. It may be true that many people care more about members of their own species and hence wish to give infants and the intellectually disabled "courtesy status" as members of the moral community. But what if they do not? A social contract theory of morality, then, offers no footing for insisting on equal consideration for the interests of those human beings.

A second justification claims that all human beings form a moral community not because of an implicit contract but because of people's natural feelings for members of the human species. Those natural feelings, it is argued, resemble the natural affection of parents for their own children, which people take as a basis for the special moral obligation they think parents have to give preference to the interests of their own children over the greater interests of the children of strangers. The natural ties between members of a species should, the argument continues, serve as the basis for holding that humans have a greater obligation to other humans than they do to members of other species (Midgley; Gray, 1991a, 1991b).

If this argument were valid, it is not clear how much experimentation on animals it would justify because people do not think that parents are justified in causing serious harm to the children of strangers in order to benefit their own children. But is this argument valid? Understandably, those who use these arguments are silent about the obvious case that lies between the family and the species: preference for the interests of the members of one's own ethnic group or race over the greater interests of members of other ethnic groups or races. It would seem that if the argument works for both the narrower circle of the family and the wider sphere of the species, it also should work for the middle case. If we reject the extension from families to ethnic groups, the further extension to the whole of the human species looks very dubious (Singer, 1991).

A utilitarian defense of the current practice might be based on the idea that the benefits produced outweigh the harm done to the animals (Paton; U.S. Congress, Office of Technology Assessment). Prominent among the claimed benefits is a considerable extension of the human life span. The first question raised by this defense is how much animal experimentation has helped extend human longevity. In polemical debates dramatic claims often are made, but the consensus among those who have studied trends in human health from a historical point of view is that almost all of the increase in human longevity that has occurred over the last century has been due to improved sanitation, diet, and living conditions rather than to medical research of any kind, whether on animals or not (McKeown; McKinlay et al.).

It is possible to accept this verdict but to maintain that medical research, including research on animals, has benefited humans. For example, defenders of the value of animal research often point to the development of coronary artery bypass graft surgery as an achievement that was facilitated by research on animals. The contribution of this form of surgery to the prolongation of life is not clear, but the surgery is more effective than conventional medication in relieving angina, a painful condition that results from coronary artery disease (U.S. Congress, Office of Technology Assessment). Thus, it may contribute to a better quality of life rather than to a greater quantity of life. Against this it might be claimed that the funds spent on this research as well as on the surgery itself would have been more effective if they had been directed toward reducing the cause of the disease by promoting healthier diets and lifestyles. It also has been argued that misleading animal models sometimes have slowed the development of a cure for major diseases, such as polio (LaFollette and Shanks).

A second point in considering a genuinely utilitarian defense of current practice in animal research is that the classical utilitarian tradition has steadfastly required people to take all suffering-that of humans and that of nonhuman animals-into consideration. The leading nineteenth-century utilitarians-Jeremy Bentham, John Stuart Mill, and Henry Sidgwick-were unwavering on this point (Bentham; Mill; Sidgwick). Modern utilitarians who cast their views in terms of the satisfaction of preferences rather than in terms of pleasure and pain are equally comprehensive in the scope of their theories (Singer, 1993 [1979]; Hare). This makes it more difficult to claim that a genuinely utilitarian approach favors animal experimentation in general or as an institution. Nevertheless, some individual experiments-those which do not involve any or very much suffering for the animals and promise major benefits for humans or animals-may be defensible on utilitarian grounds.

Some seek to justify what researchers do to animals by appealing to a human-centered version of utilitarianism. In the extreme version of this view the conscious experiences of beings who are not members of our own species do not matter at all. In the more moderate version those experiences do matter, but they do not matter as much as the similar experiences of members of our own species. Both positions frankly endorse an ethic that is limited to, or biased toward, our own species. Once such an ethic is accepted, of course, the justification for animal experimentation becomes much easier. The difficulty of this position lies in defending such a *speciesist* ethic (see below).

Finally, defenders of current practice often accuse their opponents of a lack of consistency in objecting to the deaths of animals in laboratories while continuing to participate in the practice of rearing and killing animals for food. The rise of the animal rights movement in the 1980s has made this accusation less effective because most of those actively involved in that movement have been vegetarians as well as opponents of animal experimentation. In any case, the issue of whether animal experimentation is justified cannot be resolved by reference to the character of some individuals who object to animal experimentation.

Objections to Current Animal Experimentation

Critics of the current practice of experimenting on animals tend to fall into two groups: abolitionists and reformers. Abolitionists usually rely on the principle that the end does not justify the means. To inflict pain and death on an innocent being is, they maintain, always wrong. They point out that people do not think that the possibility of advancing scientific knowledge justifies taking healthy human beings and inflicting painful deaths on them; similarly, they say, the infliction of suffering on animals cannot be justified by reference to future benefits either for humans or for other animals (Ryder; Regan).

A weakness of the abolitionist position is that when the end is sufficiently important, most people think that otherwise unacceptable means are justifiable if there is no other way of achieving the end. People do not approve of telling lies, but most people accept the idea that politicians should tell lies to mislead the enemy when their country is fighting a war that they believe is right. Similarly, if the prospects of finding a cure for cancer depended on a single experiment, most people probably would think that the experiment should be carried out.

In response to objections along these lines, some abolitionists argue that although a single experiment, taken in isolation, may appear justifiable, the benefits of such experiments do not outweigh the suffering inflicted by the institution of animal experimentation as a whole. One also must take into account, these abolitionists would say, two other factors: First, a large (if uncertain) proportion of experiments are worthless; second, even if no pain or distress is caused by the experiments, experimental animals typically have been raised in conditions that constitute severe deprivation for beings of their species. The common laboratory rat, for instance, is a highly intelligent animal with a strong urge to explore new surroundings. Rats also like to get into small, dark spaces, yet in most laboratories they are kept in bare plastic buckets with a bit of sawdust at the bottom. Such treatment indicates the lack of consideration for the interests of animals that prevails in the world of animal experimentation, and abolitionists doubt that this will ever change as long as people continue to regard laboratory animals primarily as tools for research.

Reformers believe that a changed practice of experimenting on animals could be defensible. They demand that any benefits that are believed to be likely to arise from the experimentation should be sufficiently probable and sufficiently great to offset the costs to the animal subjects; they urge that every experiment should come under close and impartial scrutiny to determine whether this is the case.

Reformers point out that although during the 1980s and 1990s several countries (for example, Australia, Sweden, Switzerland, and the United Kingdom) developed legally obligatory systems of review based on an institutional ethics committee's review of proposals to carry out experiments on animals, experimenters usually are well represented on such committees, whereas animal welfare advocates either are not represented or are heavily outnumbered by experimenters. An impartial committee that weighed the cost to the animal in the same way that people would weigh a comparable cost to a human would, the reformers maintain, approve at most a small fraction of the experiments now performed. In other countries, such as the United States, institutional ethics committees exist but are not legally required for corporations or other institutions that do not receive federal funds, and their coverage of animal experimentation is incomplete. Moreover, in the United States these committees do not always have the authority to prevent experimenters from going ahead with painful experiments if the experimenters assert that alleviating the animals' pain would interfere with the purpose of the experiment (U.S. Congress, Office of Technology Assessment; Dresser; Smith and Boyd; Gavaghan; Orlans).

Among opponents of current practices of animal experimentation the line between reformers and abolitionists is not clear-cut because questions of long-term goals and short-term strategy intervene. A threefold division might be more appropriate: In the first category one could place those whose long-term goals do not extend beyond better regulation and control of animal experiments to eliminate the most painful and trivial experiments. In the next category would be those who have the long-term goal of abolishing all or virtually all animal experiments but who consider this an ideal rather than a realistic objective for the immediate future. This group therefore seeks reforms in the interim period, and its short-term goals do not differ significantly from those of members of the first category. The third category consists of those who aim at abolition and are not interested in advocating anything less.

Although members of these three categories disagree sharply among themselves, they all agree that the current situation is indefensible. They also agree on promoting the use of alternatives to animal experimentation. The use of such alternatives by cosmetic companies to replace the Draize eye test was mentioned above. Opponents of animal experimentation suggest that alternative methods would be developed more rapidly if they received more substantial government support (Ryder; Rowan; Balls).

The ethical stance of those in the first category, who seek only limited reforms, is often of a relatively conventional type: They can be thought of as following an "animal welfare" line rather than accepting an ethic of "animal rights" or "animal liberation." They accept the idea that animals may be used for human purposes but want safeguards to ensure that the purposes are serious ones and that no more suffering occurs than is necessary for the purpose to be realized. Those who take an animal rights or animal liberation stance want to narrow the ethical gulf that separates humans from other animals in regard to conventional morality. They thus raise a philosophically deep question with implications that go beyond experimentation, extending to the treatment of animals in general.

The Moral Status of Animals

In examining the case for current practices, this entry examined some attempts to justify in ethical terms the sharp distinction that is made currently between the treatment of members of the human species and the treatment of members of other species. The problems noted in this entry bedevil all attempts to make the boundary of the human species coincide with the boundary of human moral obligations. Although it is said frequently that humans are superior to other animals in such respects as rationality, self-awareness, the ability to communicate with others, and a sense of justice, human infants and humans with severe intellectual disabilities fall below many nonhuman animals on any objective test of abilities that could mark humans as superior to other animals. Yet surely these less capable human beings are also "ends in themselves," and it would not be legitimate to experiment on them in the ways in which people experiment on animals. For a contrary view that accepts the moral possibility of harmful experimentation on both nonhuman animals and humans at a similar mental level, see Frey.

Ryder, Singer, Regan, and other critics of current practices claim that respect for the interests of those humans and comparative neglect of the interests of members of other species with equal or superior capacities constitutes *speciesism*, a prejudice in favor of "our own kind" that is analogous to and no more justifiable than racism. This argument has been seen by many people as the most difficult for defenders of animal experimentation to counter, so much so that a leading philosopher has referred to it as a "won argument" (McGinn).

Certainly the view that species is in itself a reason for giving more weight to the interests of one being than to the interests of another is more often assumed than explicitly defended. Some writers who have claimed to be defending speciesism have in fact been defending a very different position: that the morally relevant differences between species-such as differences in mental capacities-entitle people to give more weight to the interests of members of the species with the superior mental capacities (Cohen; Leahy). If this argument were successful, it would not justify speciesism because the claim would not be that species in itself is a reason for giving more weight to the interests of one being than to those of another. The real reason would be the difference in mental capacities, which happens to coincide with the difference in species. However, in view of the overlap in mental capacities between some members of the species Homo sapiens and some members of other species, it is difficult to see how this argument can be used to defend current practices. In other contexts people insist on treating beings as moral individuals rather than lumping them together as members of a group; it is precisely those who practice racism and sexism who treat all members of a group in the same way (for instance, assuming that women cannot perform heavy physical labor as well as men can) without recognizing individual variation.

Defenders of animal experimentation sometimes have portrayed the animal rights position in an extreme form, for example, as implying that it is as wrong to kill a mosquito as it is to kill a normal human adult. This is, however, a caricature. Animal advocates do not claim that all animals have the same interests, only that interests are not to be given less consideration solely on the grounds of species. Thus, it is compatible with the animal liberation view to say that the interests of beings with different mental capacities vary and that these variations are morally significant (DeGrazia, 1996, 2002). If people are forced to choose between saving the life of a being who understands the meaning of death and wants to go on living and saving the life of a being who is not capable of having desires for the future because that being's mental capacities do not enable it to grasp that it is a "self," a mental entity existing over time, it is entirely justifiable to choose in favor of the being who wants to go on living. This is a choice that is based on mental capacity and not on species membership, as one can see by considering that the former being may be a chimpanzee and the latter being a human with profound brain damage (Singer, 1990 [1975]).

At least one scientist who experiments on animals has attempted to sweep aside such issues by denying that animal experimentation raises a moral issue at all. Robert J. White, whose work has involved keeping severed monkeys' heads alive and apparently conscious for as long as possible, has written that "the inclusion of lower animals in our ethical system is philosophically meaningless" (p. 507). Unfortunately, White does not explain why, to take only one example, the clear proposal of utilitarian writers-that pain as such is evil regardless of the species of the being that suffers it—is devoid of meaning. It may be difficult to compare the suffering of a human and that of, say, a rabbit, but sometimes rough comparisons can be made. It seems undeniable that to put into the eye of a rabbit a chemical that causes the eye to blister or become ulcerated is to do more harm to the rabbit than people would do to any number of human beings by denying them the possibility of using a new type of shampoo that could be marketed only if the chemical was tested in this way. When such rough comparisons can be made, the mere fact that rabbits are "lower animals" is no reason to give less weight to their suffering.

Seen in this light, the argument that restricting experiments on animals interferes with scientific freedom and medical progress appears less conclusive. People do not grant scientists the freedom to experiment at will on humans, although such experiments would do more to advance knowledge of human physiology and be more likely to find cures for diseases such as AIDS than would animal experiments. It would seem, therefore, to be incumbent on the defenders of experiments on animals to show that there is a relevant difference between all humans and other animals that justifies experiments on the latter but not on the former. Success at this task, however, still eludes defenders of animal experimentation.

Conclusion

Controversy over experiments on animals often has been polarized, and, especially in the United States, public exchanges between those who carry out animal experiments and those who oppose them often generate more heat than light. There has been a more serious discussion of the status of animals in philosophical journals and in books by philosophers, and it can be hoped that this level of discussion eventually will influence popular debate on the use of animals in research.

> PETER SINGER (1995) Revised by Author

SEE ALSO: Animal Welfare and Rights: Ethical Perspectives on the Treatment and Status of Animals; Conscience, Rights of; Holocaust; Moral Status; Research Policy; Utilitarianism and Bioethics; Veterinary Ethics; Xenotransplantation; and other Animal Research subentries

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III. LAW AND POLICY

This entry describes the laws and policies of the United States governing the care and use of animals in research, education, and testing; the history of these policies and laws since 1966; the issues addressed by these laws; and the lawsuits that have followed publication of regulations implementing these laws. Two federal laws govern the use of animals: the Health Research Extension Act of 1985 and the Animal Welfare Act, as amended. While all states have laws governing the care of animals, research usage is often exempted. Twenty states have simple facility licensure, and a few have only very general regulations governing research usage of animals. In reality, nearly all states defer to federal law in this area. A National Institutes of Health (NIH) document, *Public Health Service Policy on Humane Care and*

Use of Laboratory Animals, which was revised in 2002, implements the Health Research Extension Act for all activities involving animals conducted or supported by the Public Health Service (PHS), while regulations implementing the Animal Welfare Act are in the *Code of Federal Regulations*, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3 (known as animal welfare regulations). The PHS includes twelve health agencies within the U.S. Department of Health and Human Services (DHHS).

History of Public Health Service Policy

Regulations have been promulgated by the PHS since 1935, originally through one of its constituents, the National Institutes of Health (Whitney). NIH guidelines have provided direction and recommendations for caring for and using laboratory animals at NIH. Subsequently, a committee of laboratory scientists assembled by the Institute of Laboratory Animal Resources of the National Research Council (NRC) wrote the Guide for the Care and Use of Laboratory Animals (NRC guide). First published in 1963 and updated many times since, this work has become the standard guide in the field. The first policy based upon the 1963 NRC guide came from NIH in 1971. The PHS published its first policy on animal care in 1973, with revisions in 1973, 1979, 1986, 1996, and 2002. Each successive revision increased the specificity and level of responsibility of animal-care committees in the supervision of animal use.

At the outset of NIH policymaking in animal care and use in 1971, all institutions and organizations using warmblooded animals for the purpose of research or other projects supported by NIH were required to give assurances that facilities for animals met "acceptable standards for the care, use, and treatment of such animals." This assurance could be met either by gaining accreditation through a professional laboratory-accrediting body (such as the Association for Assessment and Accreditation of Laboratory Animal Care International [AAALAC]) or by establishing a committee to evaluate the care and housing of animals used for NIHsponsored activities. Institutions were also obligated to follow pertinent sections of the animal welfare regulations. In 1973, the NIH policy was replaced by the first of the PHS policies. Like the NIH policy preceding it, the first PHS policy required institutions either to be fully accredited or to have a standing institutional committee with a minimum of three members, including a veterinarian for those institutions using a "significant" number of animals. These committees were required to conduct periodic facility inspections, with the review of applications and proposals involving the use of animals considered optional.