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Animal Subjects in Research

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Animal Subjects in Research presents an overview of research integrity as it relates to working with animal subjects. The Introduction will focus on major ideas in the current philosophic discussion, albeit in summary fashion. We link directly to an online course developed by Rick Fish covering a wide range of topics, including a discussion of ethics as well as a separate tutorial on models. We then focus on the regulations and guidelines, both at the national and local level as well as describing and linking to the training requirements at NC State. We present a Case Study from The Association for Practical and Professional Ethics. We consider the challenges of the Institutional Animal Care and Use Committee (IACUC) and ask what its involvement with and responsibility to the larger community might be. In the Resources section, you will find a sampling of articles, books and websites. Our faculty guide is Rick Fish, Director, University Animal Resources and Associate Professor of Clinical Sciences, College of Veterinary Medicine. I want to thank Tom Regan for his assistance in developing portions of this module.

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1) Introduction

The subject of using animals in research is complicated and contentious. In this module we seek neither to resolve the many dilemmas nor to explicate every issue. Instead, we will present a range of views, albeit briefly. Open and complete inquiry is the bedrock of philosophy and the first step in examining ethical questions. This topic, the use of animals in research, involves questions that have not yet been fully answered or agreed upon. The “animal question” as it is often called in philosophy, is one that demands much study and thought; both the introductory section and the module in general should be seen as starting points for your own further exploration.

When we debate the animal question, we are taking part in a discussion that began in earnest several hundred years ago with the advent of scientific experiment and discovery. There are many ways to think about our relationship with animals and to decide what responsibilities we as humans owe to animals. With the caveat that sometimes simplifications are useful when a topic is complicated, this introductory section will summarize some of the major ongoing conversations, each of which looks at the question from a different set of premises. It is common to make a distinction between an animal rights position vs. an animal welfare one, but in reality, there are many gradations of different stances along a spectrum.

Many people think that animals have rights of some sort, usually the right to humane treatment or the right to remain free of unnecessary suffering, but that we do have a right to use them as we see fit. The animal rights position takes the view that the core issue is not the well-being of the animal but rather the whole concept that the animal is here for our use, to meet our needs. So we see a polarity here in world-views, a fundamental disagreement over the relationship between ourselves and other species. Either animals are, as Henry Beston says (see box at the right) “other nations” having independent value, or they are, to again use his word, “underlings” having value only relative to our needs and interests.

Thus we have a basic disagreement over the phrase “innate respect,” some saying that it is a sign of “innate respect” to give animals humane treatment and consider their needs, but not at our own expense. We should consider the animals’ needs only after we’ve taken care of ourselves. The other stance is that it is a sign of “innate respect” to not make use of animals in any way.

“We need another and a wiser and perhaps a more mystical concept of animals. We patronize them for their incompleteness, for their tragic fate of having taken form so far below ourselves. And therein we err, and greatly err. For the animal shall not be measured by man. In a world older and more complete than ours, they move finished and complete, gifted with extensions of the senses we have lost or never attained, living by voices we shall never hear. They are not brethren, they are not underlings; they are other nations, caught with ourselves in the net of life and time, fellow prisoners of the splendour and travail of the earth.”

[Henry Beston](#)

Even though there are a range of views as we have said along the spectrum, there is still often a distinction made between animal welfare and animal rights. One who holds an animal welfare position believes that animals are worthy of our consideration; we ought to treat them humanely, but we are within our moral rights as humans to use non-human animals for our needs. Even though we may use animals for our needs, we still have a moral obligation to see that they are given decent treatment, adequate food, water and shelter and in general a lifestyle as close to what is normal for them as possible.

The animal rights position is very different. Here the right that matters is not decent treatment, but the right to be left alone, to not be used merely as a means to an end. Even if life in a lab is full of good food, shelter and safety, the act of making use of an animal as a "research subject," as an object for our use, is morally wrong. For the abolitionist, it is morally wrong to make use of an animal for food, scientific research or entertainment in any form.

We can see, immediately, that there is no easy middle ground between these two positions. In a well known article, David Degrazia discusses the possibility of common ground on some of the difficult questions concerning animals in research; this well known article is a good summary of the major issues. He also draws a distinction between the idea of having a right to life vs. the right to a certain quality of life. This is a difficult and important distinction. Would an animal rather live, even a life of poor quality, than die? Or is the quality of that life more important, from *the animal's point of view*.

Here is an interesting question to ponder: Rick Fish first asks us to think about this question:

"Do animals have the right to live free of suffering?"

Then, he asks us to ponder this question:

"Do humans have the right to live free of suffering?"

"The optimistic thesis of this paper is that the biomedical and animal protection communities can agree on a fair number of important points, and that much can be done to build upon common ground...If the use of animals raises ethical issues, meaning that their interests matter morally, we confront the question of what interests animals have. This question raises controversial issues. For example, do animals have an interest in remaining alive? (life interests?) ...a test case would be a scenario in which a contented dog in good health is painlessly and unwittingly killed in her sleep: Is she harmed? Another difficult issue is whether animal well-being can be understood entirely in terms of experiential well-being-quality of life in the familiar sense in which pleasure is better than pain...satisfaction better than frustration...A test case would be a scenario in which conditioning, a drug, or brain surgery removes a bird's instinct and desire to fly...Does the bird's transformation to a new, non-flying existence represent harm?"

Degrazia, David ["The Ethics of Animal Research: What Are the Prospects for Agreement?"](#)
P. 26, 27

Which is the “correct” world view? Are animals inherently valuable, and are we just one species among many others? Or are animals instrumentally important only, having value in terms of what our species needs and wants? Historically, there are a series of classic questions we have asked over time to help us make this decision.

One way to answer the question, what is our correct relationship with animals, is to ask about their moral standing, vis a vis the moral community. What do we mean by “the moral community?” Very simply, we can say that members of the moral community are to be treated as valuable in and of themselves, so much so that they cannot ethically be treated as mere means to an end. Human beings are considered part of this moral community; we are morally obliged to treat people not only with respect but also not to use them as means to an end, as an object for our use. More simply put, whoever is inside our moral community has inherent value.

How does one qualify to be a member of the moral community and what keeps one out? Historically, animals have been excluded because they lack a variety of characteristics, such as having a soul, the ability to think intellectually, to make moral decisions, self-awareness, and possession of language. Historically, the first basic question asked was “do animals have souls?” With the rise of the scientific revolution and the secular state, the question became, “can animals think?”

“Now, for some, the beating of a horse is bad because it’s bad for the man, for his immortal soul, or because it dulls him to interactions with human beings. But for most of us now in this century, beating the horse is bad for the horse’s sake. That’s because we do believe that there’s something in that horse that’s worthy of moral consideration. So we are saying that horses have a moral status, deserving of consideration, in and of themselves.”

Dr. Richard Fish, DVM, Ph.D.,
Director of University Animal
Resources, NC State University

In the eighteenth century, a utilitarian philosopher, Jeremy Bentham asked a different question. He said that the crucial issue is about suffering, not cognitive ability. This shifted the focus of the conversation from one mainly about people to one where the needs of animals became part of the moral consideration. His famous statement is quoted in the box below.

“The day may come, when the rest of the animal creation may acquire those rights which never could have been withholden from them but by the hand of tyranny. The French have already discovered that the blackness of skin is no reason why a human being should be abandoned without redress to the caprice of a tormentor. It may come one day to be recognized, that the number of legs, the villosity of the skin, or the termination of the os sacrum, are reasons equally insufficient for abandoning a sensitive being to the same fate. What else is it that should trace the insuperable line? Is it the faculty of reason, or perhaps, the faculty for discourse?...the question is not, Can they reason? nor, Can they talk? but, Can they suffer? Why should the law refuse its protection to any sensitive being? The time will come when humanity will extend its mantle over everything which breathes...”
Jeremy Bentham, [Introduction to the Principles of Morals and Legislation](#), 1789.

Tom Regan, in articulating the rights position, uses the subject-of-a-life criterion for determining membership in the moral community. For Regan, if a creature is the subject of a life, they have the status of an individual such that it is immoral to use them merely as a means, even to a good end. So here, the question has evolved to: are animals "subjects of a life" and to the extent that animals fit this criteria, they have moral standing. This approach is in the Kantian tradition of seeing the animal as an individual, and thus having certain sorts of rights.

"To be the subject-of-a-life, in the sense in which this expression will be used, involves more than merely being alive and more than merely being conscious...the ability to initiate action in pursuit of their desires and goals; a psychophysical identity over time; and an individual welfare in the sense that their experiential life fares well or ill for them, logically independently of their utility for others and logically independently of their being the object of anyone else's interests. Those who satisfy the subject-of-a-life criterion themselves have a distinctive kind of value—inherent value—and are not to be viewed or treated as mere receptacles."

Regan, Tom. "[The Rights View \(Part 1, Part 2, Part 3, Part 4\)](#)." [The Case for Animal Rights](#). Berkeley: University of California Press, 1983. 243.

Peter Singer, in criticizing the decision to keep animals out of the moral community, does not see that the immorality is due to disregarding the rights of an individual animal. Singer, like the Utilitarian Jeremy Bentham, considers suffering to be the key point; building on Bentham's approach, Singer says that the principle of equality demands that suffering be considered equally, regardless of species. Not doing this is a form of prejudice he calls "speciesism."

Speciesism is a prejudice similar to racism—not the same, but still a moral issue. For Singer, speciesism is philosophically inconsistent because there is no rational justification for favoring our own species over another. There is nothing inherently moral or right about this; it is only a preference, though an understandable one, and as such, cannot be morally defended as a valid reason for a moral decision. Since for Singer pain is to be avoided whatever the species, in considering a research protocol we must be willing that it be done to our own species, if we propose it to be done on animals.

"We have seen that experimenters reveal a bias in favor of their own species whenever they carry out experiments on nonhumans for purposes that they would not think justified them in using human beings, even brain damaged ones. This principle gives us a guide toward an answer to our question. Since a speciesist bias, like a racist bias, is unjustifiable, an experiment cannot be justifiable unless the experiment is so important that the use of a brain-damaged human would also be justifiable."

Singer, Peter. "[All Animals are Equal, Part 1 & Part 2](#)." [Animal Liberation](#), 2nd Edition. NY: Avon Books, 1990. 25.

This view is different from the Rights View that says animal research is wrong because an individual has the right not to be used merely as a means to an end. This is in the Deontic tradition where the rightness of an action depends on the

principle being followed. Here the principle is the Kantian one of never using an individual (here an animal) as a means to an end. As is true of Singer's view, however, the Rights View is critical of speciesism. In particular, the rights of animals cannot be overridden simply because animals belong to a different species than we do. For Singer, and the Utilitarians, the point is the greatest good for the greatest number; thus, if a research protocol had the possibility to save a great many lives, human and/or animal, if we chose the subjects regardless of species, it might be acceptable.

Many people think that the whole question of moral standing is misguided, saying that there are morally relevant differences between both humans and animals that justify our use of them. They say that our species' intellectual abilities put us in the unique position of making decisions for other species. Indeed, they believe that we are morally obligated to use our unique skills for the improvement of the general health and welfare. Although animal welfarists agree that suffering is indeed to be avoided or minimized, whenever possible, our moral imperative as human beings is to make the difficult decisions that will benefit all species, even if it means using or harming some of them.

Thought Question:

In the box below, we quote Jerrold Tannenbaum (1998) a leading proponent of the welfare position, a lawyer and one of the first to write in the field of veterinary ethics. Would you say he is using the word "rights" in the same way as the philosophers?

"The concept of welfare, unlike the concept of rights, allows for liberal balancing of human against animal interests and for deciding in many circumstances that human interests should prevail...Sometimes, a condition conducive to or constituent of animal welfare is so important to an animal that we can say the animal's claim to this condition rises to the level of a right. Adequate food and water are critically important to animal welfare...It is therefore not just wrong, but terribly wrong, to deprive an animal one keeps or uses of adequate food and water. One may subject animals to such treatment only for the most important of reasons. Here, those of us who believe that animals have some moral rights would say, is a right based on considerations of welfare."

Tannenbaum, Jerrold. "[*What is Animal Welfare?*](#)" *Veterinary Ethics: Animal Welfare, Client Relations, Competition and Collegiality*, NY: Mosby, 1998: 173.

In Module I, *Research Ethics: an Introduction*, we noted a major split in the road between two types of moral theory, non-consequentialism and consequentialism. In the former, an act is right or wrong depending on how closely it adheres to an overarching principle, such as honesty or justice. In the latter, what makes an act right or wrong are the results. Singer, as noted above, follows the utilitarian point of view in looking at the overall results, the aggregate good or bad, to make a moral decision of right or wrong.

Utilitarianism appeals to many people—it is practical and concrete and seems to make sense in daily life. Utilitarianism does not say using animals for research is wrong; what it does say is that to decide on the moral rightness of an action you need to look at whether that research might promote an aggregate good for a greater number of people than not doing the research. Some would include animals in this equation since animals do benefit from research. For the Abolitionist, animal research would be wrong since it is morally wrong to use an animal merely as a means, even—as we said above-- to a good end.

It is not uncommon for those concerned with making moral decisions about animals in research to think in terms of costs and benefits. In a recent textbook, author Kevin Dolan addresses the cost-benefit method of decision making, asking, "Given that pain is of the very warp and weft of life, can we feel justified in hurting a little to help a lot" (213).

While it might seem that making decisions via the Utilitarian framework is easier, more practical, than following a theoretical principle, to do it properly, one must be sure that all the details, sacrifices, outcomes and stakeholders are accounted for. In his chapter on Utilitarian decision making, Dolan presents flow charts and checklists that are used in Britain to aid in making decisions about animal use.

"We by no means claim that the use of experimental animals is desirable but is there a case for saying it may be acceptable? This may be so if we choose to regard restricted animal suffering in research as a lesser evil than allowing a continuation of suffering, which could be prevented by science...Because this ethical approach is far from absolute, there is certainly lacking the solid ring of confidence of deontology. Consequently, caution is inherent in making decisions in the context of the teleological approach. Judgements are formed on a case-by-case basis. It is necessary to pay attention to details and circumstances. It is all-important to ask the right questions."

Dolan. Kevin. "[The Cost-Benefit Balancing Act \(Part 1, Part 2\)](#)." [Ethics, Animals and Science](#), Ed. Kevin Dolan. Oxford: Blackwell Science Ltd., 1999. 214.

Historically there is a long list of research studies that have made use of animals. In reviewing these scientific discoveries, it may be of use to look at both the Abolitionist and Welfarist positions, as well as thinking about the differences between non-consequentialism and consequentialism. Is the greatest good for the greatest number the best (or only?) way to think about some of the projects listed below? Does your point of view depend on the nature of the research project? We have gotten this list from the [Foundation for Biomedical Research](#).

1726	first measurement blood pressure	horse
1790	vaccine for smallpox	cow
1880	vaccine for anthrax	sheep
1885	vaccine for rabies	dog, rabbit
1902	malaria life cycle	monkey, mouse
1905	pathogenesis of Tuberculosis	sheep
1923	Insulin developed	dog, fish
1932	function of neurons	dog, cat
1939	anti-coagulants	cat
1954	Polio vaccine	monkey, mouse
1956	Open heart surgery and pacemaker development	dog
1970	Lithium developed	rat, guinea pig
1982	Treatment for leprosy	armadillo
1984	Monoclonal antibodies	mouse
1992	Laposcopic surgery developed	pig
1995	Gene transfer for Cystic Fibrosis	mouse, non-human primate
2001	Promising drug for prevention of AIDS developed	monkey

"At some level, many scientists are abolitionists. That is, if we were able to acquire the information needed to adequately answer compelling research questions without the use of animals, who among us would not gladly do so? Nevertheless, one of the best methods we have developed to advance biomedical knowledge involves the use of animals, which, unlike the test tube, have interests. They have interests in obtaining sufficient food, in remaining free from pain, in reproducing themselves, and perhaps in living out a normal life span. Experiments can frustrate the interests of laboratory animals, and most scientists recognize this both in their concern for the humane treatment of animals and in their belief that research should be directed at important problems. The fact that animals have interests does not necessarily mean that we should never use them in biomedical experiments; however, it does mean that any such use should be preceded by a moral judgment. Do the benefits derived from the biomedical research that is being considered offset the associated moral costs?"

Fuchs, Bruce A. "[Use of Animals in Biomedical Experimentation](#)." [Scientific Integrity: An Introductory Text with Cases](#), Ed. Francis L. Macrina. Washington, DC: ASM Press, 2000. 121.

2) [Humane Care of Animals in Research](#)

Rick Fish has developed an excellent online course that covers the wide range of topics you need to be familiar with if you are going to be working with animals. It consists of five tutorials; each tutorial has an overview, links to readings and websites, and discussion questions. This site was developed as part of a larger project at NC State University.

This site, developed at North Carolina State University, is a Howard Hughes Medical Institute (HHMI) sponsored project, under the direction of George Barthalmus, Director of Undergraduate Research. The materials were written by Richard E. Fish, Director of University Animal Resources and Associate Professor of Laboratory Animal Medicine at NC State. Technical consultants: Elliott Fisher and Daniel Underwood. Faculty interested in using these materials for course credit, or in using this online "course" for credit, should contact Dr. Barthalmus.

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[Introduction](#)

Why do we care about the humane care and use of animals in research?

[Unit One](#) – *Ethics of Animal Use*

This unit starts at the beginning by asking you to think about the human-animal relationship, both intuitively and in terms of basic ethical theories.

[Unit Two](#) – *Laws, Regulations, and Policies Affecting the Care and Use of Animals in Research*

Here we look at the regulations affecting use of animals in research in greater depth, and consider the responsibilities of the institution, animal care and use committee, research staff, and veterinarian.

[Unit Three](#) – *Pain and Distress*

Humane care and use of animals relies on an understanding of animal pain and distress, from biological, ethical, and legal perspectives.

Unit Four – *Animal Husbandry and the Animal Facility*

The appropriate care and use of animals requires an understanding of the importance of husbandry and the animal environment, not only for humane reasons, but also to control unwanted variation during experimentation.

Unit Five – *Animal Models and Biomethodology*

In this unit, we look at the basics of choosing an animal model, including considerations for biomethodology (handling and restraint, sample collection, anesthesia and surgery, etc.)

Public support for the use of animals in research is by no means universal, in part because of misconceptions about how animals are used in research, combined with an ignorance of the regulations that govern such use. While there are ethical arguments about the appropriateness of using animals, in research or otherwise (see Unit One), it is useful to be aware of the misconceptions, or “myths,” that are commonly used by activists who oppose animal use in research. (See the [Foundation for Biomedical Research](#) site that addresses this issue.)

A fair question is, “Why should we invest time and energy in addressing the humane care and use of animals in research?” An excellent answer is provided in the summary of a 2002 Council on Undergraduate Research workshop, “Responsible Research with Animals”:

“Researchers who study nonhuman vertebrate animals have a responsibility to their students, peers, institution, governmental agencies, and society – and to the animals they study – to do their work humanely. Fulfilling this responsibility requires a commitment to learning about relevant principles, keeping current with policy changes, and thinking deeply about the moral and legal dimensions of the enterprise.”
<http://www.cur.org/conferences/cur2002summaries/R20.html>

That commitment to learning provided the basis for the CUR workshop, and serves equally well for our purposes in these modules.

Rick Fish, Director of Laboratory Animal Resources, NC State College of Veterinary Medicine

3) Applied Ethics: stakeholders, conflicts in duties and the theme of "right balance."

There is a question at the heart of veterinary medicine that is directly applicable to using animals as research subjects: "Who is the client: the patient or the owner?" Clearly both are stakeholders, albeit in very different ways. This is an equally crucial question for animals in research: when we ask about their well-being, who is the client?

We might list all the stakeholders involved in the particular research, going from the specific animal in front of us to the wide net of the population who will derive benefit from the study.

- The actual research animal
- Researchers involved with the project
- The individuals who are ill
- The public in general
- Animals in general
- Science in terms of generating knowledge

"Biomedical researchers feel a strong duty to heal. That is the goal that drives them and it is a respectable calling. This is a duty we need to consider, just as we have a duty to our family and our friends. Also, all scientists have a drive to increase knowledge, which can also be considered a duty."

Dr. Richard Fish,
Director of University Animal
Resources, NC State University

The Stakeholders all have a particular interest in the outcome of the research. The researcher feels obliged to consider their interests when making decisions; you can say that these are special interest groups worthy of moral consideration, even though all might not be equally affected in the same way or the same degree or at the same time. The public has a more general interest as opposed to the sick person who has a strong interest within a particular time frame. The scientific community may have a long-term interest, and not feel any particular need for speed.

Richard Fish notes that of all the stakeholders, the research animal has the ultimate interest. This, of course, brings us back to the dilemmas at the heart of research using animals. There is no way around the fact that in most cases an animal or a group of animals will die for the sake of the results. For all the stakeholders, but particularly for the animal subjects, the protocol must be impeccable. By impeccable, we mean, for example, that decisions such as the choice of species used, the sample size chosen - see Module IX, *Responsible Use of Statistical Methods* - the husbandry and personnel demands and the lack of available alternatives to using animals for this particular research question, have been rigorously studied. The reason for the research must be above reproach.

A scientist might well feel a conflict in duties when faced with the task of investigating the natural world using animal subjects. She feels an obligation to her discipline, to advance knowledge for the public good, and to improve the lives of individuals suffering from a particular illness. She feels an obligation to the animal subjects, to give them as good a quality of care as possible and yet still get the data.

For research purposes, the laboratory animal becomes objectified. She might feel a conflict between seeing the animal as within the moral community on one hand -- intrinsically worthwhile, with needs and desires, and at the same time as an object, a research tool. But is it necessarily black or white, either-or? And how do we make the shift from feeling a conflict to feeling ourselves in balance?

Thinking back to our earlier review of the questions that have been historically asked to determine moral standing, (Is there a soul? Is there cognition? Is there sentience? Is there a subject of a life?) we can ask what are the questions researchers and ethicists are asking themselves and each other now?

"I want to shift the question from the passive 'Can they be harmed?' further to 'Can we harm them?' thus reconnecting moral reflections on the 'moral patient' with the situation of the moral agent...It seems plausible to assume that an entity that exists within a subjective environment and sustains its existence may do so without any further reason and to place the burden of justification on any intruder that has the ability to reflect on its action and has a choice of options. Indeed, there are no good reasons why any living being should have to justify its existence by serving another being's needs." Biller-Andorno [Can They Reason](#). 35, 36

In this context it is very interesting to ask: Is there language? African grey parrots seem to be clearly talking "about something" and chimps and bonobos have been taught American Sign Language. It seems clear that dolphins and whales have very sophisticated communication patterns. So using language as the question for "restricted access" to the moral community has become problematic.

Nikola Biller-Andorno, an Italian doctor and researcher, says that the focus on the animals' standing is the wrong approach. She says that the issue is not what "they" can or cannot do: it is about what WE can do. Thus, she proposes that the real question is, "*Can we harm them?*" Using an expanded concept of empathy, she then proposes that the focus in animal ethics should move away from the question "Who is worthy of protection?" to "Who is in need of protection." (Gluck et. al., 25)

We, says Biller-Andorno, are the moral agents here, the ones that can actively create benefit or harm for other species and thus the question really should be addressed to ourselves and our own capacities. Can you see how she is speaking out of a Care Ethics tradition?

In this context, the idea of “the Three R’s” takes on a deeper resonance. Although the term “alternative” is often used synonymously with “replacement,” the Three R’s, as they are known in research (refinement, reduction, and replacement) (see box below), involve a wide array of strategies to minimize animal pain and distress. Refinements in animal research include such things as attention to proper animal husbandry and handling, environmental enrichments, improvements in the use of anesthetics and analgesics, and better recognition of pain and distress.

Increased attention to alternatives is the result of several historical trends. First, the moral dilemma that many feel about using animals in research gave impetus to the search for alternatives. Second, there has been a shift in social consciousness over the last twenty to thirty years, with people asking questions about animal welfare in general. Europe has a long tradition of making changes in their welfare laws and our country is feeling pressure from public opinion. Third, the scientific advances already made, the increasing skills in technology, have begun to make the creation of alternatives to animal models a possibility.

A good resource for information is the [Johns Hopkins website for alternatives](#). The Hopkins center was initially funded with money from companies engaged in cosmetics testing. These companies were responding both to public opinion and their own interest in finding new methods. It is part of the Animal Welfare Act now, that one of the stages of IACUC review is to search for viable alternatives to live animals.

The [University of California, San Francisco’s IACUC website](#) has much information and further links as well. Recently, a fourth R has been added—responsibility—referring to integration of concerns for the welfare of animals into the ethical and responsible conduct of science and teaching.

Elizabeth Choinski, the Science Librarian at the University of Mississippi Libraries has put together an impressive website: Science and Technology Sources on the Internet: [Animal Testing Alternatives: Online Resources](#). She has included a brief history of this initiative, online tutorials for aid in understanding and working with the resources available for alternative searching, bibliographic databases for online searching, and both governmental and academic information centers.

Research scientists who are using animals as test subjects are required by the *Animal Welfare Act (7 USC 2131-2156)* to consider alternatives to animal testing prior to beginning a research project. These investigators are required to search the literature for alternatives and to supply their findings to their Institutional Animal Care and Use Committee (IACUC). If no alternatives are available, investigators must supply to their IACUC a written description of their search history and databases used to look for alternatives. The Animal Welfare Information Center (AWIC) of the National Agriculture Library provides in-depth information, in a question and answer format, concerning why literature searches must be conducted for animal testing alternatives and provides definitions of alternatives. [Animal Testing Alternatives: Online Resources](#).

4) Central Theme: working with regulations, national and institutional

NC State University Regulations and Training

Every project that uses animal subjects at NC State is bound by relevant federal regulations and institutional policy as well as institutional specific requirements: you can view these details at the NC State Research Administration (SPARCS) [Animal Care and Use website](#).

All personnel who work with animals must complete a web-based training program. The [animal training module](#) is one in a series of Responsible Conduct of Research (RCR) tutorials. When you begin to work with your team, you will be given training on the particular species you are working with, the parameters of your experiment (s) and the specific guidelines for administering anesthesia and medications, taking samples, housing, feeding, etc. Each department and division will differ and your supervisor is the first person to go to with specific questions and concerns.

One way to look at such guidelines is that they are the values of our society made tangible. In Module V, *Professional Responsibility and Codes of Conduct*, we commented on the idea that professional codes are a kind of contract between society at large on one hand and the trained experts on the other. Continuing this thought, can we think about the guidelines for animal care and use as a kind of contract between researchers and society? Can we think of these regulations and guidelines as analogous to the [Belmont Report](#), protection for animals similar to the protection in place for children?

Federal Regulations, Principles and Guidelines

The NC State University Policy on Animal Use includes adherence to two sets of federal regulations that govern use of animals in research, teaching, and testing: the Animal Welfare Act set these regulation into law: the United States Department of Agriculture, [Animal and Plant Health Inspection Service \(APHIS\)](#) is your resource for specific information as to government policies.

The Health Research Extension Act (and the corresponding [Public Health Policy on Humane Care and Use of Laboratory Animals](#)) is the other arm of government oversight. This is the branch of government that includes the National Institutes of Health (NIH.) The major publication of the NIH that is the standard to follow is the [Guide for the Care and Use of Laboratory Animals](#), published online by the National Academies Press. Aside from information about regulations, this guide includes details and standards for veterinary care, husbandry, and the animals' physical environment, personnel qualifications, and occupational health and safety.

The [Office of Laboratory Animal Welfare \(OLAW\)](#) website has links to much more than regulations, e.g. information about meetings and direct links to articles of interest published in the [Institute for Laboratory Animal Research \(ILAR\)](#). The latter is the journal for professionals who work with animal subjects in research.

Agricultural animals used for agricultural purposes are not specifically regulated by the federal government, but NC State University, like most academic institutions, includes them under its animal care and use umbrella. For these species, the university relies heavily on the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, available from the [Federation of Animal Science Societies \(FASS.\)](#)

In addition, many of the grant funding agencies, in particular the National Science Foundation (NSF) and the National Institutes of Health (NIH) have their own sets of regulations. You will find that the NIH guidelines, as put forth by the Office of Laboratory Animal Welfare, are generally the guidelines that most agencies and institutions follow. This OLAW booklet, [Public Health Policy on the Humane Care and Use of Laboratory Animals](#) is published online.

Thought Question:

If we think about the regulations as a kind of contract between society and research scientists, can we also think of it as a kind of contract between the researchers and the animal subjects? Or is this a false construction, given that animals cannot give consent? Might the regulations be the sort of contract where society is the proxy for the animals? Given that every institution must have an IACUC with an attending veterinarian, is the IACUC the holder of the contract? Is the veterinarian? Who ultimately is giving consent for the animal?

"Each of these principles articulates an essential facet of what constitutes humane treatment of animal subjects in research. One of the most important of these is Principle IV, which refers to the imperative of minimization of discomfort, distress and pain. When pain or distress may occur, the Federal Animal Welfare Act requires the researcher to search for and carefully consider alternatives to those procedures."

Dr. Richard Fish, Director of University Animal Resources, NC State University

5) Case Study

This case study is from the collection published by the [Association for Practical and Professional Ethics \(APPE\)](#), posted by the [Online Ethics Center hosted by the National Academy of Engineering](#). The case, *The Painful Experience*, explores the complex issues that arise when working with animals.

We will present a summary of the Case Study here in the box to the right, but reading the original Case Study, Discussion Questions and Commentaries will enable you to go more deeply into the issues. You will find that with this case, as well as others, there are three levels of questions and/or concerns; firstly there will be specific issues germane to using animals in research; secondly, there are advisor/advisee issues to investigate; and third, there are the deeper, more complex societal implications to ponder. E.g., how should we research pain medications? Our government requires that all medications be tested on animals before they are put in the market for humans.

A rodent model of inflammatory bowel disease is used to investigate treatment of chronic pain. A surgical procedure while the rodents are deeply anesthetized places a catheter in the colon. This catheter will deliver both inflammatory producing drugs as well as various compounds being tested to reduce pain and inflammation. Eric, a research scientist asks his student, Michael, to perform a procedure to test a specific drug. Michael finds data that indicates this drug has a low possibility of success; his tests confirm this. Michael locates an alternative pain study protocol that seems to be less painful for the rodents; however, Eric decides to stay with repeating the experiment and ask Michael to perform it again. What should Michael do?

Access the original Case Study, [The Painful Experience](#), read it thoroughly, including the Discussion Questions.

Review [Tom Regan's Check List](#) from page 4 of Module 1. Doing this will enable you to see the inter-relationship of research ethics in general to the context specific concerns of using animals in research.

For example, we see in the Case Study that Eric asks Michael to keep repeating a study that already has shown inconclusive results. Can we relate Michael's dilemma to the issue of conflicting obligations? Who is Michael most obligated to; his mentor, his own career, his conscience, the research animals? How might this Case Study link to Regan's point 8: "*Are any duties of justice involved? If so, who has what rights? Against whom?*"

Cast a wide net in your thinking about these issues in terms of Regan's *Morally Relevant Questions*.

Again, as in the case study for Module 1,
What seems to you to be *resolved* in your own mind?
What seems to you to be *unresolved* in your own mind?
What do you find challenging to *articulate*?

Now review the [Commentaries by Brian Schrag](#), which accompany this case. Reading his ideas when you have already struggled with this case will add to your ability to think through the ethical issues and help you work on areas that you feel are still unresolved. Doing this will help you articulate the deeper issues of this case. One of the realities of both case studies and real life situations that involve moral dilemmas is that you might have decided on how to go forward, and yet still feel the pull of the dilemma or find that there are still areas that feel unresolved to you.

6) Study Question: IACUC membership

The general rule is that the IACUC needs to have a group with a minimum of five members from the following categories: 1) a chairman; 2) a veterinarian trained in the field of laboratory animal science; 3) a person unaffiliated with and not related to anyone in the institution; 4) a practicing scientist who has knowledge and experience in working with animals in research; and 5) a person from the larger community, not involved with a scientific career, e.g. a lawyer or a member of the clergy, or someone with a particular expertise in ethics.

One of the common dilemmas is the attitude of this fifth person toward animal research. Scientists feel it unfair that someone without scientific knowledge—perhaps even antagonistic to the work of science—would have a say on the research protocols. At the same time, the guidelines that set forth community involvement are attempting to bridge the gap between the scientific experts and society at large.

How would you design an IACUC? What about the problem of lay people having enough understanding of the scientific process? What of the other side of the problem, the charge that IACUCs just “rubber stamp” what the institution wants in the first place?

The question of the make-up of animal review committees is important in terms of the idea of conflicting obligations as discussed in the Applied Ethics portion of this module. Thinking back to Module 1, Research Ethics: an Introduction, we brought out Schrader-Frechette’s point that researchers have an obligation to the public, since much of the funding is ultimately from taxpayers. If scientists have a duty to do research—a duty to heal, as Dr. Rick Fish points out—do they also have a duty to involve the community at large in their plans and procedures? Which becomes more important? Or does the dilemma return us to the ethical theme of “right balance?”

“The term ‘community member’ means what it says although in common parlance it is often used rather loosely. Terms such as community, public, lay, unaffiliated, non-institutional, and non-scientific member, are sometimes used as if they were interchangeable, although some of these terms mean quite different things. The rationale for including such members lies in the consensus that, where federal funding is concerned, decision concerning social values should be made in a forum that includes societal involvement. Congress wanted to make clear that scientists are not free to do whatever they wish to animals—decision making should not rest solely in their hands.”

Orlans, Barbara. “[Community Members on Animal Review Committees.](#)” *In the Name of Science: Issues in Responsible Animal Experimentation*, New York: Oxford University Press, 1993. 99-117.

Resources

Articles and Journals

Beauchamp, Tom L. [*The Moral Standing of Animals in Medical Research*](#), *The Journal of Law, Medicine & Health Care*, 20.1-2: 7-16. This essay is used by the Poynter Center in their annual "Teaching Research Ethics" workshop.

[ILAR journal](#) online, well known premier journal for researchers using animals.

[Journal of Applied Animal Welfare Science](#)

[Science and Engineering Ethics](#)

Articles on animals in research:

Jamieson, Dale, *Teaching Ethics in Science and Engineering: Animals in Research* 1, 2 (1995): 185-186.

Radzikowski, Czeslaw, *Protection of Animal Research Subjects*. 12.1 (2006): 103-110.

Rowan, Andrew N. *Ethics Education in Science and Engineering: The Case of Animal Research*, 1, 2 (1995):181-184.

Schrag, Brian, Todd Freeberg and Lida Anestidou, *The Gladiator Sparrow: Ethical Issues in Behavioral Research on Captive Populations of Wild Animals: A Case Study with Commentaries Exploring Ethical Issues and Research on Wild Animal Populations*, (2004) 10. 4: 717-734.

Books

Blum, Deborah, The Monkey Wars . Oxford University Press, 1998. Pulitzer winning science writer's well known book on the dilemmas of research with primates: contains many interviews with scientists.

Gluck, John P. et. al. Applied Ethics in Animal Research: Philosophy, Regulation, and Laboratory Applications . Purdue University Press, 2002. An excellent set of essays by well known authors: an example of researchers writing to other researchers. This book is well known

Hart, Lynette A., Ed. Responsible Conduct with Animals in Research. New York: Oxford University Press, 1998. A collection of essays by well-known researchers on a variety of topics. Two that are available electronically are: John P. Gluck, [Change During a Life in Animal Research: the Loss and Regaining of Ambivalence](#) This is an autobiographical account of a well-known scientist's work with primates. Arluke, Arnold and Julian Groves, [Pushing the Boundaries, Scientists in the Public Arena](#). Discussion of the interface of science, the media and the public as it relates to animal subjects in research.

Orlans, F. Barbara, et. al. The Human Use of Animals: Case Studies in Ethical Choice. Oxford University Press, 1998. Cases include: xenotransplants, the Harvard "oncomouse," great apes language studies, among others.

Rowan, Andrew. "Ethical Principles for Animal Research and the Sundowner Principles." Bioethics and the Use of Laboratory Animals: Ethics in Theory and Practice, Eds. Kraus, A. Lanny and David Renquist. Dubuque, IA: Gregory C. Benoit, Publishing, 2000.

Fuchs, Bruce A. "Use of Animals in Biomedical Experimentation." Scientific Integrity: an Introductory Text with Cases, 2nd Edition, Ed. Francis Macrina, Ed. Washington, D.C., 2000. 101-129.

Monamy, Vaughan. "Moral Status of Animals." Experimentation: A Guide to the Issues. New York: Cambridge University Press, 2000. 35-56.

Rudacille, Deborah, The Scalpel and the Butterfly: The War Between Animal Research and Animal Protection. New York: Farrar, Straus and Giroux, 2000. Very readable account of the history of scientific research with animal subjects and the evolution of the animal protection movement.

Websites

[Animal Ethics InfoLink](#), an Australian site with much information on wide range of topics, links to other resources as well.

[Animal Research: University of Iowa](#), an extensive training site

[Animal Welfare Information Institute](#)

[Animal Welfare Institute](#)

[American Veterinary Medical Association](#)

[Contemporary Science, Values and Animal Subjects in Research](#) an ORI training and information site developed by the author of this module and colleagues at NC State University. Contains large listing of additional resources.

[Institute for Laboratory Animal Research](#)

[Trans-NIH Mouse Initiatives](#) website about mouse models.

[An IACUC Member's Guide to Animal Facility Inspections](#), ORI online tutorial (an actual walk through movie version) on IACUC from Wake Forest University

"Few areas of applied philosophy have witnessed more dramatic growth in the recent past than bioethics; moreover, in light of the pace of advances in the life sciences, from developments in preventative medicine to the cloning of sheep and mice, few areas of ethical concern are likely to grow more dramatically in the foreseeable future...Whatever the future holds, one thing is certain: other-than-human animals will be used in the name of advancing scientific knowledge, both basic and applied...While people of good will can and often do disagree in the answers they give to questions about the morality of using animals for scientific purposes, one point on which virtually everyone agrees is that these are legitimate ethical questions that must be addressed."

Regan, Tom. [Defending Animal Rights](#). Champaign: University of Illinois Press, 2001. P. 4. Chapter 1,