

Considerations for the Regulation of Research on Animals

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The following consists of personal opinions and do not represent the position of NIH or the US Federal Government.

The scientific study of living organisms is critical if we are to understand both life on earth and its disorders. Since all living organisms have a common origin we can learn much about the principles of human biology and behavior from animal models, as well as make use of our discoveries in human biology to help us understand other animals.

We are making major progress and the science of living systems grows in magnificent ways. Many of us see progress is slowing and part of the problem is the loss in balance between science and its regulation.

To go back to basics, what is our goal?:

To understand living systems and their disorders, with a particular focus on human biology and human disorders.

What should be the considerations covering the use of animals in research? Here I use the word “*considerations*” to avoid confusion with the “U.S. Government *Principles* for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training:”

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We must start with the higher goal of the research enterprise: Since all living organisms have a common origin, animals are useful in research to understand animal biology and behavior in its own right and, importantly to humans, because they help us understand general principles applicable to humans and our disorders

We use animals rather than humans in many situations because we have concluded that manipulating animals, their genetics, their environments is more acceptable than doing so to humans

Because we accept the annual use of billions of animals for food, the painless death of a small fraction of these animals bred for research is considered an acceptable ethical cost, if we have appropriate consideration of their welfare in life.

The key welfare consideration for animals in research is to minimize pain and distress and improve well-being, often considering this as a quantity over a group. The 3 Rs can be seen as flash cards for this process.

The ethical problem is to balance the gains in scientific knowledge with the costs to animals, especially pain and distress. Since no one has come up with a satisfactory calculus for looking at these offsetting ethical gains and losses, we try to develop a balance that goes further and further to minimization of pain and distress through approaches like the 3Rs, a calculus that is impossible to satisfy. This may have the counterproductive effect of limiting the scientific gains from studies while increasing the cost of each study.

The problem of improving our understanding of living systems and their disorders remains so we must constrain the growth of welfare considerations and regulations to some proportionality to the outside world of animals for food and organisms displaced by humans or killed as pests. We should consider the ethical context which includes the relative cost of welfare effort and cost effectiveness. We should not consider animal welfare in isolation from the scientific goals or the larger needs of society.

Among other things, this means we must avoid the phrase “cost is not a consideration”. (As anyone who looks at adverts for UNICEF knows)... money delivers quantifiable ethical goods so any expenditure is at the cost of alternative ethical goods. Cost in money is cost in ethical goods so the cost-effectiveness of regulation must be a consideration.

Further, we must make more effort to communicate both the scientific goals/mission as well as the considerations for animal welfare. What is the purpose and how do we minimize harm?

The 3Rs do not create an ethical justification for research on animals, nor does it communicate the effort for animal care and welfare (it only makes clear that any effort is inadequate) so they do not help either of our communication goals. They must be used as considerations for approval of research, not core principles, since as core principles our goal would be to end animal research. If we are not ready to apply this to the eating of meat or killing of pests, it should not be a core principle in research. The 3Rs must be used but do not represent a justification.

Research animal care and use must always be placed in the context of the scientific and societal missions. It has no meaning or value in isolation.

The key principle of animal regulation in research should be finding a balance of scientific progress, animal welfare and cost-effectiveness that is better than, yet proportionate to the larger treatment of animals by humans.

Centerpiece:

Ethical goods from science

- **Understanding devastating illnesses and conditions , leading to treatments, cures and prevention.**
- **Deep insights into the nature of being human**
- **Critically important insights into the biology of living things and ultimately, the web of life**

Thank you.

Now on to the show!

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The key scientific consideration for the use of animals is that they usefully model “real biology” and allow us to predict or understand outcomes of biological systems generally.

Despite major changes and improvements in the way US and European science facilities care for and use animals over the last 30 years, why have scientists made so little progress in reducing the controversy surrounding the use of animals in research?

The short answer is that the public does not understand the purpose of research involving animals and does not realize the extraordinary amount of effort for animal care and welfare in research that exceeds virtually all other efforts for animal welfare in human interactions with animals.

Why are animals useful in research?

- **Genetic homology from yeast, worm, fly, fish, bird, mouse, to non-human primates and humans - over 180 species sequenced**
- **Conserved genes are the most important**
- **Ability to manipulate genome and environment**
- **Common systems: ie. circulatory, metabolism, brain: sensory, motor, memory, emotion**
- **Species differences can be useful**