

Animal Use Laws and Regulations

US275 Scientific Ethics
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The National Institutes of Health
established the first animal research
guidelines in U.S. in 1963.

- National Institutes of Health
 - provides the majority of funds supporting biomedical research in the United States.
 - Guidelines for humane use of research animals.
 - Voluntary compliance



Animal Welfare Act

- originally passed in 1966
 - amended in 1970, 1976, 1985, 1990, 2002, 2007, 2008
- directs U.S. Dept. of Agriculture to adopt and enforce regulations
- Institutional Animal Care and Use Committee (IACUC)



Animal Welfare Act definition of an animal

- **Animal** means any live or dead dog, cat, nonhuman primate... or any other warm-blooded animal,
 - which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet.
- rats and mice are exempt from coverage



Line art drawing of a chimera
Pearson Scott Foresman

USDA

- Animal and Plant Health Inspection Service (APHIS)
 - monitors all research facilities covered by AWA
 - annual reports
 - conducts unannounced annual inspections
 - violations
 - if not corrected, can result in fines, closure, or loss of federal funding.



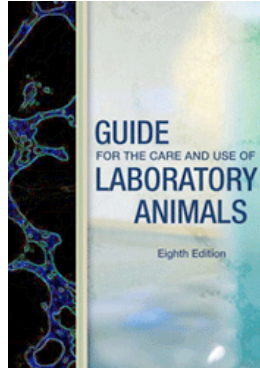
U.S. Department of Health and Human Service

- U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals.
 - policy to implement and supple AWA
 - applies to all institutions receiving federal Public Health Service funding in support of animal research



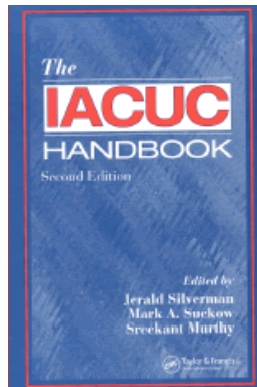
National Institutes of Health “Guide for the Care and Use of Laboratory animals.”

- Specific, stricter requirements
 - covers any vertebrate animal produced for or used in research, teaching, or testing (i.e. includes rats and mice)
 - housing space, lighting, ventilation, temperature, veterinary care, etc.
- required for all researchers with NIH funding
 - other agencies have adopted these as well



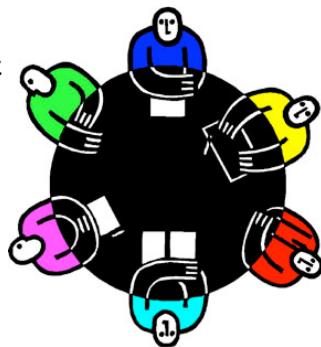
Institutional Animal Care and Use Committee:

- **Required of all Research facilities receiving federal funds**
- **IACUC Responsibilities:**
 - Develops institutional policies
 - Review and approval of experiments
 - responsible for ensuring compliance



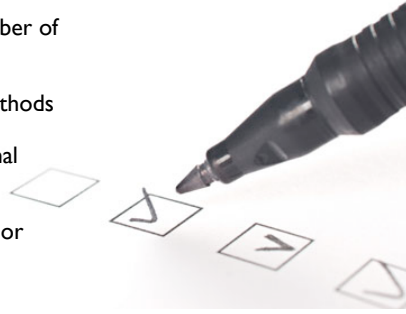
IACUC committee structure

- Committee composed of at least:
 - Veterinarian
 - Animal Research Scientist
 - Non-scientist
 - Lay person



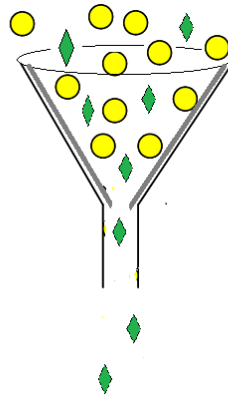
The IACUC reviews and approves all animal experimental procedures.

- Criteria
 - Rationale and purpose
 - justification of species and number of animals
 - consideration of alternative methods
 - training and experience of animal handlers and researchers
 - appropriate sedation, analgesia, or anesthesia
 - unnecessary duplication of experiments



Animal research funding goes through many levels of review prior to approval.

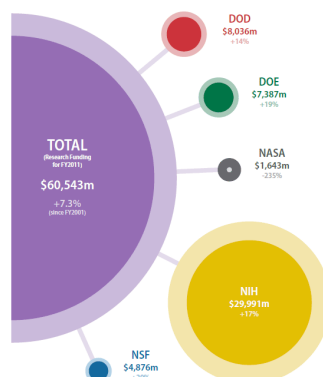
- Scientific Peer review
 - Is the science good?
 - Is the scientific question valid?
- Veterinary review
 - Are animal protocols appropriate?



Majority of animal research supported by federal funding

- Administrative review for funding:
 - is it important?
 - scientific merit
 - goals of funding agency
- Only about 1/5 submitted grants are funded
 - only the best projects are funded

U.S. federal research funding*
Comparison of 2001 and 2011 levels in the five major S&T agencies (in constant 2011 dollars)
*These data are basic and applied research only. They do not include R&D facilities and capital equipment or development funds.



U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training.

- Procedures involving animals must be relevant to human or animal health;
- The minimum number of animals must be used to obtain valid results;
- Alternatives to animals must be considered.
- Living conditions for animals must be appropriate for their species;
- Research scientists and those caring for the animals must be properly trained and qualified.



The 1985 Health Research Extension Act makes previous policies of the U.S. Public Health Service into law.

- Animal Welfare Act (amendment)
- Covers facilities with funding from:
 - National Institutes of Health,
 - Food and Drug Administration,
 - Center for Disease Control and Prevention



American Association for the Accreditation of Laboratory Animal Care

- private nonprofit organization
 - promotes the humane treatment of animals in science
 - voluntary accreditation program.
 - certifies research institutions
 - Trains animal technicians.



<http://www.aaalac.org/>

Scientific Journals and Societies have guidelines for animal use.

- Professional Standards
 - Minimal requirement is following federal and local laws
 - Most have additional, more strict criteria.
- Only those studies completed within the guidelines can be published.



Assignment

Assignment

Humane care of laboratory animals?

The United States government has established a series of laws, enforcement agencies, and review of animal research before, during, and after providing funds for the projects. However, just as violent activists affect the public's perception of peaceful animal welfare protestors, rare examples of unethical animal research damage the reputation of the majority of responsible animal scientists.

In your discussion group:

Discuss whether or not the policies, inspections, review, and enforcement procedures currently in place are sufficient to maintain humane care and use of animals in research.

Readings

Chapter 13. Legislation, regulation and policy relating to scientific procedures on animals. pp. 217 - 238. in Nuffield Council on Bioethics, (2005). *The Ethics of Research Involving Animals.*

http://www.nuffieldbioethics.org/go/ourwork/animalresearch/publication_178.html

Tutorial: PHS Policy on Humane Care and Use of Laboratory Animals. Office of Laboratory Animal Welfare, National Institutes of Health.
<http://grants.nih.gov/grants/olaw/tutorial/index.htm>



Portrait of an old woman reading
Gerard Dou, c. 1630

Any Questions?

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<http://www.vipitbullkennels.com/images/animated-question-mark.gif>