Study Director and IACUC Responsibilities: Consideration of Available Reduction, Refinement, and Replacement Alternative Test Methods

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Animal Welfare Act (P.L. 89-544) 1985 amendments

The standards shall include requirements that:

- "…ensure animal pain and distress are minimized…"
- "…that the principal investigator considers alternatives to any procedure likely to produce pain or distress in an experimental animal…"

Study Director

- FDA 58.3(m)
  The individual responsible for the overall conduct of a nonclinical laboratory study.
- EPA 792.3
  The individual responsible for the overall conduct of a study.
- OECD Section I (2.2.6)
  The individual responsible for the overall conduct of the nonclinical health and environmental safety study.

Principal Investigator

- OECD Section I
  2.2.7. Principal Investigator means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

Principal Investigator

- USDA 9 CFR Section 1.1

  An employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals

Animal Welfare Regulations

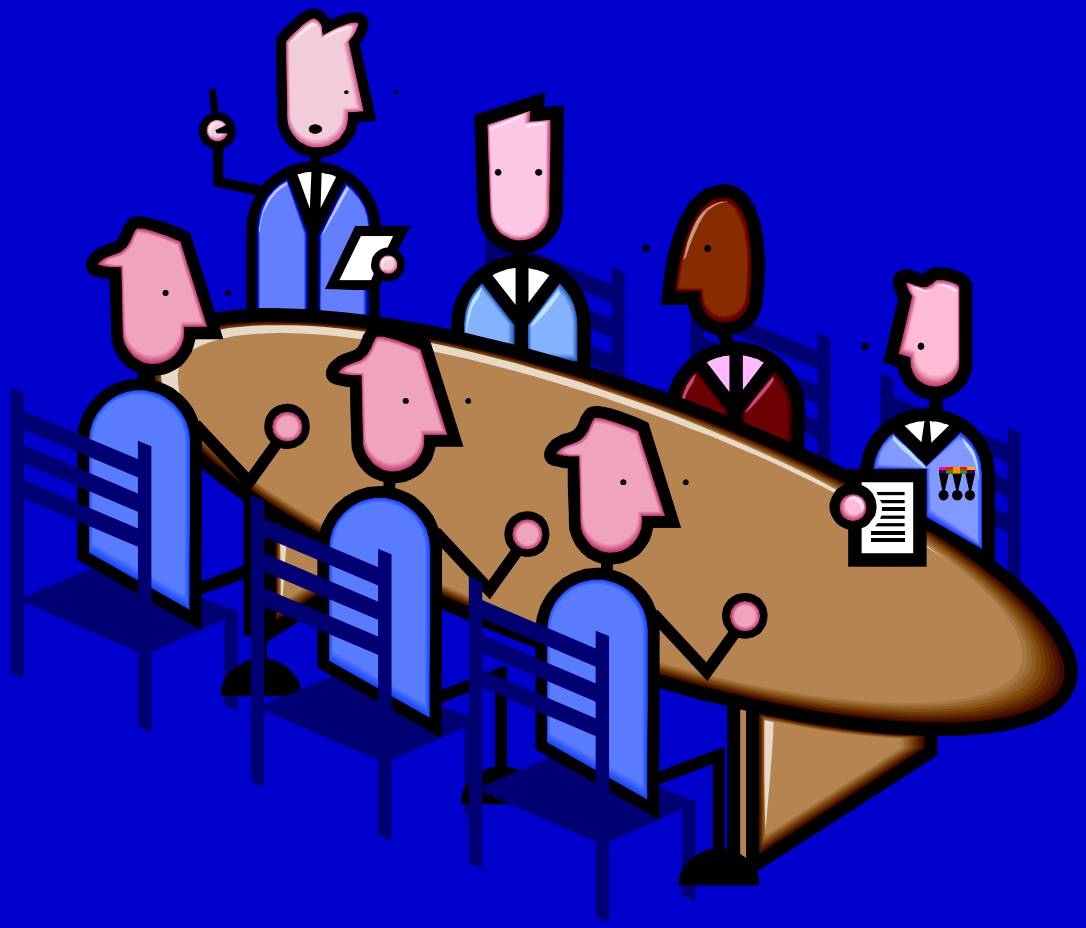
9CFR, Section 2.31(e)(2):

- A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:
  - A rationale for involving animals, and for the appropriateness of the species and number of animals to be used.
  - A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research…

Animal Welfare Regulations

Requires application of all 3 R's:

- Replacement:
  - Justify use of animals
  - Justify appropriateness of the species
- Reduction:
  - Justify number of animals
  - Assure no unnecessary duplication
- Refinement:
  - Assure that pain and discomfort will be limited to that which is unavoidable



Animal Welfare Regulations

9 CFR, Section 2.31(d)(1)(ii):

- The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, *e.g.,* the Animal Welfare Information Center, used to determine that alternatives were not available;

Consideration of Alternatives

- Adequate information for the IACUC to assess if a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods
- If a *bona fide* alternative is identified but not used, the narrative should explain why

Consider what are "alternatives"

Replacement

- *In vitro* test systems
- Organisms with lower sentience

Reduction

- Appropriate statistical design
- Replace some of the animals with non-animal techniques

Consider what are "alternatives"

Refinement:

- Modifications to the protocol that reduce pain or distress to the animal (e.g., better pain control, positive rather than negative reinforcements for training)
- Modifications that enhance animal well-being (e.g., group housing instead of individual, nesting material, foraging activities)

Mandated Regulatory Testing

- Cite the regulation or agency guideline requiring the specific test
- Ensure use of appropriate humane end-point
- Explain reason for not using a validated, agency-accepted alternative

IACUC Resources

- Animal Welfare Information Center http://awic.nal.usda.gov/

Search AWIC

Go

- Search all USDA
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Browse by Subject

- Research Animals
- Farm Animals
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- Government and Professional Resources
- Alternatives
- Literature Searching and Databases
- Pain and Distress
- Humane Endpoints and Euthanasia

The **Animal Welfare Information Center (AWIC)** is mandated by the Animal Welfare Act (AWA) to provide information for improved animal care and use in research, testing, teaching, and exhibition.

In the News

More

The following news stories are selected from external sources.

- "Events for January 2011 - Animal Welfare Info Center Events Calendar http://go.usa.gov/1e7 http://ow.ly/1aORGG" about 6 hours ago
- "Avian Influenza: Japan Is on High Alert as a Virus Infiltrates Bird-Heavy Regions http://ow.ly/1aORGL" about 6 hours ago
- "Event: Critical Evaluation of Use of Dogs in Biomedical Research & Testing http://ow.ly/1aORGH" about 6 hours ago
- "Visit USDA Wildlife Services - @APHISgov - National Western Stock Show in Denver, Jan. 6-23, Expo Hall 3. http://www... http://ow.ly/1aORGJ" about 6 hours ago
- "Wildlife Die-Offs are Relatively Common - @USGSNews - Recent Bird Deaths Caused by Impact Trauma http://bit.ly/dYYO8... http://ow.ly/1aORGI" about 6 hours ago

Spotlights

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GAO Report: Live Animal Imports. Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases.

Farm Animal Welfare and Food Safety Fact Sheets

GAO Report:

Elephants,

I Want To...

- **Find Animal Emergency and Disaster Planning Information**
- **Get Help with an Alternatives (3Rs) Literature Search**
- **Request USDA Forms for Licensing/Registration**
- **Learn About USDA's Regulation of Commercial Animal Dealers**
- **Know Who Needs to be Licensed or Registered Under the AWA**
- **Recommend Materials for the AWIC Web Site**
- **Search the NAL Catalog (AGRICOLA)**

RSS Feeds from AWIC

usda.gov/open

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Enforcement of the Animal Welfare Act

See Also

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Humane Endpoints and Euthanasia

undercu... http://ow.ly/1aQSFc" about 1 hour ago
- "Canada hospitals bow to U.S. group, quit using pigs - NationalPost.com -Two Canadian hospitals have decided to stop ... http://ow.ly/1aQ3qG" about 23 hours ago
- "Webinar: Rodent Analgesia Part 2 - Management of Pain in Laboratory Mice and Rats http://ow.ly/1aPb8p" 9:27 PM yesterday
- "Events for January 2011 - Animal Welfare Info Center Events Calendar http://go.usa.gov/1e7 http://ow.ly/1aORGG" 2:27 PM Jan 11th
- "Avian Influenza: Japan Is on High Alert as a Virus Infiltrates Bird-Heavy Regions http://ow.ly/1aORGL" 2:27 PM Jan 11th

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Spotlights

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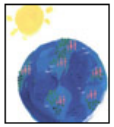
GAO Report: Live Animal Imports. Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases.

Farm Animal Welfare and Food Safety Fact Sheets

GAO Report: USDA's Oversight of Dealers of Random Source Dogs and Cats

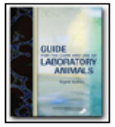
Elephants, 2010



ICCVAM Recommendations to Provide for More Humane Eye Safety Testing

Zebrafish, 2010

Recent Animal Welfare Act & Horse Protection Act Enforcement Actions



Update of the Guide for the Care and Use of Laboratory Animals

Last Modified: Nov 10, 2010

Enforcement of the Animal Welfare Act

See Also

- National Institutes of Health, Office of Laboratory Animal Welfare (NIH, OLAW)
- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- Association of Zoos and Aquariums (AZA)

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IACUC Resources

- Animal Welfare Information Center
  http://awic.nal.usda.gov/
- Altweb
  http://altweb.jhsph.edu/
- ICCVAM
  http://iccvam.niehs.nih.gov/

Animal Welfare Information Center
http://awic.nal.usda.gov

Providing information for improved animal care and use in research, teaching, and testing.

Twitter: @AnimalWelfareIC

Arkansas game officials probe mystery of falling birds - CNN.com - Arkansas game officials hope testing scheduled to... http://ow.ly/1aHKhN
7:25 AM Jan 3rd via HootSuite

China closes zoos in crackdown on abuse of animals - BBC.co.uk - Officials in China have canceled the licenses of se... http://ow.ly/1aEc4S
8:24 AM Dec 29th, 2010 via HootSuite

Cheetah births at Smithsonian research center grab biologists' attention http://ow.ly/1aEasR
7:25 AM Dec 29th, 2010 via HootSuite

28-Hour Law - Transportation of #Animals. http://go.usa.gov/CV4 http://ow.ly/1aDmuj
8:24 AM Dec 28th, 2010 via HootSuite

ICCVAM Recommendations to Provide for More Humane Eye Safety Testing http://ow.ly/1aDmuk
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Demand grows for 'animal law' expertise - BaltimoreSun.com - Lawsuit, filed against the Frederick County Sheriff's D... http://ow.ly/1aDmul
8:24 AM Dec 28th, 2010 via HootSuite

Animal attraction — how zookeepers and their charges bond - ThisIsBristol.co.uk - The joint paper, titled Human– Ani... http://ow.ly/1aCQk1
4:25 PM Dec 27th, 2010 via HootSuite

Illinois - New Law to Protect Pet Owners Takes Effect January 1, 2011 http://ow.ly/1aCQk2
4:25 PM Dec 27th, 2010 via HootSuite

Feral cat management paper grabs attention of veterinarians - VIN.com - A report published in July by the University... http://ow.ly/1aCOav
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Robins may be festive, but they're the bad boys of bird world http://ow.ly/1aCOaw
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U.S. Government Principles

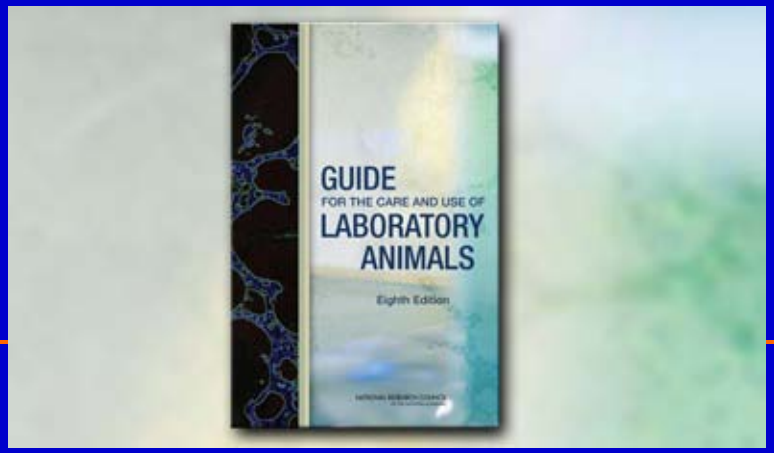
III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

Guide for the Care and Use of Laboratory Animals

Endorses the following principles:

- Consideration of alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals
- Avoidance or minimization of discomfort, distress and pain



Directive 2010/63/EU

Article 13

Choice of methods

1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

   (a) use the minimum number of animals;

   (b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

   (c) cause the least pain, suffering, distress or lasting harm;

   and are most likely to provide satisfactory results.

QUESTIONS?