

Presentation at the Third Plenary Meeting of  
the Advisory Committee on Acoustic  
Impacts on Marine Mammals  
27-29 July 2004  
San Francisco, California

*This presentation is the sole product of the author(s) and does not reflect the view of the Marine Mammal Commission or the Advisory Committee on Acoustic Impacts on Marine Mammals.*

# History

- Prior to 1966 no federal laws to address animal welfare in research
- Basis for current policies is in Health Research Extension Act of 1985 and 1985 Amendment to Animal Welfare Act

# Legislation

- Health Research Extension Act (HREA) – applies to research supported by the Public Health Service (PHS); implemented by the Office of Laboratory Animal Welfare (OLAW)
- Animal Welfare Act (AWA) – applies to institutions conducting research on animals covered under the Act; implemented by USDA (APHIS)

# Mechanism to Assure Welfare of Animals Used in Research

- Both HREA and AWA require :
  - Establishment of an animal care and use program
  - Establishment of guidelines for acceptable animal care in research (PHS Policy on Humane Care and Use of Laboratory Animals; APHIS Animal Welfare Regulations)

# Elements of Animal Care and Use Programs

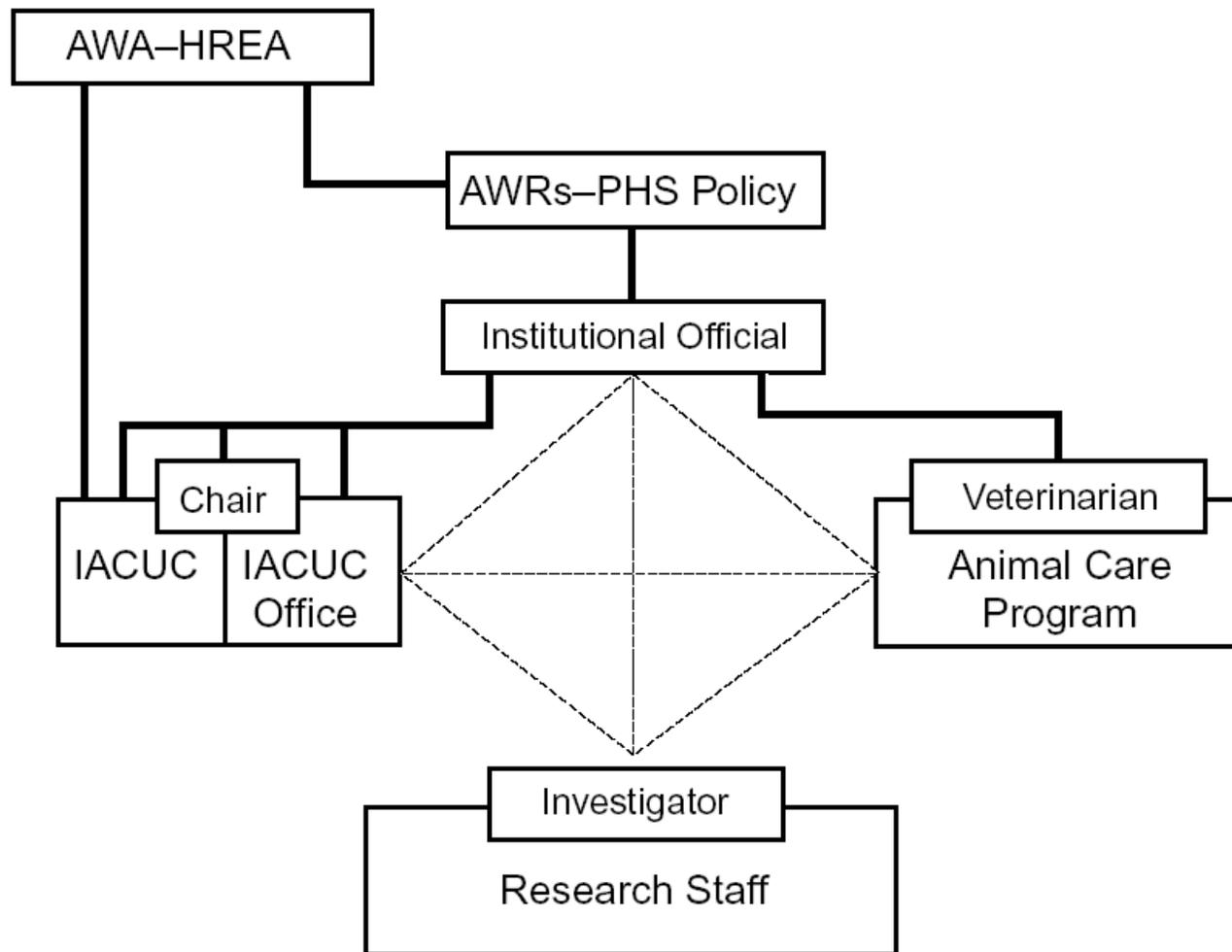
- Properly constituted and functioning animal care and use committee (IACUC)
- Procedures for self-monitoring
- Adequate veterinary care program
- Personnel training program
- Environment, housing & management programs
- Appropriately maintained facilities

# IACUC - Composition

- PHS: At least 5 members:
  - 1 DVM
  - 1 scientist
  - 1 person whose concerns are not science
  - 1 person not affiliated directly or indirectly with the institution
  - 1 public member to represent concerns of use and care of animals in research
- USDA: At least 3 members:
  - 1 DVM
  - 1 person not affiliated with the institution and represents public interest in animal care
  - not more than 3 people from same administrative unit

# IACUC - Authority

- Appointments to IACUC made by CEO (highest officer of an institution)
- Committee reports back to CEO or his/her designate (called Institutional Officer)
- IACUC's authority to review and approve protocols is independent of IO; IO cannot overrule decision to withhold approval
- IO can request further review and not allow research even if IACUC approves a protocol



Solid lines represent mandate from legislation and dotted lines represent cooperation and communication among components

# IACUC – Conflict of Interest

- IACUC members with conflict of interest must be excluded from protocol reviews
  - Personally involved in the activity
  - Involved in competing projects
  - Personal bias may interfere with impartial judgment

# Oversight - Reporting Requirements and Regulatory Agency Visits

- PHS Assurance of Compliance and USDA Registration required
- IACUC must review institution's care and use program semiannually; reports may be required to be submitted to PHS/USDA
- Both PHS & USDA require an annual report
- Site visits may be made annually by both PHS & USDA

# Animal Welfare in Research and Federal Agencies

- Animal Welfare Regulations apply to all federal agencies
- Each agency must establish an IACUC
- One difference in reporting is that deficiencies are reported to the agency head rather than the USDA
- The agency head is responsible for corrective actions

# DoD Example: Additional Requirements for DoD/Navy Marine Mammal Research

- DoD/Navy Specific

Slide provided by Bob Gisiner

- Laws

- Defense Authorization Act

- Regulations and Guidance to Implement the Law

- DoD voluntarily submits to Congress a detailed list of all animal research carried out by or funded by DoD in the prior year. \*
- Legal staff review each proposal's AWA , MMPA, ESA compliance before approving release of funds.

- Reporting and Inspection Requirements

- An extensive, detailed Animal Care and Use protocol is required, and is reviewed by the DoD Veterinarian.
- Copies of IACUC approval letter, APHIS inspection reports, NMFS permit and annual reports are all required. \*
- institutional membership in AAALAC is strongly encouraged. \*

\* involves animal ethicist and concerned citizen participation, input

# DoD Example: The Bottom Line for the Navy-funded Marine Mammal Researcher

- All research interacting in any way with marine mammals must have a NMFS permit
  - permits are reviewed by MMC, public.
  - permit approval (not application) must be in our files before funds can be released.
  - copies of permit annual reports are required.
- Laboratory or field hands-on researchers must additionally provide:
  - an extensive DoD ACU Protocol (30-40 pages, typically)
  - a copy of a current institutional IACUC approval letter
  - a copy of the most recent APHIS inspection report
  - AAALAC certification is strongly encouraged.
- Non-U.S. researchers must
  - complete a DoD ACU protocol for review by DoD Vet
  - have an institutional IACUC process comparable to U.S. process
  - provide facilities and care that meet or exceed US standards
- In addition to pre-award requirements, all projects must:
  - provide annual reports on NMFS permit status, APHIS inspections, IACUC review, AAALAC status.
  - receive site visits from DoD Veterinary staff, annually or as needed.

# Guidelines and Criteria

- Basis for criteria comes from: U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. May 20, 1985. 50 FR 20864
  - PHS Policy on Humane Care and Use of Laboratory Animals
  - USDA Animal Welfare Regulations 9 CFR, Part 2, Subpart C

# Selected Principles

- Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. ... investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or,

# Issues Based on USDA Inspector's Survey

- IACUCs do well at developing a review process, but do less well at monitoring and follow through
- Specific concerns about IACUCs:
  - Lack of power & authority by IACUC
  - Undue influence by PIs
  - Failure of outside members to be active & representative
  - Inadequate reporting
  - Poor training of IACUC members on standards
  - Failure to recognize painful or stressful procedures
  - Inadequate effort to search for alternatives

# Issues - Continued

- Feeling by APHIS inspectors that they need more time for thorough review of records
- Does APHIS enforce failures to adequately review protocols and assure animal welfare?
- What happens if Federal agencies don't have the will to assure proper animal welfare in research protocols?

# The “Real” Issue

- The legislation does not prohibit research that causes pain, stress or injury, and allows for “humane” killing of animals for research. The decision to allow or disallow a project is a balancing of the level of harm with the scientific gain. Here there is no black and white or right and wrong. The final decision when “substantial” harm or death may occur comes down to the personal beliefs of the collective IACUC members, and must weigh the impact to individuals against the benefit to the population.

# International comparison of animal experimentation regulation

	UK	FRA	GER	SWITZ	SWE	NETH	JAP	USA	AUS
<b>Personal Licence</b>	Yes	No	No	No	No	No	No	No	No
- training required	Yes	No	No	No	No	No	No	No	No
- specific to species	Yes	No	No	No	No	No	No	No	No
- specific to procedures	Yes	No	No	No	No	No	No	No	No
<b>Project Licence</b>	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
- government assessors	Yes	No	Yes	Yes	No	Yes	No	No	No
- training required	Yes	Yes	No	Yes	Yes	Yes	No	No	No
- cost-benefit assessment	Yes	No	No	No	No	No	No	No	No
- must use alternatives	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
- 'lowest' species	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No
- anaesthetics	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
- re-use of animals banned	Yes	No	Yes	No	No	No	No	No	No
<b>Institutional Licence</b>	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
- Animal Welfare Officer	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
- housing standards	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
<b>Local Ethical Review</b>	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
<b>Independent Inspectors</b>	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes
- Unannounced visits	Yes	No	Yes	Yes	No	No	No	Yes	No
<b>Record-Keeping</b>	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes

Slide provided by Ian Boyd

**B** banned  
**P** permitted

<b>Wild-caught primates</b>	B	P	B	B	B	P	P	P	P
<b>Great Apes</b>	B	P	P	P	P	P	P	P	P
<b>Cosmetic Testing</b>	B	P	B	P	P	B	P	P	P
<b>LD50</b>	B	P	P	P	P	B	P	P	P