The AWA ....and its consequences!

CL Davis & SW Thompson DVM Foundation
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Grateful Acknowledgment

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Disclaimer

• This is not an ACLAM sanctioned presentation
• All information is deemed reliable and correct
  – No warranty for accuracy
• No information presented is known to be specifically included in the ACLAM Board examinations
• I do not remember what was on the boards
• I do not know what will be on the boards
It all started with a dog …

1966: **Laboratory Animal Welfare Act**

- USDA charged with developing minimum standards of care and treatment with respect to eight areas:
  - housing
  - feeding
  - watering
  - sanitation
  - ventilation
  - shelter from extremes of weather and temperature
  - separation by species
  - adequate veterinary care

**NOTE:** Principally dealt with dogs!
Animal Welfare Act

Public Law 89-544, US Code 7 § 2131-2159,

A statute enacted by Congress in 1966.

This law governs the care & use of animals in research for both gov’t & non-gov’t facilities.

Animal Welfare Regulations

Code of Federal Regulations
9 CFR Chapter 1Subchapter A.

Every regulation listed in the CFR must have an enabling statute (in this case the AWA).

The purpose of the regulations is to describe in greater detail how an agency should interpret the law.

Animal Care Policy Manual

Guidelines for regulation interpretation (updated Oct 2015)
The Animal Welfare Act (AWA)

Congressional statement of policy  [§2131]
- To insure that animals intended for use in research facilities..... are provided humane care

Standards for humane care  [§ 2143(a)(3)]
- Care, treatment and practices in experimental procedures ensure pain and distress are minimized
USDA Animal Welfare Act

• Applies only within the USA & territories
• Selected species covered by the USDA
• Only applies if using covered species in research, testing, or teaching
• USDA responsible for developing the regulations under the Act
1970: renamed Animal Welfare Act

• Extended oversight beyond the animal holding facilities & into the laboratory

• Research facilities were required to provide an annual report:
  – The number of animals used (by species);
  – Whether pain-relieving drugs were administered or a justification for causing pain, if pain-relieving drugs were not used.

• USDA was required to compile this data in a report to Congress, to be made available to the public.
1970: renamed Animal Welfare Act

- Definition of adequate veterinary care was modified to include appropriate use of anesthetics, analgesics, tranquilizers, and other pain-relieving drugs.
- Was extended to include all warm-blooded species and additional animal uses. The expansion brought animals in zoos, circuses, shows, and the wholesale pet trade under jurisdiction.
1976: AWA – 1st Amendment
(now incorporated within AWA)

- Extended regulation to commercial carriers and intermediate handlers of animals being transported for research, exhibition, and the wholesale pet trade.

- The sizes of primary enclosures for transportation were standardized and regulations for ventilation, ambient temperature ranges, and handling procedures were implemented.

- Secretary promulgated regulations that excluded rats, mice, birds, horses, and farm animals.
1985: Food Security Act (PL 99-198)

- Mandated training of all personnel using animals in research.
- Defined duties and composition of the IACUC.
- Developed standards for exercise of dogs and promote the psychological well being of primates.
- Defined one major operative procedure only - unless scientifically justified or veterinary clinical procedure (no research data)
- Established the verification of unnecessary duplication.
- Requires the search for ‘alternatives to painful procedures’
1990: Food, Agriculture, Conservation and Trade Act  Protection of Pets (PL 101-624)

- Mandated a **minimum holding period of five days** for pounds and shelters before providing any live cat or dog to a “Class B” dealer.
2000: New Definitions

Field Study
• Means any study conducted on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study (observational, photographs, collection of feces).

Field Research
• Means any study that involves an invasive procedure or the potential to cause harm or materially alter the studied animal’s behavior (capture/release, banding, etc.)
2002: Farm Security And Rural Investment Act (PL 107-171)

- Changed definition of animal: “... excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, horses not used for research purposes ...”
The AWA is a Living Document ...

2001

- Rule on marine mammal exhibitors APHIS published a final rule that addressed several issues related to marina, keeping out vermin, necropsy recordkeeping.

2002 – 2007

- Regulation of wholesale dealers of dogs (vs. hunting, breeding, or security purposes), amended the definition of “dealer” to include only wholesale dealers, more regulations on transportation, enhanced protection of VMO from harassment form both registrants and licensees, more penalties and provisions
USDA

Animal & Plant Health Inspection Service

Investigation and Enforcement Service

Animal Care
Veterinary Service
Plant Protection and Quarantine

Western Region
Eastern Region
An Animal is:

- Any live or dead dog (all dogs including hunting, security, or breeding), cat, NHP, guinea pig, hamster, rabbit or any other warm-blooded animal intended for use in research, teaching, testing, experimentation, or exhibition purposes, or as a pet.
An Animal is NOT:

- Birds, rats of the genus *Rattus*, and mice of the genus *Mus* bred for use in research, or
- Cold-blooded vertebrates (e.g. fish or frogs), or
- Invertebrates (e.g. octopus, squid), or
- Horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.
Institutional Official:

• The individual who legally commits (on behalf of research facility) that requirements of AWA will be met.

• The ‘Go-To-Jail’ guy / gal
Attending Veterinarian:

- The individual who is appointed by the Institutional Official to oversee the institution’s program of veterinary care, and who has legal obligation to maintain the health and welfare of the institution’s animals and those used.

- Question: Who can serve as an AV? What are the stipulations?
Any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being

- Requires Attending Veterinary consultation
- Requires an Alternatives to Painful/Distressful Procedures (ATPP) lit search
Study area:

**Study Area**
- Any room, area, enclosure, or other containment outside of a main animal facility where animals are housed for more than 12 hours.
- Requires minimum environmental conditions which meet or exceed core vivarium conditions for animal wellbeing and support.

**Satellite Facility (NIH/PHS)**
- any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours
Random source animals:

- Dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises (Class B)
- Use of Class B animals (especially dogs / cats) should be scientifically justified
Primary Enclosures:

• Any structure or device used to restrict an animal or animals, such as a room, pen, or cage

• Must meet minimums required by the IACUC and the AV

• Must be inspected at least every 6 months
Veterinary Medical Officer (VMO):

- An employee of the USDA/AC who has access at any time to any USDA definition of animal record for that animal OR procedure involving an animal, which is being used for research, testing, or teaching
• An observation by the VMO of an activity which is in their opinion inconsistent with the USDA Regulations/Animal Welfare Act

• A repeat observation at any time is considered ‘continuing non-compliance’ and is potentially a finable offense!
Registration vs. Licensure

Registration
• Nonfederal research facilities
  – Registration is for research
  – Must REGISTER with AC
  – Renewed every 3 years

Licensure
• License for producer
  – Annual
IACUC

• Appointed by the CEO (IO)
• Membership
  – Chair
  – DVM
  – Non-affiliated Member
• At least 3 members
  – No more than 3 members from the same department (or Unit)

Note: Define unit to your advantage when you can!
Functions of the IACUC

1. Must review the program of animal care & use every 6 months
2. Must inspect animal facilities at least every 6 months
3. Prepare reports to the IO at least every 6 months with significant vs minor deficiencies and a plan
4. Must make recommendations to the program of animal care and use
5. Must review and investigate public complaints of animal use
6. Must review and approve/disapprove proposed activities
7. Must review and approve/disapprove proposed significant changes of on-going activities
8. May suspend an activity involving animals which is non-compliant (will be reportable to PHS / USDA / AAALAC)
Procedures must be in accordance with...

- Procedures avoid or minimize discomfort, distress, and pain
- Document the consideration of alternatives to procedures causing pain/distress
- Written assurance that activities are not unnecessarily duplicated
Procedures must be in accordance with...

- Painful procedures will be carried out with:
  - Appropriate sedatives, analgesics, or anesthetics
  - Consultation with the attending veterinarian
  - Will not involve the use of paralytics without anesthesia
- Unalleviated severe or chronic pain will be painlessly euthanatized
- Living conditions appropriate for the species
- Medical care must be available and provided
Procedures must be in accordance with...

- Personnel conducting procedures must be qualified and trained in the procedures to be performed
- All surgeries will:
  - Provide appropriate pre- and post-operative care
  - Be performed in facilities dedicated to that purpose
  - Be performed aseptically
Procedures must be in accordance with...

- No animal will be used in more than one major operative procedure unless:
  - Scientific justification is given in writing by the investigator
  - Surgery is required for routine veterinary care or to protect the health of the animal
  - In other circumstances as determined by the administrator

- Methods of euthanasia must be in accordance with the definition, unless scientific justification is provided in writing by the PI
Protocol Review Process

• All IACUC members get a list of proposed activities

• Any IACUC member may request a FCR of an activity
  – If no FCR, then at least one member must review the protocol

• IACUC members cannot vote on their own protocol (or with conflicts)

• May invite consultants
  – Cannot vote if they are not a member
Protocol Review Process

- Notify investigator in writing of decision; they can respond in writing
- Review activities annually
- Majority of quorum at a convened meeting required for:
  - FCR
  - Protocol suspension
- Suspended activity --> IO must report to APHIS and funding agency
- Other officials at the facility may review
Protocols must include

Must Include:

• Species and approximate numbers to be used
• Rationale for animal use and appropriateness of species
• Description of animal use
• Description of procedures to minimize pain

Review Options per AWA:

1. Approve,
2. Require modifications to secure approval (not approve with modifications), or
3. Withhold Approval

Note: These are all pre-activity actions! The only post activity action on an approved protocol is suspend.
Personnel Qualifications

Research facility must ensure all personnel are qualified. Training and instruction guidance in:

- Humane methods of care and use
  - Ways to minimize pain/distress
  - Use of anesthetics, analgesics, and tranquilizers
  - Methods to report animal care concern

- Utilization of services (information finding) for:
  - Care and use
  - Alternative techniques
  - Duplication
  - The AWA
Veterinary Care

- Registered institutions must have an Attending Vet <not consulting only>
  - Care to animals
  - Voting member of IACUC
  - Part-time or if consulting: need a written program of veterinary care (PVC)
    - Form 7002
    - Regularly scheduled visits (at least semi-annually)

- VC Program
  - Appropriate people, stuff, and support
  - Appropriate methods for care, including weekends/holidays
  - Daily observations of animals
  - Guidance on handling, anesthesia, euthanasia, etc.
  - Adequate pre- and post-procedural care
# Program of Veterinary Care

**INSTRUCTIONS**

For use of this form, see 9 CFR 2.40 (animal welfare regulations, Title 9, Subchapter A, Part 2, Subpart C, Section 2.40)

The attending veterinarian shall establish, maintain, and supervise programs of disease control and prevention, pest and parasite control, pre-slaughter and post-slaughter care, nutrition, examination, and adequate veterinary care for all animals on the premises or the establishment.

A written program of adequate veterinary care between the livestock operator and the veterinarian must be established. The program must include regular visits to the premises by the veterinarian. Scheduled visits are assigned to monitor animal health and productivity.

This form is an essential document for the routine examination of livestock. It serves as a guide to conducting and monitoring the veterinary care plan for our animals.

Pages or blanks which do not apply to the facility should be marked N/A. If the space provided is not adequate for a specific topic, additional sheets may be added. Ensure the additional sheets include section and form numbers.

## SECTION I. PROGRAM ESTABLISHMENT

<table>
<thead>
<tr>
<th>A. LICENSER/GRANT</th>
<th>B. VETERINARIAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. NAME</td>
<td>1. NAME</td>
</tr>
<tr>
<td>2. BUSINESS NAME</td>
<td>2. LICENSE NAME</td>
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<tr>
<td>3. LOCAL LICENSE/GRANT NUMBER</td>
<td>3. STATE LICENSE NUMBER</td>
</tr>
<tr>
<td>4. STREET MAILING ADDRESS</td>
<td>4. BUSINESS ADDRESS</td>
</tr>
<tr>
<td>5. CITY, STATE, AND ZIP CODE</td>
<td>5. CITY, STATE, ZIP CODE</td>
</tr>
<tr>
<td>6. HOME TELEPHONE</td>
<td>6. BUSINESS TELEPHONE</td>
</tr>
<tr>
<td>7. BUSINESS TELEPHONE</td>
<td>7. BUSINESS TELEPHONE</td>
</tr>
</tbody>
</table>

We have read and completed the Program of Veterinary Care and understand our responsibilities.

Schedules and dates include visits every [frequency].

__Signature__

APHIS FORM 7002
AM-2016

Recordkeeping Requirements

Must maintain records:

- Meeting minutes, proposed activities, and significant changes
- Semiannual reports
- Protocol, procedural, animal care records
- Must keep for three years after completion of project (what is a project???)

Must assure medical records for animals:

- Dogs / cats: Health certificate, animal description, USDA number, date of acquisition, vendor information, routine health assessments, treatments
- All records must be available forAPHIS and federal agency inspection and copying (FOIA)
- Must be kept for 3 years after final disposition
Annual Report to USDA

• Submitted by 1 December & signed by CEO/IO
• Period covered: October 1st – September 30th (Federal FY)

Must confirm:
– Acceptable veterinary care standards exist
– Consideration of alternatives to painful procedures
– Adhering to the AWA standards (or exemptions are duly noted)
– AV has appropriate authority to fulfill oversight obligations
– List changes in facilities
– List animals in ACTUAL pain/distress category

NOTE: THIS REPORT IS ACCESSIBLE TO THE PUBLIC!
STAND AND STRETCH!
Other items

• Dog/Cat identification
  – Official tag
    • Information: “USDA”, State and Dealer ID, & Animal Number
    • Cannot reuse within 5 year period
    • Keep 1 year after euthanasia/death
  – Official tattoo
  – Other (≤16 weeks old; pups/kittens with dam; microchip)

• Transport of dog, cat, or NHP
  – Health certificate by a licensed veterinarian
    • Animal inspected ≤10 days
    • Free of any infectious disease or physical abnormality (*research exception*)
Animal Welfare Act & Regulations - Part 3

Specific Provisions for Covered Species:
- Identification
- Housing structure; Housing conditions; Housing density
- Sanitation
- Transportation
- Surveillance
- Veterinary Care; Husbandry Minimums
- Exercise Program (dogs)
- Psychological Wellbeing (NHP)

Exemptions:
- AV approved (revisited q 30 days)
- Scientifically justified & IACUC approved (q 12 months)
Dog and Cat Facility Highlights

- Common sense items
- Hard surfaces in contact with D/C spot-cleaned daily
- Temperature range: 45°F - 85°F (with exceptions if >4hrs)
- Outdoor housing: Shelter must be large enough to allow all animals to sit, stand, lie, and turn freely.
Dog and Cat Facility Highlights

- **CATS:**
  - At least 24 in high
  - Cats up to and including 8.8 lbs (4 kg): at least 3.0 ft² (0.28 m²)
  - Cats over 8.8 lbs (4 kg) must be provided with at least 4.0 ft²
  - Clean litter can be floor space (not food/water space)
  - ≤ 12 adults in one room
  - Elevated resting surface
Dog and Cat Facility Highlights

- **DOGS**
  - At least 6 inches taller than the standing dog
  - And long enough ..... The calculation is:
  - $\leq 12$ adults in one room
  - Innovative = approved by IACUC

- Measured from base of tail to tip of nose
- \[(\text{length of dog in inches} + 6) \times (\text{length of dog in inches} + 6) = \text{required floor space in square inches} / 144 = \text{square feet of required floor space}\]
Dog and Cat Care Highlights

Exercise for dogs

- Develop, document, and follow a plan
- Plan must be approved by AV
- >12 weeks old in individual pens < 2x required floor space or
- Grouped with <100% floor space per dog
- Isolated, then needs positive physical contact with a human daily
- Cannot force exercise
- Exempted
  - AV deems appropriate; non-permanent then vet reviews Q30d
  - Scientific justification approved by IACUC
  - Reviewed annually

- Feed at least SID
- Items sanitized every 2 weeks
  - Live steam
  - Hot water (180°F)
  - Detergents and disinfectants
Dog and Cat Transportation Highlights

• In general things happen in 4 hours
  – Max time accepted before departure
  – Max time food/water offered before departure
  – Time out of temp range (except 45 mins on the move)
  – Observed (ground transport or accessible during flight)

• Temperature certification
  – If <50°F but not lower than XXX
  – Veterinarian has to sign HC within 10 days
Dog and Cat Transportation Highlights

- Terminal facility and no one is home, contact attempt every 6 hours for 24 hours; return after 48 hours
- Top and one side: “Live Animal” with 1” high letters
- Ventilation
- Maximum occupancy during travel
- Offer food Q24 hours and water Q12 hours
Guinea Pig and Hamster Highlights

• Common sense items
• Temperature range: 60°F - 85°F
• Outdoor housing: NOT HAMSTERS; GP require Deputy Administrator approval

GUINEA PIG

<table>
<thead>
<tr>
<th>Weight or stage of maturity</th>
<th>Minimum space per guinea pig (square inches)</th>
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<tbody>
<tr>
<td>Weaning to 350 grams</td>
<td>60</td>
</tr>
<tr>
<td>350 grams or more</td>
<td>90</td>
</tr>
<tr>
<td>Breeders</td>
<td>180</td>
</tr>
</tbody>
</table>
Guinea Pig and Hamster Highlights

- **HAMSTERS**
  - Can be fed on the ground

- **Transportation**
  - Need vet certificate if out of temperature ranges (45°F - 85°F)
  - ≤15 guinea pigs and ≤50 hamsters per container
  - Minimum space
  - Food and water Q6hrs

<table>
<thead>
<tr>
<th>Age</th>
<th>Minimum space per hamster (square inches)</th>
<th>Maximum population per enclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dwarf</td>
<td>Other</td>
</tr>
<tr>
<td>Weaning to 5 wks</td>
<td>5.0</td>
<td>10.0</td>
</tr>
<tr>
<td>5 to 10 wks</td>
<td>7.5</td>
<td>12.5</td>
</tr>
<tr>
<td>10 wks or more</td>
<td>9</td>
<td>15.0</td>
</tr>
</tbody>
</table>
Rabbit Highlights

- Common sense items
- Temperature range: 40°F - 85°F; Indoor don’t need heat
- Solid bottom need litter
- Dam with litter need nest box
- Cleaned Q7 days; Sanitized Q30 days
Rabbit Highlights

• Transportation
  – Need vet certificate if out of temperature ranges (45°F - 85°F)
  – ≤ 15 per container
  – Minimum space
  – Food and water Q6hrs
NHP Highlights

- Common sense items
- Hard surfaces
- Spot-cleaned daily
- Sanitized every 2 weeks
- Temperature range: 45°F - 85°F (with exceptions if >4hrs)
- Outdoor housing: Shelter must fit all and need a perimeter fence (6’ high and 3’ from primary enclosure)
- Space requirement based on category...
- Restraint >12 hours require daily unrestrained activity for one continuous hour during period of restraint
Environmental enhancement adequate to promote the psychological well being of NHP

- Plan in accordance with professional standards
- Directed by the AV
- Provisions for social needs (unless aggressive, debilitated, contagious, or incompatible)
- Means of expressing species-typical behavior (swings, perches, toys, foraging)
Environmental enhancement adequate to promote the psychological well being of NHP

- **Special cases:**
  - infants and juveniles
  - those that show signs of being in psychological distress
  - those on protocols that require restricted activity
  - NHPs that cannot see or hear NHPs of their species
  - great apes >50kg

- **Exemptions:** AV Q30days or IACUC-approved
“Our focus over the next 5 years is simple, we will build strong and trusting relationships to promote the humane treatment of vulnerable animals regulated under the Animal Welfare Act and Horse Protection Act – as well as animals affected by emergencies and disasters.

“By fostering a high-performing workforce, and enhancing communication and relationships with regulated entities, stakeholders and the general public, we will be the ‘go to’ source for animal welfare information, expertise and collaboration.”

Bernadette Juarez
Deputy Administrator, Animal Care (AC) Program
2016: New Term on USDA Inspection Reports

**Focused inspection**
Unannounced inspection that does not cover the entire facility

- VMO focuses on the issue of concern
- We have previously conducted focused inspections, but this term will now appear in the heading on the reports
2016: New Term on USDA Inspection Reports

A noncompliance item (NCI)
A finding that does not meet the regulatory requirement

- **Critical NCI**: includes all direct NCIs, falsification of records, and a refusal to allow an inspection.

- **Direct NCI** is a finding at the time of the inspection, that either has a serious/severe adverse effect on animal welfare or has the high potential to have that effect in the immediate future.
Using Microchips to Officially Identify Regulated Animals

Registrants can now use microchips to officially identify their regulated animals \textit{without having to request a variance from the agency.}

- Must do the following:
  - place the microchip in a standard, anatomical location;
  - have a functioning scanner readily available during inspections;
  - maintain records that identify each animal by microchip number, location on the animal, and the name of the microchip manufacturer.
Semiannual Inspections

- USDA agrees with OLAW that the timing of inspections/reviews can include flexibility of *within 30 days of the 6 month interval from the last inspection/review* as long as there is not forward drift of the date from year to year.
- To avoid drift, IACUCs should consider scheduling semi-annuals during the same calendar months from year to year.
2016: Petitions in the Federal Register for Comment

- Publication in the Federal Register is not an indication there will be a regulatory change
- A regulatory change requires following the rulemaking process dictated by the Administrative Procedures Act
2016: Petitions in the Federal Register for Comment

• Petition to Define Alternatives to Procedures That May Cause Pain or Distress and to Establish Standards Regarding Consideration of These Alternatives
  – Petitioned by: Physicians Committee for Responsible Medicine (PCRM)

• Federal Register: APHIS - 2014-0050

• Comment period 3/30- 5/29/2015

• Received 250 comments

• Comments under review
2016: Petitions in the Federal Register for Comment

• Petition to Provide Ethologically Appropriate Standards for Nonhuman Primates in Research
  – Petitioned by
    • New England Anti-vivisectionist Society (NEAVS)
    • North American Primate Sanctuary Alliance
    • Laboratory Primate Advocacy Group
    • Animal Legal Defense Fund (ALDF)

• Federal Register: APHIS 2014- 0098
• Comment periods 5/1/-7/24/2015, 7/24- 8/31/2015
• We received 10,136 comments
• Comments under review
2016: Petitions in the Federal Register for Comment

• Petition to Amend the Reporting Requirements for Research Facilities Under the Animal Welfare Act Regulations
  – Petitioned by: National Anti-Vivisection Society

• Federal Register: APHIS-2015-0033

• Comment period 6/24- 8/24/2015

• We received 1,722 comments

• Comments under review
2016: Petitions in the Federal Register for Comment

- Petition for Animal Care Policy and Inspection Guidance to Ensure the Psychological Wellbeing of Captive Primates in Licensed and Registered Facilities
  - Petitioned by: Humane Society of the United States

- Not placed in the Federal Register for comment because there was a petition already out for comment on a similar topic.
The Inspectors

• Qualified veterinarians who are graduates of accredited veterinary schools
• Receive comprehensive training in the regulatory requirements through the Center for Animal Welfare.
• Perform duties as outlined in the Inspection Guide
Let’s put noncompliance into perspective...

<table>
<thead>
<tr>
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<th>FY 2013</th>
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<td>1111</td>
<td>1097</td>
<td>1112</td>
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<td># of Inspections</td>
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<td># of Direct NCIs</td>
<td>22</td>
<td>26</td>
<td>36</td>
<td>27</td>
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<td># of Repeat NCIs</td>
<td>93</td>
<td>65</td>
<td>91</td>
<td>68</td>
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<tr>
<td>No NCIs</td>
<td>1172 (68%)</td>
<td>1086 (70%)</td>
<td>1109 (73%)</td>
<td>1156 (77%)</td>
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Breakdown

• 571 Total NCIs in FY 2013
  – 38% IACUC related
  – 19% Veterinary care
  – 10% Miscellaneous
  – 7% Sanitation
  – 5% Facilities, General
Top IACUC related NCIs

- IACUC Reports §2.31(c)(3)
- Significant changes to protocol §2.31(c)(7)
- Alternatives §2.31(d)(1)(ii)
- Rationale for use of animals §2.31(e)(2)
- Description of activity §2.31(e)(3)
IACUC Reports

• § 2.31(c)(3)

• IACUC: Prepare reports of its evaluations and submit the reports to the Institutional Official of the research facility
Findings

- Failure to submit a complete report, even though the evaluations were conducted
- Failure to distinguish significant deficiencies from minor deficiencies
- Failure to ensure correction by the date scheduled
Significant Changes to Protocol

• § 2.31(c)(7)
• Review and approve, require modifications to approve, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities
Findings

• Inspectors found no amendment for a significant modification to an ongoing activity.
Consideration of ATPP

• Section 2.31 (d)(1)(ii)

• The PI 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 AWIC, used to determine that alternatives were not available;...”
Findings

• The search criteria do not correlate to the painful or distressful procedure
• Insufficient information on databases used, search parameters, time frame...
Conclusion

• Research community very compliant
• Majority of NCIs are IACUC related
  – IACUC training recommended
Recommendations

• Thorough semi-annual IACUC inspections
  – IACUC training – focus on required documentation

• Be prepared for unannounced inspections
  – Personnel (designated) who know where records are kept and have access
  – Have a back-up person
    • Codes, Keys, etc. available
Had enough? 😊 Questions?