



# **IACUC Administrators Best Practices Meeting Thursday, May 30, 2019**



# Thank you to our Supporters

*Funding for this meeting was made possible in part by*

- *IACUC Administrators Association (IAA)*
- *\* Office of Laboratory Animal Welfare, National Institutes of Health, Department of Health and Human Services*
- *The University of Tennessee, Knoxville*

*\* The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official views of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.*



# Special Thanks to our Guest Facilitators!

- **Gary Borkowski**, Senior Director, AAALAC International
- **Susanne Brunkhorst**, Veterinary Medical Officer USDA, APHIS
- **Neera Gopee**, Director, Policies and Education, OLAW
- **Jane Na**, Veterinary Medical Officer, OLAW



# POST APPROVAL MONITORING OR QUALITY ASSURANCE PROGRAM

## IS THERE A DIFFERENCE?

Erin Czarniak  
Assistant Director - Quality Assurance  
University of Michigan  
Animal Care and Use Office

# GE's PAM Program

- ▶ Until ~2015
- ▶ 4 compliance staff members
- ▶ Yearly PAM visits with PIs and or laboratory personnel
  - ▶ Compare protocol to practice
  - ▶ Report noncompliance (varied)
- ▶ 1 compliance officer

# GE's QA Program

- ▶ Starting in 2016
- ▶ Addition of 5 QA specialists
- ▶ Redistribution of compliance officer role
- ▶ Biennial QA visit with PIs and or laboratory personnel
  - ▶ Discussion about current practices
  - ▶ Identifies PI's programmatic concerns
  - ▶ Find it, Fix it (data to IACUC)
- ▶ Animal Care and Use Faculty Advocacy Committee (ACU-FAC)
- ▶ PI Advocate
- ▶ Laboratory Animal Research Coordinator Certification (LARCC) Program

# Scenario

- ▶ Policy requiring the use of a specific form to notate when mice/rats expected to develop tumors are monitored for endpoints
- ▶ Protocol requires the monitoring of tumor bearing animals 3x/week
- ▶ A yearly PAM/QA meeting with the research lab reveals
  - ▶ The required form is not being completed,
  - ▶ Endpoints are being met, and
  - ▶ Animals appear healthy

# Approaching the problem with PAM

- ▶ Focuses on the identification of noncompliance
  - ▶ Compares protocol with practice
  - ▶ Identifies noncompliance
  - ▶ Reports to IACUC if necessary
- ▶ Reactive process
  - ▶ Identifying existing issues
  - ▶ Working with the PI to fix a problem
- ▶ Focuses on the individual lab/noncompliance
  - ▶ Identifies individual lab issues
  - ▶ Prevents (hopefully) reoccurrences



# Approaching the problem with QA

- ▶ Focuses on the prevention of noncompliance
  - ▶ Asks for feedback
  - ▶ Identifies potential issues
  - ▶ Compares with others
- ▶ Proactive process
  - ▶ Setting up for success
  - ▶ Working with PIs to prevent future issues
- ▶ Focuses on the process
  - ▶ Is it above regulation
  - ▶ Is it serving a purpose?
    - ▶ Helping meet regulation
    - ▶ Benefiting animal welfare
    - ▶ Benefiting compliance office
  - ▶ Identifies programmatic issues
    - ▶ Actively engages PIs
    - ▶ Actively builds relationships
    - ▶ Actively reduces burden
    - ▶ Improves the program

# Beyond the QA Visit

- ▶ Animal Care and Use Faculty Advocacy Committee (ACU-FAC)
- ▶ PI Advocate
- ▶ Laboratory Animal Research Coordinator Certification (LARCC)

# 4 Key Changes

- ▶ The IACUC empowered the QA Team
- ▶ Shift in mindset
- ▶ Research community engagement
- ▶ Focus on the Program, rather than the PI

# Summary

## PAM

- ▶ Focuses on the identification noncompliance
- ▶ Reactive process
- ▶ Looks at the individual lab
- ▶ Verifies quality

## QA

- ▶ Focus on the prevention of noncompliance
- ▶ Proactive process
- ▶ Looks at programmatic processes
- ▶ Manages quality

# Questions and Discussion

**Erin Czarniak**  
**[Leslieer@umich.edu](mailto:Leslieer@umich.edu)**

# Guidelines that Reduce Regulatory Burden: Tumors As an Example

Zach Freeman


11/2019

# What is a guideline?

- Suggested approach to an activity or issue
- Goal is to standardize a process based on “best practice”
- May be IACUC endorsed
  - Not required
- Goal is to help focus on the issue at hand

# When do we need a guideline?

[← ANIMAL CARE AND USE PROGRAM HOMEPAGE](#) [← RESEARCH A-Z GATEWAY](#) [REPORT ANIMAL CONCERNS](#)

**research a-z** | ANIMAL CARE & USE PROGRAM

[ABOUT](#) [FORMS](#) [SOPS](#) [GUIDELINES](#) [POLICIES](#) [INFORMATIONAL](#) [GLOSSARY](#) [LOGIN/INTRANET](#)



I'm Looking for Information About



BROWSE BY ▼

G

## Guidelines on Blood Collection

Unit for Laboratory Animal Medicine | Approval Date: Apr 15, 2016 12:00 am

SHARE

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LOGIN TO BOOKMARK

This document is designed to provide general information on blood collection methods for common laboratory animals. All procedures must be approved by the Institutional Animal Care and Use Committee (IACUC). The method of blood collection to be used, the intervals between blood collection procedures, and the volume of blood to be removed, must be listed in the approved protocol specific to each study.



# How do we determine best practice?

- Regulatory requirements
- Animal Care Program
  - IACUC
  - Veterinarians
  - EHS
- Industry standards
- Scientific standards
- Investigators

# How do we determine best practice relative to endpoints?

- Research outcomes
- Regulatory requirement
- Clinical outcomes
- Welfare considerations

# What is an effective guideline?

- Simplicity
  - ACU
  - Investigators
- Applies to majority of situations
- Allows for high levels of compliance

# Sources of Burden in Guidelines

# Sources of Burden in Guidelines

- Lost focus
- Subjective or Artificial endpoints
- Creating excess work by:
  - Overcomplicating
  - Creating layers of work that are not mandated
  - Dictating elements that are not important to outcomes
  - Creating opportunities for “non-relevant” non-compliance

# Tumors at University of Michigan

- Around 200 protocols for around 120 investigators
- Predominately mouse models
  - Syngeneic
  - Patient Derived Xenografts (PDXs)
- Pharmacology/treatment development
- Cancer immunology/immunotherapy development

# Guidelines and SOP on Tumor Monitoring

Unit for Laboratory Animal Medicine | Approval Date: Nov 15, 2014 12:00 am

To establish a guideline for a tumor monitoring system to be used for animals inoculated with neoplastic cells or toxic agents or animals that are genetically predisposed to develop tumors. Specifically, this guideline applies to neoplasms that are externally observable and measurable or other neoplasms that metastasize to sites where the metastases are externally observable and measurable. This guideline does not cover other types of internal neoplasms without metastases that are not externally appreciable such as leukemia, pulmonary neoplasms, etc. These tumors must still be described in the animal use protocol and are subject to the endpoints described in that document which may include the End-Stage Illness Scoring System and other more specific criteria.

This document is to be used in conjunction with the *End-Stage Illness Scoring System* to evaluate the overall health of the animal and apply humane endpoints when applicable *Policy on Surgical and Tumor Monitoring Records*.

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## RESPONSIBILITY

1. Investigative Personnel
2. ULAM Husbandry Personnel
3. ULAM Veterinary Personnel

What are some areas of burden in these tumor monitoring guidelines?



# What are some areas of burden in these tumor monitoring guidelines?

- Additional layers of “work” to be done that is not mandated
  - Tumor records
    - “New”, redundant system
  - Required monitoring frequencies
  - Cage identification

# What are some areas of burden in these tumor monitoring guidelines?

- Subjective endpoints
  - Investigators decide without much help
  - Unwritten endpoints

# What are some areas of burden in these tumor monitoring guidelines?

- Increased compliance burden
  - Who checks records?
  - Non compliance for record keeping failures
  - Lots of complexity
  - Outcomes of noncompliance?

How can we reduce the burden in these tumor guidelines?

# First Things First: What do the regulations say?

Guide pg 27, 123

- For many invasive experiments, the experimental and humane endpoints are closely linked (Wallace 2000) and should be carefully considered during IACUC protocol review. While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock.
- Criteria for euthanasia include protocol-specific endpoints (such as degree of a physical or behavioral deficit or tumor size) that will enable a prompt decision by the veterinarian and the investigator **to ensure that the endpoint is humane** and, whenever possible, the scientific objective of the protocol is achieved

# What is the goal for this guideline?

- How do we assure animals with tumors have humane endpoints?

# What are reasonable endpoints for external tumors?

- Who should involve to determine this?

# What are reasonable endpoints for external tumors?

- Who should involve to determine this?
  - Animal Care Program
    - IACUC
    - Veterinarians
    - EHS
  - Industry standards
  - Scientific standards
  - Investigators

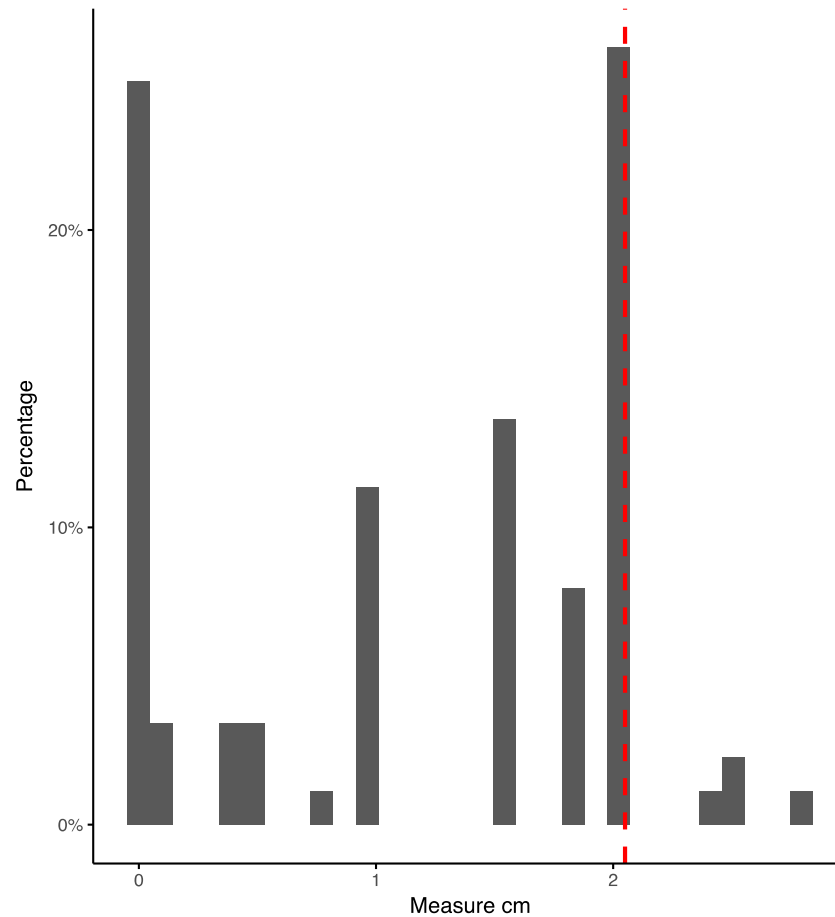


What are reasonable endpoints for external tumors?

# What are reasonable endpoints for external tumors?

- General well being
- Tumor size
- Tumor ulceration

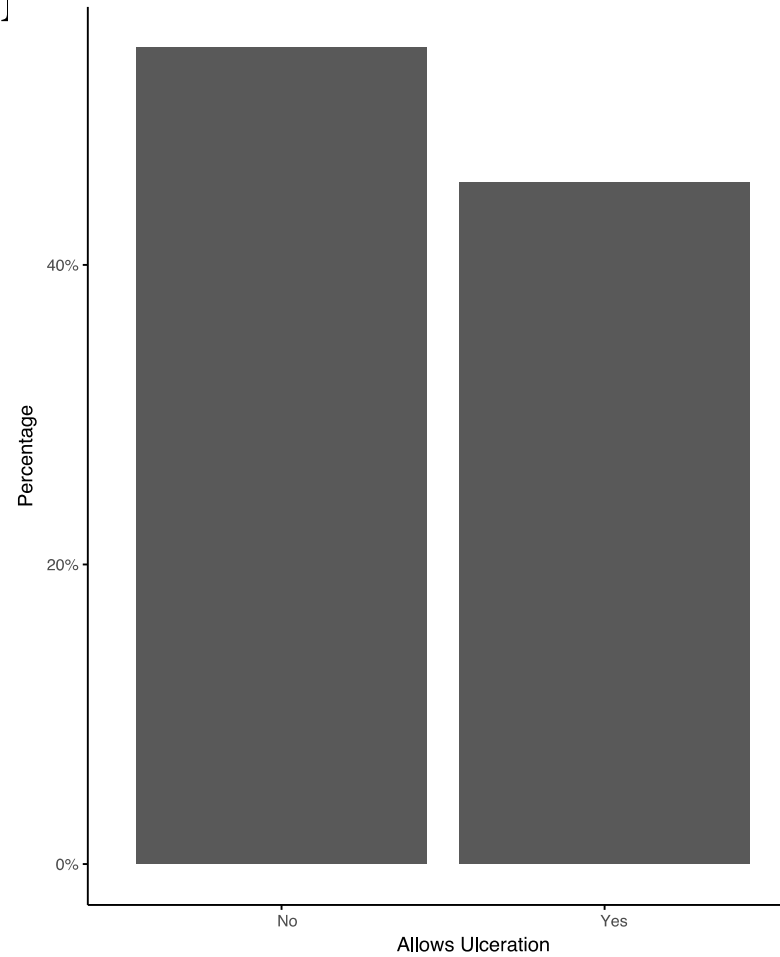
# Distribution of tumor sizes for length endpoints



# Tumor Ulceration

- Perception of being more painful but no evidence to support this
- Clinically no difference in general well-being of the animal between ulcerated and non-ulcerated tumors, especially those that are dry

# Percentage of protocols with tumor ulceration ulceration



# Tumor Ulceration

- Tumors may ulcerate for many reasons:
  - Biology
    - Cell origin
    - Architecture of tumors/Large avascular structures
    - Rapid growth rate
    - Developed for characteristics that differ from originating
  - Irritation of tumor by the animal
    - Seems less likely given the spontaneous nature of tumor formation
  - Response to therapeutic regimen
    - Common with immunotherapies

# Biasing studies by not allowing ulceration?

EUROPEAN JOURNAL OF CANCER 48 (2012) 218–225



Available at [www.sciencedirect.com](http://www.sciencedirect.com)

SciVerse ScienceDirect

journal homepage: [www.ejconline.com](http://www.ejconline.com)



## Ulceration and stage are predictive of interferon efficacy in melanoma: Results of the phase III adjuvant trials EORTC 18952 and EORTC 18991 ☆

Alexander M.M. Eggermont <sup>a,\*</sup>, Stefan Suciu <sup>b</sup>, Alessandro Testori <sup>c</sup>, Wim H. Kruit <sup>d</sup>,  
Jeremy Marsden <sup>e</sup>, Cornelis J. Punt <sup>f</sup>, Mario Santinami <sup>g</sup>, François Salès <sup>h</sup>,  
Dirk Schadendorf <sup>i</sup>, Poulam Patel <sup>j</sup>, Reinhard Dummer <sup>k</sup>, Caroline Robert <sup>a</sup>,  
Ulrich Keilholz <sup>l</sup>, Antoine Yver <sup>m</sup>, Alan Spatz <sup>n</sup>

# Tumor monitoring records



How to we ensure investigators are able to meet humane endpoints?

# How to we ensure investigators are able to meet humane endpoints?

- Ultimately by knowing that animals are not reaching endpoints
- If animals do reach endpoints, having a system in place to work with those labs to retrain/prevent this from occurring
  - Training Core
  - Vets
  - QAs

# How have we altered ability to comply?

- What were the issues before?
- How do we change it going forward?

# Compliance Data Since Change

# Reducing Burden Associated with Guidelines

- Focus on the goal of the guidelines
- Identify sources of burden through feedback and evaluation
- Realign elements based on the goals
- Evaluate how well they help with compliance

# Discussion

# Break-Time





# A Universal Protocol Template (UPT)





## Objectives

1. Progress update
2. Why an UPT
3. Pros and Cons of UPT
4. Ideas
5. Next Steps



# IAA Progress to start?

## OLAW Protocol Sample Template

- Based on a form used by the intramural NIH investigators
- Supplemented with information gathered from templates used by many different other institutions

**Resource:** (<https://olaw.nih.gov/resources/documents/animal-study-prop.htm>)

Home » Resources » Sample Documents for Implementation of the PHS Pol  
» Animal Study Proposal

### Animal Study Proposal



- [Introduction](#)
- [View the animal study proposal](#)
- [Download the sample animal study proposal](#)

## Current Status

1. IAA revised the current OLAW resource template
2. Community weigh-in and review
  - a. Compliance Staff (Best Practice and Beyond the Basics Meetings)
  - b. Veterinary Staff
  - c. Members of the scientific community (i.e., scientists)
3. Presented the idea to FDP in May of 2019
  - a. Formally submitted the idea to FDP
  - b. Development of an UPT was accepted as a formal FDP project



## Why Develop an UPT?

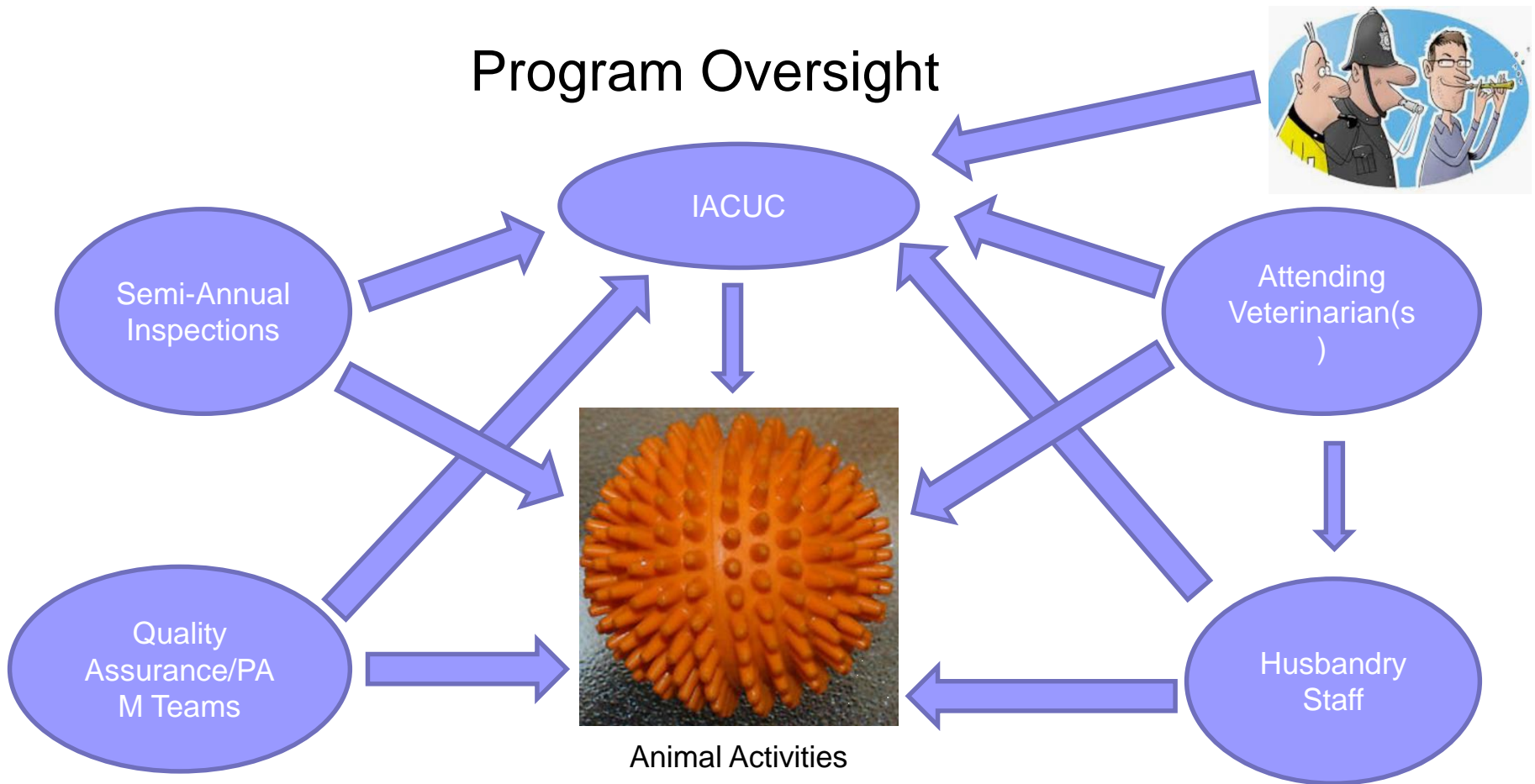
1. Minimize regulatory burden – it's the right time
  - a. Cures Act
  - b. Reducing Administrative Burden for Researchers Report
  - c. The IACUC community, OLAW and the USDA need to strategize to develop an optimal easy to use UPT
2. Build in maximum flexibility for animal procedures
3. Collaborations (i.e., institutions are using the same form)



## Pros

1. The protocol only includes information the IACUC needs to review and approve proposed animal activities (less burdensome for PIs and the IACUC).
2. The use of “check-boxes” that allow PIs to select frequently used procedures.
3. Use the UPT to define “some” specific regulatory expectations.
4. Place trust in other oversight processes used.

# Program Oversight





## Cons

1. Diverse programs across the country, so one size “may” not fit all
2. Extensive document for user’s without smart IT systems (~ 75 pages)
3. Move beyond our current perceptions

# What information needs to be in the protocol?





What information needs to be in the protocol?



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## RESEARCH OBJECTIVES



## ALTERNATIVES TO PAIN



# What information needs to be in the protocol?



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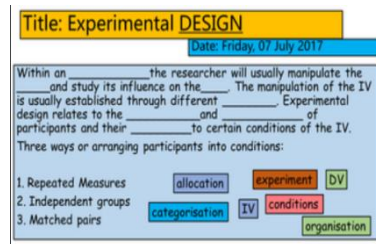
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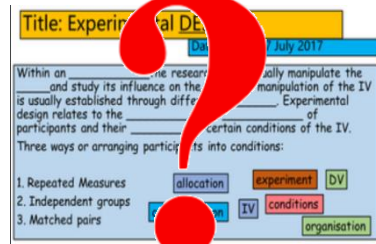


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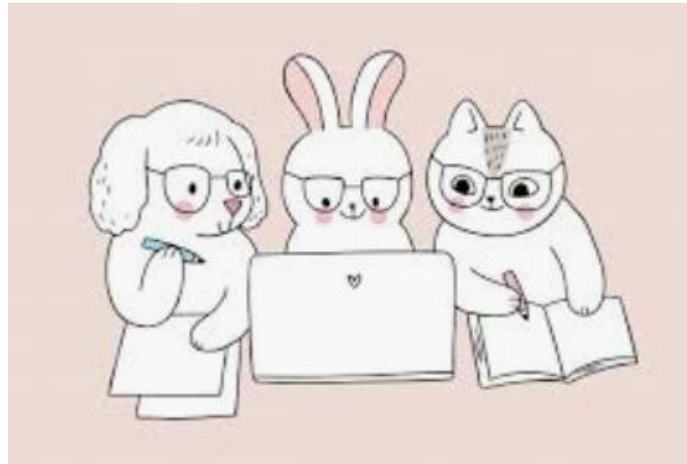




# What information needs to be in the protocol?



Animal Procedures? YES, but how specific!



# A Template for Rodents and One for Others!



Rodents play an invaluable role in biomedical research. Approximately 95 percent of all laboratory animals are mice and rats. Reducing reliance on higher-order species, rodents have become the animal model of choice for biomedical researchers because their physiology and genetic make-up closely resembles that of people. Despite certain differences between people and rodents, the similarities are strong enough to give researchers an enormously powerful and versatile mammalian system in which to investigate human disease.

The sequencing of rodent genomes has enabled researchers to recreate human diseases in rodents through genetic engineering. Researchers “knock in” or “knock out” disease-related traits in mice and rats, and new technology allows researchers to directly edit the DNA of the rodents<sup>[1]</sup>. Research with genetically modified mice and rats has led to significant new treatments, cures and therapies and continues to revolutionize science and medicine.

## Check the Box – “Build in Standardized Procedures”

- ☐ Adult mice or rats will be euthanized by gas (i.e., carbon dioxide or isoflurane) inhalation followed by one of the listed secondary physical methods (i.e., decapitation, bilateral pneumothorax, removal of a vital organ, cervical dislocation) of euthanasia.
- ☐ Up to 1% of body weight in blood (i.e., 1 ml of blood per 100 grams of body weight) may be collected from mice or rats in 14 days or less using either the lateral tail and/or saphenous vein, and/or by tail incision.
- ☐ A tail biopsy up to 5mm in length will be collected from a mouse or rat that is less than 21 days of age for genotyping.

## Human Endpoints?

- ❑ Visible Tumors: A mouse will be euthanized if the diameter of a tumor exceeds 2cm, or if the tumor ulcerates greater than  $\frac{1}{2}$  its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.
- ❑ Visible Tumors: A rat will be euthanized if the diameter of a tumor exceeds 4cm, or if the tumor ulcerates greater than  $\frac{1}{2}$  its surface area, or the tumor develops in an area that impairs normal movement/physiologic behavior.

## How about survival surgery?

Anything Standardized? Maybe surgery prep...

Aseptic technique means to use a series of practices and procedures that help to prevent contamination from pathogens. Survival surgery must be performed using aseptic technique. Consequently, please check yes to provide assurance that the following process will be followed to ensure aseptic technique is used.

The instruments and/or medical devices will be sterilized (e.g., autoclaved) prior to each surgery. The surgical area/table will be decontaminated using an appropriate disinfectant. The surgeon will wear, at minimum, a mask, a surgical cap/bonnet, sterile gloves, and a clean scrub top, disposable gown, or lab coat. The surgical site will be prepared by removing the hair followed by at least three alternating scrubs of disinfectant (e.g., betadine, chlorhexidine) and rinse (e.g., ethanol, warmed saline, sterile water) ensuring to remove any remaining visible debris.

☐ Yes

☐ No, please explain <Text

Box>

## Minimize discomfort, pain...



Steps must be taken to avoid or minimize discomfort, pain and distress associated with the surgical procedure. Please respond to the following information.

1. Please check yes to provide assurance that sterile ophthalmic ointment will be applied to each eye.

☐ Yes      ☐ No, please explain <Text

**Box>**

2. Please check yes to provide assurance that thermoregulatory support will be provided, and the animal will be continuously monitored while under anesthesia.

☐ Yes      ☐ No, please explain <Text

**Box>**



## Current Working Group

1. **Bill Greer**, Assistant VP for Research, University of Michigan
2. **Ron Banks**, Director, Division of Comparative Medicine, University of Oklahoma Health Science Center
3. **Axel Wolff**, OLAW Deputy Director
4. **Bob Gibbens**, Director, Animal Welfare Operations, USDA



## Need Working Group Volunteers

1. Compliance expertise
2. Research Scientists using vertebrate animals
3. IACUC Members



## Proposed Plan

1. Have individuals with compliance background start by reviewing, refining and enhancing the existing UPT.
2. User's groups
  - a. Researchers
  - b. IACUC Members



# Other Thoughts or Ideas?



# Promoting Protocol Flexibility to Prevent Protocol Drift

Jane J. Na, DVM, CPIA

Veterinary Medical Officer, Division of Assurances

Office of Laboratory Animal Welfare, National Institutes of Health



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# Objectives

- Recognize the frequency of reported protocol study issues
- Identify opportunities to promote protocol flexibility
- Discuss examples of how protocols can be written to prevent drift



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# Which is the most common type of reportable incident to OLAW?

- A. Physical plant issues
- B. Animal study protocol issues
- C. Failure to follow institutional policies
- D. Animal husbandry issues



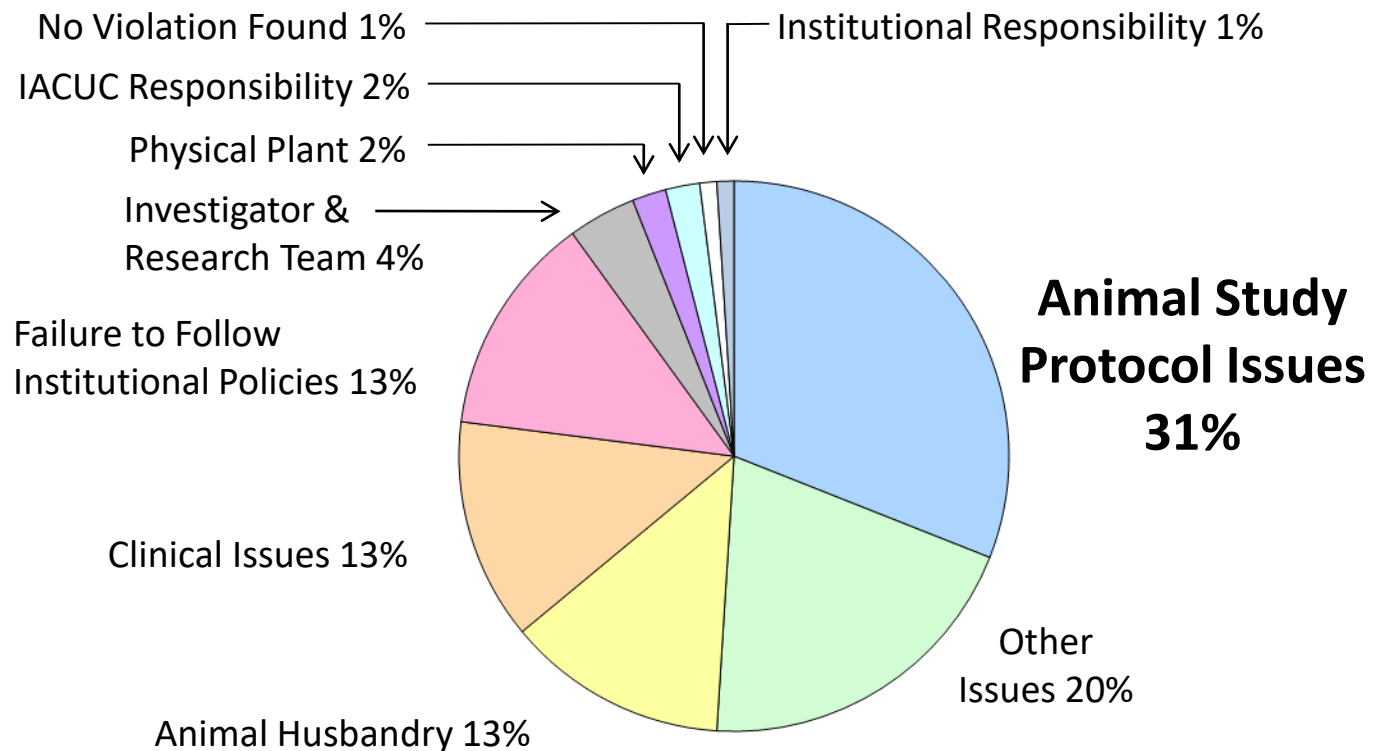
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# Which is the most common type of reportable incident to OLAW?

- A. Physical plant issues
- B. Animal study protocol issues**
- C. Failure to follow institutional policies
- D. Animal husbandry issues



# Types of Reportable Issues

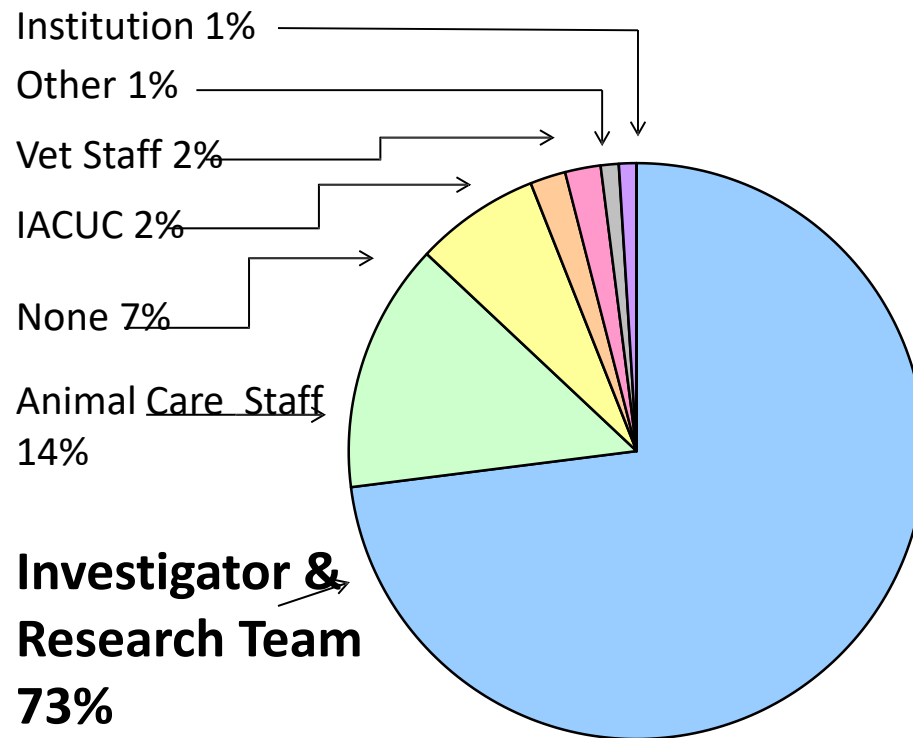


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# Individuals Responsible for Reportable Issues

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# Prevention is Key

- Emphasize the importance of the IACUC-approved protocol
- Promote protocol flexibility
  - New investigator onboarding
  - Protocol writing workshops
  - Incorporate this in the protocol form, include examples
- Assess protocols for flexibility
  - Pre-review
  - Initial approval
  - Continuing review
  - Postapproval monitoring



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Office of Laboratory Animal Welfare

# Avoid Rigidity

- Ranges (or maximums when appropriate)
  - Doses
  - Volumes
  - Durations
  - Frequency of procedures
- Example: Instead of indicating that animals will undergo imaging on days 1, 14, and 30, include the description that animals will undergo a maximum of 3 imaging events in a 30 day period.



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# Include Alternate Methods

- Animal identification
- Blood collection
  - Euthanasia
  - Routes of administration
- Example: Instead of indicating that animals will undergo euthanasia with carbon dioxide followed by decapitation, include the description that animals may undergo euthanasia with carbon dioxide or by overdose of isoflurane anesthesia and after either method, a secondary physical method such as bilateral pneumothorax, exsanguination, or decapitation would be performed.

Alternate methods should only be included when methods proposed for use would not interfere with the validity of the results.



# Citation of IACUC-approved SOPs

OLAW FAQ D14 <https://olaw.nih.gov/guidance/faqs#630>

- For routine aspects of research (e.g., species specific techniques for immunization and titer determinations during antibody production), IACUCs may approve SOPs that can be cited by investigators in their protocols in order to avoid needless repetition.
- SOPs should be reviewed by the IACUC at appropriate intervals no less than every 3 years.

Any deviations from SOPs should be described in the protocol.



# Brainstorm

Write down other examples where flexibility in the protocol form can be used.



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## Compare Lists

In groups of 2-3, compare your lists and discuss.

Be prepared to share some ideas with the whole group.



## Share



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# Objectives

- ✓ Recognize the frequency of reported protocol study issues
- ✓ Identify opportunities to promote protocol flexibility
- ✓ Discuss examples of how protocols can be written to prevent drift



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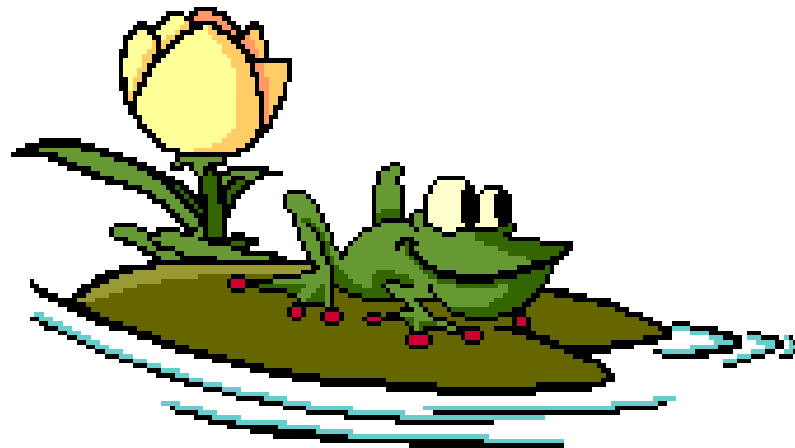


# Questions



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# Time for Lunch!!





VANDERBILT UNIVERSITY  
MEDICAL CENTER

# *Protocol Reviews Efficient Best Practices (i.e., FCR, DMR, VVC, Administrative)*

*Best Practice Meeting  
November 2019*

Erica Armstrong, BS, CPIA  
Associate Director  
Office of Animal Welfare Assurance  
Vanderbilt University Medical Center



# A Word from our Sponsors.....

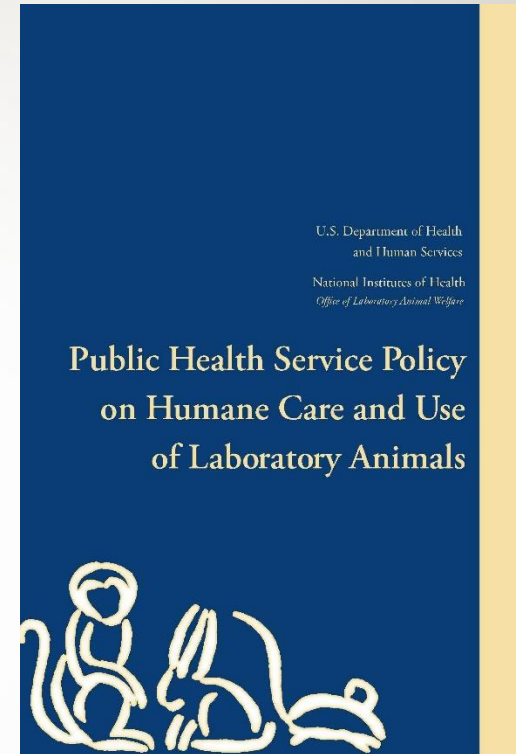
## Public Health Service Policy

### IV. Implementation by Institutions...

#### B. Functions of the Institutional Animal Care and Use Committee ....

6. review and approve, require modifications in (to secure approval) or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy;

7. review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and....





# A Word from our Sponsors.....

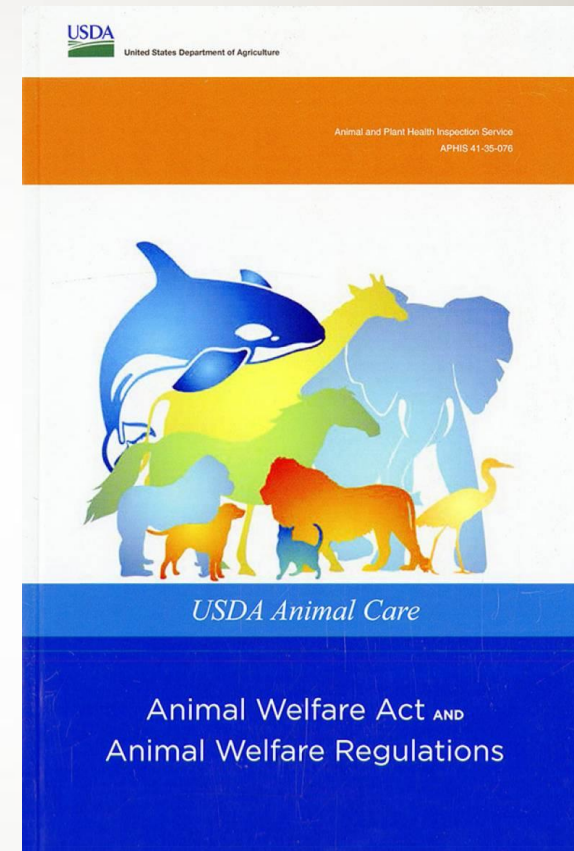
## Animal Welfare Regulations

§ 2.31 9 CFR AWR (1-1-18 Edition)

### PART 2 Subpart C: IACUC functions.

.... (6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section;

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and ....





# Protocol Review Types

FCR: Full Committee Review

DMR: Designated Member Review

VVC Process: Veterinary Verification and Consultation

Administrative



# Protocol Review at Vanderbilt...

## Policies/SOPs:

- SOP on Changes to an IACUC Approved Protocol
- Policy on the Review of Animal Care and Use Protocols

## Submission process: In-house electronic database system:

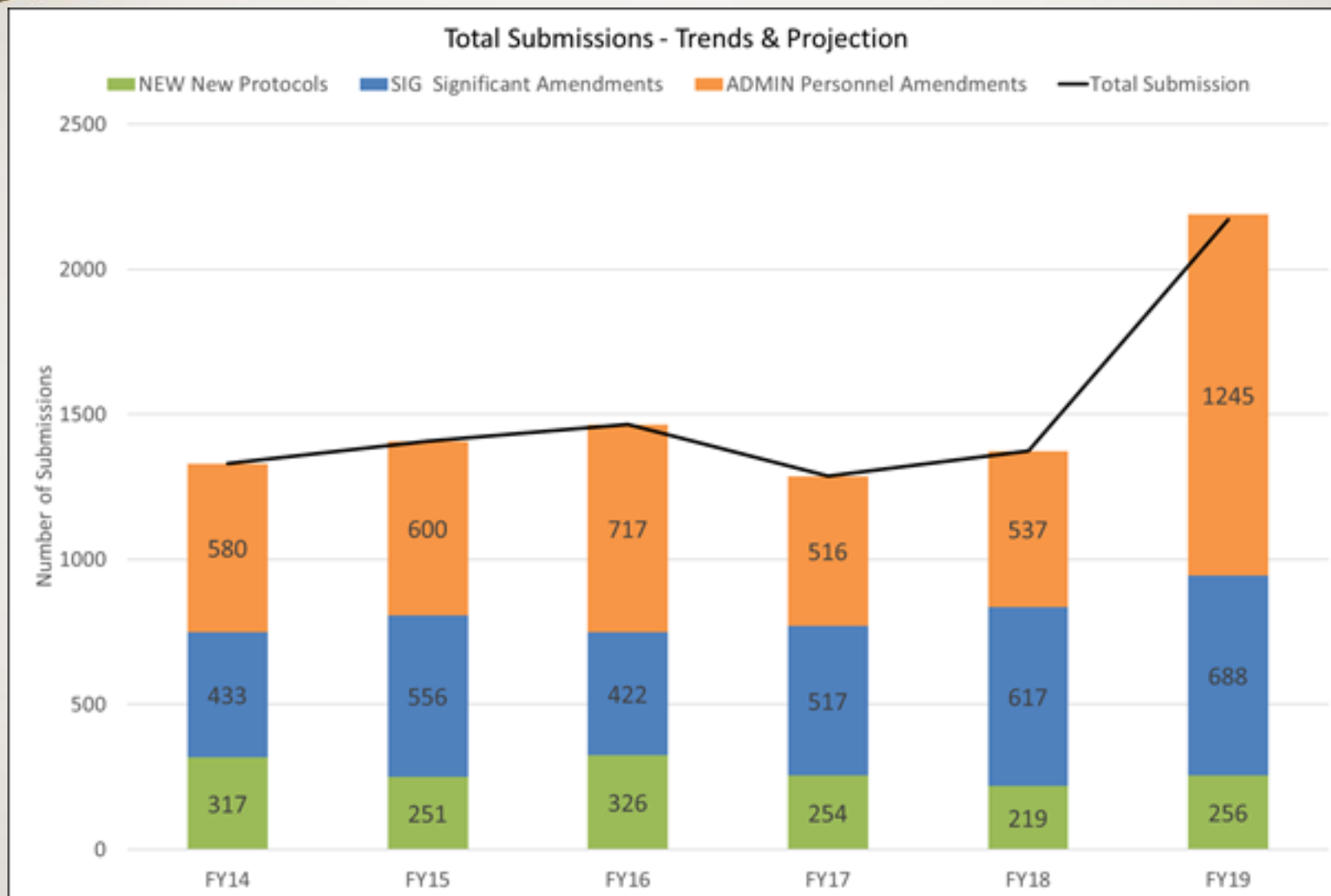
- ✓ Very basic pre-review
- ✓ Assignment
- ✓ DMR mostly (1<sup>st</sup> round 10 days, subsequent rounds 5 days)
- ✓ Administrative: currently just personnel only (average turnaround time is 1 day)
- ✓ Other administrative types (rooms, routes, etc.) - go through the 'regular' review process

Don't use VVC – but can turn it around in 72 hours in a VVC-type of situation





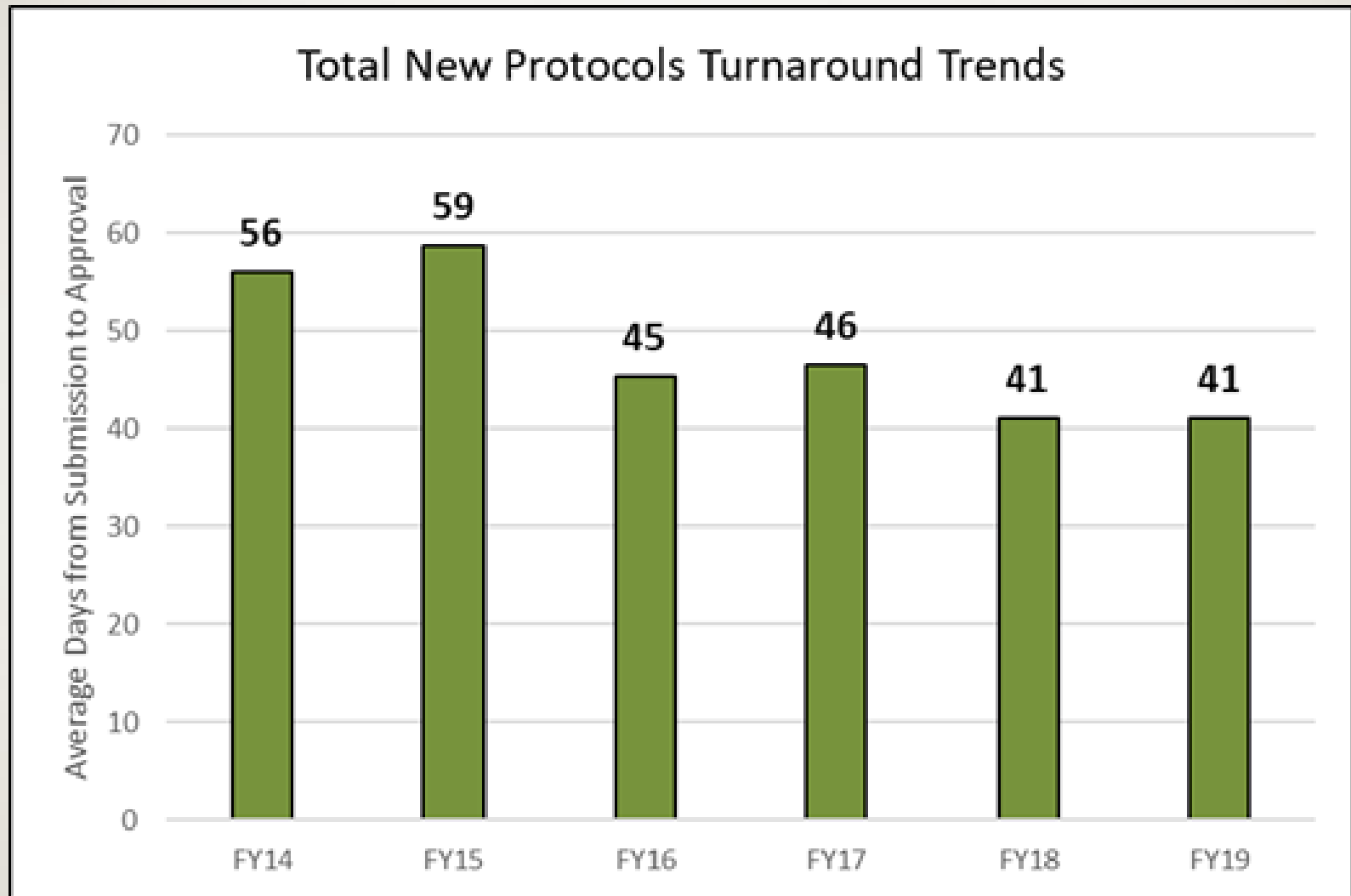
# Trend Data from Vanderbilt







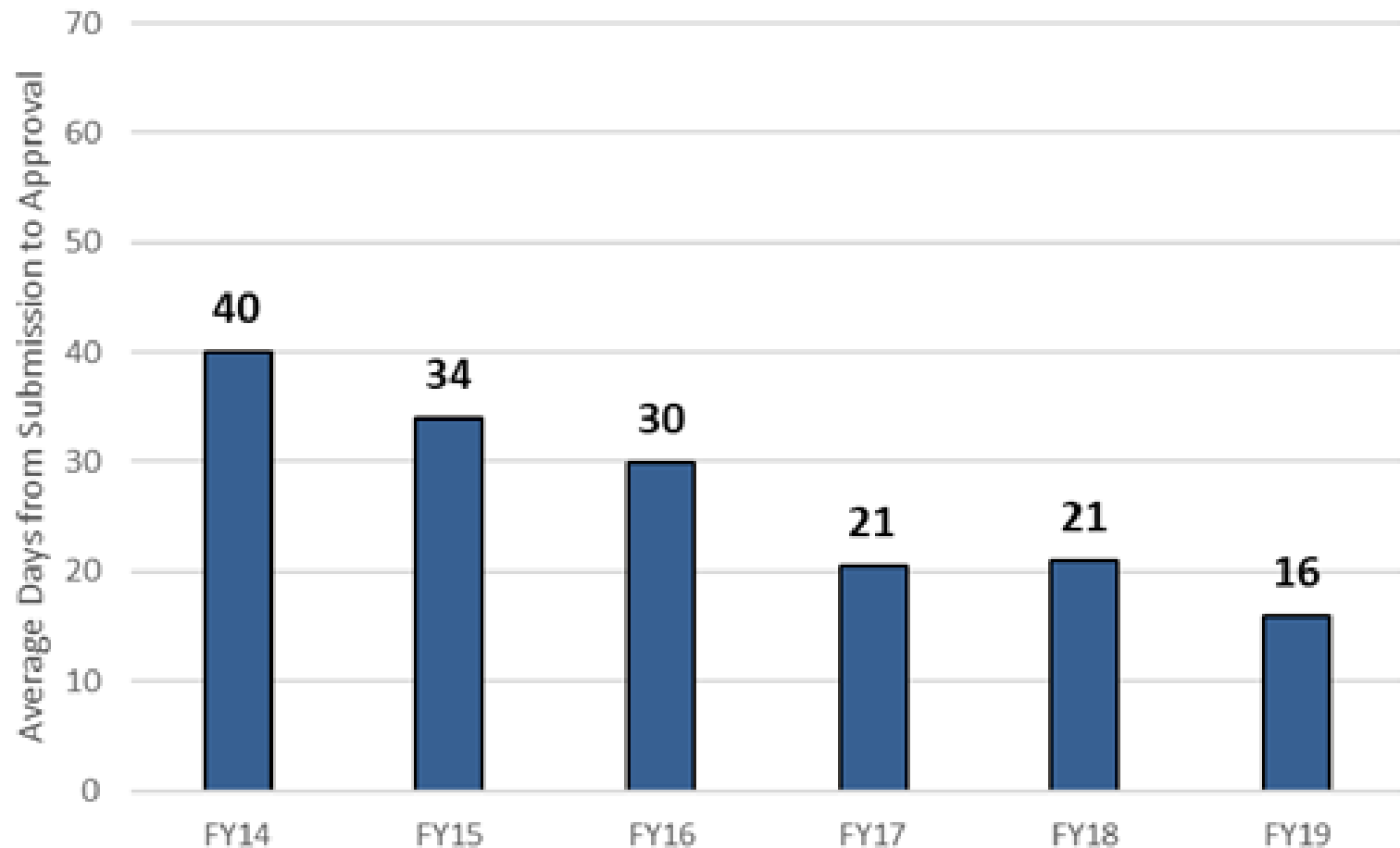
# Trend Data from Vanderbilt





# Trend Data from Vanderbilt

Total Significant Amendment Turnaround Trends





# Your Protocol Review...

- Does your Institution have a Policy/SOP that defines the types of reviews; the types of changes (significant or administrative); the IACUC process?
- Does your Institutions use:
  - Paper/email/spreadsheet system?
  - Electronic system? Completely? Only skeletal information?
  - Some hybrid system with both?
- What process does your Institution use:
  - ✓ Only FCR
  - ✓ FCR & DMR
  - ✓ Use VVC



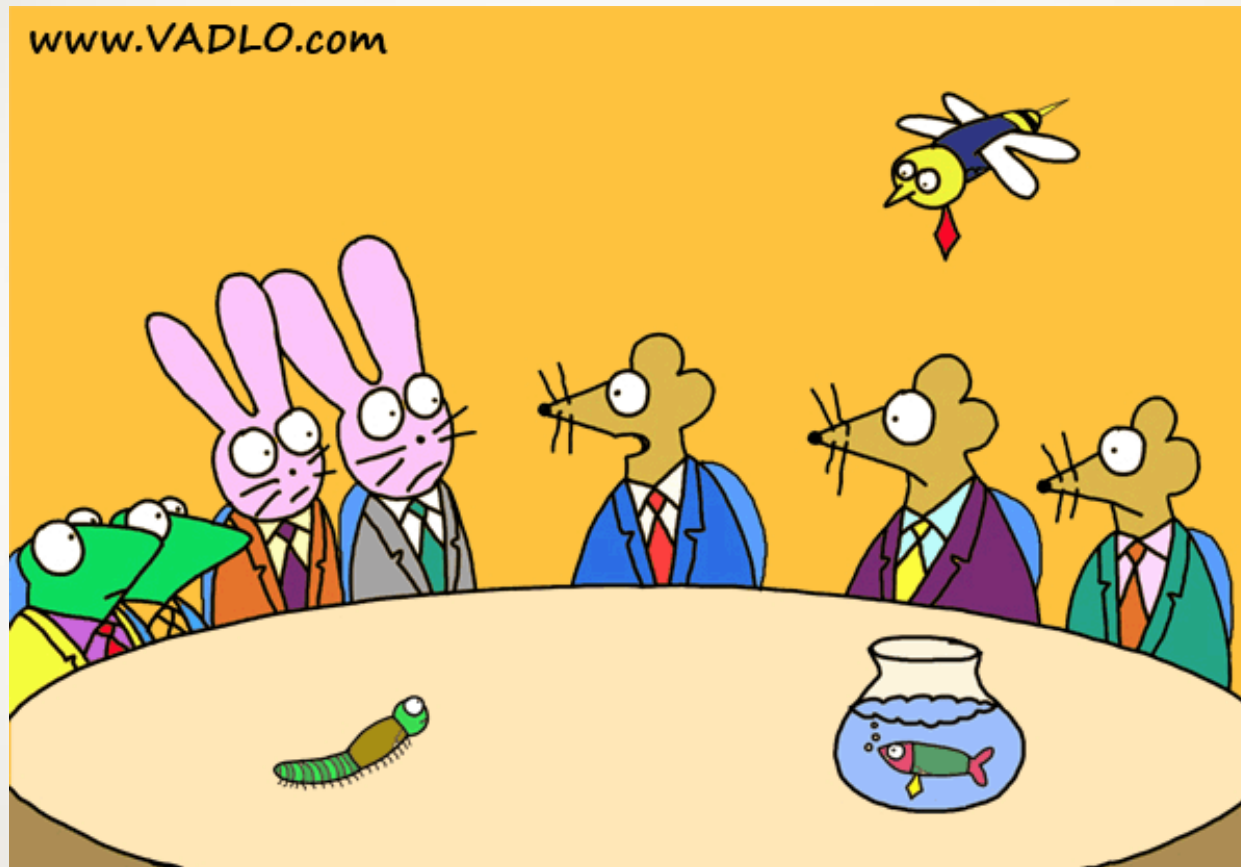
# Efficient Protocol Review – Is there such a thing?

- ❖ It all comes down to turnaround times, the PI wants it yesterday but the reviewers are busy folks.
- ❖ Each Institution/IACUC has to find their own way.
- ❖ What works for your Institution/IACUC may not work for mine.
- ❖ Is there a right answer.....?





# Discussion





# **Service Animals, Emotional Support Animals, & Pets**

**On Campus & In the Research Facility?**



# Campus Populations



- Approximately 61.5 million Americans (1:4) experience a mental health impairment in any given year.
- Approximately 13.6 million people (1:17) live with schizophrenia, major depression, or bipolar disorder.
- Increasing numbers of people claim they have been discriminated against because of their mental disability.
- Psychological disorders now account for the second greatest number of disability claims.
- Laws affecting physical & mental health afflictions:
  - Americans with Disabilities Act of 1990 (ADA)
  - Americans With Disabilities Act Amendments Act of 2008 (ADAAA)
  - Veterans Assistance Act of 2008



# ADA/ADAA Background



- ADA (1990) was being interpreted increasingly narrow by the Supreme Court, so in 2008 Congress passed the ADAAA to construe interpretation “... in favor of broad coverage of individuals ...” (42 U.S. Code). The focus must be on whether discrimination occurred and not on whether a person meets the definition of disabled.
- However, accommodations involving modifications or adjustments in policies, practices, procedures, or environments that enable qualified individuals with a disability to enjoy equal opportunities and access to university rights, privileges, benefits, and services are still not required if they cannot be made “without much difficulty or expense” (42 U.S.C. § 12181(9))



# What is in a Name?



- Service animals
- Companion animals
- Comfort animals
- Emotional support animals
- Visitation animals
- Therapy animals
- Therapy/emotional support animals
- Assistive animals
- Assistance animals
- Psychiatric service animals
- Pets

# Service Animals



- Service animals must generally be provided access to all campus locations.
- Guide dogs that assist people with visual impairments or blindness are the archetypal example of a service animal.
- The DOJ defines a service animal as “any dog [some exceptions for a miniature horse] that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability” (p. 56269).
- Other species of animals are not service animals for the purposes of this definition. The DOJ is explicit that the following animals are *not* considered service animals under the ADA and ADAAA:
  - Any animals besides dogs;
  - Animals that serve solely to provide a crime deterrent effect; and
  - Emotional support, comfort, or companionship animals (DOJ, 2011).
- The work or tasks performed by a service animal must be directly related to the individual’s disability and can include a wide variety of services, such as assisting those with low vision, alerting individuals who are hard of hearing, pulling a wheelchair, and retrieving items such as medicine or the telephone.

# Service Animals



- Service animals may perform a variety of critical functions that assist many individuals with psychiatric disabilities, including alleviating symptoms of PTSD, anxiety disorders, and panic disorders by calming the handler and reducing physical and mental effects like severe depression, preventing or interrupting impulsive or destructive behaviors, such as self-mutilation, and interrupting inappropriate repetitive behavior with a persistent nudging task.
- A service animal may be trained by a non-certified professional, a friend, a family member, or the person with the disability.
- Service animals are working animals and must be harnessed, leashed, or tethered, unless these devices interfere with the animal's work or the individual's disability prevents using these devices. In that case, the person must maintain control of the animal through voice, signal, or other effective controls.
- A service dog is not required to be registered or wear a special tag or vest identifying it as a service animal.

# Service Animals



- When it is not obvious what service an animal provides, staff may only ask only two questions:

- (1) Is the dog a service animal required because of a disability? and
- (2) What work or task has the dog been trained to perform?

Any inquiry beyond these two questions opens up organizations to litigation.

- You CANNOT:

- Ask about the person's disability,
- Require medical documentation,
- Require a special identification card or training documentation for the dog, or
- Ask that the dog demonstrate its ability to perform the work or task.

# Service Animals



- Access can be denied even to Service Animals.
- Safety considerations for denying an accommodation must be based on actual risks, rather than on mere speculation, stereotypes, or generalizations about individuals with disabilities or about a dog's breed (e.g., Pit Bull).
- A perceived threat without evidentiary basis will not likely support exclusion.
- There is no specific legal requirement as to the amount or type of work a service animal must provide.

# Emotional Support Animals



- Typically dogs and cats, but may include other animals of any species that provide support, well-being, comfort, aid, or a calming influence through companionship, non-judgmental positive regard, affection, and a focus in life simply by being close to their handler.
- ESAs do not require specific training!
- Because they are not individually trained to perform work or tasks, ESAs are not service animals but may be effective at ameliorating the symptoms of psychiatric disabilities by providing therapeutic nurture and support.
- The principal service that ESAs provide is simply companionship.
- Unlike service animals, ESAs may or may not be as well-behaved and may cause problems that a trained service animal may not. ESAs may bark and smell other people, whereas service dogs are trained not to do so.
- ESAs are virtually indistinguishable from the family pet.
- One more source of confusion for universities is that a variety of animal types can be claimed as ESAs, including rabbits, hamsters, snakes, and potbellied pigs.

# Pets



- Legal definition: Animals kept for pleasure, ordinary use, or companionship.
- Pets are not considered Service Animals or ESAs.
- Most institutions have not usually permitted them on campus (except on special 'bring your pet to work day' or if going to the vet).
- Importantly, what identifies ESAs from pets is that the owner/handler has been diagnosed by a medical professional as having a verifiable disability (physical or mental) that is not transitory and minor.

# Compare and Contrast



Table 1

*Key animal categories relevant to colleges and locations where they are generally allowed*

Service Animals	Emotional Support Animals (ESAs)	Pets
Dogs generally allowed in all campus locations	Generally allowed in student housing and in student campus jobs	Generally not allowed in any campus location



# Addressing Animal Accommodation Requests



- 1. Why is the individual requesting an exception to the institution's policy of no animals on campus? <assuming the institution has a policy>
  - **Pet.** If it is determined that the animal is a pet then the student would normally not be permitted to keep it on institutional property.
  - **Service animal.** If it appears that the animal is a service animal then the animal is exempt from the institution's no-pet policies and is permitted to accompany its owner at all times and in all areas of the premises where persons are normally allowed to go, except where animals are specifically prohibited (e.g., custodial closets, boiler rooms, wood and metal shops, <animal facilities?>). When it is not obvious what service an animal provides, only limited inquiries are allowed: A) Is a dog a service animal required because of a disability? B) What work or task has the dog been trained to perform?

# Addressing Animal Accommodation Requests



- 1. Why is the individual requesting an exception to the institution's policy of no animals on campus? <assuming the institution has a policy>
- **ESA.** If the animal is an ESA, then the individual is permitted to keep the animal at his/her residence and to have the animal accompany them to their campus jobs.
- Documentation of the need for an ESA should include the following:
  - A letter from the student explaining the need for the animal, the type of animal, a description of the animal, the animal's name, whether the animal is housebroken, the date[s] of the medical examinations and prescriptions specifying the need for such the animal, and the date when the animal was acquired.
  - A signed letter, on professional letterhead, from the student's physical or mental healthcare provider or licensed therapist or other qualified professional that includes, at a minimum, the nature of the applicant's disability, the provider's opinion that the condition affects a major life activity, how the animal is necessary to provide the impaired student access to the university's housing or employment settings, and the relationship between the disability and the assistance the animal provides.

# Addressing Animal Accommodation Requests



- 2. Is the accommodation request reasonable?
- Consider whether granting the request would constitute an undue financial or administrative burden, or would fundamentally alter the nature of the institution. In addition, animal accommodation requests may be denied if:
  - (1) the specific animal in question poses a direct threat to the health or safety of others that cannot be reduced or eliminated by another reasonable accommodation, or
  - (2) the specific assistance animal in question would cause substantial physical damage to the property of others that cannot be reduced or eliminated by another reasonable accommodation. A determination that an animal poses a direct threat of harm to others or would cause substantial physical damage to the property of others must be based on an individualized assessment that relies on objective evidence about the specific animal's actual conduct. Breed, size, and weight limitations are not applicable to ESAs. Conditions and restrictions that housing providers and employers apply to pets may not be applied to service and ESAs. For example, while housing providers may require applicants or residents to pay a pet deposit, they may not require applicants and residents to pay a deposit for ESAs.

# Addressing Animal Accommodation Requests



- ESAs do enjoy some accommodations. The federal [Air Carrier Access Act](#) has provisions for emotional support animals, which may fly with their owners provided there is adequate documentation (e.g., a note from a licensed health care professional) and/or sufficient notice. There are some restrictions, primarily size-related, on which animals are allowed to fly.
- Disabled people with emotional support animals are [protected in the realm of housing](#) under the Fair Housing Act and Section 504 of the Rehabilitation Act of 1973, according to the U.S. Department of Housing and Urban Development.
- These accommodations have met controversy in some places. At the University of Nebraska at Kearney, the question of whether college campuses must comply with the Fair Housing Act's accommodation for ESAs ended up in court in 2013, where it was decided that the Act applies to student housing.
- Some critics suggest that the designation is [misused](#) by people who might not have a genuine emotional need for an animal companion. Websites promise “hassle free emotional support animal registration” (for a fee). Vests and accessories emblazoned with “Emotional Support Animal” are readily available for purchase online.

# Emotional Support Animals



- It turns out [pigs can fly](#). And turtles and dogs too! As some household pets receive promotions from best friend to clinical roles as emotional support animals (ESAs), companions that run the gamut from furry to scaly are popping up increasingly in unexpected places ... and for a fee you can obtain documentation for your ESA.



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**\$129.00**

Primary Coverage

- ☒ Mental Health Evaluation
- ☒ ESA Letter on Official Letterhead
- ☒ Housing and Travel Forms Available
- ☒ 48 Hour PDF Delivery

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**\$179.00**

Advanced Coverage

- ☒ Mental Health Evaluation
- ☒ ESA Letter on Official Letterhead
- ☒ Choice of Housing or Airline Form
- ☒ 48 Hour PDF Delivery

SELECT COVERAGE



**\$299.00**

Comprehensive Coverage

- ☒ Mental Health Evaluation
- ☒ ESA Letter on Official Letterhead
- ☒ Choice of 3 Completed Housing or Travel Forms
- ☒ Express 24 Hour PDF Delivery

SELECT COVERAGE

# Emotional Support Animals



- A collection of all diagnosable mental disorders causing severe disturbances in thinking, feeling, relating, and functional behaviors which can result in a markedly diminished capacity to cope with the demands of daily life.
- ADA / ADAAA define a person with a disability as “Any person who has a physical or mental impairment that substantially limits one or more major life activities; has a record of such impairment; or is regarded as having such an impairment” (e.g., ADA, Section 12102).
- ADAAA indicates:
  - **Major life activities** include, but are not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, learning, reading, concentrating, thinking, communicating, and working.
  - **Major bodily functions** include, but are not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, endocrine, respiratory, circulatory, and reproductive functions.

# One Institution's Position



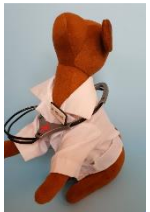
- **Indiana University:** Service Dogs in Teaching and Research Laboratories: Guidance for Faculty, Staff and Students
- Guidance developed by: Environmental Health and Safety (not IACUC)
- Operational Assistance by: Disability Services Office (not IACUC)
  - Assist with laboratory access request
  - Prepares 'Needs Assessment' for EHS review
- Animal and Personnel Safety Recommendations: Environmental Health and Safety
- Faculty / Supervisor / Staff:
  - Ensure dog handler is following requirements and recommendations
  - Responds to initial disruptions (if occur) by discussion with owner
  - Report animal behavior problems to Disability Services Officer
- Service Dog Owner:
  - Register for services through the Disability Services Office
  - Meet with area leaders to discuss accommodations prior to need.
  - Ensure dog behaves and does not cause disruption or injury to others
  - Follow requirements and recommendations
  - Provide any PPE for dog



# One Institution's Position



- **Indiana University:** Service Dogs in Teaching and Research Laboratories: Guidance for Faculty, Staff and Students
- Only dogs! No miniature horses or other types of service animals allowed in labs.
- Dogs must have appropriate PPE upon entering lab area.
  - Disposable or reusable boots
  - Disposable lab coat
  - Absorbent lab paper or pet pads to lie on
- Can be excluded from lab if:
  - Labs utilizing any Risk Group 2 (or higher) agents
  - Labs utilizing radioactive materials
  - Not housebroken or out of control.
  - Not controllable by voice command (stay, leave it)
  - Barks or growls inappropriately
  - Snapping, snarling, charging, etc.
  - Jumps on people





# Other Institutions ...



- **BYU:**      **Areas Off Limits to Service Animals**

The University may prohibit the use of service animals in certain locations due to health and safety restrictions (e.g. where the animals may be in danger, or where their use may compromise the integrity of research). Restricted areas may include, but are not limited to, the following areas: custodial closets, boiler rooms, facility equipment rooms, research laboratories, classrooms with research/demonstration animals, areas where protective clothing is necessary, wood and metal shops, motor pools, and rooms with heavy machinery.

Exceptions to restricted areas may be granted on a case-by-case basis by contacting the University Accessibility Center and the appropriate department representative. However, the person directing the restricted area has the final decision.

### ***Lab Employee Information***

Service animals are permitted to accompany people with disabilities in all areas of a facility where the person is allowed to go. If a student brings any animal *except a dog or miniature horse*, the employee can prohibit that animal from being in the lab. For a dog/ horse, the employee can ask 2 questions:

- **Univ of Alaska:**
  - Is the animal a service animal required because of a disability?
  - What work or task has the animal been trained to perform?

As long as the animal is under control of their handler at all times, the service animal is permitted in the laboratory. Service animals can only be excluded or asked to leave the room if:

- The animal is out of control and the handler does not take effective action to control it.
- The animal is not housebroken.
- For miniature horses only – if the size, weight and type of horse cannot be accommodated in the lab.

# Other Institutions ...



- **UW:**

**UW-Madison Department of Chemistry  
Policy on Service Animals in Teaching Laboratories**

If you anticipate working with a service animal in the laboratory at any time over the course of your enrollment, we want to make sure that both you and the members of the department are able to provide that opportunity without endangering the safety of you, your fellow students, or your animal. In order to achieve this goal, we will need to know the specifics of the service the animal provides with enough advance notice to make the appropriate arrangements.

Before you first set foot in the lab space for each new course, you must meet with the lab director who supervises the laboratory component of your course (see list below). It is highly recommended that you make arrangements (via email, preferably) for this meeting with plenty of notice (two or three months before the start of your class is not too much!) so that we can have all plans worked out without disrupting your class participation.

You can expect to be asked questions such as the following:

- Do you require the animal to be with you at all times or only under certain circumstances? What are those circumstances?
- Do you need a place for the animal to stay while you are in lab and not needing the animal at that time?
- Is the animal a service animal required because of a disability?
- What work or task has the animal been trained to perform?
- How does the animal alert?

We will then make sure that plans are in place to address various possible incident scenarios.

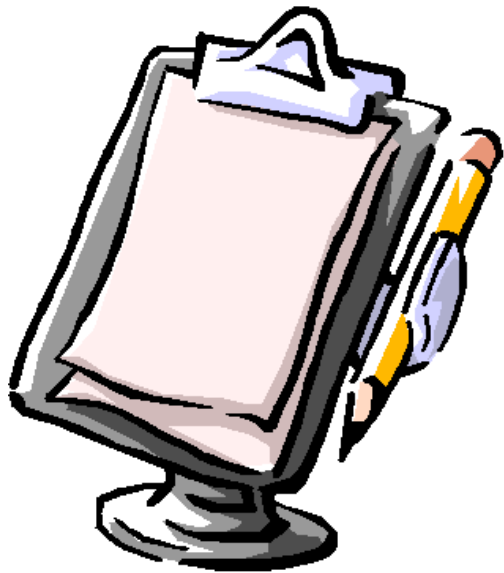
# Discussion ....



***What are your two questions?***

# Wrap-up

Please, complete your Evaluation Forms and offer suggests!



*Suggestion  
Box*

