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## Noncompliance in Animal Research Oversight

Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, DACAW  
Assistant Vice President for COI & IACUC  
President, American College of Animal Welfare

Beth Trumpower, MS, CPIA  
Manager, IACUC

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### Overview

- Introduction
- Overview of Regulatory Requirements
- Oversight Options
- Risk
- Scenarios

## Learning Objectives

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- Attendees will be given an overview of requirements relating to noncompliance in animal research, including federal laws and regulations along with accreditation guidelines, which the Institutional Animal Care and Use Committee is charged with managing.
- Attendees will learn about options available in identifying, investigating, correcting, and documenting animal research noncompliance.
- Attendees will be given different models for examining institutional risk when it comes to animal research oversight.

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## Introductions

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Let's Learn a Little About Each Other



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**Poll**

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- What type of organization do you represent?
- A – Academic with no Medical Center
- B – Academic with Medical Center
- C – Government
- D – Not-for-profit including non-academic Hospitals
- E – Other

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**Poll**

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- What is your role relevant to the IACUC?
- A – IACUC Administrator
- B – Compliance Staff with no operational role within the IACUC
- C – IACUC Member
- D – Other

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## Poll

- What is the most challenging aspect of animal research oversight?
  - A – How to proactively identify noncompliance
  - B – How to train researchers to ensure that they are compliant
  - C – How to keep up-to-date with USDA and NIH requirements
  - D – How to keep on schedule with all of the required activities (inspections, program reviews, 3-year renewals, etc.)
  - E – How to report noncompliance to the USDA or NIH

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## Poll

- What are the most common sources of animal research regulations and guidelines?

A – State and Local Laws

B – United States Department of Agriculture

C – United States Department of the Interior

D – AAALAC

E – National Institutes of Health

F – American Veterinary Medical Association

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## Animal Research Oversight

### Federal Laws and Regulations:

- Public Health Service (PHS)/ NIH Office of Laboratory Animal Welfare (OLAW)
- United States Department of Agriculture (USDA)
- Department of Defense (DOD)
- Veterans Administration (VA)

### Accreditation Guidelines:

- AAALAC International

### Euthanasia Guidelines:

- American Veterinary Medical Association (AVMA)



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## OLAW and Noncompliance



"**Review concerns** involving the care and use of animals..." (PHS Policy IV.B.4)

"The IACUC may **suspend** an activity... if it determines the activity is not being conducted in accordance with applicable provisions... after a review of the matter at a convened meeting of a quorum... with the suspension vote of a majority of the quorum present." (PHS Policy IV.C.6)

"Maintain minutes of IACUC meetings, including records of attendance, **activities of the committee**, and committee deliberations... for at least 3 years." (PHS Policy IV.E.1.b & IV.E.2)

"...Promptly **provide OLAW with a full explanation** of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
  - b) any serious deviation from the provisions of the Guide; or
  - c) any suspension of activity" (PHS Policy IV.F.3)
- Preliminary and Final Reports
  - Reporting only required for incidents supported by NIH, NSF, or NASA funding

## USDA and Noncompliance



"**Review, and... investigate concerns** involving the care and use of animals..." (9 CFR § 2.31.c.4)

"The IACUC may **suspend** an activity... if it determines that the activity is not being conducted in accordance with the description of that activity provided by the PI... after review... at a convened meeting of a quorum...with the suspension vote of a majority of the quorum present" (9 CFR § 2.31.d.6)

"If the IACUC suspends an activity... the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and **report that action with a full explanation to APHIS** and any Federal agency funding that activity" (9 CFR § 2.31.d.7)

"Minutes of IACUC meetings, including records of attendance, **activities of the Committee**, and Committee deliberations" (9 CFR § 2.35.a.1 & 2.35.f)

*Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance with the Animal Welfare Act* (May 2018 USDA TechNote)

- Only required to report: Annual Report, change of operations, suspensions, or uncorrected significant deficiencies from an inspection
- Only applies to USDA-covered species

## DOD and Noncompliance



### DOD Instruction 3216.01: Use of Animals in DOD Conducted and Supported Research and Training

For DOD supported (not conducted) work:

“The component will require the DOD supported institution **to inform the component oversight office, in a timely manner, of any significant deficiencies, noncompliance with this issuance, and reports of adverse events...**” (Section 3.2.i.4)

“**Records** that document...noncompliance with this issuance will be made accessible for inspection and copying by authorized representatives of the DOD...” (Section 3.5.c)

- Only applies to incidents supported by DOD funding

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## VA and Noncompliance



### VHA Handbook 1200.07: Use of Animals in Research

For VA supported (not conducted) work. Mostly applicable to academic medical centers with cooperative research agreements or MOUs with a neighboring VA:

“The affiliate agrees to **provide...** VA representatives... **all reports required by oversight entities.** Shared documents not available to the public **may be redacted** of material not relevant to VA animal research” (Section 8.b.1.b)

“The affiliate agrees to notify VA personnel in a timely fashion, and to provide all information needed, when concerns about potentially reportable deficiencies related to VA animal research are raised...”

Including “copies of all communications to and from regulatory and accrediting entities (e.g., USDA, OLAW, and AAALAC) relevant to VA animal research” (Section 8.b.1.d)

“When a VA investigator uses PHS funds administered by the affiliate institution for animal research, the **VA IACUC may not supersede any adverse action taken by the affiliate IACUC** against such a project.” (Section 8.c.1)

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## AAALAC and Noncompliance



[AAALAC Accreditation Program – FAQs website:](#)

### What information should be reported to AAALAC International?

Adverse events to be reported promptly:

- Unexpected animal death
- Natural disasters
- Significant animal rights activities (e.g., protests, break-in, property damage, FOIA or other open records request that includes AAALAC documents)
- Inappropriate euthanasia techniques and/or failure to confirm euthanasia
- Allegations/complaints/reports regarding animal welfare concerns
- Lack of veterinary care
- OLAW/USDA investigations

Can we submit copies of incident reports sent to OLAW or the USDA?

Yes!

"Not all issues that are reportable to OLAW or USDA require immediate reporting to AAALAC."

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## Incidents of Noncompliance

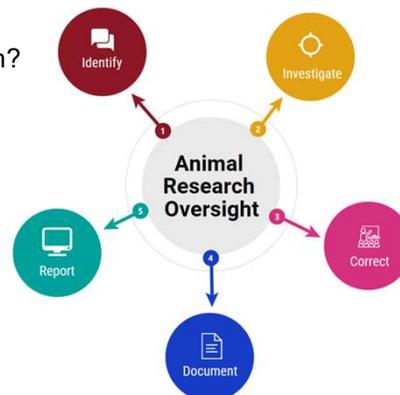
How does the IACUC identify them?

How are they investigated?

How are they corrected?

How are they documented?

Do they need to be reported to external agencies?



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## Poll

- All animal welfare concerns are incidents of noncompliance and all incidents of noncompliance are animal welfare concerns.

A – True

B – False

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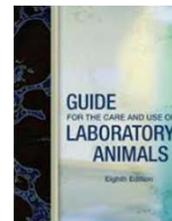
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## Identifying Noncompliance

How are members of the research community made aware of how to report concerns?

“PHS requires institutions to use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional program.” (PHS Policy IV.A.1)

- Mechanisms for reporting concerns are posted in the facilities and on the applicable website with instructions including multiple contacts, anonymity, a whistleblower policy, and nondiscrimination and reprisal protection. (*Guide*, p. 24)



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## UT Southwestern Medical Center – Dallas, TX

Background:

- IACUC Office Staff = 9
- Approved Animal Protocols = ~765
- Animal Research PIs = ~304

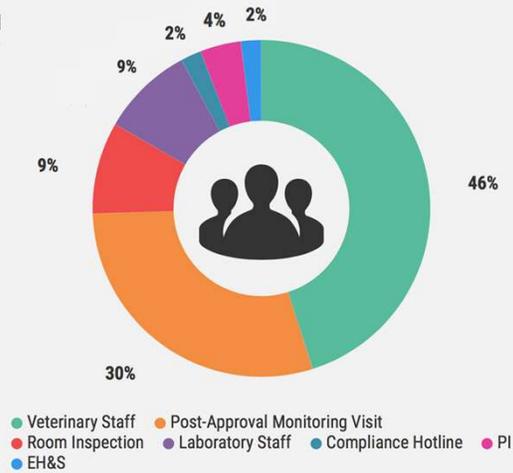
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## Identifying Noncompliance

2019 Metrics

How were we informed about noncompliance?



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## Investigating Noncompliance

- Don't call it an "investigation"
- Institutions have flexibility in their approach
- Create guidelines:
  - How are identified concerns communicated to the appropriate offices?
  - Who initiates the review?
  - How is the IACUC informed and how do they make their decisions?
  - How are reports made to agencies?

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## Correcting Noncompliance

- Once size does not fit all!
  - Corrective actions should be tailored to produce the desired outcome
- Corrective actions should be tailored to:
  - Nature of the issue
  - Immediate risks to animal and human health and welfare
  - Risk (to be discussed later)

The FASEB Journal article fJ.201601250R. Published online August 15, 2017.  
FASEB JOURNAL • REVIEW • www.fasebj.org

**Ensuring due process in the IACUC and animal welfare setting: considerations in developing noncompliance policies and procedures for institutional animal care and use committees and institutional officials**

Barbara C. Hansen,<sup>1,3</sup> Sylvia Gografe,<sup>1</sup> Stacy Pritt,<sup>2</sup> Kai-lin Catherine Jen,<sup>3</sup> Camille A. McWhirter,<sup>5</sup> Susan M. Barman,<sup>1</sup> Anthony Comuzzie,<sup>7</sup> Molly Greene,<sup>7</sup> Justin A. McNulty,<sup>7</sup> Daniel Eugene Michele,<sup>12</sup> Naz Moudidah,<sup>9</sup> Randall J. Nelson,<sup>14</sup> Karen Norris,<sup>11</sup> Karen D. Gray,<sup>16</sup> Ron Banks,<sup>13</sup> Karin N. Westlund,<sup>11</sup> Bill J. Yates,<sup>11</sup> Jerald Silverman,<sup>10</sup> Kenneth D. Hansen,<sup>15</sup> and Barbara Redman<sup>11</sup>

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## Corrective Action Options

- PI and researcher counseling
- Refresher or Retraining
- Increased veterinary or IACUC oversight (+/- competency assessment)
- Protocol changes
- Reassignment of responsibilities
- Fines
- Loss of privileges
- PI must provide their own corrective action plan
- Use of IACUC/veterinary mandated data collection processes
- PI mentorship
- Suspension of activities
- Service on the IACUC?

**What about any changes the IACUC could make to its own policies?**

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## Documenting Noncompliance

Develop a system for tracking incidents

- When does something become "noncompliance"?

How are the incidents organized?

- Unique numerical identifiers
- Sorted per calendar/academic year

How will confidentiality be maintained?

- Who has access to the documentation
- Who can edit it
- Coding system for PI/personnel identification



When is a noncompliance considered "resolved"?

How long will documentation be kept?

- 3 years (or for the duration of a protocol plus 3 years)
- What are your institutional records retention guidelines

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## Documentation Options

Provide a unique identifier

- #2020-01, 2020-02, 2020-03...

Keep a written record

- Summary of incident (who, what, when, where, etc.)
- Background information as necessary
- Names of individuals involved, protocol numbers, funding sources...
- Description of follow-up taken by the IACUC
- Results of interviews, records reviews, etc.
- Description of corrective actions taken
- Copies of relevant evidence (correspondence, observations, health records, etc.)
- Conclusions on reportability
- Copies of reports to agencies
- Date the case was resolved/closed

Consider confidentiality

- Kept on a secure shared electronic drive
- Designated individual to edit and compile records

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## Regulatory Reporting

- Different agencies and organizations have different reporting requirements
- Incidents may not need to be reported, may only need to be reported to one agency, or may need to be reported to multiple agencies
- Reporting is determined by:
  - Type of incident
  - Funding
  - Species
  - Animal ownership
- Do not over report
- Determine who should report and how

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## Metrics

Keeping metrics?

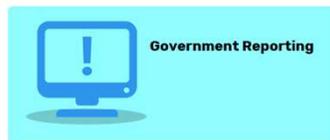
- Types of incidents
- Number of incidents
- How they were discovered
- PIs
- Species
- Reportability



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## Risk



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### Take Home Points

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- IACUCs should address how they identify, review, and report non-compliance consistently and according to relevant requirements.
- Requirements for reporting noncompliance vary, so a one-size-fits-all approach to reporting is inappropriate for animal research.
- Considerable flexibility is allowed when addressing noncompliance in animal research. IACUCs should leverage this flexibility.

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Scenario Time!

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### Scenario 1

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As your institution's compliance officer, it is time for you to audit IACUC functions.

You are aware that the IACUC must inspect animal facilities on a regular basis according to different guidelines. Since the only research animals housed at your institution are laboratory mice and rats, you focus on NIH and AAALAC requirements.

When you initiate your audit, you ask for a copy of the IACUC's inspection policy. The policy states that all animal housing areas are to be inspected once by at least two members of the IACUC as per the *Guide for the Care and Use of Laboratory Animals*. However, when you look at the *PHS Policy*, you find that inspections are to be conducted at least twice a year by a representative of the IACUC.

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### Scenario 1 – Poll 1

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- It appears that the IACUC may be noncompliant with the *PHS Policy* requirement for twice a year inspections. Is the IACUC noncompliant with their inspector requirements?

A – Yes

B – No

C – Maybe

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### Scenario 1 – Poll 2

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- Does this need to be reported to NIH OLAW?

A – Yes

B – It depends...

C – No

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### Scenario 2

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As your institution's compliance officer, you are performing an audit of IACUC functions. While reading the IACUC's policy on reviewing and approving animal protocols, you notice the policy indicates protocols using USDA-covered species will be reviewed every year, with the review of an amendment sufficing for this review, however protocols using laboratory mice and rats will only be reviewed every 3 years. The policy also states that approval letters for protocols will only be sent to PIs upon request.

You thought that all protocols must be reviewed every year, and the last time you audited the IACUC they reviewed all protocols every year.

You also remember a requirement that PIs be notified regarding the approval status of their protocols.

When you ask the IACUC Coordinator to explain, he says this policy was updated last year by the IACUC to reduce administrative burden.

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### Scenario 2 – Poll 1

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- Is the IACUC noncompliant with *PHS Policy* or USDA regulations regarding the timing of protocol reviews or informing PIs about approval status?

A – Yes

B – No

C – Maybe

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### Scenario 2 – Poll 2

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- Does the review of an amendment for a USDA-covered species protocol change the approval date of the protocol?

A – Yes

B – No

C – Maybe

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### Scenario 3

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You work in the Compliance Office at Rabbit Ridge University and just received an anonymous call through your Compliance Hotline regarding staff hearing pigs squealing one day.

Since the complaint has to do with animal welfare concerns, you forward it to the IACUC Coordinator. You communicate that your office policy is for all complaints to be investigated with a full report due back to you within 5 days.

The IACUC Coordinator informs you that she will begin reviewing this concern immediately, but the next IACUC meeting is 3 weeks away.

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### Scenario 3 – Poll 1

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- Who else should be involved in the review of this complaint?

A – Institutional Official

B – Attending Veterinarian

C – Biosafety Officer

D – Grants Administrator

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**Scenario 3 – Poll 2**

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- Can this complaint be investigated outside of an IACUC meeting?

A – Yes

B – No

C – Maybe

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**Scenario 3 – Poll 3**

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- Is this reportable to the USDA?

A – Yes

B – No

C – Maybe

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#### Scenario 4

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Peter, a research technician at Rabbit Ridge University, is busy up in his lab genotyping mice.

He had been told by his PI, and subsequently confirmed by reading the IACUC-approved protocol, that his lab is approved as an area for which mouse procedures can be performed. Therefore, according to IACUC policy, he can keep them up in the lab for up to 12 hours, which means that they must be returned to the animal facility by 6 PM since he brought them to the lab early that same day at 6 AM to get a head start on the day's activities.

At 5:30 PM, he got a text from his friend saying that a great band just announced a surprise concert at a local venue...

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#### Scenario 4 – Continued

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Peter did not have enough time to finish genotyping, put the animals back in the animal facility (it was in an adjacent building), and also get to the impromptu concert on time.

So, he decided he would finish the genotyping—as the samples had to go out in the late-night FedEx pick-up—but not take the animals back to the animal facility since no one would probably see the animals in the lab. He went ahead and set them up on a lab countertop in the corner for the night...

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#### Scenario 4 – Continued

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Peter returned to work at 7:30 AM the next day, and immediately started putting the animals away in the facility.

Later that day, he received an email from the IACUC Office stating that, during an impromptu visit to the lab that morning by a PAM Monitor, it was noticed that there were cages on the counter, so they wanted to know what their story was.

Peter admitted to the fact that animals were kept in the lab overnight, against policy, but the concert was worth it.

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#### Scenario 4 – Poll 1

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- Which is a potential corrective action for this incident?

A – PI and researcher counseling

B – Increased IACUC oversight of the laboratory room

C – PI must provide their own corrective action plan

D – All of the above

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#### Scenario 4 – Poll 2

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- Is this reportable to NIH OLAW?

A – Yes

B – No

C – Maybe

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#### Scenario 4 – Poll 3

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- If your institution has staff dedicated to performing post-approval monitoring functions, do they work in the IACUC Office or the Compliance Office?

A – IACUC Office

B – Compliance Office

C – Both

D – No dedicated PAM staff

E – Not sure

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Questions?

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