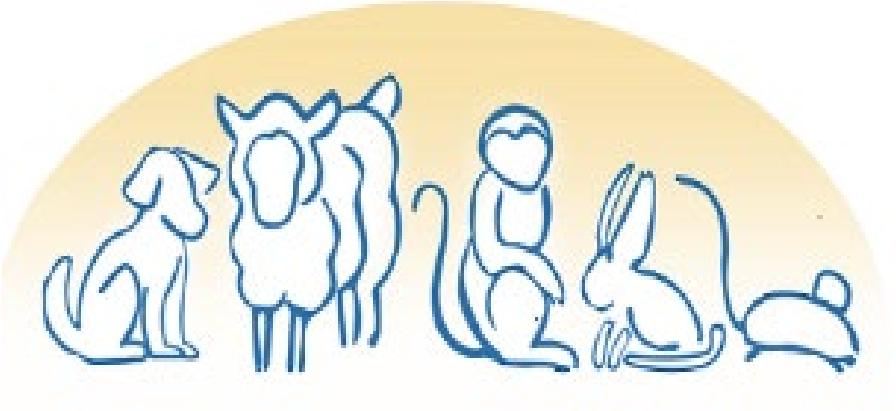
ICARE

Interagency Collaborative Animal Research Education

OLAW CONVERSATIONS

Top Noncompliances from an OLAW, USDA, and AAALAC Perspective: How to Learn from Noncompliances to Build a Better Animal Care and Use Program

Wednesday, January 19, 2022



NIH National Institutes of Health

Office of Laboratory Animal Welfare

Our Team:

NIH Office of Laboratory Animal Welfare (OLAW)

- Dr. Axel Wolff, DVM, MS, Deputy Director of OLAW
- Dr. Brent Morse, DVM, DACLAM, Director, Division of Compliance Oversight
- Dr. Jacquelyn Tubbs, DVM, DACLAM, Senior Animal Welfare Program Specialist

USDA, APHIS, Animal Care

- Dr. Elizabeth Theodorson, DVM, MPH, Assistant Deputy Administrator, Acting Associate Deputy Administrator, USDA APHIS Animal Care

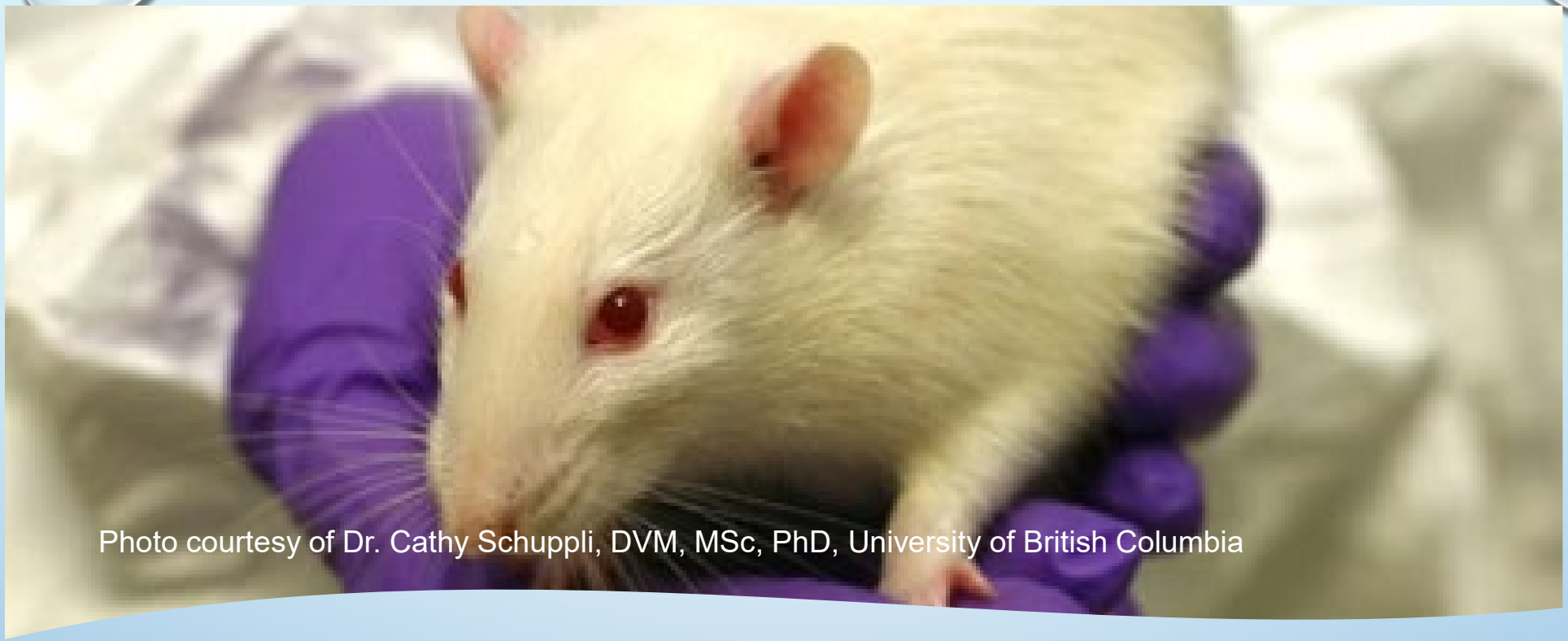
AAALAC International

- Dr. Gary Borkowski, DVM, MS, DACLAM, Global Director, AAALAC International

National Institutes of Health
Office of Laboratory Animal Welfare

Top Noncompliances Reported to OLAW

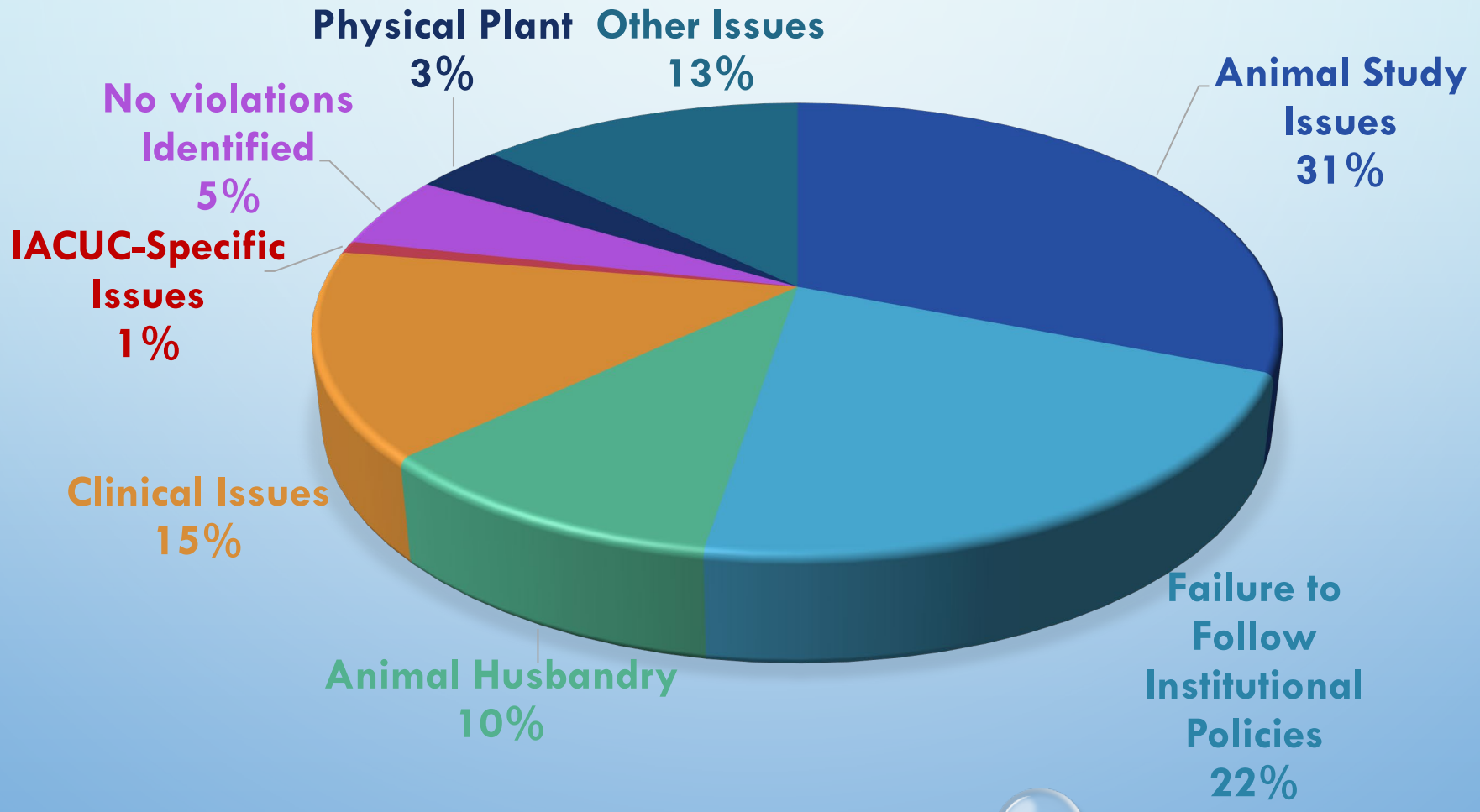
Brent C. Morse, DVM, DACLAM, Jacquelyn T. Tubbs, DVM, DACLAM,
Axel Wolff, DVM, MS
Office of Laboratory Animal Welfare
National Institutes of Health



Institutional Reporting:

- **Reporting is required by PHS Policy IV.F.3.**
  - **Any serious or continuing noncompliance with PHS Policy**
  - **Any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals***
  - **Any suspension of an activity by the IACUC**

TYPES OF REPORTABLE INCIDENTS IN 2021



THREE MOST COMMON ISSUES REPORTED TO OLAW:

- PROTOCOL NONCOMPLIANCE ASSOCIATED WITH ANESTHESIA OR ANALGESIA
- PROTOCOL AND/OR INSTITUTIONAL POLICY NONCOMPLIANCE ASSOCIATED WITH EUTHANASIA
- ANIMALS FOUND WITHOUT FOOD OR WATER

Real-Life Scenarios

Photo courtesy of Dr. Cathy Schuppli, DVM, MSc, PhD, University of British Columbia

CASE SCENARIO 1

- INVESTIGATOR AARON RODGERS (AT GREEN BAY UNIVERSITY) CONDUCTED A PROTOCOL APPROVED SURGERY ON RATS ON A PHS-FUNDED STUDY AND THE ANIMALS RECOVERED SUCCESSFULLY. DURING VETERINARY ROUNDS, THE SURGERY CARDS ON THE CAGES INDICATED THE ANIMALS WERE ADMINISTERED AN OPIOID (BUPRENORPHINE SR) AND THE RATS EXHIBITED NO SIGNS OF PAIN OR DISTRESS. HOWEVER, THE PROTOCOL STATES AN OPIOID AND NSAID (MELOXICAM) WILL BE ADMINISTERED AS THE ANALGESIC REGIMEN.

CASE SCENARIO 1 POLL

- IS THIS ISSUE REPORTABLE TO OLAW?
  1. YES, REPORTABLE
  2. NO, NOT REPORTABLE
  3. NOT SURE, OR NEED MORE INFORMATION

CASE SCENARIO 1 CONVERSATION

- WHAT IS THE NONCOMPLIANCE HERE?
- WHAT IS THE IMPACT ON ANIMAL WELFARE IF THERE WERE NO SIGNS OF PAIN?
- WHAT CAN BE DONE TO PREVENT THIS TYPE OF NONCOMPLIANCE?

HOW CAN CASE SCENARIO 1 BE AVOIDED?

- ENSURE ALL LAB MEMBERS ARE FAMILIAR WITH THE PROTOCOL (ESPECIALLY IF AMENDMENTS WERE RECENTLY APPROVED AND ADDED TO THE PROTOCOL).
- ASSIGN ROLES AND DESIGNATE WHICH INDIVIDUALS WILL PERFORM POST-OP CARE AND ADMINISTER DRUGS. WILL IT BE THE SURGEON, LAB MANAGER, OR PERSON PERFORMING EVENING CHECKS?
- UTILIZE A POST-SURGERY FORM OR CHECKLIST TO ENSURE ITEMS HAVE BEEN COMPLETED.

CASE SCENARIO 2

- DURING SUNDAY MORNING HUSBANDRY CHECKS, A CAGE OF MICE WAS DISCOVERED LACKING AN APPROPRIATE AMOUNT OF SPECIAL DIET. THE MICE WERE FOUND IN POOR CONDITION BUT RECOVERED WITH SUPPORTIVE CARE. DISCUSSIONS WITH THE LAB REVEALED THEY WERE RESPONSIBLE FOR PROVIDING THE SPECIAL DIET ON WEEKDAYS AND NOTIFYING THE HUSBANDRY STAFF TO PROVIDE THE DIET ON UPCOMING WEEKENDS AND HOLIDAYS. HUSBANDRY STAFF CLAIM THEY WERE NOT NOTIFIED FOR THIS WEEKEND.

CASE SCENARIO 2 POLL

- WHAT IS THE KEY ISSUE HERE?
    1. PROTOCOL NONCOMPLIANCE
    2. COMMUNICATION
    3. LAB OVERSIGHT

HOW CAN CASE SCENARIO 2 BE AVOIDED?

- CREATE WEEKDAY AND WEEKEND FEEDING SCHEDULE AMONG LAB MEMBERS AND HUSBANDRY STAFF.
- DOCUMENT WHEN FEEDINGS OCCUR (RECOMMEND KEEPING THE FORM IN THE HUSBANDRY ROOM IF POSSIBLE).
- HAVE SPECIFIC POINTS OF CONTACT FOR THE HUSBANDRY TEAM AND LAB STAFF. PROVIDE CONTACT NUMBERS.
- REVIEW THE PROTOCOL WITH ALL LAB MEMBERS, EMPHASIZING THE IMPORTANCE OF ADHERING TO THE MONITORING PLAN AND LAB'S RESPONSIBILITIES. INCLUDE APPLICABLE HUSBANDRY STAFF.

CASE SCENARIO 3

- A LAB MEMBER PERFORMED CO2 EUTHANASIA INVOLVING A CAGE OF MICE. THE INDIVIDUAL DID NOT PERFORM A SECONDARY METHOD OF EUTHANASIA (AS REQUIRED BY THE INSTITUTIONAL EUTHANASIA SOP REFERENCED IN THE PROTOCOL). MICE THAT RECOVERED FROM THE INCOMPLETE EUTHANASIA WERE FOUND ALIVE IN THE CARCASS REFRIGERATOR LATER THAT DAY.

CASE SCENARIO 3 POLL

- WOULD YOU CONSIDER THE LACK OF CONDUCTING A SECONDARY METHOD OF EUTHANASIA TO BE A NONCOMPLIANCE?
    1. YES
    2. NO
    3. UNSURE

HOW CAN CASE SCENARIO 3 BE AVOIDED?

- DETERMINE IF TRAINING IS APPROPRIATE (REVIEW LAB SOP, PROTOCOL TRAINING).
- DETERMINE IF POLICIES ARE CLEAR AND WELL DISSEMINATED (NOTICES VIA EMAIL, POSTING OF APPROPRIATE SIGNAGE).
- REGARDING EUTHANASIA EQUIPMENT, ONE MUST ASK: IS THE EQUIPMENT CONSIDERED EASY TO USE? IS AN AUTOMATED EUTHANASIA STATION AVAILABLE FOR USE?
- REGARDING LOCATION, IS EUTHANASIA ONLY OCCURRING IN A CENTRAL LOCATION AND/OR BY "ANIMAL RESOURCES" PERSONNEL?
- USE OF A SECURITY CAMERA/CARD READER AT EUTHANASIA STATIONS MAY BE BENEFICIAL.

CASE SCENARIO 4 (OH, NO LITTLE BUDDY!)

- DOCTOR GILLIGAN IS AN NSF-FUNDED RESEARCHER AT **UNCHARTED DESERT ISLE UNIVERSITY**. SHE USES SEA BASS IN RESEARCH AND SOME TANKS AT THE UNIVERSITY AQUATIC CENTER CONTAIN HER NSF-FUNDED FISH AND SOME CONTAIN BASS ON HER PROJECTS FUNDED BY THE STATE DEPARTMENT OF AGRICULTURE. RECENTLY, SEVERAL TANKS OF STATE-FUNDED FISH DIED WHEN THE BIOFILTERS FAILED DUE TO LACK OF MAINTENANCE. 600 FISH WERE LOST. NONE OF DOCTOR GILLIGAN'S NSF-FUNDED FISH WERE AFFECTED.

CASE SCENARIO 4 POLL

- IS THE LOSS OF THE 600 FISH REPORTABLE TO OLAW?
    1. YES
    2. NO, NOT PHS-FUNDED
    3. UNSURE

United States Department of Agriculture

January 19 OLAW Conversations

Elizabeth Theodorson DVM, MPH
Assistant Deputy Administrator

United States Department of Agriculture
Animal and Plant Health Inspection Service
Animal Care

USDA Animal Care Regulatory Updates

AWA Research Facility Registration Updates, Reviews, and Reports Regulation

Modifications to §2.30: Registration

- **Removed the requirement for research facilities to update registration every 3 yrs.**
  - Complies with 21st Century Cures Act to reduce burden

- **Clarified conditions for cancellation**
  - Submission of a written request to Deputy Administrator to cancel
  - A facility with a cancelled registration is still required to apply for registration 10 days before beginning regulated activity!

- **Eliminated inactive status**
  - A facility can no longer request inactive status
    - A facility will either be registered or unregistered

Modification to §2.31(d)(5): Continuous Review of Animal Activities Not Less Than Annually

No longer required:

- Continuous review of animal activities not less than annually after IACUC approval

Required:

- IACUC complete review of animal activities every 3 years
  - Complies with 21st Century Cures Act to reduce burden by harmonizing with the Public Health Service (PHS) Policy
  - Note: The IACUC still retains the authority under § 2.31(c) (3) to monitor animal activities at any time after approval

Modification to §2.36(a): Annual Report Signatures

- **No longer require CEO or IO to sign annual report**
  - Complies with 21st Century Cures Act by allowing others to sign the Annual Report and therefore expedite processing
    - Facilities are left to their own discretion to designate signatories
    - Note: A signatory that is not the CEO or IO, does not assume the responsibility of those positions when they sign the Annual Report

Research Facility (RF) Stats for 2021

Total Number of registered RFs : 1089
Total inspections conducted: 1247

Research Facility (RF) Stats for 2020

Total Number of registered RFs : 1055
Total inspections conducted: 1001

Top 3 2021 Citations Listed (Highest to Lowest):

§2.33(b)(3) Attending veterinarian and adequate veterinary care

§2.38(b) Miscellaneous- Access and inspection of records and property

§ 2.31(c)(3) Institutional Animal Care and Use Committee (IACUC)

Questions?

THANK YOU

Reporting Noncompliance and Adverse Events

OLAW Conversations
January 2022

Gary L. Borkowski, DVM, MS, DACLAM
Global Director

Rules of Accreditation
Standards

- The accredited unit shall submit an annual report which describes elements of the animal care and use program as specified by AAALAC International.
- In addition, the accredited unit shall promptly notify AAALAC International (e.g., through copies of correspondence) of adverse events relating to the animal care and use program.
- Examples include investigations by the USDA or OLAW, as well as other serious incidents or concerns that negatively impact animal well-being.

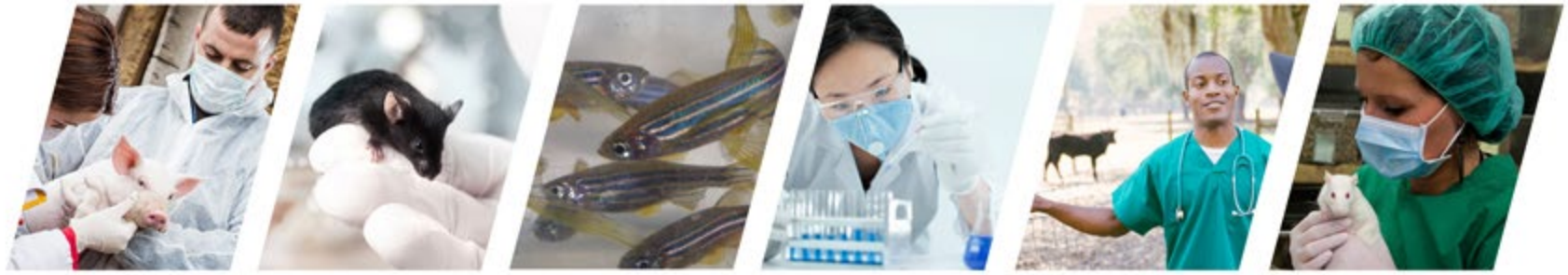
Program Description
Post-approval monitoring

- If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies.
- *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.
- Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

FAQ:
Maintaining Accreditation

Annual Report	Report Promptly
Protocol violations	Investigations by national oversight bodies
Animal use not approved by IACUC	Unexpected animal deaths
Protocol suspensions	Lack of veterinary care
Changes in facility size, location, name	Significant animal rights activities
Changes in IACUC composition or members	Inappropriate euthanasia techniques and/or failure to confirm euthanasia
Other changes in the animal care & use program	Natural disasters

Thank you!



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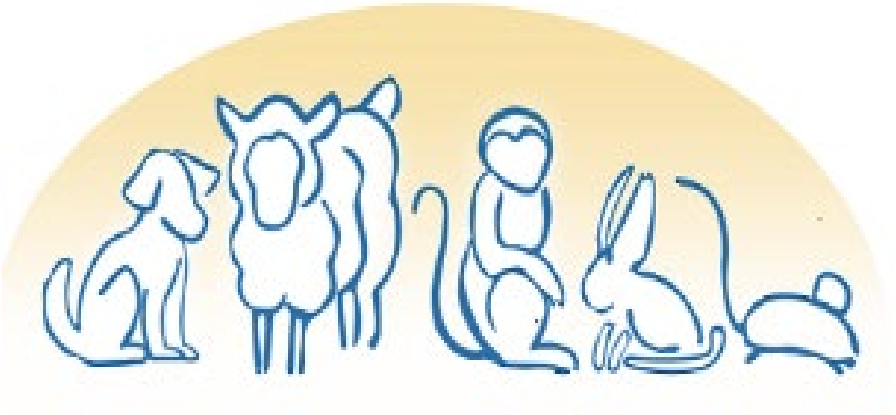
Thank you!

Next session: TBD



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