

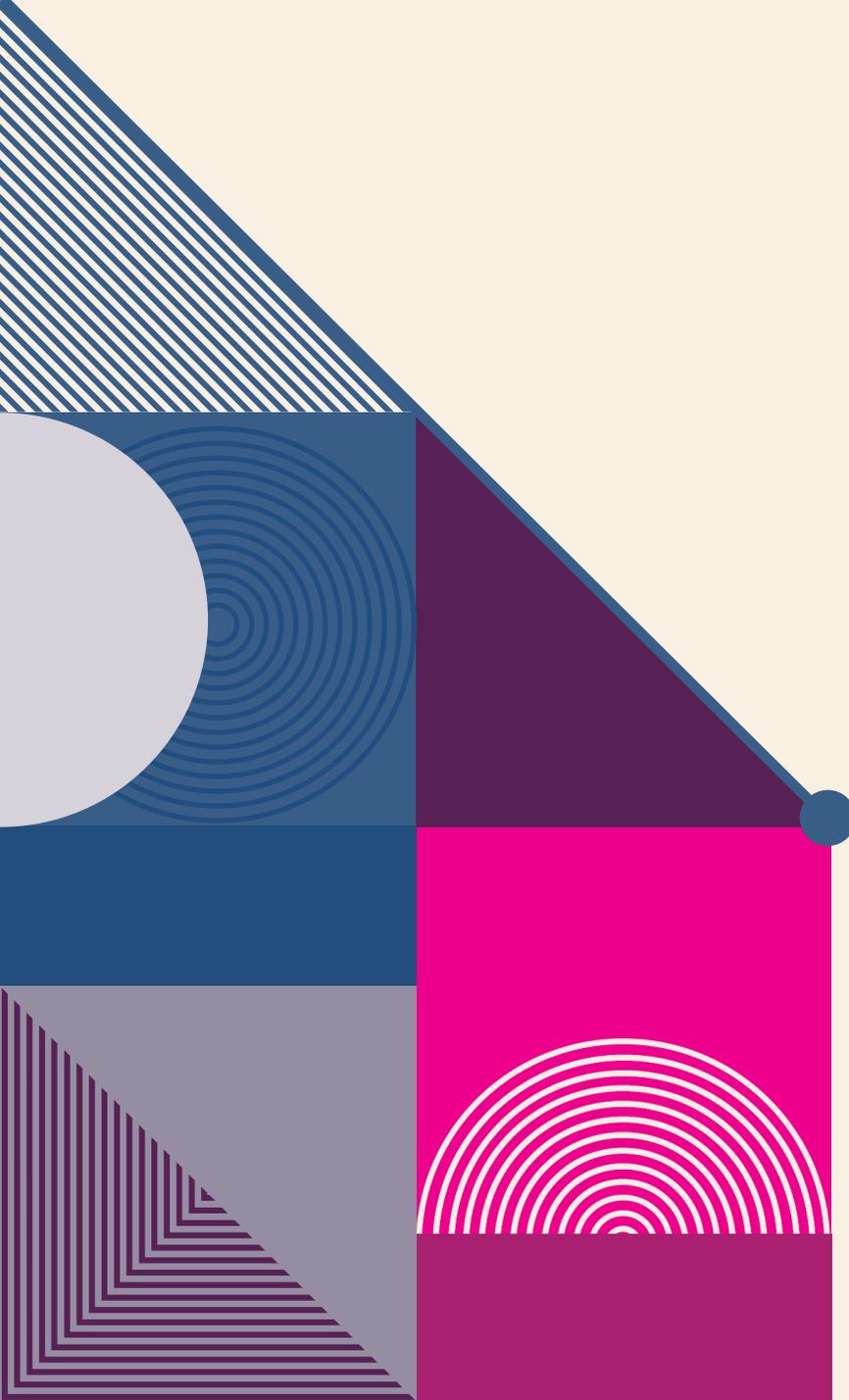
# ANIMAL RESEARCH OVERSIGHT INCLUDING INTERNATIONAL RESEARCH COLLABORATIONS

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SRA INTERNATIONAL  
ANNUAL MEETING  
**CHICAGO 2024**  
OCTOBER 26-30

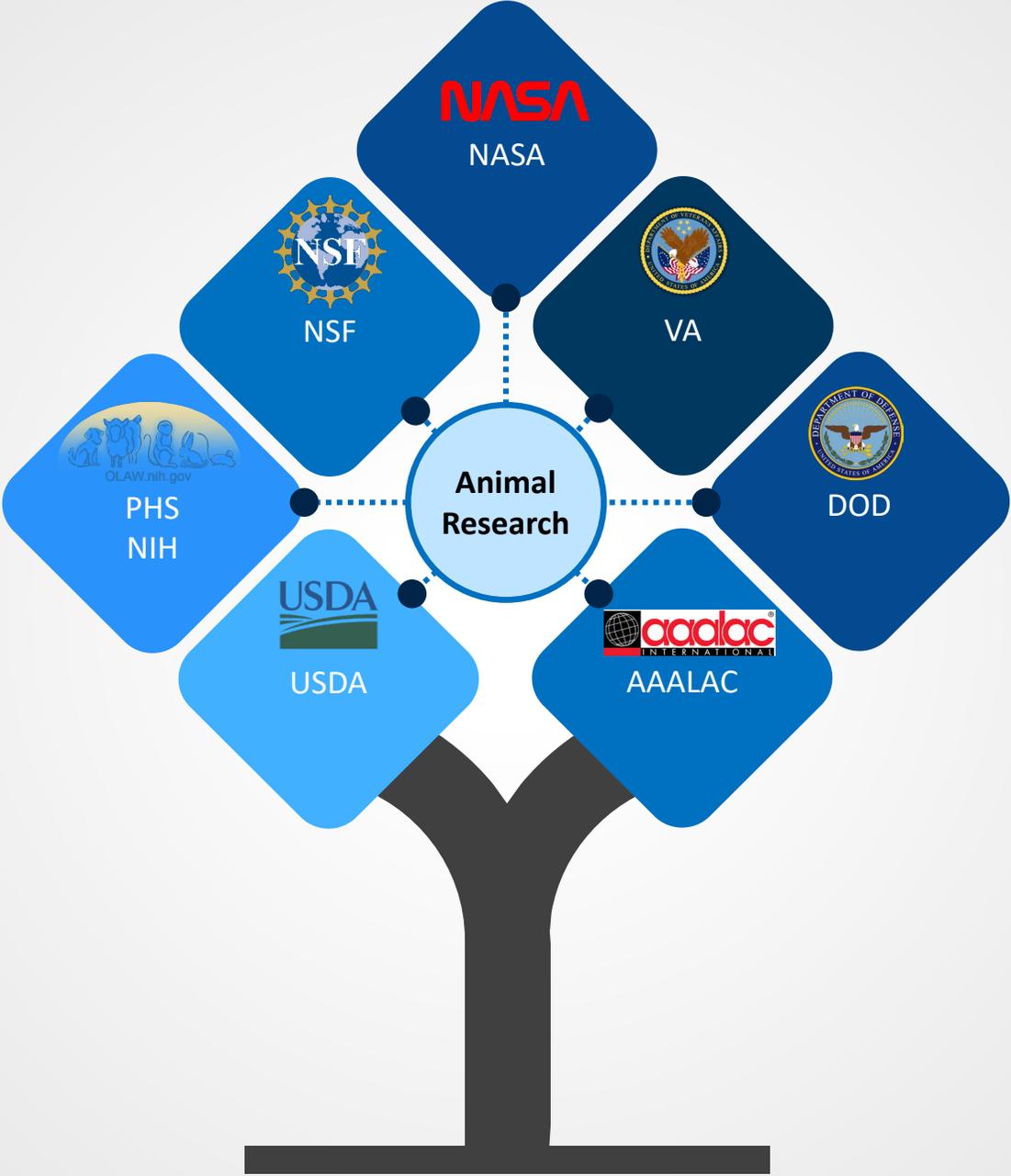


# LEARNING OBJECTIVES

- Review and discuss the foundations of animal research oversight in the United States.
- Identify institutional obligations and reporting requirements with a focus on federally funded animal research.



# WHO GOVERNS ANIMAL RESEARCH?



# FEDERAL AGENCIES

## USDA

- Regulations and Standards:
  - Animal Welfare Act &  
Animal Welfare Regulations
- Definition of animal: warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation.



# USDA CONTINUED

## USDA

- EXCLUDES:
  - birds, rats of the genus *Rattus* and mice of the genus *Mus*, bred for use in research,
  - horses not used for research purposes,
  - privately owned pets used in research (vet clinical trials)
  - non-invasive field studies with wildlife in natural habitat
  - and farm animals used for food, fiber, or production purposes.
- Applicable when covered-species are used or intended for use for research, teaching, testing, experimentation regardless of funding



# FEDERAL AGENCIES

## PHS (NIH), NSF, NASA

- Regulations and Standards:
  - PHS Policy
  - Guide for the Care and Use of Laboratory Animals (Guide)
  - U.S. Govt Principles
- Definition of animal: vertebrate animal
- ONLY applicable when certain federal funding is utilized
- OLAW



**NASA**

## VA

- Regulations and Standards:
  - Voluntarily adopts PHS Policy
  - VA Handbook 1200.07
- Definition of animal: vertebrate animal
- ONLY applicable when VA funds are used



# FEDERAL AGENCIES

## DOD

- Regulations and Standards:
  - DOD Instruction 3216.01
- Definition of animal: : vertebrate animal
- ONLY applicable when DOD funding is utilized
- ACURO



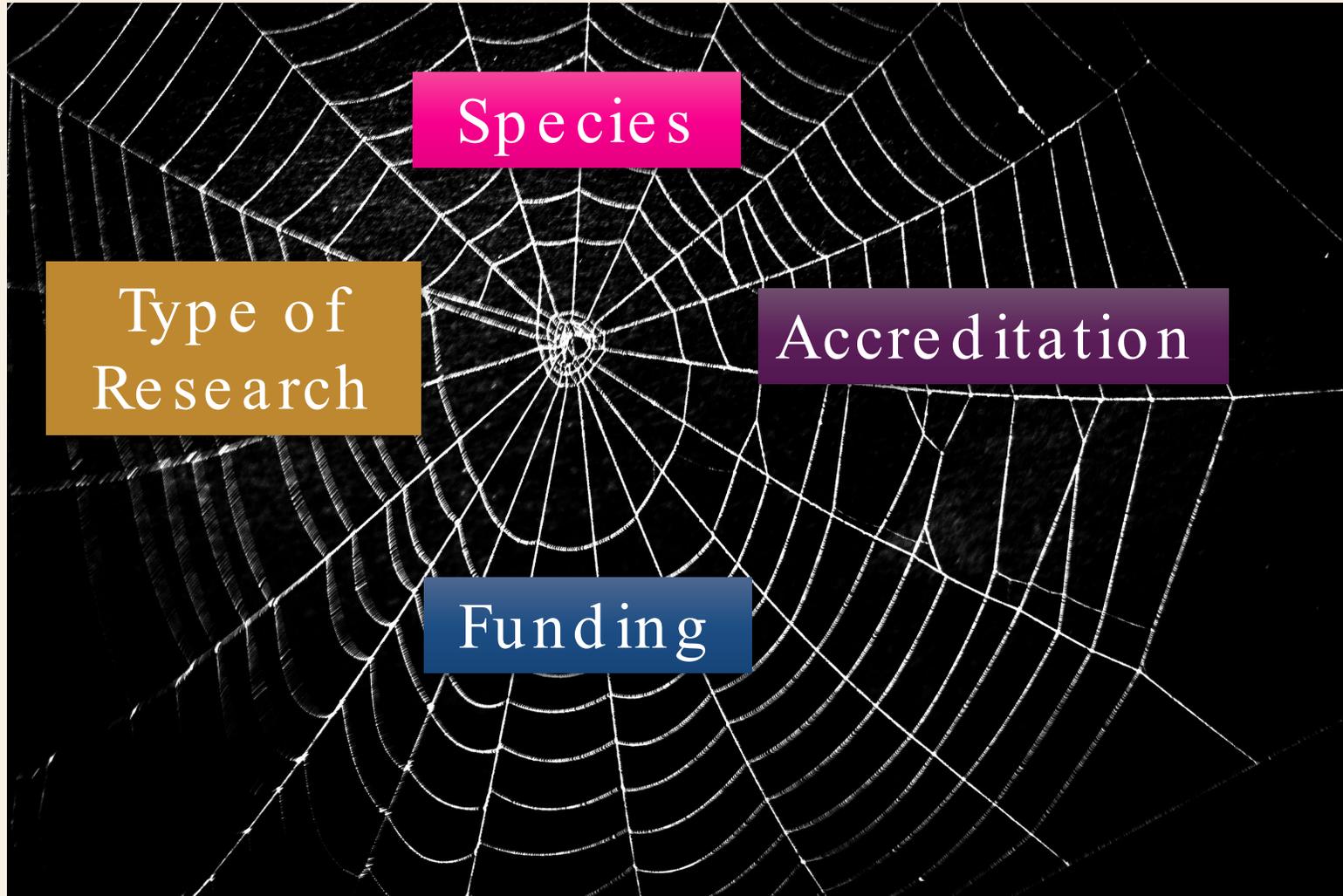
# AAALAC ACCREDITATION

## AAALAC

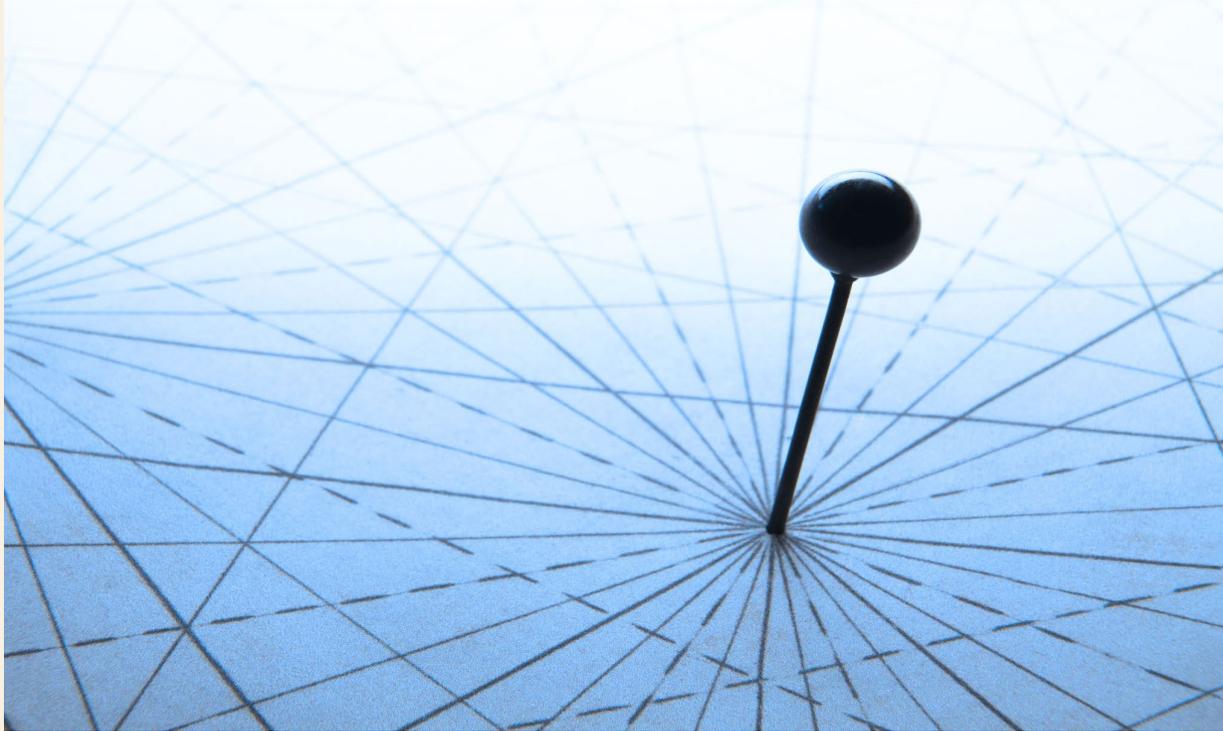
- Standards:
  - Guide; Ag Guide
  - Rules of Accreditation
- Definition of animal: vertebrate or invertebrate\*
- Voluntary accreditation; non-profit international organization



# REGULATORY OVERLAP



# COMMON GROUND...



## INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)



# WHAT IS THE IACUC?

# IACUC

- The IACUC oversees and evaluates all aspects of the institution's animal care and use program
- Institutional committee of appointed members. Membership Requirements:

Category	USDA	PHS (& NSF, NASA, VA)	Guide
Veterinarian	✓	✓	✓
Nonaffiliate	✓	✓	✓
Scientist		✓	✓
Nonscientist		✓	✓
Chair	✓		
Minimum	3	5	4

# INSTITUTIONAL OFFICIAL (IO)

- Typically NOT an IACUC Member
- Who is the IO?
  - Senior administration representative
  - Authorized to legally commit on behalf of research institution and allocate resources to the program
  - IO relies on the IACUC to oversee the program and make suggestions to them about the program
- Functions
  - Resource allocation
  - Reviews and acknowledges semi-annual reports from the IACUC
  - Makes reports to the federal agencies (e.g. suspensions, reports of noncompliance/adverse events)



# WHAT DOES THE IACUC DO?

# KEY FUNCTIONS

- Maintain Regulatory/Accreditation Status
- Protocol Review
- Semi-Annual Program Review, Inspection & Report to the IO
- Post Approval Monitoring
- Review Concerns Involving Animals
- Reporting Requirements
- Training & Occupational Health and Safety Oversight
- Disaster Planning
- Record Keeping



MAINTAIN  
REGULATORY/  
ACCREDITATION  
STATUS

# REGULATORY/ ACCREDITATION STATUS

- Animal Welfare Assurance with the Public Health Service (PHS)
  - Approved by the Office of Laboratory Animal Welfare (OLAW)
  - Required to receive certain federal funding via grants or contracts
  - Renewed every 4-years
- Registered Research Facility with the United States Department of Agriculture (USDA)
  - Research facilities using USDA covered species are required to register with USDA
  - Does not require renewal
  - Annual Inspection
- Accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
  - Voluntary accreditation and assessment program
  - Must comply with local, state and federal laws regulating the use of animals in research
  - Submission of a Program Description and a site visit every 3-years



# PROTOCOL REVIEW

# PROTOCOL REVIEW

Protocol Written by Researcher  Submitted to the IACUC for Review

- Protocol Contents:
  - Research Aims
  - Species and number of animals needed
  - Description of procedures
  - Identifies individuals working on the research
  - Includes considerations for the Replacement, Reduction, and Refinement of animal use

# PROTOCOL REVIEW

## Protocol review methods:

- Designated Member Review (DMR)
  - Designated reviewer(s) appointed by the Chair
  - Shared with the entire committee to allow for opportunity to call for FCR
- Full Committee Review (FCR)
  - Reviewed by the IACUC at a convened meeting of quorum (>50%)
  - Discussed in real-time (in-person or virtually)

## Amendment review methods:

- DMR & FCR
- Administrative (by IACUC Office)
- Veterinary Verification and Consultation (NOT-OD-14-126)

Protocols are approved for a maximum of 3-years (USDA/PHS Policy)

# FOREIGN COLLABORATIONS WITH PHS, NSF, AND NASA FUNDS



# PROTOCOL REVIEW

- When the awardee is a domestic institution, the IACUC approval requirement applies.
- [OLAW FAQ #D13](#): The awardee remains responsible for animal activity conducted at a foreign site and must provide verification of IACUC approval.
  - That approval certifies that the activity, as conducted at the foreign performance site, is acceptable to the awardee.
  - The awardee IACUC may accept, as its own, the approval of a foreign entity's IACUC; however, the awardee IACUC remains responsible for the review.
  - Additionally, the foreign institution must complete the Animal Welfare Assurance for Foreign Institutions ([Foreign Assurance](#)) available from OLAW.



Determine if a Foreign Assurance is in place

If this foreign institute does not maintain a Foreign Assurance, then OLAW will need to be contacted.

Obtain a copy of the translated protocol

Obtain a translated copy of the approved IACUC protocol from the foreign institute.

Perform the grant to protocol congruency review

Using the foreign institute's protocol and applicable portions of the grant, perform a grant to protocol congruency review.

Once congruent, proceed with IACUC review.

Provide the IACUC with the foreign institute's protocol for their review.

Accept approval

The protocol may only be approved for up to 3-years.



# SEMI-ANNUAL INSPECTIONS & PROGRAM REVIEW

# SEMI-ANNUAL FACILITY INSPECTIONS & PROGRAM REVIEW

- Inspections: Locations involving animal work/housing are evaluated by the IACUC every 6 months
  - Inspectors:
    - PHS Policy – IACUC representative (no minimum member requirement)
    - USDA AWA - Minimum of 2 IACUC members present
  - Deficiencies
    - Minor vs Significant
- Program Review: The animal program is evaluated by the IACUC every 6 months and summarized in a report to the IO.
  - What is included in the semi-annual report to the IO?
    - Semi-Annual Inspection Report and Program Review
    - Minority Opinions
    - Deviations from the Guide or departures from AWA
    - Status of AAALAC Accreditation
    - Signed by majority of the IACUC



# POST APPROVAL MONITORING

# POST APPROVAL MONITORING

- Regulatory requirement for continued IACUC oversight of animal activities
- Post-Approval Monitoring (PAM) is outlined in the Guide as an option, among others, for continued monitoring
- What is PAM?
  - Procedural based observation of activities occurring under an approved protocol
  - Proactive focus on education and training
  - Provides an opportunity for open dialogue
  - Visits may be announced or unannounced; routine or for cause
  - Follow-up visits may be performed to verify corrective actions were implemented



# REVIEW CONCERNS INVOLVING ANIMALS

# CONCERNS & INCIDENTS

- Receipt of concerns or incidents:
  - Concerns involving the care and use of animals at the research facility received from public compliant or from institutional personnel
  - Training is provided to employees on how to report welfare concerns and signs are posted within the animal facilities with contact information for reporting concerns (whistleblowers protected)
- IACUC Actions:
  - Reviewed by the IACUC to determine corrective actions and reportability
  - The IACUC may suspend animal activities (must be done at a convened meeting with quorum and majority vote)
  - If reportable, a prompt preliminary report is made followed by a final report that summarizes the concern/incident and corrective actions taken

Creating a Safe Environment  
for Whistleblowing

TODAY at 2:30pm (T410)

How do you know what concerns or incidents are reportable to OLAW, USDA, DOD, and AAALAC?



# REPORTING REQUIREMENTS

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OLAW (PHS, NSF, NASA, VA)	USDA	DOD	AAALAC
Annual Report	Annual Report	USDA Inspection Report (if applicable)	Annual Report
<p>Promptly Provide Reports:</p> <ul style="list-style-type: none"> <li>Any serious or continuing noncompliance with PHS Policy</li> <li>Any serious deviation from the provisions of the Guide</li> <li>Any suspension of an activity by the IACUC</li> <li>[NOT-OD-05-034]</li> </ul>	<p>Promptly Provide Reports:</p> <ul style="list-style-type: none"> <li>Change in operations</li> <li>Uncorrected significant deficiencies from SAFI</li> <li>Suspensions</li> </ul>	<p>Promptly Provide Reports:</p> <ul style="list-style-type: none"> <li>Significant deficiencies</li> <li>Noncompliance</li> <li>Adverse Event</li> <li>Suspension</li> <li>Change in an institution's AAALAC international accreditation status</li> </ul>	<p>Promptly Provide Reports:</p> <ul style="list-style-type: none"> <li>Change in operations</li> <li>Inadequate veterinary care</li> <li>Conditions that resulted in unexpected animal harm or deaths (e.g. natural disasters)</li> <li>Significant animal rights activities</li> <li>Substantiated complaints or reports regarding animal welfare concerns</li> <li>Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death</li> <li>Significant human health issue directly related to the animal care and use program</li> </ul>



# OTHER FUNCTIONS

# OTHER FUNCTIONS

## Training

- Training must be made available to personnel
- Monitoring, reviewing, and making suggestions for improvement to the IO falls under the scope of responsibility of the IACUC

## Occ Health Safety

- Health program for personnel who work with animals or have frequent contact with animals

## Disaster Planning

- Planning to account for adverse, emergency, and unexpected events to safeguard health and welfare

## Record Retention

- 3-years past project completion date (PHS Policy & AWR)



# THANK YOU

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