IACUC Administrator Association

IACUC Administrators Best Practices Meeting Wednesday, May 29, 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

IAA The IACUC Administrators Association

Questions? E-mail IAA.

- About IAA
- Join IAA
- Meetings
- Resources
- Contact

Network with other administrators. Share successful procedures and practices.
Keep current on changes in laws, regulations and policies, and other professional standards.

Who We Are

We are a society of professionals who serve in the trenches of animal care & use oversight. Our roles are many and our challenges several, but we have a common thread – humane care and compassionate use of animals in an appropriate regulatory environment!

Why Join IAA?

1. To network with other IACUC Administrators who are dealing with issues similar to yours.

2. To get the 'inside scoop' on new ideas at the Best Practice meetings.

3. To have access to previous Best Practice

Our Next Meeting...

What is the IAA?

An organization that provides a "professional home" specifically for IACUC Administrators

THAT facilitates opportunities for them to network and communicate, discuss programmatic issues with peers, and to discover, develop and implement successful plans/best practices.

What's the primary mission of the IAA?

To give those working in the trenches of animal care and use programs, a way to share proven work methodologies, develop best practices, and to provide a forum for discussing ideas to resolve common problems.

To help administrators connect with colleagues from OLAW, AAALAC and USDA .

Current Projects

1. Working on a standardized protocol template;

2. Developing a tool kit for wildlife compliance research; and

3. Developing emergency disaster plan shared resources

IACUC Administrator Association

Join by completing an online application:

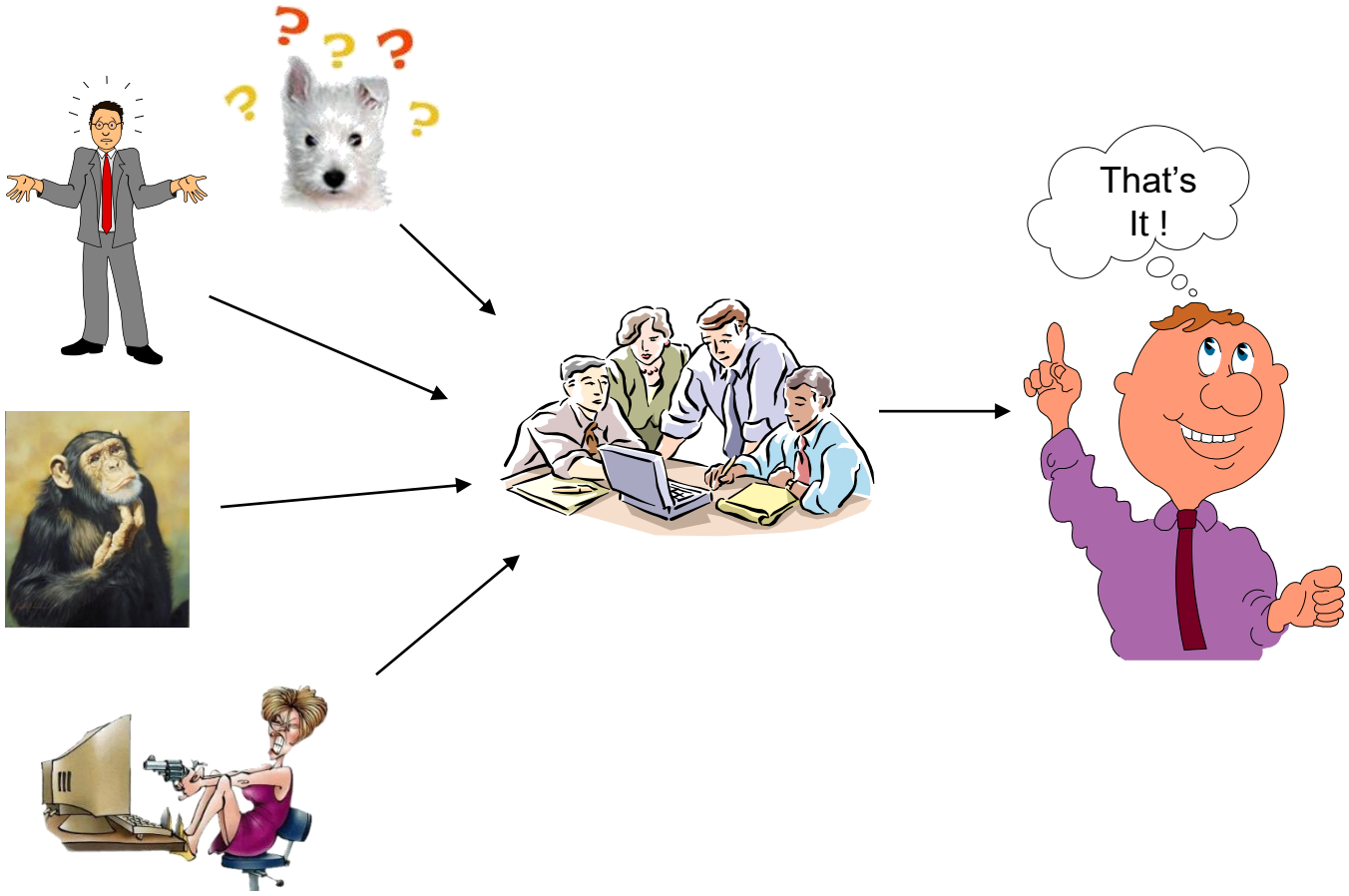
- http://iacucaa.org/
- http://iacucaa.com/

Best Practice Meeting Format

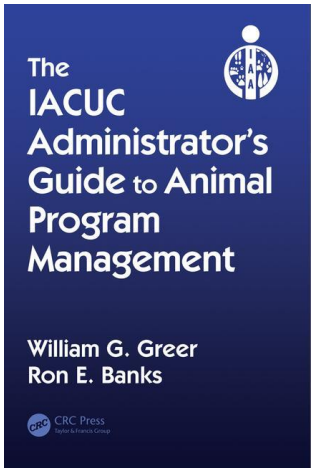
Our meeting model?

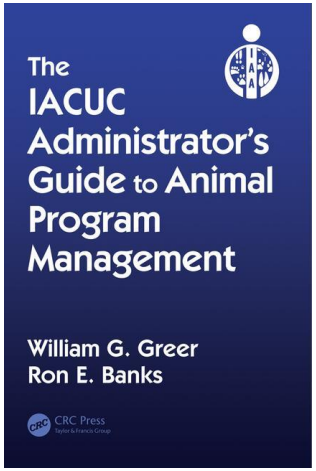
- The facilitator promotes a continuous discussion
- Attendance is limited to about 50.
- An informal discussion is initiated with a 10 – 15 minute presentation from one of our peers.
- Representatives from OLAW, the USDA and AAALAC are present to participate in the discussions.

Common Problems and Unique Solutions



10 years of Meeting Proceeds





After 30 meetings with over 1500 attendees.

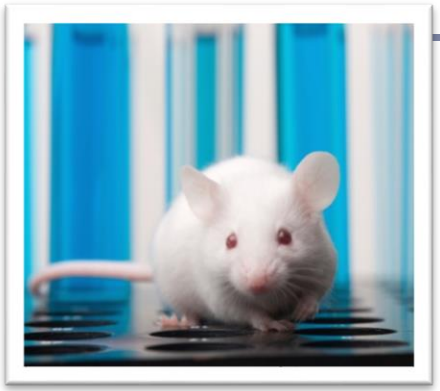
2020 Meeting Schedule

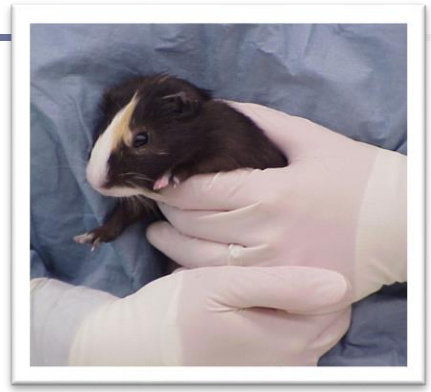
1. Cincinnati, OH (March 17-18, 2020) - Confirmed
2. New Haven, CT (TBD)
3. San Diego, CA (TBD)
4. Oklahoma City, OK (TBD)
5. State College, PA (TBD)
6. Austin, TX (TBD)
7. Fairbanks, AK (TBD)
8. Bozeman, MT (TBD)

Questions

Animal Care and Use Program

Excellence & Compassion. Better Together.





Bill Greer

Assistant Vice President for Research, Research Compliance

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
UNIVERSITY OF MICHIGAN

“Regulatory Reform”
Efforts Update and Discussions

Some History

1. 2005 Federal Demonstration Partnership survey of investigator (42%)
2. 2009 National Research Council (NRC) report stated that the problem of excessive regulatory burdens on university research programs could cost "billions of dollars over the next decade."
3. A 2012 survey of FDP faculty members (seven years after the first survey) found that the average time that PIs of federally sponsored research projects spend on associated administrative tasks remained at 42 percent.
4. A 2013 review by the Council on Governmental Relations' (COGR) November, demonstrated there continues to be an ongoing increase in regulations affecting PIs and research institutions.
5. 2014 National Science Board Report - Reducing Investigators Administrative Workload for Federally Funded Research (AKA – Reducing Regulatory Burden) – average remained 42%
6. A 2018 survey of FDP faculty members (six years after the first survey) found that the average time that PIs of federally sponsored research projects spend on associated administrative tasks remained at 44 percent.

21st Century Cures Act

1. The 21st Century Cures Act, Section 2034 (d) was signed into law on December 13, 2016, which requires regulating agencies (e.g., OLAW and the USDA) to review animal research regulations and make revisions that would result in reduce administrative burden for investigators.

2. On February 24, 2017, President Trump issued an Executive order: (**139 - Executive Order 13777)** to enforce the Regulatory Reform Agenda**.** http://www.presidency.ucsb.edu/ws/index.php?pid=123412

3. Upon completing their assessment of the animal research regulations; on March 14, 2018, federal regulators offered ideas for proposed changes through the Federal Register (https://www.federalregister.gov/d/2018-05173/page-11221).

4. Through the federal register (Federal Register / Vol. 83, No. 50 / Wednesday, March 14, 2018) (83 FR 11221) information from the animal research community was requested.

Regulatory Reform, the Next Step

1. March 14, 2018 – Input from the research community was requested as a result of the 21st Century Cures Act.

2. The Cures Act Working Group reviews the public comments, issues a Draft Report on "*Reducing Administrative Burden to Researchers for Animal Care and Use in Research*", and asks the research community for comments (Due February 20, 2019)

3. The comment period has closed with the information being considered by the relevant federal working groups.

4. On August 28, 2019 NIH Notice "NOT-OD-19-136" – the final "Report on Reducing Administrative Burden for Researchers: Animal Care and Use in Research" was released.

Cures Act Follow-up

Notice Number: NOT-OD-19-136

Report on Reducing Administrative Burden for Researchers: Animal Care and Use in Research

08/28/2019

NIH announces in NOT-OD-19-136 the publication of Reducing Administrative Burden for Researchers: Animal Care and Use in Research (PDF), a report by the NIH, the United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA). The report describes the recommendations of the 21st Century Cures Act, Section 2034(d), Working Group and decisions of the agencies.

More information can be found on the OLAW website at https://olaw.nih.gov/21st-century-cures-act.htm.

This page last updated on: Nov 1, 2019
Content Questions: E-mail OLAW
Technical Issues: E-mail Webmaster

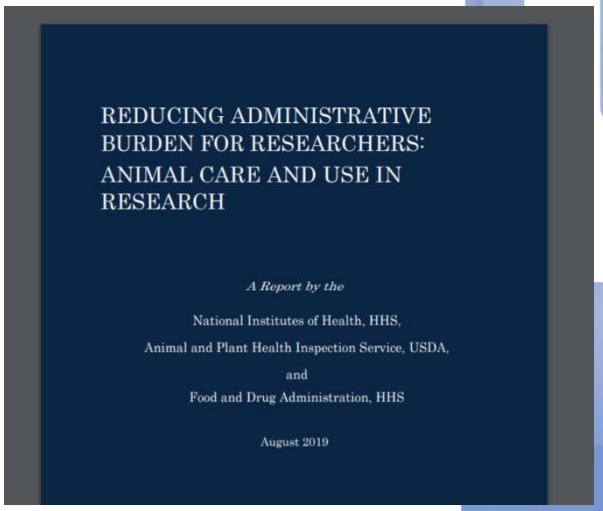
This notice is to announce publication of Reducing Administrative Burden for Researchers: Animal Care and Use in Research (PDF), a report by the National Institutes of Health (NIH), the United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA). The report describes the recommendations of the 21st Century Cures Act, Section 2034(d), Working Group and decisions of the agencies.

Background

Title II, Section 2034(d) of the 21st Century Cures Act (P.L. 114-255) was enacted December 13, 2016, and requires the NIH in collaboration with USDA and FDA to complete a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. The Act instructs NIH to: (1) seek the input of experts, if appropriate; (2) identify ways to ensure applicable regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative; (3) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and (4) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

NIH, USDA, and FDA convened a Working Group of federal subject matter experts to identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies and prepare a report of their recommendations as directed in the 21st Century Cures Act. The report on Reducing Administrative Burden for Researchers: Animal Care and Use in Research (PDF) describes the efforts of the Working Group, their recommendations, and the decisions of NIH, USDA, and FDA on the recommendations.

Regulatory reform – an opportunity



Example highlights:

- Propose to align USDA and PHS protocol re-review requirements

- Update guidance on the use of non-pharmaceutical drugs and agents.

Develop a resource that defines what is exempt from IACUC review

"Reducing Administrative Burden for Researchers: Animal Care and Use in Research"

Some Highlights

1. Reduce Duplicative Regulations and Policies
2. Define the flexibility that exists within the standards
3. Establish resources defining what is exempt from IACUC review
4. Proposed elimination of annual reviews for USDA species
5. NIH will continue to support the efforts of the IAA to create a repository of Best Practices

What can We do in Preparation for Regulatory Reform?

If the minimum expectation isn't good enough, then it wouldn't exist!!

1. Review and understand the *"Reducing Administrative Burden for Researchers: Animal Care and Use in Research"*

AND

2. Ensure you institution's program takes full advantage of the flexibility offered in the current standards

Understand Self Imposed Regulations (Regulatory Creep)

Why there's regulatory drift.

- Risk Aversion
- Goal to be perfect

What can result in self-imposed regulatory burden?

1. The “Snow Ball” affect!

2. The lack of risk awareness

“Now, Connor, I want you to go over and apologize to those people for rolling that big snowball down the hill.”

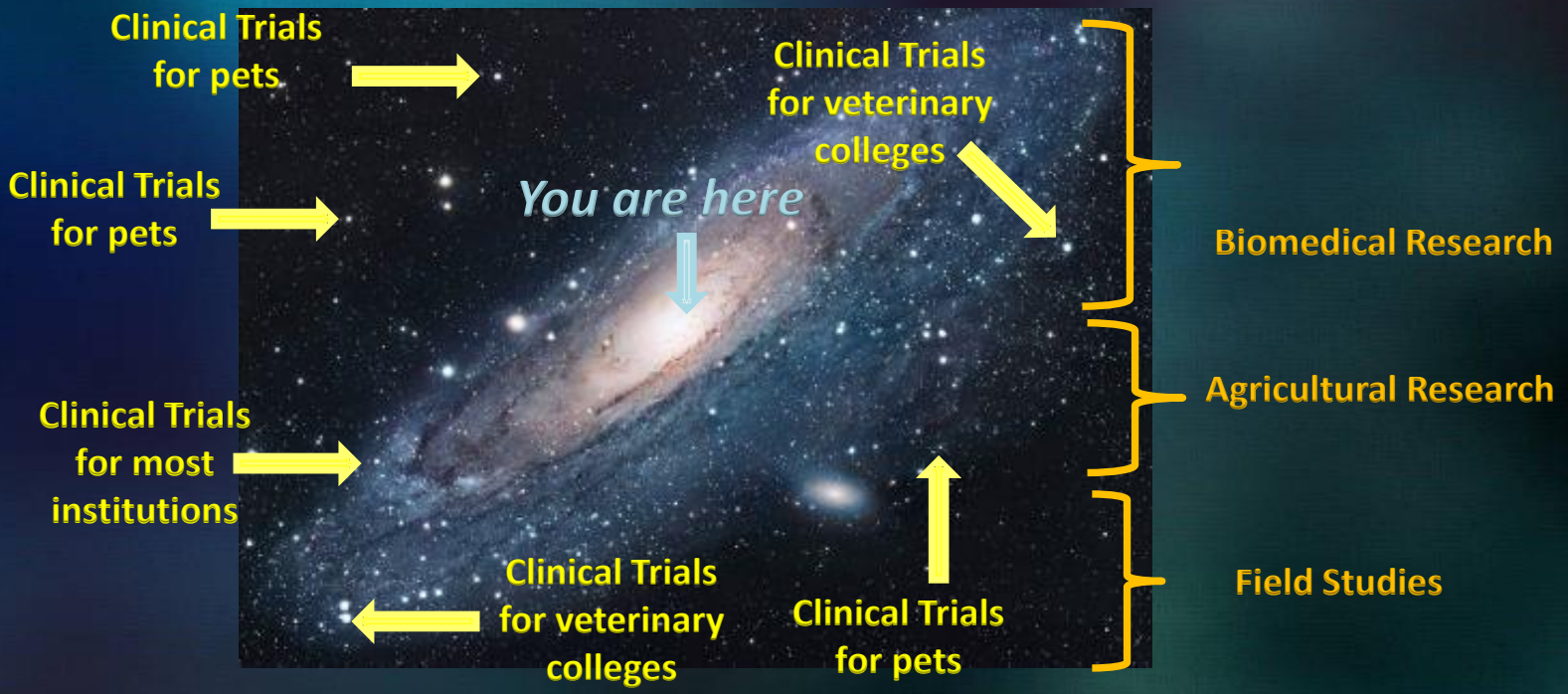
Questions/Discussion Scenario

During a routine IACUC inspection, IACUC members found live mice in the carcass freezer. Upon review by the AV, it was discovered that the animals had been euthanized by CO2 asphyxiation, but the secondary method was not successfully conducted. Outcomes:

1. **Self imposed regulations:** To ensure this event never reoccurred, the IACUC required everyone that uses CO2 asphyxiation for euthanasia to undergo an extensive 2 hour hands on re-training course. In addition, the course was incorporated into an already 4 hour mandatory training program taken by new animal users.
2. **Avoid additional regulations:** the specific research team was retrained.

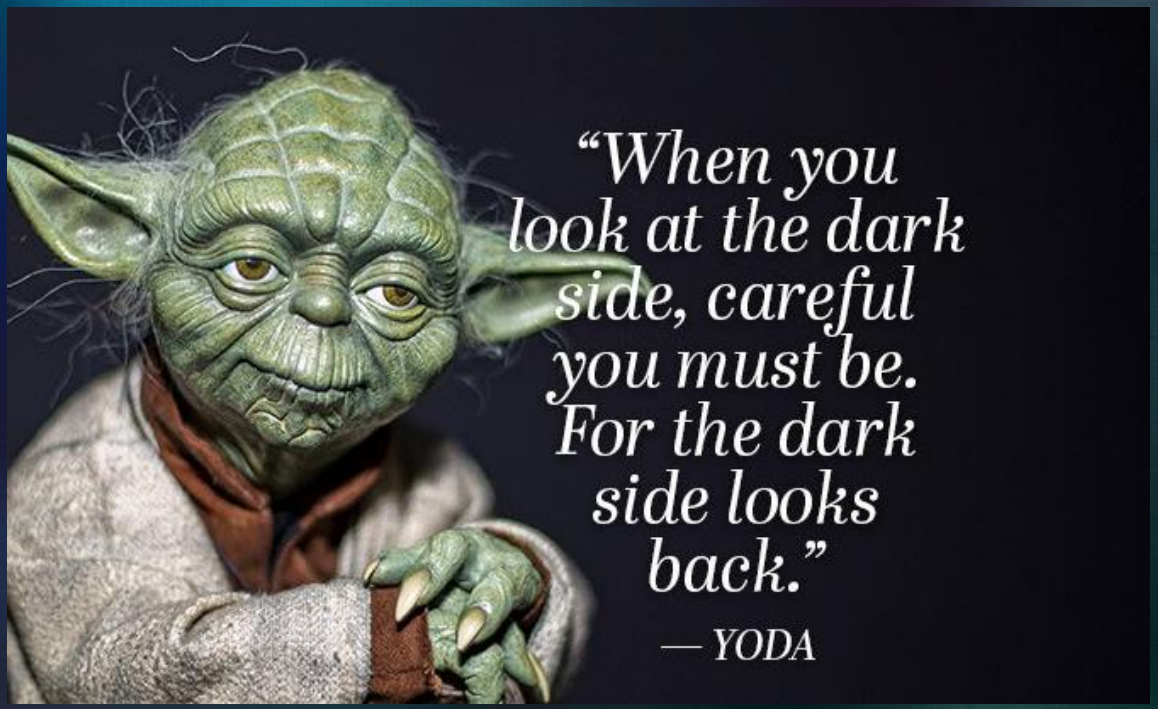
Clinical Trials / Clinical Research / Clinical Studies

The galaxy that is animal based research ……



The Cosmological question:

When does a CT/CR/CS cross the line and require IACUC Involvement?????



What do we KNOW about CT/CR/CS?

Maybe not much ….. But this we should know:

- Clinical trials are generally viewed favorably by most folks.
- The purpose of a CT/CR/CS is to provide conclusive resolution to a clinical problem.
- CT/CR/CS is comparative medicine at its climax!
  - Basic research –> translational research –> clinical trials –> healthy patient! (famous doctor)
- Clinical care of a privately owned animal (e.g., standard of care provided in a competent and humane manner consistent with current veterinary medical practice) is not a research activity and does not require IACUC approval.
- Non-standard care (e.g., a trial, research, or study) provided in a competent and humane manner consistent with current veterinary practice standards is a research activity and MAY require IACUC approval …. depending:
  - Ownership
  - Funding
  - Species

When is a Clinical Trial Not Research?

- PHS / NIH / NSF:
  - The PHS Policy covers live vertebrate animals used or intended for use in research, research training, and biological testing activities conducted or supported by the PHS NIH or NSF or DoD or ……).
  - The PHS Policy and the Animal Welfare Act and Regulations (AWAR) do not distinguish between animals owned by the institution and privately owned animals. Pets used in *research* must be covered:
    - Under an IACUC-approved protocol.
    - At an OLAW-approved Animal Welfare Assurance covering all performance sites.
  - The institution should ensure that the informed consent of the owner is obtained prior to the conduct of the research. The institution may want to involve their legal counsel in the development of informed consent documents.

When is a Clinical Trial Not Research?

- AWA:
  - The AWA is not so clear in its definition of animal. "The term "animal" means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal that is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes"
  - Some guidance was provided in commentary from the USDA in a case scenario involving research using privately owned animals (Lab Animal 2010). The distinction is made between research activities using tissue obtained from medically justified procedures (standard care) versus those procedures that may be considered "experimental"—specifically, the live animals' roles in those activities, that is, patient or research subject. Oversight by the USDA may not extend to those animals with a documented VCPR.

When is a Clinical Trial Not Research?

- AAALAC:
  - Who owns the animal?

Clinical Trial Scenario

- Dr. Lisa Archer, a board-certified veterinary oncologist at the Great Eastern University College of Veterinary Medicine, had a particular interest in canine mast cell tumors. Before she began treating an affected animal, which usually included surgically removing the tumor, she would ask her client to sign a release allowing part of the tumor tissue to be used for her research. The release also stated that the identity of the owner and the animal would be removed from the tissue sample. Her research, which was done entirely *in vitro* using the tumor tissue, was funded by a grant from the National Institutes of Health. Other than asking clients to sign the release, Archer did not solicit subjects for the study, because the clinic's case load almost guaranteed that she would obtain a large enough sample size. The college's Clinical Research Committee (CRC), but not the IACUC, had approved the study because the animals involved were privately owned, were brought to the school for clinical treatment and received exactly the same treatment as did animals whose owners chose not to participate in the study.

Clinical Trial Scenario

- A client whose dog had a mast cell tumor was talking to Archer and mentioned that he was a physician at the Great Eastern University School of Medicine. He said that at the medical school, a study like Archer's would require approval by the Institutional Review Board (a committee that oversees the protection of human subjects). Archer knew that the Public Health Service *Policy on Humane Care and Use of Laboratory Animals* did not draw distinctions between privately owned and institutionally owned animals, but she did not want to rock the boat and make more work for herself. Nevertheless, some discrete inquiries on her part revealed that at one time, the Great Eastern IACUC did require that similar studies obtained its approval, but over time decided that its approval was not truly required and ceded the responsibility to the CRC.

Does Archer's study require IACUC approval, or is approval from only the CRC appropriate for her research?

What is INFORMED CONSENT?

- Emphasis on the fact that participation of one's pet in a clinical research study is voluntary
- Declination of participation will not result in the loss of benefits the pet would otherwise be entitled to
- Information on other treatment options not directly related to the study
- Discussion with other family members and the primary care veterinarian is encouraged
- Clarifications of any medical terms will be provided by the study veterinarian
- Purpose of the study (e.g. investigating a new device, drug or therapeutic plan)
- Amount of time the pet will be on study
- Number of other pets that may be included may aid in the owner's decision to enroll if the pet will be one of only a few or one of many other patients
- Description of the test/procedures that the pet may undergo, including the number of times the test may be performed
- Clarification on which tests/procedures are standard care (routine procedures or therapies normally used for the disease being treated and studied) and which are "experimental" (procedures or therapies that are being studied but are not routinely practiced)

What is INFORMED CONSENT?

- Complete explanation of any risks or discomfort the pet may experience
- Explanation of the possible benefits of the study and a clarification that there may not be any benefit to an individual pet if the experimental therapy is not effective or the pet receives the placebo
- New information discovered (e.g. unexpected side effects) during the course of the study will be relayed to the client, as this information may alter the agreement of consent
- Description of any waiver of costs or the provision of monetary compensation
- How adverse reactions/events will be managed and who will be financially responsible for the management of an adverse event
- Postmortem evaluation may be expected for animals if they die while on study
- The client may withdraw the pet from the study at any time; full financial compensation may or may not be contingent on completion of the study
- Explanation of privacy, for example, who else may see the pet's clinical and study records.

What do others think about CT/CR/CS?

- AVMA encourages 'third party review of all research and teaching activities – it provides legal and ethical protections not otherwise present'
- Publication in journals generally required an oversight committee review.
- IACUCs may be traditionally focused and unable to effective address CT issues …. Consider:
  - A subcommittee of the IACUC for all CT studies.
  - @ Cornell: Clinical Veterinary Medical Research Clinic:
  - @ OSU: Clinical Research & Teaching Advisory Committee: one standing member of the IACUC
  - @ U Penn: Privately-Owned Animal Protocol Review Committee (& IACUC): POARC includes member with IRB experience.

Break-Time

"SEMI-ANNUAL PROGRAM REVIEWS – WAYS TO BETTER ENGAGE THE IACUC MEMBERS"

Mike Ream

Quality Assurance Specialist

University of Michigan

EVERY IACUC IS DIFFERENT!

THEY DO HAVE ONE THING IN COMMON THOUGH!

THINGS TO CONSIDER WHEN DECIDING HOW TO DO YOUR SEMI-ANNUAL REVIEW

- Size of your IACUC
- Size of your program
- Engagement level of your IACUC

HOW WE USED TO DO IT AND WHY WE CHANGED

- We crammed the entire semi-annual program review in one IACUC meeting but occasionally it would trickle to a second meeting.
- Typically the same people speak up about issues
- Lot less engagement for alternate member and other staff that can be used as resources.
- Time becomes a factor and could compromise the review
- New format allows for a more thorough review.

HOW WE DO IT NOW

- Semi-Annual Program Review by subcommittees
- Each subcommittee has a chair
- All IACUC members and alternate members are assigned to a subcommittee
- All members from the Animal Care and Use office are also assigned to the subcommittees as a resource and support for the subcommittee
- Each subcommittee is given a section/ or sections to review and then present to the rest of the IACUC

HOW IT WORKS

- Subcommittee chair is in charge of coordinating a meeting time for the group to meet.
- Chair leads the meeting
- Subcommittee goes through their section/ sections and ranks their findings
- The subcommittee prepares a presentation to present to the rest of the IACUC on what their findings and recommendations are.

THE RANKINGS

- **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

SUBCOMMITTEE ASSIGNMENT SHEET

Program Section	IACUC Voting Members	IACUC Alternate Members	Other Resources
• Disaster Planning and Emergency Preparedness			
• Protocol Review (special considerations)			
• Occupational Health and Safety			
• Animal Care and Use Program • The IACUC • IACUC Memberships and Functions • IACUC Records and Reporting			
• Veterinary Care • Personnel Security and Reporting Concerns			
• Pain, Distress, Anesthesia and Analgesia • Animal Procurement, Transportation and Preventative Medicine			
• IACUC Member Training • Personnel Qualifications and Training			
• Clinical Care and Management			
• Surgery			
• Euthanasia and Drug Storage			

CHECKLIST EXAMPLE

1. Animal Care and Use Program NEW	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (*Guide*, p 1) [must]					
• IO has authority to allocate needed resources (*Guide*, p 13)					
• Resources necessary to manage program of veterinary care are provided (*Guide*, p 14) [must]					
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the *Guide* (*Guide*, pp 11, 15)					
• Program needs are regularly communicated to IO by AV and/or IACUC (*Guide*, p 13)					
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (*Guide*, p 14) [must]					
• Inter-institutional collaborations are described in formal written agreements (*Guide*, p 15)					
• Written agreements address responsibilities, animal ownership, and IACUC oversight (*Guide*, p 15)					

CHECKLIST EXAMPLE

1. Disaster Planning and Emergency Preparedness NEW	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (*Guide*, p 35, p 75) [must]					
• Plans include provisions for euthanasia (*Guide*, p 35) [must]					
• Plans include triage plans to meet institutional and investigators' needs (*Guide*, p 35)					
• Plans define actions to prevent animal injury or death due to HVAC or other failures (*Guide*, p 35)					
• Plans describe preservation of critical or irreplaceable animals (*Guide*, p 35)					
• Plans include essential personnel and their training (*Guide*, p 35)					
• Animal facility plans are approved by the institution and incorporated into overall response plan (*Guide*, p 35)					
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (*Guide*, p 35)					

- https://grants.nih.gov/grants/olaw/sampledoc/cheklist.pdf
- https://olaw.nih.gov/sites/default/files/cheklist.doc
  (this link is the downloadable document)
- https://grants.nih.gov/grants/olaw/sampledoc/chek1a.htm

QUESTIONS/ DISCUSSION

VANDERBILT UNIVERSITY
MEDICAL CENTER

Re-using Animals: Is it OK? Are there any limits?

Best Practice Meeting
November 2019

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

The 3Rs

The **Three Rs** (**3Rs**) in relation to science are guiding principles for more ethical use of animals in testing. They were first described by W. M. S. Russell and R. L. Burch in 1959. The 3Rs are:

1.Replacement: methods which avoid or replace the use of animals in research.

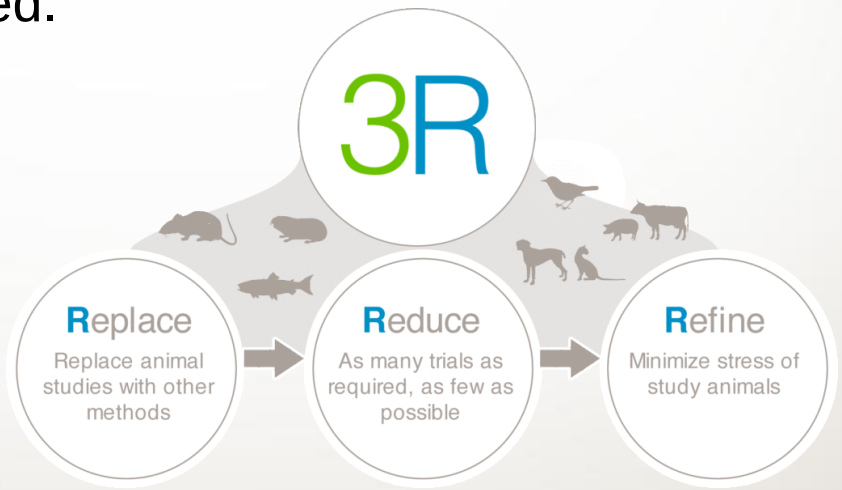
2.Reduction: use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.

3.Refinement: use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.

The 3Rs: Replacement, Reduction, and Refinement, are important from a legal, ethical and scientific standpoint.

The 3R's Conflict

Conflicts between each "R" have also been identified as a limitation, such as the conflict between the goal of reducing overall numbers and the goal of minimizing pain and distress for individual animals (Refinement). The advent of newer and less invasive methods of data collection make it possible to re-use animals; however, this reduction strategy has the potential to increase harm to individual animals, and so must be carefully balanced.



Reuse OK?

"Easy" types of reuse:

1. Shared tissues
2. Shared use in a non-survival procedure
3. Use the 'extra' animals that didn't meet experimental needs for training/research
4. Others…

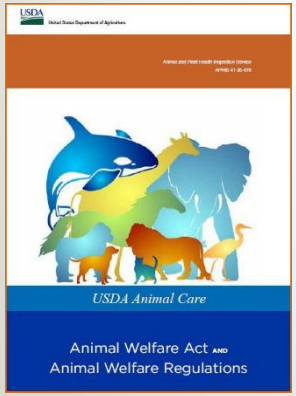
Other types of reuse:

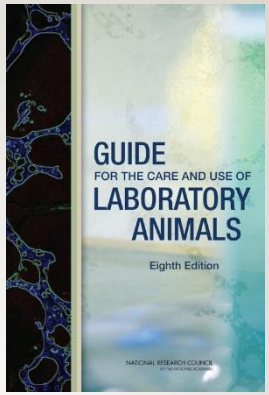
1. Repeat use of a trained animal for behavioral tasks
2. Repeat clearings/repairs of instrumented animals
3. Use of instrumented/trained animals with 'other' types issues
4. Others……

The Regulatory Agencies

From the USDA:

No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity, veterinary care or other special circumstances as determined by APHIS. The Institutional Animal Care and Use Committee (IACUC) must ensure that survival surgery will avoid or minimize pain and is aseptically performed by qualified personnel.





The Regulatory Agencies

From the *Guide*:

Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical reasons. Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC.

Justifications for allowing animals not regulated by the USDA to undergo multiple survival procedures that meet the above criteria should conform to those required for regulated species. If multiple survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes.

At Vanderbilt…

- SOPs:
  1. Maximum Administration Volumes by Species & Route
  2. Blood Sampling Volumes
  3. Multiple Survival Surgeries and Relevant Recordkeeping

- Yearly update to the IACUC regarding survival surgeries on several of the USDA-covered species.

- No formal policy on what is *too many*…but lots of discussion at the IACUC meetings. Handled on a case-by-case bases.

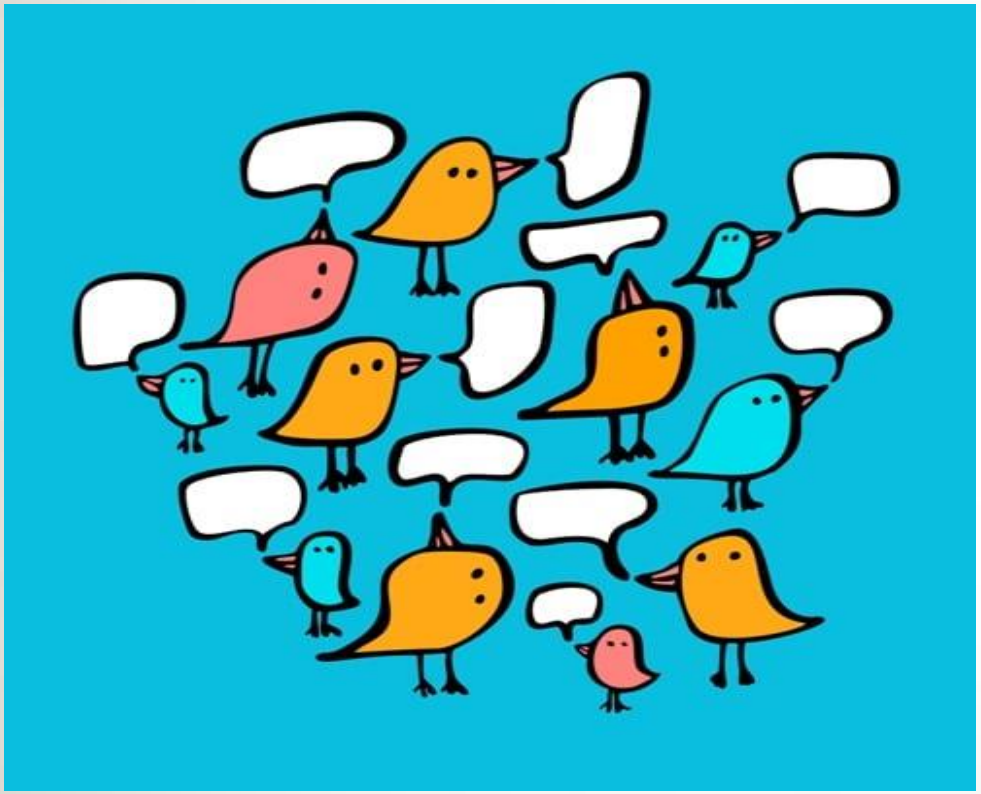
Does your Institution have:

A Policy/SOP for:

- ✓ Sharing animals (tissues/training)
- ✓ Number of procedures (blood collections) per animal
- ✓ Number of surgeries allowed per animal

❖ Does USDA-covered or not matter?

Discussion



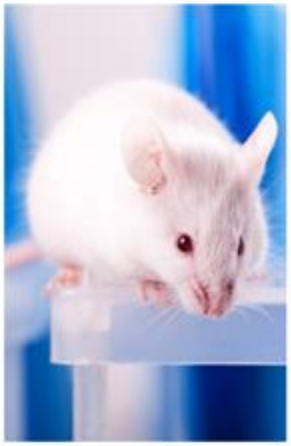
Regardless of classification, multiple surgical procedures on a single animal should be evaluated to determine their impact on the animal's wellbeing.

Time for Lunch!!

AAALAC International Update

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






Staff Changes - Dr. Gary Borkowski

- Global Director
- Oversee the accreditation program globally
- Part of AAALAC's distributed staff
  - Based in Missouri

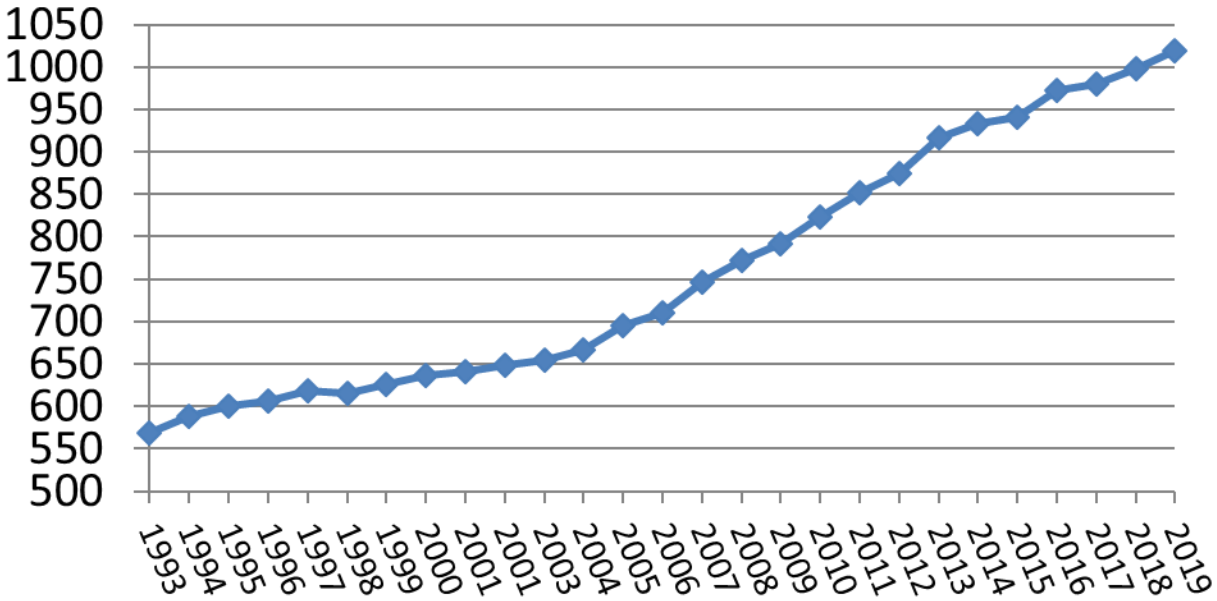
Staff Changes - Dr. Helen Diggs

- Senior Director
- Education & Outreach/Facilitate Accreditation Activities
- Part of AAALAC's distributed staff
  - Based in Oregon

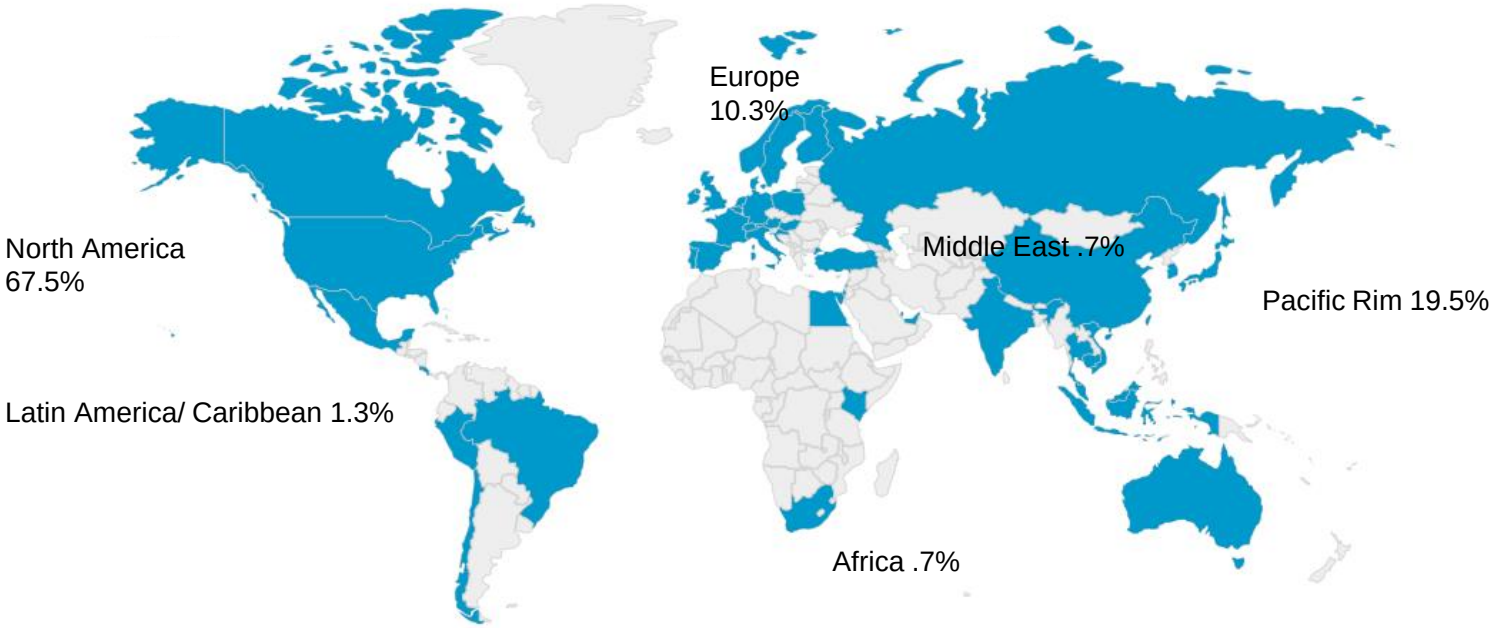
Staff Changes - Dr. James Swearengen

- Director of Special Projects

Number of Accredited Programs

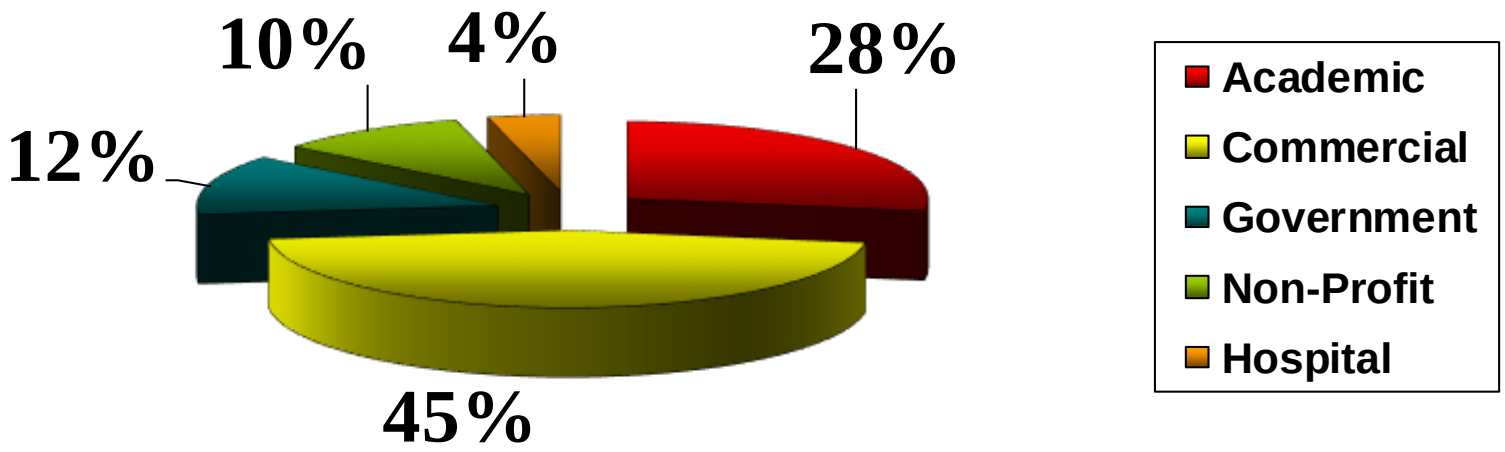


1030 Accredited Programs in 49 Countries/Regions



Demographics

(proportion of accredited programs by industry sector)



Approximately 98% of institutions are in a Full Accreditation status

Logo From Members Only Section

Cephalopods

- Annual Report Accounting of usage

11. Approximate annual usage for the above stated reporting period (for U.S. units, USDA Annual Report figures may be used for regulated species):

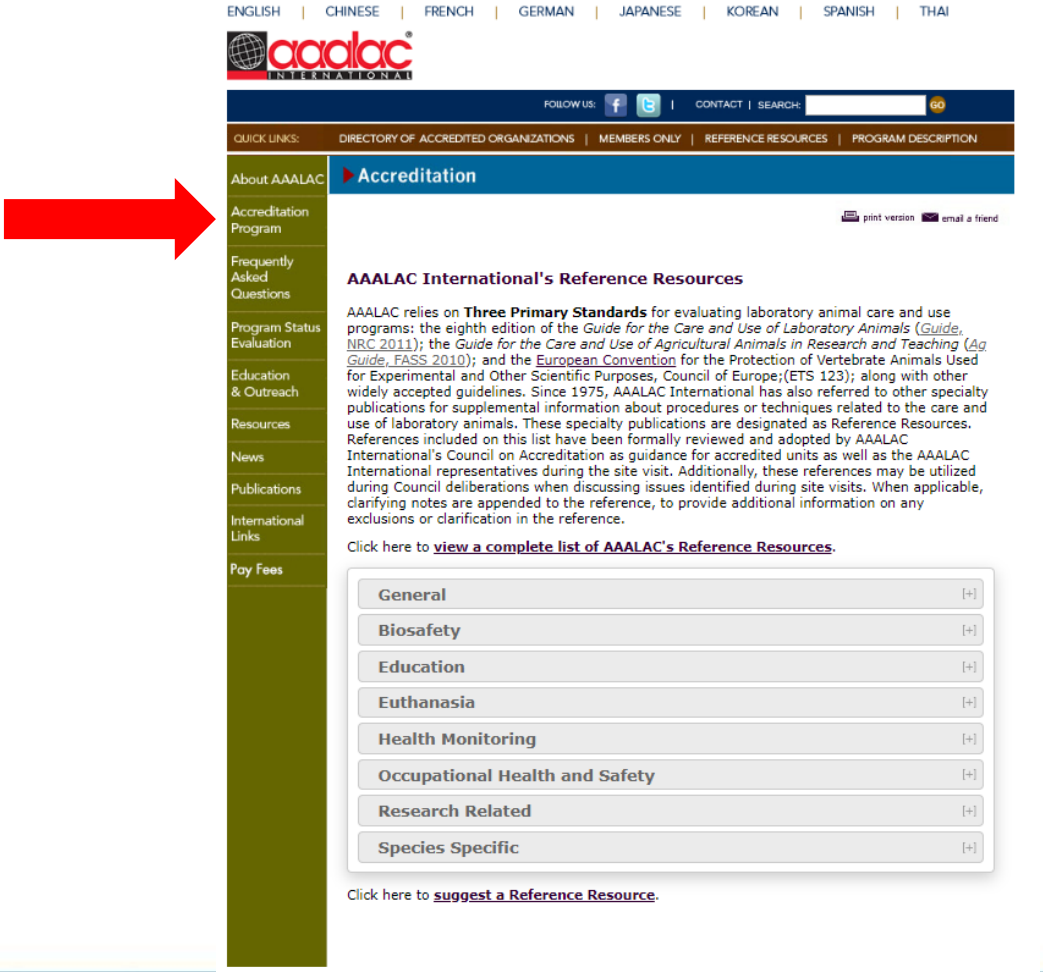
	Annual Usage		Annual Usage
Mice		**Horses**	
Rats		**Cattle**	
Hamsters		**Sheep**	
Guinea Pigs		**Swine**	
Rabbits		**Poultry**	
Dogs			
Cats		**List Others:**	
New World NHP			
Old World NHP			
Birds			
Fish			
Amphibians			
Reptiles			
Cephalopod			

Program Description
Inclusion of Cephalopods

Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, cephalopods **(whose use may be described in Appendix 18 in lieu of each section of the Program Description)**, etc.

New Reference Resource



Species Specific [–]

Amphibians and Reptiles
DOWNLOAD PDF | VIEW IN READER

Cephalopod
DOWNLOAD PDF | VIEW IN READER

Dogs
DOWNLOAD PDF | VIEW IN READER

Fish

CCAC Guidelines on The Care and Use of Fish in Research, Teaching and Testing
DOWNLOAD PDF | VIEW IN READER

Guidance on the housing and care of Zebrafish (Danio rerio)
DOWNLOAD PDF | VIEW IN READER

Guidance on the severity classification of scientific procedures involving fish
DOWNLOAD PDF | VIEW IN READER

"Guidelines for the Use of Fishes in Research" Use of Fishes in Research Committee
DOWNLOAD PDF | VIEW IN READER

Nonhuman Primates

APV Food Restriction Guidelines for Nonhuman Primates in Biomedical Research
DOWNLOAD PDF | VIEW IN READER

Guidelines for Use of Fluid Regulation for Nonhuman Primates
DOWNLOAD PDF | VIEW IN READER

Health monitoring of non-human primate colonies
DOWNLOAD PDF | VIEW IN READER

AAALAC International

Study on Accreditation of Institutions Conducting Research with Animals

Prepared in compliance with ISO 20252 International Quality Standard for Market, Public Opinion and Social Research, to which EurekaFacts is certified

Smart Research Solutions

Analysis of Reducing Administrative Burden for Researchers: Animal Care and Use in Research (NIH, USDA, FDA 2019)

Page Number	Section	Excerpt from Report
3	2. Listening Sessions and Meetings with Organizations and Stakeholders	AAALAC International Council Teleconference Meeting, January 29, 2018, Working Group members: Patricia Brown, Estella Jones, Betty Goldentyer
4	3. Public Comments on Proposed Actions-Requested Feedback	Encourage the use of sections of the AAALAC International (AAALAC) program description in applicable parts of the OLAW Animal Welfare Assurance, for institutions accredited by AAALAC.
5	Steps to Reduce Duplicative Regulations and Policies with a Focus on Inspection, Review, and Reporting Requirements	Semiannual Inspections: NIH OLAW allows the substitution of the AAALAC site visit for the semiannual program evaluation and provides details on the criteria for this provision. USDA allows additional flexibility in how and by whom the semiannual inspections are conducted. For example, AAALAC site visits that are consistent with Section 2.31(c) of the Animal Welfare Regulations may be counted as one of the IACUC semiannual inspections.
6	Steps to Reduce Duplicative Regulations and Policies with a Focus on Inspection, Review, and Reporting Requirements	Reporting: NIH OLAW will change the instructions to the domestic Animal Welfare Assurance to support the use of AAALAC program description (PD) elements, thereby enabling consistency and limiting the rewriting of responses relevant to both documents. NIH OLAW will coordinate with AAALAC to develop options for harmonizing documents to meet both organizations' requirements. An institution's AAALAC PD would not be collected or viewed by NIH OLAW as part of this plan.
28	Appendix 2: Analysis of Responses to RFI	A2: Allow annual reporting to OLAW and USDA on the same reporting schedule and as a single report through a shared portal. AAALAC report should also be included.
48-50		B1: Encourage the use of sections of the AAALAC International program description in applicable parts of the OLAW Animal Welfare Assurance for institutions accredited by AAALAC International. NIH OLAW plans to change the instructions to the domestic Animal Welfare Assurance to support the use of certain elements of the AAALAC program description (PD) to enable consistency and limit rewriting of responses relevant to both documents. NIH OLAW plans to coordinate with AAALAC about options for harmonizing documents to meet both organizations requirements. NIH OLAW does not and will not obtain institutional information from AAALAC for the Animal Welfare Assurance document. The Freedom of Informatior Act only applies to documents in a federal agency's possession at the time of a request.
53		B4: Encourage the use of new or existing tools to streamline protocol review through use of Designated Member Review (DMR), DMR subsequent to Full Committee Review (FCR), and/or Veterinary Verification and Consultation (VVC). Disagree- protocols that go to FCR often have more thorough reviews; when AAALAC finds one of our protocols has problems, it is usually a protocol that went through DMR.
58		B6: Other tools or resources not previously mentioned. Decrease the frequency of USDA inspections based on: consideration of AAALAC full accreditation (e.g., every three years vs annually (NB: one of three proposed criteria). USDA Response: Regarding AAALAC, USDA already allows a site visit conducted by AAALAC to substitute for an IACUC semiannual inspection as long as the requirements as set forth in 9 C.F.R. § 2.31(c) are met.
61	Appendix 3: Analysis of Responses to the Draft Report of the Working Group	1C. Semiannual Inspections: flexibility for conducting inspection - NIH OLAW allows flexibility in the use of the AAALAC site visit as a substitution for the semiannual program evaluation and provides details on the criteria for its application.
64		3B. Reporting: use of AAALAC PD for Assurance. Agree - support harmonizing NIH Assurance with AAALAC PD. Disagree - detail in AAALAC PD is beyond PHS requirements; use of AAALAC activity to fulfill a federal policy or regulatroy requirement would therefore be subject to FOIA. Working Group Analysis and Ageny Decisions - NIH OLAW will coordinate with AAALAC about options for harmoi=nizing documents to meet both organizations' requirements. An institution's AAALAC PD would not be collected or viewed by NIH OLAW as part of this plan.
71	OLAW: miscellaneous	Assurance for accredited institutions: Comment - AAALAC accreditation should be considered in lieu of providing details of a previously peer-reviewed program in Assurance. Working Group Analysis and Ageny Decisions - Assurance of compliance with the PHS Policy is a requirement for award for all PHS supported activities involving animals. PHS Policy IV.A.1. stipulates the elements required in the Assurance program description for activities involving animals and provides no exemption based on accreditation status.
75	Appendix 5: Acronyms Used in the Report	AAALAC = AAALAC International

AAALAC mentions in report, "Reducing Administrative Burden for Researchers…"

AAALAC e-brief

THE AAALAC E-BRIEF IS PUBLISHED AS A SERVICE TO ACCREDITED INSTITUTIONS.

Pay your organization's Annual Fee online

Dear colleagues,

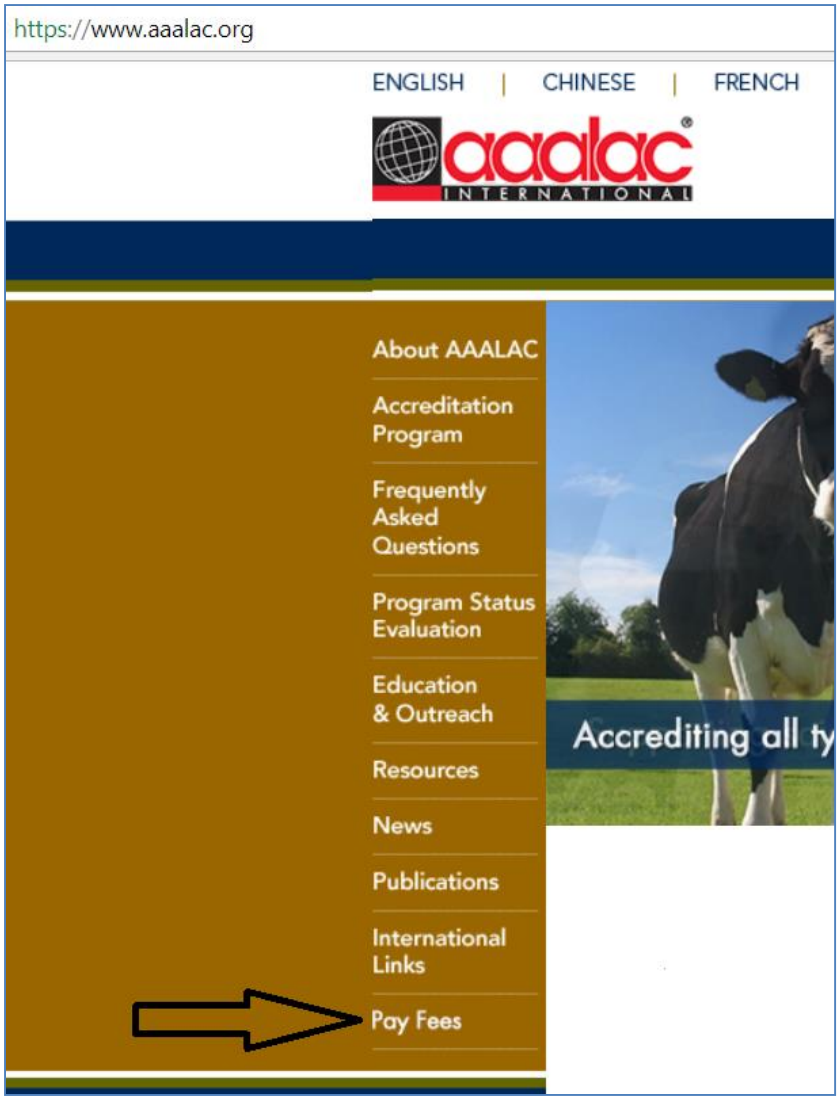
AAALAC International is now able to securely accept payments online. You may pay your organization's annual fee due to AAALAC by visiting www.aaalac.org/commerce/PayFee.cfm. You will need the invoice you received from AAALAC International in order to enter the correct amount owed. If you need a duplicate copy of your invoice, please email finance@aaalac.org.

All accredited institutions are assessed an annual fee based on the size of their animal care and use program facilities. These fees cover the cost of regular site revisits and administrative costs. Annual Payments are due in March. **Invoices for 2018 Annual fees will be sent in early February.**

If you have additional questions please email finance@aaalac.org. We appreciate your participation in the AAALAC International accreditation program.

Thank you!

you will need the invoice you received



DIRECTORY OF ACCREDITED ORGANIZATIONS

Advanced Search

Accredited Unit Name | Country | State/Province | Category | search

About AAALAC

The AAALAC International Fellowship Award

The AAALAC International Fellowship Award is presented by AAALAC International through grants from Priority One Services, Inc. and Datesand Group Ltd, in cooperation with AALAS, IAT, the Medical Research Council, and the National Institutes of Health.

The AAALAC International Fellowship recognizes two outstanding individuals -- one IAT Registered (RAnTech) and one AALAS Registered (RALAT, RLAT, RLATG, CMAR) -- who have made (or have the potential to make) significant contributions to the field of laboratory animal care and use.

See past recipients ...

See **complete criteria** ...

If you are AALAS Registered...

Deadline for receiving application packages is October 1.

Download the 2020 flyer here... (for AALAS Registry Participants)

The AALAS registered winner will receive a week-long guest visit to prestigious biomedical research facilities in the U.K. next spring, plus complimentary attendance at the conjoint (IAT, LASA and LAVA) AST 2020 Animal Science and Technology Conference (www.ast2020.org), the U.K.'s largest laboratory animal science and technology meeting. All registration, travel, lodging, meals, and out-of-pocket expenses are covered (receipts are required).

Timeline for the AALAS Registered Participants nomination process:

- Call for nominations: **June, July, August, September**
- Nomination package deadline: **October 1**
- Selection Committee reviews nomination packages: **October-November**
- Award recipients notified: **December 1**

If you are IAT Registered...

Deadline for receiving application packages is June 1.

Download the 2020 flyer here... (for IAT Registry Participants)

The IAT Registered winner will receive a week-long guest visit to prestigious biomedical research facilities in the U.S. this autumn, plus complimentary attendance at the National AALAS Meeting, the U.S.'s largest laboratory animal science and technology meeting. All registration, travel, lodging, meals, and out-of-pocket expenses are covered (receipts are required).

News

THE GLOBAL 3RS AWARDS PROGRAM

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

aaalac INTERNATIONAL

****

Download the flyer

****

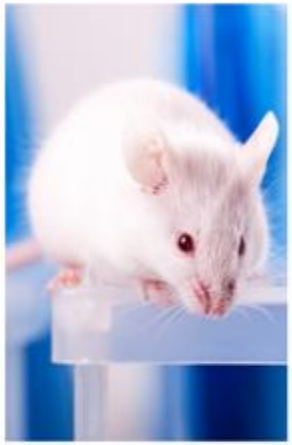
The Global 3Rs Awards program recognizes significant innovative contributions toward the 3Rs of animal research to advance ethical science, by any researcher[1,2] (nominated author, principal investigator, or research team leader) in academia or industry in any area of biology (e.g., basic science, discovery, development, teaching, testing, manufacture for new medicines, vaccines, medical devices or healthcare products for humans and animals).

Up to four Global Awards (North America, Europe, Pacific Rim, and the Rest of World) **will be presented in 2019 in the amount of $5,000 (USD) each.** Award nominations must be based on a primary research paper that advances any of the 3Rs (i.e., the Refinement, Replacement or Reduction of animal use) and is published in a peer-reviewed journal in the last three (3) years. These may include modifications to existing research techniques or any innovative research approach including, but not limited to: improvements to whole-animal models, tissue-based models (e.g., cell lines, tissue cultures), molecular techniques (e.g., proteomics), analytic and computational models, study design or technique refinements (e.g., sampling technologies, improved test methods), and translational medicine applications. Meta-analyses that develop fundamental new insights into the 3Rs are also eligible, but the methodology must be described within the paper as this is one of the scoring criteria.

Nomination Package/Publication Criteria:

A commitment to purpose

Accreditation

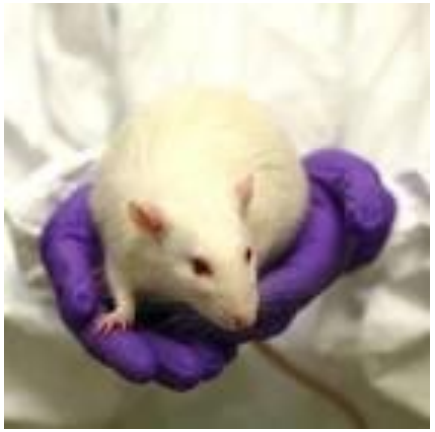


Education

Assessment

www.aaalac.org

THANK YOU



OLAW Update

Neera Gopee, DVM, PhD, DABT, DACLAM
Director, Policy and Education
Office of Extramural Research
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health (NIH)

IACUC Administrators Best Practice Meeting
Nov 6-7, 2019
Knoxville, TN

Objectives

1. Discuss proposed changes to regulations and policies to reduce administrative burden on researchers
2. Categorize trends in noncompliance reporting
3. Distinguish the training options offered by the ICARE Project and other OLAW-supported workshops

Which action would MOST reduce burden on your PIs?

A. Encourage use of DMR for low risk activities

B. Clarify what is exempt from IACUC review

C. Change frequency of continuing review to 3 years for USDA-regulated species

D. Harmonize with VA and DoD

NIH Steps
Update guidance on:

- Flexibilities in semi-annual inspections
- Use of DMR for low-risk activities and use of VVC for significant changes
- What is exempt from IACUC review
- Options for IACUC review for non-pharmaceutical grade substances
- Reporting noncompliance
- Departures from the Guide

NIH Steps to Improve Coordination

- Annual reporting on same schedule as USDA (not for 2019 report)
- Change instructions for Domestic Assurance to support use of AAALAC Program Description elements
- 60-day comment period for policy and guidance changes
- Update OLAW disclaimer on policy guidance

More Steps to Improve Coordination

Review

- Review grant-protocol congruence guidance

Engage

- Engage with DoD and VA to harmonize

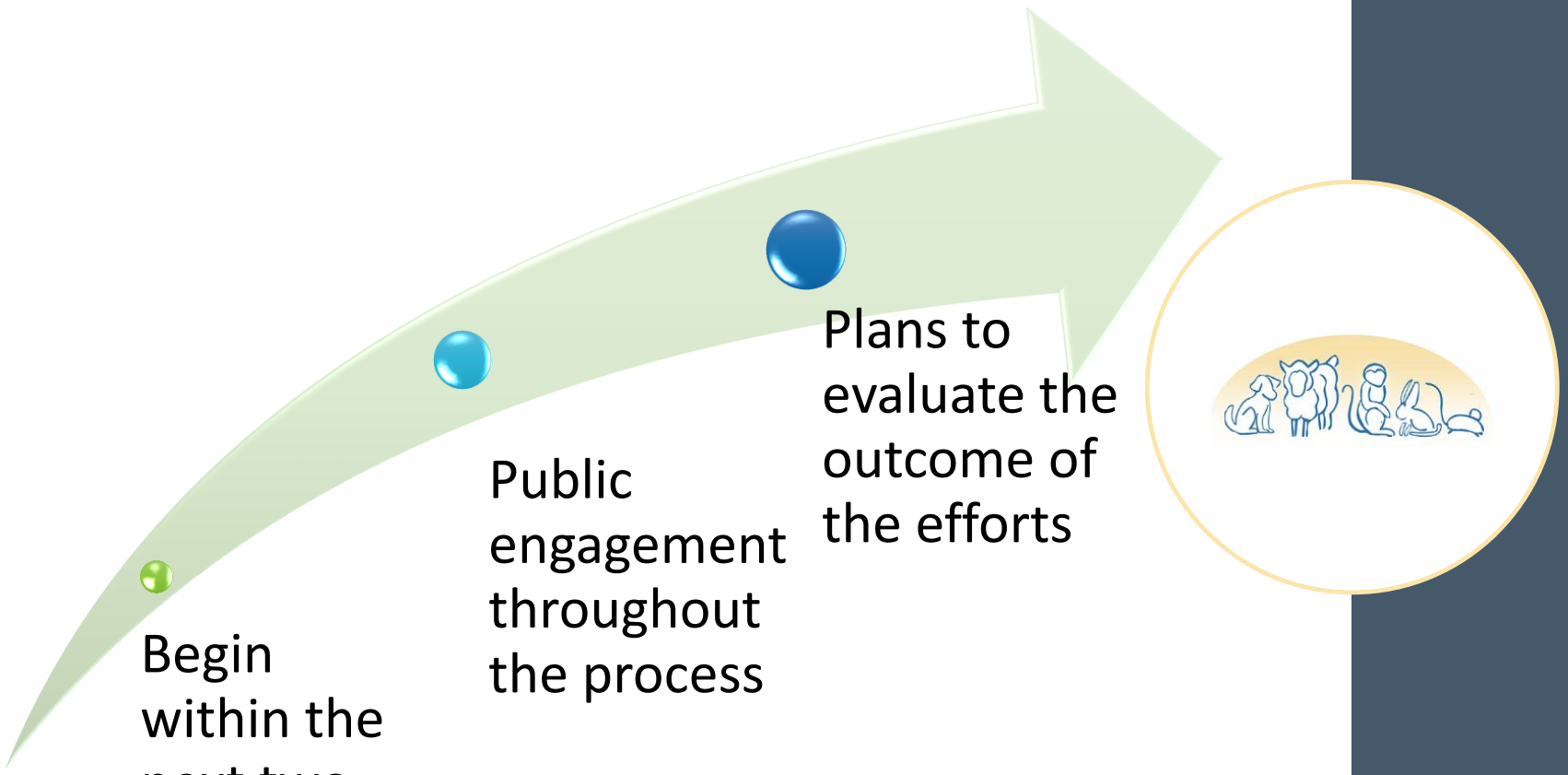
Support

- Support industry-led training and resources:
  - Training IACUCs to reduce burden (ICARE, IACUC 101,SCAW, PRIM&R)
  - CUSP through FDP
  - Universal IACUC protocol through FDP
  - IACUC best practices through IAA

Update

- Update OLAW website resources

Implementation



Find the final report and more at:

https://olaw.nih.gov/21st-century-cures-act.htm

NIH National Institutes of Health
Office of Laboratory Animal Welfare


What do you do if you're not sure if you should report an event to OLAW?

Answer…..

Review OLAW's web site on reporting noncompliance at:

- olaw.nih.gov/guidance/reporting-noncompliance.htm

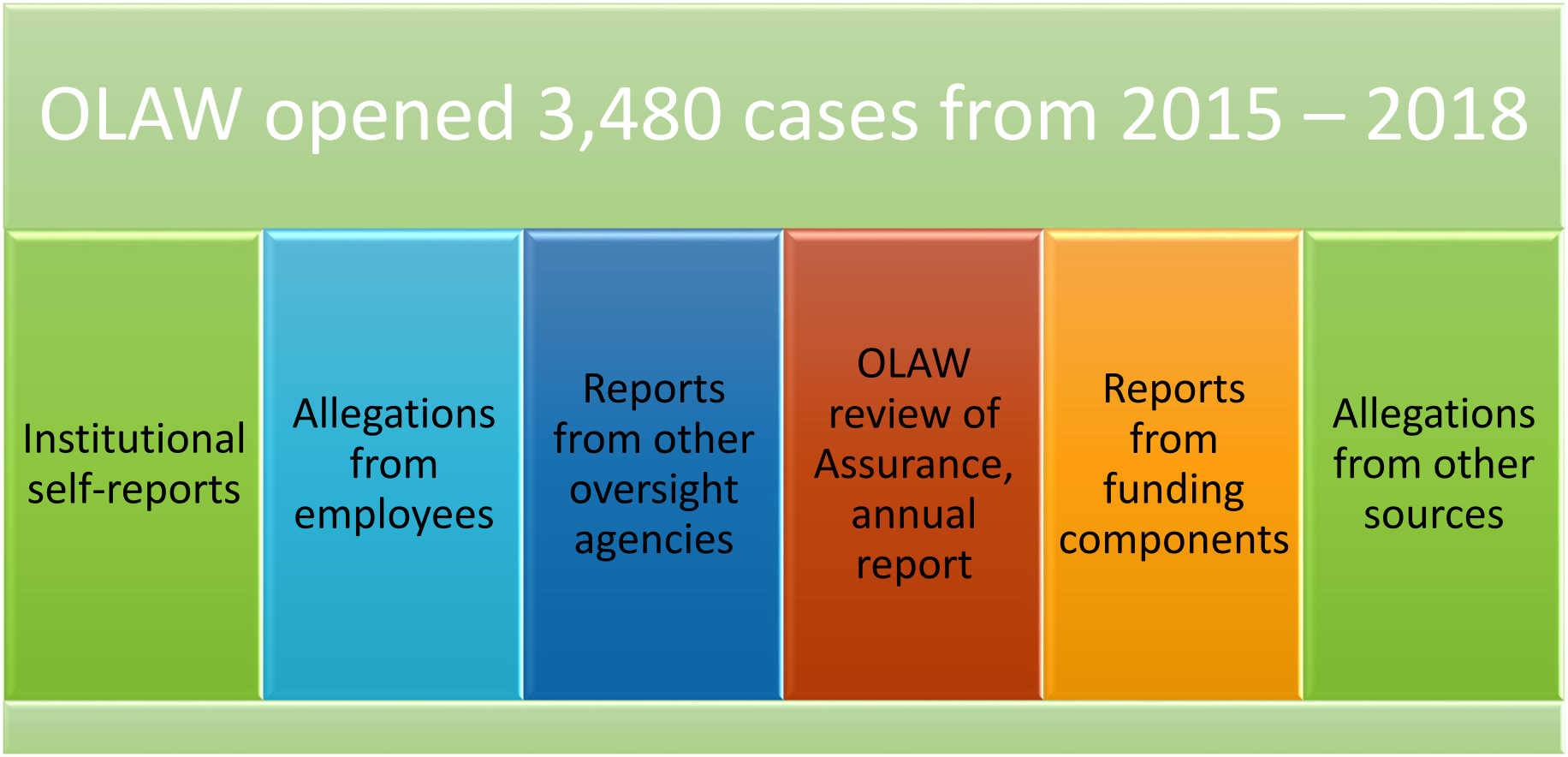
Call OLAW's Division of Compliance Oversight:

- 301-594-2921 or 301-594-2061

Reporting is a Cooperative Process

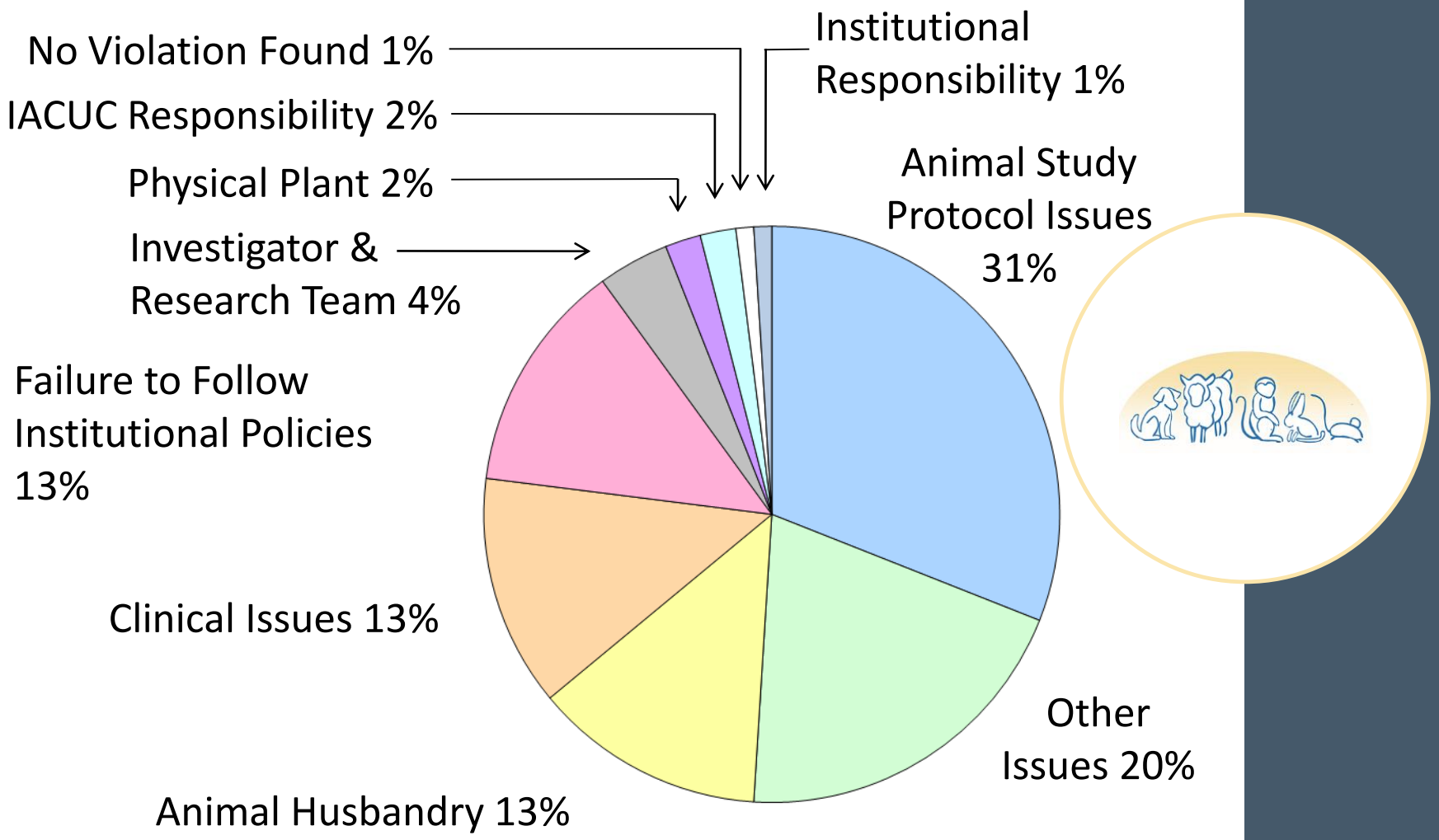
- ✓OLAW will provide assistance and guidance
- ✓Institution must demonstrate that corrective actions are being implemented
- ✓OLAW will evaluate appropriateness of the actions in correcting and preventing the reportable issue
- ✓Self-reporting is part of enforced self-regulation

Reportable Issues Data Analysis



OLAW opened 963 cases in 2018

Types of Reportable Issues



Institutional Corrective Actions

- Retrain personnel
- Counsel, reprimand, terminate employment
- Modify institutional policies
- Repair or modify facility
- Enhance PI and study oversight, probation
- Modify, suspend, or terminate animal study protocol

Implications of Reportable Issues

Corrective actions and improved systems

Special terms and conditions of awards

Enhanced reporting requirements

Cost disallowance

Suspension or termination of award (possible repayment of funds)

Restriction or withdrawal of Assurance

Criminal prosecution

What workshops or conferences use active learning?

A. ICARE Academies
B. IACUC 101s/201s/301s
C. SCAW workshops & conferences
D. PRIM&R conferences
E. All of the above

What workshops or conferences use active learning?

A. ICARE Academies

B. IACUC 101s/201s/301s

C. SCAW workshops & conferences

D. PRIM&R conferences

E. All of the above

ICARE

Interagency Collaborative Animal Research Education

Upcoming ICARE 2020 Schedule Registration is open!

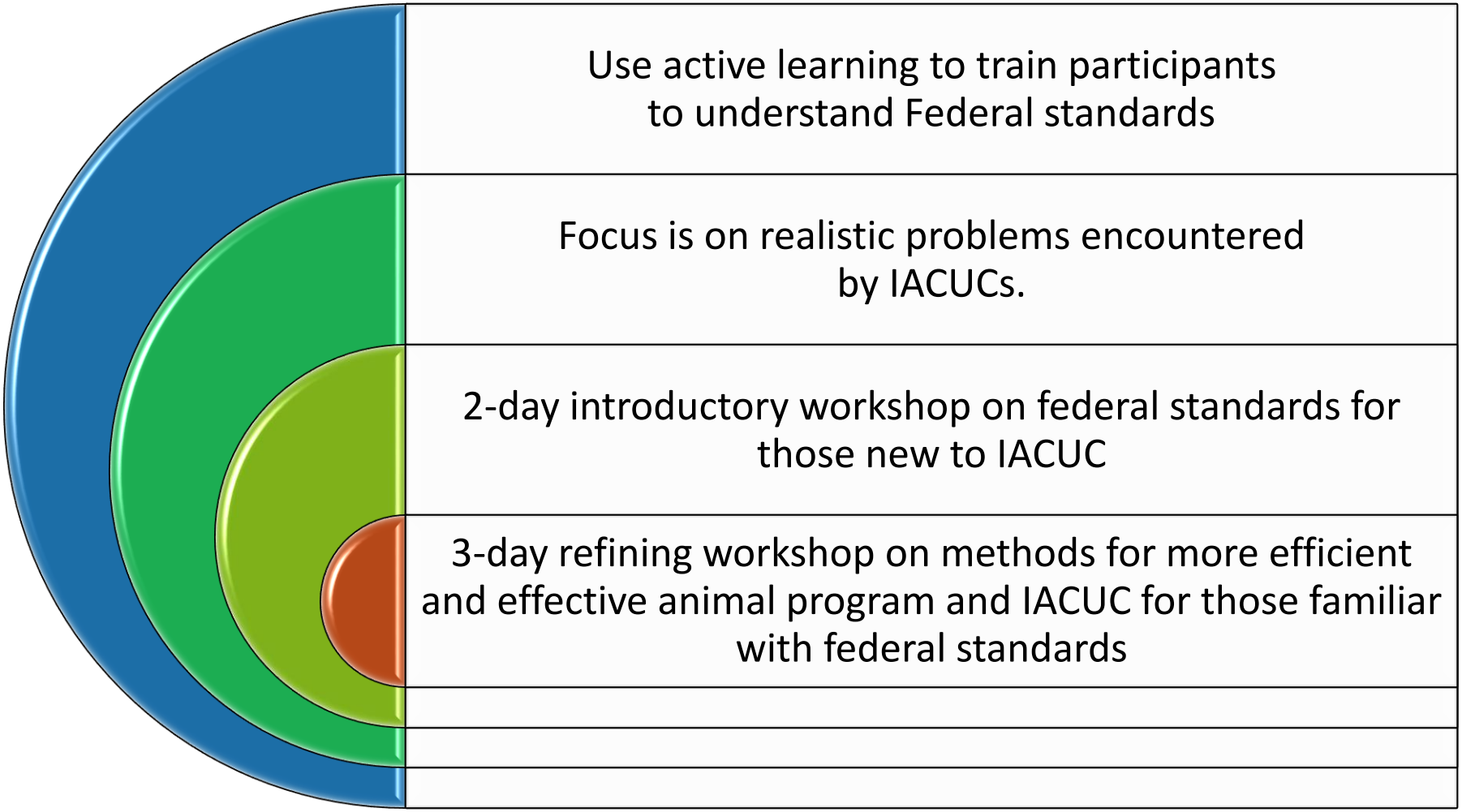
2020 ICARE Training	Date & Length		Location
ICARE Academy (Refining)	Jan. 14-16	3 days	Tampa, FL
ICARE Academy (Intro)	March 2-3	2 days	Durham, NC
ICARE Academy (Refining)	April 28-30	3 days	Denver, CO
Train the Trainer Institute	June 23-26	4 days	Detroit, MI
ICARE Academy (Intro)	Sept. 2020	2 days	St. Louis, MO

olaw.nih.gov/education/icare-interagency

Questions? Contact OLAW: olawdpe@mail.nih.gov

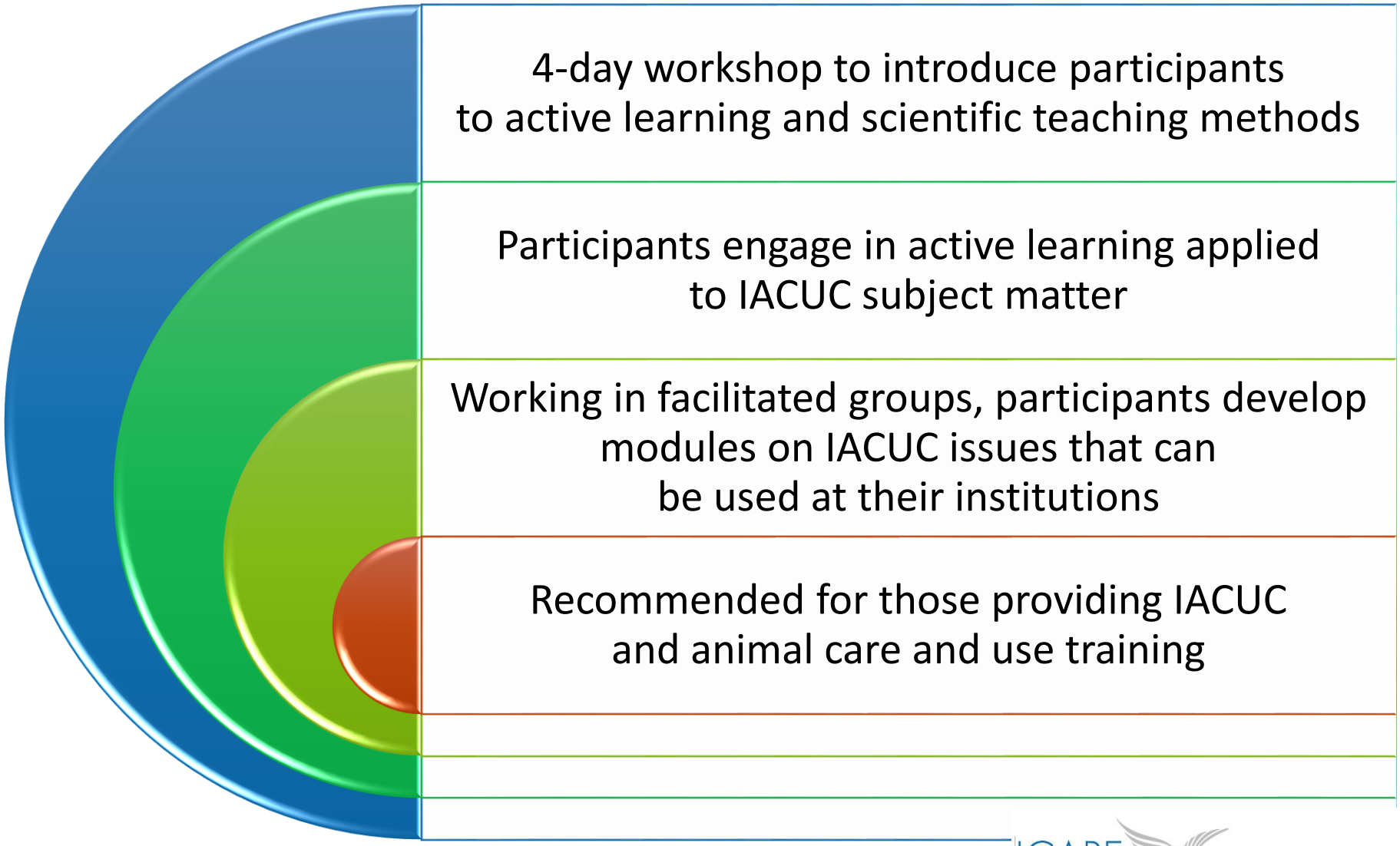
NIH National Institutes of Health
Office of Laboratory Animal Welfare

ICARE Academies (IA)



ICARE
Interagency Collaborative Animal Research Education

ICARE Train the Trainer Institutes



ICARE
Interagency Collaborative Animal Research Education

Upcoming Workshops and Conferences

IACUC 101/201/301 Series Workshops - 2019

- November 6-8, Houston, TX

SCAW - 2019

- November 22, Chicago, IL
- December 9-10, San Antonio, TX

USDA AWIC Workshops - Beltsville, MD

- March 12-13, 2020
- May 14-15, 2020
- October 8-9, 2020

PRIM&R IACUC Conference – Orlando, FL

- April 6-7, 2020

OLAW Online Seminars

December 5, 2019:
21st Century Cures Act: Next Steps

- Patricia Brown, NIH,
- Betty Goldentyer, USDA
- Brianna Skinner, FDA

September 26, 2019:
Application of the AVMA Guidelines for the Depopulation of Animals to Biomedical Research

- Samuel Cartner, Univ. of AL Birmingham
- Jennifer Pullium, NYU
- Axel Wolff, OLAW

Recordings of past seminars available at:
https://olaw.nih.gov/education/educational-resources

Commentary in Lab Animal

A Word from OLAW and APHIS. Pressure's on: is it time to move ahead with nonhuman primates? *Lab Animal* 2019; 48(10)

A Word from OLAW. A late notice & personal conflict – was suspension warranted? *Lab Animal* 2019; 48(09)

A Word from APHIS and OLAW. On hold: what to report after a study is halted? *Lab Animal* 2019; 48(08)

Available at: olaw.nih.gov/guidance/commentary.htm

Objectives

1. Discuss proposed changes to regulations and policies to reduce administrative burden on researchers
2. Categorize trends in noncompliance reporting
3. Distinguish the training options offered by the ICARE Project and other OLAW-supported workshops

OLAW Leadership

Patricia Brown, VMD, MS

- Director

Axel Wolff, DVM, MS

- Deputy Director

Eileen Morgan,

- Director, Division of Assurances

Brent Morse, DVM

- Director, Division of Compliance Oversight

Neera Gopee, DVM, PhD

- Director, Division of Policy and Education

New OLAW Staff

Nicole Lukovsky-Ahksanov, DVM, MPH	Division of Assurances
Nicolette Petervary, VMD	Division of Policy and Education
Catharine Pritchard, PhD	Division of Policy and Education
Jacquelyn Tubbs, DVM	Division of Compliance Oversight

OLAW Contacts

E-mail:
- olaw@od.nih.gov

Phone:
- 301-496-7163

Website:
- https://olaw.nih.gov

Twitter:
- @NIH_OLAW

ListServ or RSS feed
- subscribe through OLAW webpage for news and announcements

APHIS, Animal Care Update

Updates

- Statistics
- Inspections and Inspection Processes
- Compliance Support Processes
- Outreach and Training
- Other Recent Changes

Fiscal Year 2018

Approximately 1,100 registered research facilities

Of approximately 1,300 inspections conducted:

- 91% full compliance

Fiscal Year 2018 – Top 3 Citations

- 2.33 Attending Veterinarian and Adequate Veterinary Care
- 2.31 Institutional Animal Care and Use Committee
- 2.35 Recordkeeping and 2.38 Miscellaneous

Inspection Processes

- Animal Inventories
- Photographs and Videos
- Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance
- Focused Inspections
- Appeal Process

Incentives for Identifying, Reporting, Correcting, and Preventing Noncompliance

Animal Care will not cite a Critical NCI occurring prior to an inspection if all of the following criteria are met by the facility:

- No repeat or critical NCIs during the preceding 12 months,
- Discovers the noncompliance on its own in a timely manner,
- Has not voluntarily reported a critical noncompliance that falls within the same section and subsection of the AWA regulations and standards during the preceding 24 months,
- Immediately takes appropriate corrective action and establishes measures to prevent reoccurrence,
- Promptly reports the incident

Focused Inspections

- AAALAC accredited
- Good compliance history
- Focused on:
  - Records, or
  - Facilities, or
  - Animals, or
  - Sampling of some/all of the above
- Focus resources on higher risk facilities

NOTE: VMO will do full inspection upon request.

Appeal Process

- Each appeal team includes:
  - ✓Director
  - ✓Assistant Director
  - ✓Supervisory Animal Care Specialist
  - ✓Staff Veterinarians or Specialists

- Appeals (or notification) must be received within 21 days, or they will not be accepted

- The ruling of that appeal team will be final, and represent USDA's final determination of the appeal

Compliance Support Processes

- Courtesy Visits
- Teachable Moments
- Optimal Hours
- Supercharging Compliance Program

Courtesy Visits

- Non-inspection visits or calls
  - ✓ No inspection report
- Visits are voluntary and scheduled
- Check on compliance status of current licensees, applicants, and potential applicants
- Follow-up on inspection findings
- Answer questions
- Review new construction, SOPs, plans, etc.

The goal is to improve compliance, communication, and animal welfare.

Teachable Moments

Not cited as an NCI on inspection reports

- Minor NCI
- Has no discernable impact to animals,
- Is not likely to soon become a serious, direct or repeat NCI,
- Can be easily corrected, and in the inspector's judgment, is likely to be corrected quickly by facility, and
- Has not been cited previously and/or is not a repeat teachable moment.

Optimal Hours

- All 'routine' inspections are unannounced
- High level of attempted inspections
- Business hours: reasonable number of hours, Monday through Friday, between 7 a.m. and 7 p.m.
- Implemented Optimal Hours
  - ✓Licensee/Registrant identifies 4 hour blocks of time, at least 3 days per week
- Optimal hours have cut the number of attempted inspections in half, while still doing unannounced inspections
- Retain the authority to conduct an inspection any time during business hours.

Outreach and Training

- Animal Care Aids
- Updating Policy Manual
- Inspection Guide Revisions

Other Recent Changes

- Licensing Exemptions
- Online Annual Reports
- Propose Rule: Amendments to Licensing Provisions and to Requirements for Dogs
- Animal Care Licensing and Registration Assistant

Licensing Exemptions

- Created a new licensing exemption for exhibitors with 8 or fewer specific types of animals

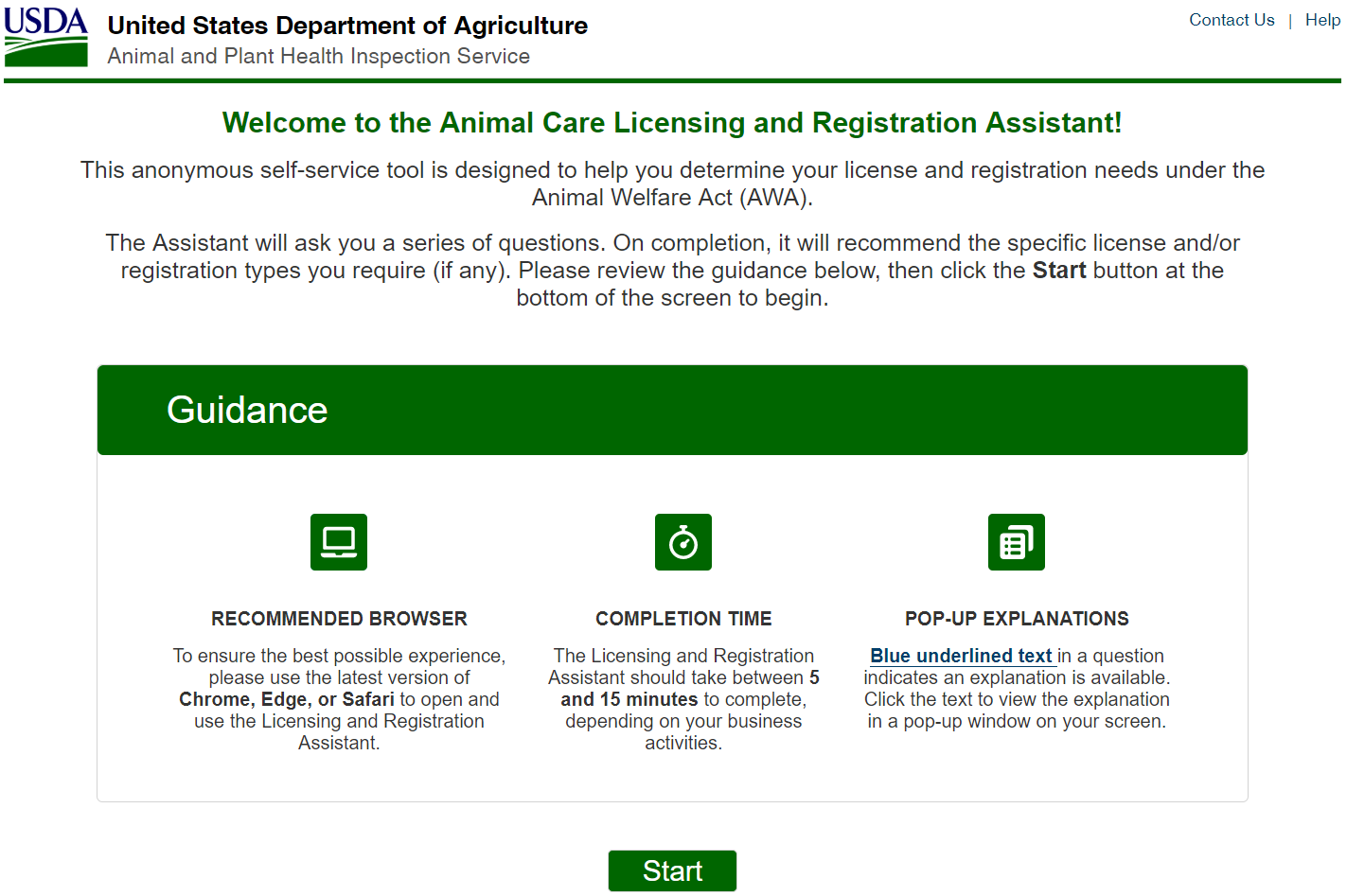
- Clarified the exemption for exhibits advancing agricultural arts and sciences

- Expanded the licensing exemption for breeders with 4 or fewer breeding females to include additional types of pet animals and domesticated farm-type animals

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare

Proposed Rule – Reviewing Comments

https://efile.aphis.usda.gov/LRAssistant/s/



Sources of Information

- Your Animal Care VMO and Area Supervisor
- Animal Care Raleigh Office: 919-855-7100
- Animal Care Ft. Collins Office: 970-494-7478
- Animal Care Riverdale Office: 301-851-3751
- Animal Care Website: www.aphis.usda.gov/animal_welfare/index.shtml
  - *Animal Welfare Act and Regulations ("Blue Book",2017)*
  - *Animal Welfare Inspection Guide: Chapter 7*
  - *Animal Care Policy Manual*
- APHIS stakeholder registry (to receive notices and updates):

https://public.govdelivery.com/accounts/USDAAPHIS/ subscriber/new

THANK YOU!

Afternoon Break

VIRGINIA TECH

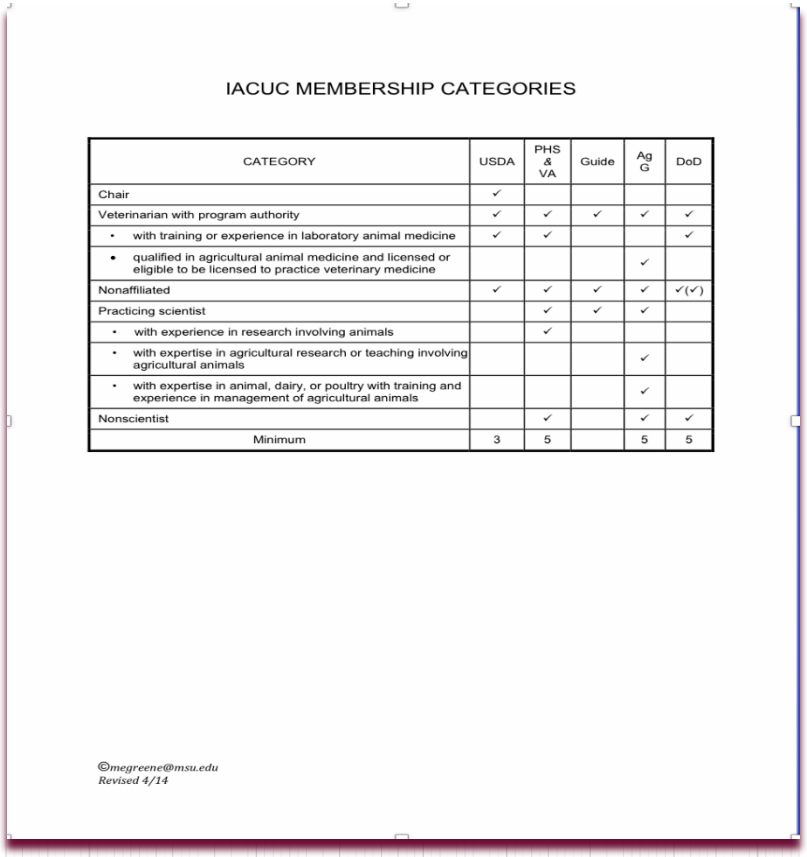
IACUC Memberships – recruiting and maintaining active members

STEPHANIE TROUT, MS, CPIA

NOVEMBER 6, 2019

Member Requirements

No more than three primary voting members from the same administrative unit of the institution.



IACUC MEMBERSHIP CATEGORIES

CATEGORY	USDA	PHS & VA	Guide	Ag G	DoD
Chair	✓				
Veterinarian with program authority	✓	✓	✓	✓	✓
• with training or experience in laboratory animal medicine	✓	✓			✓
• qualified in agricultural animal medicine and licensed or eligible to be licensed to practice veterinary medicine				✓	
Nonaffiliated	✓	✓	✓	✓	✓(✓)
Practicing scientist		✓	✓	✓	
• with experience in research involving animals		✓			
• with expertise in agricultural research or teaching involving agricultural animals				✓	
• with expertise in animal, dairy, or poultry with training and experience in management of agricultural animals				✓	
Nonscientist		✓		✓	✓
Minimum	3	5		5	5

Revised 4/14

Member Recruitment: Veterinarian

- Definition: A Doctor of Veterinary Medicine either certified (e.g., by ACLAM, ECLAM, JCLAM, KCLAM) or with training and experience in laboratory animal science and medicine or in the use of the species at the institution.
- At our institution this member role is held by the Attending Veterinarian.
- Send nominations to Institutional Official with Nomination Memo

Member Recruitment: Scientist

- Definition: Practicing scientist with experience in research involving animals.
- Identify College/Department animal users
- Request nominations from Department Heads for member/alternates
- Discuss nominations with IACUC Chair
- Send nominations to Institutional Official with Nomination Memo

Member Recruitment: Non-Scientist

- Definition: Member whose interests, training, and education are in a nonscientific area, can be affiliated with the institution.
- Network: Ask other committees, IACUC members, neighbors, church (members/clergy), Out-going Non-Scientist, non-scientific departments within the institution.
- Discuss nominations with IACUC Chair
- Send nominations to Institutional Official with Nomination Memo

Member Recruitment: Non-Affiliate

- Definition: Member who represents the general community interest and is not a present or former laboratory animal user or scientist, is not affiliated with the institution, and is not an immediate family member of a person who is affiliated with the institution.
- Most difficult member requirement to fill, especially in a small town with a large institution, with the most rewards from the member.
- Network: Ask other committees, IACUC members, neighbors, church (members/clergy), Out-going Non-Affiliate.
- Discuss nominations with IACUC Chair
- Send nominations to Institutional Official with Nomination Memo

Member Recruitment: Chair & Vice Chair

- Members that have served on the IACUC for at least two years are discussed between the IACUC Administrator and the Associate Vice President of Scholarly Integrity and Research Compliance.
- Attributes considered during discussion: Attendance at meetings, participation in discussion/semi-annuals/protocol reviews, demeanor, time commitment, “rank” within the institution.
- Send entire list of potential list to Institutional Official with recommendations including reasons.
- Institutional Official meets with “candidates” then appoints for five-year terms (initial three-year term followed by two year terms) with yearly reviews.

Member Retention

- Evenly distribute the workload
- Training opportunities
- Food
- Travel
- Renewal Process

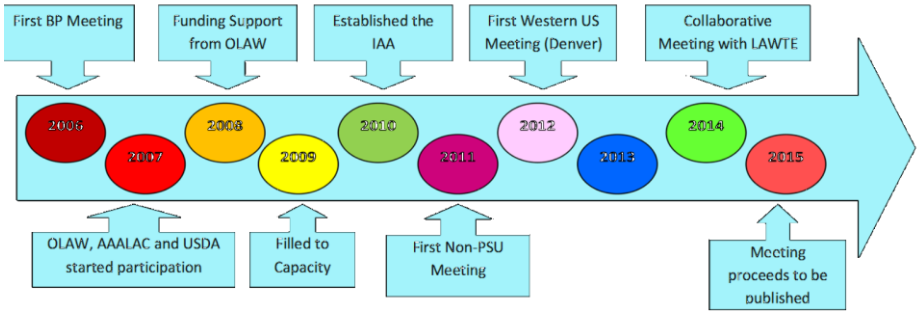
Questions?
Open for Discussion

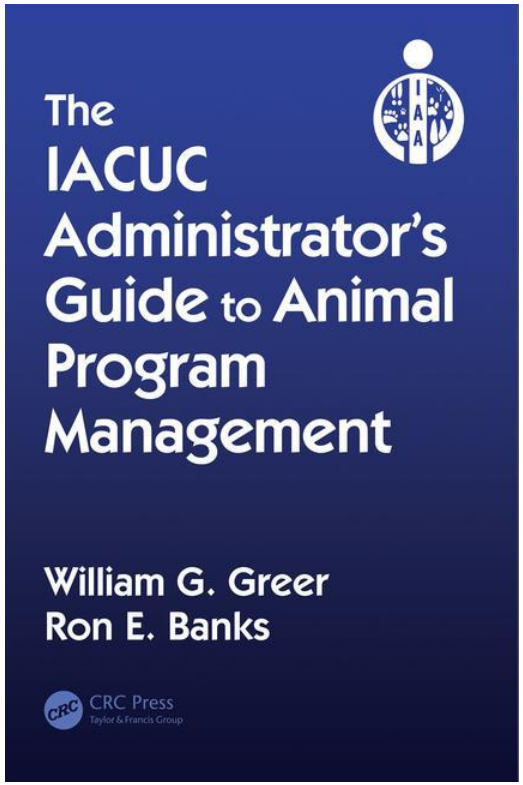
IACUC Administrator Association

IAA The IACUC Administrators Association

What's Next for IAA?

IACUC Administrators Association (IAA)





IAA's Role

1. Support
2. Bridge
3. Harmonize

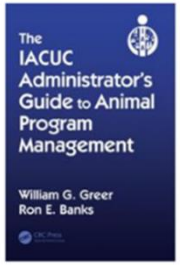
IAA Projects

1. Establish**ed** a venue for the IACUC Administrative Community to regularly meet to discuss common challenges
2. Publish**ed** common practices used to manage ACUP
3. Work**ed** on FAQs with OLAW on the VVC process
4. Incorporate MOU language into OHSP subcontracts
5. Develop a common resource for disaster plan development
6. Develop a tool kit for reviewing and overseeing wildlife studies
7. Develop an IACUC universal protocol template

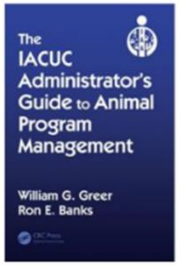
IAA BP Meetings

"The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) is pleased to endorse this volume of best practices for operation of animal care and use programs (ACUP) at Public Health Services (PHS) – assured institutions. But more than this static collection of operational practices, we support your practice of coming together to share your methods of operating programs at your institutions – large and small, academic , government, nonprofit and for –profit organizations." Susan Silk, Director, Division of Policy and Education , NIH Office of Laboratory Animal Welfare

Double Thanks to



You,



and to over 300 other IACUC Administrative Staff Members that have attended meetings over the past years and provided their valuable input.

FAQ's and OLAW

1. VVC: Discussion during a IACUC Administrators' BP meeting led to FAQ's shared on the IAA Website.

IACUC Administrator Association

Frequently Asked Questions about VVC (OLAW reviewed and approved)

1. How can the Veterinary Verification and Consultation (VVC) process be used?

2. Non-Pharma OLAW FAQ (2015 BP Meeting)

4. **May investigators use non-pharmaceutical-grade substances in animals?**

OLAW and USDA agree that pharmaceutical-grade[1] substances, when available, must be used to avoid toxicity or side effects that m
welfare of vertebrate animals and / or interfere with the interpretation of research results[2]. However, it is frequently necessary to use
substances such as investigational substances, veterinarian- or pharmacy-compounded[3] substances, and / or Schedule I[4] controlled s
scientific and research goals.

The IACUC is responsible for evaluating the potential adverse consequences of non-pharmaceutical-grade substances when used for
evaluation, the IACUC may consider factors including, for example:

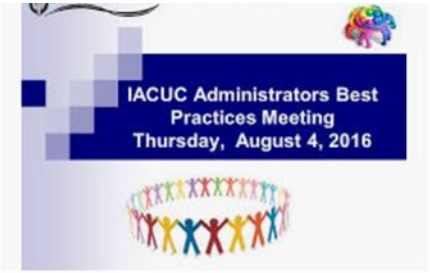
- grade,

Current IAA Working Groups

1. Common resource for disaster planning
2. Tool kit for reviewing and overseeing wildlife studies
3. An IACUC universal protocol template

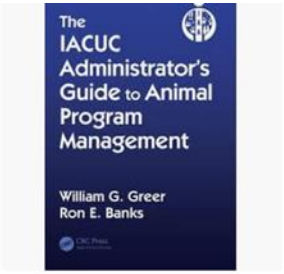
What's next?

Home | IACUCAA
iacucaa.org



IACUC Administrators Best Practices ...
slideplayer.com

About the Best Practice Me...
iacucaa.org



Animal Program Manageme...
crcpress.com

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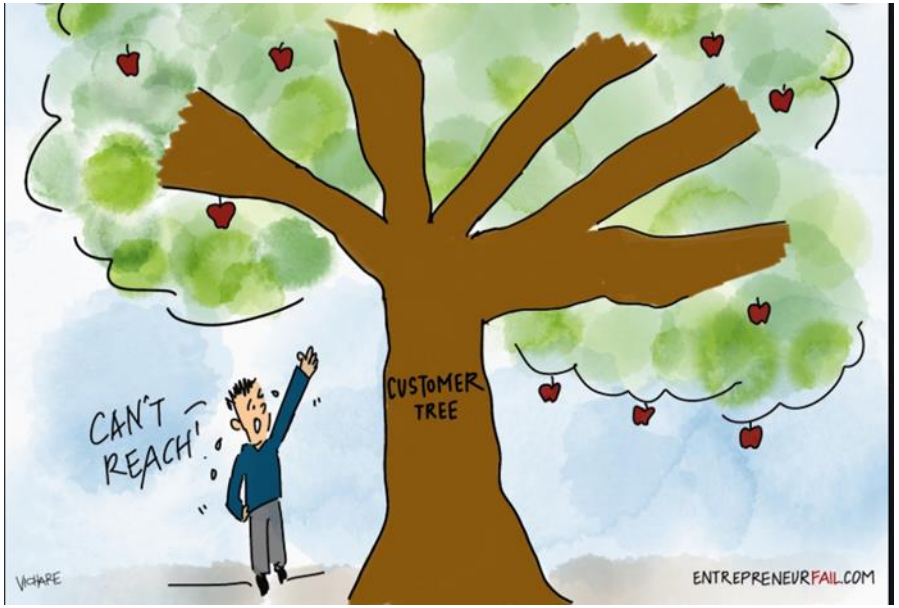
Low Hanging Fruit
or
Needle in the Haystack?



Future of IAA

Satisfy the community needs?

1. **Suggestions**
2. **Thoughts, and**
3. **Ideas**

Brainstorming Session

Take 10 minutes

IACUC Administrator Association

Top Five Weaknesses with the Animal Care and Use Program at my Institution

	Weakness	Impacted Group (e.g., PI, IACUC, AV, Admin)
1		
2		

Shout out and Discussion

IACUC Administrator Association

IAA The IACUC Administrators Association

The ABC's of Animal Field Research

Session Goals

1. What activities require IACUC review?
2. Identifying the challenges for IACUC review?
3. What resources do IACUCs and Administrators need?

What wildlife activities require IACUC review?

Theoretically speaking all

Field Study or Field Research?

(Compliments of T. Thompson and R. Sikes)

Field Study

- “study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms or materially alters the behavior of an animal under study.” [9 CFR Part 1.1 Definitions]
  - Exempt from AWA
  - IACUC MUST review all proposed activities to determine if research or Field Study

How about…

Field Research

Study involving free-ranging wild animals that involves procedures that may:

- Be Invasive— USDA considers these as major operative procedures, eg. Abdominal transponder placement.

- Materially alter behavior—materially is the key here, not defined currently but should be discussed by IACUC with PI input; a pilot study with IACUC oversight may be warranted if not sure of impact of procedures

- Harm—also not defined currently; consider if more than momentary or slightly painful or distressful; no analgesia or anesthesia is used to relieve pain and distress could be considered harmful; a pilot study with IACUC oversight may be warranted if not sure of impact of procedures.

Scenario

1. Mist Netting Bats to gather species demographics

   - Bats are captured in mist nets;
   - Removed from the nets by the technicians;
   - Weighted, measured; and
   - Released

How about this one?

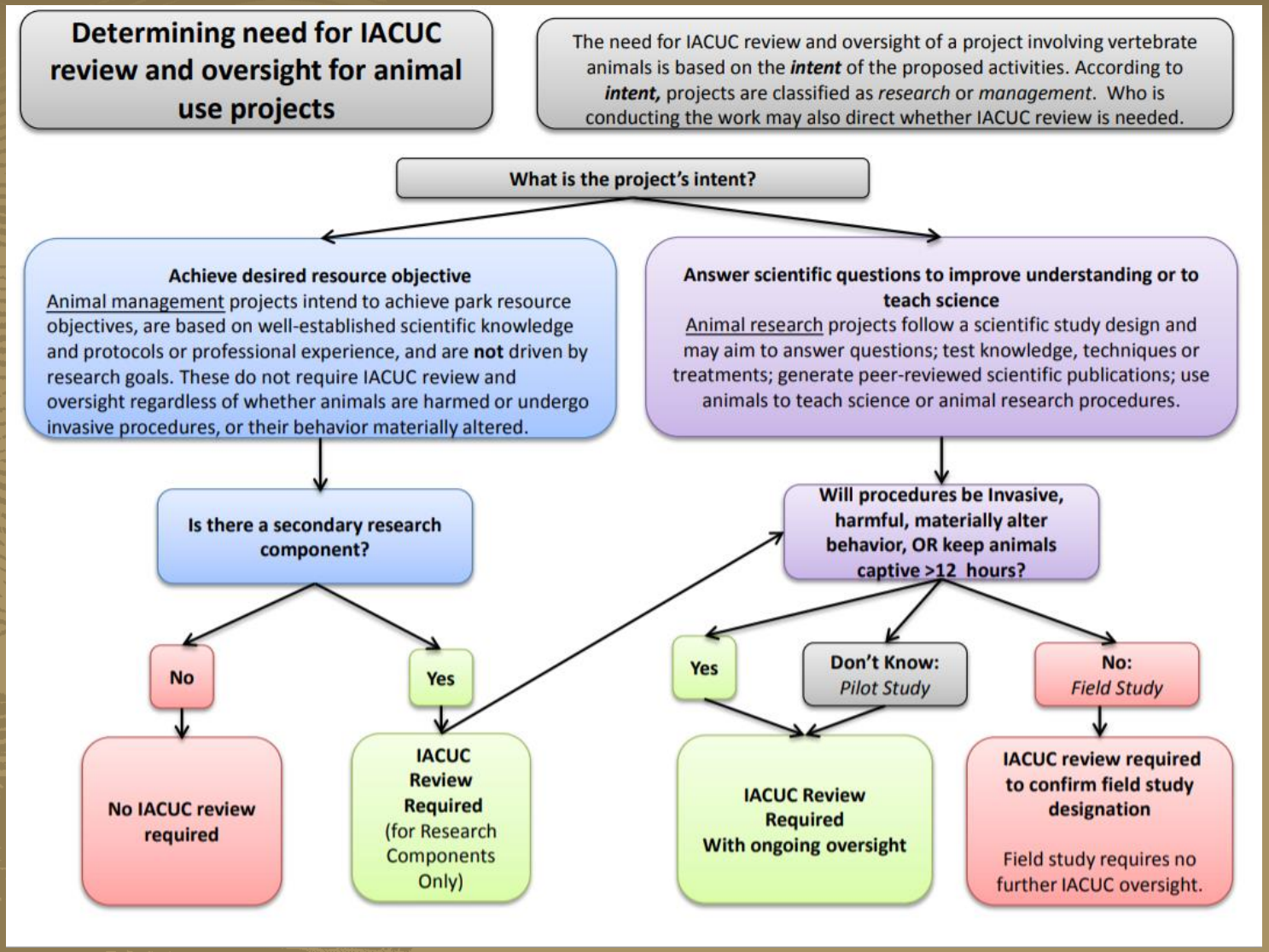
2. Placing radio transmitter collars on bear

- Bear are captured in a culvert trap and tranquilized;
- Their eyes are covered and the collar is placed;
- Weights and measurements are taken; and
- The bear is recovered and released.

2.

- Their eyes are covered and the collar is placed;

Does the Activity Require IACUC Review? Tracy



Is your IACUC Qualified to Conduct the Review?

Imagine the activities on an elk collaring protocol:

- Tranquilizing the elk using a dart rifle;
- Immobilizing the elk while the collar is placed; and
- Recovering and releasing the elk.

Is your IACUC Qualified to Conduct the Review?

Imagine the activities on an elk collaring protocol:

- Tranquilizing the elk using a dart rifle;
- Immobilizing the elk while the collar is placed; and
- Recovering and releasing the elk.

Dart Placement

supposed to accompany them. The mis-aimed dart had penetrated the sheep's abdomen, causing hemorrhage and death. The biologists had not yet secured approval f immediate shut-down and investigation once the Park au

The Carcass?

One more

Red Squirrels are trapped behavioral traits

Protocol described activities:

1. Squirrels will be trapped using Sherman Traps;
2. They will be companion housed for 2 weeks in field cages;
3. Their behaviors will be observed over the 2 week period; and
4. They will be released where they were captured.

Hmm,

Red Squirrels Habits. **Red Squirrels** lead solitary lives, and each defends a **territory** of between 2 and 5 acres from others of the same species and from gray **squirrels**. Despite its smaller size, these are much more aggressive than Gray **Squirrel**, and will chase the larger Gray out of its **territory**.

Therefo

1. Ho apped in t in fig
2. Re the ar ult in the (more fig

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Therefore:

1. Housing squirrels together that were trapped in different areas would probably result in fighting for “cage” dominance; **and**

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Therefore:

1. Housing squirrels together that were trapped in different areas would probably result in fighting for “cage” dominance; **and**

2. Releasing the animal after 2 weeks in the area it was caught would probably result in the it trying to re-establish dominance (more fighting).

How about Euthanasia or Humane Killing

Whether euthanasia or humane killing, it is expected that investigators will use the most humane technique(s) feasible that is also consistent with study objectives.

Even if you do not intend to end animals' lives at any point in your project, a **method of euthanasia or humane killing must be listed in cases of emergency** except in instances where permits or statutes prohibit the killing of individuals of the species involved.

What If euthanasia or humane killing is **prohibited** or required by law or by permit conditions, provide supporting documentation.

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How about Euthanasia or Humane Killing

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18-Foot Python Captured in Florida...
nbcnews.com

What do you know about Permit Requirements

State and Federal; oh yeah - International

CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA

EXPORT PERMIT
RE-EXPORT CERTIFICATE
OTHER CERTIFICATE

1. Original Permit/Ce 18US999672C/9
2. Valid until 01/17/2019

3. Permittee (name and address, country)
W GINSENG INC.
901 MAIN STREET
MARATHON, WI 54448
U.S.A.

W GINSENG CITE EXPORT PERMIT
FOR WILD AMERICAN GINSENG

4. Consignee (name and address, country)

5. Special Conditions
MUST COMPLY WITH ATTACHED SPECIAL CONDITIONS FOR EXPORT OF WILD AMERICAN GINSENG.

EXPORT MUST BE THROUGH A USDA DESIGNATED PORT.

PERMITTEE MUST COMPLETE BLOCKS 4 AND 11 PRIOR TO EACH SHIPMENT.

AUTHORIZED TO EXPORT WILD AND WILD-SIMULATED ROOTS 5 YEARS OF AGE OR OLDER HARVESTED IN THE 2017 SEASON.

5a. Purpose of Transaction
T

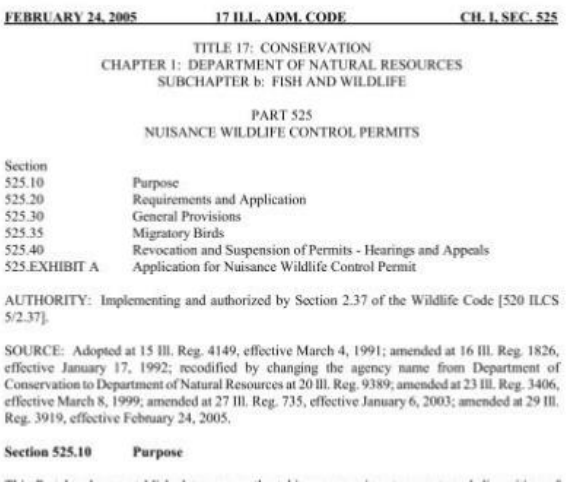
6. U.S. Management Authority
Department of the Interior
U.S. FISH AND WILDLIFE SERVICE
DIVISION OF MANAGEMENT AUTHORITY
BRANCH OF PERMITS, MS: IA
5275 LEESBURG PIKE
FALLS CHURCH VA 22041-3803

U.S. CITES Management Autho

07/18/2018
Issuing Date

United States Management Aut

For live animals, only valid if the transport conditions comply with the CITES Guidelines for Transport of Live Animals or, in the case of air transport, with



FEBRUARY 24, 2005 17 ILL. ADM. CODE CH. I, SEC. 525

TITLE 17: CONSERVATION
CHAPTER I: DEPARTMENT OF NATURAL RESOURCES
SUBCHAPTER b: FISH AND WILDLIFE

PART 525
NUISANCE WILDLIFE CONTROL PERMITS

Section
525.10 Purpose
525.20 Requirements and Application
525.30 General Provisions
525.35 Migratory Birds
525.40 Revocation and Suspension of Permits - Hearings and Appeals
525.EXHIBIT A Application for Nuisance Wildlife Control Permit

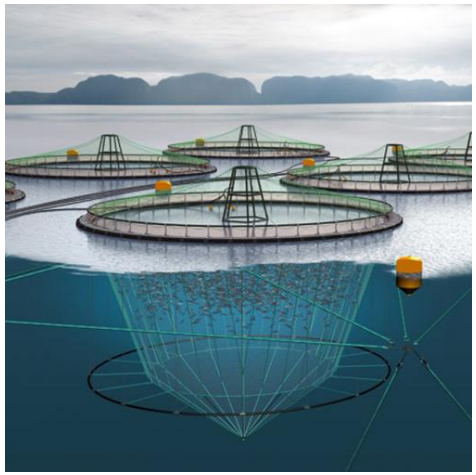
AUTHORITY: Implementing and authorized by Section 2.37 of the Wildlife Code [520 ILCS 5/2.37].

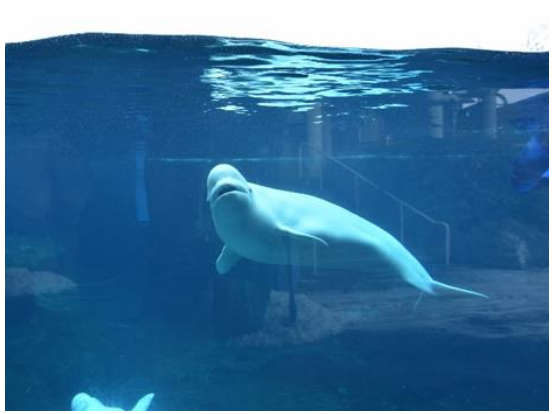
SOURCE: Adopted at 15 Ill. Reg. 4149, effective March 4, 1991; amended at 16 Ill. Reg. 1826, effective January 17, 1992; recodified by changing the agency name from Department of Conservation to Department of Natural Resources at 20 Ill. Reg. 9389; amended at 23 Ill. Reg. 3406, effective March 8, 1999; amended at 27 Ill. Reg. 735, effective January 6, 2003; amended at 29 Ill. Reg. 3919, effective February 24, 2005.

Section 525.10 Purpose

Knowledgeable in Field Activities and Capturing Techniques?

How about inspecting facilities used to hold captive wildlife?





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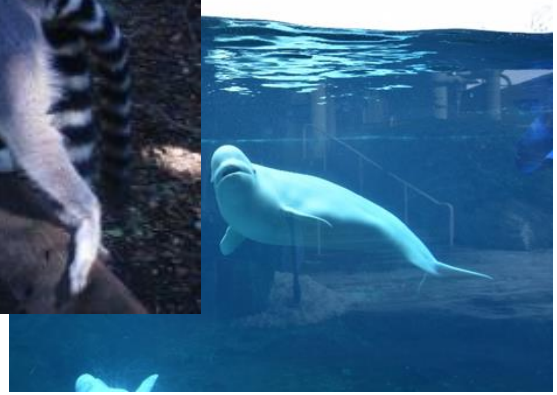

Regulatory Guidance References

1. American Society of Mammalogists Animal Care and Use Guidelines
2. Ornithological Council Guidelines to the Use of Wild Birds in Research
3. American Fisheries Society, American Institute of Fishery Research Biologists, and American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research
4. American Society of Ichthyologists and Herpetologists Guidelines to the Use of Amphibians and Reptiles in Research
5. Sikes, R.S., E. Paul, and S. Beaupre. 2012. Standards for Wildlife Research: Taxon-Specific Guidelines Versus US Public Health Services Policy. BioScience 62(9):830-834.Sikes, R.S. and E. Paul. 2013.Fundamental differences between wildlife and biomedical research. ILAR Journal 54(1):5-13.
6. Paul, E. and R.S. Sikes. 2013. Wildlife researchers running the permit maze. ILAR Journal 54(1):14-23.
7. Nisbet, I.C.T. and E. Paul. 2000. Ethical issues concerning animal research outside the laboratory. ILAR Journal 45(3):375-377.

Wildlife Tool Kit for Administrators and IACUCs

What has been done?

1. Fairbanks, Alaska Meeting
2. Grand Canyon, AZ Meeting with the National Parks System
3. 2020 – working group to finalize some documents…

What does an Administrators Wildlife Toolkit Look Like?

Wrap-up

Please, complete your Evaluation Forms and offer suggests!