



# OLAW Online Office Hour

Patricia Brown, VMD, OLAW Director

Eileen Morgan, Assurances Director

Axel Wolff, DVM, Compliance Oversight Director

OLAW Online Webinar  
December 3, 2015





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# OLAW Office Hour



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# Question 1: Nonaffiliated Member?

We are very concerned about the new guidance on the nonaffiliated member. The guidance seems to be so broad that even a college humanities major, who took a zoology class to fulfill a science requirement, wouldn't be eligible.

We just wasted a lot of work recruiting and training a nonaffiliated member who is now not qualified to be nonaffiliated because he had past scientific training.

Why did OLAW start requiring the nonaffiliated member to be a non-scientist?

# Answer 1: Nonaffiliated Member

IACUCs were increasingly selecting individuals that did not meet the intention of the PHS Policy and the *Guide* to serve as nonscientist and nonaffiliated members.

Therefore, OLAW issued NOT-OD-15-109 to clarify the qualifications of those membership roles.



# Guidance on Qualifications of IACUC Nonscientific and Nonaffiliated Members

**Notice Number:** NOT-OD-15-109

## Key Dates

**Release Date:** June 9, 2015

## Related Announcements

None

## Issued by

National Institutes of Health ([NIH](#))

## Purpose

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the qualifications of nonscientific and nonaffiliated members of the IACUC.

### Background

The PHS Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) (IV.A.3.) defines the membership of the IACUC and requires that the Chief Executive Officer (CEO) appoint the members. If the CEO delegates appointment authority, the delegation must be specific and in writing. The Policy specifies that the committee shall be qualified

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-109.html>

# Nonaffiliated Member

“...individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.” PHS Policy IV.A.3.b.(4)

“...to represent general community interests in the proper care and use of animals and should not be a laboratory animal user.” *Guide* p24



# Nonaffiliated Qualifications

Nonaffiliated member is also referred to as the unaffiliated, community, or public member:

- Independent of the institution
- Represents the general community interest
- Not a laboratory animal user



# Nonscientist Qualifications

Nonscientific member

- No scientific background (naïve attitude)
- May be from within or outside the institution



# Nonscientist Nonaffiliated Qualifications

Institutions may choose to have one person serve as both nonaffiliated and nonscientist member. Such an individual must

- Be independent of the institution
- Represent general community interest
- Have no scientific background



# Question 1 con't: Nonaffiliated Member?

Why is the nonaffiliated member required to be a non-scientist?

# Answer 1 con't: Nonaffiliated

## Nonaffiliated member

- **NOT** required to be a nonscientist
- may not be a current or former laboratory animal user to increase the diversity of perspectives represented in the membership of the IACUC



# Policy IACUC Membership Requirements

...shall consist of not less than five members and shall include at least one:

- Veterinarian with training or experience in lab animal science and medicine and direct or delegated animal program authority and responsibility for animal activities;
- Practicing scientist experienced in research involving animals;
- Member whose concerns are in a nonscientific area;
- Individual who is not affiliated with the institution.

PHS Policy IV.3.b.



# Question 1 con't: Nonaffiliated

The guidance seems to be so broad that even a college humanities major who took a zoology class to fulfill a science requirement wouldn't be eligible.

Who is qualified to serve as a **nonaffiliated** member?

# Answer 1 con't: Nonaffiliated

## Nonaffiliated member

- Examples: clergy, ethicists, nurses, police, fire fighters, bankers, teachers, librarians, clinical medical doctors, veterinarians from a veterinary practice (not involved in research), insurance adjusters
- Represents the general community interest
- Not a current or former lab animal user
- Has no affiliation with the institution, except through the IACUC
- Is not an immediate family member of an individual affiliated with the institution. Immediate family includes parent, spouse, child, and sibling



# Question 1 con't: Nonscientist?

Who is qualified to serve as a **nonscientific** member?

# Answer 1 con't: Nonscientist

## Nonscientist member

- Examples: ethicists, lawyers, clergy, librarians, those working in business or finance, or instructors in English, history, or other liberal arts disciplines, secretaries, barbers, tradespersons, and artisans
- Naïve attitude with regard to science and scientific activities
- May be affiliated with the institution or not



# Answer 1 con't: Not a Nonscientist

Examples of individuals **NOT** qualified to serve as nonscientist:

- those with an animal science or veterinary technical degree
- individuals working as veterinary technicians
- Laboratory research assistants that works with animals
- IACUC administrators



# Question 2: Nonscientist Criteria?

Would the following fulfill the criteria of nonscientist?

- A reverend with a BA in theology that took 6 undergraduate courses in sciences including biology, chemistry, and physics.
- A lawyer who took high school took science classes every year (including education on the scientific method). He won a prize during high school for a science project. The lawyer is currently not involved in scientific litigation or anything related to science, nor did she take science classes in college.
- A business manager who oversees the budget for a non-profit organization. The NPO applies for grants, using scientific processes for justification of their proposal. He contributes to the budget section and is aware of the scientific process for writing grants but really does not know science very well and has had no scientific training.

# Answer 2 : Nonscientist Criteria

Evaluate the criteria of the proposed nonscientist.

- Reverend may serve as a nonscientist
- Lawyer may serve as a nonscientist
- Business manager may serve as a nonscientist



# Question 3: IACUC Role?

Does each member of the committee have to be designated as a veterinarian, scientist, nonscientist, or nonaffiliated member?

We designate individuals such as vet techs or EH&S representatives as nonscientists, but understand this is no longer allowed according to NOT-OD-15-109. These people don't fit the definition of a practicing scientist that uses animals. To stop appointing these individuals to our committee would be a serious loss.

How do we describe their positions in our Assurance?

## Answer 3: IACUC Role

No, each member of the committee is not required to be designated as one of the four required membership roles: veterinarian, scientist, nonscientific member, nonaffiliated member.

These roles must be filled to have a duly constituted committee. If an IACUC member meets the qualifications of the PHS Policy roles, it is best to designate the member as fulfilling that role.

Other members may simply be designated as “member.”



# Question 3 con't: IACUC Membership Requirements?

We have been designating individuals such as vet techs or EH&S specialists as nonscientists because they don't fit the definition of a practicing scientist that uses animals. But now, according to OLAW's Guide Notice, we don't think nonscientist is correct, either. To stop appointing these individuals would be a serious loss to our committee.

How do we describe their positions in our Assurance?

# Answer 3 con't: IACUC Membership Requirements

The IACUC must be “...qualified through experience and expertise to oversee the institution’s animal program, facilities, and procedures.” PHS Policy IV.3.a.



# Question 4: IACUC Alternates?

May our committee designate a veterinarian who works in the compliance office as an alternate for a scientific member?

# Answer 4: Alternates

Yes, a veterinarian may serve as the alternate for a scientific member.

The PHS Policy defines a scientist as a “practicing scientist experienced in research involving animals.”

PHS Policy IV.A3.b.(2)



# Answer 4 con't: Alternates

- The CEO must appoint alternates to the IACUC in writing.
- Alternates may only serve as an alternate in the membership role for which they are qualified.
- One alternate may be appointed to serve for multiple regular members provided the alternate fulfills the specific membership role of the members for whom he or she is substituting.
- An alternate may not represent more than one member at any one time.
- Multiple alternates may be appointed as alternates for one regular member.



# Question 5: Unqualified Alternates?

If an alternate serves on the IACUC in a role for which they are not qualified:

- Is the IACUC appropriately constituted?
- If this alternate's presence is needed to form a quorum, is the official business in which they voted rendered invalid?
- What should be reported to OLAW?

# Answer 5: Unqualified Alternates

If an alternate serves on the IACUC in a role for which they are not qualified, the IACUC is not appropriately constituted.

If the inappropriately appointed alternate's presence is needed to achieve a quorum, official business that the committee voted on would be invalid and the vote would need to be repeated.

This is a noncompliant situation that must be reported to OLAW.



# Question 6: NSF-funded PHS-Assured?

Our university has a current PHS Animal Welfare Assurance. As of October 2015, the PHS Assures NSF animal activities.

However, if I understand correctly, the PHS **does not** recognize taxon specific guidelines (e.g., *Guidelines to the Use of Wild Birds in Research*) as standards for animal welfare compliance, but the NSF **does** recognize taxon specific guidelines.

Should we comply with the *Guide* or the taxon specific guidelines for our NSF funded research which is now Assured by OLAW?

# Notice of Memorandum of Understanding Between NIH and NSF Concerning Laboratory Animal Welfare

Notice Number: NOT-OD-15-139

## Key Dates

**Release Date:** August 10, 2015

## Related Announcements

none

## Issued by

National Institutes of Health ([NIH](#))

## Purpose

This Notice announces a memorandum of understanding (MOU) between the NIH Office of Laboratory Animal Welfare (OLAW) and the National Science Foundation (NSF).

### Memorandum of Understanding

NIH and NSF operate under a MOU to ensure consistent and effective oversight of the welfare of animals used in activities funded by the NSF. The agreement provides a framework to enhance communication and harmonize the agencies' efforts while reducing regulatory burden to supported institutions. The MOU is posted at [http://grants.nih.gov/grants/olaw/references/mou\\_nsf.htm](http://grants.nih.gov/grants/olaw/references/mou_nsf.htm).

### Impact on NSF-supported institutions

Effective October 1, 2015, institutions receiving NSF support must:

- include NSF-supported activities with live vertebrate animals as covered activities in their OLAW Animal Welfare Assurance (Assurance); and

# Answer 6: NSF-funded PHS-Assured

To be in compliance with the PHS Policy, your NSF funded research must adhere to the standards of the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and the AVMA Guidelines for the Euthanasia of Animals.

The taxon specific guidelines may be used as supplemental references as long as they do not conflict with the PHS Policy, the *Guide*, or the AVMA Guidelines.

The IACUC must also ensure compliance with the regulations and permit requirements of pertinent local, state, national, and international wildlife regulations.



# Question 7: Impact of MOU?

How will the relationship described in the MOU between NSF and OLAW impact my institution?

# Answer 7: Impact of MOU

Effective October 1, 2015, institutions receiving NSF support for animal activities must have an approved Animal Welfare Assurance with OLAW.

- If you **do not** have an Assurance - NSF will request that OLAW negotiate an Assurance with your institution.
- If you **do** have an Assurance - you must add NSF to the Applicability section.



# Answer 7 con't: Impact of MOU

Institutions must promptly report noncompliance and adverse events to the OLAW Division of Compliance Oversight.



# Question 8: Other Agencies?

What impact does the PHS Policy have on animal research funded by other federal agencies (e.g., US Fish and Wildlife Service)?

# Answer 8: Other Agencies

The PHS Policy applies to animal activities funded by the PHS and to programs Assured by the PHS. The PHS Policy does not apply to research funded or regulated by the US Fish & Wildlife Service.

The PHS Policy states, “This Policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the AWA, and other Federal statutes and regulations relating to animals.” PHS Policy II



# Question 9: Taxon Specific Guidelines?

What is the role of taxon specific guidelines in IACUC review of PHS Assured NSF-funded research?

# Answer 9: Taxon Specific Guidelines

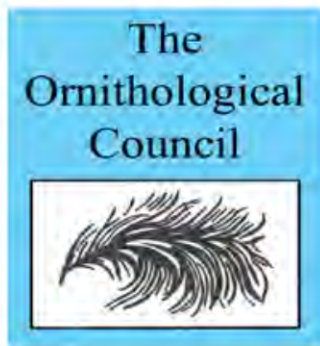
Taxon specific guidelines may be used as supplemental resources.

When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, the IACUC must ensure that proposed studies are conducted in accordance with the *Guide*.

Methods of euthanasia must be consistent with the recommendations of AVMA Guidelines.

Departures must be justified for scientific reasons by the investigator and reviewed and approved by the IACUC.





PROVIDING  
SCIENTIFIC  
INFORMATION  
ABOUT BIRDS

## IMPORTANT ACTION ALERT FROM THE ORNITHOLOGICAL COUNCIL

### FOR WILDLIFE RESEARCHERS,

### IACUC ADMINISTRATORS AND INSTITUTIONAL OFFICIALS

In August 2015, the Office of Laboratory Animal Welfare of the National Institutes of Health (aka “PHS”) and the National Science Foundation entered into a [Memorandum of Understanding](#) (effective 1 October 2015) whereby OLAW would ensure compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) for all NSF grants and cooperative agreements involving research with live vertebrate animals.

Under this MOU, OLAW is to:

- Negotiate, review and approve Animal Welfare Assurances in support of NSF grants, and cooperative agreements;
- Distribute lists of approved Assurances on the OLAW website;
- Advise and educate on implementation of the PHS Policy;
- Provide guidance on interpretation of the PHS Policy;
- Evaluate allegations of noncompliance with the PHS Policy;
- Authorize waivers to the PHS Policy; and
- Conduct site visits to selected institutions.

In addition, at the request of NSF, OLAW will negotiate Animal Welfare Assurances for NSF-affiliated institutions that do not receive direct PHS support for activities involving live vertebrate animals.

American Ornithologists' Union

Association of Field Ornithologists

Birds Caribbean

CIPAMEX (Sociedad para el Estudio y  
Conservación de las Aves en México)

Cooper Ornithological Society

North American Crane Working Group

Neotropical Ornithological Society

Pacific Seabird Group

Raptor Research Foundation

Society of Canadian Ornithologists/  
Société de Ornithologistes du Canada

# OC Action Alert **Inaccuracy 1**



“The Animal Welfare Assurance is an agreement between a research institution that **receives PHS** (NIH or other PHS organization) for research the PHS. As mandated by a federal law known as the Health Research Extension Act of 1985...

Although the Health Research Extension Act of 1985 does not apply to NSF, NSF also requires an animal welfare assurance...**As PHS will not accept an assurance agreement from an institution that does not receive PHS funding**, the NSF developed its own assurance process for institutions that receive NSF but not PHS funding.”

# OLAW Comments

OLAW Assures institutions that conduct research involving animals funded by:

- Department of Health and Human Services
  - Biomedical Advanced Research Development Authority (BARDA)
  - Public Health Service
    - NIH
    - CDC
    - FDA
- VA
- NASA
- NSF



# OC Action Alert **Inaccuracy 2**



“This new agreement between PHS and NSF **creates a problem because the two organizations differ as to the animal welfare standards that must be followed.** The NSF Grant Procedure Guide directs that the taxon-specific guidelines...be followed for wildlife research funded by the NSF. In contrast, the PHS requires that research funded by PHS adhere to the *ILAR Guide*...

# OLAW Comments

The NSF Grant Procedure Guide is being updated to reference the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and the AVMA Guidelines for the Euthanasia of Animals as the primary standards for NSF-funded research.

Institutions must comply with the PHS Policy and adhere to the *Guide* and AVMA Guidelines.

Taxon specific guidelines may be used in a supplementary role as long as they do not conflict with the primary standards.



# OC Action Alert **Inaccuracy 3**



“Of greater concern is a ‘must’ (i.e., mandatory) requirement in the *Guide* that ‘Veterinarians providing clinical and/or Program oversight and support must have the experience, training, and expertise necessary to appropriately evaluate the health and wellbeing of the species used in the context of the animal use at the institution.’

...Most veterinarians at research institutions have no training in wildlife research or veterinary care of wildlife in captivity or in the wildlife...**Lacking a veterinarian who has ‘experience, training, and expertise’ would mean that every PHS-assured institution would be out of compliance with PHS Policy even if the project was not PHS funded.**

# OLAW Comments

The basic tenets of appropriate veterinary care such as anesthesia, analgesia, appropriate animal handling, euthanasia, and medical treatment apply to **all** species.

Therefore, a wildlife veterinarian is not the only practitioner that would be qualified to evaluate the health and wellbeing of the species used at an institution.

A skilled laboratory animal practitioner, a skilled zoo practitioner, an exotic small animal veterinarian, or a general practitioner with additional training would all be acceptable as having experience, training, and expertise to oversee wildlife work. A consulting or part-time veterinarian with such expertise would also be acceptable.



# OC Action Alert Inaccuracy 4



“...unless the veterinarian accompanies the researcher on each day field work is conducted (including remote locations and locations outside the U.S.), the veterinarian has no opportunity to evaluate the health and wellbeing of the species ...used in the context of animal use at the institution.”

# OLAW Comments

OLAW does not interpret the *Guide* as requiring a veterinarian to be onsite during field research.

The *Guide* states, “Some aspects of the veterinary care program can be conducted by persons other than a veterinarian, but a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the responsible veterinarian about issues associated with animal health, behavior, and well-being, and that appropriate treatment or euthanasia is administered.”

This would apply to both laboratory and field research.

*Guide* p106



# OLAW Comments

If the IACUC approved protocol is being followed and the objectives of the study are being met, routine communication between researcher and veterinarian may not be required. Unexpected outcomes that affect the animals' well-being would be important to communicate. Communication could be by phone, Skype, or email and is not required to be face-to-face.

The *Guide* does not limit the investigator or the IACUC to seeking advice only from wildlife vets and states, "IACUCs engaged in the review of field studies are encouraged to consult with a qualified wildlife biologist." *Guide* p32





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### IACUC ADMINISTRATORS AND INSTITUTIONAL OFFICIALS

In August 2015, the Office of Laboratory Animal Welfare of the National Institutes of Health (aka “PHS”) and the National Science Foundation entered into a [Memorandum of Understanding](#) (effective 1 October 2015) whereby OLAW will implement the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) for all NSF grants and cooperative agreements in research with live vertebrate animals.

Under this agreement, OLAW is to:

- Negotiate, review and approve Animal Welfare Assurances in support of NSF grants and cooperative agreements;
- Distribute approved Assurances to the OLAW website;
- Advise on implementation of the PHS Policy;
- Provide interpretation of the PHS Policy;
- Evaluate compliance with the PHS Policy;
- Approve waivers of the PHS Policy; and
- Conduct site visits to selected institutions.

In addition, at the request of NSF, OLAW will negotiate Animal Welfare Assurances for NSF-affiliated institutions that do not receive direct PHS support for activities involving live vertebrate animals.

# Question 10: Reporting Noncompliance to OLAW?

Our institution is PHS Assured but our Assurance does NOT state that all noncompliance, regardless of funding source, will be reported to OLAW.

When should noncompliance involving research that is not funded by the PHS be reported be reported to OLAW, if ever?

# Answer 10: Reporting Noncompliance to OLAW

Noncompliance involving animal activities not funded by PHS must be reported to OLAW if there is a potential or actual effect on PHS funded activities.

Noncompliance that occurs in a functional, programmatic, or physical area that could affect PHS funded activities must be reported to OLAW.

Examples: inadequate program of veterinary care, training of technical or husbandry staff, occupational health, inadequate sanitation due to malfunctioning cage washer, or room temperature extremes due to HVAC failure.

Noncompliance involving NSF funded activities must be promptly reported to OLAW Division of Compliance Oversight.



# Question 11: Exempt Review Process?

My institution requires a process that we call “IACUC Exempt Review” when students review secondary data that involves animals. It is similar to the process used by IRBs in human subjects research reviews.

- What should be included in an exempt application?
- Can the IACUC designate the IACUC administrator to make exempt determinations?

# Answer 11: Exempt Review Process

The PHS Policy does not require such a review. Therefore, we do not have any advice on what to include.

The institution should determine what information is required to meet needs that the review was developed to address. It would be up to the institution to determine who could address the administration of their process.

Human subjects regulation differs from animal research oversight. Even though there are similarities between the human and animal side, it would be a mistake to assume the same rules and regulations apply to both.



# Question 12: IACUC Responsibility?

What are the IACUC's responsibilities regarding:

1. Tissue samples collected from vertebrate animals by a PI at another institution and sent to a PI at our institution to be analyzed (e.g., population genetic research).
2. Analysis of archival data (e.g., video-taped behavior) gathered on vertebrate subjects.

# Answer 12: IACUC Responsibility

When tissue is collected from live animals, IACUC review and approval is required. When that tissue is subsequently analyzed at another institution, further IACUC review is not required.

This is similar to obtaining off the shelf tissues from a repository or commercial source. No review is required.

Similarly, no review is required for analysis of archived data such as videotaped behavior.



# Question 13: Signatures?

We are not required to obtain signatures on approved animal study proposals.

- May we rely on meeting minutes to confirm that relevant approvals were obtained?
- How should we confirm approval of proposals that were reviewed by the DMR process?

# Answer 13: Signatures

There is no Federal regulation that requires signatures on approved animal study proposals.

The PHS Policy allows institutions the latitude to develop business practices that meet their needs.

Yes, you may rely on meeting minutes to confirm that relevant approvals were obtained.



# Question 14: DMR Reassignment?

Occasionally our IACUC Chair will appoint someone for DMR, but the designated reviewer cannot complete the protocol review on time for unexpected reasons, such as illness, family emergency, or lack of time.

In such situations, can the Chair reassign the DMR to another member?

If this is allowed, can OLAW suggest an acceptable process for such a reassignment?

# Answer 14: DMR Reassignment

Yes, it is perfectly acceptable for the Chair to reassign the designated member review to another qualified reviewer.

The IACUC is free to determine a process that works well in their program. It is important to document the reassignment.

The PHS Policy requires that the designated member be qualified and appointed by the IACUC Chair. It is not necessary to contact the IACUC members as they have previously consented that the protocol be reviewed by DMR. PHS Policy IV.C.2.



# Question 15: SOPs?

Our IACUC would like to allow investigators to use IACUC approved SOPs as part of a protocol submission.

- Can SOPs be referenced by number or is it necessary to include each SOP in the protocol?
- Do you have suggestions on best practice or advice on what pitfalls to avoid?

# Answer 15: SOPs

Yes, IACUC approved SOPs can be referenced for inclusion in a protocol. The SOP can be referenced by title or number.

The most likely pitfall is that the SOP content is not familiar to the laboratory staff or a different SOP is used than intended.

SOPs should be reviewed by the IACUC every three years to ensure that they are accurate and up to date.



# Question 16: Refinement?

Can the IACUC withhold IACUC approval based on refinement issues?

For example, if the IACUC believes that there is a blood collection or surgical technique that is less stressful to the animal than the one proposed by the investigator, can the IACUC require the investigator to use the procedure it prefers?

# Answer 16: Refinement

It is the IACUC's responsibility to work with the investigator to ensure that the best technique is used to ensure animal welfare and accomplish the aims of the study.

In this example, the IACUC might ask the investigator, why he or she chose this particular method and suggest the use of an alternative.



# Question 17: Euthanasia?

What level of detail about euthanasia should be included in an animal study proposal?

# Answer 17: Euthanasia

The IACUC should request enough detail to determine if the procedure will be consistent with the AVMA Guidelines for the Euthanasia of Animals.

OLAW's optional sample ASP:



Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the methods of euthanasia include those **not** recommended by the AVMA Guidelines, provide scientific justification as to why such methods must be used. Indicate the method of carcass disposal.

OLAW sample ASP [http://grants.nih.gov/grants/olaw/sampledoc/animal\\_study\\_prop.htm](http://grants.nih.gov/grants/olaw/sampledoc/animal_study_prop.htm)  
AVMA Guidelines <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

# Question 18: Pain Category?

Recently a PI submitted a protocol to our IACUC in which they will be using Freund's complete adjuvant in mice. They listed the pain category as C (momentary pain or distress).

They also submitted a pain management plan if pain or distress is noted in the mouse.

Our IACUC discussed if this would be the proper pain category. Discussion was tabled until more guidance could be provided. Any help on this issue would be greatly appreciated.

# Answer 18: Pain Category

Pain categorization is required for the use of USDA regulated species. The PHS Policy does not require pain categories, but it does require that “procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.” PHS Policy IV.C.1.a.

OLAW recognizes that some institutions choose to assign USDA pain categories to species that are not USDA regulated as part of their process to meet the PHS Policy requirement to minimize pain and distress.

If unsure about the potential for pain caused by the procedure, the IACUC could ask the investigator to provide additional information or consult a subject matter expert.



# Question 19: Departures?

The first time the IACUC approves a departure, it must be reported in the next semiannual report to the IO. A record of the departure must be maintained for as long as the departure is active and approved.

If the animal use protocol, containing the same exemption is renewed as a *de novo* protocol after a third year review, would I need to report the exemption to the IO again? Or is the one time report, regardless of how long the exemption exists, sufficient?

# Answer 19: Departures

Departures from the *Guide*, including the reason for the departure, should be provided in the next semiannual report to the Institutional Official after the initial review and approval by the IACUC.

A mechanism for listing all active approved departures should be retained for review and tracking. Relevant personnel, including the IO, IACUC members and staff, should be able to access the list.

The departure should be maintained on the list as long as it is active.



# Guidance on Significant Changes to Animal Activities

**Notice Number:** NOT-OD-14-126

## Key Dates

**Release Date:** August 26, 2014

## Related Announcements

[NOT-OD-14-063](#)

## Issued by

National Institutes of Health ([NIH](#))

## Purpose

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on significant changes to animal activities.

## Background

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) ([IV.C.1.](#)) and Animal Welfare Regulations ([9 CFR 2.31 \(d\) \(1\) \(i\)-\(iv\)](#)) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution's Assurance, the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and must be consistent with the [Guide](#) unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy [IV.C.1.a-g](#).

IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR) or designated member review (DMR). Additionally, institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every three years to ensure they are appropriate and accurate.

## Significant Changes to Animal Activities Previously Approved by the IACUC

## Question 20: VVC?

Can VVC be used if an investigator realizes, months after protocol approval, that there is a need for a one time tail vein blood withdrawal? The approved protocol does not mention any blood withdrawal.

The IACUC has an approved VVC policy and has an approved policy for tail vein blood collection that defines allowable volume per draw and frequency.

The investigator's request for approval of the one-time withdrawal meets all of the requirements of the approved policy.

# Answer 20: VVC

Specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The vet is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance.

Consultation with the veterinarian must be documented. The vet may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies. This includes changes in:

- a. anesthesia, analgesia, sedation, or experimental substances;
- b. euthanasia to any method approved in the AVMA Guidelines; and
- c. duration, frequency, type, or number of procedures performed on an animal.

## Answer 20 con't: VVC

The question tells us that the approved protocol does not mention any blood draws.

Even though this procedure falls within the parameters of the IACUCs approved blood collection policy, the VVC process may **not** be used to add a new procedure to a previously approved protocol.

The blood draw would need to be added to the protocol by full committee or designated member review.



## Question 21: VVC?

Can VVC be used if an investigator realizes that an additional cardiac procedure is needed (anesthesia, venous cut-down, cardiac catheterization, closure and recovery) after the protocol has been approved?

The approved protocol specifies 4 procedures and the PI requests a 5<sup>th</sup>. The IACUC has an approved policy that permits VVC. They also have an approved policy that permits up to 6 catheterizations.

# Answer 21: VVC

Yes, the VVC process can be used to administratively handle this significant change to this protocol.

- IACUC has approved policies in place
- request is a significant change to an already approved procedure
- veterinarian confirms that the policies are being applied appropriately



# Question 22: Contract Congruence?

Is there a requirement for congruence between contracts and IACUC protocols, similar to the requirement for grant/protocol congruence?

Since contracts are often undergoing negotiations right up until the time of award, completing an accurate comparison can be challenging.

# Answer 22: Contract Congruence

Yes, verifying congruence between the description of the animal activity in the contract proposal and that in the IACUC approved protocol is required for contracts in the same manner as grants.



# Question 23: Animal Ownership?

How does OLAW define animal ownership?

Should animal ownership be addressed in an MOU?

# Answer 23: Animal Ownership

OLAW considers that the animals are the responsibility of the Assured institution that houses them.

In the section on Collaborations, the *Guide* states, “...the participating institutions should have a formal written understanding (e.g., a contract, memorandum of understanding or agreement) that addresses the the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight.”

*Guide* p15



# Question 24: Verification of IACUC Approval?

Our IACUC is often notified by investigators about a pending grant award with a very short turn around (days) for IACUC review and approval.

What can the IACUC do to meet the requirements for the grant process?

Is the investigator at risk of losing their award?

# Answer 24: Verification of IACUC Approval

The PHS Policy requires that

- Verification of IACUC approval be provided before an award is made. Under no circumstances may an IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval.
- Modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval. It is the responsibility of institutions to communicate any IACUC-imposed changes to NIH grants management staff.



# Question 24 con't: Verification of IACUC Approval?

Our IACUC is often notified by investigators about a pending grant award with a very short turn around (days) for IACUC review and approval.

What can the IACUC do to meet the requirements for the grant process?

Is the investigator at risk of losing their award?

# Answer 24 con't: Verification of IACUC Approval

Typically the answer is no, but it depends on the time in the Federal fiscal year and the intent to make an award as communicated to the PI by the NIH grants management staff. NIH Institutes and Centers vary in their funding practices.

OLAW recommends that the investigator discuss the situation with the IACUC as early as possible.

It is beneficial to provide the anticipated IACUC approval date to NIH grants management.



# Answer 24 con't: Verification of IACUC Approval

At the end of the federal fiscal year, NIH grants managers may make awards but restrict the draw-down of funds to the portion of the grant that does not include the use of animals until valid IACUC approval is provided. This is called a restricted award.



# Reminder: Annual Reports to the Office of Laboratory Animal Welfare due January 31, 2016

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**Notice Number:** NOT-OD-16-022

## Key Dates

**Release Date:** November 16, 2015

## Related Announcements

None

## Issued by

National Institutes of Health ([NIH](#))

## Purpose

This Notice is to remind awardee institutions that annual reports for the period January 1, 2015 through December 31, 2015 are due to the NIH Office of Laboratory Animal Welfare (OLAW) by January 31, 2016. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) requires Assured institutions to submit a written report to OLAW at least once every 12 months.

## What to Include

Information to be reported consists of any change in the institution's program of animal care and use, any change in the Institutional Official or the Institutional Animal Care and Use Committee (IACUC) membership, the dates that the IACUC conducted its semiannual evaluations of the program and facilities, and any minority view by an IACUC member.

Remember to include any program changes in response to recent OLAW policy updates:

- **Guidance on Significant Changes to Animal Activities:** If your IACUC established policies for administrative handling of some significant changes, indicate that you have a program change and list what these policies are. You do not need to attach or provide copies of the policies. (See [NOT-OD-14-126](#))
- **Guidance on Qualifications of Nonscientific and Nonaffiliated Members:** Include an updated IACUC roster if you've had membership changes such as changes to comply with guidance on the qualifications of nonscientific and nonaffiliated members. (See [NOT-OD-15-109](#))
- **For Institutions with National Science Foundation (NSF) Supported Animal Activities:** Indicate that you have a program change and attach an update to your Assurance Part I. Applicability section so that it reads: I. Applicability of Assurance – "This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and NSF. This Assurance covers only those facilities and components listed below." (See [NOT-OD-15-139](#))

# OLAW Comment: Annual Report

Remember to include any program changes in response to recent OLAW policy updates:

- If your IACUC established policies for administrative handling of some significant changes, indicate that you have a program change and list what these policies are. You do not need to attach or provide copies of the policies. (See [NOT-OD-14-126](#))
- Include an updated IACUC roster if you've had membership changes such as changes to comply with guidance on the qualifications of nonscientific and nonaffiliated members. (See [NOT-OD-15-109](#))
- For Institutions with NSF-Supported Animal Activities – Indicate that you have a program change and attach page 1 of your Assurance (Part I. Applicability) so that it reads: “I. Applicability of Assurance. This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and NSF. This Assurance covers only those facilities and components listed below.” (See [NOT-OD-15-139](#))



# Upcoming OLAW Online Seminars

March 3, 2016 – New Vertebrate Animal Section,  
Grants Policy, and Congruence

June – TBD

September – TBD

December – TBD

Send your topic ideas for upcoming webinars to

[olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov)

