

Welcome!

FASEB Webinar on

“Streamlining Institutional Requirements for Animal Research”

*FASEB/COGR Series: Institutional Administrative Requirements for Animal Research
Pt. 1 of 2*

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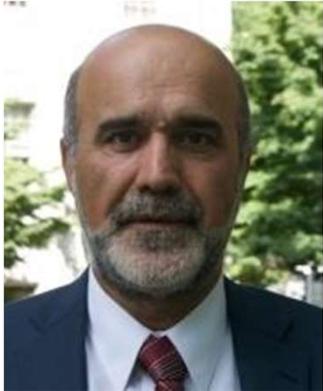
COGR

Council On Governmental Relations

Streamlining Institutional Requirements for Animal Research

**FASEB/COGR Series: Institutional Administrative
Requirements for Animal Research – Pt. 1 of 2**

Speakers



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Director of Animal
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Agenda

◆ 2018 COGR Survey Report

◆ Three major topics for discussion:

- Annual Protocol Review
 - VVC, DMR
- Protocol Re-write at Triennial Review
- Animal Numbers, Pain/Distress Classification and Literature Review

◆ Q & A

NIH OLAW and USDA Representatives will speak towards existing policies. Details on new/revised policies cannot be provided so early during the review process

To Ask A Question

Type your question in the white box and click “Send” (gray button)

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Reducing Burden ~~=~~ Reducing Animal Welfare

Reducing Burden = More resources for animal care & enrichment
More time for scientists to conduct humane research

2018 COGR Survey Report

- ◆ 2018 survey of COGR members on actions that institutions can take to reduce administrative burden associated with animal research.
- ◆ Ninety-four of COGR's 188 members responded.
- ◆ **Institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty.**
- ◆ Agencies could provide significant assistance to institutions by distinguishing between requirements and best practices.
- ◆ A contributing factor is the complexity of multiple sets of regulations, policies, and guidelines. Steps to align agency requirements would help to alleviate this.
- ◆ To access the report: <https://www.cogr.edu/cogr-survey-report-institutional-administrative-requirements-animal-research>

Annual Protocol Review

2018 COGR Report: 47% of institutions indicated they have eliminated protocol renewals for non-USDA species and non-DOD protocols for which they are not required

Annual Protocol Review

PHS Policy IV.C.5: The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1-4 at least once every three years.

- **For PHS animals, no requirement for Annual Review (as with USDA)**
 - For convenience, some institutions combine PHS requirement with USDA and conduct Annual Review for non-USDA animals as a way to fulfill the continuing review requirement
- **“continuing” does not necessarily mean annual review**
 - Annual review can be one of the “appropriate intervals” the IACUC chooses
- **Other ways to accomplish continuing review:**
 - Post-approval monitoring
 - Semiannual review
 - Laboratory visits (IACUC coordinator or veterinarian)
 - Self-reports to IACUC from technicians, animal care staff, investigators, etc.

Designated Member Review

2018 COGR Report: 66% of institutions indicated that they do use DMR as the default. Of those that indicated that their institution does not use DMR as the default, 3% indicated that their institution plans to implement this action.

Suggestions:

- Creating a hierarchy of protocols that require Full Committee Review (FCR) can be an effective approach and ensure that the most invasive studies are appropriately reviewed.
- There is also value, however, in having some flexibility to determine what goes to DMR/FCR.
- Institutions should review their approach to ensure that it is improving animal welfare without creating unnecessary administrative burden.

Veterinary Verification and Consultation

2018 COGR Survey: 77% percent of the 94 institutions responding indicated that they have adopted this process. Of those that have not adopted VVC, 11% indicated that they plan to adopt it.

- **VVC process was implemented and encouraged by OLAW and USDA to support expedited review of procedures already approved by IACUC**
 - Can decrease the number of changes/amendments IACUC needs to approve
- **Does require some work upfront**
- **Several templates are available to help accomplish this:**
https://www.aalas.org/iacuc/iacuc_resources/veterinary-verification-and-consultation

Veterinary Verification and Consultation

Items that Do and Do Not Require IACUC approval

Yes (IACUC only)	No (No IACUC, no VVC)
Changing from non-survival to survival surgery	Correction of typographical errors
Changes which result in greater pain, distress, or degree of invasiveness	Correction of grammar
Housing/using animals in a location not part of the animal program overseen by IACUC	Contact information updates
Change in species	Change in personnel other than P.I.
Change in study objectives	
Change in P.I.	
Change that impacts personnel safety	

NIH Guide Notice—NOT OD 14-126: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

Protocol Re-write at Triennial Review

2018 COGR Report: 33% indicated that their institution does not require a protocol re-write. Among those that do, 13% indicated that they would eliminate this requirement and 52% that their institution would not.

PIs ranked the so-called triennial review as the most onerous task in the 2018 FDP survey

PHS Policy does not require a rewrite—just a review of an ongoing study:

Policy IV.C.5: “The IACUC shall conduct continuing review of each previously approved, ongoing activity..., including a complete review in accordance with IV.C.1.-4 using DMR or FCR”.

Protocol Re-write at Triennial Review

Clarifying the Term *de novo*:

It appears that the initial use of the term *de novo* appeared in 1993 ILAR News, 35 (3-4): 47-49:



Question: *"7. Implementing regulations of the Animal Welfare Act require that animal study protocols be reviewed and acted upon by the IACUC annually. The PHS Policy requires that such reviews be conducted every three years. For the purpose of complying with OPRR's oversight policy, how frequently must our IACUC perform such reviews?"*

Answer: The PHS Policy **requires that de novo IACUC reviews of all PHS-supported protocols be conducted on a triennial basis.** The Policy also states that "... institutions are required to comply ... with the Animal Welfare Act, and other Federal statutes and regulations."

<https://grants.nih.gov/grants/olaw/references/ilar93.htm>

Protocol Re-write at Triennial Review

Clarifying the Term *de novo*:

- 2002 Institutional Animal Care and Use Committee Guidebook (p.96): *The PHS Policy requires that a complete IACUC review of PHS supported protocols be conducted at least once every three years.*
- **This triennial review is interpreted by OLAW as a requirement for *de novo* review**
 - criteria and procedures for review specified in IV.C of the PHS Policy must be applied not less than once every three years.
- The 3 year renewal protocol document does not need to be completely re-written **because it is not a new project. It is a renewal of ongoing activity.**
 - updates and changes need to be included
 - obsolete information should be removed.
 - It is a best practice to incorporate added amendments (although, they can also be attached)
 - This document should then be reviewed by the IACUC in accordance with IV.C.1-4 using DMR or FCR

Animal Numbers

2018 COGR Report: 44% of institutions have taken the action of providing an approximate number or range of animals needed for a research project.

USDA regulations: 2.31 (e) (1) states that the proposal must contain the “*approximate number of animals to be used.*”

- An approximate number or a range is appropriate, and meets this requirement
- USDA encourages facilities to use approximate animal numbers
- Any questions or concerns, please let us know

Animal Numbers

PHS Policy IV.D.1: Applications and proposals (competing and noncompeting) for awards submitted to the PHS that involve the care and use of animals shall contain the following information:

- Identification of the species and approximate number of animals to be used;

The Vertebrate Animals Section of the NIH grant application asks for the “total number of animals by species”

The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, Training III states:

- “The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results.”

Animal Numbers

Although the PHS Policy does not explicitly require a mechanism to track animal usage by investigators, it does require that proposals specify a rationale for the approximate number of animals to be used and be limited to the appropriate number necessary to obtain valid results

- Institutions should establish mechanisms to document and monitor number of animals acquired and used
- Guidance on Significant Changes to Animal Activities: A significant change that may be handled administratively according to an existing IACUC-reviewed and approved policy without additional consultation or notification is an **increase** in previously approved animal numbers.
- Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.

Pain and Distress Classification

2018 COGR Report: 15% of respondents indicated that their institution has discontinued the USDA pain and distress classifications for non-AWA species

It is not a regulatory requirement to categorize non-USDA/non-DOD projects into pain categories, as outlined in the PHS Policy, U.S. Gov't Principles, and Vertebrate Animals Section of the grant application

Pain and Distress Classification

US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on un-anesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

PHS Policy

IV.C.1.a Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design

b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific

reasons in writing by the investigator

c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

IV.D.d. Applications and proposals for award shall contain a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

VAS

Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

Have you described:

- Circumstances when animals may experience discomfort, distress, pain or injury
- Procedures to alleviate discomfort, distress, pain or injury
- Use of tranquilizers, analgesics and anesthetics (identify drugs by name/class)
- Provisions for palliative care or housing
- Plans for post-surgical care, if applicable
- Humane experimental endpoints, if relevant

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Literature Search for Category D and E Procedures (Non-USDA Species)

2018 COGR Report: 25% of respondents indicated their institution has eliminated the requirement for a literature search for category D and E procedures for non-USDA species.

Of the 76% that responded 'no', 62% indicated their institution would not implement this change; 10% would

Literature Search for Category C Procedures (Momentary Pain or Distress) (USDA and non- USDA species)

2018 COGR Report: 62% of institutions indicated they have eliminated the requirement for a literature search for category C procedures for all species

First subparagraph under 2.31 (d) IACUC review of activities involving animals: *“Procedures involving animals will avoid or minimize discomfort, distress, or pain to the animals”*

- Also describes alternatives to procedures that may cause more than momentary pain or slight pain of distress

USDA Policy states very clearly that a literature search is not required for Column C procedures, which, by definition, involve no pain or distress or pain relieving drugs.

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Other Questions?

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