



The 2016 Vertebrate Animals Section, Grants Policy, and Congruence

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OLAW Online Webinar
March 10, 2016



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Webinar Objectives

1. Explain the requirements for achieving grant and protocol congruence.
2. Describe how the recent changes to the Vertebrate Animal Section of NIH grant applications impact the requirements.
3. Identify the roles, relationships, and responsibilities of the IACUC, institution, and PIs in ensuring congruence.
4. Assess best practices for congruence review and their applicability to your institution.



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Webinar Objective 1

Explain the requirements for achieving grant and protocol congruence.




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What is Congruence?

Congruence is the state achieved by coming together, the state of agreement. Congruence, as opposed to equivalence or approximation, is a relation which implies a kind of equivalence, though not complete equivalence. [Wikipedia](#)

Congruence is agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC.

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Why is Congruence Required?

The NIHGPS provides the terms and conditions that must be met to receive a grant award.

- Compliance with the PHS Policy is a term and condition of NIHGPS.
- The NIHGPS defines contractual and legal obligations between the institution and NIH.



National Institutes of Health
Office of Extramural Research

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Why is Congruence a requirement?

NIH Grants Policy Statement (NIHGPS)

“It is an institutional responsibility to ensure that the research described in the application is **congruent** with any corresponding protocols approved by the IACUC.”

[NIHGPS Part II, A, 4.1.1.2](#) Verification of IACUC Approval



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When May Congruence Be Determined?

Any time **prior** to grant award.



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Webinar Objective 2

Describe how the recent changes to the Vertebrate Animals Section (VAS) of NIH grant applications impact the requirements.



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Why Change 2016 Grant Application?

Purpose of Vertebrate Animals Section update:

- Remove redundancy with IACUC review, while still meeting PHS Policy requirements.
- Simplify the VAS criteria to reduce burden on applicants.



2016 Grant Application Changes

Changes that were made:

- Justification for the number of animals has been moved to the Research Strategy Section where it is an element of rigor in the experimental design.
- Description of veterinary care is no longer required in the VAS.
- Description of the euthanasia method is no longer a part of the VAS.

For more information:

http://grants.nih.gov/grants/forms_updates_faq.htm



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2016 PHS 398

Section 8 Vertebrate Animals

1. **Description of Procedures.** Provide a concise description of the proposed procedures. Identify the species, strains, ages, sex and total number of animals by species to be used.
2. **Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model.
3. **Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize pain and distress.

<http://grants.nih.gov/grants/olaw/VASchecklist.pdf>

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Webinar Objectives 3

Identify the roles, relationships, and responsibilities of the IACUC, institution, and PIs in ensuring congruence.



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Who Must Meet the Contractual Obligations of the Grant?

By signing the grant application:

- The Authorized Organization Representative (**AOR**) commits the institution to meet the terms and conditions of the NIHGPS.
- The **PI** commits to meeting PHS Policy standards and to conducting animal activities according to an approved IACUC protocol.



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Is the IACUC Required to Review the Grant Application?



OLAW Frequently Asked Question D10



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Who May Review for Congruence?

Someone who is qualified to identify inconsistencies and has access to the IACUC protocol and grant application, e.g., :

- IACUC staff
- Sponsored projects staff
- Compliance oversight personnel



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Who is Responsible?

- **Institution** verifies congruence by providing IACUC approval date
- **Institution** (via the AOR) and **PI** are responsible for notifying NIH of a change in scope or IACUC required modifications
- **PI** must notify IACUC of change in scope as a result of NIH review
- **PI** is responsible for obtaining IACUC approval of proposed animal activities



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Responsible for Documentation

The **institution** must document IACUC approval of the animal activities proposed in the grant.

- The **institution** must be able to associate each grant(s) with relevant IACUC protocol(s).
- If the **institution** uses a protocol numbering system, it must be able to link protocol numbers to grant numbers.
- 1:1 ratio is not required.



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What About Other Agencies?

- Department of Veterans Affairs
- National Science Foundation
- Department of Defense
- USDA National Institute of Food and Agriculture



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Department of Veterans Affairs

MOU between OLAW and DVA requires compliance with PHS Policy



http://grants.nih.gov/grants/olaw/references/mou_olaw.htm



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National Science Foundation

- Institution must be PHS Assured.
- IACUC approval required before an award can be made.
- Evidence of IACUC approval must be verified in a letter with approval date and appropriate organizational signature.
- "The approval letter must affirm that an animal-use protocol covering the proposed activities has been approved, and should explicitly list the proposer's name, the title and number of the NSF proposal, and the date of IACUC approval."

http://www.nsf.gov/pubs/policydocs/pappguide/nsf16001/gpg_2.jsp#IID7



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Department of Defense

- No specific congruency review requirement between DOD grant and IACUC protocol.
- Dual-Review Process: “Extramural research proposals using live animals are administratively reviewed and approved by a DOD veterinarian trained or experienced in laboratory animal medicine and science prior to release of funding for animal research.”

http://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations



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USDA

National Institute of Food and Agriculture

- IACUC approval is required before a USDA award can be made.
- “If the proposed project involves research including live vertebrate animals, the verification date of IACUC approval along with any IACUC-imposed changes must be submitted.”

http://nifa.usda.gov/sites/default/files/resource/NIFA_policy_gde_Oct_2014.pdf



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Where to Look in the Grant

- Vertebrate Animals Section
- Research Strategy Section



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What Content Should Be Compared?

- Species
- Total animal numbers proposed
- Procedures



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Not Congruent

Procedure in Grant is NOT in IACUC Protocol

- Ask PI for clarification
- Amend protocol to be consistent with grant

OR

- Inform NIH if procedure will not be conducted as originally proposed

Procedure in IACUC Protocol is NOT in Grant

- Ask PI for clarification
- PI determines if there is a change in scope.

Note: This would apply when there is a one-to-one grant to protocol ratio. If multiple grants are associated with a single IACUC protocol, the institution must ensure that PHS funds are expended as described in the PHS grant or grants.



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NIH Change in Scope

“The grantee (PI) must make the initial determination of the significance of a change and should consult with the Grants Management Officer of the NIH funding component as necessary.”

[NIHGPS Part II: Subpart A: 8.1.2.5](#) Change in Scope

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Indicators of Change in Scope

- Change in the specific aims approved at the time of award
- Substitution of one animal model for another
- Change from the approved use of live vertebrate animals
- Shift of the research emphasis from one disease area to another

[NIHGPS Part II: Subpart A: 8.1.2.5 Change in Scope](#)



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Change in Scope?

YES

PI, through Authorized Organization Representative (AOR), contacts NIH Grants Management Officer (GMO) to obtain approval of change

NO

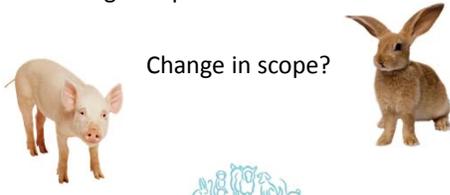
PI provides explanation that institution may file with the congruency review documentation



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Issues That May Require Clarification

- Animal numbers
- Performance site
- Administration of agents
- Change in species



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Does the IACUC Protocol Match the Grant?



How do you know?

Is it documented?

- Institutions should maintain congruence review records for their own purposes and have them available for possible review by NIH.
- There are numerous ways to achieve and verify congruence.
- Institutions may develop and implement their own policies and procedures, as long as those policies and procedures satisfy the requirements of the PHS Policy and the terms and conditions of NIH Grants Policy.



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Congruence Review Strategy Summary

- Concentrate on Vertebrate Animals Section
- In Research Strategy, focus on Approach
- Look for key words describing procedures in the IACUC protocol and in the grant
- If inconsistent, have PI clarify and provide explanation
- If PI changes protocol or grant, notify NIH if grant is impacted



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Webinar Objective 4

Assess best practices for congruence review and their applicability to your institution.



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Some Best Practices for Congruence Review

Samuel Varghese, Ph.D.
Director, IACUC/IBC
University of Massachusetts Medical School

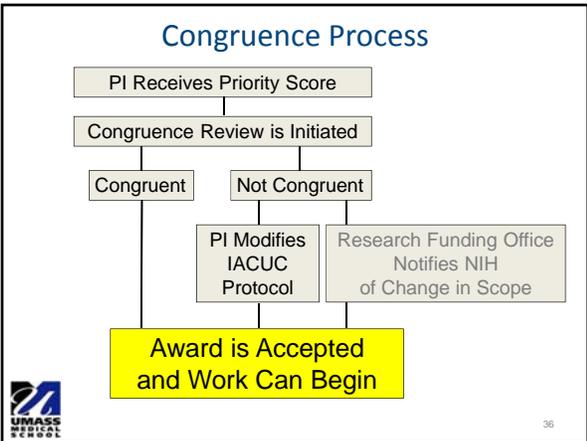


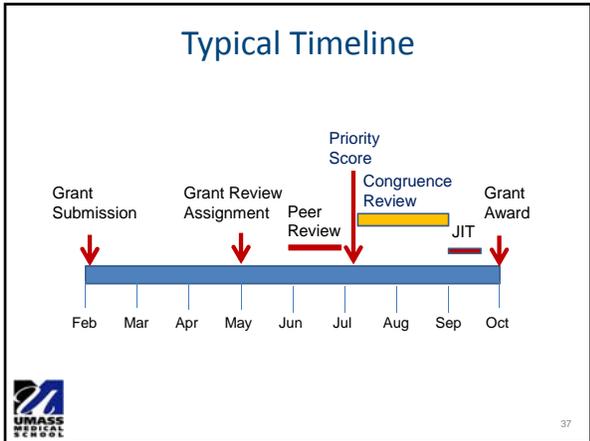
U Mass Med Policy Statement

A congruency review is required for all PHS funding that uses live vertebrate animals to ensure that the work described in the proposal is in agreement with an active, approved protocol.

We use one-to-many/many-to-one system which means a funded proposal can be linked to one or many protocols, and one protocol can be linked to one or many grant proposals.







- ### Review Focus
- Side-by-Side Comparison**
- General scope of the work (e.g., disease model)
 - Experimental procedures and endpoints
 - Agents (experimental and therapeutic)
 - Species (including strain(s), if the conduct of the proposed study or the disease model is dependent on the strain)
 - Approximate numbers of animals
 - Euthanasia method
- The UMass Medical School logo is in the bottom left, and the number 38 is in the bottom right.

Congruence

A reasonable matching description of the six areas listed in the previous slide between the grant proposal and IACUC-approved protocol will be regarded as congruent.

If significant changes to the IACUC protocol are necessary, the grant proposal will be considered non-congruent.

The UMass Medical School logo is in the bottom left, and the number 39 is in the bottom right.

If Not Congruent

Ask PI for clarification

- Amend protocol to be consistent with grant
- OR
- Inform NIH if procedure will not be conducted as originally proposed, indicating a **change in scope**



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Now, for Some Real World Scenarios...



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Scenario 1

Even though the investigator has an IACUC-approved protocol that is congruent with the grant application, the protocol is expiring before or within a few weeks of the start date of the grant.



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Scenario 1

Even though the investigator has an IACUC-approved protocol that is congruent, it is expiring before or within a few weeks of the start date of the grant.

Solution: Advise the investigator to submit a new protocol or a 3-year renewal of the IACUC protocol.



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Scenario 2

A grant application is funded for 5 years. The IACUC protocol covers studies in the grant for 3 years. How do you verify IACUC approval and congruence for the animal studies planned for the 4th and 5th year?



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Scenario 2

A grant application is funded for 5 years. The IACUC protocol covers studies in the grant for 3 years. How do you get approval for animal studies planned for the 4th and 5th year?

Solution: A brief description without experimental details and procedures for the studies planned for the 4th and 5th year can be included in the IACUC protocol for review and approval. The 4th and 5th year studies must be addressed in more detail at the time of protocol renewal.



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Scenario 3

An investigator's IACUC-approved protocol does not include the alternative experimental approaches described in the grant application. Does the IACUC need to approve alternative approaches since the investigator is not likely to use most of the alternative approaches?



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The investigator's IACUC-approved protocol does not include the alternative approaches described in the grant application. Does the IACUC need to approve alternative approaches since the investigator is not likely to use most of the alternative approaches?

Solution: We will advise the PI to include a brief description of the alternative approaches in the IACUC protocol, without experimental details and procedures, for review and approval by the IACUC. The PI must amend the protocol to include the alternatives if he or she uses them.



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Scenario 4

If vertebrate animal studies are to be performed off-site by collaborators, how will you verify congruence of the off-site animal studies?



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Scenario 4

If vertebrate animal studies are to be performed off-site by collaborators, how will you verify congruence of the off-site animal studies?

Solution: We ask the PI to submit a U Mass off-site protocol form that contains a brief description of the studies, supporting documentation such as IACUC approval letter from the other institution, proof of collaboration, and if necessary, a copy of the IACUC-approved protocol and/or a MOU asserting congruence review.

Alternatively, we ask the administrators at the institution to perform a congruency review and provide documentation to our institution verifying congruence.



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Scenario 5

The PI of the IACUC-approved protocol is not the PI of the grant. What do you do in this circumstance?



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Scenario 5

The PI of the IACUC-approved protocol is not the PI of the grant. What do you do in this circumstance?

Solution: If the IACUC protocol PI is mentioned in the grant as an investigator or collaborator, we will use that protocol for congruency review.

If the IACUC protocol PI is not even mentioned as a collaborator in the grant, we will advise the PI of the grant to submit a new IACUC protocol.



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Scenario 6

Some of the reagents (e.g., custom antibodies) in a grant application are to be produced by a vendor registered with USDA and accredited by AAALAC, but without an OLAW Animal Welfare Assurance. Is it OK to use the vendor's IACUC-approved protocol for congruency review or are there other steps you take first?



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Scenario 6

Some of the reagents (e.g., custom antibodies) in a grant application are to be produced by a vendor registered with USDA and accredited by AAALAC, but without an OLAW Animal Welfare Assurance. Is it OK to use the vendor's IACUC-approved protocol for congruency review or are there other steps you take first?

Solution: No, it is not OK, because NIH requires the vendor used by the grantee to be Assured. Therefore, we will address this immediately so that the PI's research is not delayed. We either require the vendor to contact the NIH grants manager to request that OLAW negotiate an Assurance. Or, require the PI to switch to a PHS Assured vendor before verifying congruency.



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Scenario 7

An investigator proposes in the application to collaborate with a researcher in a foreign institution that does not have an Animal Welfare Assurance for Foreign Institutions. Is it OK to use the foreign collaborator's protocol for congruency review or are there other steps you take first?



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Scenario 7

An investigator proposes in the application to collaborate with a researcher in a foreign institution that does not have an Animal Welfare Assurance for Foreign Institutions. Is it OK to use the foreign collaborator's protocol for congruency review or are there other steps you take first?

Solution: No. First we would require the foreign institution to contact the NIH grants manager to request that OLAW negotiate a foreign Assurance. Even after they obtain a foreign Assurance, our institution remains responsible for the animal activities conducted at the foreign site and must provide verification of our IACUC's approval to NIH. Our IACUC may accept the approval of a the foreign Assured institution's IACUC review; however our IACUC is responsible for the review as if it was our own.



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Scenario 8

Training grants from NIH support training only (e.g., salaries for postdoctoral fellows) and provide no funds for animal care and use. Is a congruence review necessary?



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Scenario 8

Training grants from NIH support training only (e.g., salaries for postdoctoral fellows) and provide no funds for animal care and use. Is a congruence review necessary?

Solution: No. Training grants where no independent research with animals is supported do not require a congruence review.



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Additional Resources

- NIH Grants Policy Statement <http://grants.nih.gov/grants/policy/nihgps/index.htm>
- OLAW Frequently Asked Question D10 <http://grants.nih.gov/grants/olaw/faqs.htm#623>
- Garnett, N.L. & DeHaven, W.R. A word from OPRR and USDA [protocols and grant applications]. *Lab Animal* 28, 21 (1999).
- Klemfuss, H. Matching protocols to grant proposals. *Lab Animal* 31, 36-39 (2002).
- Wolff, A., Garnett, N., Potkay, S., Wigglesworth, C., Doyle, D., Thornton, V. Frequently Asked Questions About the Public Health Service Policy on Humane Care and Use of Laboratory Animals. *Lab Animal* 32, 33-36 (2003).



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Question 1

Is it correct that the IACUC should not feel pressured to review a related amendment, for example, within 48 hours to support a Just-In-Time (JIT) award?

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Question 2

If a grant funds multiple IACUC protocols, which IACUC approval date should be provided? The most recent?

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Question 3

If two institutions are involved in a project, which one is responsible to ensure congruence? The institution that receives NIH funds or the institution that has an IACUC and provides animal care?

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Question 4

What constitutes a change that needs to be conveyed to the NIH?

For example: During a congruency review, it is determined that anesthetics being used for procedures specified in the grant are different than those specified in the protocol. The PI indicates that he will use the anesthetics described in the protocol, not the agents that are specified in the grant.

Should this change be conveyed to the NIH?

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Question 5

What are the responsibilities for congruency review after the first year of a multi-year award?

For example, if a congruency review (for all animal use) is conducted prior to Year 1 of an NIH award and found to be congruent, are additional reviews required for the Year 2, etc. awards?

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Question 6

A PI has an IACUC approval for AIM 1 and 3 of the application. AIM 2 is not in the IACUC protocol because it won't be performed until a much later date.

How do we indicate this in the congruency approval?

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Question 7

Is it better to have one protocol for each grant or to have several grants associated with one protocol?

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Upcoming OLAW Online Seminars

June 9, 2016 - Risk: Benefit Analysis: Science, Ethics, and Public Interests by Allyson Bennett

September 8, 2016 – Topic TBD

December 15, 2016 – Topic TBD

Send your topic ideas for upcoming webinars to olawdpe@mail.nih.gov



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