



GRANT TO PROTOCOL CONGRUENCE

OLAW CONVERSATIONS

SEPTEMBER 16, 2021

**RAISE YOUR
ZOOM HAND IF
YOU CONDUCT
CONGRUENCE
REVIEWS!**



NIH PERSPECTIVE

- PHS Policy and NIH Grants Policy require that Assured institutions prior to award provide the date of IACUC approval of “those components related to the care and use of animals”.

PHS Policy IV.D.2. and V.B.

NIH GPS 4.1.1.2



INSTITUTIONAL PERSPECTIVE

- “We use a protocol review form in which investigators provide detailed information about the proposed animal use to the IACUC for their review.
- Why do we have to do more?”





**DOES THE
PROTOCOL
MATCH
WHAT IS IN THE
APPLICATION?**

**HOW DO YOU
KNOW?**

NIH Grants Policy 4.1.1.2

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



**RAISE YOUR
ZOOM HAND IF
YOU THINK THE
STATEMENT IS
TRUE OR NOT!**





TRUE OR NOT?

- The IACUC is responsible for the congruence review.

MISCONCEPTION CORRECTED

- While the IACUC may choose to perform grant to protocol congruence review, it is not a required IACUC function and may be performed by other institutional personnel qualified to conduct the review.



TRUE OR NOT?

- NIH expects a side-by-side comparison of the entire grant application with the IACUC protocol.

MISCONCEPTION CORRECTED

- There is no explicit requirement to do a side-by-side comparison of an entire application and the IACUC protocol.
- Institutions are free to devise a workable mechanism of review using policies and procedures that prevent inconsistencies between the information.



TRUE OR NOT?

- Grant to protocol congruence review has no impact on animal welfare or research integrity.

MISCONCEPTION CORRECTED

- NIH grant recipients are collaborative partners with NIH and both parties have mutual obligations and responsibilities as stewards of Federal funds to ensure compliance with the PHS Policy and other Federal requirements.
- Congruence review ensures that public funds are used to promote the highest level of scientific integrity, public accountability, and social responsibility as reflected in humane animal care.
- Congruence review may prevent noncompliance by identifying unapproved activities that require IACUC review.



TRUE OR NOT?

- NIH and HHS eliminated grant to protocol congruence review for Institutional Review Boards (IRBs), so OLAW should do the same.

MISCONCEPTION CORRECTED

- The requirement for institutions to verify congruence between what the IACUC has reviewed and approved and the proposed animal research in the grant is similar to the requirements of the Final Rule on the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.
- Under the revised Common Rule [[45 CFR 46.103\(d\)](#)], NIH no longer requires IRB review of the *entire grant application*. However, recipients must certify to NIH that the IRB has reviewed and approved the human subject research (i.e., *IRB protocols*) and provide the date of approval (see [NOT-OD-19-055](#)).



TRUE OR NOT?

- If the key elements of the animal use described in the grant matches with the IACUC protocol(s) it meets the congruence expectations of NIH.

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.

MISCONCEPTION CORRECTED

- The review should confirm that the species and all procedures agree and that the animal numbers proposed are approximately similar. It's not necessary to use a microscope to make this comparison.
- There are two primary areas in the grant to concentrate on when conducting grant congruency review: the Vertebrate Animals Section and the Approach part of the Research Strategy Section.



TRUE OR NOT?

- The sponsored programs office is the organization that NIH recommends to conduct the congruence review.

WHO MAY REVIEW FOR CONGRUENCE?

Someone who is qualified to identify inconsistencies and understands the IACUC protocol review process, e.g.,:

- Sponsored programs staff
- Compliance oversight personnel
- IACUC staff

TRUE OR NOT?

- If the IACUC during protocol review requires changes to the protocol that are not reflected in the grant application, then at the time of certification of IACUC approval the institution must notify the NIH grants manager of the changes.

MISCONCEPTION CORRECTED

- It is the responsibility of the institution to communicate any IACUC-required changes to NIH grants staff as part of the Just-in-Time information (JIT).
- The JIT feature in the eRA Commons allows the Authorized Organization Representative (also known as the Signing Official) to electronically submit additional grant application information, such as the IACUC-required modifications. PI's can upload the JIT information into the Commons for the Authorized Organization Representative to submit.



TRUE OR NOT?

- In order to meet PHS Policy requirements, the IACUC may accept a brief description of the animal activities planned for the 4th and 5th year of a grant award in the animal protocol.

MISCONCEPTION CORRECTED

- A brief description of the animal activities planned for the 4th and 5th year of the award period should be provided in the animal protocol, recognizing that the experimental details and procedures will be refined or amended at a later time or at the time of the 3-year renewal.

MISCONCEPTION CORRECTED, CONT.

- Any future IACUC approvals should reflect the ongoing research that is described in the investigator's annual progress reports to NIH.
- Progress reports are required annually to document the PI's accomplishments including any significant changes. If these changes involve the animal activities, then the IACUC protocol should be revised by the PI to reflect the changes.
- Congruence review is not required beyond the initial review at time of award.



TRUE OR NOT?

- It is okay that one funded grant is linked to more than one IACUC protocol or that one IACUC protocol is linked to more than one funded grant.

MISCONCEPTION CORRECTED

- A one-to-one relationship between the grant and the approved protocol is not required, and more than one protocol may be associated with one grant and vice versa.



**NOW ON TO
ANY
QUESTIONS**

REFERENCE URLS

- **Reducing Administrative Burden for Researchers: Animal Care and Use in Research:** https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf
- **Request for Information (RFI) on Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency (NOT-OD-20-153):** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-153.html>
- **PHS Policy IV.D.2.:** <https://olaw.nih.gov/policies-laws/phs-policy.htm#InformationRequiredinApplications-ProposalsforAwardsSubmittedtoPHS>
- **PHS Policy V.B.:** <https://olaw.nih.gov/policies-laws/phs-policy.htm#ResponsibilitiesofPHSAwardingUnits>
- **NIH GPS 4.1.1.2.:** https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.1_animal_welfare_requirements.htm#Verifica
- **Revised Common Rule:** <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.103>
- **NOT-OD-19-055:** <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-055.html>