Congruence Review

National Institutes of Health
Office of Laboratory Animal Welfare

January 18, 2024

Let's grow knowledge about congruence review by starting with the basics

- Congruence review is the process that ensures that the information in IACUC protocols reflects information in the application to be awarded
- Verification of IACUC approval is an institutional responsibility
- The signature of the Authorized Organization Representative on the application certifies that the organization will comply with all applicable Federal laws and regulations, including required certifications such as verification of IACUC approval prior to award

What congruence review is NOT:

- Not a requirement for side-by-side comparison of entire application with protocol
- Not a requirement for exact equivalence
- Not a requirement for a 1:1 relationship: more than one protocol may be associated with one award and vice versa.

https://unsplash.com/photos/red-wrong-way-signage-on-road--Cmz06-0btw

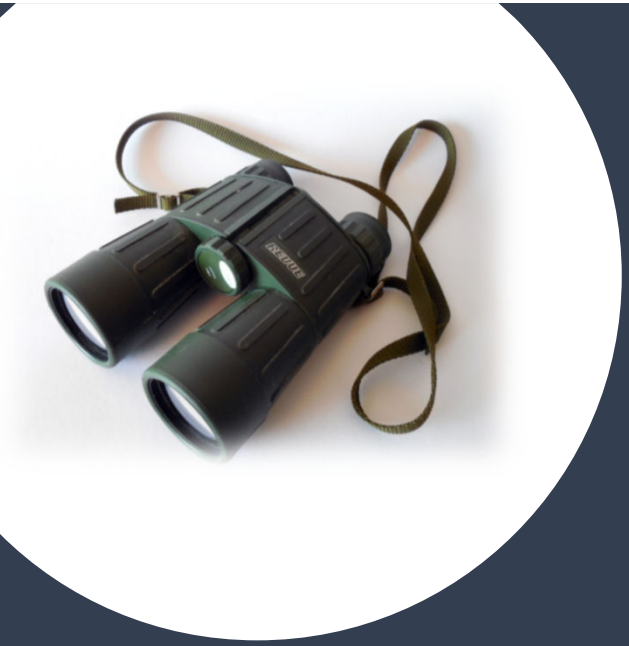
Other terms and concepts:

- Just-in-time (JIT):
  - Allows certain elements of an application for funding (such as verification of IACUC approval) to be submitted later in the application process
  - Allows efficiency (may address once you know an application is competitive)
  - Applicants notified (primarily by e-mail) when JIT information is needed (THIS IS NOT A NOTICE OF AWARD)
  - JIT procedures vary with funding Institutes/Centers (ICs)
  - NIH Grants Policy Statement 2.5.1

Other terms and concepts:

- Restricted Awards
  - Upon request by NIH funding components, restricted awards may be issued because of the limited time available to fulfill requirements for Assurance(s) and/or verification of IACUC approval.
  - Allows NIH funding components in conjunction with OLAW to issue awards with the restriction that live, vertebrate animal activity cannot commence or be charged to the award until all necessary documentation is in place
  - Usually at end of government fiscal year
  - On occasion, restricted awards have been provided for non-NIH funding entities, upon request.

Overview: What Grant Applications Require Congruence Review?



Grants using live vertebrate animals:
Prior to **initial award**
Prior to **Type 2 Renewals** (“competing continuation”)
Type 7 Change of Grantee or Training Institution

Type 3 Competing Revisions:
Where there is an expansion of the scope of the grant-approved activities in which **live vertebrate animal activities are added where there were none before**

How often does congruence review need to be repeated?

- Congruence review is not required beyond the initial review at time of award for the application types on the previous slide

Overview: General Process

PI notified of fundable score/JIT notification

PI submits protocols to IACUC

IACUC Review Approval

Congruence review

Grant and protocol congruent?

Yes

Institutions submit verification of IACUC approval

No

Why?

Coordinate and resolve with PI, IACUC, Grants Management Officer or appropriate funding entity contact, and Authorized Organization Representative, as applicable

Stopwatch, runner, CC0 Public domain

Didn't NIH eliminate grant to protocol congruence review for Institutional Review Boards? OLAW should follow suit!

Why is Congruence Review Required?

- The requirement for institutions to verify congruence between what the IACUC has reviewed and approved and the proposed animal use in the application to be awarded is similar to those of the Final Rule on the Federal Policy for the Protection of Human Subjects, (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).

How is Congruence Review Performed? It's flexible!

The review should confirm that species and all procedures agree and that animal numbers proposed are approximately similar (needn't be exact)

- Institutional responsibility:
  - Many offices can do it:
    - Sponsored Programs
    - Compliance
    - IACUC Offices
  - Provided staff are appropriately trained and qualified
- 2 main areas to focus on:
  - Vertebrate Animals Section
  - Approach part of Research Strategy Section

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But what about messier situations...

...like animal work for year 4 or 5 of the grant?

- A brief description of the animal activities planned for the 4th and 5th year of the award period should be provided in the 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

See OLAW FAQ D.20.

https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50346

...or if there is a different PI on the protocol and application?

- It is acceptable to have different individuals named as PIs on the grant application and IACUC Protocol

See OLAW FAQ D.18.

https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50333

https://www.pexels.com/photo/two-men-having-an-online-class-9040433/

...or the IACUC requires changes to the protocol?

- It is within the IACUC's purview to request changes.
- Some changes require prior approval from the NIH funding institute or center, e.g.:
  - Changes in scope such as a change in:
    - Specific aims
    - Animal model
  - Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

See OLAW FAQ D.21.:

https://olaw.nih.gov/faqs#/guidance/faqs?anchor=56902 , and

8.1.2. of the NIH Grants Policy Statement (GPS)

For such changes in activities funded by other entities subject to the PHS Policy (e.g., PHS, NSF, NASA VA), contact those funding entities directly.

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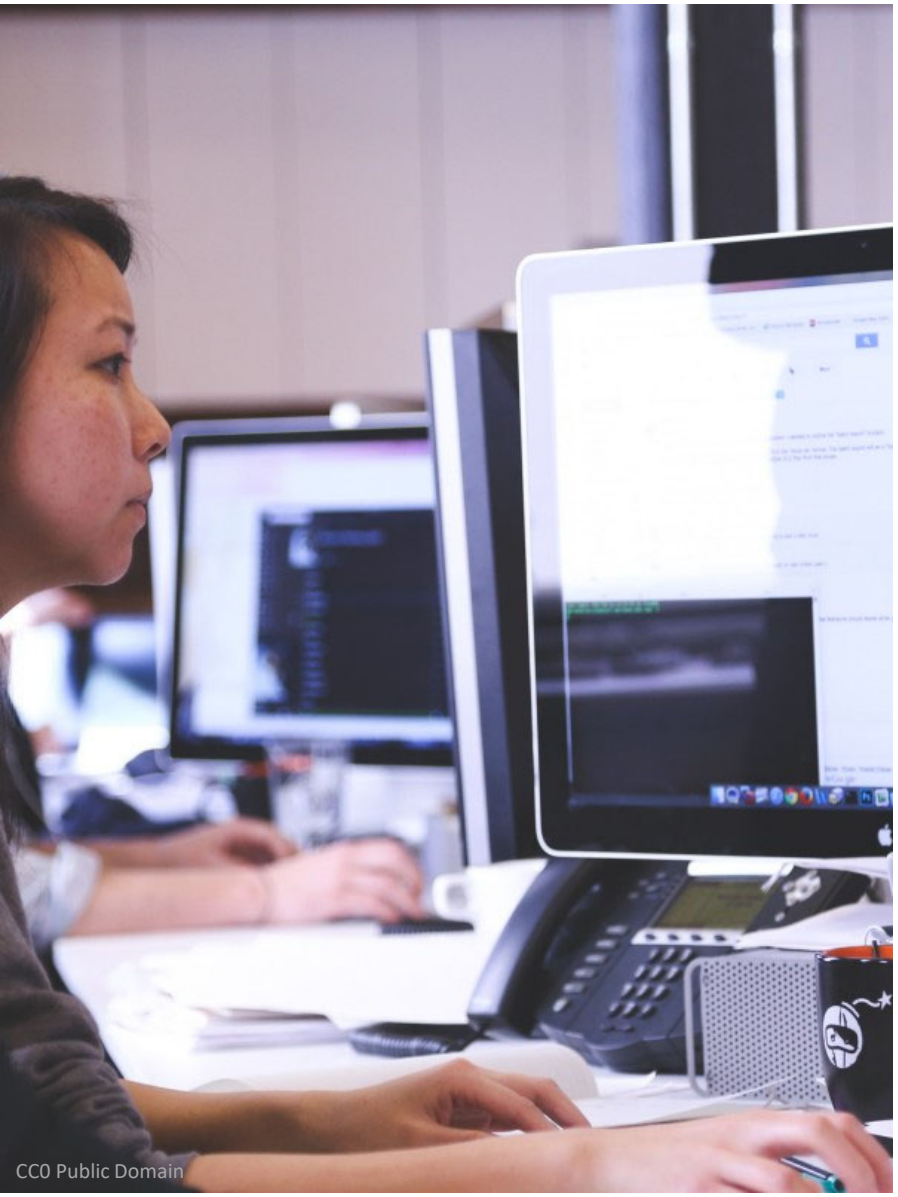
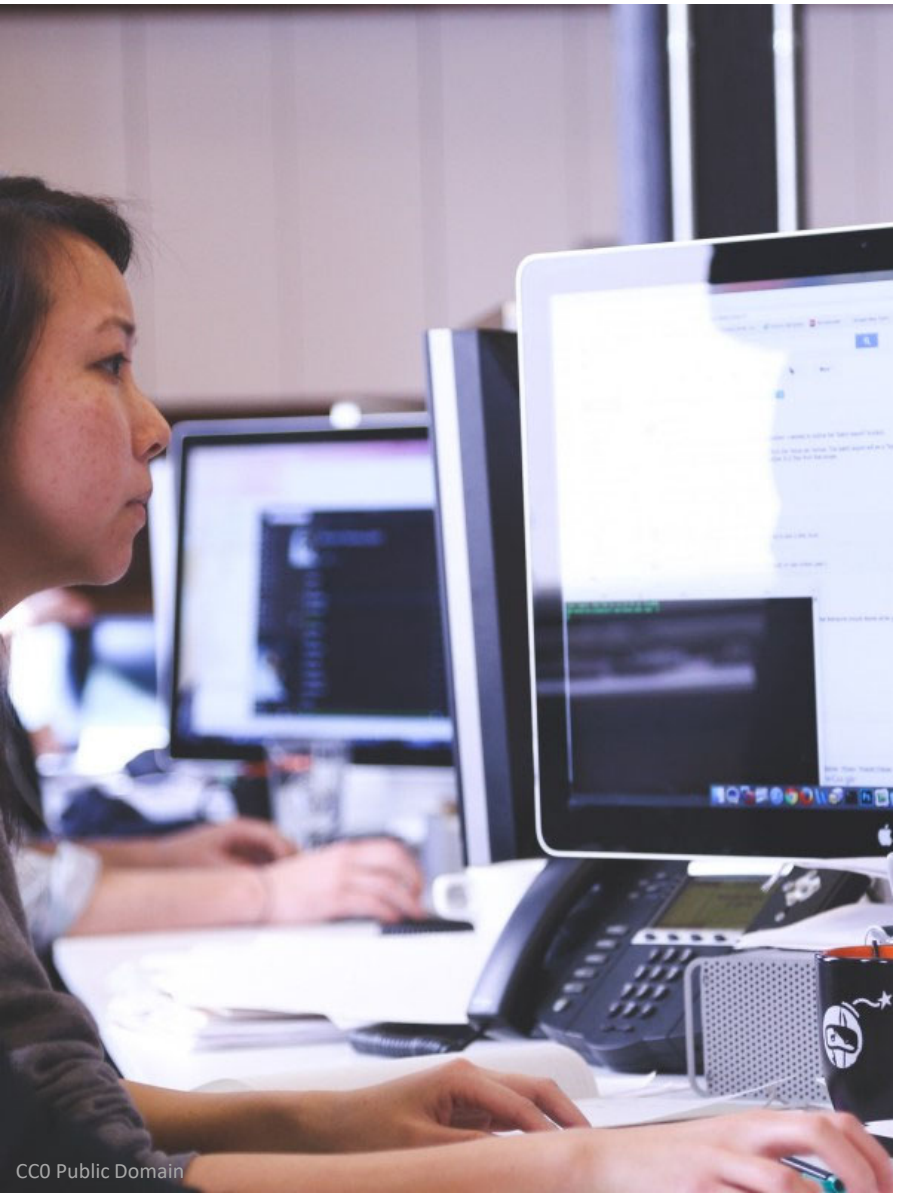


- If the IACUC requires changes to the protocol that are not reflected in the grant application, then at the time of certification of IACUC approval the institution must notify the funding entity. The PHS Policy IV.D.2. states that if verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC.

- For applications involving NIH institutes or centers, it is the responsibility of the institution to communicate any IACUC-required changes to the grants staff of the funding institute or center as part of the Just-in-time information (JIT).



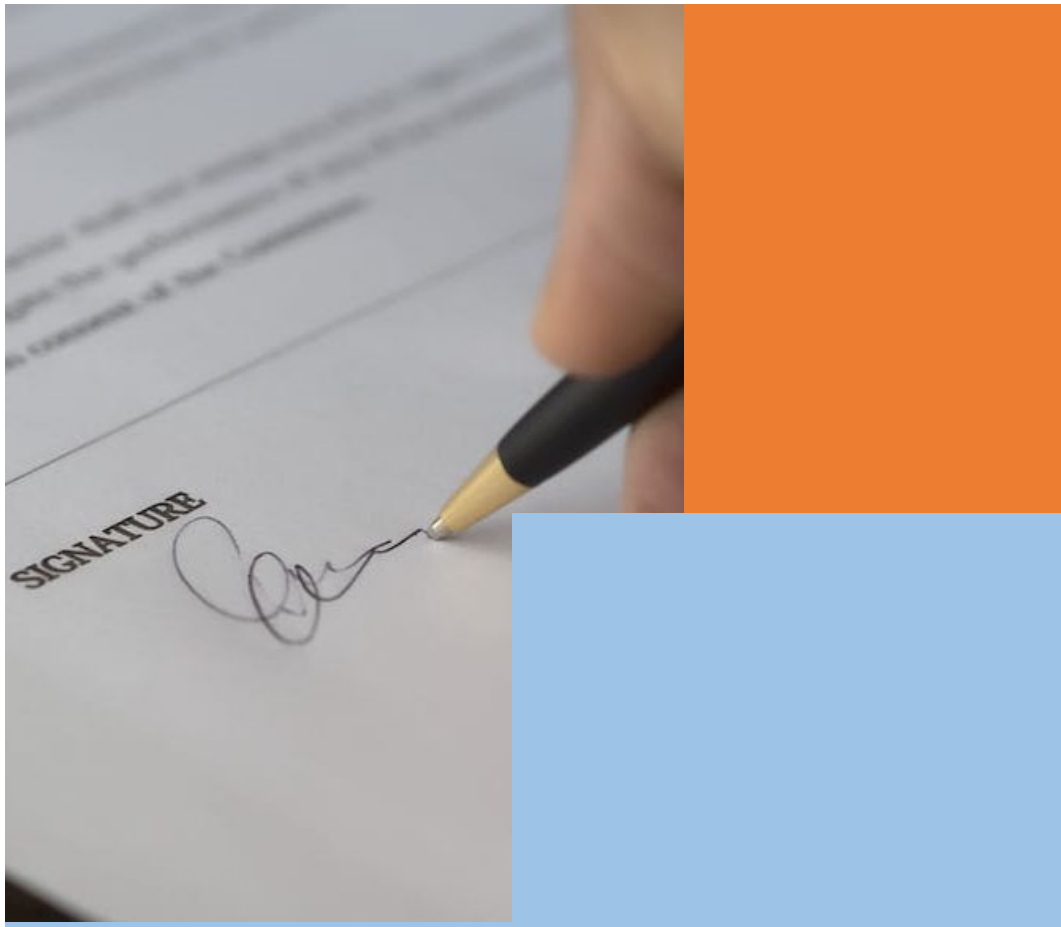
- For NIH applications, the JIT feature in the eRA Commons allows the Authorized Organization Representative (Signing Official) to electronically submit additional grant application information, such as the IACUC-required modifications.

- PIs can upload the JIT information into the Commons for the Authorized Organization Representative to submit.

What about applications to other funding entities (other PHS entities, VA, NSF, and NASA)?

Congruence review is required for **all entities complying with PHS Policy.**

PHS Policy (IV.D.) requires the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals.



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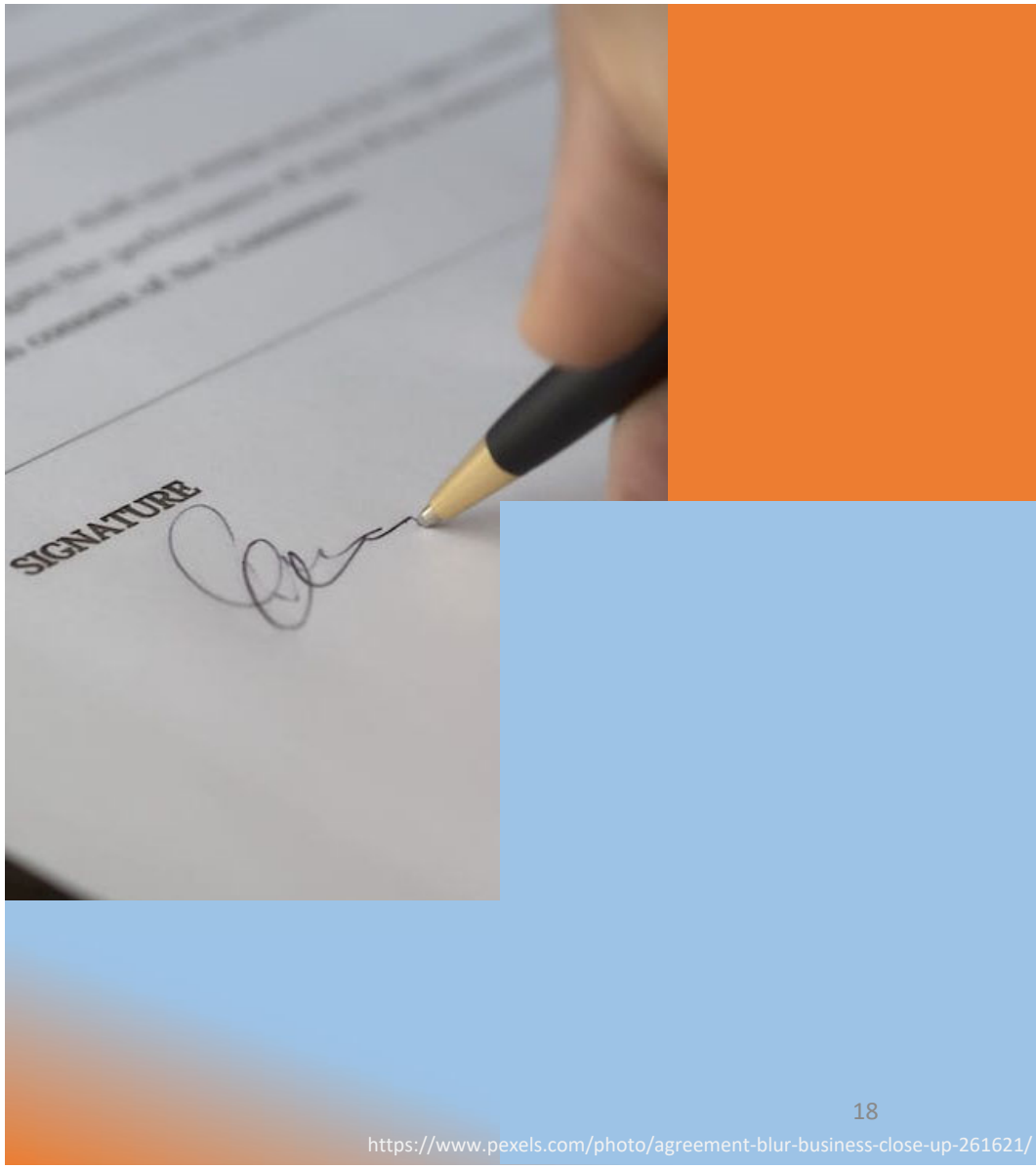
What about applications to other funding entities (other PHS entities, VA, NSF, and NASA)?

This applies to PHS applications but also to other funding entities that require compliance with the PHS Policy as well.

The VA, NSF, and NASA have directives or guidance that require compliance with PHS Policy, so congruency is a requirement for all animal activities funded by these entities.

Please contact the funding entities directly for instructions on specifics or any additional requirements.



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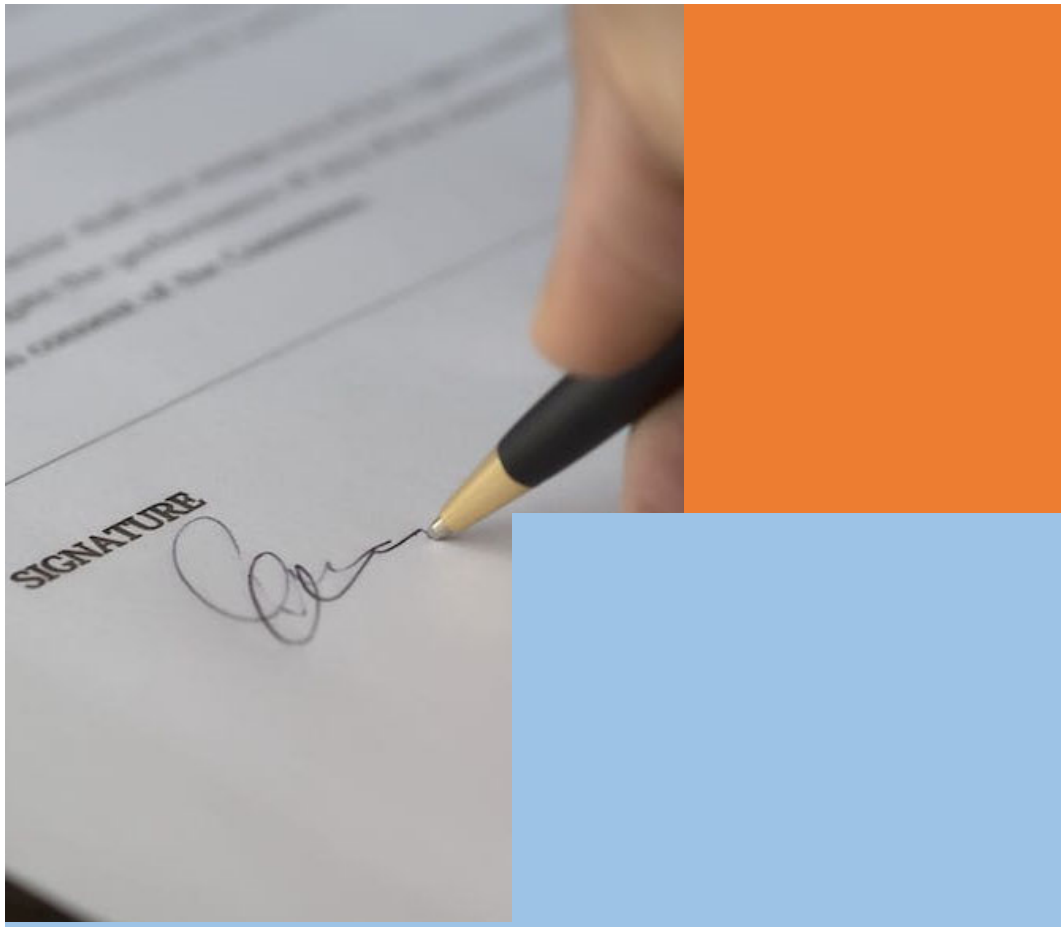
What about contracts?

- Requirements are from the Health and Human Services Acquisition Regulation and therefore different from grant congruence review, but as with grants, verification of congruence review must be provided prior to award, and is an institutional responsibility

See NOT-OD-22-006

https://grants.nih.gov/grants/guide/notice-files/not-od-22-006.html



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References: Grants and Contracts

Topic	Reference	URL
Information Required in Applications and Proposals for Awards Submitted to the PHS	PHS Policy IV.D2.	https://olaw.nih.gov/policies-laws/phs-policy.htm#InformationRequiredinApplications-ProposalsforAwardsSubmittedtoPHS
Responsibilities of PHS Awarding Units	PHS Policy V.B	https://olaw.nih.gov/policies-laws/phs-policy.htm#ResponsibilitiesofPHSAwardingUnits
Reducing Administrative Burden for Researchers: Animal Care and Use in Research	21st Century Cures Act (CCA) Final Report	https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf
OLAW FAQs related to congruence review	B.13.,D.10.,12., 18., 20., 21.; G12., 13.	https://olaw.nih.gov/faqs#/guidance/faqs
Revised Common Rule	2018 Common Rule	https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.103
Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and Contract Proposals Related to Research	NOT-OD-19-055	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-055.html

References: Grants

Topic	Reference	URL
Grant application animal welfare requirements	NIH GPS 4.1.1.2	https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.1_animal_welfare_requirements.htm#Verifica
Just-in time procedures	NIH GPS 2.5.1.	https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm#:~:text=NIH%20uses%20Just%2Din%2DTime,the%20review%2C%20but%20before%20award
Prior Approval Requirements	NIH GPS 8.1.2.	https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1.2_prior_approval_requirements.htm#:~:text=8.1.-,2.6%20Change%20in%20Status%2C%20Including%20Absence%20of%20PD%2FPI%20and,to%20submit%20a%20prior%20approval
OWAL 21st CCA webpage on grant to protocol		https://olaw.nih.gov/policies-laws/21st-century-cures-act/grant-and-contract-to-protocol-congruence-review/Grants-to-Protocol-Congruency
Notice of Clarification of Institutional Responsibilities Regarding NIH Grant to Protocol Congruence Review	NOT-OD-22-005	https://grants.nih.gov/grants/guide/notice-files/not-od-22-005.html

References: Contracts

Topic	Reference	URL
OLAW 21st CCA webpage on contract to protocol congruence		https://olaw.nih.gov/policies-laws/21st-century-cures-act/grant-and-contract-to-protocol-congruence-review/Contract-to-Protocol-Congruence-Review
Notice of Clarification of Offeror Responsibilities Regarding Contract to Protocol Congruence Review	NOT-OD-22-006	https://grants.nih.gov/grants/guide/notice-files/not-od-22-006.html
Instructions for Completion and Technical Evaluation of the Vertebrate Animal Section (VAS) in NIH Contract Proposal	NOT-OD-10-049	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html

OLAW Recorded Webinars

21st Century Cures Act: Updates and Your Questions Answered	March 10, 2022
21st Century Cures Act: Next Steps	December 05, 2019
The 2016 Vertebrate Animals Section, Grants Policy, Congruence	March 10, 2016
Grants Policy and Congruence	June 07, 2012
When Terms and Conditions Are Not Met	December 04, 2008

GRANT CONGRUENCY COMMON CHALLENGES

Institutional Perspectives

Julie M. Sharp, DVM, CPIA, DACLAM (she/her)
Executive Director
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University of California, San Francisco

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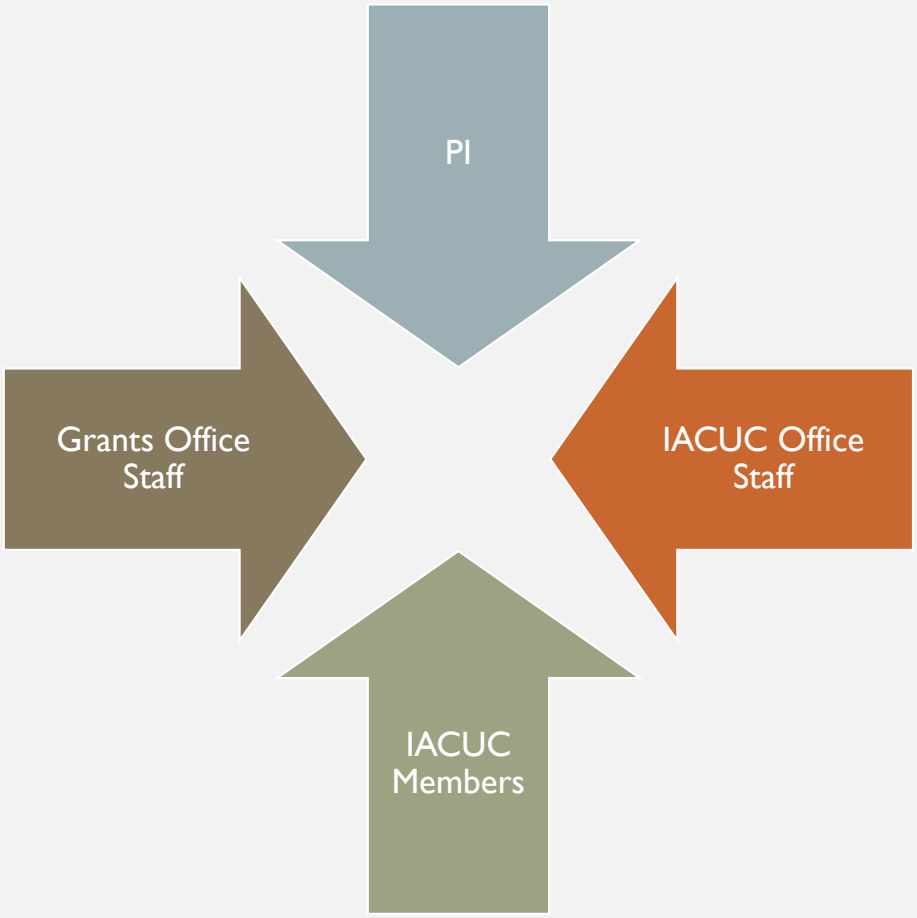
Director – Research Safety & Animal Welfare
Institutional Contact for Dual Use Research (ICDUR)
University of California, Los Angeles

COMMON QUESTIONS

1) Who confirms grant congruency?
2) How many grants can I associate with a protocol?
3) How can we facilitate communication & documentation?
4) What do I do when the award includes collaborations?
5) What if the grant and protocol aren't congruent?
6) How can we reduce regulatory burden?
7) What happens if the grants office submits an IACUC approval date prior to performing the grant congruency?

1) WHO CONFIRMS CONGRUENCY?

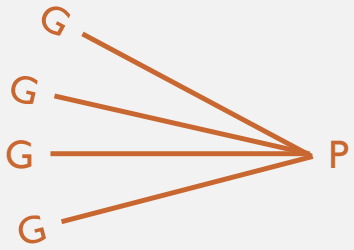


2) HOW MANY GRANTS CAN I ASSOCIATE WITH A PROTOCOL?

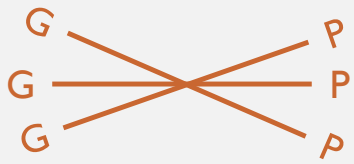
- One grant : One protocol

- One grant : Multiple protocols

- Multiple grants : One protocol



- Multiple grants : Multiple protocols



3) HOW CAN WE FACILITATE COMMUNICATION & DOCUMENTATION?

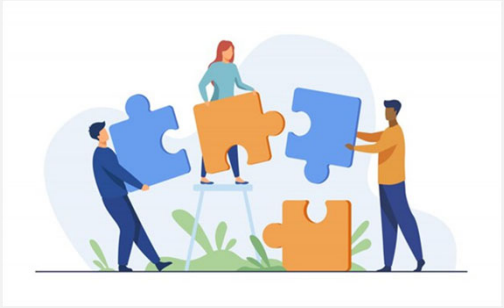
Communication

- External
  - NIH and the PI (e.g., timing of the notice of award, JIT)
  - NIH and the Institution (e.g., JIT requirements, PI/grant transfer to another institution)
- Internal
  - Finding the right person in the grants office
  - Routing the PI to the IACUC office
  - Collecting information and documents to perform the congruency review

Documentation of Congruency

4) WHAT DO I DO IF THE AWARD INCLUDES COLLABORATIONS?

- Examples of Collaborations:
  - Some of the animal work occurs at your location, and some of the work occurs at another location
  - All of the work occurs at another location
  - International: does your collaborator have the required Foreign Assurance?
  - Program project/center grants (P) and research project cooperative agreements (U)



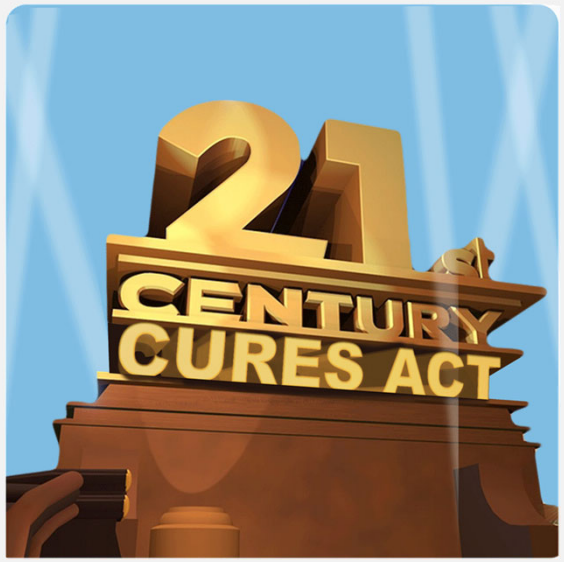
- How does your institution handle collaborations?
  - What are your home institution IACUC requirements?
  - How do you know when there's a collaboration if there's no animal work at your home institution?
  - Do you accept the offsite collaborator IACUC review/approval?
  - When do you coordinate an MOU with the collaborator?
  - How do you manage congruency with dynamic P and U awards?

5) WHAT IF THE GRANT AND PROTOCOL AREN'T CONGRUENT?

- 3 year protocol vs. 5 year grant
- A currently approved protocol requires modification
  - At what point in the process do you submit the IACUC approval date to the NIH?
- The protocol isn't yet approved…
  - How much time do we ***really*** have?
  - What are the options for release of funds?
    - What can the institution do?
    - What can the funding component do?

6) HOW CAN I REDUCE REGULATORY BURDEN?

- Do you require dual review by your home IACUC for offsite collaborations?
- Do you require specific grant : protocol association (e.g., 1:1)?
- How do I manage the pressure from the PI to meet deadlines for release of funds?



7) WHAT HAPPENS IF THE GRANTS OFFICE SUBMITS AN IACUC APPROVAL DATE PRIOR TO PERFORMING THE GRANT CONGRUENCY?

OTHER QUESTIONS?

Next Webinar

NIH National Institutes of Health
Office of Laboratory Animal Welfare

Spring, 2024
Topic TBD

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