All Things Being Equal: Insuring Grant and IACUC Congruence

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Welcome

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Learning Objectives

- Evaluate the pitfalls and challenges that you face when it comes to Insuring Grant and Protocol congruence.
- Analyze your current institutional process and identify ways to strength your current procedures to enhance with OLAW and PHS policies.
What is Congruence?

Webster’s Dictionary defines congruence as the quality or state of agreeing, coinciding, or being congruent.
Who Is Responsible?

• The AOR (Authorized Organization Representative) represents the entire institution. His or her signature verifies, to the NIH, the institution's commitment to the Grants Policy Statement terms and conditions, including IACUC approval of all PHS-funded animal activities.

The PI commits to meeting PHS Policy standards and to conducting animal activities according to an approved IACUC protocol.
OLAW Definition of Congruence

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

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
IACUC Protocol Approval

The IACUC reviews an animal use protocol. If the protocol complies with all applicable laws and regulations governing the use of animals in research, approval is granted by the committee and the PI may initiate the study.

IACUC protocol approval does not equate to grant congruency.
If an IACUC protocol is identified as federally funded, a grant congruency review is initiated. This review can occur concurrently or subsequent to the IACUC protocol review. Verification is an institutional responsibility that must occur prior to using federal funds to support animal use activities.
Congruency
The IACUC protocol, research design and methods, and the vertebrate animal section of the grant are compared to determine if the proposed funded research and the IACUC protocol are congruent.

Things should match; not identically but the protocol should align with the grant. Both documents should describe the same study (objectives), species, and procedures. If not, the IACUC protocol should be amended.

This is a PHS/NIH requirement ONLY.
Who should do this?

Depends on the organization and available resources.

At Northwell Health, congruency review is conducted by one or more IACUC members. Usually those assigned by the chair as the designated reviewers of the protocol. Alternatively, the IACUC Administrator may conduct the review.
Next steps?

A grant congruency verification letter is prepared by the IACUC office and provided to the Grants Management Office. Includes the grant number, title of grant, corresponding IACUC protocol(s), title of protocols and approval period.

Grant verification does not need to preclude IACUC approval but it does hinder the ability to use federal funds to support the activity.
Best Practice

The Grants Management Office does not set-up an account for a new award until IACUC Congruence has been verified. Additionally an account is placed on hold when subsequent years of the award are received, pending confirmation that IACUC Congruence is verified and no major changes were made to the protocol.
Northwell IACUC Congruence Review Flow

Proposal

Just In Time
Submit Research Strategy and Vertebrate Animal Section to IACUC
IACUC reviews the protocol, research strategy, and vertebrate animal section to determine congruency

Notice of Award (NOA)
Submit NOA, Research Strategy and Vertebrate Animal Section to IACUC for review
IACUC reviews the protocol, research strategy, and vertebrate animal section to determine congruency

If congruent, IACUC notifies the GMO. The GMO notifies NIH/PHS Agency of the congruence and submits IACUC approval notice
If it is not congruent, IACUC notifies the PI via email with a copy to the GMO of the inconsistencies. The project is on hold until changes are made and IACUC confirms congruence.

Once PI responds to the inconsistencies, IACUC issues a Congruency Verification notice to the GMO. The GMO submits verification of congruence and the IACUC approval notice.

If congruent, IACUC notifies the PI via email with a copy to the GMO of the inconsistencies. The project is on hold until changes are made and IACUC confirms congruence.

Once PI responds to the inconsistencies, IACUC issues a Congruency Verification notice to the GMO. The GMO continues project set-up.
An IACUC protocol is a contract between the institution and the Principal Investigator.

Ensuring IACUC Congruence is an important step in maintaining good grant stewardship.
Each year, the United States Government awards more than $500 billion in Federal Assistance Agreements, most commonly in the form of grants which includes funding for scientific research, studies, and analysis. This financial assistance provides support or stimulation to accomplish a public purpose.

Unfortunately, grant dollars are susceptible to fraud, waste, and abuse. Effective and efficient congruency verification processes can protect your organization and the source of your federal funds.
QUESTIONS
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