

Grants Policy and Congruence

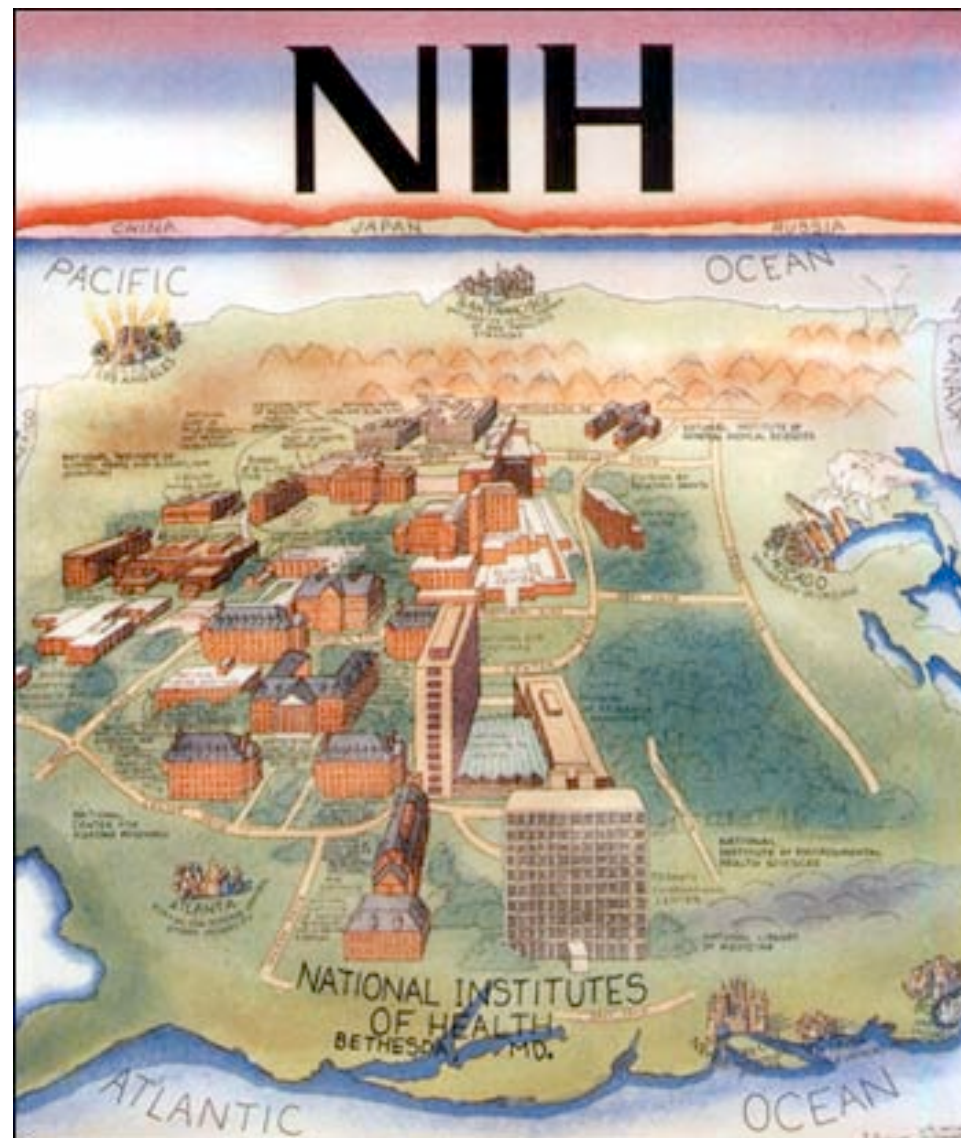
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OLAW Online Seminar
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Special Thanks To

Tina Neill-Hudson
Regulatory Research Associate
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What is NIH GPS?

- The NIH Grants Policy Statement (NIHGPS) provides the policy requirements that serve as the terms and conditions of NIH awards to grantees in a single document
 - Defines contractual obligations between accepting institution and funding source
 - Terms and conditions of grant award include all federal regulations including PHS Policy
 - PHS Policy defines OLAW responsibilities

Contractual Obligations

Contract between institution and NIH

AOR commits the institution to meeting terms and conditions of NIHGPS by signing grant application

Contract between institution and PI

PI commits to PHS Policy by signing grant application and conducting animal activities according to approved IACUC protocol

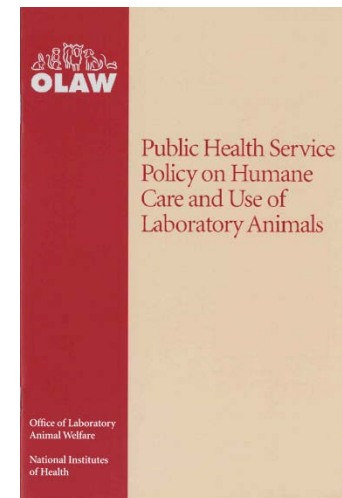
Why is Congruence an Issue?

NIH Grants Policy Statement

Grantee organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported animal activities.

Why Is This An Issue?

PHS Policy requires that applications or proposals from Assured institutions include date of IACUC approval of **those components related to the care and use of animals.**



Why Is This An Issue?

NIH Grants Policy Statement

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

NIH Grant Application

Form SF 424

Research & Related Other Project Information
Date of IACUC Approval

Form PHS 398

Research Plan Attachments
Section 10 Vertebrate Animals

1. * Are Human Subjects Involved?

☐ Yes ☐ No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used?

☐ Yes ☐ No

2.a If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number

IACUC Approval Date

3. * Is proprietary/privileged information included in the application?

☐ Yes ☐ No

4.a. * Does this project have an actual or potential impact on the environment?

☐ Yes ☐ No

Additional NIH Grants Policy

- IACUC approval date may be submitted to NIH **prior** to grant award under Just-in-Time policy

Additional NIH Grants Policy

- If IACUC review occurs **after** the application is submitted, the institution bears the responsibility for supporting the decisions of the IACUC.
- The IACUC may not be pressured to approve a protocol or be overruled on its decision to withhold approval.
- If the IACUC requires modifications, changes should be reported by the institution to NIH with the IACUC approval date.

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

☐ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
(for RESUBMISSION or REVISION only)				
2. Specific Aims	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
4. Inclusion Enrollment Report	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

6. Protection of Human Subjects	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

10. Vertebrate Animals	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
11. Select Agent Research	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

Section 10 Vertebrate Animals

1. Species, strains, ages, sex and numbers to be used
2. Justification for use, choice of species and numbers to be used
3. Veterinary care
4. Minimization of discomfort, distress, pain and injury
5. Method of euthanasia and reason for selection

Does the IACUC Protocol Match the Grant?

How do you know?



Is the IACUC Required to Review the Grant Application?

OLAW Frequently Asked Question
D10



FAQ D10 Answer

- No explicit requirement for the IACUC to do a side-by-side comparison
- Institution is responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application or proposal
- Institutions are free to devise a workable mechanism to accomplish this end

FAQ D10 Answer

- One method is to implement a procedure for direct comparison
- Responsibility may be delegated to a particular office or position (e.g., sponsored programs or compliance office)

Institutional Responsibility

- The institution must document IACUC approval of the animal activities proposed in the grant
- Institution must be able to associate each grant(s) with relevant IACUC protocol(s)
 - If institution uses a protocol numbering system, it must be able to link protocol numbers to grant numbers
 - A 1:1 ratio is not required

What is Congruence?

Congruence is the state achieved by coming together, the state of agreement.

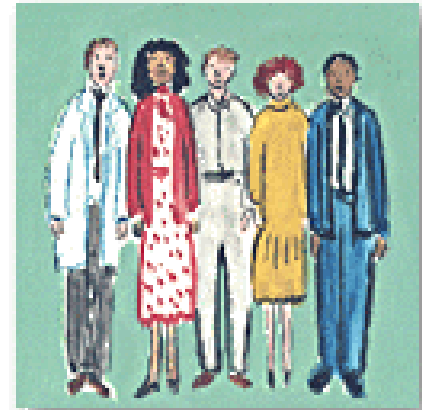
Congruence, as opposed to equivalence or approximation, is a relation which implies a kind of equivalence, though not complete equivalence.



Who May Review for Congruence?

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

- IACUC staff
- Sponsored programs staff
- Compliance oversight personnel



When May Congruence be Determined ?

Any time prior to grant award

Where to Look in Grant

- Vertebrate Animal Section
- Research Strategy Section



What Content Should be Compared?

- Species
- Animal numbers proposed
- Procedures



What if Not Congruent?

Procedure listed in the grant is **not** in the 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

What if Not Congruent?

Procedure in IACUC protocol is **not** in grant

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

Comment: this applies to 1:1 grant to protocol ratio. Institutions are reminded that when multiple grants are associated with 1 IACUC protocol, the institution must ensure that PHS funds are expended as described in the grants.

NIH Change in Scope

The grantee (PI) must make the initial determination of the significance of a change and should consult with the GMO as necessary.



Potential Indicators

- 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

Change in Scope

If PI determines there **is** a change in scope
PI, through AOR, contacts NIH GMO to obtain
approval of change (e.g., change of species or
procedure)

If PI determines there is **not** a change in scope
PI provides explanation that institution may file
with congruency review documentation

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



Whose Responsibility Is It?

- Institution verifies congruence by providing IACUC approval date
- Investigator is responsible to IACUC for approval of animal activities
- PI and institution are responsible for notifying NIH of change in scope or IACUC required modifications
- PI must notify IACUC of change in scope as a result of NIH review

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Congruence, as opposed to equivalence or approximation, is a relation which implies a kind of equivalence, though not complete equivalence.

Questions ?

OLAW Online Seminar Series

Upcoming Schedule



- September 13, 2012 – Topic: TBD
- December 13, 2012 – Topic: TBD