Grants Policy and Congruence

Patricia A. Brown, V.M.D., M.S., DACLAM
Director, Office of Laboratory Animal Welfare

OLAW Online Seminar
June 7, 2012
Special Thanks To

Tina Neill-Hudson
Regulatory Research Associate
University of Iowa
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.

PHS Policy IV.D.2.
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
SF424

RESEARCH & RELATED Other Project Information

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: ____________________________

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 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.

NOT-OD-10-128 and PHS Policy IV.B.6.-7.
# 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**
   
2. **Specific Aims**
   
3. **Research Strategy**
   
4. **Inclusion Enrollment Report**
   
5. **Progress Report Publication List**

**Human Subjects Sections**

6. **Protection of Human Subjects**

7. **Inclusion of Women and Minorities**

8. **Targeted/Planned Enrollment Table**

9. **Inclusion of Children**

**Other Research Plan Sections**

10. **Vertebrate Animals**

11. **Select Agent Research**
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
- 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.
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
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.

Questions? 
OLAW Online Seminar Series

Upcoming Schedule

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