



The ACC Connection

Volume 3, no. 6, NOV / DEC 2007

WELCOME to the 11th edition of the **ACC Connection**, a bi-monthly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. Our 11th issue is designed to help investigators understand the relationship between their grants (in particular, PHS sponsored grants) and their referenced animal care and use protocols.

Public Health Service

The Public Health Service Policy on Humane Care and Use of Laboratory Animals is what dictates the relationship between your PHS grant submissions and your animal care and use protocols. All new animal care and use protocol submissions must be accompanied by the grant application associated with the protocol, if applicable. It is a requirement of PHS policy that the procedures that are outlined in the grant application have been approved by an Institutional Animal Care and Use Committee (IACUC), here at the Health Center known as the Animal Care Committee (ACC).

PHS Policy IV(D)(1)(a-e) states that information required in applications and proposals for awards submitted to PHS (competing and non-competing) that involve the care and use of animals shall contain the following: identification of the species and approximate number of animals to be used; rationale for involving animals and for the appropriateness of the species and numbers used; a complete description of the proposed use of the animals; a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to the animals; and a description of any euthanasia method to be used.

PHS Policy IV(D)(2) continues to state that institutions that have an approved assurance, which the Health Center does, applications or proposals (competing and non-competing) covered by this Policy shall include verification of approval (including the date of the most recent approval) by the IACUC of those components related to the care and use of animals. For competing applications or proposals only, such verification may be filed any time prior to award unless specifically required earlier by the funding component. 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. The verification shall be signed by an individual authorized by the institution, but need not be signed by the Institutional Official.

So, what does this actually mean?

First, if you route your grant stating that you have approval for your proposal- and place an ACC number on the routing slip- the ACC office will verify that claim.

1. The final, approved version of the protocol, with any approved modifications, will be reviewed and compared with the procedures written in the grant proposal.
2. The ACC will ensure that the latest approval date of the approved protocol is correct. Often, PIs list the original approval date of the protocol- this is incorrect. The approval date listed should be the **date of the latest approval** (latest annual review approval) granted by the ACC.
3. If there is a discrepancy between the grant and the approved animal care and use protocol in which the grant states a procedure or procedures will be performed to the animals, **and that procedure is not approved in the animal care and use protocol**, the grant routing sheet will be changed to “pending”. The grant submitter (and PI of the animal care and use protocol, if different than the grant PI) will be notified that there is a discrepancy, that the grant contains procedures not approved in the protocol, and outlines the PI's options.

4. If there is a discrepancy between the grant and the approved animal care and use protocol in which the animal care and use protocol contains procedures that are not in the grant, no action is needed for the ACC. However, this might require changes in the grant application; PIs should consult with their ORSP Project Officer.

Second, the ACC Office will ensure that you have the correct PHS Assurance number on the grant application. Frequently, PIs give the animal care and use protocol number as this number. This is incorrect. At the University of Connecticut Health Center, the **PHS Assurance Number is A3471-01 (effective dates 4/10/06 – 4/30/10)** and it is this number that should be reflected on the grant application (including the dash).

Third, if your grant application is listed as “pending” for vertebrate animal approval, the grant will not be reviewed by the ACC office. However, it will be reviewed at some point prior to award of money from PHS to the institution (under the Just-in-Time Rule) to ensure that the procedures in the grant are in the approved animal care and use application that will be submitted at a later date by the PI. ***It should be noted that ORSP will not prepare the fiscal package and Finance will not be able to set up the account without the ACC approval even if you receive the Notice of Grant Award.***

PLEASE REMEMBER- Grant Submissions and Animal Care and Use Protocols are NOT the same thing!

What are the options if there is a discrepancy?

1. The easiest thing to do is leave the proposal as “pending” for the vertebrate animal section. If the grant proposal is likely to be funded, then the issue can be addressed. This is perfectly acceptable as of the 2002 revision of PHS policy which included what is commonly called the “Just-in-Time” rule and ***does not affect the review of your grant application.***
2. The PI on the grant can delete the procedures in the grant that are not approved by the ACC. This can be done easily and, after receiving the changes required, the grant can be processed as being approved by the ACC.
3. The PI on the approved protocol has the option to modify the animal care and use protocol to include the procedures that are not approved. This is an option if the procedures in the grant that need approval are appropriate to the original protocol, taking into account the original protocol's stated scope.
4. The PI on the grant has the option to submit a new animal care and use protocol application to the ACC. This is usually the appropriate option if the PI on the grant is not the PI on the approved animal care and use protocol and the scope of the work does not match the scope of the original, approved protocol.

Just in Time Rule

The National Institutes of Health changed the PHS Policy to permit institutions with PHS Assurances to submit verification of IACUC approval for competing applications after peer review, but prior to award. This change in PHS Policy was effective as of 1 September 2002 [Federal Register 67, 51289-51290 (7 August 2002)]. Therefore, an application for funding from NIH agencies may choose to utilize the “Just-in-Time” (JIT) rule when processing proposals by checking “pending” in the approval date block. The NSF subsequently adopted this policy and, as of 2005, OCAST permits application of the JIT rule. When notification of funding or likelihood of funding is received, the protocol application must be processed and approval obtained before the award. If discrepancies are identified in the animal care and use protocol by the ACC review, these must be corrected and then the funding agency is notified. ***You typically get 60 days notice to get your letter of IACUC approval to the funding agency.***

However, there is a chance that, if you wait for your notification from the granting agency to submit your animal care and use protocol application to the ACC, you won't have an approval in 60 days. Much depends on how the application is written and how complete it is. It is generally recommended that, as soon as the PI hears that the proposal is likely to get funded, s/he should submit the animal care and use protocol application to the ACC for review.

Many private foundations that sponsor animal research do allow a “Just-in-Time” submission process, but some do not and require the animal work be approved when the grant is submitted. Please check with your ORSP Project Officer if you are submitting to a private organization and do not know if they allow the JIT submission.

Grants and Animal Use Protocols

Frequently, there is confusion regarding the relationship between grants and subsequent animal care and use protocols submitted to the ACC. It is important to realize that the two documents, though related, are not the same thing and different information is required for each document.

A grant is generally an overview of what will happen during the grant; the PI needs to state what the aims are, how they will evaluate the work, etc. An animal care and use protocol is very specific about what exactly will be done to the animals. The purpose of a study section review is to determine if the proposed work has scientific merit and if the NIH wishes to spend money on that project. The purpose of an animal care and use protocol is to evaluate the animal welfare issues associated with what will be done to the animals.

For example, a grant may state that animals will undergo an ovariectomy during the course of the grant project. An animal care protocol must state exactly how the ovariectomy will be performed- how the animals will be anesthetized, how the animals will be prepped, how instruments will be prepared, how the procedure will be performed, what sutures will be used, how the animals will be monitored post-surgically and who will perform those observations, what pain-relieving drugs will be used (along with dosage, route of administration, frequency of administration, volume to be given). This type of information is generally not given in a grant, but must be in the animal protocol.

An animal care and use protocol should not be a "cut-and-paste" of grant aims; this will not result in sufficient detail regarding animal procedures that are required in an animal care and use protocol and will generally result in a submission to be deferred. The ACC office has an excellent resource for writing animal care and use protocols. *Working with the IACUC: Writing an Animal Protocol* was written by the American Association for Laboratory Animal Science. If you are writing animal care and use protocols, you should have this document. Contact the ACC office to obtain your free copy.

Frequently Asked Questions

What if you have to modify your grant as a result of the ACC review?

Your 398 grant application form certifies, among other things, that the institution's IACUC has (or will have within 60 days of the application) reviewed and approved all animal-related activities associated with that grant application. If the ACC requires modifications to secure approval for the animal care and use protocol application, these changes must be communicated to the Public Health Service and it is the responsibility of the PI to do this.

When is the Just-in-Time (JIT) rule generally applied?

The JIT rule is generally applied when a grant applications receives a percentile score of 20% or less.

Why has my grant received scientific merit from the NIH and yet the ACC has yet to approve the animal protocol?

Grant proposals and animal protocols are two vastly different things. The primary focus of the animal protocol is toward animal welfare. Grants typically state broad animal care use and animal protocols are typically very specific. If the ACC has any concern regarding the procedures to be used on any animal, they will explain these concerns to the PI who must revise the animal care and use protocol prior to approval- even if the grant has received federal funding. Therefore, though the animal care and use protocol may be related to a grant, the specifics in each document are very different and it is understandable that one approval does not automatically generate the other.

Upcoming Training, November 2007 – December 2007

New Animal Users Initial Basic Core Training

Monday, November 19

9:00 am – 12:00 pm

Building 20 conference room

Monday, December 17

9:00 am – 12:00 pm

Building 20 conference room

New Institutional, State, or Federal Regulations

Institutional

ACC Policy

10/25/07

Policy on Animal Stabilization Requirements. To view policy, go to:
<http://clacc.uchc.edu/ACC/Policies/Animalstabilization.htm>.

State

None

Federal

None



Next Issue: Animal Training Requirements

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