

## Guidelines on Congruence of IACUC Protocols and Federal Grants

Public Health Service agencies such as NIH only make grant awards for research involving live vertebrate animals if the applicant organization and all performance sites are operating with an approved Animal Welfare Assurance. This includes verification that the institution has a properly constituted IACUC which reviews and approves those sections of the project that involve the use of live vertebrate animals. For the IACUC, this means that the review process must include a congruency check which verifies that research involving vertebrate animals in the grant is included in the IACUC protocol. The principal investigator (PI) should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) submitted to the IACUC. A copy of the grant abstract and vertebrate animal section must be submitted to the IACUC with any protocol application that involves federal funding.

Congruency between an IACUC protocol and a federal grant is checked during the IACUC review in a “side-by-side” comparison. Information in the Abstract and Vertebrate Animals sections of the grant are compared to the IACUC application. An IACUC application and grant are considered congruent if they are *approximately equivalent*. They do not have to be entirely equivalent. Verification of grant and protocol consistency is concentrated on animal use and does not include judgment of scientific merit. In conducting congruence evaluations, the IACUC focus includes, but is not limited to, the following:

- Are the aims in the grant consistent with those described in the IACUC application?
- Are the species used and number of animals requested in the grant proposal included in the IACUC protocol?
- Are animal care and use procedures described in the grant proposal included in the IACUC protocol?

There are two types of amendments to animal research protocols that have specific relevance to this policy:

### 1. Change in funding source from nonfederal source to a federal grant

A change in funding source for a protocol involves the PI submitting an Administrative Change application to the IACUC requesting a change in funding source from a non-federal to a federal grant. Typically, the IACUC Chair conducts the congruency check for administrative change applications. The congruency check will include a confirmation that the species, procedures, and specific aims relating to the use of animals described in the funding proposal generally match those specified in the IACUC protocol to which the PI wishes to link with the grant. If the review indicates that congruency between a new grant and an existing IACUC protocol is not sufficient, the PI will be directed to submit a new protocol.

2) Significant change/s in animal use procedures.

Any significant change in animal procedures requires that the PI submit a Significant Change application to the IACUC that must be reviewed and approved prior to initiating any of the changes. Significant change applications are reviewed by the IACUC's standard designated member review (DMR) process. The IACUC understands that research projects evolve over time and that the direction of a project may evolve to include new pilot experiments or procedures requiring a Significant Change to the IACUC protocol. As long as the proposed changes are generally consistent with the overall objectives, purpose, and aims stated in the federal grant, they can qualify as congruent. It is the PI's responsibility to demonstrate how the changes relate to the original grant/protocol. Because the determination of congruence between the grant and original protocol has already been established, there will typically be no need to re-verify congruence via a "side by side" grant:protocol comparison for significant amendments. However, the IACUC reviewer/s may request additional information from the PI to verify any questions about congruency that may arise.

NOTE: For PHS-supported grants it is the PI's responsibility to describe any significant changes in the use of vertebrate animals they made in the summary section of their Non-Competing Continuation Progress Reports.