

Grant-to-Animal Protocol Congruence Standard Operating Procedure (SOP)

Congruency

Congruence as it relates to animal care protocols and grant-funding agencies is an agreement between the animal activities described in a grant and the animals activities reviewed and approved by the Institution Animal Care and Use Committee (IACUC).

Congruence is required per the *National Institute of Health Grants Policy* Statement and provides the terms and conditions that must be met to receive a grant award. Per this policy, “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC”.

Grant congruency at UC Davis is the responsibility of the Principal Investigator (PI) listed on the award.

It is highly suggested that the PI submit an animal care and use protocol when they receive a priority score from NIH indicating that an award is likely, if an animal protocol is not already in-place. If the PI listed on the IACUC protocol is not listed as a collaborator on the grant application, then the PI on the grant should submit their own animal protocol.

This SOP applies to all awards funded by the Public Health Service (PHS) and non-PHS organizations that have adopted PHS regulations a complete list can be found [here](#).

Congruency Process (performed by the PI)

1. Perform a side-by-side comparison of the grant(s) and animal protocol(s). For NIH grants the animal-related information can be found in the Vertebrate Animal Section (VAS) and the Research Strategy Section of the grant application. For all other funding agencies, the information can be found in the methods section of the grant proposal that describes the animal work. Comparisons should include:
 - General scope of work
 - Experimental procedures and endpoints
 - Experimental agents
 - Species (strain(s) included if it represents a model)
 - Approximate number of animals
 - Euthanasia method(s)

* Note, a one-to-one, grant-to-animal protocol ratio is not required but highly suggested to make congruency reviews easier to complete. A one-to-many system may also be used where more than one grant proposal may be linked to one, or many animal protocols and one animal protocol may be linked to one, or many grant proposals. If not all the grant aims are covered in the animal protocol because they will be performed at a later date, a brief summary of the aim should be included in the animal protocol that covers the other aim(s) with a statement that a new protocol or amendment will be [submitted](#) a later date to cover the work.

2. Ensure that section 10 (Funding Source) of the animal protocol lists each of the grant proposals that are associated with the work described in the animal protocol including the Cayuse project number for each grant proposal.
3. Complete the [Sponsored Programs Protocol Certification Form](#), which certifies that as the PI, you have performed a congruency check between your animal protocol(s) and your grant proposal(s). The animal protocol expiration date listed should be the 3-year expiration date rather than the annual renewal date. Please contact the IACUC office if you are not sure of the exact expiration date to list. Please submit the form to Sponsored Programs via the methods provided at the bottom of the form.

Congruency Review Must be Done by the PI:

1. New Awards

The PI must re-certify congruency when he/she receives new (defined as: previously not accounted for) PHS funding.

Any new PHS-funded award with animal work that **is not approved** in an existing animal protocol, must have a corresponding approved animal protocol or an existing protocol must be amended to cover the work described in the grant. Once the protocol or amendment is approved by the IACUC, it is the PIs responsibility to perform the congruency review and complete the Sponsored Programs Protocol Certification Form. The animal protocol must contain the name of the granting agency and the Cayuse project number.

Any new PHS-funded award that covers work that **is already approved** in an existing animal protocol must be added to the protocol [via an amendment](#). The amendment must contain the name of the granting agency and the Cayuse project number. Following approval of the amendment, it is the PI's responsibility to perform the congruency review and complete the Sponsored Programs Protocol Certification Form.

2. Change in Scope of Awarded Project

The PI must re-certify congruency when the awarded grant project has changed in scope.

Examples of changes in scope include changes in the specific aims, substitution of an animal model, and shift in scope of work (i.e. type of cancer or disease). The PI is responsible for determining the significance of a change and should consult with the IACUC office if clarification is needed or if an additional congruency check is needed. Animal [protocols must be amended](#) to ensure that any changes in scope are approved by the IACUC. **The PI should also contact their Awards Analyst at SPO to determine if an award modification is necessary when there is a change in scope**.

Contact Information

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Grants- SPO—530-754-7689 giliu@ucdavis.edu

References

1. Brown, P., & Varghese, S., (2016, March 10). The 2016 Vertebrate Animal Section, Grants Policy and Congruence [Webinar]. In *OLAW Online Webinars*. Retrieved from: <https://olaw.nih.gov/education/educational-resources/webinar-2016-03-10.htm>
2. NIH Grants Policy Statement Part II, A, 4.1.1.2 Verification of IACUC Approval <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>
3. NIH Grants Policy Statement Part II; Subpart A; 8.1.2.5 Change in Scope <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>