



Confirming Animal Protocol Approval in Association with a Federal Grant

Objective/Purpose

It is the institution's responsibility to ensure that the IACUC has approved the proposed use of animals described in a grant application or contract proposal. This is required to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals as stated in [Section V.B.](#):

*PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution and all other participating institutions have approved Assurances on file with OLAW, and the awardee institution has provided **verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals**....No award shall be made until all required Assurances have been submitted by the institution(s), been approved by OLAW, and the institution(s) have provided **verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals**. [emphasis added]*

The current process has put the burden of this review on the investigator submitting a proposal by assuring that the use of animals described in the proposal has IACUC approval. This document describes the process used by the Institution to verify that any work funded that involves the use of animals has been reviewed and approved by Ohio State's IACUC and is congruent with the information in the grant. Procedures are conducted by staff in the Office of Sponsored Programs and Office of Responsible Research Practices.

What is a Congruency Review?

A congruency review is a review of a proposal to ensure the animal activity outlined in that proposal has been approved by the Ohio State Institutional Animal Care and Use Committee (IACUC) in an active, approved protocol.

OSP will notify the PI and department staff when a vertebrate animal restriction has been placed on the award and, if the PI can certify that there is initial work that can be completed that does not involve vertebrate animal research, the SPO will set up the award and add a term to the award that vertebrate animal research cannot be conducted until notified that NIH has removed the vertebrate animal restriction.

Proposal Preparation Process

1. PA-005: The PI will indicate if research with vertebrate animals will be conducted. If the research project (including sub-awards) will involve the use of any vertebrate animal, the research protocol must be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) prior to initiation of the study. Contact ORRP IACUC office at IACUCInfo@osu.edu for information regarding when a protocol is required.



- If the use of vertebrate animals applies, “yes” should be marked In Section 6 (Compliance) of the PA005. “Yes” should be indicated if animals are to be utilized at any time during the award period.
 - Marking “Yes” to the use of vertebrate animals prompts the need to indicate whether there is an approved protocol in place or a protocol is pending IACUC review.
 - If there is an approved protocol in place, mark “no” for pending review and indicate the date of the most recent approval and the protocol number.
 - Proposed projects must be reviewed for the protocol identified on the PA-005. If the PI plans to use an existing protocol for the project being proposed, the PI should review the IACUC approved protocol to help determine if the protocol needs to be amended for the new proposal. This will help the PI know what action will be needed prior to a congruency check. It is recommended that this step be taken at the time the PI has received a NIH fundable score (if applicable). See “Congruency review process by ORRP” below regarding information that should be congruent.
 - If there is not an approved protocol in place, mark “yes” for pending review.
2. Proposal: The PA-005 and the application must be consistently marked. If the PA-005 indicates that vertebrate animals will be used in the project, the application must match. Also, if the PA-005 indicates that a vertebrate animal protocol is pending, the application should indicate the same.
- A. In Cayuse, NIH vertebrate animal compliance is indicated as follows:
- Are vertebrate animals used? Yes? No?
 - If “Yes” is the IACUC review pending? Yes? No?
 - If “no” provide the IACUC approval date

“Just In Time” Process for Federally Funded Projects

1. As soon as the PI receives a score within fundable range on their NIH application, contact the SPO to initiate the congruency review process. **Please note that the PI is the only one that receives this notification. Starting the process now may help save time later.** If the proposal was submitted to NIH, the Grant Policy Statement’s Just In Time Policy applies, as follows: *“Verification of IACUC Approval. If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable.”*
2. Once confirmation of congruency has been received from the Office of Responsible Research Practices, OSP will submit the information to NIH. ORRP will provide documentation that activities described in the proposal have been reviewed and approved in the associated IACUC protocol.
3. Proposals that indicated a previously approved vertebrate animal protocol on the PA-005 and the application must be provided to ORRP so that the proposal can be reviewed for congruency and amended for the specific protocol being used, if needed.
4. Proposals that indicated the PI would be submitting a new protocol request must complete an IACUC protocol using the eProtocol system. In the funding section of the protocol, upload any parts of the proposal that describes the work with animals. At a minimum, the Research Strategy Section and the Vertebrate Animal Section of the proposal should be provided. This information will be compared to the activities described in the IACUC protocol as described below in the Congruency Review Process section.

Award Restriction

In rare instances, when IACUC approval of vertebrate animal use is not yet available, NIH will issue an award with a vertebrate animal use restriction that prohibits charging and billing any costs associated with research involving vertebrate animals. Such costs cannot be incurred until NIH issues a revised Notice of Award (NoA) removing the vertebrate animal use restriction.

OSP will notify the PI and department staff when a vertebrate animal restriction has been placed on an award and, if the PI can verify that there is work that can be completed that does not involve vertebrate animal research, the SPO will set up the award with a term that prohibits vertebrate animal research until we receive a revised NoA removing the restriction.

Congruency Review Process by ORRP

For pending PHS funded proposals, ORRP will be contacted by the PI's SPO (send request to IACUCinfo@osu.edu). Information to be provided includes the IACUC protocol number and the most recent proposal (budget information not necessary to be included). The following steps describe the process the ORRP staff member will follow to determine if the grant proposal is congruent with an existing IACUC protocol.

1. If grant has not been provided as part of the request, then check the protocol to confirm that pertinent information has been provided (project scope, Vertebrate animal section, research strategy section involving animal work).
2. Compare information that is in the grant proposal, to what is provided in the protocol. The IACUC protocol may have additional information, but all animal work in a grant proposal needs to be included in the IACUC protocol. Specifically:
 - general scope of work (i.e., disease area, target organs, etc.)
 - species and sex of animals
 - approximate number of animals requested
 - procedures conducted including use of anesthetics and analgesics, euthanasia method, agents administered including method of administration
3. If information in the grant proposal is not part of IACUC protocol, the PI will be contacted for clarification. The IACUC protocol may need to be amended to be consistent with the grant proposal. An ORRP staff member will determine if an amendment is needed and will work with the PI to help complete the review process in a timely manner.
4. ORRP will prepare a grant congruency email and notify the PI and SPO once it is determined that the protocol covers activities described in the grant proposal. The email will include the IACUC protocol number and title, the most recent date of approval for the protocol (may be the annual review date) and the title of the associated grant proposal in the information provided to the PI. If not already included, the PI will also need to submit an amendment to update the funding information in the protocol. If requested, this information can be submitted as a letter for the agency.