News and Information from the IACUC Office
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Congruence between IACUC Protocols and Grants is a condition of accepting PHS funds

Public Health Service (PHS) policy states that awards may not be issued unless the awardee’s IACUC “provide[s] verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals,… .” To this effect, the PHS Policy and the NIH Grants Policy Statement require institutions to ensure that the information the IACUC reviews and approves, is congruent with what is in the application/proposal. This includes preliminary data, specific aims, research design and methods as well as the vertebrate animals section.

Therefore, an investigator should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. In eSirius, keeping Protocol Section 4, Project Funding, up-to-date will facilitate the grant-protocol comparison process.

One commonly accepted method to prevent inconsistencies between the information submitted to PHS and that on the IACUC protocol is to implement a procedure for direct comparison. At Cornell University, this responsibility is delegated to the Office for Research Integrity and Assurance (ORIA).

ORIA performs a comparison of the grant proposal with the approved IACUC protocol referenced in the OSP Form 10. Verification of grant and protocol consistency concentrates on animal care and use and does not include a judgment of scientific merit. Common areas of non-congruence between grants and protocols include: specification of drugs, use of hazardous agents, performance of specific procedures, treatments, animal strains or even species that are proposed in the grant application but are not described in the IACUC protocol. Often, this comes about because of revisions to the grant which refine and focus the research based on grant reviewer comments. Since protocol and grant preparation are on different time cycles this may result in drift in the details of the animal work proposed in the revised grant from that which is approved on the protocol.

If the comparison identifies material discrepancies, the Office of Sponsored Programs (OSP) cannot accept the award until those discrepancies have been resolved either by an amendment to the IACUC protocol or a revision of the grant proposal. The IACUC office will work with the Principal Investigator to facilitate and expedite the process so that the funding opportunity is not jeopardized. However, significant discrepancies between the two can lead to delays. Please contact the IACUC office at 255- 2214 if you have any questions about this process.

Charges to NIH awards during periods of non-compliance for activities involving animals

Principal Investigators are responsible for ensuring that all work performed under their approved protocols is within the parameters authorized by the IACUC. Conducting any animal work not covered by an approved animal protocol may be a cause for an Incident Report to OLAW (Office of Lab Animal Welfare), a division of NIH. In accordance with updated guidance from the NIH “the Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time
that the terms and conditions of the NIHGPS are not upheld. Institutions are required to report such situations to the Institute/Center (IC) supporting the award and to OLAW. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges.” (For a full statement of the guidance issued, please go to the NIH website at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html.)

The bulleted list below cites some examples of incidents that would constitute such unauthorized activity and would require removal of charges related to such activities. An extended list of other examples of reportable incidents is provided on the OLAW website at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html. The IACUC office and CARE veterinary staff are available to assist and provide guidance in maintaining compliance with your approved protocol and to prevent such incidents from occurring.

- Conduct of animal-related activities without appropriate IACUC review and approval;
- Failure to adhere to IACUC-approved protocols;
- Implementation of any significant change to IACUC-approved protocols without prior IACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review is required at least once every three years);
- Failure to correct deficiencies identified during the semiannual inspection in a timely manner;
- Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained; and
- Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry).

In case a situation arises where adjustments need to be made to the charges to a grant, the Principal Investigator will need to work with the facility staff to determine the amount of the charges. The IACUC office will work with the Principal Investigator, OSP, and Sponsored Financial Services (SFS) to process the financial transaction and report it to the funding agency as required.

If you have any questions or comments regarding these or any other topics relevant to the IACUC, please contact the IACUC office at iacuc@cornell.edu. Also visit the IACUC website (www.iacuc.cornell.edu) for updates and other information pertinent to conducting research or teaching activities with animals at Cornell University. The IACUC review timeline is available at http://www.iacuc.cornell.edu/requirements/IACUC%20timeline.pdf.