



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 1 of 6

Table of Contents

Overview.....	2
Purpose	2
1. Grant Congruency Verification Procedures if IACUC Approval is not obtained	3
2. Grant Congruency Verification Procedures if IACUC approval is already obtained for the animal work described in the grant application	4
3. Subcontracts/Collaborations.....	5
4. Responsibilities.....	5
4.1 Office for Research & Innovation Responsibilities	5
4.2 Principal Investigator Responsibilities]	8
5. Resources.....	6
6. Revision and Workgroup Members	6
6.1 Revision	6
6.2 Workgroup Members.....	8



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 2 of 6

Overview

Purpose

Federal regulations, including **PHS Policy** and the **NIH Grants Policy Statement**, require institutions to confirm—prior to award—that all proposed animal work has been reviewed and approved by the **Institutional Animal Care and Use Committee (IACUC)**. This process, known as **Grant Congruency Check**, ensures that the research described in grant applications aligns with approved IACUC protocols.

At Drexel University, this verification is managed by the **Office of Research and Innovation (ORI) IACUC Office**, with qualified staff and/or the IACUC chair or designated chair performing the review.

Key Requirement:

Institutions must verify that the research in the application is congruent with IACUC-approved protocols, as outlined in NIH Grants Policy (Section 4.1.1.2).

Scope

To ensure compliance, this procedure applies to all grant proposals involving live vertebrate animals, regardless of funding source.

For most instances, a single approved IACUC protocol can be supported by multiple grants, and one grant can support multiple approved IACUC protocols. Exemptions may apply based on funding agency requirements. For example, The Department of Defense (DoD) and The Congressionally Directed Medical Research Programs (CDMRP) no longer accept partially funded IACUC protocols for review. It is the Principal Investigator's (PI) responsibility to ensure all work within the IACUC protocol is entirely funded by the DoD. They will accept protocols that are funded by multiple awards, if all the work in the protocol is funded by the DoD.

IACUC approval is valid for a three-year period. For work performed in years four and five of the grant, NIH has provided the following guidance:

“The IACUC must review and approve the proposed use of animals described in the application or proposal prior to the conduct of any PHS-supported animal activity ([PHS Policy V.B.](#))... A brief description of the animal activities planned for the 4th and 5th year of the award period should be provided in the animal protocol recognizing that the experimental details and procedures will be refined or amended at a later time or at the time of the 3-year renewal.”

“In rare cases, IACUC review of animal activities is conducted later in the life cycle of a grant or contract. IACUC review may be delayed if animal activities will not occur until a year or later in the award period as part of the research design described in the grant application or contract proposal (e.g., the initial development of a drug or device with subsequent animal testing projected into the future). In these circumstances, the funding component will issue a Notice of Award with a special term and condition indicating that no funds may be drawn from the grant or contract for animal activities until a valid IACUC approval date has been provided to the funding component.”



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 3 of 6

1. Grant Congruency Verification Procedures if IACUC Approval Has Not Already Been Obtained

- 1.1 If IACUC approval has not been obtained for animal work described in the grant application, there are two options: 1) submit an amendment to an existing approved IACUC protocol; 2) submit a new IACUC protocol. *Note: a new IACUC protocol is not required for each grant, unless specified by the funding agency.*
- 1.2 Within the amendment or new protocol submission, provide the sponsor and Vertebrate Animal Section, Research Strategy section, and the Performance Site section.
 - 1.1.1 The IACUC will work with the PI to review the new IACUC protocol or amendment submission within the JIT timeline provided. The IACUC will work with the PI to review and approve the protocol or amendment submission in a timely manner while adhering to federally regulated review methods and ensuring the protocol is consistent with the Guide, conforms to Drexel's Animal Welfare Assurance, meets the requirements of the PHS Policy and U.S. Government Principles, and is conducted in accordance with the Animal Welfare Act (where applicable).
 - 1.1.2 If JIT provides a short turnaround time the IACUC Office will work with the PI, Grants Administrator, and Grant Program Officer to inform them that the IACUC review process is underway, describe the process for a thorough review of an IACUC protocol, and work together to determine an appropriate due date for the submission of the IACUC approval letter.
- 1.3 The IACUC Office will provide the PI and the Office of Research and Innovation Grant Administrator with the Grant Congruency Verification Letter and IACUC Approval Letter.



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 4 of 6

2. Grant Congruency Verification Procedures if IACUC Approval is Already Obtained for the Animal Work Described in the Grant Application

- 2.1 For the NIH and other sponsors utilizing JIT notices, PIs are instructed to complete the Grant Congruency Check Request Form and submit to the IACUC Office at iacuc@drexel.edu
- 2.1.1 The IACUC Office strives to complete all Grant Congruency Check requests within 5 business days depending on current volume.
- 2.1.2 If a PI receives notice that their grant is likely to be awarded based on their impact score, it is advisable to initiate the grant congruency check as soon as possible to avoid a delay.
- 2.1.3 The grant congruency check request form can be found on the IACUC website.
- 2.2 The IACUC Office will facilitate the grant congruency check
- 2.2.1 Professional staff of the IACUC Office and/or the IACUC chair or designated chair will complete a side-to-side comparison of the grant application outlining animal work and the IACUC protocol(s) provided within 5 business days of the submission.
- 2.2.2 All animal work outlined in the grant application must be approved by the IACUC in the submitted IACUC protocol(s). The IACUC Office or IACUC chair or designated chair conducting the check will focus on the following areas of the grant application and submitted IACUC protocol(s) during the side-by-side comparison of the documents provided:
- Species
 - Procedures
 - Drugs (Agents, Dosages and Route of Administration)
 - Experimental Endpoints
 - Method(s) of Euthanasia
- 2.2.3 If any discrepancies between animal use activities described in the grant application or contract and the corresponding IACUC-approved protocols are identified, the PI will be notified so that appropriate actions can be taken (e.g., submitting an amendment or a new IACUC protocol application).
- 2.3 Once the check is completed, The IACUC Office will provide the PI and the Office of Research and Innovation Grant Administrator with the Grant Congruency Verification Letter and IACUC Approval Letter.



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 5 of 6

3. Subcontracts/Collaborations

3.1 If work with live animals is being done externally by collaborators not affiliated with Drexel University through a sub-award or a sub-contract, and Drexel University is the awardee institution, the terms and conditions of the grant flow through to the sub-awardee. Prior to a Drexel University investigator conducting animal work at a non-Drexel University institution or company, or contract or sub-contact animal work to a collaborator at another institution, a formal written agreement known as an IACUC oversight memorandum of understanding (MOU) or a contract must be established. The MOU should address the responsibility for offsite animal care and use, animal ownership, IACUC review and oversight, and ensure compliance with federal regulations.

3.2 Using information provided in the grant congruency check request form, Drexel's IACUC Office will execute the IACUC Oversight MOU with the collaborating institution's IACUC Office. Drexel's IACUC Office will confirm the following:

- 3.2.1 All institutions and locations where live vertebrate animal work takes place using federally sponsored funds must be covered under a PHS Animal Welfare Assurance. Animal use sites which produce custom antibodies, tissues, or other bodily fluids which are specifically collected for a federally sponsored research project also fall under this mandate.
- 3.2.2 All institutions and locations which house or perform research with USDA covered species owned by Drexel University must be registered as a research facility with the USDA-APHISAC.
- 3.2.3 All institutions where research occurs with Drexel University owned live animals must be accredited by AAALAC, International.

3.3 Once the MOU is established, a completed copy will be provided to the PI, the collaborating institution, and the Office of Research and Innovation Grant Administrator

4. Responsibilities

4.1 Principal Investigator Responsibilities

The Principal Investigator is ultimately responsible for ensuring all animal work described in the grant application is approved by the IACUC, and specifically the following:

- Submit an IACUC protocol or an amendment to an existing IACUC protocol to obtain IACUC approval for all work described in the grant application.
- Submit a grant congruency check request form to the IACUC office to verify all animal work described in the grant application has obtained IACUC approval



Grant Congruency Check – Guidance Document

Document No.:	Version No.:	Effective Date:	Page:
ACU-009	001	January 1, 2026	Page 6 of 6

4.2 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, training, granting exceptions, and monitoring. For inquiries regarding these procedures, please contact the Director of Animal Welfare, as part of the Office for Research & Innovation (ORI).

The IACUC Office, as a part of the Office for Research & Innovation, and in conjunction with the IACUC, will be responsible for the following:

- Upon notification of a pending award by the PI, review grant application and the PI's approved IACUC protocol(s) [if applicable] for congruency.
- Notify PI of discrepancies and request corrective actions (e.g., amendment or new IACUC protocol submission).
- Confirm congruency and notify PI and Office of Research and Innovation Grant Administrator when all animal activities are covered by approved IACUC protocols.
- Establish an IACUC Oversight MOU with subcontract collaborating institutions where animal work will be conducted.

5. Resources

- [PHS Policy on Humane Care and Use of Laboratory Animals | OLAW](#)
- [NIH Grant Policy 4.1.1 Animal Welfare Requirements](#)
- [https://olaw.nih.gov/faqs/#!/guidance/work conducted in year 4-5](https://olaw.nih.gov/faqs/#!/guidance/work%20conducted%20in%20year%204-5)

6. Revision

6.1 Revision

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