

<b>Prepared by:</b> IACUC Office	<b>Approved by:</b> DFCI IACUC	<b>Effective Date:</b> 3/5/2010 <b>Updated:</b> 10/5/2018; 3/6/2020, 6/15/2022, 3/3/2023, 1/23/2024
-------------------------------------	-----------------------------------	---

- 1.0 Purpose**
- 2.0 Background**
- 3.0 Agencies Requiring Congruency Review**
- 4.0 Initiating Congruency Review**
- 5.0 Grant Congruency Review Process**
- 6.0 Resolution of Discrepancies**
- 7.0 References**

## **1.0 Purpose**

This policy describes the grant to protocol congruency review process. Congruency review is required by some sponsors when grant funding that involves the use of animals in research, testing, or teaching activities is awarded to.

## **2.0 Background**

Grant congruency is the process by which Institutions ensure that all animal activity outlined in a grant application has been approved by the IACUC in an approved animal protocol. This review is intended to confirm congruency, but not complete equivalence.

The principal funding source for live vertebrate animal research at DFCI is the U.S. Department of Health and Human Services (HHS), primarily through the Public Health Service (PHS) and its National Institutes of Health (NIH). In order to receive funds for live vertebrate animal research, DFCI is required to follow PHS and NIH policy. Excerpts from both the HHS and NIH Grants Policy Statements are noted below.

PHS Policy and the NIH Grants Policy Statement (Part II, Terms and Conditions) require institutions to verify, *before award*, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. The NIH funding process has continued to become more competitive, therefore receiving a “Just-in-Time (JIT) Notification” from the NIH is no longer a guarantee of funding. The NIH Just-In-Time policy includes all applications that receive an overall impact score of 30 or less. Accordingly, only those grants that are likely to be funded (receiving a fundable score) will be reviewed.

For Department of Defense [DoD] grants, the IACUC is not required to do a congruency review. Instead, the DoD conducts an administrative review of the protocol. Department of Defense regulations require that any animal study either conducted or sponsored by the DoD be reviewed by a DoD veterinarian trained and experienced in lab animal medicine.

### **2.1 HHS Grants Policy Statement**

“The PHS Policy on Humane Care and Use of Laboratory Animals (the PHS Policy) requires applicants proposing to use vertebrate animals in HHS-supported activities to file a written Animal Welfare Assurance with OLAW. An awarding office will not make an award for research involving live vertebrate animals unless the applicant organization and all

performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the PHS policy. If an application is selected for award and the verification of IACUC review has not been submitted, the awarding office will contact the organization with instructions for negotiating an assurance or submitting the IACUC verification.”

## **2.2 NIH Grants Policy Statement**

“It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.” (sec.4.1.1.2 “Verification of IACUC Approval”, NIH Grants Policy Statement)

“NIH will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy.”

## **3.0 Agencies Requiring Congruency Review**

The IACUC will only perform congruency review when required by the funding source. The following funding agencies require congruency review:

- Public Health Service (PHS)/National Institutes of Health (NIH)
- All NIH subdivisions (e.g. NCI, NHLBI, NIAID, NIDDKD, NIAAA, etc.)
- National Science Foundation (NSF)
- National Aeronautics and Space Administration (NASA)
- US Department of Health & Human Services (DHHS)
- USDA National Institute of Food and Agriculture
- Alex’s Lemonade Stand Foundation
- American Heart Association (AHA)
- American Cancer Society (ACS)
- Department of Veterans Affairs (VA)
- Susan G. Komen
- American Association for Cancer Research (AACR)
- Dana-Farber/Harvard Cancer Center (DF/HCC)
- Harvard Catalyst\*

This list will be updated if/when other agencies adopt the requirement.

\*Catalyst awards may involve federal funds. Harvard is the prime awardee on the Catalyst grant but would expect the subawardee to handle congruency review. For Catalyst awards, the IACUC Office will determine whether federal funds are involved and, if so, coordinate congruency review.

## **4.0 Initiating Grant Congruency Review**

Grant congruency review is coordinated by the IACUC Office as part of protocol review (e.g., during a 3-year rewrite) or by request (e.g., for a Just-In-Time request, when a new grant receives a fundable score).

For DFCI-awarded NIH grants, it is not necessary to submit a copy of the grant at the time congruency review is initiated. For NIH grants awarded to other institutions (e.g., where DFCI is a

subrecipient) and for other sponsors, submitting a copy of the grant when congruency review is initiated will facilitate the review process. Please see section 5.0 for more information.

**4.1 Protocol review:** No specific request is required in this case. PIs provide an up-to-date list of funding sources in each new protocol or 3-year rewrite. The IACUC Office will use the list of funding sources to coordinate congruency review for new grants from sponsors in section 3.0 and competing renewals of NIH, NSF, and NASA grants from sponsors in section 3.0.

Congruency review is done toward the end of the animal protocol review process – when the animal protocol is in final/near final condition – to ensure an accurate review. If there is an urgent need to obtain certification of congruency for a grant during protocol review, the IACUC Office staff member coordinating the protocol review must be notified.

**4.2 By request:** When certification of congruency is needed independent of a protocol review, requests for congruency review should be submitted to the IACUC mailbox ([dfci\\_iacuc@dfci.harvard.edu](mailto:dfci_iacuc@dfci.harvard.edu)).

Requests should be submitted as early as possible – congruency review typically takes 1-3 business days and may take longer (e.g., if discrepancies are found).

Each request must include the following information:

- DFCI animal protocol number(s) for congruency review
- Name of the funding agency
- Name of the grant PI
- Grant number or award number (if sponsor assigns one)
- Grant title (if sponsor requires one)
- Name of the prime grantee (i.e., the institution to which the grant will be awarded)
- **If DFCI is NOT the prime grantee**, a brief statement to explain why DFCI's IACUC needs to handle congruency review
  - For example: The wording of a subcontract may place responsibility for congruency review on the subrecipient's IACUC. For grants where DFCI is not the prime awardee and where there is a subcontract, please include a copy of the subcontract with your request.

Grant applications will be reviewed in the order in which they were received or in order of priority. Grant applications requiring review on an emergency basis will be given priority and reviewed as soon as possible. Every effort will be made to accommodate funding/award deadlines, but PIs should allow sufficient time for IACUC members to review the grant application.

## 5.0 Grant Congruency Review Process

DFCI-awarded NIH grants will be pulled from eRA Commons for congruency review. If a grant cannot be pulled from eRA Commons, the IACUC Office will contact the person who initiated congruency review to obtain all necessary grant materials.

To ensure compliance with PHS policy, a designated member of the DFCI Institutional Animal Care and Use Committee (IACUC) perform a side by side comparison of the grant application and the corresponding IACUC protocol(s). Focus will be on the following areas of the grant application and protocol(s) during the side by side comparison of the documents:

- General scope of work
- Species

- Procedures (including custom generation of antibodies contracted off-site)
- Drugs (agents, dosages and route of administration)
- Experimental Endpoints
- Method(s) of euthanasia
- Performance site

**PHS/NIH:** For PHS/NIH-funded studies, a designated IACUC member reviews the Specific Aims, Research Strategy section, and/or Vertebrate Animals section (VAS) of the grant application against the associated animal protocol. The grant and protocol are considered congruent if they are approximately equivalent in the areas listed above. The PHS provides instructions on completing the VAS here: <http://grants.nih.gov/grants/funding/phs398/phs398.pdf>. (See 5.5.5.)

**Other Funding Sources:** Comparisons will be based on the grant format and relevant information provided therein.

PIs will be contacted with the results of the grant congruency review within 1-2 business days of completion of the grant review. If there are no discrepancies between the animal work described in the grant application and the corresponding animal protocol(s), an email will be sent to the PI indicating that the documents were congruent.

*Please note that a grant application and animal protocol are still considered congruent if the animal protocol includes procedures not covered by the grant.*

## **6.0 Resolution of Discrepancies Between the Grant Application and the IACUC Protocol**

If the congruency review identifies discrepancies between the grant application and the IACUC protocol, the IACUC Office will email the grant PI (or animal protocol PI if the grant was awarded to another institution) with a detailed description of the discrepancies and suggestions on how the discrepancies can be resolved. Discrepancies between the grant application and the IACUC protocol(s) are usually resolved by providing an explanation or submission of a new amendment or protocol.

Depending on the PI's response and on the nature of the discrepancies (e.g., severity, number, scope), the IACUC may be able to certify congruency with the understanding that an amendment will be made in future. This will be determined on a case-by-case basis by the IACUC Office and may involve consultation with the PI, the grant reviewer, other IACUC Office staff, and/or members of the IACUC. In a case where congruency is certified with discrepancies, a brief summary of the discrepancies and the planned resolution for each will be listed in the congruency certification.

## **7.0 References**

1. PHS [Public Health Service]. 2015. Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington DC: US Department of Health and Human Services. [PL 99–158 Health Research Extension Act, 1785.] <https://olaw.nih.gov/policies-laws/phs-policy.htm>
2. The National Institutes of Health Grants Policy Statement (NIHGPS). 2017. <https://grants.nih.gov/policy/nihgps/index.htm>