Grant Application/IACUC Protocol Congruency FAQs

1) **What is grant congruency?**

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.

2) **Where can I find more information about the UNC-CH procedure for grant application/IACUC protocol congruency?**

A detailed SOP outlining the grant congruency process can be found on the IACUC website at: https://research.unc.edu/files/2012/11/Grant-Congruency-Procedures-2013-7-25.pdf.

Additionally, you may contact Michelle Denning, IACUC Manager and Grants Specialist (michelle.denning@unc.edu, 919-843-1023) or Russell Hermans, IACUC Grants Specialist (russell.hermans@unc.edu, 919-966-6399) with any questions.

3) **Why must my grant application be congruent with my IACUC protocol?**

The principal funding source for live vertebrate animal research at UNC-Chapel Hill (UNC-CH) 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). HHS/NIH funding accounts for the majority of all award dollars granted at UNC-CH. In order to receive funds for live vertebrate animal research, the University is required to follow PHS and NIH policy. Excerpts from both the HHS and NIH Grants Policy Statements are noted below.

**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
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.”

“Verification of the IACUC review may be filed at any time before award unless required earlier by the institutional committee. Therefore, following peer review and notification of priority score/percentile, applicant organizations with approved Assurances should proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range. Regardless of when the review occurs, the IACUC should ensure that the research described in the application is consistent with any corresponding protocols reviewed and approved by the IACUC. 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.”

4) What is the procedure for requesting a grant application/IACUC protocol congruency review?

The NIH funding process has continued to become more competitive, therefore receiving a “JIT Notification” from the NIH is no longer a guarantee of funding. The NIH has changed its Just-In-Time policy to include all grants that were scored, as opposed to only those grants that have a high probability of being funded. Accordingly, OACU staff are only reviewing those grants that are likely to be funded.

At the time that a PI receives a fundable score from the NIH, he/she should complete the online form entitled “Request for Grant Application/IACUC Protocol Congruency Review.” This form allows the PI to indicate any additional information he/she would like to communicate to OACU staff about the grant application prior to its review. PIs should also ensure that their grant application has been uploaded into RAMSeS for review.

Upon completion of this online form, OACU staff will receive an email notification of the request for congruency review. Requesting the congruency review at this time is advantageous because it will allow for any discrepancies between the grant application and the IACUC protocol(s) to be resolved prior to the award of grant funds.

5) What if I don’t submit a request for grant congruency review? Will my grant application still be reviewed?

If the PI does not request a grant application/protocol congruency review at the time he/she receives a fundable score from the NIH, OACU staff will be notified via email once the status of
a grant application has been updated in RAMSeS to “JIT Request Approved.” Once OACU staff receive this notification, they will call and/or email the PI to inquire about the likelihood of the grant being funded. If it is likely that the grant will be funded, OACU staff will conduct a congruency review of the grant application with the corresponding IACUC protocol(s). Reviewing the grant application and corresponding IACUC protocol(s) at this time is not ideal because IACUC approval has already been submitted to the NIH by UNC-CH grants administration staff. This issue can be problematic if there are procedures proposed in the grant application that are not typically approved by the IACUC. (For example, LD50 studies, the use of death as an endpoint, etc.) If OACU staff identifies serious discrepancies between the grant application and the IACUC protocol(s), the NIH may have to be notified of these issues.

6) When will the grant congruency review be completed?

Grant applications will be reviewed by OACU staff in the order in which they were received or in order of priority. Grant applications will be reviewed within one week of receiving a request from the PI or email notification from RAMSeS. Grant applications requiring review on an emergency basis will be given priority and reviewed immediately. OACU staff will make every attempt to accommodate funding/award deadlines but PIs should allow sufficient time for OACU staff to review the grant application.

7) How will OACU staff check for congruency between grant applications and IACUC protocols?

OACU staff will perform a side by side comparison of the grant application and the corresponding IACUC protocol(s). All animal work outlined in the grant application must be approved by the IACUC in a corresponding IACUC protocol(s). OACU staff will focus on the following areas of the grant application and corresponding IACUC protocol(s) during the side by side comparison of the documents:

- Species
- Procedures (including custom generation of antibodies contracted off-site)
- Drugs (Agents, Dosages and Route of Administration)
- Experimental Endpoints
- Method(s) of Euthanasia

8) What are the common types of discrepancies found between grant applications and IACUC protocols?

- Proposed use of agents (analgesics, anesthetics and/or experimental drugs) in the grant application that are not included in the IACUC protocol or are included at different doses than the doses indicated in the grant application
- Proposed procedures in the grant application that are not included in the IACUC protocol
- Methods of euthanasia are different in the grant application than the methods indicated in the protocol

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• Proposed custom generation of antibodies in the grant application (UNC-CH is responsible for the use of animals even if the antibody production is conducted off site so any references to the use of antibodies in the grant application must be clarified as to whether they are custom generated or available “off the shelf”.)
• Proposed animal work performed off site by a collaborating site, a subcontract, or a fee for service arrangement
• The experimental endpoints in a grant application are different than those described in the protocol. For instance, the length of time an animal survives after a survival surgical procedure is longer in the grant application than in the protocol.

9) How will I be notified of the results of the congruency review?
PIs will be contacted with the results of the grant congruency review no later than 24 hours of completion of the grant review, or sooner, as necessary. If there are no discrepancies between the animal work described in the grant application and the corresponding IACUC protocol(s), an email will be sent to the PI indicating that the documents were congruent.

10) What do I do if discrepancies are identified between my grant application and my IACUC protocol(s)?
If an OACU staff member identifies discrepancies between the grant application and the IACUC protocol, the PI will be emailed 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.

PIs should respond to the email regarding grant/protocol application discrepancies as soon as possible. PI responses to grant congruency discrepancies will be reviewed and processed within 72 hours of their receipt or sooner, if necessary, to accommodate funding/award deadlines.

11) What if I need to submit an amendment or new protocol to resolve the grant congruency discrepancies and I need IACUC approval of these documents ASAP?
If resolution of the discrepancies requires submission of a new amendment or protocol, the Chair of the IACUC has initiated a process by which grant application and animal protocol congruency can be established with potentially minimal delays. Specifically, in instances where there is a lack of congruency between the grant and an IACUC protocol, the PI can submit an amendment with rapid turnaround request. Such amendments will be processed as quickly as possible. If an amendment is not sufficient and a full protocol is required in order to establish congruency, or if a protocol is currently under review, the protocol will be processed by the IACUC Chair and a Division of Laboratory Animal Medicine (DLAM) veterinarian in order to ensure a rapid and thorough review. If this protocol review does not coincide with the monthly IACUC meeting, the protocol will be reviewed by designated member review rather than full
Committee review. Please be aware that all efforts will be made to accommodate funding/award deadlines, but federal regulations require all IACUC members to receive a copy of all submitted amendments and full protocols. Upon receipt and review, any IACUC member can request a full Committee review which requires review of the amendment or protocol at the next scheduled monthly IACUC meeting, and this may delay time to approval.

12) What can I do to facilitate my grant congruency review?

- Request the grant congruency review at the time that you have a fundable score. This time point will allow more time to resolve any discrepancies between the grant application and the IACUC protocol(s) before the award of grant funds.
- When requesting the grant congruency review, please specify any additional information that you think would be helpful to the OACU staff member reviewing your grant application.
- If you have a special circumstance requiring a quick congruency review, please contact OACU staff to explain your situation. OACU staff will make every attempt to accommodate your situation.
- Ensure that your grant application has been uploaded into RAMSeS for review.
- If OACU staff finds discrepancies between your grant application and the corresponding IACUC protocol(s), please respond to the email regarding these discrepancies as soon as possible.