Slide 1: No notes.

Slide 2: What is grant congruency and why is it important?

Simply stated, grant congruency is ensuring that all of the animal activity described in the grant application is approved in an IACUC protocol.

Although it is good practice to ensure that all non-NIH grant applications be congruent with their corresponding IACUC protocols, the NIH explicitly requires that the two documents be congruent. PHS Policy and the NIH Grants Policy Statement “require the institution 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.”

What this means is that prior to award, all animal activities in the grant application should be described and approved in an IACUC protocol. So, long story short, if it's in the grant application, it should be in an IACUC protocol.

The NIH does not dictate the method that each institution should use to ensure congruency.

Ensuring congruency of the grant application with the IACUC protocol is an institutional policy and not specifically an IACUC responsibility. Here at UNC, the Office of Animal Care and Use has been charged with this task. Currently, we have 1.5 FTE to perform this procedure and potentially hundreds of NIH grant applications to review.

Slide 3: At UNC, grant congruency was previously performed by having the PI provide assurance that the documents were congruent. Studies have been performed that demonstrate that relying on the PI certification may not be sufficient. In a survey taken of institutions, 20% of respondents indicated that grant congruency is found in less than 50% of the reviews. We have collected data beginning in 2009 (when we first initiated the congruency review of NIH grants here at UNC) indicating that most NIH grant applications are not congruent with their corresponding IACUC protocols upon our initial review of the documents.

We were reviewing all NIH grant applications for which the status of the grant application had been updated in RAMSeS to “JIT Request Approved.” This status change in RAMSeS occurs when a PI receives
a “JIT Request” from the NIH and submits all of the information requested by the NIH to the UNC grants offices for submission to the NIH. Upon notification that the status of the grant application had changed in RAMSeS, an automatic email notification is triggered to the Office of Animal Care and Use advising us of a grant application in need of a congruency review. Because the NIH funding process has continued to be more competitive, receiving a “JIT Notification” from the NIH is no longer a guarantee of funding.

Because the number of potential grants to review is more than 1.5 FTE can complete and so that we do not waste your time asking about grants that may not be funded, we are only reviewing those grants that are likely to be funded. Once we receive notification that a PI has provided all of the JIT requested information to the NIH, we call and/or email the PI to inquire about the likelihood of the NIH grant being funded. If it is likely that the NIH grant will be funded, we will conduct a congruency review of the NIH grant application with the corresponding IACUC protocol.

PIs can also request a congruency review from our website.

**Slide 4:** The current method of grant congruency review involves performing a side by side comparison of the grant application with the IACUC protocol to ensure that the animal activity in the grant application is approved in the corresponding IACUC protocol.

Common discrepancies include a different species being used in the grant than is approved in the protocol, proposed procedures in the grant application that are not included in the IACUC protocol, agents, such as analgesics, anesthetics and/or experimental drugs, in the grant application that are not included in the IACUC protocol or are included at different dosages or different routes of administration than indicated in the IACUC protocol, or differences in the methods of euthanasia or experimental endpoints.

If we find discrepancies between the grant and the IACUC protocol we contact the PI to resolve the discrepancies. These discrepancies are resolved various ways but usually involve the PI providing an explanation clarifying the discrepancies, submission of an amendment to add the omitted information to the IACUC protocol, submission of a new IACUC protocol, or modification of the grant application.

**Slide 5:** Our future plans involve the review of subcontracts. The type of item requiring our review are those situations in which UNC is subcontracting animal work to other institutions. For any NIH grant applications being awarded to UNC, the NIH regulations hold UNC responsible for all the animal work described in the grant applications, even if they are being performed off site. Therefore, we need to ensure that we are in compliance with all NIH regulations/expectations. Additionally, the NIH has minimum requirements that institutions receiving subcontracts must meet. Our review of these subcontracts is to ensure that all subcontracts are going to entities who can meet the NIH requirements and to ensure that we have appropriate documentation on file for each of these subcontracts demonstrating their eligibility.
If you are working in a laboratory in which animal work will be subcontracted to another institution, ensure that your PI only subcontracts the animal work to those institutions who meet the NIH requirements. These requirements are the following:

- A valid PHS Assurance on file with the NIH.
- Evidence of IACUC approval from their institution’s IACUC for the animal activity they will be performing.
- Registration with the USDA if the animal work is being performed in a USDA covered species.
- UNC policy also requires that all subcontracts involving animal work be performed at an AAALAC accredited institution. If this isn’t possible, the subcontract should clearly state that the other institution owns the animals.

**Slide 6:** So, how can you help make this process go more smoothly for your PI?

First, when assisting your PI in writing his/her grant applications and IACUC protocols, keep in mind that the animal activity described in both documents must be congruent. Ensure that all animal activity in the grant application is included in the IACUC protocol.

Ensure that the NIH grant application is included as an attachment in RAMSeS. Having to contact the PI to obtain a complete copy of the grant application significantly slows down the process.

Request a grant congruency review from the IACUC website instead of waiting for us to receive the automatic email notification from RAMSeS. Requesting the grant congruency review is the most advantageous method because it will allow for any discrepancies between the grant application and the IACUC protocol to be resolved prior to the award of grant funds. Waiting for us to receive the automatic email notification from RAMSeS can be problematic if there are procedures proposed in the grant application that are not typically approved by the IACUC. Because all the discrepancies between the grant application and the IACUC protocol must be resolved prior to award, requesting the congruency review will allow more time to resolve potential discrepancies between the grant and the IACUC protocol.

**Slide 7:** If we find discrepancies between the grant application and the IACUC protocol, please respond to them as soon as possible.

If you are subcontracting animal work to another institution, please ensure that all animal work being subcontracted meets UNC requirements.
Slide 8: If you have any questions about the grant congruency process, there is detailed information on the IACUC website. Please also feel free to contact Russell Hermans or me. You may also contact the main number or email for the Office of Animal Care and Use.

Slide 9: No notes.