Grant Application-IACUC Application Congruency

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What is grant congruency and why is it important?

- Ensuring that the animal activity in a grant application has been approved in an IACUC protocol

- Institutional Responsibility

- Necessary requirement to fulfill regulatory expectations (NIH requirement)
  - PHS Policy
  - NIH Grants Policy Statement (Terms and Conditions)
  - “What Investigators Need to Know About the Use of Animals” (NIH Publication No. 06-6009)
How should grant congruency be conducted?

- Include an assurance statement on the protocol for the PI to confirm.
  - Not always reliable
  - (Only 21% of UNC grants are congruent upon initial review.)

- Conduct a side by side congruency review on a portion of the sponsored projects (Risk based assessment of grants)

- Review of all grants
  - UNC Process
  - Process followed by peer institutions (Yale, Duke, etc.)
The Internal Processing Form (IPF)

- PI indicates “Yes” to Vertebrate Animal Use on IPF
  - Attach IACUC approval for all outside institutions
  - PHS Assurance
  - AAALAC accreditation
  - USDA Registration Number (If USDA covered species)
The Internal Processing Form (IPF)

Animal Subjects

* Does this research involve ANIMAL SUBJECTS? (NOTE: This includes any animal work conducted at UNC-CH, other domestic institutions, and/or foreign institutions. Please take into account any animal work performed at collaborating sites, fee-for-service arrangements, and/or subcontracts.)

  - Yes
  - No

* Is animal work being conducted at UNC-CH as part of this research?

  - Yes
  - No

  * If yes, has your research team submitted an application for IACUC approval?
    - Yes
    - No

* Is animal work being conducted at institutions other than UNC-CH as part of this research?

  - Yes
  - No

  * If yes, please check all that apply and list the institutions and species below:

    - Domestic Institutions:
      - Subcontract
      - Fee-for-service
      - Collaborating Site

    - Foreign Institutions:
      - Subcontract
      - Fee-for-service
      - Collaborating Site

Please list all institutions where animal work will be conducted:

Please list all animal species to be used in the project:

Note:

* If animal work will be performed at institutions other than UNC-CH, for each institution please attach via the IPF Attachments screen (1) evidence of the institution’s IACUC approval, (2) a copy of its most recent AAALAC accreditation letter, and (3) evidence of PHS Assurance. If the work involves USDA-covered species, please also provide the institution’s USDA Registration Number.

* If the proposal is not subject to “JIT,” it is required to attach all documents at the time of the IPF submission.
The UNC Process

- PI receives a fundable score from the NIH and initiates a review by completing the online form entitled “Request for Grant Application/IACUC Protocol Congruency Review”

- OACU staff will receive an email notification.

- 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
The UNC Process

- Once status of grant application has been updated in RAMSeS to “JIT Request Received” OACU staff will receive email notification.

- OACU staff will contact the PI to inquire about likelihood of funding.

- If likely to be funded, OACU staff will conduct review.

- If unlikely to be funded or unknown, OACU staff will follow up on an appropriate basis.
The UNC Process

- OACU staff will perform a side by side comparison of the grant application and the corresponding IACUC protocol(s).

- Grants will be reviewed within one week of receiving request and in the order received.

- 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.
The UNC Process

- OACU staff will focus on the following areas of the grant application and corresponding IACUC protocols (s):
  - Species
  - Procedures (including custom generation of antibodies contracted off-site)
  - Drugs (Agents, Dosages and Routes of Administration)
  - Experimental Endpoints
  - Method(s) of Euthanasia
The IACUC Process

- 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 no discrepancies, an email will be sent to the PI indicating that the documents were congruent.

- If discrepancies-PI will be emailed with a detailed description of the discrepancies and suggestions on how the discrepancies can be resolved.

- Discrepancies are usually resolved by providing an explanation or submission of a new amendment or protocol.
The IACUC Process

- PI responses to discrepancies will be reviewed within 72 hours or sooner, if necessary.

- If resolution requires submission of a new amendment or protocol, there is a process to review these items with a rapid turnaround, if necessary.
What Can You Do to Expedite the Process?

- Ensure that the IPF is completed correctly
  - Specify “Yes” to Vertebrate Animal Work being performed regardless of location (subcontracts, collaborations and fee for service)
  - Ensure all regulatory documents are attached in RAMSeS for animal work performed outside of UNC (UNC IACUC must review and approve.)

- Ensure your grant application has been uploaded into RAMSeS for review.

- Ensure that the IACUC protocol information is correct in RAMSeS.
What Can You Do to Expedite the Process?

- Request the grant congruency review at the time that you have a fundable score.

- This allows for more time to resolve any discrepancies between the grant application and the IACUC protocol(s) before the awarding of funds.

- Specify any additional information that you think would be helpful to the OACU staff member reviewing your grant application.
What Can You Do to Expedite the Process?

- 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.

- If discrepancies are discovered, respond to them as soon as possible.
How can you learn more about grant congruency?

- Go to the IACUC website.  
  http://research.unc.edu/offices/iacuc/index.htm

- Contact Michelle Denning or Russell Hermans  
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Comments/Questions?