



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.)
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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)

Browser address bar: <https://apps.research.unc.edu//ramses/index.cfm?event=proposal.researchSubjects>

Page Title: Ramses

Navigation Menu:

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Buttons:

Form Fields:

Yes No

Animal Subjects [Help](#)

* 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:
(Mouseover ?'s for details)

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
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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.
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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.
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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.
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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

michelle.denning@unc.edu

russell.hermans@unc.edu

iacuc@med.unc.edu

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Comments/Questions?