

Institutional Animal Care and Use Committee		UNTHSC
Title: Protocol to Grant Congruence Verification		
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A. BACKGROUND INFORMATION

- a. This Standard Operating Procedure (SOP) is to define the IACUC’s policy on adhering to the NIH Grants Policy and the PHS Policy’s requirement to ensure congruence between the reviewed and approved IACUC protocol to the grant proposal.
- b. NIHGPS Part II, A, 4.1.1.2 Verification of IACUC Approval, “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.”
- c. PHS Policy IV.C.1: Review of PHS Conducted or Supported Research Projects, “...the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the Guide unless acceptable justification for a departure is presented.”

B. RESPONSIBILITY

- a. It is the Institution’s Responsibility to ensure the NIH Grants Policy and PHS Policy requirement for grant congruence is met, through a collaborative effort between the PI, the IACUC, and the Office of Sponsored Programs (OSP).
- b. It is the responsibility of the Principal Investigator to notify the IACUC when funding for a project is received, by providing a copy of the grant proposal to attach either to a new protocol or an amendment form.
- c. It is the responsibility of the IACUC through the IACUC Office to perform the grant to protocol congruence check.

C. DEFINITIONS

- a. Merriam-Webster
Congruence: the quality or state of agreeing, coinciding, or being congruent
- b. OLAW
Congruence: the agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC.

D. PROCEDURES

- a. The IACUC Office receives a notification for a grant congruence check, either through a New Protocol, an Amendment, or a notice from OSP.
- b. The notice should include the following information:

- i. The Principal Investigator's Name
 - ii. The Protocol Number and Title
 - iii. A copy of the Vertebrate Animal Section and other sections (such as the Research Strategy Section) may be requested in order to have all the information needed to conduct the congruence review.
- c. For grant proposals associated with a new IACUC protocol, it is the PI's responsibility to attach a copy of the Vertebrate Animal Section, and be prepared to include the Research Strategy Section, if needed, of the grant proposal to the IACUC protocol form.
- d. For existing approved IACUC protocols, the IACUC Administrator can receive a copy of the proposal in one of two ways:
 - i. The appropriate individuals from OSP will provide a copy of the Vertebrate Animal Section and, if needed, the Research Strategy Section along with the PI name and IACUC protocol number to the IACUC Administrator.
 - ii. The PI submits an amendment form to the IACUC Administrator to add the grant to the IACUC protocol. Attached to the amendment form, the PI should include the Vertebrate Animal Section and, if needed, the Research Strategy section.
- e. The IACUC Administrator will use a checklist to assess the grant and protocol to assure congruency for the following areas (if applicable):
 - i. PI
 - ii. Title
 - iii. Species and approximate numbers of animals to be used
 - iv. Hypothesis/ major scope of the overall project
 - v. Procedures performed on live animals
 - vi. Method of euthanasia
- f. If inconsistencies between the grant and protocol are discovered, the IACUC Administrator will contact the PI to seek further clarification. Congruency can be achieved in one of the following ways:
 - i. If the scope of the overall project falls within the lines of the protocol; however, if minor changes are needed in order to gain congruence, the PI may amend the protocol through an amendment to ensure the information delineated in the protocol matches the grant.
 - ii. If the overall goals/scope of the project differ from the protocol, then a new protocol will need to be submitted.
 - iii. The PI may choose to amend the grant to match the protocol. In this case, the PI should work with OSP to contact the funding agency in regard to the appropriate changes that will need to be made.
- g. Amendments and New Protocols submitted to achieve congruency between the grant and protocol will then be reviewed and approved by the IACUC.
- h. Once approved, an approval letter will be sent to the PI.

- i. For congruency checks initiated by the Office of Sponsored Programs, a written response will be sent to the one requesting the congruence check, indicating the congruence verification.

E. REFERENCES:

- a. [PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- b. [NIH Grants Policy Statement Part II, A, 4.1.2](#)