

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 Investigators Name
 - ii. The Protocol Number and Title
 - iii. A copy of the Vertebrate Animal Section and if needed, the Research Strategy Section of the grant proposal.
- 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:
- a) The OSP pre-award specialist 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.
 - b) 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):
- PI, Title
 - Species and approximate numbers of animals to be used
 - Hypothesis/ major scope of the overall project
 - Procedures performed on live animals
 - Method of euthanasia
- f. If inconsistencies between the grant and protocol are discovered, the IACUC Administrator will contact the PI to seek further clarification, or request modifications to the protocol until congruency is achieved, or request for a new protocol to be submitted.
- g. Amendments and New Protocols submitted in association 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, indicating the congruence verification.