IACUC Policy 22: Review of Grant Content with IACUC Protocol

1. Purpose

The NIH and NSF require verification of research protocols by grantee institutions to ensure compliance with the terms of the award. Further, the Institution is responsible for ensuring that the information that the IACUC reviews and approves is congruent with what is in the application or proposal. This may require comparison of the proposed or funded research protocol with approved protocols of Institutional Review Boards. Currently, the NIH and NSF require confirmation that proposed experiments involving animals have been reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). This policy establishes a method of assuring that the TTUHSC IACUC complies with these requirements.

2. Definitions and Mandates

A. Congruence, as opposed to equivalence or approximation, is a relation that implies a kind of equivalence, though not complete equivalence.

B. Change in scope. Although not defined specifically by OLAW, potential indicators of a change in scope include:

   1) Changes in specific aims of the award.
   2) Changes in animal model.
   3) Changes from the approved use of live vertebrate animals.
   4) Shifts of the research emphasis from one disease area to another.

C. Content that should be compared:

   1) Species
   2) Animal numbers proposed
   3) Procedures, including minimization of pain and distress.

3. Protocol Procedures

The IACUC is a standing institutional committee specifically charged with the protection of animals used in research. Because it has no direct knowledge of grants filed or funded, this policy will be implemented with the cooperation of the Office of Sponsored Programs, as follows.

A. The PI will ensure that each NIH/NSF grant submission will be supported by a single corresponding IACUC protocol (1:1 grant to protocol ratio).

B. The Office of Sponsored Programs will:

   1) Notify the IACUC of a newly approved or renewed NIH or NSF grant when TTUHSC is the primary recipient and animals will be used.
   2) Supply a file containing the relevant portions of the grant to the IACUC staff, if the PI is unavailable.
C. The IACUC Chair or the IACUC staff will assign the grant review to a member of the IACUC (generally the same member of the committee assigned to review the IACUC protocol).

D. The IACUC member will complete a timely review of the grant document(s) and the protocol and determine the general level of congruence.

1) If no change in scope is noted, this result will be documented in iRIS.

For instances where there may be a change in scope:

2) In cases where the grant describes animal experiments that are not part of an approved protocol, but no animals have been used:
   a) The Reviewer will ask the PI for clarification or request that the protocol be amended to be consistent with the grant.
   b) The Principal Investigator will be responsible for notifying the funding agency and providing documentation of such to the IACUC if any procedures will not be conducted as originally proposed.

3) In cases where the grant describes animal experiments that are not part of an approved protocol (or diverge significantly from animal experiments that have been approved) and animals have been used:
   a) The matter will be handled in accordance with Policy 11 ("Complaints of Mistreatment of Animals and Policy Noncompliance at TTUHSC").
   b) The IACUC Chair and Institutional Veterinarian will investigate and take necessary action, which may include suspension of animal use (Policy 11, Sections 5-7).
      i. If no violation or a minor violation is found, the matter will be addressed in accordance with Policy 11, Sections 6 and 7.
      ii. If a major violation is found, the matter will be referred to the IACUC Protocol Violations Subcommittee for appropriate action. The Subcommittee will report to the IACUC, which will determine final action (Policy 11, Section 7.B.).

4) In cases where a procedure is described in an approved protocol but is not described in the grant, whether or not animals have been used, the reviewer will first determine if the procedures in the protocol significantly extend or modify the scope of the grant. If necessary, the reviewer will then ask the PI for clarification or request that the protocol be amended in order to be consistent with the grant. If amended, the changes will be reported to the NIH.