TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER.
EL PASO

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**
**Policy #22**
**REVIEW OF GRANT CONTENT WITH IACUC PROTOCOL AT TTUHSC EL PASO**
In concurrence with
TTUHSC El Paso Assurance #D19-01056
and Federal Regulations and Guidelines

**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 El Paso IACUC complies with these requirements.

**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.

**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 Sponsored Programs, as follows.

1) The PI will ensure that each NIH/NSF grant submission that proposes to utilize species protected by the PHS policy will be supported by an IACUC protocol that covers the animal species and experiments described in the grant, according to the deadlines set out by the grant sponsor. For NIH/NSF applications, a 1:1 association between the grant and the approved protocol is not required; one grant may be

associated with more than one protocol and vice versa. The IACUC protocol need not describe every experiment listed in the grant at the commencement of the project, but should describe, at a minimum, an outline of the experimental study and the initial experiments that will be completed for the study. Where specific experiments listed in the grant are not included in the initial IACUC protocol, the PI should acknowledge that the protocol will be amended to include the details of the activities prior to their start.

2) When the PI receives notice that the grant will be funded, they must submit an amendment to add the funding source to the IACUC protocol. In the amendment description, they should describe which specific experiments listed in the protocol relate to the funded grant, and supply a file containing the relevant portions of the grant application (Vertebrate Animal Section and all sections of the Research Strategy describing the animal studies).

3) For NIH/NSF application, congruence review will be performed prior to the initial grant award. The requirement for congruence review prior to award is also applicable to renewal applications. Such verification can be submitted any time prior to the award unless there are any specific requirement by the funding component.

4) Once the PI is informed about the score, which may indicate that the application might fall into the funding range, the PI can request for congruency review or submit an amendment to align the experiments required for the application.

5) For just-in-time (JIT), PI can request for congruency review, but PI should be mindful of the timeline required to review any amendment that is needed to bring the protocol into congruence with the grant (see IACUC Policy #13: Protocol Approval, Implementation, Review and Amendment Processes).

6) The IACUC will send notification of the congruence approval to Sponsored Programs, so that it may be reviewed prior to the JIT pre-award submission.

7) For DoD applications, the PI may need to submit a new protocol to keep a 1:1 grant to protocol congruence for the entire funding period; the PI should be mindful of the timeline required to review a new protocol (see IACUC Policy #13: Protocol Approval, Implementation, Review and Amendment Processes).

8) For awards that require 1:1 congruence, the PI may specify a brief description of the animal activities planned for the 4th and 5th year of the award period in the IACUC protocol, in case there are changes in procedures during the 3-year renewal.

9) Since the scientific observation or derivations are not stationary, changes in animal activities are anticipated and can occur at any time during the life of the IACUC-approved protocol. If there is a change in scope after the initial congruence review prior to award, there is no requirement to conduct further congruence review. The PI should consult the funding body to obtain any necessary approvals for change in scope.

10) The IACUC Chair will designate an IACUC Member to conduct the congruency review once the PI notifies IACUC.  The PI will provide the relevant portions of the grant application (specified in point 2 above). Sponsored Programs may supply a file containing the relevant portions of the grant to the IACUC staff, if the PI is unavailable.

Information to be reviewed will include:
   a.  Scope of the study with animals – disease area, target organs, etc.
   b.  Number of animals, Species and sex
   c.  List of agents which will be administered (including anesthetics, analgesics and experimental drugs or vectors)
   d.  Techniques or procedures involved to administer the agent

Reviewed and Approved by the TTUHSCEP IACUC: 04/08/2022

e. Surgical or other procedures that will be performed on animals

f. Euthanasia Method

11) An IACUC Member will complete a timely review of the grant document(s) and the protocol and determine the general level of congruence. If no change in scope is needed, confirmation of congruency will be documented in iRIS.

12) In cases where the grant describes animal experiments that are not part of an approved protocol, the assigned IACUC Member will ask the PI for clarification or request that the protocol be amended to be consistent with the grant.

13) 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 assigned IACUC Member will first determine if the procedures in the protocol significantly extend or modify the scope of the grant. If necessary, the assigned IACUC Member will then ask the PI for clarification or request that the protocol be amended in order to be consistent with the grant.

14) The PI 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.

Related Policies Investigators must comply with all other institutional policies at TTUHSC El Paso and Federal Guidelines. This list includes, but is not limited to, the following:

IACUC Policy #0: Introduction to IACUC Policies and Procedures
IACUC Policy #7: Designated Reviews
IACUC Policy #13: Protocol Approval, Implementation, Review and Amendment Processes
IACUC Policy #20: Administrative Approval of Amendments