<div align="center">**GRANT CONGRUENCY REVIEW GUIDELINES**</div>

What is a congruency review?

A congruency review is a review of a proposal to ensure the animal activity outlined in that proposal has been approved by the Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Institutional Animal Care and Use Committee (IACUC) in an active, approved protocol as required by federal granting agencies.

It is the institution's responsibility to ensure that the IACUC has approved the proposed use of animals described in a grant application or contract proposal. This is required to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals as stated in Section V.B.

Funding agencies ask for this verification by requesting an IACUC approval date. **It is the release of the approval date that verifies to the agency that a congruency comparison has been completed.** Therefore, the approval date cannot be released until TTUHSC El Paso has verified that the proposal and the protocol(s) are congruent.

When is a congruency review required?

Congruency review is required for PHS agencies and other federal sponsors, such as, the National Science Foundation (NSF), Department of Veterans' Affairs (VA), and Department of Defense (DOD). A review will be conducted for all newly awarded federal grants before the funds are released. The requirement for congruence review prior to award is also applicable to renewal applications. Sponsored Programs (SP) will not look retrospectively at grants already on existing protocols. Contact SP with grant related questions at sponsoredprograms.ep@ttuhsc.edu.

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. For DoD applications, the Principal Investigator (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.

What do I do if my work is part of a collaboration with another institution?

If the animal work is to be completed at another institution as part of a subaward, then that institution's PI must provide the approved IACUC protocol to the TTUHSC El Paso PI. The IACUC will work with the TTUHSC El Paso PI to verify that the procedures listed in the award are approved in that institution's protocol. It is the PI's responsibility to provide the appropriate approvals from collaborating institutions. SP will coordinate with the other institution's SP for any further follow-up.

How do I get my funding released as quickly as possible?

As soon as the PI learns that he or she has a score that is likely in the fundable range, the PI should initiate the congruency review process. This is done by submitting an iRIS amendment for grant congruency review with the *Vertebrate Animal Section* & *Research Strategy* (*VAS-RS*), describing the animal studies of the funded grant, and attaching a copy of the submitted proposal. These will be reviewed. The animal studies in the proposal will be compared with the corresponding animal protocol(s).

If no relevant discrepancies are noted, the PI will receive an iRIS outcome letter which provides confirmation that the grant is congruent with the protocol(s) and will provide the approval date(s). If discrepancies are noted, the PI will be notified of the items and the PI will need to amend the protocol(s) before the approval date(s) can be provided.

NOTE: The PI is the only person on campus who receives notification of fundable scores. Therefore, it is the PI's responsibility to initiate the congruency review at this early stage. Otherwise, the review process will not start until SP receives the award documents from the sponsor. This will increase the possibility of a delay in NIH or PHS releasing the funds.

Who is conducting this congruency check?

At TTUHSCEP, congruency checks are conducted by designated IACUC member(s) (e.g. Institutional Veterinarian). Once the PI receives notification that their grant may be funded, they will need to submit the request through iRIS for the congruency review. PI's are encouraged not to wait until Just-In-Time (JIT) notification to avoid delays.

How is congruence between grant proposals and animal activity protocols verified?

Congruence will be evaluated for several important parts of protocols and proposals. The Vertebrate Animal Section and the Approach part of the Research Strategy Section are the primary areas of the grant that will be compared with the protocol. The information to be reviewed include:
- Scope of the study with animals – disease area, target organs, etc.
- Number of animals, Species and sex
- List of agents which will be administered (including anesthetics, analgesics and experimental drugs or vectors)
- Techniques or procedures involved to administer the agent
- Surgical or other procedures that will be performed on animals
- Euthanasia Method

What if I am notified that my grant is not congruent with my approved animal protocol?

SP will work closely with investigators to clarify information on the grant proposal. The IACUC will provide the PI with information needed and the PI is responsible for submitting the modifications to be consistent with the grant.

What if the animal work is not anticipated to occur until later in the award?

PHS policy requires all animal work to be covered in an approved IACUC protocol, including what will be planned for years 4 or 5 of an award. In these cases, NIH has issued guidance that only a summary of the later work is necessary to comply with this policy. This is the preferred and more expatiated method of completing this requirement. However, other options do exist:

In rare cases, IACUC review of animal activities is conducted later in the life cycle of a grant or contract. IACUC review may be delayed if the animal activities will not occur until a year or later in the award period as part of the research design described in the grant application or contract proposal (e.g., the initial development of a

drug or device with subsequent animal testing projected into the future). In these circumstances, the funding agency will issue a Notice of Award with special terms and conditions indicating that no funds may be drawn from the grant or contract for animal activities until a valid IACUC approval date and/or approved protocol has been provided to the prime funding agency or lead funding institution (when a subaward is issued).

I already obtained an approval date; can I just include it in my proposal?

Even if you received the approval date, it cannot be submitted to the funding agency until a congruency has been confirmed by the IACUC. If the proposal has not yet been reviewed and/or selected for funding, please put the word "pending" in the area that requests an IACUC approval date. Once the proposal has been selected for funding AND the final version decided upon, then a congruency request can be made to the IACUC.

References:

1. IACUC Policy #13: Protocol Approval, Implementation, Review and Amendment Processes
2. IACUC Policy #22: Review of Grant Content with IACUC Protocol
3. Notice of Clarification of Institutional Responsibilities Regarding NIH Grant to Protocol Congruence Review. Notice Number: NOT-OD-22-005
4. Notice of Clarification of Offer or Responsibilities Regarding Contract to Protocol Congruence Review. Notice Number: NOT-OD-22-006
5. PHS Policy on Humane Care and Use of Laboratory Animals