GUIDELINES ON CONGRUENCE FOR NIH FUNDED ANIMAL STUDIES

NIH REQUIREMENTS

- The NIH Grants Policy Statement states that grantee organizations must establish appropriate policies and procedures to ensure the humane care and use of animals for PHS funded projects.
- As part of any NIH award, it is the responsibility of the institution to ensure that the proposed animal activities are congruent with corresponding IACUC approved protocols.

OLAW DEFINITION OF CONGRUENCE

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

DETERMINING CONGRUENCE

- The Liberty University IACUC has determined that the best method for determining congruence is for a direct, side-by-side comparison of the awarded grant and the IACUC protocol. This is consistent with OLAW recommendations for determining congruence.

GRANT CONGRUENCE PROCEDURES FOR IACUC STUDIES

- The reviewer must determine that the scope of work is similar for the grant and the protocol.
    - Aims and objectives must be congruent.
    - Ensure that research has not shifted from one area of emphasis to another.
- The reviewer must pay careful attention to the Research Strategy and Vertebrate Animal sections of the grant when comparing it to the protocol.
    - It is likely that the grant will be less detailed in its description due to page limits.
- OLAW maintains an understanding that research processes are often fluid, and as such allows PI discretion for study methodology, as long as it is within the scope of work.
- The reviewer must compare the animal species used, the animal numbers, and procedures proposed. OLAW does not expect the review to be “at the level of a microscope”.
    - Differences in animal numbers, procedures, test agents, doses, or routes, may not be incongruent, so long as the scope of the work is similar, e.g., injection vs. drug administration by gavage, substitution of one drug for a similar drug in a related class.
    - Addition of experimental groups, procedures, agents may not be incongruent, so long as the scope of work is similar, e.g., addition of a different behavioral test to measure neurological symptoms, implantation of a mini-osmotic pump instead of daily drug injections.
    - Changes in strains, such as genetically modified animals may not be incongruent, so long as the scope of work is similar, e.g., addition of a new KO strain in the same gene of interest.
    - Change in animal species may not be incongruent, so long as the scope of work is similar (e.g., KO mouse instead of wildtype rat).
        - However, change in animal species may often signal a change in scope and must be examined more critically.

- There is no expectation that standard veterinary drugs used for analgesia, anesthesia, or euthanasia must be identical, e.g., ketamine-xylazine is used instead of isoflurane.

WHAT TO DO IF A PROCEDURE LISTED IN THE GRANT IS NOT IN THE IACUC PROTOCOL:

- The PI shall be asked for clarification. Explanations are documented in the protocol file.
- The PI may want to revise parts of the protocol to be consistent with the grant, or may want to inform NIH that procedures will not be conducted as originally proposed.

WHAT TO DO IF A PROCEDURE LISTED IN THE IACUC PROTOCOL IS NOT IN THE GRANT:

- The PI shall be asked for clarification. Explanations are documented in the protocol file.
- The PI determines if there is a change in scope (as defined by the NIH), and if so, must notify the Grants Administration.
- Conversely, the PI must notify the IACUC of a change in scope as a result of NIH review.

WHAT TO DO IF A PROTOCOL AND GRANT ARE NOT CONGRUENT:

- The non-congruent research or procedure is documented on the review sheet.
- The non-congruent research or procedure is listed on the approval letter, which is sent to NIH by the PI.

Note: Investigators must perform research reviewed and approved by the IACUC, regardless of what is written in the grant.

The NIH relies on the IACUC to both review and approve animal procedure and ensure that the research is congruent with the scope of work approved by the NIH.