

Title/Subject: **ANIMAL USE PROTOCOL AND GRANT CONGRUENCE VERIFICATION**

Applies to: faculty staff students student employees visitors contractors

Effective Date of This Revision: July 27, 2021

Contact for More Information: Office of Research and Graduate Studies - Office of Research Compliance

Board Policy Administrative Policy Procedure Guideline

BACKGROUND:

Many research sponsors including government agencies and private foundations either require compliance with PHS Policy or have their own similar policies or requirements that an institution verify IACUC approval or protocol and grant congruence prior to award.

The National Institutes of Health Grants Policy Statement (NIH GPS) defines contractual and legal obligations between a grantee institution and the National Institutes of Health (NIH). Compliance with Public Health Service (PHS) Policy is a term and condition of NIH GPS. The NIH GPS states that "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC", (NIH GPS Part II, A, 4.1.1.2).

By signing an NIH grant application, the Authorized Organization Representative (AOR), who may also be the Institutional Official (IO), commits the institution to meet the terms and conditions of the NIH GPS. The Principal Investigator (PI) submission of a grant application commits to meeting PHS Policy standards to conduct animal activities according to an approved IACUC protocol and PHS Policy. In particular, this may include ensuring congruence review is conducted as required by sponsor agencies.

PURPOSE:

This standard operating procedure defines the process for conducting congruency verification of IACUC approved protocols and their associated external grant applications. The procedure will be applied to the review of IACUC protocols related to grants from any external funding source, regardless if congruency is required by the funding source.

DEFINITIONS:

Congruence: The state achieved by coming together, the state of agreement. For the purposes of PHS Policy, congruence is agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC. Congruence is agreement rather than a requirement for an exact 1:1 match.

POLICY:

The Office of Sponsored Programs (OSP) and the Office of Research Compliance (ORC) within the Office of Research and Graduate Studies (ORGS), in cooperation with the IACUC Chair, or designee, will ensure congruence verification is conducted between any external grant application involving vertebrate animals and the associated IACUC approved protocol(s).

Authority: [leave blank]
History: [leave blank]
Indexed as:

Title/Subject: ANIMAL USE PROTOCOL AND GRANT CONGRUENCE VERIFICATION

PROCEDURE:

I. Congruency Review:

- A. If CMU is an awardee or a sub-awardee, congruence verification will be conducted as indicated in sections II through IV.
- B. In cases where (1) CMU is the prime-awardee, and (2) and portion of the research involving the use of animals will be conducted by sub-awardees or sub-contractors, the sub-awardees or sub-contractors are required to:
 - 1. Have obtained IACUC approval through the IACUC at their home institution.
 - 2. Have obtained verification from their home IACUC that the work outlined in the sub-award/sub-contract is congruent with their approved IACUC protocol.
 - 3. Verify B.1 and B.2 by signing the sub-award/sub-contract agreement.
 - a. OSP will include verbiage in the sub-award agreement contract for special requirements regarding congruence review.
 - b. Example: *“AOR signatures on this agreement confirms that, if IACUC congruency review is required by the prime sponsor, sub-recipient has verified congruence and will maintain related documentation in accord with the record retention policy of this project. A copy of the IACUC approval letter will be provided to the PTE upon execution of this agreement.”*
- C. In the event a new investigator joins the institution and brings grant funding from a prior institution, a congruence review will be performed to ensure the animal protocol is congruent with the grant application and will follow a similar process as indicated in sections II through IV.

II. Initiating Congruency Review:

- A. ORGS receives notification of a pending award or a priority score indicating that a proposal is likely to be funded, or if that doesn't occur, when an award is received.
 - 1. An email, including the grant proposal, will be sent to the IACUC Chair and IACUC Coordinator (IACUC_Admin@cmich.edu) requesting a congruency review.
 - 2. If a protocol number or title was not provided at the time of the grant application, or the protocol approval has since expired, the IACUC Coordinator will instruct the PI to provide the protocol identification, if needed.
Note: The protocol must be active for appropriate congruence verification.
 - 3. In some cases congruence verification may be time sensitive. The IACUC Chair and Coordinator may delegate congruence verification to IACUC staff, ORC Staff, or another member of the IACUC provided that the designee has appropriate knowledge and experience to conduct the review.
- B. In the event the funding will extend beyond the animal protocol approval period:
 - 1. OSP will send an email to the PI and the IACUC Chair and Coordinator regarding a grant-funded protocol that will be expiring.
 - 2. The IACUC Chair and Coordinator will determine if additional congruence verification is required based upon application information completed by the PI during the new protocol submission process.
 - 3. The IACUC Chair, Coordinator, or designee, will communicate with OSP regarding if congruence verification is not required or a determination regarding congruence review as indicated in sections III and IV.

III. Performing Congruency Review:

- A. Congruence will be defined as a reasonable matching description between the IACUC approved protocol and the grant proposal in the following six areas (developed from OLAW guidance):
 - 1. General scope of the work
 - 2. Experimental procedures and endpoints

Title/Subject: **ANIMAL USE PROTOCOL AND GRANT CONGRUENCE VERIFICATION**

3. Agents (experimental and therapeutic)
4. Species - including strain(s), if the conduct of the proposed study or the disease model is dependent on the strain
5. Approximate number of animals
6. Euthanasia method(s)

B. The information may be located in the Vertebrates Animals Section and the Research Strategy Section for PHS grant applications and by looking for the same key words in each document.

Note: Animal protocols typically contain much more detail on how procedures are carried out than is required in grant applications.

IV. Congruency Review Determination:

- A. The protocol is determined to be in congruence with the grant – the reviewer will email the OSP Post-Award Staff, IACUC Chair and Coordinator with the determination.
- B. The protocol is determined to be inconsistent with the grant (non-congruent) – an email will be sent directly to the PI or to the IACUC Chair and Coordinator indicating the concerns which may require clarification and/or amendment to their IACUC protocol.
 1. If a protocol is amended, the congruence verification will be repeated upon approval of the amendment.
 2. If the PI verifies non-congruence and determines that there is a change in scope, identified as a change in the direction, aims, objectives, purposes, or type of research or training, the PI will follow-up with the OSP post-award staff.
 3. If the PI determines that the finding of non-congruence does not represent a change in scope, a written explanation must be provided to be included with the congruency review documentation.
 - a. This explanation will be sent to Executive Director for Research and Innovation who will raise the determinations and information to the AOR for further review and determination.
 - b. Any subsequent measures will depend on the expectations or policies of the research sponsor or granting agency.