Subject: Grant Congruency Requirements

BACKGROUND

The Department of Health and Human Services (HHS), primarily through the Public Health Service (PHS) and the National Institutes of Health (NIH) is the principal funding source for research using live vertebrate animals at Wayne State University. The PHS and NIH Grants Policy requires institutions to verify, before award, that all proposed animal work has been reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). The NIH Grants Policy Statement (10/12), Terms and Conditions of NIH Grants Award (4.1.1.2 Verification of IACUC Approval) states “NIH will delay an award for research involving live vertebrate animals until the grantee organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the grantee has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals.” and “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.”

IACUC Procedure

As outlined above, grant congruency verification to ensure IACUC approval is required prior to award for all NIH grants; to maintain the highest standard of compliance and program consistency, WSU applies this requirement to all grant proposals. Funding proposals using live vertebrate animals must be reviewed by the IACUC to ensure that all of the work proposed has received IACUC approval before the award can be processed.

Because “Just-in-Time (JIT)” notification from the NIH does not allow enough time for the IACUC to process a protocol, the PI should prepare a protocol in anticipation of grant funding and secure approval even if the protocol does not have 100% congruency with all grant submissions that are in preparation or pending agency review. IACUC protocols can be amended to include a new grant preferably at the time of receiving a competitive score or immediately upon receiving a JIT notification. WSU performs grant congruency verification through the IACUC amendment (or new protocol) review process. The IACUC cannot guarantee that an amendment will be sufficient to secure approval if the grant and approved protocol are significantly different. The IACUC cannot be pressured to review protocols or amendments to fit an award schedule, although urgency can be imparted to the IACUC office so that the IACUC is aware of deadlines.

Due to Department of Defense (DoD) protocol review and approval requirements, the IACUC requires that all DoD funded research be described in its own protocol application. DoD funded protocols should remain a 1:1 document for the entire funding period.

It is the Principal Investigator’s responsibility to submit grants to the IACUC for review; this must include the cover page, research strategy, aims, and vertebrate animal sections. Sponsored Program Administration (SPA) does not submit grants to the IACUC office. The Principal Investigator (PI) is responsible for providing an IACUC approval letter to SPA prior to award. Preferably the title of the IACUC protocol should match the awarded grant (with the number) so that SPA can easily verify approval. Currently, multiple grants can be associated with one IACUC protocol; the protocol title field can accommodate multiple grant titles. The PI is also responsible for notifying the IACUC of changes in scope as a result of NIH review.

Additional References:

- PHS Policy on Humane Care and Use of Laboratory Animals Frequency Asked Questions
- PHS Policy on Humane Care and Use of Laboratory Animals
- OLAW Online Seminar “Grants Policy and Congruence” by Dr. Patricia Brown, Director OLAW