Policy 12 – Public Health Service Policy Change Affecting National Institutes of Health (NIH) Grant Applications, Awards, and IACUC Review (9/1/2002)

12.1.0 Amended Public Health Service Policy

The National Institutes of Health has amended the PHS Policy on Humane Care and Use of Animals (PHS Policy) to permit institutions with PHS Animal Welfare Assurances to submit verification of Institutional Animal Care and Use Committee (IACUC) approval for competing applications subsequent to peer review but prior to award.

12.2.0 Effective Date Of Policy Amendment

September 1, 2002 (i.e., for all applications submitted for the May-June 2003 Advisory Council dates).

12.3.0 Scope And Purpose

- IACUC verification is no longer required to be submitted prior to NIH peer review, but instead is required prior to award.
- The purpose of the change is to enhance flexibility of institutions and reduce burden on applicants and IACUCs, allowing resources to be focused on substantive review of applications likely to be funded. The change permits funding components to require verification of IACUC approval at an earlier date if necessary.

12.4.0 NIH Principles And Expectations

- The fundamental PHS Policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains unchanged. The amended policy affects only the time of the submission of the verification of the IACUC review.
• The Policy change is intended to permit flexibility and discretion on the part of the institutions. It is not a requirement that the IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to peer review in certain circumstances.

• Under no circumstances may the IACUC be pressured to approve a protocol or be overruled on its decision to withhold approval. Peer review is not a replacement for IACUC review. An institution that elects to use this policy bears the responsibility for supporting the role of the IACUC.

• It is incumbent upon the investigators to be forthcoming and timely in conveying to the IACUC any modifications related to the project and animal usage that may result from the NIH review and award process. Should the IACUC find that an investigator has disregarded his/her responsibilities, the IACUC may determine that all animal protocols from that investigator become subject to review and approval before it will permit submission of an application to the agency from that investigator.

• The existing PHS Policy requirement that modifications required by the IACUC be submitted to NIH with verification of IACUC approval remains in place, and it remains the responsibility of the University to communicate any IACUC-imposed changes to the NIH staff.

• The NIH will ensure that the University is given adequate notice to allow for timely IACUC review prior to award and will take appropriate internal measures to fulfill its responsibility to establish timely feedback.