The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)- (iv)) define the responsibilities of the Institutional Animal Care and Use Committee (IACUC) regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution’s Assurance, the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and must be consistent with the Guide unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy IV.C.1.a.-g.

According to the PHS 'NOT-OD-14-126,' institutions may establish and IACUCs may approve policies for conduct of animal activities. The institution is charged with developing the approval mechanisms, within the context of USDA and PHS boundaries. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every three years to ensure they are appropriate and accurate.

2. POLICY

IACUC approval of proposed changes to previously approved animal activities is granted after Full Committee Review (FCR), Designated Member Review (DMR), Veterinary Verification & Consultation (VVC), or Administrative Review (AR). The IACUC has some discretion to use IACUC-reviewed and -approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy IV.C.1.a.-g.

Changes requiring PI to submit Amendment for review by FCR or DMR include:

- Change from non-survival to survival surgery;
- Change resulting in greater pain, distress, or degree of invasiveness;
- Housing or use of animals at a location that is not part of the animal program overseen by the IACUC;
- Change in species;
- Change in study objectives;
- Change in Principal Investigator (PI);
- Change that negatively impacts personnel or animal health and safety;
- Addition of a new procedure (defined by broad categories such as imaging, surgery, specimen collection, test substance administration, etc.);
- Strain, stock, breed or genetic modification associated with greater pain, distress, or unusual mortality or morbidity at a stage beyond embryonic development;
- Increasing approved animal numbers by greater than 15%