1. **BACKGROUND:**
Both the Animal Welfare Act Regulations [9 CFR §2.31(c)(7)] and the *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy, IV.B.7.) require investigators to seek IACUC approval for significant protocol changes to ongoing activities using animals prior to initiation.

The PHS Policy and the Animal Welfare Act Regulations (AWAR) also require the same review procedures, either full committee review or designated member review, for proposed significant modifications in ongoing activities as for new protocols [PHS Policy, IV.C.2; AWAR, §2.31(d)(2)].

2. **POLICY:**
During the course of work on an approved protocol, changes that researchers or the veterinarian realize or expect will refine, reduce or replace the use of animals while still accomplishing approved goals can and should be done immediately without amendment with the exception of change in vertebrate species. Refine is here defined as a change that reduces animal pain or distress. In addition, researchers may elect not to perform all or any part of the research approved in a protocol without amendment unless doing so jeopardizes animal welfare or human health and safety. *Changes that are inconsequential to animal welfare or human safety, but consistent with approved goals and not appearing in this document do not require review or approval.*

**EXAMPLES OF CHANGES NOT REQUIRING REVIEW OR APPROVAL**
- Replacement of animals that die or are euthanized before research manipulations occur.
- Use of carcasses, tissues, organs, blood, eggs, etc. from animals euthanized on other approved protocols (see Appendix B of IACUC Policies and Procedures Manual) or obtained by other means.
- Decreases in number of experiments, experimental procedures or surgeries.
- Decreases in invasiveness, mutilation, tissue or organ removal or length of incision.
- Increase in the time interval between procedures or surgeries unless animal welfare is negatively affected.
- Collection or use of tissues, organs or blood from animals that are terminally anesthetized as part of an approved protocol.
- Practicing surgery or procedures on animals that are terminally anesthetized as part of an approved protocol.
- Changes in type, dose, concentration, volume, configuration or other aspect of experimentally administered substances or implants that would reasonably be expected to improve or not change animal welfare (this does not include analgesics or anesthetics).
- Change in strain, stock or breed when there is no effect on animal welfare or study objectives.
3. **Responsibilities:**

   A. GT IACUC - review modifications to protocols to ensure consistency with the provisions of this policy.

   B. GT ORIA - provides resources and guidance to the IACUC, animal research investigators, and care staff on current regulatory and laboratory animal standards in protocol review.

   C. GT Attending Veterinarian - provides resources and guidance to animal research investigators and research teams on need for protocol modification or approve insignificant changes.

   D. Animal research investigators and research teams - ensure that modifications to approved animal studies are submitted and approved by the IACUC prior to initiation and that they meet the provisions described in this policy.
4. REFERENCES:
   
   
   C. OLAW FAQ. What is considered a significant change to a project that would require IACUC review? http://grants.nih.gov/grants/olaw/faqs.htm#d9
   
   

REVISION HISTORY:

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<th>Revision Number</th>
<th>Summary of Revisions</th>
<th>Revision Date</th>
</tr>
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<tr>
<td>1</td>
<td>Update links</td>
<td>March 10, 2015</td>
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<tr>
<td>2</td>
<td>Remove of example: (Increase in animal numbers by less than or equal to 100%)</td>
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