When an Institutional Animal Care and Use Committee (IACUC) of a DoD-supported activity approves significant changes\(^1\) to an approved protocol that was administratively reviewed by the Component headquarters oversight office, the Component headquarters oversight office must review and approve those changes to the IACUC-approved protocol before they can be implemented. This document provides Animal Care and Use Review Office (ACURO) guidance for review and approval of protocol changes.

1. **Significant changes** include any changes that have, or may have, a negative impact on animal welfare. Changes that must be reviewed and approved by ACURO before they can be implemented include:

   a. Change in Principal Investigator.
   b. Addition of procedures.
   c. Change in species.
   d. Change in study objectives.
   e. Changes in anesthesia, analgesia, sedation, tranquilization, or experimental substances.
   f. Changes in euthanasia methods.
   g. Increase of animal numbers.
   h. Changes involving increased risk to personnel and/or animal safety (e.g. addition of hazardous agents)
   i. Changes in duration, frequency, type, or number of procedures performed on an animal.
   j. Change in housing and/or animal use location that is NOT overseen by the IACUC.

2. The following changes are **NOT** considered significant and do **NOT** require ACURO review and approval prior to implementation:

   a. Administrative changes, e.g. correction of grammatical and/or typographical errors, contact information, etc.
   b. Personnel changes, with exception of the Principal Investigator.
   c. Change of strain.
   d. Decrease in animal numbers.
   e. Change in housing and/or animal use location that is overseen by the IACUC.

3. For questions regarding submission of protocol changes, please contact the ACURO Office Manager by e-mail: usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil or phone: (301) 619-6694.

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\(^1\)Significant changes are commonly referred to as major modifications or major amendments.