1. **Purpose**

The purpose is to establish a policy on approving significant changes to activities on Animal Use Protocols at North Carolina Central University (NCCU). The impetus for establishing this policy is based on the Guidance on Significant Changes to Animal Activities issued by the National Institutes of Health on August 26, 2014 in [Notice NOT-OD-14-126](#). The Notice was released to provide guidance on to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on significant changes to animal activities.

2. **General Principles**

2.1 The 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. IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after full committee review (FCR) or designated member review (DMR).

2.2 Institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. 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.

3. **Significant Changes to Animal Activities Previously Approved by the IACUC**

---

**REG - 50.02.1 - SIGNIFICANT CHANGES TO ACTIVITIES ON PROTOCOL FOR THE USE OF LIVE VERTEBRATE ANIMALS FOR RESEARCH, TESTING, OR EDUCATION**

<table>
<thead>
<tr>
<th>Authority: Chancellor</th>
<th>Responsible Office: Division of Research and Sponsored Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number: REG - 50.02.1 - SIGNIFICANT CHANGES TO ACTIVITIES ON PROTOCOL FOR THE USE OF LIVE VERTEBRATE ANIMALS FOR RESEARCH, TESTING, OR EDUCATION</td>
<td></td>
</tr>
<tr>
<td>History: Effective Date: 12/01/2015</td>
<td></td>
</tr>
<tr>
<td>Related Policies/Sources: HHS NOT-OD-14-126, Public Health Service Policy on Humane Care and Use of Laboratory Animals,</td>
<td></td>
</tr>
<tr>
<td>Contact Info: Animal Resources Complex, 919-530-7023</td>
<td></td>
</tr>
</tbody>
</table>
3.1 The following significant changes will be approved by one of the valid IACUC approval methods (FCR or DMR):

3.1.1 Change from non-survival to survival surgery

3.1.2 Change resulting in greater pain, distress, or degree of invasiveness

3.1.3 Change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC

3.1.4 Change in species

3.1.5 Change in study objectives

3.1.6 Change in Principal Investigator (PI)

3.1.7 Changes that impact personnel safety

3.2 The specific significant changes listed below, may be handled administratively according to IACUC reviewed and approved policies in consultation with a veterinarian authorized by the IACUC. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC reviewed and approved policies.

3.2.1 This includes changes in:

3.2.1.1 anesthesia, analgesia, sedation, or experimental substances

3.2.1.2 euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals

3.2.1.3 duration, frequency, type, or number of procedures performed on an animal

3.2 One significant change that may be handled administratively according to an existing IACUC reviewed and approved policy without additional consultation or notification is an increase in previously approved animal numbers (PHS Policy IV.D.1.a.).

4. Minor Changes

4.1 Changes to be handled administratively without IACUC approved policies, consultations, or notifications include:

4.1.1 Correction of typographical errors

4.1.2 Correction of grammar

4.1.3 Addition of PI and Supervisor signatures

4.1.4 Contact information updates

4.1.5 Change in personnel, other than the PI. (There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)

4.2 Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.