Significant Changes to Previously Approved Animal Activity

**Background:** Animal Welfare Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require the Animal Care and Use Committee to review and approve significant changes regarding the use of animals in ongoing activities previously approved by the Animal Care and Use Committee. Significant changes have potential to impact substantially and directly on the health and wellbeing of the animals.

The following list was compiled by the Office of Laboratory Animal Welfare as examples of significant changes:

1. Changes in the objectives of the study
2. Proposal to switch from non-survival to survival surgery
3. Changes in the approximate number of animals used
4. Changes in personnel involved in animal procedures
5. Changes in anesthetic agents
6. The use or withholding of analgesics
7. Methods of euthanasia
8. Changes in duration, frequency or number of procedures performed on the animal
9. Changes in the degree of invasiveness of a procedure or discomfort to an animal
10. Change from adult to juvenile or juvenile to adult

This is not an exhaustive list. Whether or not other modifications are significant is determined by several factors. When in doubt consult the Animal Care and Use Committee or a veterinarian before instituting any changes.

In writing your protocol, try to anticipate procedural changes that fall in the categories above and incorporate them in the original protocol them explicitly in the original protocol to avoid having to write numerous amendments.

All significant changes to previously approved activity must be reviewed and approved by the Animal Care and Use Committee before they can be instituted.

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2 9 CFR Subchapter A § 2.31 (c) 7
3 PHS Policy IV. B. 7.
4 [http://grants1.nih.gov/grants/olaw/references/lab95.htm#1](http://grants1.nih.gov/grants/olaw/references/lab95.htm#1)