Significant Changes to Previously Approved Animal Activity

Background: Animal Welfare Regulations\(^2\) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require the Animal Care and Use Committee\(^3\) 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\(^4\):

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. Change in species (Note- a change in strain is not considered significant)
5. Change in Principal Investigator
6. Changes in personnel involved in animal procedures
7. Changes in anesthetic agents
8. The use or withholding of analgesics
9. Methods of euthanasia
10. Changes in duration, frequency or number of procedures performed on the animal
11. Changes in the degree of invasiveness of a procedure or discomfort to an animal
12. 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.

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\(^1\) Approved by the Animal Care and Use Committee: September 19, 2002; Revised July 24, 2007, reviewed September 25, 2012, modified July 24, 2013.
\(^2\) 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)
All significant changes to previously approved activity must be reviewed and approved by the Animal Care and Use Committee before they can be instituted.