

## Guideline Regarding Significant Changes to Animal Study Proposals

The Animal Welfare Regulations and the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), which implements the Health Research Extension Act of 1985, require that Animal Care and Use Committees (ACUCs) review and approve significant changes regarding the use of animals in on-going activities described in an ACUC approved Animal Study Proposal (ASP). The NIH interprets significant changes to mean those that have the potential to impact substantially and directly on the health and well-being of the experimental animals, and thus need review and approval by the ACUC. To aid the ACUCs in fulfilling their responsibilities regarding changes in approved Animal Study Proposals (ASP), the NIH Animal Research Advisory Committee (ARAC) offers the following examples of changes that should be considered significant:

1. A change in the overall aims or objectives of the study;
2. A change which may involve an increase in the levels of pain, distress, and/or discomfort;
3. A change from non-surgery to surgery, from minor to major surgery, from non-survival to survival surgery, or from single to multiple survival surgery;
4. An increase (greater than 5%) in the approximate number of animals used;
5. A change in the genus or species of animals used;
6. A change in the principal investigator for an ASP<sup>1</sup>; or
7. The addition of the use of hazardous agents in animal procedures.

This list of examples is not meant to be comprehensive. Whether or not other modifications are significant is determined by several factors. It should be understood that changes covering details beyond what is required in the original ASP are not to be considered significant, and do not need ACUC review and approval. In this regard each ACUC should specify the level of detail it requires for the evaluation of procedures involving animals. Inclusion of trivial details, especially those that cannot be reliably anticipated, or may need to be altered, should be discouraged.

To fulfill their responsibilities regarding review of changes in previously approved ASPs, and to perform that review expeditiously, ACUCs may find it useful to designate one member, (e.g. the Chair or the Animal Program Director), to determine the significance of other intended changes within the context of that ASP. Minor changes, not deemed significant, such as changes in trained personnel performing animal activities<sup>1</sup>, which are then reviewed and approved by the designated reviewer(s) should be reported to the ACUC at its next regular meeting.

ACUCs may further require principal investigators to report minor changes to update an ongoing ASP.

Reference:

1. NIH Guide Notice OD-03-046, June 6, 2003 - OER Revised Guidance Regarding IACUC Approval of Changes in Personnel Involved in Animal Activities

APPROVED: June 16, 1992 - NIH Animal Care and Use Committee

Reapproved - 5/8/96.

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