

Guidelines Regarding Modifications to Animal Study Proposals

In accordance with the *Animal Welfare Act Regulations*, *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, and the *Guide for the Care and Use of Laboratory Animals*, the Frederick National Lab Animal Care and Use Committee [ACUC] is responsible for reviewing changes to approved Frederick National Lab Animal Study Proposals. Therefore, investigators are required to notify the ACUC [via modification memorandum or email] with proposed changes to his/her study for review and approval in advance of implementation. For all requested modifications, the study objectives must be related to the parental study or a new ASP submission will be required. The following list of modification examples has been provided for guidance:

- Changes in personnel involved with the ASP. If any individuals will be in contact with live animals, the PI must detail the procedures that they will be conducting and their experience;
- Any change or addition to the experimental design involving live animals [i.e., experimental manipulations, blood collections, surgical procedures, endpoints, euthanasia method, tissue collections, etc.];
- The addition of study groups or experiments that relate to the original ASP study objectives;
- An increase in the estimated number of animals to be used;
- A change in the species of animals used [related to the original ASP study objectives];
- The addition [or change in administration] of hazardous/experimental agents;
- Change in Principal Investigator;
- Addition of or change in location where animals will be housed.

The addition of cell lines [with the appropriate viral test results appended], biologicals, and other agents can be added via the "[Frederick National Lab Addition of Agents and Cell Lines](#)" addendum form. This form is reviewed and approved by the ACUC Safety Representative and the IBC [as applicable] and applies to the addition of agents only; any additional changes to the ASP [as listed above] must be submitted via separate modification.

This list is not meant to be comprehensive. Please contact the ACUC Coordinator [301-846-7544 or stahlam@mail.nih.gov] if there are any questions regarding changes to your approved ASP. Modifications are submitted for designated member review [please refer to *Guidelines for the Designated Member Review and Expedited Review Process*].