

## *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 NCI-Frederick Animal Care and Use Committee [ACUC] is responsible for reviewing changes to approved NCI-Frederick 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:

- 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;
- 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.
- A change or addition to the strain(s) of animals covered under the proposal;
- The addition of cell lines with the appropriate MAP and Human Pathogen test results appended;
- The addition or change of animal holding/research locations.

This list is not meant to be comprehensive. Please contact the ACUC Coordinator (301-846-7544 or [ahaltm@ncifcrf.gov](mailto:ahaltm@ncifcrf.gov)) if there are any questions regarding changes to your approved ASP. Modifications are either reviewed at the ACUC monthly meetings or submitted for designated member review [please refer to *Guidelines for the Designated Member Review and Expedited Review Process*]. Please refer to the ACUC submission deadline dates for those modifications requiring review at monthly meetings.