IACUC Protocol Task Force Document 1

Guidance on Avoiding Excessive Amendments to IACUC Protocols

Examples of alterations that would not require a protocol amendment

- Addition of a new variant of an already approved investigational drug group as long as it is expected to have similar properties to what is already approved in the protocol
- Addition or change in an animal strain or strain combination that is not expected to require additional animal numbers or result in increased animal welfare concerns. (Example replacing one Cre-expressing mouse strain with another)
- Addition of post-mortem tissue collection or changes to the tissues collected for non-act species animals

Tips to streamline submission of protocol amendments:

- Use Standard procedures whenever possible
- If you have generated a team procedure that will be used across multiple protocols/groups, contact the IACUC office to inquire about promoting this to a Standard Procedure.
- Use categories, classes, or families of investigational drugs in original approvals rather than listing every potential variant of a class.
- Provide dose ranges for substance administration, including concentration and volume ranges, whenever possible.
- List ranges for frequency of substance administration or procedure performance when possible and allowable within the experimental design (example: 3 times over the first two weeks, with a minimum of two days between each time point versus specifying injections will be on days 5,7,13).
- Include more than one choice for agents such as analgesia and anesthesia when applicable.
- Provide flexibility in procedures such as euthanasia and blood collection by including more than a single method as appropriate.
- Provide ranges for the total number of tissue collections, substance administrations or other routine procedures (example 4-7, not 6).