**Major vs. Minor Protocol Amendments**

In an attempt to help Iowa State University investigators determine what course of action is necessary when making amendments to an existing IBC (Institutional Biosafety Committee) protocol, the IBC has generated three lists of examples. These lists are in no way complete and are shown here only as a guide to help investigators make informed decisions when amending existing protocols.

***Please note****: A change in Principal Investigator (PI) is not an amendment but rather, requires submission of a new Protocol.*

The following is a list of amendments that the Institutional Biosafety Committee (IBC) deems to be **major** and, as such, require **submission of an “Amendment” by the PI** (via a-tune) and **review and approval by the IBC** (*Please note: If the changes are considered significant enough, the IBC may require submission of a new application*):

1. Adding a new organism or toxin.
2. Changing aspects of the recombinant or synthetic nucleic acid molecules (e.g., host, host range, nature of DNA, etc.).
3. Addition of a new biohazardous material.
4. Changing or adding objectives to the study.
5. Changing the biosafety level of a study.
6. Changing the species of animal or plant to be used.
7. Changing the inoculation route of a human pathogen.
8. Moving isolates from long term storage to active research.

The following is a list of amendments that the IBC deems as **minor** and, as such, require **submission of an “Amendment” by the PI** (via a-tune) for review and **approval by the IBC Chair and Biosafety Officer:**

1. Changes in personnel other than the principal investigator. When adding personnel, list their role/duties on the project and list their training.
2. Adding a new transgenic line to the protocol. (Species must already be approved, and currently approved biosafety level and NIH Guidelines do not change with this addition.)
3. Changing the supply source of animals.
4. Changing the campus housing location or laboratory location~~.~~
5. Changing the disposal of animals, plants, and culture.
6. Changing the inoculation route of a non-human pathogen.

The following is a list of items for which the IBC does not require submission of an amendment or a new protocol as the changes do not alter the biosafety aspects of the study:

1. Adding more animals of the same species already approved on the protocol.
2. Collection of additional IBC-approved samples that may contain infectious agents/recombinant or synthetic nucleic acid molecules, etc.
3. Transferring mice from an exempt breeding colony to an exempt study protocol.
4. Changes in personnel (except a change in PI) on an exempt study.
5. Receiving isolates and placing them in long-term storage, unless they are select agents. Make sure to update the biological materials inventory with EH&S.