IBC Guidance for when to submit a new protocol or when to amend an existing protocol

When an amendment is likely appropriate:

- Adding new species/strains of animals for the same work.
- Adding a non-viral vector to an approved recombinant DNA protocol
- Adding new genes of interest that are not tumor suppressors, oncogenes, or that would enhance the virulence of an organism
- Adding new recombinant DNA to a protocol already approved for recombinant DNA work that doesn’t change the biosafety risk mitigation (e.g., adding fluorescent protein expression)
- Adding new samples types to a protocol already approved for similar materials (e.g. adding a different tissue to a protocol already approved for human source material, changing sites for wastewater collection)

When a new protocol is appropriate:

- If the biosafety risks are different from your existing protocol? (adding a new type of pathogen or adding human source material such as primary cells or sera)
- If a new agent or recombinant DNA changes the risk mitigation strategies from your existing protocol? (e.g., adding virus work such as adenovirus or lentivirus vectors to an existing protocol)
- If you offer services as a core facility or biorepository and have personal research projects.
- If the scope of the project has changed
- If the project adds recombinant DNA (e.g., CRISPR genome editing, gene expression modulation systems) to a project not currently approved for recombinant DNA

In these situations, a new protocol will be preferred over amending an existing protocol. If you are not sure then please contact IBCinfo@osu.edu for additional assistance by providing a brief summary of the changes proposed.

Amendments with significant changes and new protocols go through the same process and review. Therefore, the time duration for review will not differ between the submission of an amendment to an existing protocol or creation of a new protocol for the work.