How to submit a new amendment to an IACUC Protocol

If you decide to change anything about your project once it has been approved, you must submit an "Amendment to an Approved Protocol" form and also revise each form that was part of the original submission if information contained in them will be changed. This includes the "UMCP – IACUC Animal Study Protocol" smart form, where appropriate (ie., adding animals or animal numbers, or changing species, pain categories, method of euthanasia, or exceptions to *The Guide*). **The goal is to have the amendment stand alone as much as possible, which will speed up the approval process**.

NOTE: If your amendment includes any changes in animal species, animal numbers, pain category, literature search, experimental conditions requiring exceptions from the *Guide*, or method of euthanasia, **you must submit a revised version of your UMCP – IACUC Animal Study Protocol (ASP) form** with your amendment package.

To submit a new amendment for review and approval

1. To amend a protocol, log in to IRBNet, select "My Projects" from the left menubar, and select the protocol you'd like to amend.
2. Click on "Designer" either in blue in the middle of the page or on the lefthand menubar.
3. On the next page, click "Create New Package." (You should create a new package for each amendment you submit.)
4. At the top of the next screen, under "Step 1," select the IACUC library in the first drop-down menu, then select "Amendment" in the second drop-down menu. Click "Download."
5. This downloads a template "Amendment to an Approved Protocol" form to your computer.
6. Using the downloaded form, fill out the reason for your requested change to the protocol and other details as required. **A one or two sentence description at the beginning is extremely helpful** (e.g., "Request to add a new species" "Request to add animal numbers") Save this document to your desktop.
7. In the upper blue box, use the pulldown menu to select "Amendment" from the list of options.
8. Type a description of the amendment in the box.
9. Click "Choose File" - select the amendment file from your desktop that you have filled out and saved.

10. Click "Attach" – this will upload the amendment form to the package.
11. If your amendment requires changes to the protocol form (as described above), you must add a new ASP. You may do this by cloning a previous version and updating it to reflect the new information. Under Step 2 on the **Designer** page, click the "Add New Document" button.
12. Select "UMCP – IACUC Animal Study Protocol" from the lower blue box and click Add.
13. You will see a prompt "What would you like to do?" To clone an ASP, select "Clone one of my existing wizards."
14. A listing of your previous protocol ASPs will appear. Select the ASP you want to clone and click Continue.
15. The ASP wizard comes up, - from here you can "Jump" to the sections of the ASP you need to edit (e.g., for a change in animal numbers, jump to Animal Information, adjust the total number of animals there).
16. Save and exit.
17. On the left menubar, click "Sign this Package" and sign it.
18. Finally, click "Submit this Package" on the left menubar, select the IACUC, and click "Continue" to submit.

NOTE: Once a package is submitted, it is locked and cannot be modified without being unlocked by an IACUC administrator. Please do not submit until all documents are complete. In the event you accidentally submit the package before it is ready to be reviewed by the IACUC, please contact the IACUC staff immediately to request your package be unlocked. Be ready to provide the IRBNet ID number.

NOTE: If you are unsure about an amendment, please feel free to contact the IACUC office or the University Attending Veterinarian for advice on any procedure or submission process. This will allow you to take care of many problems before the protocol is reviewed, and will likely expedite the approval process.