Submission Procedure for iRIS-Submitted Proposal Modifications

Notes to PI/IACUC Protocol Manager
- Changes to the Principal Investigator, must use the "Click here to add or remove personnel" form.
- To add or remove Proposal participants, it is recommended you must use the "Click here to add or remove personnel" form.
  - Because this form can be administratively approved, it is usually much quicker than a full modification review for a simple addition.
  - If you are making other changes to the body of the modification, participant changes (other than PI changes) may be made with these modifications. Personnel Additions made through a modification will not be approved until the full modification is approved.

1. Log into iRIS at https://iris.louisville.edu/.

2. Click [Study Assistant].
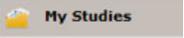
3. Click [My Studies]. You will be directed to the "My Studies" page.

4. Navigate to the approved Proposal to be modified and click under "Click to open". You will be directed to the "Submissions" page.

5. Under the heading "IACUC Forms", hover over and click [Click Here to Modify an Approved IACUC Protocol]. You will be directed to the "Click Here to Modify an Approved IACUC Protocol" page.

6. Click [Add a New Form]. You will be directed to the "Modification of an Approved Proposal" page.

7. Please check to make sure the information is correct in Section 1.1 Proposal Information. If any of the information is incorrect, please notify the IACUC office by calling 852-7307 or sending an email to iacuc@louisville.edu stating the information which is incorrect. Please note that the Proposal Title can be changed during the modification process and should be submitted with the modification request.

8. In Section 1.2 Type of Modification, place a check in each box for the different types of modifications requested.

9. In Section 1.3, type in a brief description/rationale for the requested changes. This will serve as the cover letter.

10. In Section 1.4, click [Click here to attach the application.]. A pop-up window will appear.
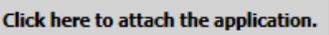
11. In the "Attaching Study Application" page, click [Add Revision].
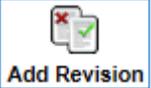
12. Confirm that you want to create a revision by clicking "OK", "Yes", or other affirmation provided by your browser. A new, unapproved version of the approved Proposal will appear.

13. Staying in the "Section View of Application," make all necessary revisions to the Proposal in each appropriate section. Remember to save the section prior to moving on to a different section.

14. Once all appropriate sections have been modified, navigate to and click Section 31 "End of Form".

15. Click [Save and Continue to Next Section]. You will be directed back to the Modification form.

16. Verify that the new version of the Proposal appears in Section 1.4 as in this example:

Remove	Show Rev.	Edit/ View	Version	Title
❌	📁	📝	1.5	IACUC Application (Version 1.5) - Attached

17. In Section 1.5, you have the option to attach any other study documents for IACUC review (e.g., SHAD, humane endpoint criteria). Click "Add a New Document" to attach a document that has not previously been uploaded to iRIS; click "Select or Revise Existing" to attach a document already associated with this protocol.

18. Click [Save and Continue to Next Section] at the top of the page. You will be directed to the "Form has been Completed!" page.

19. Click [Signoff and Submit]. You will be directed to the "Submission Routing Signoff Sheet" page. Navigate through the submission routing signoff until you have the option to [Approve] to approve the submission.

20. Enter your Ulink UserID and Password in the required locations.
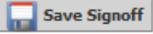
21. Click [Save Signoff]. You are finished!

22. Your modification submission is sent to the IACUC office for processing and review.

23. If stipulations are sent back for any part of the modification to be clarified, refer to the stipulation response instruction sheet found on the IACUC website: http://louisville.edu/research/iacuc/protocol-management