Revised: July 2021



INSTRUCTIONS: SUBMITTING A REVISION & PROGRESS REPORT (IRB & IACUC)

Submit a revision to the IRB (research with human subjects) or IACUC (research with animals):

A revision (or amendment) may be submitted when a researcher would like to make changes to an already approved project. Any changes to an approved project *must* be reviewed by either the IRB or IACUC and approved before changes may be implemented.

Submit a progress report to the IACUC:

Progress reports are required *only* for IACUC submissions. Please use the Annual Progress Report form for the first and second progress report of an approved animal protocol. *Note*: The third-year renewal of an approved animal protocol requires submission of a new application for full-committee review. Progress reports must be signed and submitted using IRBNet. If modifications to the protocol are required at this time, please complete an Amendment form. In order to make changes to the protocol, please download the Amendment Form and follow the instructions provided. Amendment requests must be submitted separately – no changes to the approved protocol can be made on the Annual Progress Report form.

- 1. Login to IRBNet (www.irbnet.org). This will take you to the 'My Projects' page.
- **2. Select the Project to Revise.** Click on the title of the project that you would like to revise. Then click on '**Project History**' located on the left-side of the screen.
- 3. Create a New Document Package. Click on 'Create New Package' in the center of the Project History page, and then click on 'New Document Package'.
- **4. The Designer Page.** You will now be on the **Designer** page. You can access this page at any time by clicking on '**Designer**' on the left-side of your screen. From here, you can either upload newly revised documents for your project or you can 'update' a document that was submitted with your original project.

Note: Please highlight any revisions on your application and associated materials as this makes it easier for the IRB and IACUC to locate your revisions within your document(s).

- A. <u>Upload a revised document</u>: Click on 'Add New Document'. Browse for your revised documents and any other relevant files from your computer and click 'Attach'.
- B. <u>Update a document</u>: Documents from a previous package will be listed under the 'Documents from Previous Packages that you can Revise' header. Click on the pencil icon in the row of the document you wish to update. Browse for your revised document and click 'Update'. This will swap out the original document for a revised document. You should

now see that your 'updated' document will now be listed under the 'New and Revised Documents in this Package' header. If there are no other documents from your original package that can be revised, the 'updated' document will instead be listed in the 'Documents in this Package' section of the page.

- C. <u>Attach the Appropriate Form for Review</u>: The appropriate form(s) to submit will depend on if you're submitting to the IRB (research with human subjects) or IACUC (research with animals). Please see below for the form needed for either the IRB or IACUC.
 - If submitting a revision to the IRB: Submit the 'Revising an Approved Study' form.
 Download the form template from the document library. Select 'Fort Hays State University IRB, Hays, KS' from the "Select a Library" drop-down menu. Next, select the 'Revising an Approved Study' and click 'Download'. Upload the completed revision form and related documents. From the Designer screen, upload documents for your project in the Step 4 section of the page by clicking on 'Add New Document'. Browse for your completed revision form and click 'Attach'.

*If the revisions you are submitting will change other documents previously submitted (e.g., application, consent form, information statement, etc.) you must include these revised documents along with the revision form. You can do this using the same procedure as outlined in Step 4. Please make sure all revisions are highlighted.

• If submitting an amendment or progress report to the IACUC: Submit the appropriate 'Amendment' or 'Progress Report' form. Download the form template from the document library. Select 'Fort Hays State University Institutional Animal Care and Use Committee, Hays, KS' from the 'Select a Library' drop-down menu. Next, select the appropriate form (Amendment or Progress Report) and click 'Download'. Upload the completed form and related documents. From the Designer screen, upload documents for your project in the Step 4 section of the page by clicking on 'Add New Document'. Browse for your completed amendment or progress report form and click 'Attach'.

*If the revisions or progress report you are submitting will change other documents previously submitted (e.g., application) you must include these revised documents along with the revision or progress report form. You can do this using the same procedure as outlined in Step 4. Please make sure all revisions are highlighted.

- **5. Share this Project.** If you have not done so already, share the project with your research team or faculty research advisor. Click '**Share this Project**' located on the left-side of your screen. Click on the blue '**Share**' link within the text to grant access to this project.
 - **A.** Select 'Fort Hays State University' from the organization box. Then click 'Select Organization'. If the individual is not affiliated with FHSU, select the organization under which they registered with IRBNet.
 - **B.** Search for registered users with whom you would like to share this study (i.e., your faculty research advisor, co-PIs, research assistants, consultants). Grant each user a level of access:
 - Full: User may add/edit/delete study documents, share the study with other users, and submit the study. Individuals with full access to a study will receive auto-notification when

- an action has been taken regarding the study. It is recommended that students give this level of access to their faculty research advisors.
- Write: User may add/edit/delete study documents, but cannot share the study with other users or submit the study.
- Read: User may only view the project documents.
- **C.** Selected users will be notified via email that the project has been shared with them. You may enter comments to be included in this email in the 'Your Comments' section. Click 'Save'.

Note: If the individuals you are seeking are not in the list of registered users, please ask them to register with IRBNet.

6. Sign the Project.

- <u>If submitting to the IRB</u>: Principal Investigators (and faculty research advisors, if the PI is a student) <u>must</u> sign the studybefore it is submitted.
- If submitting to the IACUC: Principal Investigators must sign the study before it is submitted. Faculty must sign as the PI; students may not sign as the PI.
- **A.** Click on 'Sign This Package' located on the left-side of your screen. Select your role from the drop-down menu, and then click 'Sign'.

Note: A designee may NOT sign for the PI. Studies will not be scheduled for review if required signatures are missing.

- 7. Submit your Study. Once you have attached all of your necessary documents and signed your study, you should be readyto submit your study. Click on 'Submit this Package' located on the left-side of yourscreen.
 - If submitting to the IRB: Make sure that 'Fort Hays State University IRB, Hays, KS' is highlighted in the 'Select a Board' box. If it's not, type in the word "Fort" in the 'Search for an Organization' box and click 'Search'. Click 'Continue'. In the 'Submission Type' drop-down menu, select 'Revision' and click 'Submit'.
 - If submitting to the IACUC: Make sure that 'Fort Hays State University Institutional Animal Care and Use Committee, Hays, KS' is highlighted in the 'Select a Board' box. If it's not, type in the word "Fort" in the 'Search for an Organization' box and click 'Search'. Click 'Continue'. In the 'Submission Type' drop-down menu, select 'Revision' and click 'Submit'.

NOTE: The '**My Projects**' screen (located on the left-side of your screen) will show you the list of studies to which you have access – those you have created and those which have been shared with you at any level of access. Studies that have not been submitted are labeled '**Work in Progress**.' Studies that have been submitted but not reviewed are labeled '**Pending Review**.' Clicking on the title of any study will take you to the Project Overview for the selected study. If you need further assistance with this process please contact the Research Compliance Administrator (IRB@fhsu.edu or IACUC@fhsu.edu).