FORT HAYS STATE UNIVERSITY

Forward thinking. World ready.

INSTRUCTIONS:
SUBMITTING REQUIRED MODIFICATIONS
(IRB & IACUC)

When modifications are required for approval:
A project has been reviewed and was *not* approved by the IRB (research with human subjects) or IACUC (research with animals). Before approval can be granted, the IRB or IACUC require changes or clarifications to the research protocol. The IRB or IACUC must review and approve the modifications before your research will be allowed to proceed.

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1. **Login to IRBNet (www.irbnet.org).** This will take you to the '**My Projects**' page.

2. **Select the Project to Modify.** Click on the title of the project that you would like to modify. 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 modified documents for your project or you can 'update' a document that was submitted with your original project.

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

5. **Upload Documents.** 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 modified document and click '**Update**'. This will swap out the original document for a modified document. You should now see that your '**updated**' document will 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.

   To add a new document, from the **Designer** screen click on **'Add New Document'**. Browse for any other documents containing information or modifications requested by the IRB or IACUC and click **'Attach'**.

   > *Note*: If the required modifications will impact or change other documents that you've previously submitted, you must include these additional modified documents. You can do this using the same procedure as outlined above.

6. **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 actionhas 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 automatically 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.

7. **Sign the Project.**
   - **If submitting to the IRB:** Principal Investigators (and faculty research advisors, if the PI is a student) must sign the study before 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.

8. **Submit your Study.** Once you have attached all of your necessary documents and signed your study, you should be ready to submit your study. Click on **'Submit this Package'** located on the left-side of your screen.
   - **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 '**Modification/Amendment**' and click '**Submit**'.

- **<u>If submitting to the IACUC</u>**: 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 '**Modification/Amendment**' 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).