FORT HAYS STATE UNIVERSITY
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OFFICE OF SCHOLARSHIP AND SPONSORED PROJECTS

INSTRUCTIONS FOR SUBMITTING REQUIRED MODIFICATIONS

What it means when modifications are required for approval…

A project has been reviewed and was not approved by the IRB. Before approval can be granted, the IRB requires changes or clarifications to the research protocol. These IRB must review and approve the modifications before your research will be allowed to proceed.

1. Login to IRBNet (www.irbnet.org).

This will take you to 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 the '**Project History**' button located on the left-hand side of the screen.

3. Create a New Document Package

Click on the '**Create New Package**' button 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 the '**Designer'** button on the left-hand side of your screen. From here, you can either upload modified documents or update a document that was submitted with your original proposal.

> * Please make sure that all modifications to your documents are highlighted as this makes it easier for the IRB to locate the modifications within your document(s).

5. Upload Documents

Documents from a previous package will be listed underneath the "Documents from Previous Packages that you can Revise" header within the Step 2 section of the page. 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 the revised document. You should now see that your updated document will now be listed underneath 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. From the Designer screen, click on **'Add New Document'**. Browse for any other documents containing information or modifications requested by the IRB, including revised documents or any other relevant files from your computer and click '**Attach**'.

* If the modifications you are requesting will affect other documents that you've previously submitted (i.e. narrative, informed consent document, etc.) you must include these other modified documents . You can do this using the same procedure as outlined above in Step 5.

5. Share this Project

If you have not done so already, share the project with your research team. Or faculty research advisor. Click the '**Share this Project**' button located on the left-hand 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'd like to share this study (i.e., your Faculty Sponsor, co-PIs, research assistants, consultants). Grant each user a level of access:

i. 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 student and non-affiliated PIs give this level of access to their Faculty Research Advisors.*

ii. Write: user may add/edit/delete study documents, but cannot share the study with other users or submit the study.

iii. Read: user may only view the project documents.

* If the individuals you are seeking are not in the list of registered users, please ask them to register with IRBNet. Instructions on registration may be found here:

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**'.

6. Sign the project.

Principal Investigators (and Faculty Sponsors, if the PI is a student) **must** sign the study before it is submitted.

A. Click on the '**Sign This Package**' button located on the left-hand side of your screen. Select your role from the drop-down menu, and then click '**Sign**'.

* The lead researcher should sign as "Principal Investigator". A designee may NOT sign for the PI.

* The Faculty Research Advisor should sign as the "Advisor." A designee may NOT sign for an Advisor. It is the student's responsibility to contact their Faculty Research Advisor when the study is ready for his/her signature. **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 ready to submit your study. Click on the '**Submit this Package**' button located on the left-hand side of your screen.

A. Make sure that Fort Hays State University 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**'.

B. In the Submission Type drop-down menu, select '**Modification/Amendment** and click '**Submit**'.

General Information:

My Projects (can be found by clicking on the My Projects button located on the left-hand 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" in the Status column. Studies that have been submitted but not reviewed by the IRB 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 Research Compliance at 785-628-4349 or lpaige@fhsu.edu