FORT HAYS STATE UNIVERSITY
Forward thinking. World ready.

OFFICE OF SCHOLARSHIP AND SPONSORED PROJECTS

INSTRUCTIONS FOR SUBMITTING A REVISION

What it means to submit a revision…

A study has been reviewed, and approved by the IRB. The researcher requests changes to the approved protocol.

These changes must be reviewed and approved by the IRB before they may be implemented in the project.

The following instructions are for studies that originated on IRBNet.
(If your project originated on paper, please proceed to page 3.)

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 the '**Project History**' button located on the left-hand side of the screen.

3. Create a New Document Package

Click on '**Create New Package**' button in the center of the Project History page, and then click on '**Designer**'.

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 newly revised documents for your project or you can 'update' a document that was submitted with your original project.

> * Make sure that all revisions are highlighted as this makes it easier for the IRB to locate your revisions within your document(s). **Please note that studies will not be scheduled for review unless the revisions are highlighted.**

A. *Upload a revised document:* Click on **'Add New Document'** button located within the Step 2 section of the page. Browse for your revised documents and any other relevant files from your computer and click '**Attach**'.

B. *Update a document:* 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 a 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.

C. Attach the FORM REVISING AN APPROVED STUDY
Down load the form template from the document library. **Select "Fort Hays State University" from the "Select a Library" drop down menu.**

Next, select the "FORM REVISING AN APPROVED STUDY" and click "Download". Fill in the necessary information and choose File>Save As" to save the document to your computer.

Upload the Completed Revision Form and related documents. From the Designer screen, upload documents for your project in the Step #2 section of the page by clicking on **'Add New Document'**. Browse for your completed IRB Modification Form and click '**Attach'.**

If the revisions you are submitting will change affect other documents previously submitted (IRB application, consent form, etc.) you must include these revised documents along with the IRB Revision form. You can do this using the same procedure as outlined in Step 5. Please make sure all revisions are highlighted in some manner.

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 Research Advisor, 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 students 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.

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**'.

* 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:

6. Sign the project.

Principal Investigators (and Faculty Research Advisors, 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 '**Revision'** and click '**Submit**'.

General Information:

The My Projects screen (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 the Office of Scholarship and Sponsored Projects at 785-628-4349 or lpaige@fhsu.edu

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SPECIAL INSTRUCTIONS FOR STUDIES THAT WERE ORIGINALLY SUBMITTED AS PAPER

****As of April 14, 2009, the IRB stopped accepting submissions on paper.**
The following instructions are for studies that originated on paper.**

1. Have you registered with IRBNet?

If not, follow the Instructions for New Users . If you have already registered, please proceed to Step 2.

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

You will automatically be taken to the Study Manager page after logging in.

3. Click on the 'Create New Project' button located on the left-hand side of your screen.

Complete all fields designated with a red asterisk AND the Funding Sponsors field. The Funding Sponsors field should list any funding sponsors (e.g. external funding agencies, internal funds, etc.) that are presently connected with the study AND sponsors which may become involved at a future date. The degree(s), Keywords, and Internal Reference Number fields are optional. After filling in all of the required information, click '**Continue'.**

4. Download and Complete Revision Form

You will now be on the Study 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 upload original and revised documents for your study by clicking on **'Add New Document'**.

A, Select "**Fort Hays State University**" from the **Select A Library** drop down menu.

B. Next, select the **Revise an Approved Study Form** from the **Select A Document** drop down menu, and click **download.** Fill in the necessary information on the form. When the form is complete, choose **File>Save As** to save the form to your computer.

5. Upload completed Revision Form and Related Documents

From the Designer Screen, browse for your original and revised documents, any other relevant files and the completed Revision Form from your computer and assign the proper **Document Type** for each from the drop down menu. Click '**Attach**'.

* Make sure that all revisions are highlighted as this makes it easier for the IRB to locate your revisions within your document(s). **Please note that studies will not be scheduled for review unless the revisions are highlighted.**

*** If you do not have an electronic version of your original study, you may:**

i. Scan the original documents using a scanner and create a pdf or jpg to upload.
ii. Include a letter explaining that the original documents are not available in a digital format, and indicate the date and title of the original paper submission to the FHSU IRB.
iii. Contact the Office of Scholarship and Sponsored Projects at 785-628-4349 or lpaige@fhsu.edu if you do no have a paper or digital copy of the original documents.

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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 '**Revision**' and click '**Submit**'.

Once your project has been submitted, the coordinator will notice that you have submitted a first package (12345**-1**) for revision, which indicates that the project originated using the paper process.

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