



**FORT HAYS STATE
UNIVERSITY**

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INSTRUCTIONS: CONTINUING REVIEW OR CLOSING A STUDY (IRB)

Submit a request for continuing review:

If a study has been reviewed and approved by the IRB, then *prior* to the expiration date, the PI may request that the time frame for the study be extended. If the study is complete, then the PI should close the study (see below). If the PI wants to continue the study, a request for continuing review is needed. The PI should submit the request no later than 45 days prior to the expiration date, due to the IRB meeting schedule. However, if the study expires during the summer session, the PI is strongly encouraged to submit the request for continuing review in time for the IRB's last meeting of the spring semester. Other changes in the approved study may be requested at the same time (also complete and attach the Request for Revision to Approved Research Form). The request must be reviewed and approved by the IRB before the expiration date.

Submit a request to close your study:

If your project has been approved by the IRB and is now completed, then the PI should submit a request to close the study. In order for the IRB to close the file on the project, the PI must provide a summary of the results of the project (see Continuing Review or Close Study form). This starts the clock on the required time that project documentation must be retained (3 years by federal regulation) by the institution.

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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 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 to locate your revisions within your document(s).

- A. Upload a revised document:** Click on 'Add New Document'. 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 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. Attach the Appropriate Form for Review:** The same form (**Continuing Review or Close Study**) should be used if the PI would like to either request for an extension of the project (continuing review) or if the PI would like to close the study.
- Submit the **'Continuing Review or Close 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 **'Continuing Review or Close Study'** form and click **'Download'**. Upload the completed form and related documents (based on your request to either extend the project or close the project). 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 **'Continuing Review or Close Study'** form and click **'Attach'**.

*If you submit any revisions with your request for continuing review and these revisions will impact other documents previously submitted (e.g., application, consent form, information statement, etc.) you must include these revised documents along with the continuing review 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 automatically via email that the project has been shared. 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. Principal Investigators (and faculty research advisors, if the PI is a student) *must* sign the study before it is submitted.

- 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 ready to submit your study. Click on '**Submit this Package**' located on the left-side of your screen.

- **If submitting a request for continuing review:** 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 a request to close your study:** 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 '**Close/Final Report**' 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).
