



OFFICE OF SCHOLARSHIP AND SPONSORED PROJECTS

INSTRUCTIONS ON CREATING A NEW STUDY- Student Researchers

NOTE: CITI Training must be completed prior to submitting a proposal to the IRB!

Principal Investigators (faculty and students), faculty supervising student research, and all members of the research team **MUST** complete CITI training **BEFORE** submitting an application to the IRB.

Please see <http://www.fhsu.edu/academic/gradschl/ossps/CITI-Training/> for more information!

1. Have you registered with IRBNet?

If not, follow the Instructions for [New Users](#) on our website. If you have already registered, please proceed to Step 2.

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

You will automatically be taken to the My Projects 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. 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.

5. Download IRB Documents:

- A. Select '**Fort Hays State University**' from the '**Select a Library**' drop-down menu.
- B. In the '**Select a Document**' drop-down menu, you will find all of the IRB forms and templates.
- C. Select the necessary document and click **Download**. You will have to repeat this action for each document required.

* PDF forms may be completed, saved, and edited in Adobe Reader (Adobe Acrobat is no longer required for saving completed forms.)

• DOCUMENTS REQUIRED BY THE IRB:

- **Completed IRB application form (download from IRBNet)**
- **Exemption, Expedited or Full Request Form (download from IRBNet)**
- **All materials (emails, letters, scripts) used for recruitment**
- **Copy of instruments, interview questions, focus group questions, survey questions, etc.**
- **Consent/assent materials, unless consent will be waived. (Almost all studies will require informed consent; however, some will not require a consent form, or will use an alternate method for ascertaining participant consent. If the study will not use a consent form, the content and method for informed consent must be clearly described.)**
- **Debriefing materials, if used**
- **Permission letters to be used for schools, nursing homes, hospitals, etc. requesting access to potential participants.**
- **Other documents, as needed**

DO NOT ATTACH A THESIS, FIELD STUDY OR RESEARCH PROPOSAL OR PROSPECTUS.

Failure to upload the appropriate documents, or submitting an incomplete application form will delay the review and approval of your research.

6. Upload Completed IRB Documents

- A. Upload your completed documents by clicking on '**Add New Document**'.
- B. Select the type of document you are uploading from the **Document Type** drop-down menu. Then click on the '**Browse**' button to search for your document.
- C. Click on the '**Attach**' button.

* Most file types are supported by this system. However, please do not upload documents to your study as .docx files because some people cannot open them.

7. Share the study with your research team.

A. 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 study.

B. 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.

C. 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.

* 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](#):

D. Selected users will be notified automatically via email that the study has been shared with them. You may enter comments to be included in this email in the **'Your Comments'** section. Click **'Save'**.

8. AFTER YOUR FACULTY RESEARCH ADVISOR APPROVES YOUR PROPOSAL - Share your study with the Department Human Subjects/Ethics Review Committee or with the Department Chair. If your faculty research advisor has been given full access to your proposal, s/he may share the study using IRBNet, or provide you with the list of committee members for sharing.

A. For Departments **with** Human Subjects/Ethics Review Committees:

Once you are done uploading all your documents, give access (share) your submission with the members of your Department Human Subjects/Ethics Review Committee.

B. For Departments **without** Human Subjects/Ethics Review Committees:

Once you are done uploading all your documents and have given access (shared) your submission with all relevant individuals, share the study with the department Chair.

9. Sign the study.

Principal Investigators (STUDENT) and Faculty Sponsors must sign the study before it is submitted.

For Departments **with** Human Subjects/Ethics Review Committees:

Following their meeting, the committee chair will may use the email feature (or regular email) to send you the appropriate completed form (exempt, request for expedited review, or request for full review). Upload the form into your Study Designer. Sign your study, and make sure the committee chair (with whom you shared the study) also electronically signs your study. The committee chair should only sign as Department Representative when your documents are finalized for submission, i.e., just before you are ready to submit the package to the IRB.

For Departments **without** Human Subjects/Ethics Review Committees: *Your department chair (with whom you shared the study) will need to electronically sign your study. The department chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit the package to the IRB.*

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.

* The Department Humans Subjects /Ethics Review Committee chair signs as "Department Representative"

* The Department Chair signs as "Chair"

10. Submit your Study

Once you have attached all of your necessary documents and signed your study, you should be ready to submit your study to the IRB. 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 **'New Project'** and click **'Submit'**.

General Information:

The My Projects page (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 lp Paige@fhsu.edu

After submission, further information will be sent to you and your faculty research advisor using email.

If the Departmental Human Subjects/Ethics Committee has determined that your research is Exempt from IRB review, you will have received a Determination of Exempt Form completed by the committee. This form should be submitted with your study package to the IRB. AFTER you receive a letter from the IRB confirming the Exempt status, you may begin your research.

For all non-exempt research, you and your faculty research advisor will receive notification from the IRB regarding the status of your research study. The email will contain an official letter that; 1) approves your study, 2) requires modifications or additional clarifications to your study prior to approval, or 3) denies approval.

If the proposed activity is non- research, activities should not be initiated until you have received an official approval letter email from the IRB.

