



**FORT HAYS STATE
UNIVERSITY**

Forward thinking. World ready.

INSTRUCTIONS: CREATING A NEW STUDY (IRB & IACUC)

NOTE: CITI Training must be completed prior to submitting a proposal to the IRB and IACUC.

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

Please visit [FHSU Research Compliance](#) for more information.

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- 1. Register with IRBNet.** Follow the 'Instructions for Registering with IRBNet' located at [FHSU Research Compliance](#).
 - 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' located on the left-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 'Designer' on the left-side of your screen.
 - 5. Download Project Documents:** To download the correct documents and to ensure that your project is submitted correctly for review, please select the correct library based on the type of research you are conducting based on if you are submitting to the IRB or IACUC.

Are you conducting research with human subjects (IRB)? If so, select 'Fort Hays State University IRB, Hays, KS' from the 'Select a Library' drop-down menu. In the 'Select a Document' drop-down menu, you will find all of the IRB forms, narrative guidelines, and sample documents. Select the necessary document and click 'Download'. Repeat this action for each document you will submit for IRB review.

- **DOCUMENTS REQUIRED FOR IRB SUBMISSIONS:**
 - Completed IRB application form
 - All materials (emails, letters, scripts) used for project 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.
- Documentation of CITI training
- Other documents, as needed

-OR-

Are you conducting research with animals (IACUC)? If so, select '**Fort Hays State University Institutional Animal Care and Use Committee, Hays, KS**' from the '**Select a Library**' drop-down menu. In the '**Select a Document**' drop-down menu, you will find all of the **IACUC** forms, narrative guidelines, and sample documents. Select the necessary document and click '**Download**'. Repeat this action for each document you will submit for IACUC review.

- **DOCUMENTS REQUIRED FOR IACUC SUBMISSIONS:**
 - Completed IACUC application form
 - Copies of special collection permits and licenses, if needed
 - Documentation of CITI training
 - Other documents, as needed

6. Upload Completed 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 '**Browse**' to search for your document.
- C. Click on '**Attach**'.

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

7. Share the Study with your Research Team.

- A. 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 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 would like to share this study (i.e., your faculty sponsor, co-PIs, research assistants, consultants). If you're a student submitting your project to IACUC, your faculty research supervisor *must* be designated as the PI.

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.

Note: If the individuals you are seeking are not in the list of registered users, please ask them to register with IRBNet.

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. Share your study with the Department Ethics Review Committee (if required):

- A. For Departments **with** an IRB or IACUC Ethics Review Committee: Once you are done uploading all of your documents, give access to (share) your submission with the members of your Department Ethics Review Committee.
- B. For Departments **without** an IRB or IACUC Ethics Review Committee: Once you are done uploading all of your documents and have given access to (shared) your submission with all relevant individuals, share the study with the department Chair, if that is required in your department. Otherwise, you may submit directly to the IRB or IACUC.

9. Sign the study. Principal Investigators (and faculty sponsors, if the PI is a student) must sign the study before it is submitted. Click on '**Sign This Package**' located on the left-side of your screen. Select your role from the drop-down menu (see below for information on your role), and then click '**Sign**'.

A. If submitting to the IRB:

- For Departments **with** Human Subjects/Ethics Review Committees: 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 and that require Chair review: 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).
- For Departments **without** a Human Subjects/Ethics Review Committee or a requirement for Chair review: You may sign the study and directly submit to the IRB.

B. If submitting to IACUC:

- If this is a graduate student activity, the faculty research supervisor signs as the 'Principal Investigator'. The student signs as 'Associate Investigator'.
- If this activity does not involve students, the individual submitting the application signs as the Principal Investigator. Other signatures may be necessary for Co-Investigators or Team Members.
- If this application is for a NON-Research activity, the person responsible for the activity should sign as Principal Investigator.

Note: A designee may NOT sign for the PI. Studies will not be scheduled for review if required signatures are missing.

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

A. 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 '**New Project**' and click '**Submit**'.

B. If submitting to the IACUC: 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 '**New Project**' and click '**Submit**'.

Note: If you're unable to locate the correct 'Board' by typing in "Fort" to the organization search, uncheck the 'Only show me Default Boards' option.

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).
