KANSAS STATE UNIVERSITY

PHS FCOI
Investigator's Guide to
IRBManager

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What is IRBManager?

IRBManager is a database designed to hold study information across Kansas State University's three research committees:

1. Institutional Animal Care and Use Committee (IACUC)
2. Institutional Biosafety Committee (IBC)
3. Institutional Review Board (IRB)

The University Research Compliance Office (URCO) has also begun the process of utilizing IRBManager to handle both Export Controls and Public Health Service Financial Conflict of Interest (PHS FCOI) forms.

This database utilizes xForms, which take the place of our previous application and review forms, to gather and organize study information - for efficient processing, reviewing, and approval.

Logging into IRBManager

https://ksu.my.irbmanager.com

User Name: K-State eID

Password: K-State eID Password

The IRBManager website will lead to the log in page shown below. Click on the "click here" hyperlink to navigate to K-State's SSO log in page, where users will input their K-State eID and password to access the system.

Note: Before a user can be added as a collaborator on a study, they will need to populate their information into the IRBManager system by logging in at least one time following the steps above.

Completing and Submitting Annual PHS FCOI Declarations

Each investigator who needs to submit an annual PHS FCOI declaration will receive an email from comply@ksu.edu with a link to start the form. Investigators will also be able to start a PHS FCOI declaration from their dashboard, which will be detailed later in this document.

Note: If an investigator needs to complete and submit an additional FCOI declaration and/or an additional travel reporting form after their original PHS FCOI declaration is approved, they will need to do so from their IRBManager dashboard.

Annual PHS FCOI Declarations

When an investigator receives their annual email, it will include a link to start their PHS FCOI declaration form. This will open the xForm for them to complete and submit.

xForms are conditioned to show and hide questions based on the information entered. This allows us to have a form that only contains information relevant to each individual investigator.

A drop-down menu at the top of the form allows users to move quickly between sections. However, using this feature when initially completing the form is not recommended, ensuring that no question is skipped and that all information provided is correct and complete.

Note: The following screenshots may include a "Draft Form" watermark due to these instructions being written when the forms were still being developed. Users will not see this watermark when they are completing their xForms.

Share Form Access

The individual who starts an xForm (also called the submitting user) is the only person who will have access to that form in data entry, unless other users are given form access. Our office recommends manually adding any individuals who may need to make changes to the form, at the beginning of the data entry stage. We also recommend giving them edit, manage, and submit rights.

Note: This only applies to individuals that need to have access to the form, not necessarily every person involved in the study.

Instructions for sharing form access are as follows:

1. Click on the "Share Form Access" link at the top of the application.

2. Enter the email address of the individual to grant access to in the pop-up.

3. Select the type of access:
   a. Edit – allows the individual(s) to make changes to the form
   b. Edit & Manage – allows the individual(s) to make changes to the form and add other collaborators
   c. Edit, Manage, & Submit – allows the individual to make changes to the form, add collaborators, and submit the form.
4. In the "Note for Share Form Access" box, include the text that you would like to have sent via automated email notification to the added collaborator. This is not required.
5. **If you would like to delete an individual you have added, simply click the red X that will appear next to their name after adding**.
6. Once added, the individual will see the xForm on their dashboard under "xForms awaiting your attention."

Form Navigation and Saving

There are two ways for users to navigate between pages when filling out an xForm:

1. Clicking the drop-down menu at the top of the page

2. Clicking the "Previous" or "Next" buttons at the bottom of the page

Note: Clicking "Previous" or "Next" will automatically save the information that has been entered into the form.

Note: As mentioned previously, we recommend limiting use of the drop-down menu when initially completing the application form, to prevent accidentally skipping or providing incomplete information.

Additionally, users may decide they would like to leave the xForm and return to complete it at a later time. To do this, click the "Save for Later" button located at the bottom of the form.

Note: Our office recommends that only one individual answer questions in an xForm at a time. Other users may leave input by utilizing the "Add Note" feature on each question. This This approach helps to avoid accidentally overwriting responses within the xForm, which can cause confusion.

Entering Study Personnel

Study personnel are added by typing individual names or email addresses into the "Name" box on the project collaborators page of the form. This table will prompt the submitter to include the role, department, and phone number for each individual entered. Click the "Save" button at the end of the row to save the entry.

Note: If an individual's name and/or email does not appear when entered, they will need to log into IRBManager using their K-State credentials to establish them as a contact in the system.

Submitting the xForm

When the form is complete, click "Submit" to submit the form. If the form creator <u>is not</u> the principal investigator, it will be routed to the PI for signature.

IRBManager Dashboard

Upon logging into IRBManager, users will be taken to the switchboard: a screen that allows the user to select the appropriate committee type (shown below). This is helpful for users who have protocols across multiple committees (IACUC, IBC, and/or IRB) so that the user can better view specific protocols without being distracted by too much information. Users can also select "Show Everything" to see all protocols and committees with which they are involved.
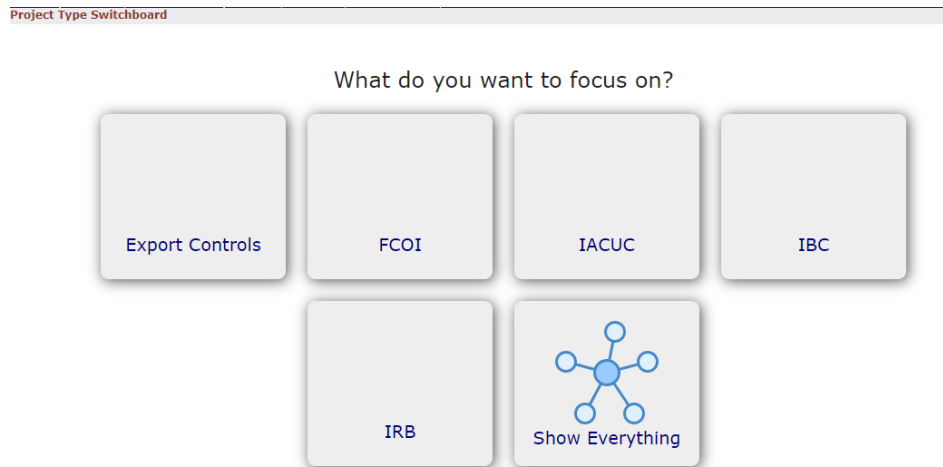
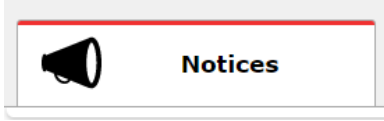**Note:** Users can switch between committees after entering IRBManager by either clicking the switchboard icon or using the dropdown; both are located at the top right-hand corner of the screen.

Once the user enters IRBManager, they will be taken to their dashboard. Each user's dashboard will look a little different based upon the studies with which they are involved. An example of the dashboard is shown below:

Elements of the Dashboard

|	
Home	Return to the user dashboard
All Projects ∨	Drop-down menu used to switch between different committees (IACUC, IBC, IRB)
(switchboard icon)	Switchboard icon that will lead to the initial screen, allowing users to switch between different committees (IACUC, IBC, IRB)
(search icon)	Allows users to search for protocols they are involved with, based upon protocol number, principal investigator, and/or collaborators
(user icon)	Menu icon that allows users to personalize their IRBManager settings
Start xForm	Allows the user to start a new xForm
Notices	Updates and notices from the Research Compliance Office, when available, will be posted here
0 xForms	Allows the user to view their current and past xForms

Submitting an Additional PHS FCOI Declaration and/or Additional Travel Reporting Form

To submit an additional PHS FCOI declaration and/or an additional travel reporting form, log in to IRBManager and select "FCOI" from the switchboard. This will take you to your FCOI dashboard. Click the tab that reads "Records", shown below:
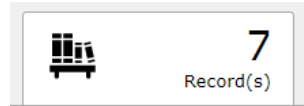
This will bring up all of your previously submitted and approved PHS FCOI declarations. Find the most recent one and click on the record title, circled below:
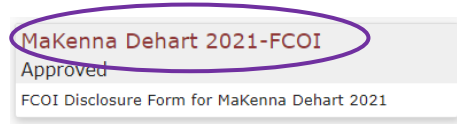
This will open a new page that will show the entire record of that submission. Along the left-hand side of the page will be a menu entitled "Actions" and about halfway down that list will be a link that reads "Start xForm" (shown below).

Start xForm

Clicking on "Start xForm" will bring up a separate page that will have a link to the additional declaration/travel reporting form. Click on the link shown below to open up the form. Once the form has been opened it just needs to be completed and submitted into the URCO office for review.

Select xForm to start		
Action	**Form (Click to start)**	**Description**
🖨	PHS FCOI - Additional FCOI Declaration/Additional Travel Reporting Form (Draft)	PHS FCOI - Additional FCOI Declaration/Additional Travel Reporting Form. This form would be used to report a change additional FCOI declarations in between annual submissions and/or additional travel instances.

Components of IRBManager

User Roles

There are a handful of different roles within IRBManager that collaborators can be assigned to when added to a study. The roles that apply to the annual PHS FCOI declarations are as follows:

- **Principal Investigator (PI)** - The lead investigator on a study. Must be a K-State faculty member.

- **Form Creator/Submitting User** – The individual that initiates the xForm. This user may or may not be the principal investigator.

Submission and Use Tips

General Tips

- If copying text from another source to paste into the application xForm, be sure to use the "copy as plain text" feature within a browser, as in some cases code from the original text source can cause glitches.

- Users can download a PDF of any xForm by opening the xForm, clicking on "More" at the bottom of the screen, and selecting "View as PDF".
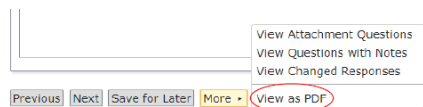
Document Naming and Uploads

- Be intentional and consistent when naming documents to upload to IRBManager. This makes it easier for users to keep track of what they are uploading.
- Be as descriptive as possible when naming documents to upload. This will help reviewers understand what each file is when they are completing their review.
- **When possible, separate supporting materials before uploading.** For example, upload survey questions, consent form, interview questions, debriefing statement, etc. as separate documents instead of as one large file.
- When an attachment has been updated outside of IRBManager, users can choose one of two options to update the old file.

  o Clicking on the green arrows will allow users to replace the old file with the new version.
  o Alternatively, clicking on the red X will delete the current attachment.

Notifications

IRBManager will send automated emails to researchers when action is required of them. These emails will include a link to the application to make it easy for users to navigate to the form in question in order to make changes, or complete the requested forms. Examples of these emails include:

- Notifying the principal investigator to review and/or sign off on the application.
- Notifying investigators when URCO has requested additional information or action on their application form.

Note: IRBManager Emails will come from **no-reply@ksu.my.irbmanager.com**. These emails are not spam. Please do not delete.