Investigator's Guide to IRBManager

TABLE OF CONTENTS

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)

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.

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.

Project Type Switchboard
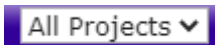
What do you want to focus on?

| IACUC | IBC | IRB | Show Everything |
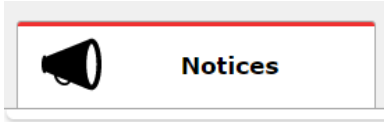
Note: Users can switch between committees after entering IRBManager by either clicking the switchboard icon or using the dropdown; both are located at the top right-hand corner of the screen.

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:

My Protocols

| 1 Protocols | 1 IRB | 0 IACUC | 5 xForms | 6 Events | Notices |

Search Protocols | Export to Excel | Start xForm

1 Expiring Soon! 1 Co-Investigator

12000-BH
Approved   Exp 09/21/2020
IRBManager, IRBManager
0098234
IRBManager Test Protocol

Inactive Protocols
PI 1   Graduate Student 1

Messages & Links

Welcome to IRBManager at **K-State**

<u>**Elements of the Dashboard**</u>

Home	Return to the user dashboard
All Projects ⌄	Drop-down menu used to switch between different committees (IACUC, IBC, IRB)

	Switchboard icon that will lead to the initial screen, allowing users to switch between different committees (IACUC, IBC, IRB)
	Allows users to search for protocols they are involved with, based upon protocol number, principal investigator, and/or collaborators
	Menu icon that allows users to personalize their IRBManager settings
Start xForm	Allows the user to start a new xForm
Export to Excel	Downloads an Excel document with information on all xForms, including when they were started and their current stage.
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
3 Protocols	Allows the user to see all research protocols they are currently involved with
3 IRB	Allows the user to see all protocols they are involved with, within a specific committee (IACUC, IBC, IRB)
8 Events	Displays the number of events (submissions) the user has open (i.e. ones that have not been approved or otherwise finalized)

Dashboard tips:

- The tabs at the top can be rearranged by clicking and dragging them into place.
- Each tab has additional boxes at the top, which act as filters. Clicking these will narrow down the studies in that tab based upon the criteria selected. Some examples of these filters include:
  - **Expiring Soon** – indicates studies that are about to expire.

- o **PI** – shows studies where the user is the named PI of the protocol.
- o **Co-Investigator** – shows studies where the user is named as a Co-Investigator on a protocol.
- o **Research Assistant** – shows studies where the user is named as a Research Assistant on a protocol.
- o **Responsible Graduate Student** – shows studies where the user is named as a Responsible Graduate Student on a protocol.
- o **Graduate Student** – shows studies where the user is named as a Graduate Student on a protocol.
- o **Undergraduate Student** – shows studies where the user is named as an Undergraduate Student on a protocol.

Components of IRBManager

Study Components

xForm	Dynamic versions of forms that were previously formatted in Adobe. These include application forms, annual review forms, triannual review forms, etc.
Pages	Different screens/sections within an xForm.
Study	Broad study information (title, protocol number, sponsors, etc.)
Study Site	Specific study information (study status, approval date, expiration date, etc.)
Event	Type of submission (initial protocol submission, modification, annual/continuing review, triannual review, etc.)

xForm Types

Application

- To submit a new study for review, users will need to submit an xForm application for approval. The form may be started by selecting one of the following options, located the middle portion of the screen (example image below):
  - Start xForm
  - Start Other xForm
  - Start IRB Application for Approval
  - Start IBC Registration Document
  - Start IACUC Application
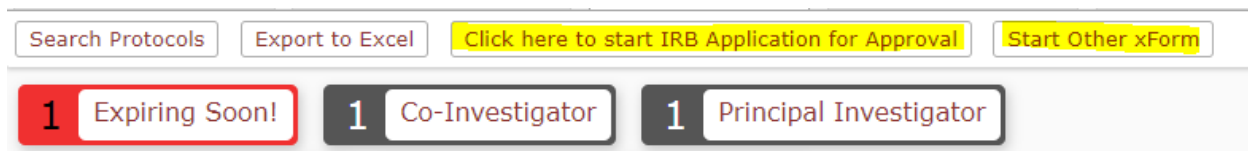
- Application xForms will need to be completed for both initial submissions **and** modifications to protocols that were submitted and approved through IRBManager. Anything submitted/approved prior to the launch of IRBManager will be handled using the previous process, which is discussed further later on in this guide.

Annual/Continuing Review

- Annual reviews (for protocols that are not approaching their expiration date) will be emailed to investigators 60 days prior to when they are due, and again 30 days prior if no response to the initial reminder is received. Each email will contain a link to the xForm where investigators can go to provide updated information for their study.

Triannual Review

- Triannual reviews (for protocols that are approaching their expiration date) will be emailed to investigators 60 days prior to expiration, and again 30 days prior if no response to the initial reminder is received. Each email will contain a link to the xForm where investigators can go to indicate if their study is completed or if they intend to resubmit a new protocol for approval.

User Roles

There are a handful of different roles within IRBManager that collaborators can be assigned to when added to a study. These roles are as follows:

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

- **Responsible Graduate Student** – The lead graduate student, if applicable to the study. Typically the individual who will be conducting the majority of the research with the support of the principal investigator.

- **Co-Investigator** – Additional K-State faculty members who may also be responsible for the study.

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

- **Research Staff** – Additional individuals working on the study, who are not considered "lead" investigators but are fulfilling vital roles in the collection and analysis of research data. This includes:
  - Research Assistants
  - Graduate Students
  - Undergraduate Students

Study Status and Event Steps

Information regarding the current status of a submitted protocol can be found on the study page, in the Study Site (under the "Protocol-Site" header).

Information included in this section is as follows:

- Study Status – the current stage of the submitted application(see below table for a list of study statuses)
- Approval – the date of approval for approved protocols
- Expiration – the date of expiration for approved protocols (this will be blank for exempt or non-research protocols)
- Other Expirations – the annual review due date

IRBManager Study Statuses			
Under URCO Oversight		Not Under URCO Oversight	
Active	Protocol has been approved by the respective committee	**Completed**	Protocol is complete per the principal investigator and is now inactive
Approved	Protocol has been approved by the respective committee	**Disapproved**	Protocol was not approved by the respective committee
Concurrence	Protocol has been approved by a different university but research is being done concurrently at K-State (IRB only)	**Inactive**	Protocol has passed the expiration date and is now inactive
Exempt	Protocol has been approved as exempt (IRB only)	**Never Undertaken**	Project has not been undertaken and will not be undertaken in the near future
Pending	Protocol has been submitted and is currently under review; not yet approved	**Non-Research**	Protocol has been approved as non-research (IRB only)
Provisional Approval	Protocol is incomplete, but has been approved for the purpose of securing a grant; when the protocol is completed it will be reviewed and approved as normal (IRB only)	**Withdrawn**	Protocol has been withdrawn by the principal investigator
See Comments	Special circumstances may apply to this protocol (applies only to protocols that were transferred from the old database)		

Event Steps

On the Event page in IRBManager, users can view the processing steps associated with a specific event/submission (initial application submission, modification, annual review, triannual review, etc.).

Steps (15)					☑Hide Skipped
Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Submission		08/31/2020	Yes		
Training Review		08/31/2020	Yes		
Administrative Review		08/31/2020	Yes		
Notify Researcher of Results			No		

Note: Steps will differ depending on the event in question. For example, an IACUC initial submission will have different event steps than an IRB initial submission, and both will be different than an annual review, etc.

Submitting an Application for a New Study

To submit a new application, choose "Start xForm" on the dashboard. This will bring up a list of xForms that the user can begin.

xForms are conditioned to show and hide questions based on the information entered. This allows us to have a single application form per committee (IACUC, IBC, IRB) that only contains information relevant to each individual application.

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."
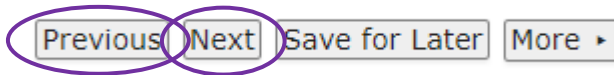
Form Navigation and Saving

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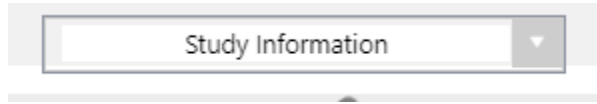
2. Clicking the "Previous" or "Next" buttons at the bottom of the page

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.

If the Principal Investigator Does Not Approve of the Form as Written

If a form is submitted by an individual that is **not** the principal investigator, the principal investigator will receive an email from IRBManager letting them know they need to go into IRBManager to review, approve, and sign the form.

At this stage, the PI can request that the form creator make changes to any part of the application that they feel needs to be edited.

To do this, click the link in the email to go into the submitted application form. Review the form completely along with any attachments. At the end of the form, a page will appear asking the PI if the application is ready for submission to the IRB.

- If the application is ready for IRB review, select "yes", then "next" at the bottom of the page to navigate to the next page and sign off on the application.
- If the application is **not** ready for IRB review and changes need to be made, select "no" and list the required edits the box that appears (shown below). Then click "next" and "submit" to send the form back to the form creator to make changes.

At this point, if changes are needed, the form creator will receive an email from IRBManager with a list of changes that need to be made – an example of this email is shown below:
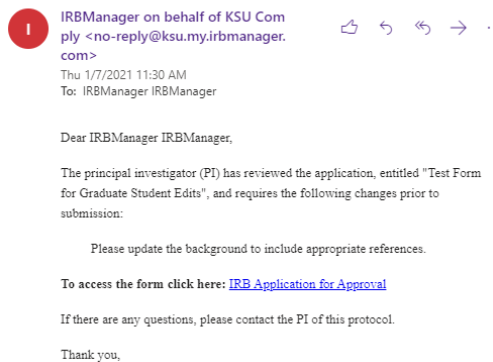
The form creator will at this point click the link in the email to go into the form and make the requested changes. They will then resubmit the form to the PI for review and approval. The PI will then get another email prompting them to go review the submitted form, and all changes that were made by the form creator will be highlighted in yellow, as shown below.
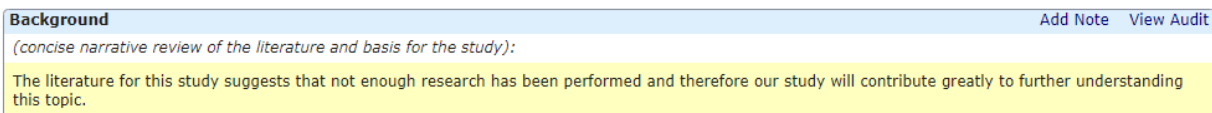
From here, the process outlined above starts again. The PI will reach a page that asks them if the application is ready to be submitted for review by the IRB.

- If the application is ready for IRB review, select "yes", then "next" at the bottom of the page to navigate to the next page and sign off on the application.
- If the application is **not** ready for IRB review and changes need to be made, select "no" and once again list the required edits the box that appears. Then click "next" and "submit" to send the form back to the form creator to make changes.

This process can occur as many times as needed until both parties are happy with the application and feel it is ready to be submitted to the IRB for review.

Submitting an Amendment/Modification

The *initial submission* of a protocol refers to the first application xForm for a study that has been completed, submitted, and approved. Changes made to the protocol after this initial submission are referred to as amendments or modifications, and are completed using the "copy for amend" feature of IRBManager. This makes a copy of the most recently approved version of the xForm and allows researchers to make the necessary changes.
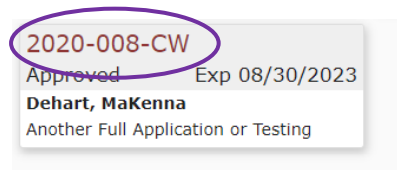
A form that is copied for amendment is an exact copy of the last approved form, so researchers will not need to reenter study information. However, in order to keep studies accurate and complete, researchers will need to update the relevant portions of the xForm to reflect their current modification.

Note: If a user has recently submitted an xForm application for a study that <u>has not yet been approved</u>, they will need to wait for approval of the protocol before submitting an amendment/modification. To request changes before approval is complete, contact URCO to have the xForm returned.

<u>For Protocols Initiated in IRBManager</u>

To create a copy in order to amend and submit an amendment/modification, follow the below steps.

1. Locate the study to modify on the dashboard.

2. Click on the protocol ID to open the study details.

3. Navigate to "Reference xForms" on the study page.

4. Click the pieces of paper icon to the left of the xForm name. This will create a copy for amendment that can be edited.

5. Within the resulting xForm, answer the questions provided.

6. Finish updating the form and submit.

For Protocols Approved Prior to IRBManager

Protocols that were approved prior to the launch of IRBManager will be processed using the previous approval process. Please edit the original application form to reflect any modifications, making sure to include the changes in the Modification box on the first page. When the form is complete, email the updated application form to comply@k-state.edu for review and approval.

Submitting Other Study-Specific Forms

Reminders will be sent to investigators to complete some study-specific forms, such as annual/continuing and triannual reviews. However, these forms can also be accessed by investigators at any time, along with the adverse event reporting form, should the need arise. The steps to do this are as follows:

1. Locate the study on the dashboard.
2. Click on the protocol ID to open the study details.
3. In the left hand actions menu, click the xForms link.
4. Select the type of xForm to complete (annual/continuing review, triannual review, adverse event, etc.)
5. As with all xForms, the researcher will want to add any collaborators who they would like to have access in this stage.
6. Finish completing the form and submit.

Locating Approved Information and Materials

All study information and files are stored within IRBManager. When a user clicks on the study ID from the dashboard, they will be routed to the study page, which contains all basic study information (title, sponsor, status, approval date, expiration date, collaborators, etc.). Attachments and xForms for each study can be accessed within the relevant event (i.e. initial submission, modification, historical attachments, continuing review, etc.).

Protocols Approved in IRBManager

Researchers can locate their xForm and attachments for their individual studies via the following series of steps:

1. Starting at the user dashboard, click on the study ID
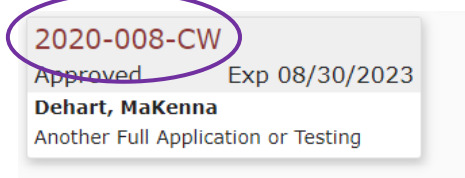
2. Navigate to the event on the study page.

3. To quickly see any uploaded attachments that are part of the study, click the number under the "Att" column.

4. The following screen will appear. To view an attachment, simply click on the title.

5. To see any xForms, or for an alternate way to view attachments, click on the title of the event.

6. On the Actions menu located on the left side of the page, select either xForms (to view any xForms associated with the protocol) or Attachments (to view any attachments that were uploaded).
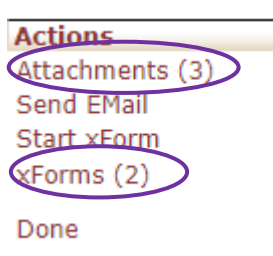
Historical Attachments

Studies that were approved prior to the launch of IRBManager will still be accessible from the user's dashboard, but upon clicking on the study ID and opening the study page, there will only be one event: Historical Attachments. Within this event, click on "Attachments" in the left hand Actions menu to view any materials that were previously sent into URCO for review and approval.

Note: Historical Attachments will not include any xForms, as these forms are unique to IRBManager and were not utilized in the past. Previous study application forms can be located within the Attachments hyperlink.

To view historical attachments, simply click on the study ID on the user dashboard to be taken to the study's page. Under the Events section, there will be an event entitled "Historical Attachments – Manual".

To see the attachments, users can utilize one of two options:

1. Click on the event title to be taken to the event location. To see attachments from within the event, users will need to click <u>Attachments</u> in the left-hand Actions menu.
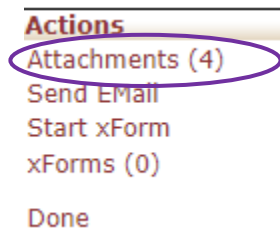
2. Click on the number under the "Att" column to be taken straight to attachments.

To view an attachment, simply click on the attachment title and it will download.

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".
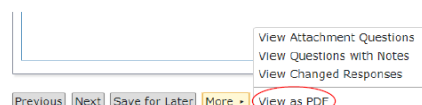
Document Naming and Uploads

- 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.
- Notifying investigators when they need to fill out a continuing/annual review or triannual review.
- Notifying investigators when their study approval has expired and has been closed.

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

Notes

Investigators have the option to add notes to the pages of their xForms; these serve as sticky notes to allow investigators to communicate with one another and/or with the URCO office. To add a note, simply click the "Add Note" link in the appropriate area of the xForm.
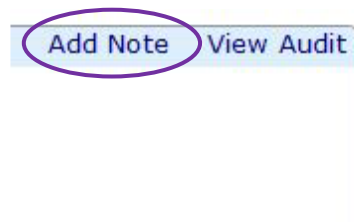
Note: Any note removed by the research team prior to submission will not be seen by the URCO office.