IRBManager Guidance Manual

**What is IRBManager?**
IRBManager is an online submission, workflow, and data management system for Radford University’s Institutional Review Board (IRB) and soon to be, Institutional Animal Care and Use Committee (IACUC). IRBManager is a fully web-based system. This means users can log-in anywhere they have internet access. The electronic forms provided within the system allow users to complete submissions for IRB and IACUC review. This includes forms for new studies, continuing reviews, amendments/modifications, as well as reports for unanticipated problems, adverse events, and study closures. These forms are then used to electronically route the submission through the required review process.

Through IRBManager, Principal Investigators (PIs) have access to see the studies they are conducting at Radford, as well as any separate study-sites, if applicable. Each protocol’s study-site will provide a list of events submitted to the IRB/IACUC. Events are types of submissions within the IRBManager system. Events can be reviewed as folders for these submission events required for each study-site such as the initial submission, amendments, and continuing reviews, etc. Each event will contain all associated forms, documents, stamped forms and letters along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process. Study personnel indicated on the protocol application will have access to the study in IRBManager.

All study documents submitted to the IRB/IACUC will be maintained in the IRBManager system and be accessible by Users given access to the study. It is highly recommended that you maintain your own copies of these documents outside of the system.

**Getting Started**
IRBManager can be accessed on the One Campus using their Radford email address and password. Using One Campus, access to IRB Compliance/IRBManager may be located by searching under the “Teaching category.”

As a security precaution, IRBManager will lock your account after three (3) incorrect password attempts. If your account is locked, please email irb-iacuc@radford.edu or contact the Research Compliance Office (RCO) to unlock your account.

*Note:* Should your IRBManager account lock, it does not affect your Radford email account.
User Settings
IRBManager has a dark mode option. To turn it on, go to “Settings” in the top right corner of the screen.

On the following page, you will see a list of settings. Click “Turn on Dark Mode.”

Your view should now look like this:
From the settings, you can also change the look of your dashboard by engaging the “Bubble Dashboard.” Click on “Switch Dashboard.”

IRBManager will ask you to confirm this change:

After confirming your request, your dashboard will look like this:

You can switch back at any time by selecting “Reset Dashboard” in “Settings.”

**Your Dashboard**
Once logged into IRBManager, you will be taken to your “dashboard”. Your dashboard is the starting point. Here, you will be able to see active protocols with which you are associated, check on the progress of submissions, and find approved protocols.
Selecting the “Home” button on any page will bring you back to your dashboard.

“xForm” is the name of the electronic, web-based IRB/IACUC application form.

**DASHBOARD**
The xForms section of your dashboard shows the forms or applications currently being processed at this time.
Protocols
This user is associated with two (2) active protocols. By clicking the underlined link to active or total studies, the user will be able to view the details of their associated protocols.

Note: A protocol is not created when a user submits an xForm. A study is created and a protocol number assigned when the IRB/IACUC determines the protocol is ready for review.

From the dashboard, a user may view the following information about their studies, including:
1. The protocol number.
2. The main site where the research is taking place.
3. The PI’s name.
4. The project title.
5. The expiration date of the protocol (if this is blank, the protocol has not yet been approved).
6. Status
   a. Pending (if not yet approved)
   b. Active
   c. Exempt (if IRB)
   d. Deferred
   e. Expired
   f. Suspended

Note: Closed protocols will not display here.
xForms

1. This user has one (1) unsubmitted xForms. This shows the user started one xForm, but has not submitted the form for review. The user may have selected ‘Save for Later’ or closed out of the form without submitting the form.

   **Note:** By clicking on the link, the user can go directly to a list of unsubmitted xForms.

2. The dashboard, above, shows the user does not have any (0) xForms being processed at a later stage. Any forms the user had submitted that are currently awaiting review and signature by the PI (or other necessary party) or are being processed by the IRB, may be found here.

   **Note:** By clicking on the link, the user can go directly to a list of xForms being processed at a later stage and see what stage the xForm is in currently.

3. The user has three (3) xForms currently awaiting their attention. This shows that the user has three xForms that currently needs action by the user (i.e., review and signature required, revisions requested by the IRB, etc.).

   **Note:** By clicking on the link, the user can go directly to the xForms that need the user’s attention.

Events

This section of the DASHBOARD shows all open events and the types of submission(s), such as initial submission, closures, continuations, and modification. The dropdown box following ‘Only show events where I am’ allows the user to filter the events according to their role in the associated study.
Note: An event stays open until the board is notified of the approval. It is possible for the xForm to be complete and approve, but the event will still show as “open” until an IRB meeting takes place.

Creating a New Application
Prior to initial study approval, “xForm” is the term used to identify general forms that can be submitted anytime and are not already tied to a specific study (i.e. new study submission forms and requests to add new contacts to the system).

Under “Actions” (left-side tool bar), a user can start an IRB/IACUC Initial Application form also known as xForm.

Note: Secondary applications including Amendments, Continuing Reviews, Closure Reports, and Unanticipated Problem or Adverse Event Reports cannot be started from this area and must be started from within the study itself.
Recent Items
The hyperlinks under this heading will show the seven (7) most recent items viewed in IRBManager. Click on any link under “Recent Items” to go directly to that item.

Messages
This heading is an area the IRB will use for communication to all users within the system.

My Documents & Forms
This heading is an area the user can attach frequently submitted documents. For example, if a user is required to upload CVs for multiple persons, they can use “Attachments”.

The “xForms” under this header provides a table with xForms associated with you as a user of IRBManager across the entire system. The picture above, note 24 xForms with which the user is associated.

Protocol Team Access to the Protocol
The only member of the study/protocol team with access to an unsubmitted xForm or xForm in progress is the submitter of the xForm. If the PI did not originate the application and is NOT the submitter, they will not be able to see the application on their dashboard or make any changes to the application. For example, if a student begins the xForm, listing his/her faculty member as PI, that PI will not have access to the application until it is received for PI sign-off and submission for review by the IRB.

Should a study team member other than the submitter require access to an xForm while it is being completed, the submitter will need to add that person as ‘Collaborator’ to the form. The link for this is located at the top of the xForm application.

A Collaborator may be granted the following permissions: View Only / Edit / Edit and Manage / Edit, Manage, and Submit.

This function is form specific. Collaborators will only be able to see the form to which they are added and does not carry over to the other xForms created in a study.
The rest of the study team will be able to view the xForm once a determination is made by the IRB.

**Navigating Pages Within the Protocol Application**

There are several pages to the application with additional pages added based on responses to individual questions in the protocol application.

To skip to different application pages, use the drop-down box at the top of the page and select the page you want to access. Your changes will be automatically saved when you jump to a new page.

Answer each question on the page. Once ALL of the questions have been completed, click “Next” at the bottom of the page. Your changes will be saved as you move to the next page.

**Note:** You may also click “Save for Later” and return to the application at any time.

**Please note that if you have not filled in all the required answers, when you click “Next”, it will not advance to the next page.**
Instead, sections with missing information will be highlighted in red text. You can select the issues listed in red text and jump to those questions, which saves time on longer pages. If you do not know the answers to those questions, use the page skip feature outlined above or click “Save for Later” and return to them at a later time.

### Adding Attachments

In several places on the application, you will be asked to attach documents, such as consent forms, recruitment materials, advertisements, etc. Simply click on the “Add Attachment” button.

### Saving Information in Tables

For some needed information, such as personnel, there are tables where the user will have to save information. These tables allow the user to add multiple iterations of similar details.

In these instances, the user will enter the required information and then click “Save” on the right-hand side.

Once this information has been saved, a new row will appear, allowing the user to repeat the process.

**Note:** You **must** click “Save” before the system will allow you to move to the next page.

### Student Submissions

In many instances, the person completing the protocol application may not be the PI. In these instances, the protocol requires the review and sign-off of the student’s PI faculty member.
The student will complete the protocol, sign and click “Submit”. The protocol application will be routed to the student’s faculty advisor/PI to review.

**Faculty Review, Sign-off, and xForm Submission**

Once the user (PI or student submitter) has filled out the form completely, it must be electronically signed before submitting. If the submitter is a student and not the faculty member PI, they will need to submit to their faculty member for review and submission for official IRB/IACUC review.

The faculty PI will receive an email asking to review the protocol application. A link to the pending protocol application will be provided in the email, allowing the PI to access the protocol in IRBManager. Selecting the link will open the completed application for review and PI submission.

Dear Faculty PI X

This is a notification that a new application Title of the Protocol has been submitted by Student Y and your review and signature is required.

Please click here to go directly to the form IRB - Initial Application

Thank you

**PI Protocol Sign-off and Submission**

Please make sure to read and understand the entire section of Investigator Assurances and Acknowledgements before signing. Researchers and research personnel will be held accountable for these items.
Review this section and click “Sign”. A new window will open and the PI prompted to enter sign-on using their Radford email and password. The signature time stamp will populate where the signature box was located.

Once you have signed and the signature stamp has populated, select “Next”.

You will be directed to a new page and notified the form is completed. You MUST click “Submit” on this page for your application to be sent for review.

Revisions of Returned Protocols
Should an IRB or IACUC submission need revisions in order to secure approval following the review of the protocol, PIs will receive an email from IRBManager.

Dear ________

Please note the following study 2020-xxx Protocol Title application is being returned to you for the reasons below.

1.
2.
3.

Please click on the following link to make the necessary corrections and resubmit the form. IRB - Initial Application

Thank you,

Research Compliance Office, IRB/IACUC

A link to the protocol will be provided in the email, allowing the user to access the protocol and make the necessary revisions.
Events in IRBManager (Adverse Event Submission, Continuation Submission, Modification/Amendments, and Study Closures)

For any action related to an approved project, such as a Continuing Review, Protocol Modification, Adverse Event Submission, or Study Closure form, you must first go to the protocol. Active studies/protocols may be found in the “My Protocols” section at the bottom of your dashboard.

Select the hyper link associated with the corresponding xForm or active project/protocol. One the next screen, the Actions menu on the left will show all actions available for the project. Most actions needed are found by selecting “Start xForm.”

Starting a supplemental form within an active protocol/project automatically associates it with that protocol/project.

This will open a new screen with a list of application forms available along with a description of each form. Select/click on the name of the form you wish to complete.
**Adverse Events**

Use the Adverse Event form to submit an Event Report, including Protocol Deviations, Event Requiring Reporting by a Study Sponsor, an Unanticipated Problem or Adverse Event.

1. On the home page under ‘My Protocols,’ select the project number for the project that requires the reporting of an event to the IRB.
2. Select “Start an xForm”
3. Select the “Adverse Event Submission” xForm.

4. Address the necessary portions of the xForm, explaining the adverse event, date of the event, and actions taken to correct the adverse event.
5. Sign off and submit the form for IRB review.

**Study Continuation**

While it is the responsibility of the PI of the study/protocol, to maintain the project in an active status, IRBManager will send email reminders, 60-30-7 days prior to the expiration date of your study. A link to access the continuation form may be found in that notification.

If the user does not utilize this notification and link, it is necessary for the user to first access the study. Active studies/protocols may be found in the “My Protocols” section at the bottom of your dashboard as directed above.

1. On the home page under ‘My Protocols,’ select the project number for the project that requires the reporting of an event to the IRB.
2. Select “Start an xForm”
3. Select the “Request for Continuation” xForm.

4. Address the necessary portions of the xForm, uploading the required documents.
5. Sign off and submit the form for IRB review.
**Protocol Modification/Amendment**

Any changes to the study/protocol must be reviewed and approved by the IRB prior to initiation except when necessary to eliminate apparent immediate hazards to the subject.

1. On the home page under ‘My Protocols,’ select the project number for the project that requires the reporting of an event to the IRB.
2. Select “Start an xForm”
3. Select the “Request for Protocol Modification” xForm.

4. Address the necessary portions of the xForm, uploading any new required documents.
5. Sign off and submit the form for IRB review.

**Study Closures**

The Study Closure xForm is submitted to close a study following the completion of all study procedures, data analysis and preferably, following the acceptance of any pending publications.

1. On the home page under ‘My Protocols,’ select the project number for the project that requires the reporting of an event to the IRB.
2. Select “Start an xForm”
3. Select the “Study Closure” xForm.

4. Complete and Save the Closure Form.
5. Sign off and Submit the form for IRB review.