IRBManager Guidance Manual

IRBManager is an online submission, workflow, and data management system for Radford University’s Institutional Review Board (IRB) and 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, annual continuing reviews, amendments/modifications, as well as reports for unanticipated problems, adverse events, and study closures.

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

Getting Started

Logging On
IRBManager can be accessed under One Campus, using your Radford University email address and password and searching for IRBManager. (see figure 1)

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.

Figure 1 OneCampus Radford University
Understanding Your Dashboard
Once logged into IRBManager, you will be taken to your dashboard. (see figure 2)
Your dashboard is the starting point. Here, is where you will start forms, check the progress of applications, and find your approved protocols.

The “Notices” section at the right of your dashboard, has basic help and contact information. (see figure 2)

Selecting the “Home” button on any page will bring you back to your dashboard. (see figure 3)
IRBManager has a dark mode option. To turn it on, go to “Settings” in the top right corner of the screen. (see figure 4)

Figure 4 Settings button on the top right of your dashboard

On the following page, you will see a list of settings. Here, you can change the way your dashboard looks. IRBManager has a dark mode option.

To turn it on, go to “Settings” in the top right corner. Click “Turn on Dark Mode.” (See figure 5)

Figure 5 Setting to turn on Dark Mode

Your view should now look like this: (see figure 6)

Figure 6 Dark Mode view
From the settings, you can also change the look of your dashboard by engaging the “Bubble Dashboard.” Click on “Switch Dashboard.” (see figure 7)

IRBManager will ask you to confirm this change: (see figure 8)

After confirming your request, your dashboard will look like this: (see figure 9)

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

The dashboard will allow a user to get a broad overview of protocols they are associated with and the status of those applications.
**Protocol View**
You are able to view a list of the protocols that you are associated with from the Dashboard. By clicking on the underlined link, you will be able to view the details of your associated protocols and access protocols based on your role on the protocol.

Each protocol’s study-site will provide a list of events submitted to the Research Compliance Office for IRB/IACUC review. Figure 10 shows 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 officially created when you submit an xForm. A study is created and a protocol number assigned when the IRB/IACUC has received the application and determined it is ready for review.

![Figure 10 Your active protocols](image)

**xForm View**
**xForm** is the name of the electronic, web-based IRB application form. The xForms section of your dashboard shows the forms or applications currently being processed at this time.

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). (see figure 11)

- In figure 11, this user has one (1) unsubmitted xForm, showing that 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 xForm(s).
The dashboard, above, shows the user does not have any (0) xForms being processed at a later stage. Any xForms the user had submitted and 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.

The user has three (3) xForms currently awaiting their attention and currently need actions taken by the user (i.e., review and signature required, revisions requested by the IRB/IACUC, etc.).

By clicking on the link, you can go directly to the xForms that need your attention.

From the dashboard, you may also view the following information about their studies, including:

- The protocol number
- The main site where the research is taking place
- The PI's name
- The project title
- The expiration date of the protocol (if this is blank, the protocol has not yet been approved)
- Status
  - Pending (if not yet approved)
  - Active
  - Exempt (if IRB)
  - Deferred
  - Expired
  - Suspended

![Figure 11 xForms: Your protocol submissions in progress](image)

Study personnel indicated on the protocol application will have access to the study in IRBManager after a determination is made about the protocol by the IRB/IACUC.
**Note:** Closed protocols will not display on your dashboard. In addition, the status of the protocol will depend on whether the protocol is still under initial review or if elsewhere in the protocol’s lifecycle.

**Event View**

The Events section of the DASHBOARD shows all open types of submissions within the IRBManager system such as initial submission, closures, continuations, and amendments/modifications. (see figure 12)

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. 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 IRB/IACUC is notified of the approval. It is possible for the xForm to be complete and approved, but the event will still show as “open” until an IRB/IACUC meeting takes place.

![Events](image)

**Figure 12 Events are different types of submission of an IRB/IACUC protocol**

You may begin a new IRB/IACUC Initial Application form also known as xForm under the **Actions** (left-side tool bar). (see figure 13)

**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.
Left Tool Bar

On the left side of your dashboard screen is another tool bar. (see figure 13)

![Figure 13 Tool bar on the left-side of your dashboard](image)

**Recent Items** accessed are also found on the left-side tool bar. 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** The Messages heading is an area the IACUC/IRB Office will use for communication to all users within the system.

**My Docs & xForms** on the left side tool bar will also provide a table with xForms associated with you as a user of IRBManager of IRBManager across the entire system. The picture above, notes there are 30 xForms with which the user is associated. (see figure 13)
My Docs & xForms  The My Docs & xForms heading is an area you can attach frequently submitted documents. For example, if you are required to upload CVs for multiple persons, you can use “Attachments”. (see figure 14)

![Figure 14 View of the "Attachments" hyperlink](image)

**Creating a New IRB/IACUC Application**

To begin your application, click on “**Start a xForm**” under your “**Actions**” menu on the tool bar on the left of your dashboard. (see figure 15)

![Figure 15 Left-side tool bar](image)

There are several pages to the application with additional pages added based on responses to individual questions in the protocol application.
When you are completing the application, **answer each question on the page.**

**If you have not filled in all the required answers, you will not be able to advance to the next page when you click “Next.”**

Instead, sections with missing information will be highlighted in **red text.** (see figure 16) 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.

![Initial Application -- General Information](image1)

*Figure 16* Answer each question on the page. Missed questions are noted in red.

You can click on the outstanding issues you need to address at the top of the page to be taken directly to those questions.

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. (see figure 17)

![Next, Save for Later, More](image2)

*Figure 17* Located at the bottom of the page

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

**To navigate pages within the application** and 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. (see figure 18)

![Collaborators](image3)

*Figure 18* Located on the top of the page of your IRB/IACUC submission
Saving Information in Tables
For some needed information, such as the addition of personnel or study participant information, there are tables where you will have to enter and save information.

In these instances, you will enter the required information and then scroll over and click **“Save”** on the right-hand side of the table. (see figure 19)

Once this information is saved, a new row will appear and allow you to repeat the process.

You must click “Save” before it will allow you to move on to the next page.

Attaching Documents
There are several places on the application, you will be asked to attach documents, such as consent forms, recruitment materials, advertisements, grant proposal pages, scientific collection permits, etc. Simply click on the “Add Attachment” button. (see figure 20)

Once you have clicked the button, a window will pop-up allowing you to choose the file destination.

Giving Protocol Access to a Team Member on the Protocol – Adding a Collaborator
The only member of the study/protocol team with access to an unsubmitted xForm or xForm in progress is the submitter (the person who started the application) of the xForm. If the PI did not create 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/IACUC.

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. (see figure 21)
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 any of the other xForms created in a study.

If you are unable to add the collaborator, you may need to add him/her as a contact in the IRBManager system. Using the General Information drop-down list at the top of the xForm, will allow you to access the personnel table on the IRB application. (see figure 22)

Select the hyperlink “Add a New Contact”, located at the bottom of the personnel table. (see figure 23). This will lead you through the steps to add personnel.
The rest of the study personnel will be able to view the xForm only once a determination is made by the IRB/IACUC.

**Submitting an IRB/IACUC Protocol**

**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, click “Next”, and on the next page, click “Submit”. The protocol application will then 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. As noted above, if the submitter is a student and not the faculty member PI, the application needs to be submitted to their faculty member for review, sign-off, and submission for official IRB/IACUC review.

The PI will receive an email asking notifying of a new protocol application for their review. 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. (see figure 24)

![Image of IRBManager email notification](image)

**PI Protocol Sign-off and Submission**
Once the IRB or IACUC application has been completed, it must be electronically signed before submission. (see figure 25)

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.
Figure 24 PI Assurance and Acknowledgement

Review this section and click “Sign”.

A new window will open and you will be prompted to enter sign-on using the credentials used to sign in to IRBManager (your Radford email and password). The signature time stamp will populate where the signature box was located. (see figure 26)

Figure 25 PI signature - Select “Next” to submit

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. (see figure 27)
Revisions of Returned Protocols

Should an IRB/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-xx 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

Figure 27 IRBManager email of the return of a protocol for needed revisions

A link to the protocol will be provided in the email, allowing the user to access the protocol and make the necessary revisions. (see figure 28)

Events in IRBManager
Adverse Event Submission, Continuation/Annual Report Submission, Modification/Amendments, and Study Closures

For any action related to an approved project, such as a Continuing/Annual Report, Protocol Modification/Amendment, 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. (see figure 29)
Figure 28 Find your active studies at the bottom of your dashboard

Select the hyperlink associated with the corresponding xForm or active project/protocol. On 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.” (see figure 30)

Figure 29 The first step in taking an action on an approved IRB.IACUC protocol
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. (see figure 31)

### 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. (see figure 32)

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/IACUC.
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/Annual Report
It is the responsibility of the PI of the study/protocol, to maintain the project in an active status. As a courtesy, 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/IACUC.
2. Select “Start an xForm”
3. Select the “Request for Continuation” xForm. (see figure 33)
4. Address the necessary portions of the xForm, uploading the required documents.
5. Sign off and submit the form for IRB/IACUC review.

Protocol Modification/Amendment
Any changes to the study/protocol must be reviewed and approved 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/IACUC.
2. Select “Start an xForm”
3. Select the “Request for Protocol Modification” xForm. (see figure 34)

4. Address the necessary portions of the xForm, uploading any new required documents.
5. Sign off and submit the form for IRB/IACUC 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/protocol number for the project that has been completed and is to be closed.
2. Select “Start an xForm”
3. Select the “Study Closure” xForm. (see figure 35)
4. Complete and Save the Closure Form.
5. Sign off and Submit the form for IRB/IACUC review.

**Checking on the Progress of an Application**
You can log into your dashboard at any time to check on the progress of your application. Your active projects (protocols) will be displayed under “Projects.” You can check on the status of protocols that have been submitted for review under “xForms”, found in the center of your dashboard. The user in figure 36 has 8 xForms that are being processed at a later stage. By clicking on the link “8 xForms,” you will be able to see the stage of review for the project.

```
4 unsubmitted xForms.
8 xForms being processed at a later stage.
10 xForms awaiting your attention.
```

Figure 36 Select to check on the progress of an IRB application

Please be aware that it may take several minutes for your newly submitted IRB application to show up here. It will not be instantaneous.

**Obtaining a Copy of Your Approved Protocol**
To access a PDF copy of your approved IRB protocol, select the link for the application you wish to access.

On the following page, under the “Actions” menu, select “xForms.” Select the hyperlink to the application you would like to access. A new window will open where you may print or save to PDF.