

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 research projects 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)

Please note: 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 to unlock your account.

Note: Should your IRBManager account lock, it does not affect your Radford email account.

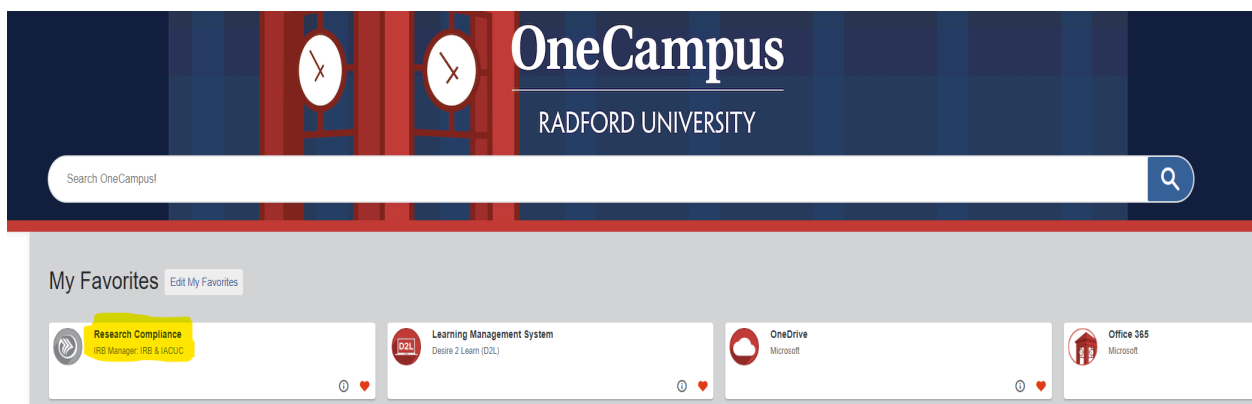
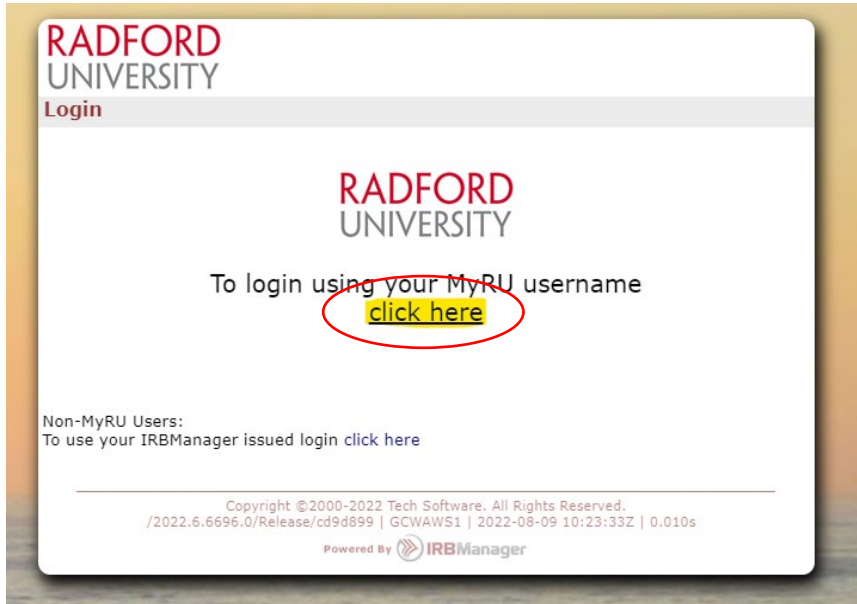


Figure 1 One Campus Radford University

Once you have logged into OneCampus, select the IRB Compliance tile. (See figure 1) On the next screen, "click here." (See below) This will take you to your dashboard.



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.

My Protocols (37 Active)

- You are associated with **37 active** Protocols and **55 total** Protocols.
- You are the PI for **37 active** and **55 total** Protocols.
- You are the Co-Investigator for **1 active** and **3 total** Protocols.
- You are the CRO for **0 active** and **1 total** Protocols.
- You are the Only Researcher for **27 active** and **40 total** Protocols.
- You are the Research Assistant for **1 active** and **1 total** Protocols.
- You are the Student Researcher for **1 active** and **2 total** Protocols.
- Committee IACUC has **40 active** and **48 total** Protocols.
- Committee IRB has **240 active** and **384 total** Protocols.
- Committee Test Committee has **2 active** and **2 total** Protocols.

xForms (4 Active)

- You have **0 unsubmitted** xForms.
- You have **4 xForms** being processed at a later stage.
- There are **1 xForms** awaiting your attention.

Events (70 Open)

Only show events where I am:

- You have **6 Amendment** events.
- You have **2 Continuation** events.
- You have **13 IACUC Amendment** events.
- You have **3 IACUC Closure** events.
- You have **32 IACUC-Initial Submission** events.
- You have **11 IRB Closure** events.
- You have **3 IRB Initial Submission** events.
- You have **70 Total Open** events

My Protocols (37 Active)

Protocol	Site	PI	Title	Expires	Status	Reference Doc(s)
2020-149-RU	Radford University	[REDACTED]	[REDACTED]	Exempt	New From PI	

Notices

[Radford University Institutional Official / IRB & IACUC](#)

Dr. Jeanne Mekolichick, Institutional Official and Associate Provost for Research, Faculty Success, and Strategic Initiative

Contact information: 540.831.6504
jmekolic@radford.edu

Please update your IRB informed consent forms to reflect this change with the annual continuation or amendment(s) of your protocol.

Figure 2 Dashboard View

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)

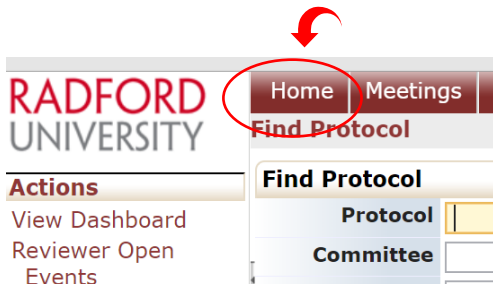


Figure 3 Home button located on the top of your dashboard

IRBManager has a dark mode option. To turn it on, go to "Settings" in the top right corner of the screen. (See figure 4)

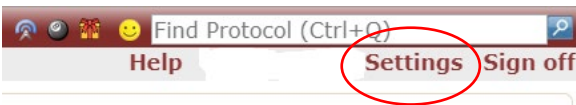


Figure 4 Settings button on the top right of your dashboard

On the next 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)

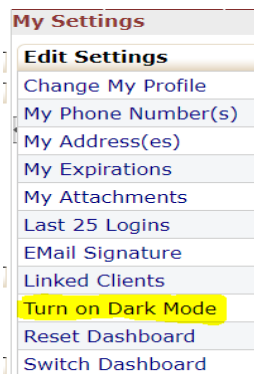


Figure 5 Setting to turn on Dark Mode

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

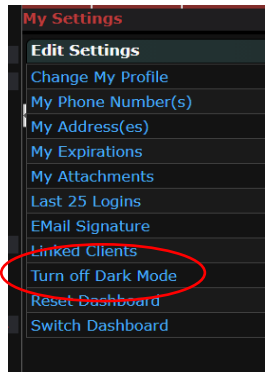


Figure 6 Dark Mode view

From "Settings", you can also change the look of your dashboard by engaging the "Bubble Dashboard." Click on "Switch Dashboard." (See figure 7)



Figure 7 Switch the look of your dashboard

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

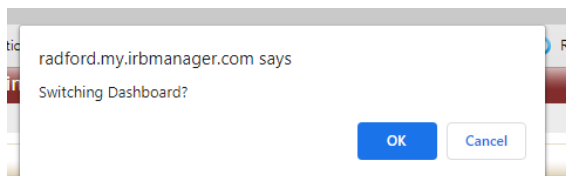


Figure 8 Confirm your dashboard change

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

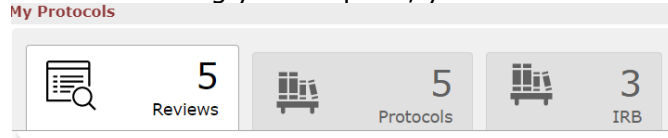


Figure 9 The new look of your dashboard

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 can view a list of the protocols that you are associated with from the Dashboard. By clicking on the underlined link on your dashboard, you will be able to view the details of your associated protocols and access protocols based on your role on the protocol.

When you click on the hyperlink associated with the protocol you would like to access, you will be able to see the protocol's study-site. 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 Research Compliance Office has received the IRB/IACUC application and determined it is ready for review.



Figure 10 Your active protocols

xForm View

xForm is the name of the electronic, web-based IRB/IACUC application form. The xForms section of your dashboard shows the xForms 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, below, 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/IACUC, 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

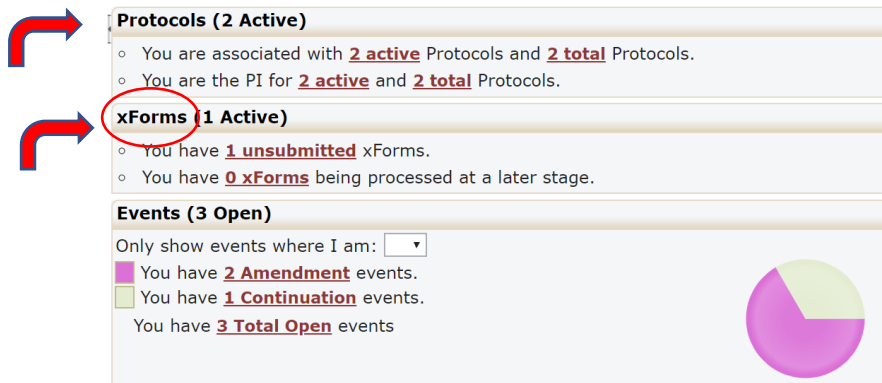


Figure 11 xForms: Your protocol submissions in progress

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 submissions, closures, continuations/annual reports, 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.

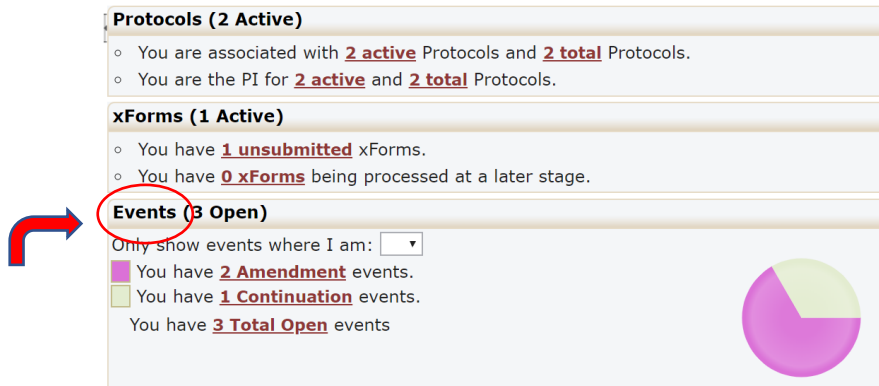


Figure 12 Events are different types of submission of an IRB/IACUC protocol

Left Tool Bar

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

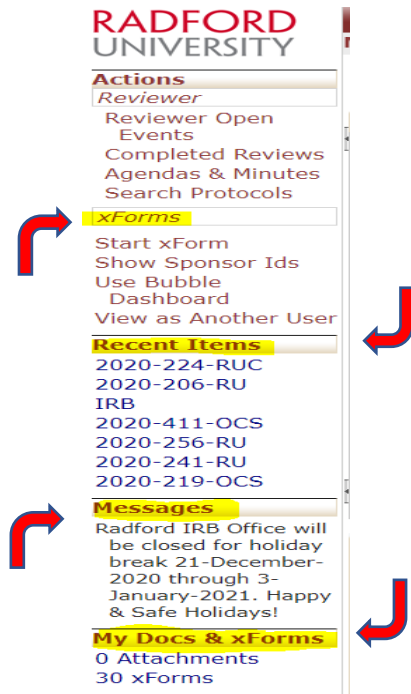


Figure 13 Tool bar on the left-side of your dashboard

From the **Actions** menu, you may begin a new IRB/IACUC Initial Application form also known as xForm (left-side tool bar).

Note: Secondary applications such as Amendments, Continuing Reviews, Closure Reports, and Unanticipated Problem or Adverse Event Reports cannot be started from this area. **These applications must be started from within the protocol/study itself.**

Recent Items accessed are also found on the left-side tool bar. Hyperlinks under this heading will show the seven (7) most recent items you have viewed in IRBManager. Click on any link under "Recent Items" to go directly to that item.

Messages The Messages heading is an area the Research Compliance Office will use for communication to all users within the system.

My Documents & Forms on the left side tool bar will also provide a table with xForms associated with you as a user of IRBManager across the entire system. The picture above, notes there are 30 xForms with which the user is associated. (See figure 13)

My Documents & xForms The My Documents & xForms heading is also an area in which 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)

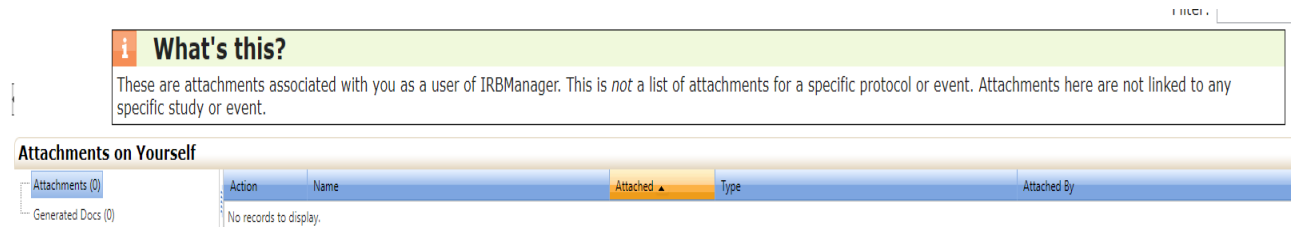


Figure 14 View of the "Attachments" hyperlink

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)

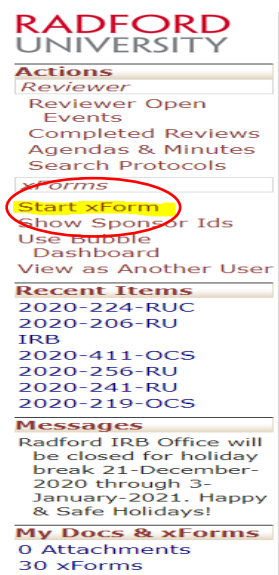


Figure 15 Left-side tool bar

There are multiple pages to the IRB/IACUC application with 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

The following issues exist. Click on an issue to jump there.

- Title of Study - Required.
- Primary Investigator - Required.

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)

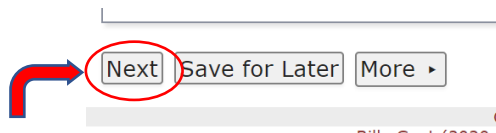


Figure 17 Located at the bottom of the page

If you have not completed the application and need to exit the program, remember to select "Save for Later." This will save the information you have already input into the IRB/IACUC application and allow you to return to the application at any time.

Note: If you do not "Save for Later," you will not only lose the information you have already entered, but the system will also begin a new protocol application.

If you would like to navigate pages within the IRB/IACUC application and skip to different pages without having to address all the required sections on a page, you can use the drop-down box at the top of the page and select the page of the IRB/IACUC application you would like to access. (See figure 18)

Figure 178 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 to the right and click **"Save"** on the right-hand side of the table. (See figure 19)

Display Personnel Table *(Required)*

Please hit the save button after you have uploaded all necessary information and documentation for the additional researchers.

If you are the only researcher on your study, please add yourself and select 'only researcher' as your role.

Name*	Department*	Please choose the applicable level of personnel. *	Role*	CV/Resume	Undergraduate CITI Req. - Student Class Project	Graduate Student Req. - Revised Common Rule	Grad Req. - Social & Behavioral Basic Refresher	Faculty Req. - Revised Common Rule	Faculty Req. - Social & Behavioral Basic Refresher	Action
<input type="button" value="Add Contact"/> <small>No answer provided.</small>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Add Attachment"/>						<input type="button" value="Save"/>

Figure 19 Scroll to the right-side of the screen to "save"

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

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. (See figure 20)

Please attach any questionnaires, surveys, tests, interview questions, or manipulation descriptions.

Figure 20 Select "Add Attachment" to attach documents.

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

Uploading Revised Documents

During the review process, you may be asked to revise a document such as the informed consent form for IRB applications. Once you have revised the needed document and need to upload the new version to your IRBManager application, click on the two green circling arrows. (See figure 21)

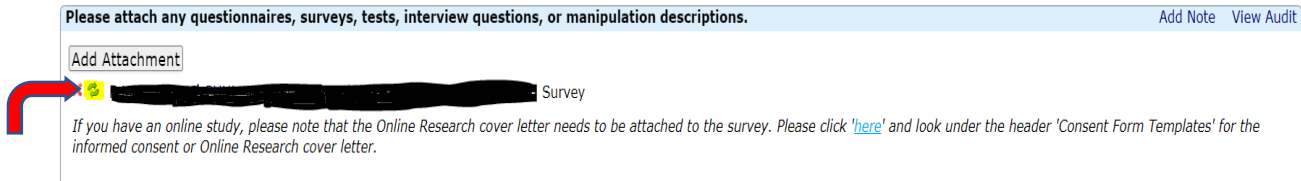


Figure 21 Select "the two green circling arrows" to attach a new version of the document.

Once you have clicked the two green circling arrows, a window will pop-up allowing you to choose the file destination and upload the revised document for review. (See figure 22)

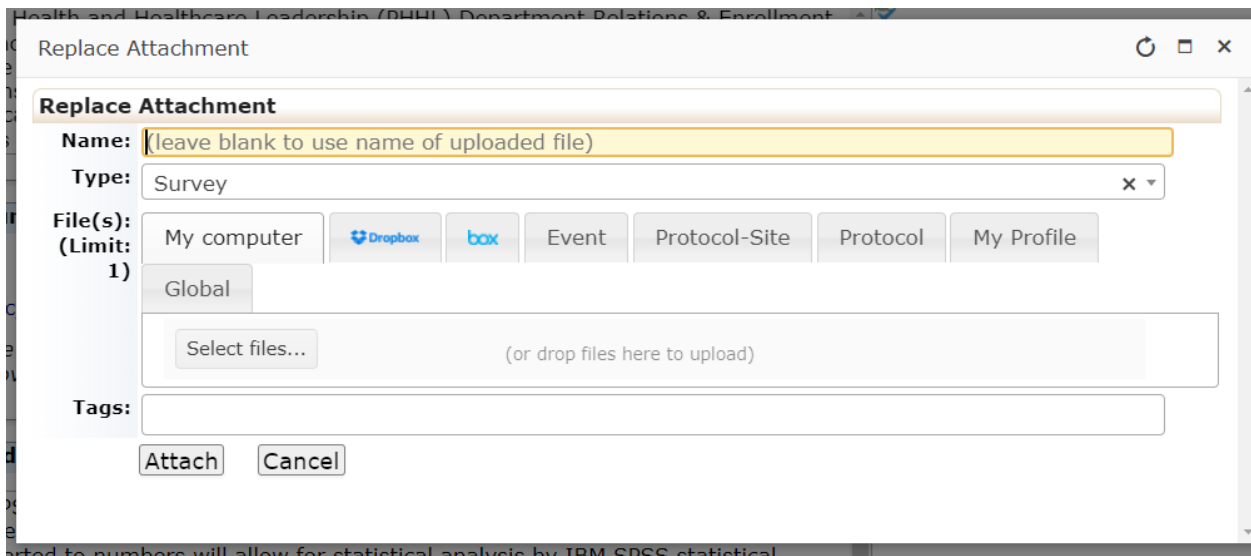


Figure 22

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.

Access to the data entry portion of the protocol is not available to anyone other than the submitter until the application is submitted for review.

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 23)

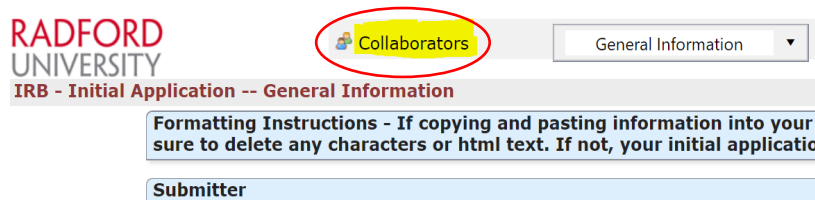


Figure 23 Adding a collaborator gives access to the application before it is submitted

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.

Note: 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/IACUC application. (See figure 24)

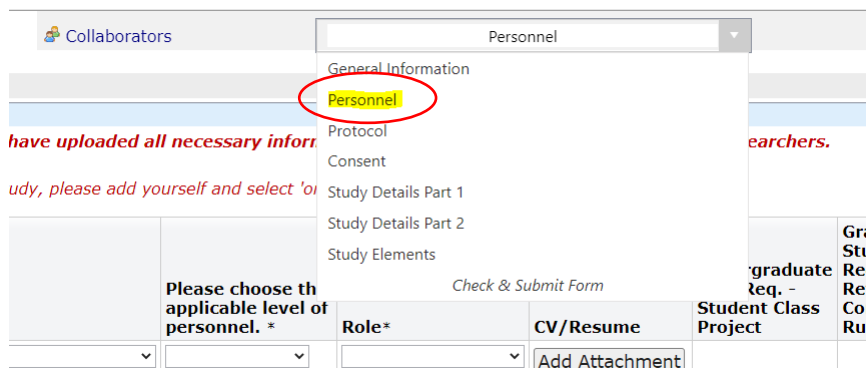


Figure 184 Skip to the Personnel section to add a contact

Select the hyperlink "Add a New Contact", located at the bottom of the personnel table. (See figure 25). This will lead you through the steps to add personnel.

* It is not necessary to upload CITI certificates to your IRB/IACUC application. IRBManager performs a sync with CITI each morning. If study personnel registered with CITI using their Radford.edu email address, training will automatically be reflected in your application. However, if study personnel registered with CITI using another email address, the information will not register on the IRB/IACUC application.

The Research Compliance Office will confirm training upon receipt of the xForm for review and notify the PI of any needed CITI course completion.

Once the protocol is approved, all study personnel have access to “start xForm” under that protocol.

Display Personnel Table Add Note View Audit

Please hit the save button after you have uploaded all necessary information and documentation for the additional researchers.

If you are the only researcher on your study, please add yourself and select 'only researcher' as your role.

Name*	Department*	Please choose the applicable level of personnel. *	Role*	CV/Resume	Undergraduate CITI Req. - Student Class Project	Graduate Student Req. - Revised Common Rule	Grad Req. - Social & Behavioral Basic Refresher	Faculty Req. - Revised Common Rule	Faculty Req. - Social & Behavioral Basic Refresher	Action
Add Contact <small>No answer provided.</small>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Save

Please click on the link below to add new personnel to IRBManager. Once the form is filled out and submitted add the personnel on the table.

[Add New Contact](#)

Figure 25 Add a New Contact

Submitting an IRB/IACUC Protocol for Review

Student Submissions

In many instances, the person completing the protocol application may not be the PI. This person is identified in IRBManager as the “submitter.” 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 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 notification 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 26)

Dear [REDACTED]

This is a notification that a new application \$\$Q2\$\$ has been submitted by [REDACTED] and your review and signature is required.

Please click here to go directly to the form \$\$Form\$\$

Thank you

Figure 26 IRBManager email notification to the PI of sign-off and submission needed for IRB review

If, during the PI's review of the IRB/IACUC application, revisions are needed prior to submission to the Research Compliance Office, the PI should state the application is not ready for submission by clicking "No" and adding any comments in the text box provided. Clicking "Next" and "Submit" on the following page, will return the application to the submitter to make the needed changes. The student/submitter will then resubmit to the PI for review, sign-off, and submission for IRB/IACUC review.

PI Protocol Sign-off and Submission

Once the IRB or IACUC application has been completed, it must be electronically signed before submission. (See figure 27)

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.

BY SUBMITTING THIS DOCUMENT, THE INVESTIGATOR AGREES: [Add Note](#) [View Audit](#)

1. No participants will be recruited or entered under the above protocol number until the Principal Investigator receives written notification of IRB protocol approval.
2. Any modifications of the protocol or consent form must be approved by the IRB Chair or the IRB Chair's designee.
3. All protocol continuation requests will be completed and submitted no later than thirty (30) days before the expiration of the protocol.
4. All participants will be recruited and consented as stated in the IRB protocol. If written consent is required, all participants must sign a copy of the consent form that has an unexpired IRB approval stamp.
5. The IRB office will be notified within thirty (30) days of the closure of a study
6. The IRB office will be notified within thirty (30) days of a change in Principal Investigator or change in Principal Investigator affiliation with Radford University.
7. All individuals associated with this research will complete, or have completed, the IRB Human Subjects Training before the start of any research.

I certify that the information entered above is correct. I understand that submission of false or incorrect data can result in suspension of my research at Radford University. Final submission of this form into the IRBManager online system within my account constitutes my signature for this form.

Figure 197 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 28)

Signed Wednesday, August 26, 2020 9:35:40 AM ET by

Figure 28 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 29)

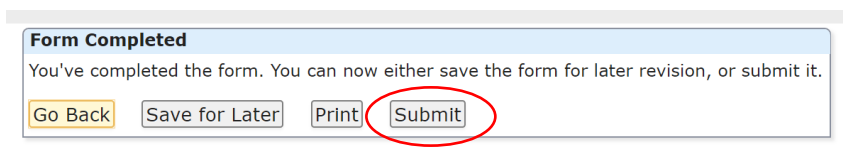


Figure 29 Final step of protocol submission



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-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

Figure 30 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 30)

Events in IRBManager (Adverse Event Submission, Continuation/Annual Review Submission, Modification/Amendments, and Study Closures)

For any action related to an approved project, such as a Continuing/Annual Review, Protocol Modification/Amendment, Adverse Event Submission, or Study Closure form, you must first go to the protocol.

Your active studies/protocols may be found in the "My Protocols" section at the bottom of your dashboard. (See figure 31)

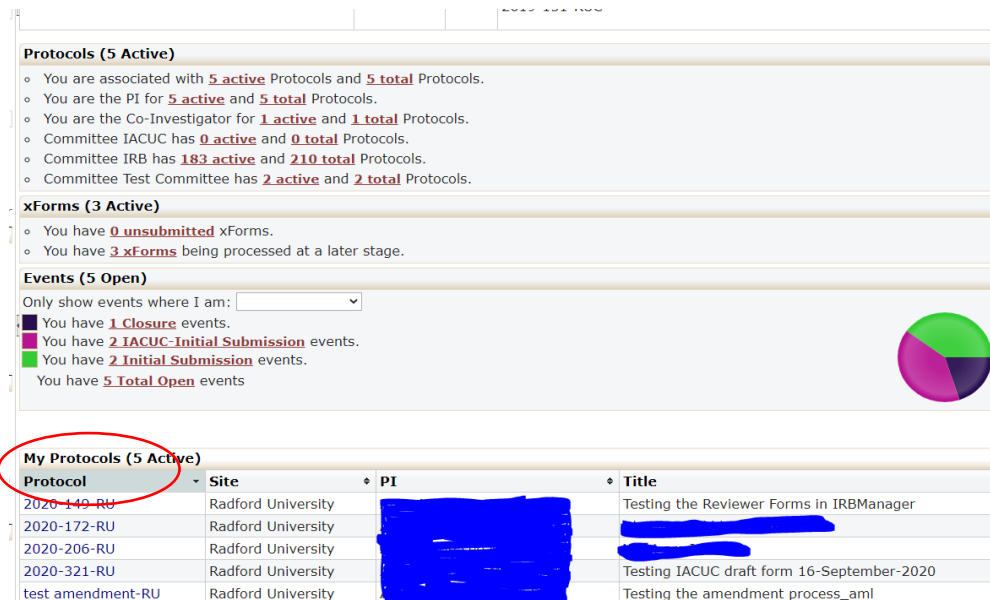


Figure 31 Find your active studies at the bottom of your dashboard

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 32)

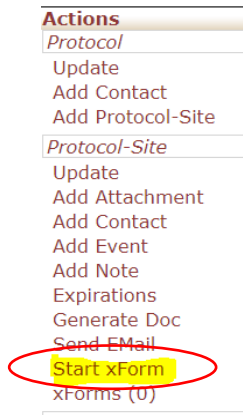


Figure 32 The first step in taking an action on an approved IRB protocol

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 33)

Select xForm to start		
Action	Form (Click to start)	Description
	IACUC Adverse Event Report Form	Use this form for notification of IACUC adverse events/protocol deviations.
	IACUC Amendment Form	Please use this form to make any changes to your currently approved IACUC protocol.
	[REDACTED]	[REDACTED]
	IACUC Protocol Closure Report	Please use this form for the closure of your IACUC protocol.
	IRB Adverse Event Submission	Adverse Event Submission-IRB
	[REDACTED]	[REDACTED]
	IRB Request for Continuation - Full Board Approved Protocols	Use for the Continuation of ONLY Full Board Review Protocols (This form does not apply for Expedited and Exempt protocols).
	IRB Request for Protocol Modification	Use This Form to Make Changes to Your Currently Approved IRB Protocol
	IRB Study Closure Form	Use this form to close your IRB study.

Figure 33 Available actions available with an approved protocol

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 34)

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/Report" xForm.

Select xForm to start	
Action	Description
Form (Click to start)	
IACUC Adverse Event Report Form	Use this form for notification of IACUC adverse events/protocol deviations.
IACUC Amendment Form	Please use this form to make any changes to your currently approved IACUC protocol.
IACUC Protocol Closure Report	Please use this form for the closure of your IACUC protocol.
IRB Adverse Event Submission	Adverse Event Submission-IRB
IRB Request for Continuation - Full Board Approved Protocols	Use for the Continuation of ONLY Full Board Review Protocols (This form does not apply for Expedited and Exempt protocols).
IRB Request for Protocol Modification	Use This Form to Make Changes to Your Currently Approved IRB Protocol
IRB Study Closure Form	Use this form to close your IRB study.

Figure 34 Adverse Event – IRB/IACUC

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/IACUC review.

Study Continuation

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.
2. Select “Start an xForm”
3. Select the “Request for Continuation” xForm. (See figure 35)

Select xForm to start	
Action	Description
Form (Click to start)	
IACUC Adverse Event Report Form	Use this form for notification of IACUC adverse events/protocol deviations.
IACUC Amendment Form	Please use this form to make any changes to your currently approved IACUC protocol.
IACUC Protocol Closure Report	Please use this form for the closure of your IACUC protocol.
IRB Adverse Event Submission	Adverse Event Submission-IRB
IRB Request for Continuation - Full Board Approved Protocols	Use for the Continuation of ONLY Full Board Review Protocols (This form does not apply for Expedited and Exempt protocols).
IRB Request for Protocol Modification	Use This Form to Make Changes to Your Currently Approved IRB Protocol
IRB Study Closure Form	Use this form to close your IRB study.

Figure 35 Select to complete your request to continue research on a protocol

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

Note: The IACUC Annual Continuation report form is not yet “Live” in IRBManager. Access to the current paper Annual Continuation report is available on the Radford University IACUC website.

Protocol Modification/Amendment

Any changes to the study/protocol must be reviewed and approved by the IRB and/or IACUC 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" / "IACUC Amendment" xForm. (See figure 36)

Select xForm to start		
Action	Form (Click to start)	Description
	IACUC Adverse Event Report Form	Use this form for notification of IACUC adverse events/protocol deviations.
	IACUC Amendment Form	Please use this form to make any changes to your currently approved IACUC protocol.
	IACUC Protocol Closure Report	Please use this form for the closure of your IACUC protocol.
	IRB Adverse Event Submission	Adverse Event Submission-IRB
	IRB Request for Continuation - Full Board Approved Protocols	Use for the Continuation of ONLY Full Board Review Protocols (This form does not apply for Expedited and Exempt protocols).
	IRB Request for Protocol Modification	Use This Form to Make Changes to Your Currently Approved IRB Protocol
	IRB Study Closure Form	Use this form to close your IRB study.

Figure 36 Select to begin your amendment/modification

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 number for the project that requires the reporting of an event to the IRB/IACUC.
2. Select "Start an xForm"
3. Select the "Study Closure" xForm that applies to your project (IRB or IACUC). (See figure 37)

Select xForm to start		
Action	Form (Click to start)	Description
	IACUC Adverse Event Report Form	Use this form for notification of IACUC adverse events/protocol deviations.
	IACUC Amendment Form	Please use this form to make any changes to your currently approved IACUC protocol.
	IACUC Protocol Closure Report	Please use this form for the closure of your IACUC protocol.
	IRB Adverse Event Submission	Adverse Event Submission-IRB
	IRB Request for Continuation - Full Board Approved Protocols	Use for the Continuation of ONLY Full Board Review Protocols (This form does not apply for Expedited and Exempt protocols).
	IRB Request for Protocol Modification	Use This Form to Make Changes to Your Currently Approved IRB Protocol
	IRB Study Closure Form	Use this form to close your IRB study.

Figure 37 Select to complete and officially close a protocol – IRB/IACUC

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 38 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.

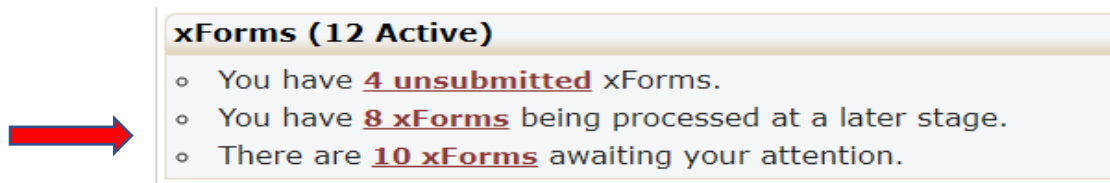


Figure 38 Select to check on the progress of an IRB application

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

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.

If you have any difficulty or need further assistance, please contact the Research Compliance Office at 540.831.5290 or irb-iacuc@radford.edu.