IRBManager

INSTRUCTION MANUAL

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1.0   IRBManager

1.1   What Is IRBManager?

IRBManager is an electronic management system that serves as the "front door" for the submission, tracking, and retention of research protocols and research compliance documents. This includes Human Research Review Committee (HRRC) and Institutional Animal Care and Use Committee (IACUC) application forms, as well as the GVSU Investigator Conflict of Interest (COI) Declaration and Certification Form. Users can fill out and submit forms directly in IRBManager, and all forms, attachments, and documents submitted with a participating study will be accessible via IRBManager.

IRBManager is a fully web-based system that is accessible both on- and off-campus.

1.2   How Do I Access IRBManager?

IRBManager can be accessed here: https://gvsu.my.irbmanager.com/.

The following login page will appear:

1.2.1 GVSU-Affiliated Users

Click the "To login using your GVSU username and password click here" link (or simply click the large GVSU logo in the middle of the page).
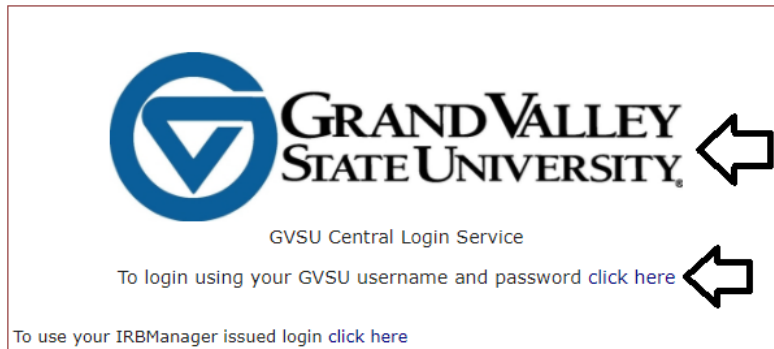
You will then be prompted to enter your GVSU email and network password in a separate pop-up window.

Upon entering your credentials, you will automatically be redirected to the IRBManager Dashboard screen (homepage).
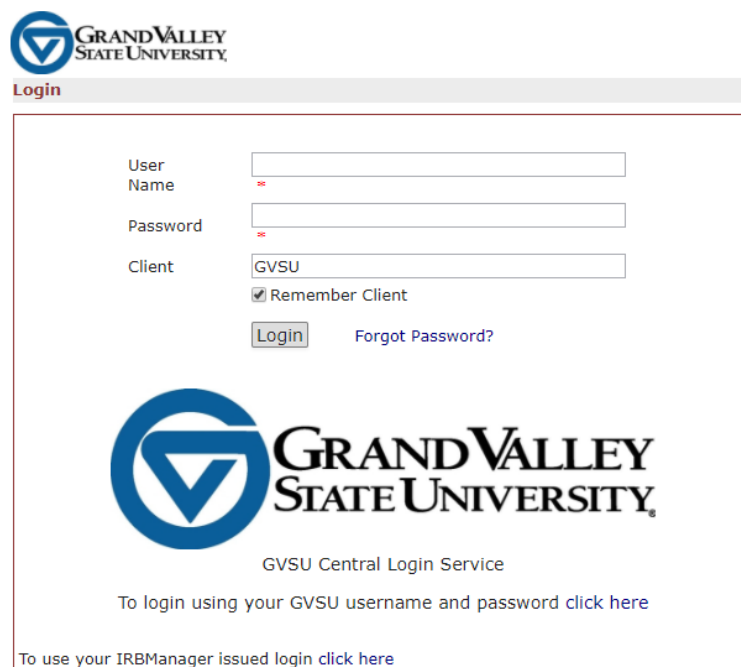
1.2.2 Externally-Affiliated Users

Non-GVSU users (i.e., project co-investigators at another institution, etc.) must be issued an IRBManager username and password to access the system. This can be done one of two ways: 1) any existing IRBManager user can add a new user into the system using the "Contact Look-Up/Add New Contact" xForm, or 2) users can be added manually by the Office of Research Compliance and Integrity (contact rci@gvsu.edu for access).

Upon being added to the system, the new user will receive an email with their username and temporary password. Once non-GVSU users receive their initial IRBManager credentials, they can login via the "To use your IRBManager issued login, click here" link.
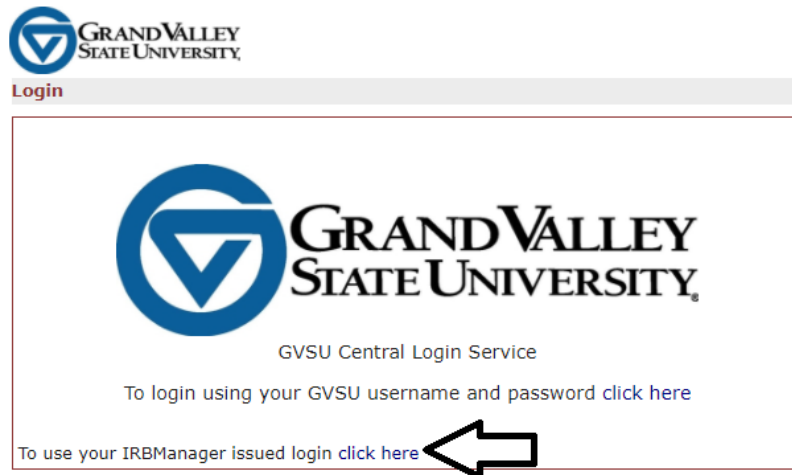
Enter the user name and password provided, and enter "GVSU" as the client. If you have forgotten your password, please click the "Forgot Password?" link.
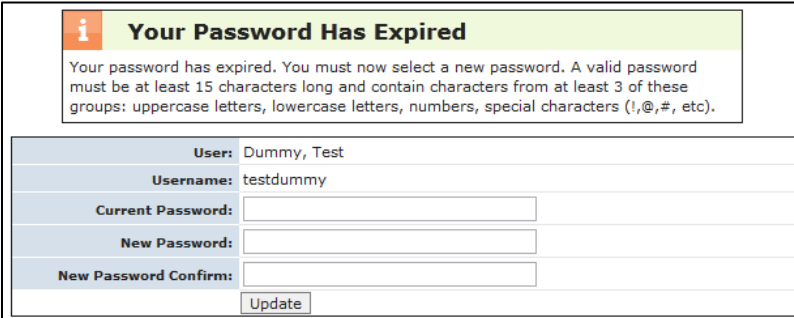
2.0   Passwords

2.1   GVSU-Affiliated Users

GVSU users are prompted for their email address and <u>current</u> network password upon login to IRBManager. (So if your GVSU network password has recently changed, you will need to enter your new network password the next time you login into IRBManager.) You will never need to change your password in IRBManager.

2.2   Externally-Affiliated Users

For those unaffiliated with GVSU, on your first log-in, you will be prompted to change your password.

Your new password must be at least 15 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (!,@,#, etc.).

To change your password and proceed:

1. Enter current password
2. Enter new password (see requirements above) and then enter new password again to confirm
3. Click "Update"

If on any future log-ins you enter the wrong username/password three times, IRBManager locks your account as a security precaution. If that happens, you can click the "Forgot Password" link from the login screen. After filling in the information requested, a new password will be emailed to you and your account will be unlocked.

Once you log in with your username and password, you'll be able to provide an electronic signature on any xForm by entering your password.

3.0   Navigating the Home Page – Dashboard

On the left side of the page, there are several headers:

1. Actions
2. Recent Items
3. Messages (note: will not appear if there aren't any messages posted)
4. Useful Links (note: will not appear if there are no links posted)
5. My Documents and Forms

3.1   Actions

Access forms by clicking "Start xForm" to see a full list and description of available forms. Please note that certain forms (e.g., Continuing Review) can only be completed for a protocol active in IRBManager. These forms are not available from the Dashboard.

"Show Sponsor's Study Id" will only be used if you are working on a study that is sponsored. This will allow you to view your studies listed by sponsor protocol numbers instead of HRRC protocol numbers.

Note: If you have multiple sponsors, the Sponsor Protocol Numbers view will show one line for each sponsor, so a study may have multiple listings in this view.

3.2   Recent Items

The hyperlinks under this heading will show the most recent items you have viewed in IRBManager. You can click on any link under "Recent Items" to go directly to that item.

3.3   My Documents and Forms

This heading shows how many attachments and xForms you have submitted. Note if you click the "xForms" link, it will take you to a separate page showing your forms. On this page, under the "Actions" menu on the left side of the screen, there is a toggle button to Show Complete/Hide Complete forms. So if you do not see previously completed forms on this screen, it likely means you need to press the "Show Complete" button.

3.4   Studies

This shows the studies you are associated with (as principal investigator, co-investigator, project coordinator, research assistant, or authorizing official) and shows studies you are the Principal Investigator on.

Note: By clicking on the underlined link, you will be taken to a separate screen showing the studies with which you are associated.

3.5   xForms

The xForms tab shows the forms currently active at this time for the user. An xForm is also referred to as a submission.

In this view of the Dashboard:

- "You have 2 unsubmitted xForms" = the user has 2 xForms (submissions) started, but has not yet submitted them for further processing. (The user may have clicked "Save for Later" or just closed a form before pressing the "Submit" button at the end of the form.)

Note: By clicking the underlined link, "2 unsubmitted," the user can go straight to the unsubmitted xForms.

- "You have 3 xForms being processed at a later stage" = the user currently has 3 forms being processed. In this case, the user has successfully submitted the forms, and forms are currently under review at a later stage in the processing cycle (e.g., Authorizing Official review or ORCI processing).

- "You have _ xForms in error" = the user has a form that has a back-end error. This is a software issue that the ORCI will be made aware of and will resolve.

- "There are 1 xForms currently awaiting your attention" = the user has 1 form that requires their attention and will not be processed to the next stage until the user addresses and submits the form. This will appear if someone else sends a form to the user. (For example, an Authorizing Official will see this when a PI sends a form to them for review and approval. A PI would see this if the ORCI returned a form for clarifications, etc.).

Note: By clicking the underlined link, "1 xForms," the user can go straight to the xForm that needs attention.

3.6   Events

The events section of the Dashboard shows the submissions open by submission type.

This section shows all open events and the submission name, such as continuing review, initial review, subject materials and modifications.

Note: An event stays open until the board is notified of the approval. It's possible for the xForm to be complete and approved, but the event is still open until a board meeting occurs.

3.7   My Studies

Study	Site	PI	Title	Expires	Status
2017-011-GVSU	Grand Valley State University	ORCI, Test	CTRL		New from PI
2017-026-GVSU	Grand Valley State University	ORCI, Test	SATURATION		New from PI
2017-027-GVSU	Grand Valley State University	ORCI, Test	4:44		New from PI

This is a list of all the studies the user is associated with active studies.

Note: By clicking on the blue link under "Study" the user can go straight to the study.
By clicking the arrow beside the Study, Site, PI, Study Title, Expiration Date and Status, the user can sort the studies accordingly.

- Studies can be sorted by protocol number
- Site can be sorted alphabetically

- PI is sorted alphabetically
- Study Title can be sorted alphabetically
- Expiration dates are sorted by numerical date
- Status is grouped and sorted alphabetically

3.8   Top Headings
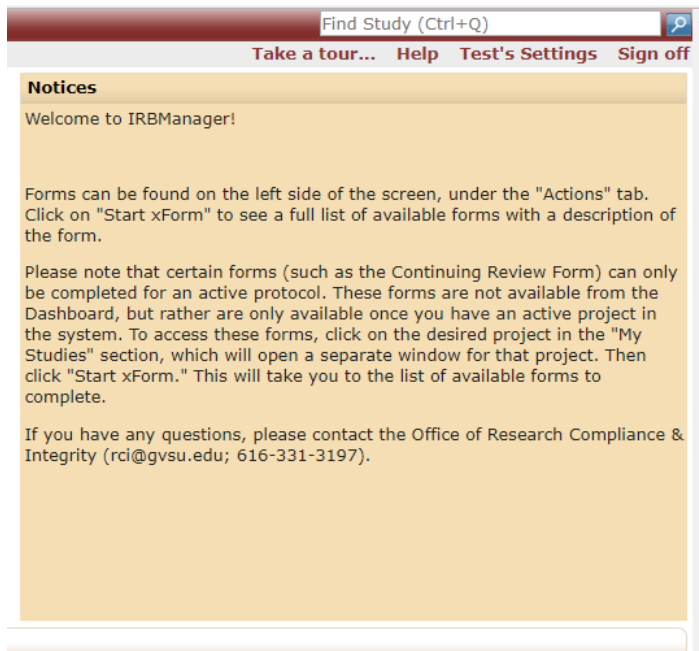
Find Study toolbar – Search bar to find existing studies. Studies can be searched by protocol number, site, PI name, title, expiration date, or status.

Take a tour… - Provides an overview of the sections on the Dashboard.

Help – Hovering over the "Help" button brings up several options, including "Contact Administrator." Clicking on "Contact Administrator" allows you to send an email directly to ORCI via the system. (Note: If you click on "Help," rather than hovering the cursor over "Help," you currently will get a message saying there is no help available for this page.)

Test's Settings – allows the user to edit their profile settings. "Test" will be replaced with your first name.

Sign off – Click to log off IRBManager.

Under My Settings you can:
1. Change your password (applicable for non-GVSU users only)
2. Change your profile
3. Change your phone number
4. Change your address
5. View last 25 logins
6. Create an email signature

3.8.1 Change Password

This is applicable only for users without a GVSU email. Click on "change password" link. You will then see this view:

Change Password

User	ORCI, Test
Username	ORCI Test Email
Old Password	
New Password	
New Password Confirm	

Update

1. Enter old password.
2. Enter new password. Your new password must be at least 15 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (!,@,#, etc.).
3. Click "Update."

3.8.2 Change Your Profile

1. Click on "Change My Profile" link.
   You will then see this view:

My Profile

User Information

Prefix (Mr, Dr, etc):	Ms.	First Name:	Test
Middle Name:		Last Name:	ORCI
Suffix (Jr, III, etc):		Degree:	
Specialty:		Email Address:	
		From Address for Outbound Email:	

Update

2. Update your name, phone number or email address.
3. Click "Update."

3.8.3 My Phone Numbers

1. Click on "My Phone Number" link.
   You will then see this view:

My Phone Numbers

Phone Book (1)

Action	Primary	Type ▼	Number
✉ ✗	✓	Home	1-3197

2. Click the "hand holding a piece of paper" icon.
   You will then see this view:

3. Update your name, phone number or email address.
4. Click "Update Phone."

3.8.4 My Address

1. Click on "My Address(es)" link.

   You will then see this view:

2. Click the "hand holding a piece of paper" icon

   You will then see this view:

3. Update your name, phone number or email address.
4. Click "Update Address."

3.8.5 Log-In Information

Lists the time and date of the last 25 times the user logged into IRBManager.

3.8.6 Email Signatures

Allows you to enter an email signature when sending email(s) through IRBManager.

1. Click on "Email Signature" link.
2. Enter your signature (see below)
3. Click "Save."
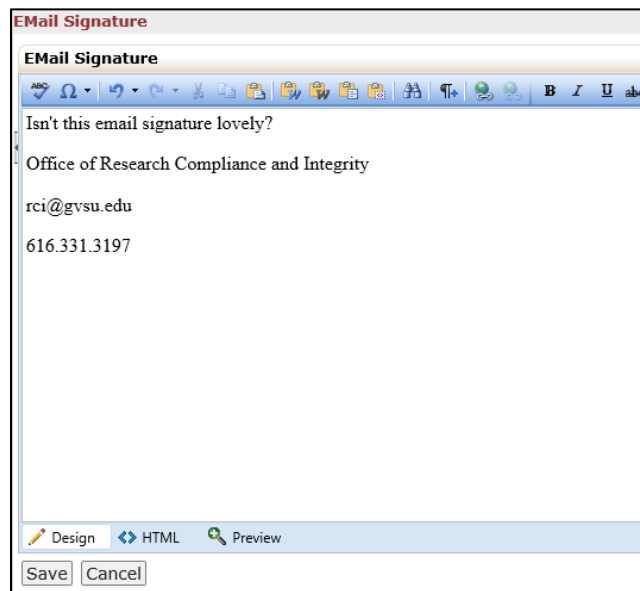
3.9   User Attachments

This function allows the user to attach documents (certificates, forms, etc.) to their IRBManager Contact. These documents will be available on any "Add Attachment" question. They can be accessed by clicking on the "My Profile" tab in the pop-up window that appears when clicking "Add Attachment."
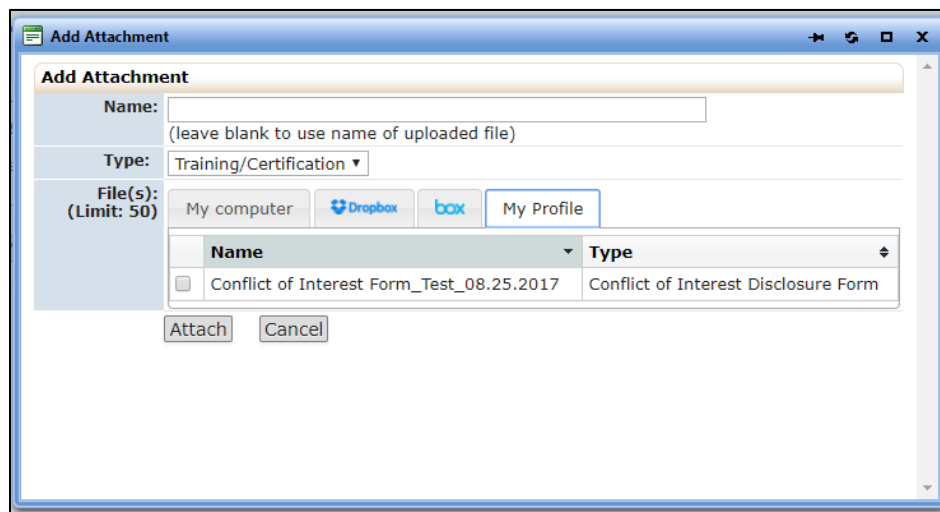
4.0   Navigating the Study Protocol Page

From the home page, you can access the study details for each of your studies. Click on the blue Study Code (Protocol Number) link to access the specific study.

4.1   Study

This section notes all of the basic information about the protocol, such as:
- Protocol number
- Sponsor
- Committee (if there are more than one IRB then this notes the IRB the study was reviewed at)

- Sponsor ID or Acronym of the study
- Category of study
- Grants (if applicable)
- Agent Type (methodologies used in the study)
- CRO (contract research organization, if applicable)
- Study Title
- Year of first review
- Acronym (same as Sponsor ID)
- Number of Approved Subjects
- Conditions (if an applicable subpart should be supplied, it will be noted here)
- Comments from the IRB related to review of the study

▼Study			
Study:	2017-028	Sponsor(s):	
Committee:	HRRC	Sponsor Id:	
Category:	College of Test	Grants:	
Department:	Test		
Reviewer:	Researcher, Test Ph.D.	Secondary:	Researcher, Test Ph.D.
Last Review:		Next Review:	
Agent Types:	Survey	CRO:	
Title:	BLONDE	Year:	2017
Exempt Categories:	Exempt Category 2	Expedited Categories:	
Comments:			

You can click on any blue link; in this section, you can click to view more information on the sponsor.

4.2   Study-Site

This section notes information about the study and the study site, such as:

Study-Site			
Site(s):	GVSU - Grand Valley State University	PI:	ORCI, Test
Status:	Active and Open	Additional:	N
Approval:		Expiration:	
Initial Approval:		Other Expirations:	
Comments:			

- Status (active, data analysis, closed, etc.)
- Initial approval date
- PI name
- Expiration date for continuing review
- Comments

4.3   Contacts

This section list the contacts associated with the study.

▼Contacts (1)		
Action	**Name** ▼	**Role** ⬍
📝 ❌	Researcher, Test Ph.D.	Co-Investigator, Faculty/Staff

4.4   Events

This section lists all the IRB "events" or submissions that have been or are being conducted for this protocol. The event line contains the following sections:

- Type of Event (Initial, Modification, Closure, Subject Materials, etc.)
- Att – number of attachments associated with that event or review.
- Instance/UDF – the material being reviewed for the submission.
- Start – the date the event was started or loaded into IRBManager
- Complete – the date the event was completed and reported to the board.
- Last Mtg – shows the last meeting this event or review was submitted to. Even if a submission is expedited, it will show up in the meeting minutes for that month.

You can click on any blue event link in this section to view information specific to the event. After clicking on the blue link, it will take you to the event details (See Section 5.0).

5.0   Event Details

Event Details are specific to the event or submission.

5.1   Study Site

The Study Site section shows basic study information, including protocol number, name of principal investigator, etc.

5.2   Event

The Event section shows specific details about the submission you are viewing.

Event	
Type:	IRB Initial Submission (#19)
Instance:	
Committee:	Inherited from Study
Primary Reviewer:	
Action Date:	

These include:
- Type (New Submission, Renewal Request, Revision Request Form, etc.)
- Instance (documents or information related to the event)
- Committee (HRRC or IACUC)
- Action date (the date the event was completed)

5.3   Notes

Lists the summary of communication on the study, including any notes from ORCI to the research team and emails between ORCI and the research team that were sent within the IRBManager system. (This section may be empty, and therefore not displayed, for many studies.)

▼Notes (1)
Note
Look at this note!

5.4   Steps

This shows the steps of the submission with the dates. Each event will have the steps listed with a planned date, actual date and when it will go to the full board for either review or notification.

Steps (12)		
Step	**Planned**	**Actual**
Receive Application	08/16/2017	08/16/2017
Initial Office Review		08/16/2017
Notify Board of Exempt Determination	08/22/2017	
Assign to Full Board Review		
Notify PI of Results	08/18/2017	08/18/2017

5.5   Actions in the Event Details

Actions in the event details screen are as follows:

- Attachments – shows the attachments related to the event detail
  - Generated Docs – shows documents generated by ORCI for the study (e.g., approval documents associated with the study)
- Send Email – Allows user to email ORCI directly from IRBManager
- X-Forms – shows the form used to submit the event.

5.5.1 Attachments

"Attachments" Button: These are the attachments uploaded by the PI. This may also include approval letters from other institutions, consent forms, survey instruments and all other documents provided for this submission.

Attachments on Event IRB Initial Submission Started 08/16/2017 on 2017-028-GVSU

	Name	Attached ▲	Type
Attachments (2)			
Generated Docs (1)	Training/Certification	8/16/2017	Training/Certification
	Conflict of Interest Disclosure Form	8/16/2017	Conflict of Interest Disclosure Form

"Generated Docs" Button: Shows all of the documents that have been generated by ORCI for this study.

Attachments on Event IRB Initial Submission Started 08/16/2017 on 2017-028-GVSU

	Name	Attached ▲	Type
Attachments (2)			
Generated Docs (1)	Approval Letter	8/18/2017	Generated Document

5.5.2 xForms

Shows the application associated with the event. This is the application completed by the researcher.

Home	Create Study	Reports	Contacts	Administration	
Forms					

Action	Form	⬍	Identifier	⬍	Stage/Status	⬍
📘	HRRC New Protocol Submission Form		ORCI, Test		Complete	

6.0   xForms (Application Forms)

6.1   How to Open an xForm

6.1.1 Opening a New xForm for a New Study (Initial Protocol Submission Form)

On the Dashboard, click "Start xForm" under the "Actions" menu on the left side of the screen.

This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete. Note that only certain forms are available from the Dashboard (including new HRRC/IACUC protocol forms, conflict of interest forms, etc.). Forms that can only be completed once a study is already approved (such as a Contining Review form) are not available from the Dashboard; these must be opened within a study (Section 6.2 below).

Note: As described in more detail in Section 6.4 below, these forms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may or may not appear. If you wish to see the entire form (i.e., all questions, regardless of the user's responses), this can be done by clicking the Print icon to the left of the form name. This will generate a PDF of all questions contained in the form.

6.1.2 Opening a New xForm for an Existing Study (Modification Request, Continuing Review, etc.)

In order to complete an event (submission) for an active study, such as a Continuing Review, Change in Approved Protocol or Closure Report, you must first go to the study. Active studies can be found in the "My Studies" section on the bottom of the Dashboard (see Section 3.8 above).

```
Study-Site
Update
Add Attachment
Add Contact
Add Event
Add Note
Expirations
Generate Doc
Send EMail
Start xForm
xForms (1)
```

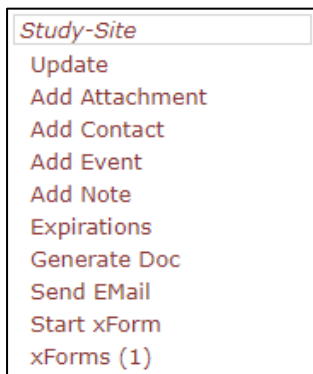Once you are in the study, you click the Start xForm button under the "Study-Site" menu on the left. This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete.

6.1.3 Opening an Existing Unsubmitted Form

To return to a form you previously began, but did not yet submit, you can access the form via one of two methods:

- The "xForms" link under the "My Documents and xForms" menu on the left side of the Dashboard (see Section 3.3)
- The "You have _ unsubmitted xForms" link from the "xForms" section in the middle of the Dashboard (see Section 3.6)

Click on the form name to open the form and continue work on it.

6.2   Completing an xForm

6.2.1   General Instructions

xForms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may appear. For example, if you answer that your study is funded, subsequent questions will prompt you to describe the funding source. If you indicate that you do not have funding related to the study, those subsequent questions asking about funding details will be hidden.

The majority of questions in the xForms require a response; however, some may be optional. IRBManager will not allow the user to submit the form until all required responses have been completed.

Note that some information in the form may be automatically generated. For example, when completing a Continuing Review form, the system will automatically populate the study details (such as project title, name of PI, etc.) on the top of the form.

Please carefully read all instructions provided on the form and answer all required questions.

6.2.2 Navigation Buttons at the Top of Each Page

The top of each xForm page will contain a header that looks as follows:
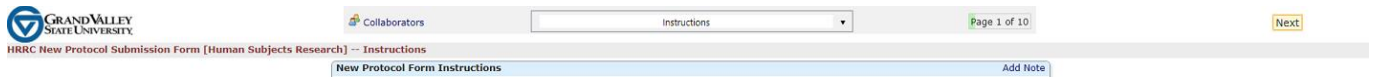
6.2.2.1 Collaborators

The person originally opening a form is initially the only individual who initially will have access to the form. In order to allow others access to the form, these other users must be added via the "Collaborators" function located in the upper left of the header.
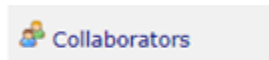
*Note that collaborators on a **study** (e.g., co-Investigators, Project Coordinators, Research Assistants, etc.) are added by responding to the study personnel questions in the application xForm; adding a collaborator to your study does <u>not</u> automatically give them access to the **form** itself.*

Upon clicking the "Collaborators" button, a pop-up window will appear.

- Enter the email address of the user you would like to grant access to the form. Note the user must already have a Contact established within IRBManager to be added as a Collaborator. If you need to add a Contact, you can do this by completing the "Contact Look-Up/Add New Contact" xForm
- Select the access rights you wish to grant

- o "View only" will give the user view only access.
- o "Edit" will allow the user to make edits only.
- o "Edit and manage" will allow the user to make edits and add other collaborators.
- o "Edit, manage and submit" will allow the user to make edits, add other collaborators, and submit.
- Add a note for the collaborator (optional). Text entered in this box will be included in the email sent to the collaborator.
- Click Add. This will automatically send an email to the collaborator with instructions to access the form.

6.2.2.2 Page Titles Drop-down Menu

Allows you to "jump" between pages of a form before completing all required questions on a page. Note that depending on the responses to the questions in a form, entire pages of questions may not be required. Therefore, there may be some pages that are not listed in the drop-down menu.

6.2.2.3 Page Numbers

Shows "Page x of y" on each page of the form. Allows you to "jump" between pages of a form before completing all required questions on a page.

6.2.2.4 Next Button

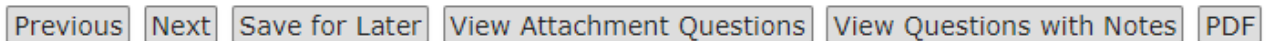Saves your progress on the current page and takes you to the next page in the form.

6.2.3 Navigation Buttons at the Bottom of Each Page

The bottom of each xForm page will contain a footer that looks as follows:

| Previous | Next | Save for Later | View Attachment Questions | View Questions with Notes | PDF |

Note: Depending on level of user access, some of these buttons may not appear.

- Previous – Saves your progress on the current page and takes you to the previous page in the form
- Next – Saves your progress on the current page and takes you to the next page in the form
- Save for Later – Saves your current progress
- View Attachment Questions – Shows only the questions in the form that have "Add Attachment" buttons [Available to reviewers only]
- View Questions with Notes – Shows only those questions where a Note has been added via the "Add Note" feature (Section 6.2.4 Below) [Available to reviewers only]

- PDF – Allows you to save the form as a PDF file. If you plan to close the form following selecting this PDF button, ensure you Save for Later.

6.2.4 "Add Note" Feature

Each section of the xForm includes an "Add Note" button on the right-side of the section title.

IRBManager Instructions	Add Note

This feature allows the user to enter reminders to themselves and/or comment/questions to an individual farther down the review chain (e.g., Authorizing Official, the ORCI, etc.).

Clicking on this button brings up the following note box:

Enter Note:

OK Cancel

Once entered, the note will be highlighted in red. You have the option of deleting notes when you no longer need them by pressing the red "X" delete button in the upper right-hand corner of the note.

6.2.5 Attaching Documents

Attachments can be added to xForms wherever an "Add Attachment" button is found.

Add Attachment

Documents to be attached will depend on the xForm being submitted. For example, these may include consent forms, recruitment materials, licensing permits, etc.

To attach a document:
1. Click "Add Attachment".
2. Enter the name for your attachment. (Optional. If left blank, the system will use the filename.)
3. Select the type of attachment in the drop-down list. (On some questions only a certain type of document is intended to be attached, and the type is pre-set.)
4. Click the "Browse" button to locate the file on your computer or drag-and-drop file(s) into the box.
5. Click "Attach" to finish the process.
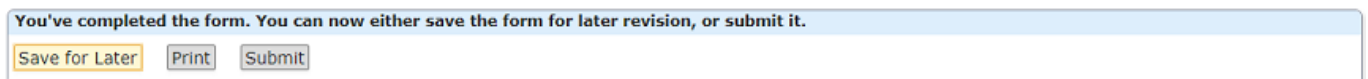
6.2.6 Signatures

Most xForms require the submitter to electronically sign the form and attest to the accuracy of the information provided within the form, as well as other compliance stipulations. This electronic signature is equivalent to a paper signature.

GVSU-affiliated users: Click the "Sign" box. This will bring up a pop-up window for you to enter your GVSU email and network password.

Externally-affiliated users: Enter your IRBManager password in the signature box.

6.3   Submitting an xForm

Once all of the required questions have been answered and the form has been signed, IRBManager will allow you to advance to the submission screen.

> You've completed the form. You can now either save the form for later revision, or submit it.
>
> Save for Later   Print   Submit

You may either save the form for later, print the form, submit the form, or press the browser's back button to return to the previous page in the form.

You must click the "Submit" button to advance the form to the next person/office in the review chain. If you choose any other action than "Submit," the form will remain in your list of unsubmitted xForms and will not reach the ORCI. The form will automatically route to the next person in the chain—you do not need to specifically add your Authorizing Official to the form or study.

Note: Clicking "Submit" is equivalent to mailing a paper version of the form to the next person/office in the chain. Once Submit is pressed, you will <u>not</u> have the opportunity to make any changes to the form unless it gets returned to you by someone further down the approval chain (e.g., Authorizing Official, ORCI, etc.).

If an applicaiton form is submitted by someone other than the PI (for example, a student researcher who was added as a collaborator on the form), the form will be routed to the PI. Only the PI can submit the form forward to their Authorizing Official/ORCI.

When a form is submitted, an email will be sent to the submitter indicating the form was successfully submitted. The next individual/office in the routing chain will also receive an email indicating a new form has been received and requires attention. Once the form has been submitted to ORCI (after PI submission and Authorizing Official approval, if necessary), IRBManager will automatically assign a study event on the protocol page (see Section 4.0). You can then click on the event name (blue link) to track the event progress.

7.0   Authorizing Official Review

The following forms require Authorizing Official (AO) signature before being routed to the ORCI:

- Human Research Review Committee (HRRC) New Protocol Submission Form
- Human Research Review Committee (HRRC) Change in Approved Protocol Form
- Institutional Animal Care and Use Committee (IACUC) New Protocol Submission Form

Note: Human Research Review Committee (HRRC) Significant Adverse Event/Unanticipated Problem Forms do not require AO signature due to the time sensitivity of the form, but AOs will be notified upon submission of the form.

Certain Departments/Units may have additional review requirements for other forms. If these exist, they are automatically built into IRBManager and do not require additional action by the PI. All routing to AOs occurs automatically in IRBManager when the PI clicks "Submit."

AOs are automatically notified by the system via email when a PI has submitted a protocol for approval.

7.1   AO Viewing of Protocol

AOs can access the protocol via one of two methods.

7.1.1 Via Email

The AO will receive an email similar to the one below:

The following Human Research Review Committee (HRRC) protocol has been completed by a researcher in your unit and requires Authorizing Official (AO) approval before it can be submitted to the Office of Research Compliance and Integrity (ORCI) for processing.

Principal Investigator: Test Researcher
Project Title: My test

To go directly to the protocol, please click here: HRRC New Protocol Submission Form [Human Subjects Research].

If you approve the submission, please review the AO certification statements and electronically sign the document in IRBManager, click "Next", and then click "Submit." Please note the form is not received by ORCI until the AO has clicked "Submit."

If you require changes/clarifications, please enter those in the box provided on the form and click "Submit." This will route the application back to the PI, informing them of the changes needed.

If you have any questions, please contract ORCI at rci@gvsu.edu or 616-331-3197

Thank you,
Office of Research Compliance and Integrity

The link in the email will take the AO directly to the form. (The AO will be prompted for their GVSU email address and network password upon clicking the link.)

7.1.2 Via Dashboard

Alternatively, the AO can access the protocol from the xForms section in the middle of their Dashboard, under the "There are _ xForms awaiting your attention."

xForms (5 Active)

- You have **2 unsubmitted** xForms.
- You have **3 xForms** being processed at a later stage.
- There are **1 xForms** awaiting your attention.

Clicking on the underlined link will open a screen with all xForms awaiting attention by the AO.

To open the form, click on the form name in blue. Note: If the AO has xForms awaiting their attention for other reasons (such as from their role as a PI or committee member), the forms needing approval can be filtered by clicking the "Show forms requiring approvals ONLY" checkbox in the upper right of the screen.

7.2   Protocol Review

7.2.1 Reading the PI's protocol

Upon clicking open the form, the AO will see the entire application form as submitted by the PI.

To review the protocol, simply scroll through the page.

Additional features to aid in the review process:
- "Hide Help Text" – this hides the form instructions the PI viewed when filling out the form. When this is checked, all responses from the PI will still be visible.
- Page Name Drop-Down menu at top of page – Use this to jump to a particular section of the form.
- "Add Note" button – This feature allows you to enter a note that will be viewable by the PI (if the form is returned for changes) and/or by the ORCI when the form is submitted.

7.2.2 Completing the AO Review

Once you have finished reading the protocol, click "Next" either at the top of the page or at the very bottom of the page. This will take you to the AO review page.

If you approve the protocol:

    1. Answer "yes" to the question asking if the protocol is ready for submission to ORCI.

    2. Read the AO attestation and electronically sign the form by clicking the "Sign" box and entering your GVSU email address and network password.

    3. Click "Next" to take you to the submission page.

    4. Click "Submit". **Note: You must click "Submit" for the form to be routed to ORCI for processing.**

> You've completed the form. You can now either save the form for later revision, or submit it.
>
> Save for Later   Print   Submit

If you require changes to the protocol:

    1. Answer "no" to the question asking if the protocol is ready for submission to ORCI.

    2. Enter the changes you want the PI to make in the text box. All text entered in this text box will be sent to the PI via email. Note: If you made your comments via the "Add Note" feature, inform the PI of this in the text box, so they know to look for the notes when they open the protocol again to make the changes.

    3. Click "Next" to take you to the submission page.

    4. Click "Submit". **Note: You must click "Submit" for the form to be routed back to the PI.**

    5. The PI will receive an email indicating you require changes. Once the PI has made the changes, the form will be routed back to the AO again for approval.

> You've completed the form. You can now either save the form for later revision, or submit it.
>
> Save for Later   Print   Submit

7.3   Post-AO Approval

For all forms requiring AO approval, the AO will be copied on all emails from ORCI to the PI, including final decision notifications.

Note: If the ORCI needs to return the form to the PI for any reason, the AO approval process will need to be repeated upon re-submission of the form by the PI.

8.0   Help and Support

If you have any questions or problems using IRBManager, please contact the Office of Research Compliance and Integrity at 616-331-3197 or rci@gvsu.edu.