



Office of
**Research
Compliance**



USER GUIDE

Created: June 2019

On June 3, 2019, the Central Michigan University Office of Research Compliance adopted the IRBManager Internet-based submission system. We will only accept submissions electronically through IRBManager. This User Guide provides step-by-step instructions for each type of submission.

[Go to CMU's IRBManager Page](https://cmich.my.irbmanager.com/)

<https://cmich.my.irbmanager.com/>

For any questions regarding IRBManager, please contact the ORC at
989-774-1152 or email tracee.wilson@cmich.edu

Thank You!

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1.1 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for CMU's compliance committees, the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC). IRBManager is a fully web based system, meaning users can login anywhere they have internet access.

The electronic forms provided within this system allow users to complete submissions for each phase of the research process. This includes forms for new studies, continuing reviews, amendments, as well as reports for unanticipated problems, adverse events, and study closures.

Investigators have access to view past and current studies reviewed by a CMU compliance committee. The system defines a study as a *Project*. Each project's study-site will provide a list of *Events* (actions) that have been submitted to the appropriate compliance committee for review and approval. Each event will contain all associated forms and supporting documents, along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process.

Study personnel indicated on the project application will have access to the study in IRBManager.

1.2 How to Access IRBManager

Go to <https://cmich.my.irbmanager.com/>

Note: Certain versions of Internet Explorer and Microsoft Edge are not compatible with IRBManager. Consider utilizing Mozilla-Firefox or Google-Chrome as your browser.

1.3 Initial Login for Users with CMU Email Accounts

User profiles from IRBNet were converted over to IRBManager. To activate the account, users will need to log in to IRBManager following the instructions below::

- 1 Click "click here" on the homepage to be directed to your CMU sign-in page.
- 2 Enter your CMU Global ID and accompanying password (i.e. the same password you use to sign into your cmich account).
- 3 Click "Sign In."

Note: You may already be signed into your cmich account and not need to reenter your Global ID and password. In this case, you will be automatically redirected to the IRBManager homepage.

2.1 Navigating the Dashboard

The screenshot shows the IRBManager dashboard for Central Michigan University. The top navigation bar includes 'Home', 'My Projects', and a search bar 'Find Project (Ctrl+Q)'. The main content area is divided into several sections: 'Projects (0 Active)' with a message 'You are not associated with any Projects.'; 'xForms (2 Active)' with a message 'You have 1 unsubmitted xForm(s) and 1 xForm being processed at a later stage.'; 'Messages' with a welcome message; and 'My Docs & xForms' with 0 Attachments and 2 xForms. A table titled 'My Projects (0 Active)' is visible, with columns for Project, PI, Title, Expires, Status, and Reference Doc(s). Three red arrows with numbers 2.1, 2.2, and 2.3 point to specific elements: 2.1 points to the 'Start xForm' link in the Actions section; 2.2 points to the 'My Projects (0 Active)' link; and 2.3 points to the '1 unsubmitted' link in the xForms section. The footer contains copyright information and the IRBManager logo.

2.1 Actions

Under 'Actions,' a user can start any of our applications by clicking "Start xForm."

Note: Secondary applications including Amendments, Continuing Reviews, Closure Reports, and Unanticipated Problem or Adverse Event Reports cannot be started from this area and must be started from within the study itself. (See Section 3.3.1, 'How to Submit an xForm').

2.2 My Projects

Projects

A user can view a list of the projects that they are associated with from the Dashboard. The user will have access to projects if they are listed as Principal Investigator, Co/Sub-Investigator, Regulatory or Research Coordinator and/or Research Staff. Users will be able to access projects that migrated from IRBNet under 'Projects as well. A project will not show up under your active projects unless you are added as Key Personnel for the project.

Note: By clicking on the underlined link to active or total projects, the user will be able to view the details of their associated projects. Users will be able to access projects based on their role in the projects.

1. The 'Active Studies' include all associated studies with the following statuses:
 - a. Active
 - b. Active-Opened to Enrollment
 - c. Active-Closed to Enrollment
 - d. Active-in Data Analysis
 - e. Active-Long Term Follow-Up Only

f. Exempt

Note: Studies that are Suspended are also located here.

2.3 xForms

The xForms section shows the forms or applications currently being processed at this time.

Note: An xForm is an electronic, web-based form.

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.

In this view of the DASHBOARD:

1. The user has two (2) unsubmitted xForms. This shows the user started two xForms, but clicked 'Save for Later' or closed out of the form without submitting the form.

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

2. The user has three (3) xForms being processed at a later stage. This shows that the user has submitted three forms that are currently awaiting review and signature by the PI (or other necessary party) or are being processed by the IRB.

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

3. The user has one (1) xForm currently awaiting their attention. This shows that the user has one xForm that currently needs action by the user (i.e., review and signature required, revisions requested by the IRB, etc.).

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

2.4 Events



The events section of the DASHBOARD shows the total number of open events and the number of events categorized by name, such as Initial, Continuing Review, Amendment, Protocol Deviation or Closure. The dropdown box following 'Only show events where I am' will allow a user to filter the events according to their role in the associated study.

2.5 My Studies

All the active studies a user is associated with will appear here.

Note: A study is not created when a user submits an xForm. A study is created when the IRB determines that the study is ready for review. From the DASHBOARD, a user can view the following information regarding their studies, including:

1. The project number.
2. The main site where the project is taking place. (Note: If the project is taking place at more than one site, the project will be listed twice with each site listed.)
3. The PI name.
4. The project title.
5. Expiration date of the project (if blank the study has not yet been approved).
6. Status
 - a. Pending (if not yet approved)
 - b. Active
 - c. Exempt
 - d. Deferred
 - e. Expired
 - f. Suspended

Note: Closed studies will not display here. In addition, the status will depend on whether the project is still under initial review or if elsewhere within the project's lifecycle.

Note: By clicking on the blue link under 'Project,' the user can go directly to the project. By clicking the small arrow to the right of 'Project, Site, PI, Title, Expires, and Status,' a

user can sort the studies accordingly.

1. Project can be sorted by Project Number
2. Site can be sorted alphabetically
3. PI is sorted alphabetically
4. Title is sorted alphabetically
5. Expiration dates are sorted by numerical date
6. Status is grouped and sorted alphabetically

DICTIONARY OF IRBMANAGER TERMINOLOGY.

xForm: IRBManager uses web-based forms called xForms. Users submitting to the CMU IRB and/or IACUC will submit the xForm appropriate to the type of request. Some requests (i.e., Amendment, Continuing Review, Protocol Deviations, etc.) will not be immediately available in your dashboard, but instead will become available inside an already approved project.

Event: Similar to “packages” that were used in IRBNet, your submission to either review board is considered an “Event.” All correspondence and responses to revisions will be considered an individual “Event.” After final approval is given, additional Events can be created, such as when protocol changes are requested or when continuing review is required.

3.1 Managing Forms in IRBManager (i.e., xForms)

3.1 IRB Application to Conduct Exempt Research Involving Human Subjects

Use this form if the research activities fall into one or more of the categories listed at the below link:

https://www.cmich.edu/office_provost/ORGS/ComplianceandResearchIntegrity/InstitutionalReviewBoard/Documents/Exemption%20Categories.pdf

3.2 IRB Application to Conduct Research Involving Human Subjects

Use this form to propose research that is more than minimal risk or does not fall into an exempt category that involves human subjects

3.3 IRB Does My Project Need IRB Review? Form

Use this form if you are unsure whether your project requires IRB Review. This is used for research that does not meet the definition of research (per §46.102 (l)) or does not involve human subjects (per §46.102 (e))

3.4 IACUC Animal Use Application

Use this form to submit a project in which live, vertebrate animals will be utilized.

3.5 Other Forms

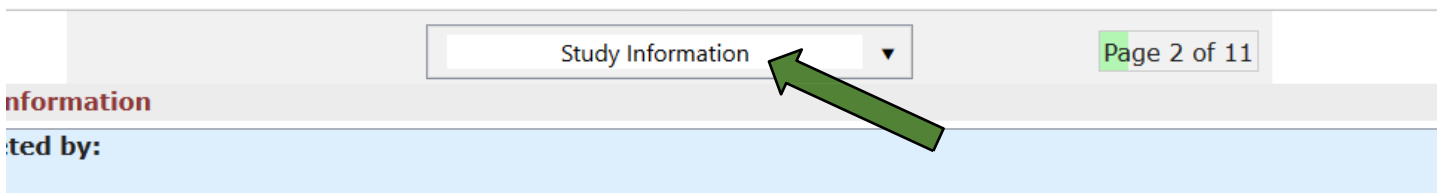
There may be other various forms that need to be completed that may not show up when selecting "Start xForm" from your dashboard (e.g., Protocol Change Forms, Continuing Review Forms, etc.). These forms are not available until *after* your project has been given final approval and are located in the event itself. In order to access these forms:

1. Go to your dashboard and choose the project you are working on
2. On the left-hand Action menu under Project-Site, select "Start xForm"
3. Choose the appropriate form

3.6 Completing an xForm

After entering basic study details, the questions in the xForms are directed by the answers given. For example, research involving retrospective data analysis will not ask about investigational drug intervention in research and vice versa. Changing responses on the form will enable subsequent questions that were hidden or hide questions that are no longer applicable.

1. To navigate an xForm, click 'Next' to move on to the next page of the xForm. Click 'Previous' to move to an earlier page. You can also use the drop-down at the top-center of the screen to navigate between pages. Click 'Save for Later' to stop working on the form. The xForm can then be reopened by going to the xForm link under 'My Documents and Forms' or 'Unsubmitted xForms' on the DASHBOARD.




2. Most questions on the form are required (the question will be labeled 'Required'). All required questions on the form must be completed before submitting. If they are not, a red error message will appear. The system will not allow the user to continue until the field has been populated.
3. All required questions on a page must be completed before clicking 'Next'. To skip to another page on the form without answering all questions on the page at that time, use the navigation drop down at the top of the page.

3.6.1 Submitting the xForm

Note: Before submitting an xForm, review the form completely. Changes cannot be made once an xForm is submitted unless the IRB requests changes.

After all pages on the form are complete, the submission screen will appear. Click 'Submit.'

Note: The form will not move to the next stage if 'Submit' is not clicked.



You've completed the form. You can now either save the form for later revision, or submit it.

Save for Later

Print

Submit

3.7 Checking the Status of an xForm

On the left side of the screen under 'My Documents & Forms,' select the xForms to see a list of all the xForms a user is associated with (either as a PI, Submitter, or Collaborator).

- **Action:** If a form can be deleted or copied for an amendment, those options will display in this column. **Note:** An xForm can only be deleted when in data entry.
- **Form:** Name of the form
- **Identifier:** This is generally the PI of the project
- **Owner:** The owner of the form will be the user who started the xForm until an event is created and then the form is owned by the study.
Note: An event will be created within IRBManager after the pre-review has been assigned to a reviewer.
- **Stage:** This is the current stage that the form is in.

3.7.1 Stage Types and Definitions

Review Stages

- **Data Entry:** The form is currently with the user to complete or make changes
- **PI Signature for Non-PI submission:** The Form Creator is not the PI; therefore, the application needs to be signed by the PI before submission to the IRB or IACUC
- **Administrative Review:** The form is currently with the ORC for review before being sent to reviewer(s)
- **Under Review:** Your xForm is currently under review by the board.

3.7.2 Decision Notification

Once the IRB Office or the IRB reviewer(s) have completed their review, the research















team will receive an email detailing the IRB decision. If approved or deferred for modifications, the appropriate approval/determination letter will be attached.

4.1 Navigating the Study Page

From the DASHBOARD, access a study page for each study. Click on the blue study number link to access this page.

4.1 Events

This section lists all the IRB 'Events' or submissions that have been or are being conducted for the study. The event line contains the following sections:

▼ Events (7)										
Action	Event	Att	FE	Instance/UDF	Start	Complete	Reviewers	Last Mtg		
 	IRBNet Response/Follow-Up	5			06/09/2017	06/12/2017				
 	IRBNet Continuing Review/Progress Report	12			06/02/2017	06/07/2017				
 	IRBNet Amendment/Modification	15			04/09/2017	04/27/2017				
 	IRBNet Amendment/Modification	10			03/01/2017	03/08/2017				
 	IRBNet Amendment/Modification	15			02/12/2017	02/22/2017				
 	IRBNet Amendment/Modification	12			11/28/2016	11/29/2016				
 	IRBNet New Project	10			06/07/2016	06/08/2016				

- Event: The type of event (Initial Submission, Amendment, Study Closure, Non-Compliance, etc.)
- Att: Number of attachments associated with that event or review.
- Instance/UDF: Usually this will be blank. If the event is an amendment, a summary of the amendment appears here.
- Start: The date the event was started or loaded into IRBManager
- Complete: The date the event was completed
- Last Mtg: This shows the last meeting this event or review was submitted to. Even if a submission is expedited, it shows up on a meeting agenda as an expedited review report.

Click on any blue event link to view the event details specific to the event. (See Section 5.0)

4.2 Event Emails

Email correspondence through IRBManager can be found in the event details for your project.

- Select the desired Project from your dashboard
- Select the Event you want to look at under Events

Home Meetings Create Project Reports Contacts Administration

Event Details: IRB - Non Human Subject Determination on 2019-362-Mt. P

Project-Site

Project: _____ Site: Mt. P - CMU - Mt. Pleasant
 Title: _____ Committee: _____
 PI: _____ Sponsor Id: _____

Event

Type: IRB - Non Human Subject Determination Started: 06/19/2019
 Instance: _____ Completed: _____
 Committee: Inherited from Study
 Review Type: _____
 Action Date: _____

Emails (1)

Subject	Date	Del	To/From
Additional Information on Recent NHSR IRB Submission	06/19/2019		

Steps (5)

Step	Planned	Actual	Complete
Receive a Human Subject Determination Request		06/19/2019	Yes
Admin Review		06/19/2019	Yes
Assign to Reviewer		06/20/2019	Yes
Receive NHS Determination			No
Notify PI of Results			No

4.3 Actions in the Event Details

Actions in the event details screen are as follows:

- **Attachments:** This shows the attachments related to the event detail
 - **Generated Docs:** This shows the approval documents associated with the study
- **xForms:** This shows the form used to create the event
- **Done:** This returns the user to the next most logical page depending on previous actions

4.4 Accessing IRBNet Legacy Documents

Your documents from your previous IRBNet Submissions should be available to you on IRBManager.

- Select a past project from your dashboard
- Select the number under Att in the Events section to get access to your old documents

Home Meetings Create Project Reports Contacts Administration

Project: -Mt. P (IRB)

Project

Project: _____ Funding Source(s): _____
 Committee: CMU IRB Sponsor Id: _____
 College: _____ Grants: _____
 Department: _____ CRO: _____
 Agent Types: _____ Year: 2015
 Title: _____ Species and approved number: _____
 Level of Review: _____
 Comments: _____

Project-Site

Site(s): Mt. P - CMU - Mt. Pleasant PI: _____
 Status: Closed - Expired Additional: N
 Approval: _____ Expiration: **October 23, 2017**
 Initial Approval: _____ Other Expirations: _____
 Comments: _____

Project-Site Contacts (3)

Action	Name	Role	Phone	EMail
		IRBNet-FULL		
		IRBNet-FULL		
		IRBNet-FULL		

Events (5)

Action	Event	Att	FE	Instance/UDF	Start	Complete	Reviewers
	IRBNet Unknown	12		-1	06/04/2019	06/04/2019	
	IRBNet Unknown	3		-2	06/04/2019	06/04/2019	
	IRBNet Unknown	4		-3	06/04/2019	06/04/2019	
	IRBNet Unknown	5		-4	06/04/2019	06/04/2019	
	IRBNet Unknown	4		-5	06/04/2019	06/04/2019	

4.5 Helpful Hints

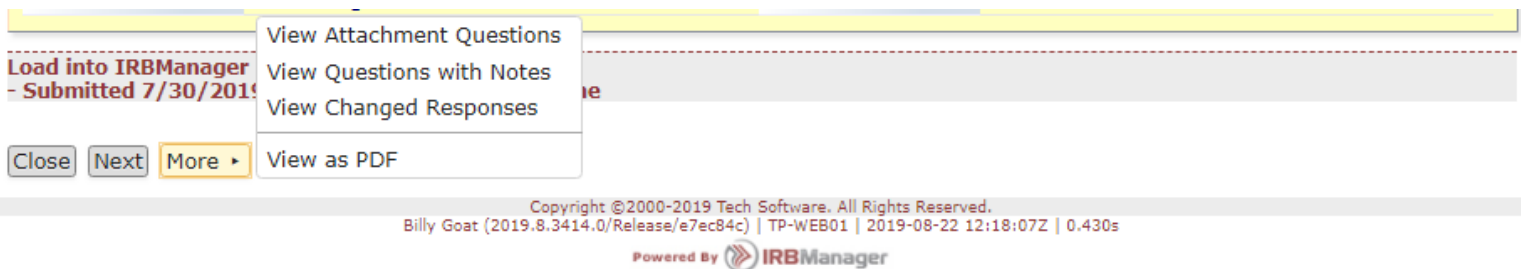
For any further questions regarding a project status or using IRBManager, contact the ORC Staff at tracee.wilson@cmich.edu or by phone at 989-774-1152

4.5.1 Email Notifications:

- Email notifications will be sent to the study team from IRBManager via cmuirb@cmich.edu or IACUC_ADMIN@cmich.edu.
- All required signatories will receive an email with a link to the xForm they are being requested to review and sign off on.
- Email notifications will be sent to the study team when the determination of an event has been completed.
- The email will include the determination letter

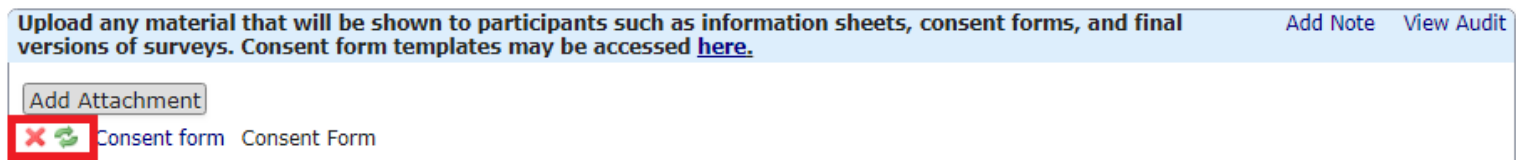
4.5.2 Downloading PDF copies of your application

- At the bottom of your xForm, there is a button labeled "More"
- Clicking this will give you an option to save your application as a PDF



4.5.3 Replacing old versions of documents on an xForm

- There are times where the board will ask for changes to certain documents. When submitting an edited version, you can replace the old version by clicking the green arrows next to the red X button.



APPENDIX 1:

5.1 Frequently Asked Questions

Why can't my study team see the xForm I created?

The only members of the study team that have access to an unsubmitted xForm are the PI and the submitter of that xForm. The rest of the study team will be able to view the xForm once a determination is made.

Should a study team member other than the submitter and the PI require access to an xForm while it is being completed, the submitter or PI can add that person as a 'Collaborator' of that form. The Collaborator functions exactly like the 'Read/Write/Full' access from IRBNet.

A Collaborator can 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 each form they are added to. Collaborator access does not carry over to other xForms created in a study.

Does everyone on my study team need to receive email notifications?

The short answer is no. However, if you are listed as key personnel on the application, you can always access the emails sent by the committees by going into the project you are key personnel for and then selecting the appropriate event. There will be a section listing the emails sent through IRBManager.

I am trying to add a member to the study team and the xForm is saying "contact not found", what does that mean?

If you are receiving the "contact not found" message that usually means that the person you are attempting to add has not logged into IRBManager to activate their User Account. While everyone with a CMU email address and password has access to IRBManager, each User must sign into the system to activate their account. Unfortunately, if a contact is not found that researcher cannot be added to the study team until their email address can be added to the xForm in the appropriate Personnel field. Some applications will have a separate personnel table to add non-CMU researchers. In these situations, this separate table should be used.

STAFF AT COVENANT HEALTH WILL STILL USE IRBNET