

Overview of IRB Manager

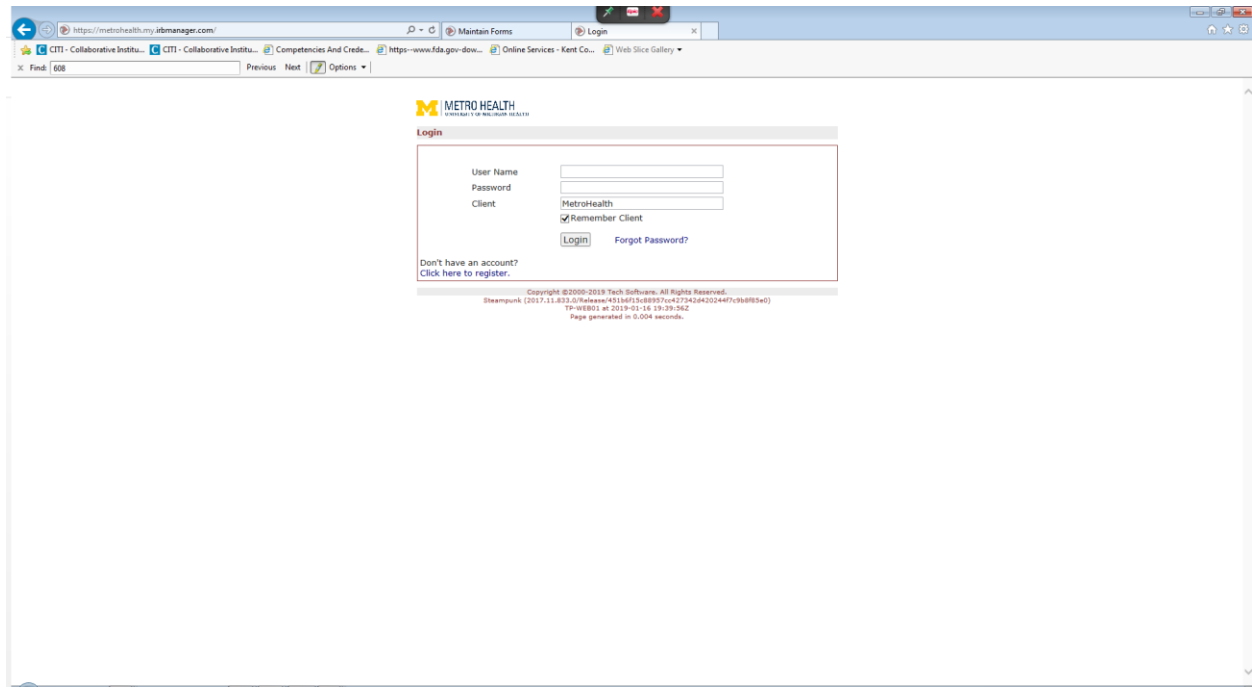
IRBManager is the electronic submission system used at Metro Health for research involving human subjects. All IRB submission must be made through IRBManager; paper submissions will not be accepted. The following are types of iRBManager submissions:

1. **Application for Human Subjects Research:** Includes new protocols, retrospective chart reviews, exemption requests, human subject research determinations, and HUDs.
2. **Modification of Approved Human Research:** This form is used for any modifications on an existing study.
3. **Continuing Review Progress Report:** This form is used to summarize study progress and experiences to date for continuing renewal.
4. **Reportable New Information:** This form is used to report new or increased risks, harms experienced that were unexpected and related, noncompliance, internal and external audit reports, protocol deviations, breaches of confidentiality, changes implemented without IRB approval, complaints, suspensions, and unanticipated device effects.
5. **Study Completion Notification:** This form is used to report the closure of a study

Accessing IRB Manager

IRBManager is a web-based tool and can be accessed from any internet browser at:

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



The screenshot shows a web browser window with the URL <https://metrohealth.my.irbmanager.com/>. The browser's address bar and tabs are visible at the top. The main content area displays the MetroHealth logo and a "Login" section. The login form includes fields for "User Name", "Password", and "Client" (pre-filled with "MetroHealth"). There is a "Remember Client" checkbox and "Login" and "Forgot Password?" buttons. Below the form, a link says "Don't have an account? Click here to register." At the bottom, small text provides copyright information: "Copyright ©2000-2019 Tech Software. All Rights Reserved. Steamship (2017-11-03 10:54:44) MetroHealth (11/16/19) TP-WEB001 at 2019-01-16 19:39:36Z Page generated in 0.004 seconds."

METRO HEALTH
UNIVERSITY OF MEDICINE & DENTISTRY

Login

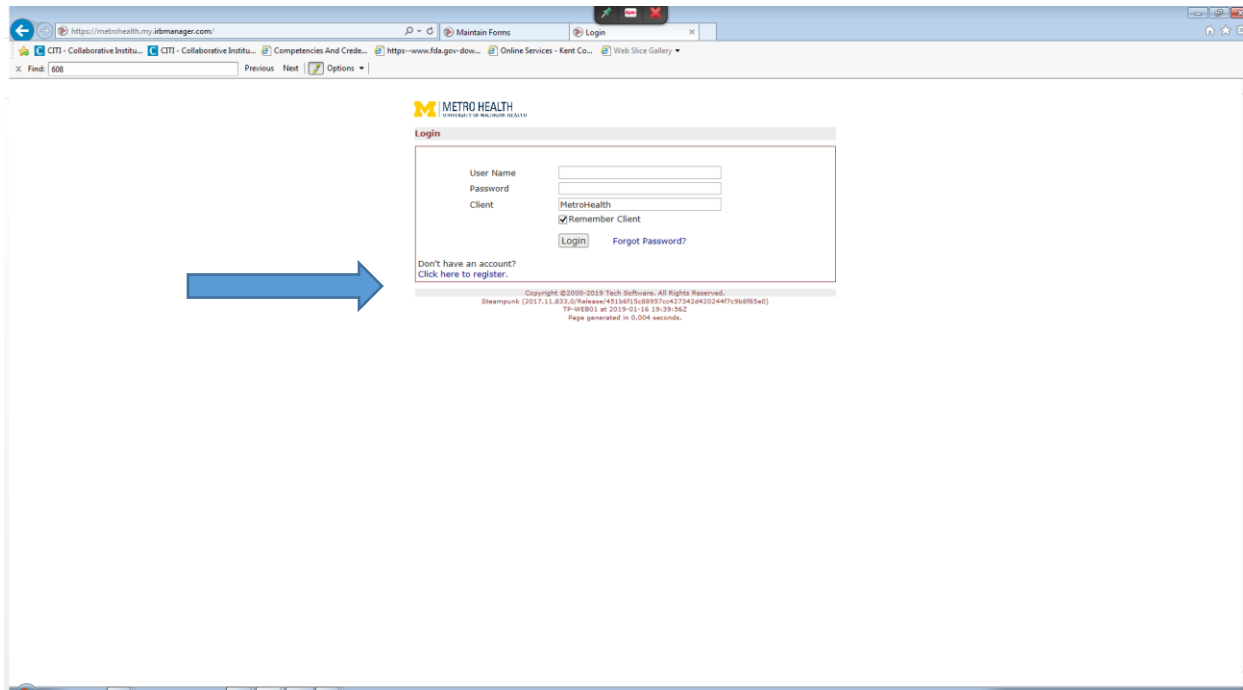
User Name:
Password:
Client:
☒ Remember Client
 [Forgot Password?](#)

Don't have an account?
[Click here to register.](#)

Copyright ©2000-2019 Tech Software. All Rights Reserved.
Steamship (2017-11-03 10:54:44) MetroHealth (11/16/19) TP-WEB001 at 2019-01-16 19:39:36Z
Page generated in 0.004 seconds.

Obtaining a User Login to Access IRBManager

All research staff will need a username and password to access the IRBManager system.



The screenshot shows a web browser window with the URL <https://metrohealth.my.irbmanager.com/>. The page displays the MetroHealth logo and a 'Login' section. The login form includes fields for 'User Name', 'Password', and 'Client' (with 'MetroHealth' selected). There is a 'Remember Client' checkbox and 'Login' and 'Forgot Password?' buttons. Below the form, it says 'Don't have an account? Click here to register.' A blue arrow points to the login form.

Copyright ©2009-2018 Tech Solutions. All Rights Reserved.
Steampunk (2017-11-832-0/Release/4513671368957/c4273424620447/9a883e0)
TP-088821 at 2019-01-16 19:29:56Z
Page generated in 0.004 seconds.

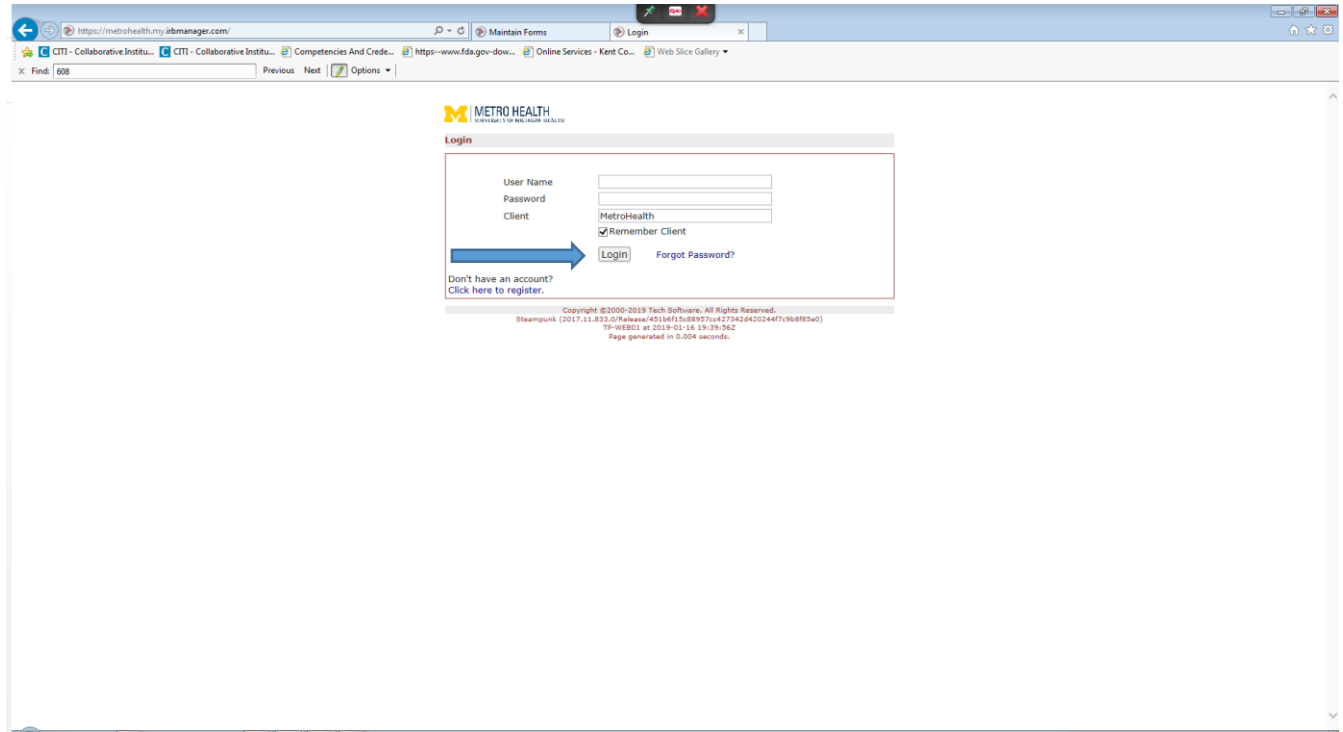
1. You will be asked for your:
 - a. email address
 - b. organization
 - c. first name
 - d. last name
 - e. degree
 - f. phone #
2. You will then receive an email with your login information, including:
 - a. User Name (email address you provided)
 - b. Password
 - c. Client: Metrohealth
3. You will then be prompted to reset your password.

Logging In

Go to <https://metrohealth.my.irbmanager.com> and enter the following user login information:

User Name: Email address you provided at registration
Password: Enter password
Client: Metrohealth (Check “Remember Client” box to save this information)

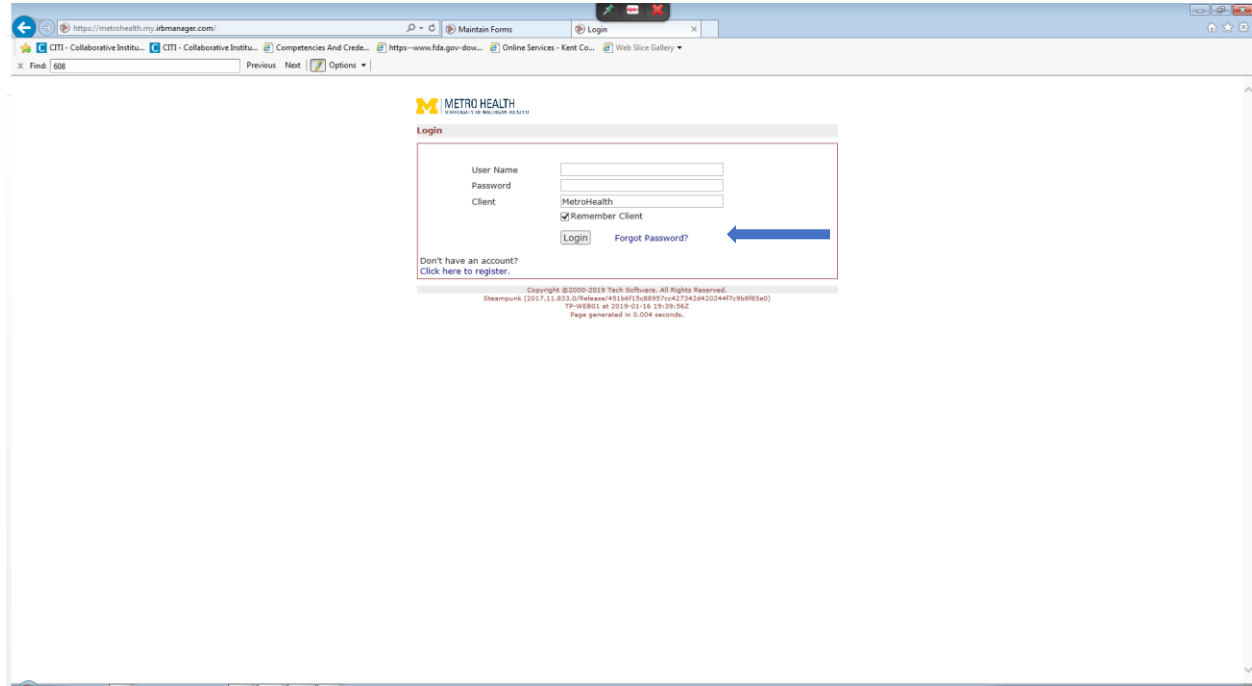
Click “login.”



The screenshot shows a web browser window with the address bar displaying <https://metrohealth.my.irbmanager.com/>. The browser's tab bar shows several open tabs, including "Maintain Forms", "Login", and "Web Slice Gallery". The main content area displays the MetroHealth logo at the top, followed by a "Login" section. This section contains three input fields labeled "User Name", "Password", and "Client". The "Client" field is pre-filled with "MetroHealth". Below these fields is a checked checkbox labeled "Remember Client" and a "Login" button. A blue arrow points to the "Login" button. To the right of the "Login" button is a link labeled "Forgot Password?". Below the login fields, there is a link that says "Don't have an account? Click here to register." At the bottom of the page, there is a small copyright notice: "Copyright ©2000-2019 Tech Software, All Rights Reserved. SteamPunk (2017-11-03 20:16:56) / 4514675-0889754427742462024477c9e8f85a0 TP-WEB01 at 2019-01-16 19:39:26Z Page generated in 0.004 seconds."

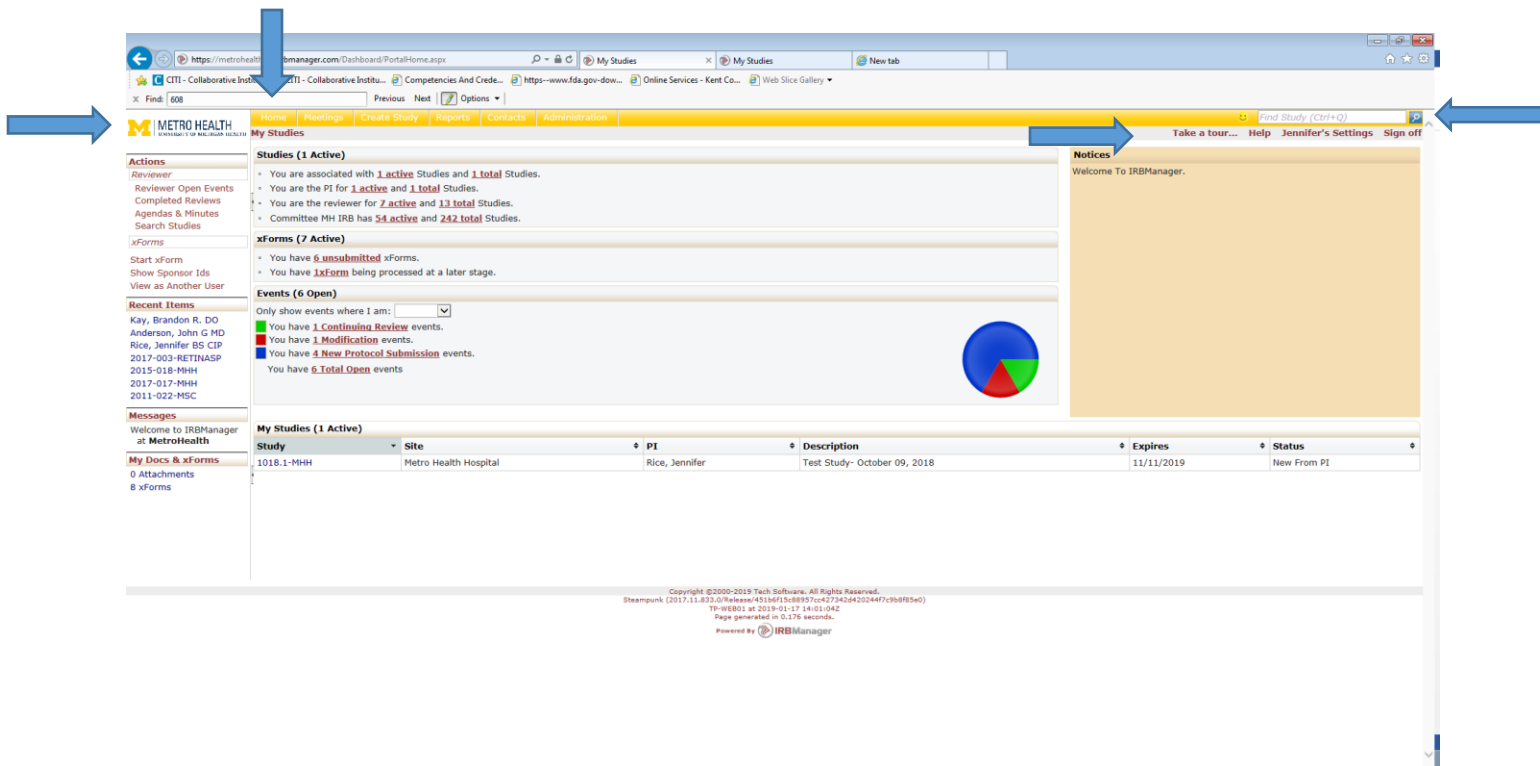
Forgot Password for Login

If you have forgotten your password, you may either contact IRB staff directly to have it reset, or you may request a new manager through the IRBManager login screen by clicking “Forgot Password.” *Note: if you enter the wrong username/password three times, as a security precaution, IRB Manager locks your account.* If that happens, you will have to contact the IRB Staff to unlock your account.



The screenshot shows a web browser window with the URL <https://metrohealth.my.irbmanager.com/>. The page features the MetroHealth logo and a "Login" section. The login form includes fields for "User Name", "Password", and "Client" (with "MetroHealth" selected). There is a "Remember Client" checkbox and a "Login" button. A blue arrow points to the "Forgot Password?" link. Below the login form, there is a link for "Don't have an account? Click here to register." and a small copyright notice at the bottom: "Copyright ©2000-2019 Tech Software. All Rights Reserved. SteamPunk (2017.11.833.0/Release/431168713c88957c42724264202447c9a8895ed) IP=10801 at 2019-01-16 19:39:26Z Page generated in 0.004 seconds."

Basic Navigation within IRBManager



The IRBManager Header is the top part of the screen, and will remain consistent within any main screen of IRBManager (except an xform). There are four main parts:

1. The Metro Health logo
2. The “Home” option: Clicking this will take you to your dashboard
3. The white “Find Study” search box: You can quickly search for a study by typing in the IRB number, PI, part of the study title, etc.
4. Personal options for the user including:
 - a. Take a tour...: This will provide a general overview of IRBManager sections and options
 - b. Help: This will provide very brief text related to that page: researchers are encouraged to contact the IRB office for additional assistance
 - c. Settings: This is where you can update your password and other personal information.
 - d. Sign off: To log out of IRBManager within a browser

The Left Side Panel Menu

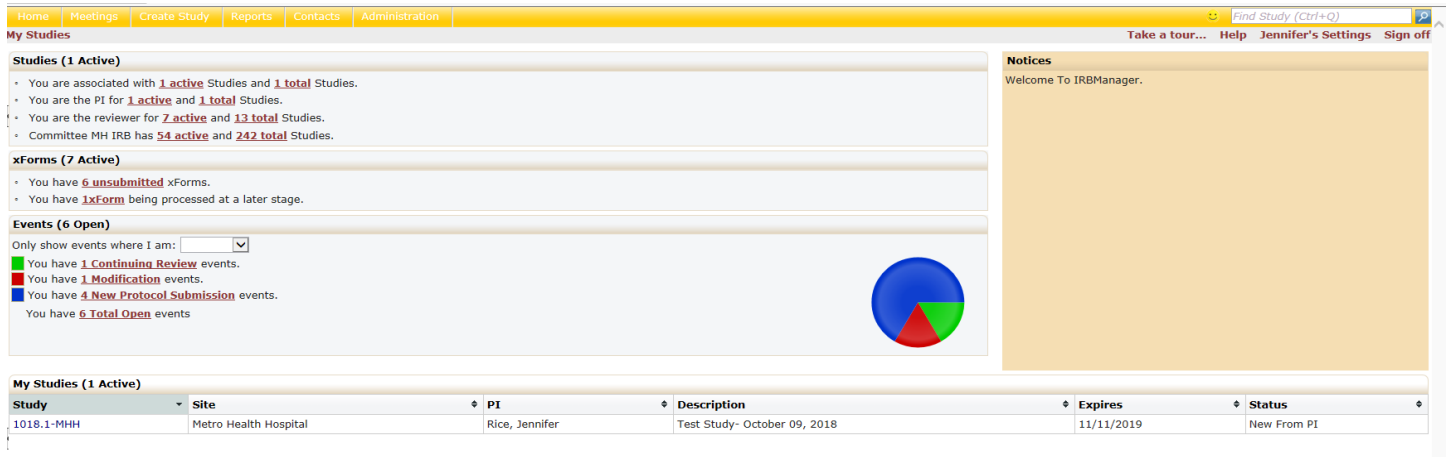


The left side panel menu is on the left portion of most IRBManager pages and consists of five parts:

1. **Actions:** These are actions you can perform on the CURRENT page. Please note the actions will change depending on what page you are on, and some pages may not have any actions.
2. **Recent Items:** These are hyperlinks to the items that you most recently viewed in IRBManager; clicking them will take you directly to that item.
3. **Messages:** The IRB may list messages here.
4. **My Documents & Forms:** These are quick links to any user attachments and xForms that user has ever started (i.e. as the submitter).

The Dashboard

The dashboard is the main page in your IRBManager account. It is the first page you see upon logging into the system, and the page that you are directed to when you click “Home.”




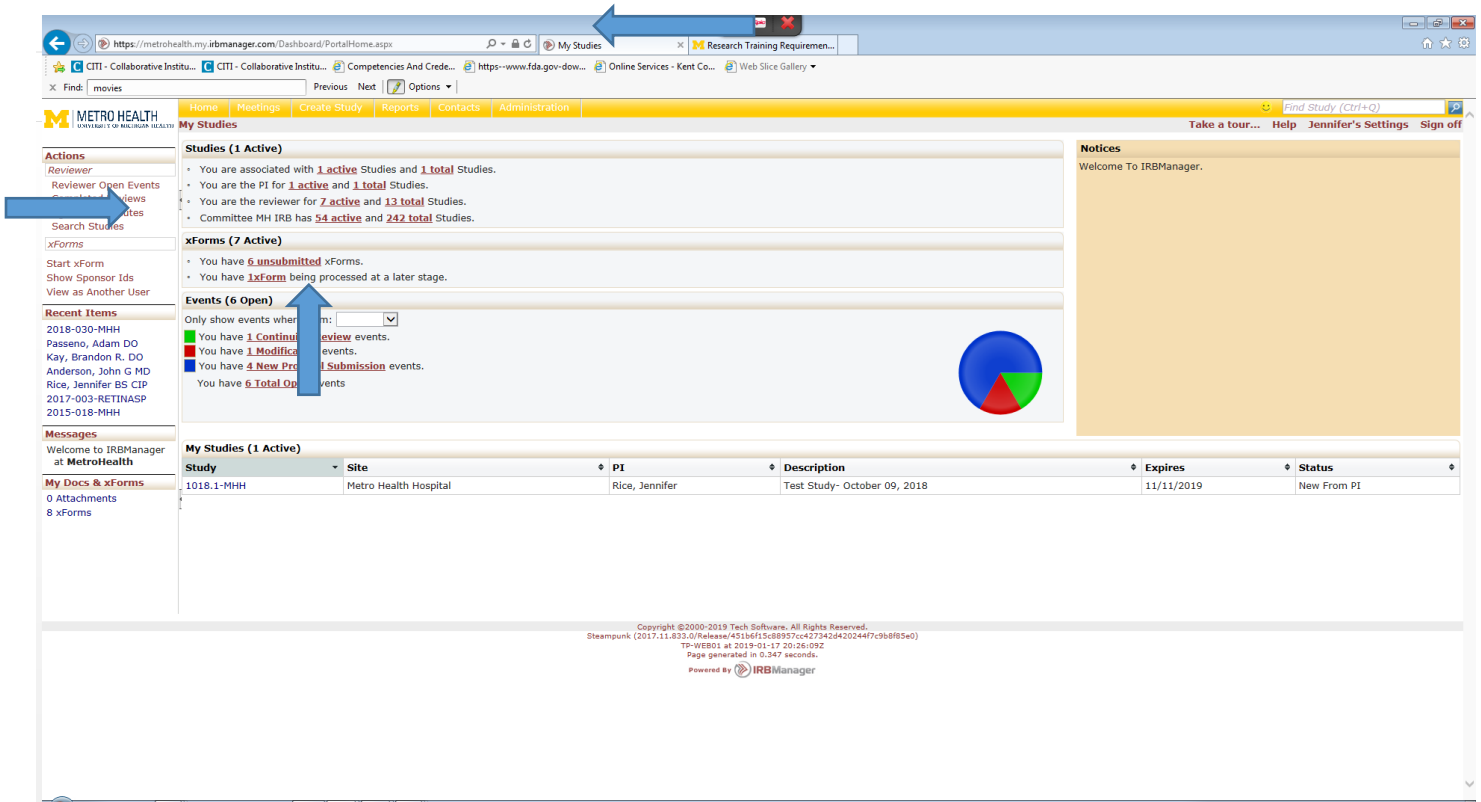
On the right side of the screen are notices from the IRB. These notices are updated periodically to provide you with important and relevant information.

In addition to the notices, there are 4 sections to the dashboard that are specific to each user. Each of these sections will give you an overview of pertinent information; clicking on the underlined hyperlink will open a new page with more information relevant to that choice:


1. **Studies:** This section displays the number of studies and your IRBManager designated role (Principal Investigator, Study Coordinator, etc.) on which studies you are associated. Clicking on a link will open a new window which will display the study number, site, study title, expiration, PI and status.
2. **xForms:** This section displays the xForms that you are working on that are unsubmitted; those that have been submitted but are awaiting others' signatures (such as PI signature) those that have been submitted and are being processed at a later stage, and those that are awaiting your attention (for example, something requires your action in order to move the form forward).
3. **Events:** This section provides an overview of the active/open events associated with the user. If you have multiple study roles, you can use this drop down menu to only show events where you are a specific role (e.g. Coordinator).
4. **My Studies:** This section lists all studies you have access to (in order to have access to a study, you must be listed as a contact on the study's homepage). Study number, site, study title, expiration, PI, status, and any applicable reference documents for that study.

Navigating to a Study/Protocol Homepage

Each protocol in IRBManager has a study/protocol homepage. You can get to a study homepage by clicking the blue hyperlink with the study number (e.g. from the “Studies” or “My Studies” section of your dashboard, or under “Recent Items” on the left panel menu, or by entering the study number in the white  in the upper left corner of the header.



The screenshot displays the IRBManager dashboard for Metro Health. The interface includes a top navigation bar with links like Home, Meetings, Create Study, Reports, Contacts, and Administration. A left sidebar contains sections for Actions, Recent Items, Messages, and My Docs & xForms. The main content area is titled 'My Studies' and shows statistics for active studies, xForms, and events. A table lists the active study: 1018.1-MHH at Metro Health Hospital, managed by Jennifer Rice. A search bar in the top right header is highlighted with a blue arrow, indicating where to enter a study number. Another blue arrow points to the 'My Studies' link in the top navigation bar. A third blue arrow points to the 'Recent Items' section in the left sidebar, which lists recent studies and protocols.

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SteamPunk (2017.11.833.0/Release/451b6f15c8b957cc42734264202447c9b085e0)
TP-WEB01 at 2019-01-17 20:26:09Z
Page generated in 0.347 seconds.
Powered By  IRBManager

The Study/Protocol Homepage

In addition to the header and left side panel menu, there are four main components of the study homepage. With the exception of “Study-Site,” clicking the green arrow next to each sections header will either hid or expand the section.

Study

Study: 1018.1
Committee: MH IRB
Category: Orthopaedic
Department: Orthopaedic
Last Review: Test Study- October 09, 2018
Agent Types:
Description:
Adult/Pediatric Indicator:
Ceded IRB Approval Letter Date:
Current Protocol Version:
Device Risk Determination:
Funding Type:
IB Date:
Investigator Initiated:
Peds Risk Determination:
Reliance IRB of Record:
Study Completion Signed Date:
Subjects Approved for Enrollment:
Vulnerable/Targeted Populations:
Comments:

Sponsor(s):
Sponsor Id:
Grants:
Next Review:
CRO:
Year: 2018
Bill IRB Fees:
Current Assent Form Date:
Data Collection Tools Date:
Drug Determination:
HIPAA:
Informed Consent:
Level of Risk:
Regulatory Oversight:
Study Application Signed Date:
Study Trial Phase:
Subjects Enrolled Since Last Renewal:

Study-Site

Site(s): MHH - Metro Health Hospital and others
Status: New From PI
Approval: November 12, 2018 for 12 months
Initial Approval: November 12, 2018
Location(s):
Comments:

PI: Rice, Jennifer
Additional: N
Expiration: November 11, 2019
Other Expirations:

Study-Site Contacts (2)

Action	Name	Role	Primary	Phone	E-Mail
	Rice, Jennifer	Coordinator	✓	616-252-5020	Jennifer.rice@metrogr.org
	Zeng, Steven	Coordinator			stevenZ@techsoftware.com

Events (1)

Action	Event	Att	FE	Instance/UDF	Start	Complete	Reviewers	Last Mtg
	New Protocol Submission	1			10/11/2018	11/02/2018		

1. **Study:** This section contains identifying information of the protocol as well as applicable IRB determinations.
2. **Study-Site:** This contains additional protocol information including the PI, status, approval and expiration dates, and any other applicable information.
3. **Contacts:** This section lists current approved contacts and their approved role on the study. Only contacts listed on the homepage will have access to the study (with the exception of IRB Members and Staff). You can click on a contact name to view their contact information, including training and expirations.
4. **Events:** This section lists all IRB submissions/reviews that have taken place or are currently taking place. Each event line has the following information:
 - a. **Event:** Type of event created. Clicking on the event will open up a new page, the event page.
 - b. **Att:** All attachments associated with that event. You can click directly on the number to access the attachments within the event (if 0, there are no attachments).
 - c. **FE:** Follow-up Events or “Child Events”- these occur when a separate event is created that is related to the original event. In many cases, these events are used for IRB staff purposes and will not be viewable to researchers.
 - d. **Instance/UDF:** This is an optional field completed by IRB staff to summarize or otherwise include identifying information on an event.
 - e. **Start:** This date is initially the date that the event was created in IRBManager, but is updated by IRB staff when the event contains a complete submissions (e.g. all submission requirements for that particular event have been met).
 - f. **Complete:** This date is completed by the IRB Staff and corresponds to when the event received final review or completion.

- g. **Last Mtg:** If the event is scheduled for Full Board review, this will display the date the event went to the meeting.

Navigating an Event Page

Clicking on any event from a study homepage will take you to the Event Page. In addition to the header and left side panel menu, there are four main components of the event page. Clicking the green arrow next to the notes header will either hid or expand the section.

Event Details: Continuing Review on 2017-11-30/2017 Help Jennifer's Settings Sign off

Study-Site	
Study:	2017-11-30/2017
Description:	Collaborative Ocular Oncology Group Uveal Melanoma Validation Study Number 2 (COOG2)
PI:	11/30/2017
Site:	RETINASP - 11/30/2017
Committee:	MH IRB
Sponsor Id:	

Event	
Type:	Continuing Review
Instance:	
Committee:	Inherited from Study
Primary Reviewer:	Oostendorp, Maureen A MM, CIP
Review Type:	
Determination Date:	
Effective Date:	
XForm Signed:	
Started:	11/30/2017
Completed:	11/30/2017
Secondary Reviewer:	
Documents Reviewed:	Continuing Review Progress Report form signed 10/26/2017; Study Protocol version #1 dated 11/28/2016; Informed Consent version date 01/18/2017
Regulatory Categories:	category (5)

Notes (1)

Emails (1)

Action	Subject	Date	Del	To/From	Int
	2017-11-30/2017	11/30/2017		11/30/2017	Yes

Steps (15) ☒ Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Continuing Review Application Received	11/30/2017	11/30/2017	Yes		
Continuing Review Progress Report	11/30/2017	11/30/2017	Yes		
Current Approved Protocol	11/30/2017	11/30/2017	Yes		
Current Approved Informed Consent	11/30/2017	11/30/2017	Yes		
Internal IRB Pre-Review	11/30/2017	11/30/2017	Yes		
Send for Expedited Review	11/30/2017	11/30/2017	Yes		
Recieve for Expedited Review	11/30/2017	11/30/2017	Yes		
Notify Board of Expedited Review	11/30/2017	01/12/2018	Yes	01/12/2018	
Notify PI of Review Determination	11/30/2017	11/30/2017	Yes		

Each event page contains the following sections:

- Study Site:** Displays some identifying information from the Study Site on the study homepage.
- Event:** Displays some identifying information regarding this particular event, including which committee is reviewing that specific event as well as other revisions have been requested.
- Notes:** the notes section will contain any notes for the research staff. Any notes regarding requested revisions will display here (research team will also be emailed a notification when revisions are requested) as well as approval letter notes and notes to PI, if applicable.
- Steps:** You can track the status of an event via the steps. As steps are completed, the “actual” date will be entered and at the event will be marked as a “Yes” in the complete column. If a step has not been completed (for example, if revisions have not been received from research staff), the event’s actual date and complete columns will be blank.

***Note:** The “Planned,” “Minutes,” and “Micro Notes” columns in the event steps are generally used for IRB member and staff purposes and will often appear blank.

XForm Navigation

Form Stages

Although the terminology of the stage/status may differ slightly between forms, they follow the same pattern:

Data Entry Stage- This is the only stage that research team can make edits (the exception is the PI, who can edit in PI signature stage).

- Enter data to complete form
- Attach documents
- Save form until all information has been entered
- Press the “Submit” button when information is complete

PI Signature Stage-

- Requires electronic signature by PI (password is signature)
- The form can go no further without signature
- IRB Administration and/or PI can return the form to the Data Entry Stage for modification

IRB Determinations Stage-

- IRB staff review the form and accept it into the IRBManager system
- If submission is a new study or new determination, a new study homepage will be created and assigned a number
- Event will be created for study (accessible from study homepage)
- Form can be returned to the Data Entry Stage for revisions (by IRB)

Reviewer Stage-

- IRB staff notify research staff of any requirements needed prior to assigning for review
- IRB staff will assign submission for review
- Reviewer has the option of using this stage to submit comments to the investigator
- Form can be returned to the **Data Entry Stage** (by IRB)

Complete-

- All changes have been made, study has received approval from the IRB
- No revisions can be made to the form

Starting a New xForm

Clicking start the “Start xForm” option on the left side panel menu will provide you with a list of xForms you can start from that particular page. Note the options under “Start xForm” are DIFFERENT if starting from your DASHBOARD or EVENT vs starting from a STUDY HOMEPAGE:

Start xForm from Dashboard:

The screenshot displays the MetroHealth IRBManager Dashboard. The left sidebar contains a menu with the following items: Actions, Reviewer, Reviewer Open Events, Completed Reviews, Agendas & Minutes, Search Studies, xForms, Click here to start a New Submission, **Start xForm** (highlighted with a blue arrow), Show Sponsor Ids, View as Another User, Recent Items, 0219-2-MHH, 2018-016-MHH, 0219-4-MHH, 2015-011-OAM, 2014-025-MHV, 2010-012-MHH, 2019-023-MHV, Grant, Sarah E. PA-C, Messages, Welcome to IRBManager at MetroHealth, My Docs & xForms, 0 Attachments, 39 xForms.

The main content area shows a notification: "You have 4 reviews pending." Below this is a table titled "My Reviews (4 Open)" with columns: Type, Assigned, Due, Review Item, and Request Details. The table lists four reviews: Non-Committee Review, Committee Review, Committee Review, and Committee Review.

Below the reviews table are sections for "Studies (1 Active)", "xForms (13 Active)", and "Events (6 Open)". The "Studies (1 Active)" section lists active studies. The "xForms (13 Active)" section lists active xForms. The "Events (6 Open)" section lists open events.

The bottom section, "My Studies (1 Active)", shows a table with columns: Study, Site, PI, Description, Expires, and Status. The table lists one study: 1018.1-MHH, Metro Health Hospital, IRB Member, Doctor Test, Test Study- October 09, 2018, 02/20/2020, New From PI.

Start xForm from Study Homepage:

The screenshot shows the MetroHealth IRB Manager interface for Study 0219.4-MHH (IRB). The 'Start xForm' button is highlighted with a blue arrow. The interface includes a sidebar with navigation options, a main content area with study details, and a table of reviews and events.

Study Details:

- Department: Cardiovascular
- Last Review: [blank]
- Agent Types: [blank]
- Description: Expedited to FB
- Adult/Pediatric Indicator: [blank]
- Ceded IRB Approval Letter Date: [blank]
- Current Protocol Version: [blank]
- Device Risk Determination: [blank]
- Funding Type: [blank]
- IB Date: [blank]
- Investigator Initiated: [blank]
- Peds Risk Determination: [blank]
- Reliance IRB of Record: [blank]
- Study Completion Signed Date: [blank]
- Subjects Approved for Enrollment: [blank]
- Study Site: MHH - Metro Health Hospital
- Status: New From PI
- Approval: December 25, 2018 for 12 months
- Initial Approval: December 25, 2018
- Location(s): [blank]
- Comments: [blank]

Reviews on Open Events (3)

Action	Event	Type	Reviewer	Review Item	Outcome	Due	Complete
Modification	Non-Committee Review	Rice, Jennifer	Modification of Approved Human Research	Requires Full Board Review	04/25/2019		
Modification	Non-Committee Review	Rice, Jennifer	Modification of Approved Human Research	Approve/Determination	05/09/2019		
Modification	Committee Review	Rice, Jennifer	Modification of Approved Human Research	Defer	04/26/2019	05/07/2019	

Events (3)

Action	Event	Att	FE	Instance/UDF	Start	Complete	Reviewers	Last Mtg
Modification	1			straight expedited approval	05/09/2019		Jennifer R	
Modification	4			hbvgghjgbvjh	04/25/2019		Jennifer R	
New Protocol Submission	2				02/28/2019	04/18/2019		

Emails (7)

Action	Subject	Date	Del	To/From	Int
Modification of Approved Human Research Form Submitted/0219.4	05/09/2019 at 11:30 AM		irb@metrogr.org	Yes	
Modification Submission Complete with PI Signature and Submitted to IRB for Review/Expedited to FB	05/09/2019 at 11:30 AM		Jennifer.rice@metrogr.org	Yes	
	05/09/2019 at 11:28 AM		leah@techsoftware.com	No	

Thus, the following forms are available **anywhere** you click “Start xForm;” these will be independent submissions, not linked to any particular study or event:

1. New System Contact
2. Initial Application

The following forms are **study-specific** and WILL be linked to the study homepage where they are started; once submitted and accepted into the system by IRB Staff, these forms will create events on that study’s homepage:

1. Modification of Approved Human Research
2. Continuing Review Progress Report
3. Reportable New Information
4. Study Completion Notification

Accessing a Previously Started xForm

There are multiple ways to access xForms in IRBManager. This is not an all-inclusive list of ways to access specific forms, but the most common. Please contact the IRB office if you have difficulty locating a particular form.

If a form has **NOT** entered IRB Determinations (e.g. is in data entry, PI signature stage for the first time), the most direct way to access the form is through your dashboard, under xForms.

My Studies

Studies (1 Active)

- You are associated with [1 active](#) Studies and [1 total](#) Studies.
- You are the PI for [1 active](#) and [1 total](#) Studies.
- You are the reviewer for [7 active](#) and [13 total](#) Studies.
- Committee MH IRB has [54 active](#) and [242 total](#) Studies.


xForms (7 Active)

- You have [6 unsubmitted](#) xForms.
- You have [1 xForm](#) being processed at a later stage.

Events (6 Open)

Only show events where I am:













- You have [1 Continuing Review](#) events.
- You have [1 Modification](#) events.
- You have [4 New Protocol Submission](#) events.
- You have [6 Total Open](#) events



Clicking on the underlined text will link you to a page with the relevant xForms. In the example above, if the user wanted to resume work on an unsubmitted Initial Application, they would click the “6 unsubmitted” link:

Filter:

What's this?
This table shows xForms associated with you as a user of IRBManager across the entire system.

Action	Form	Identifier	Owner	Stage	As Of
 	Non-Committee Review (Draft)		New Protocol Submission 1018.1-MHH	Non-Committee Review Data Entry	12/13/2018
 	Initial Application (Draft)		Rice, Jennifer (Jennifer.rice@metrogr.org)	Data Entry	11/20/2018
 	Initial Application (Draft)		Rice, Jennifer (Jennifer.rice@metrogr.org)	Data Entry	10/15/2018
 	Continuing Review Progress Report (Draft)		1018.1-MHH Rice, Jennifer	Continuing Review Data Entry	10/11/2018
 	Initial Application (Draft)		Rice, Jennifer (Jennifer.rice@metrogr.org)	Data Entry	06/22/2018
 	CR 32-A: Application for Human Research		Rice, Jennifer (Jennifer.rice@metrogr.org)	Application form Data Entry	05/25/2018

The list of unsubmitted xForms becomes available. The “filter” box can be used to help identify key words in any of the columns (for example, you could type in “Research on Human Subjects” so only those forms with that phrase in the title would be listed, or part of the study title/protocol number if displayed in the “identifier” column). Clicking directly on the blue link will open the form. Clicking the red x will delete the form.

Note: If a form is started from the study homepage, you can navigate to the study and click on “xForms” to see the unsubmitted forms for that particular study; however, remember that only the submitter and collaborators will be able to access it in data entry.

The screenshot shows the Metro Health Study 1018.1-MHH (IRB) page. The left sidebar contains a menu with 'xForms (1)' highlighted. A blue arrow points from this menu item to the 'Investigator Initiated' field in the study details table.

Study	
Study:	1018.1
Committee:	MH IRB
Category:	
Department:	Orthopaedic
Last Review:	
Agent Types:	
Description:	Test Study- October 09, 2018
Adult/Pediatric Indicator:	
Ceded IRB Approval Letter Date:	
Current Protocol Version:	
Device Risk Determination:	
Funding Type:	
IB Date:	
Investigator Initiated:	
Peer Risk Determination:	

If a form HAS already been accepted from “IRB Determinations” by IRB staff (this means the form has been successfully submitted and an event has been created):

The most direct way to access a form once it’s been accepted into the system is to go to the EVENT PAGE.

Once in the event page, click on “xForms” on the left side panel menu.

From there, you will be able to see the form available within that event and the stage of review.

The screenshot shows the Metro Health Forms page. The left sidebar contains a menu with 'xForms' highlighted. The main table shows a list of forms with columns: Action, Form, Identifier, Stage/Status, Started, Submitted, and By. A blue arrow points from the 'xForms' menu item to the 'Continuing Review Progress Report' form.

Action	Form	Identifier	Stage/Status	Started	Submitted	By
	Continuing Review Progress Report		Continuing Review Data Entry	10/11/2018		Rice, Jennifer

Clicking the blue form link will take you into the form.

Navigating an xForm

The following is an example of an xForm's basic elements:

The screenshot displays the 'Study Basic Information' section of an xForm. At the top, there is a dropdown menu for 'Study Basic Information' and a page indicator 'Page 1 of 15'. The form is divided into several sections, each with a title and 'Add Note' and 'View Audit' links. The 'Submitting User' section contains fields for 'Rice, Jennifer', 'Email: Jennifer.rice@metrogr.org', and 'Business: 616-252-5020'. A reminder text states: 'Reminder: If your research involves the services of any ancillary departments, approvals from those individual areas may be required. It is the responsibility of the investigator to secure all required approvals prior to the enrollment of subjects in the research.' The 'Indicate the full protocol title. (Required)' section has a text area with 'Determination Request TEST'. The 'Enter the principal investigator's email address. (Required)' section has a text area with 'Jennifer.rice@metrogr.' and a name field with 'Rice, Jennifer'. The 'Choose all appropriate type(s) of research being conducted (Required)' section has checkboxes for 'Retrospective Chart Review (Does not involve any subject interaction)', 'Request for Determination (Research/QI/Engagement/Relliance)', 'Device Study', 'Humanitarian Use Devices (HUD)', 'Drug Study', and 'All Other Research Studies (Observational, Registry)'. The 'If you or your research team will be collaborating with any research organizations or universities for this research project please enter the name(s). Enter N/A if you are not collaborating with any other research organizations. (Required)' section has a text area with 'NA'. The 'Select appropriate area of research study (Required)' section has a dropdown menu with 'Cardiovascular' selected. The 'Indicate the Sponsor of the research- If self sponsoring, indicate INVESTIGATOR (Person or organization that initiates but may not conduct a clinical study. The sponsor assumes responsibility for the investigation including responsibility for compliance with applicable laws and regulations. Often times this is a drug or device manufacturer or the lead research institution or federal department granting funds). (Required)' section has a text area with 'INVESTIGATOR'. A 'Check & Submit Form' button is visible at the bottom right of the form.

1. At the top of the form:
 - a. **Drop down window:** The drop down window provides quick navigation to pages within an xForm.

This screenshot shows the same xForm as the previous one, but with the 'Study Basic Information' dropdown menu open. The menu lists the following options: 'Study Basic Information', 'Submission Documents- Determination', 'HIPAA', 'Investigator Signature- Determination', 'Resources Available to Conduct Human Research', 'Recruitment Methods', 'Procedures Involved in the Human Research', 'Participant Safety', 'Risks and Benefits', 'Privacy', 'Maintain Confidentiality', 'Compensation and Cost', 'Sharing Results with Participants', 'Submission Documents', and 'Investigator Signature'. The 'Check & Submit Form' button is also visible at the bottom right of the form.

- b. **Page number:** The “Page x of y” displays how many pages are within the form; these numbers may change depending on how you answer particular questions. For example, if a question on page A asks if you will be obtaining consent, an additional page may appear related to consent.
- c. **The “Next” Button:** The next button appears at the top and bottom of the xForm and can be used to advance the form to the next page. Note: if there are any questions that require an answer, you will not be able to advance the form using “Next” until that question is addressed (you can, however, use the drop down menu to temporarily navigate to a different page; you will be required to answer any required questions before submitting).

2. At the bottom of the page:

- a. **The “Next” Button:** The next button appears at the top and bottom of the xForm and can be used to advance the form to the next page. Note: if there are any questions that require an answer, you will not be able to advance the form using “Next” until that question is addressed (you can, however, use the drop down menu to temporarily navigate to a different page; you will be required to answer any required questions before submitting).
- b. **Save for Later:** This will save and close the form. You will see the following message:

- c. **More:** The next button contains options for:
 - i. **View Attachment Questions-** This will display any questions where there are attachments.
 - ii. **View Questions with Notes-** This will display any questions where there are notes (for example, reviewer notes that require comment or revision by research staff.
 - iii. **View Changed Responses-** This will display any responses to previous questions or notes.
 - iv. **View as PDF-** You can save the xForm with your submitted answers as a PDF. This can be retained as your documentation for your regulatory binder.

3. Questions: There are different types of questions in IRBManager; free text, drop down lists, single select, multi-select checkboxes, etc.

Choose all appropriate type(s) of research being conducted. (Required) [Add Note](#) [View Audit](#)

☐ Retrospective Chart Review (Does not involve any subject interaction)
☒ Request for Determination (Research/QI/Engagement/Reliance)
☐ Device Study

☐ Humanitarian Use Devices (HUD)
☐ Drug Study
☐ All Other Research Studies (Observational, Registry)

If you or your research team will be collaborating with any research organizations or universities for this research project please enter the name(s). Enter N/A if you are not collaborating with any other research organizations. (Required) [Add Note](#) [View Audit](#)

NA

Select appropriate area of research study (Required) [Add Note](#) [View Audit](#)

Cardiovascular

Indicate the Sponsor of the research- If self sponsoring, indicate INVESTIGATOR (Person or organization that initiates but may not conduct a clinical study. The sponsor assumes responsibility for the investigation including responsibility for compliance with applicable laws and regulations. Often times this is a drug or device manufacturer or the lead research institution or federal department granting funds). (Required) [Add Note](#) [View Audit](#)


INVESTIGATOR

Select the primary funding source. (Required) [Add Note](#) [View Audit](#)

☐ Industry/Commercial
☐ Government
☐ Private
☐ Still Seeking Funding
☒ Non-funded/Self-funded

- Add Note:** Researcher staff may add notes to alert IRB staff or reviewers of particular comments. However, all answers should be provided in the answer box; notes should not be used directly to answer questions. Notes are submission specific, they will not copy.
- Help Text:** If applicable, will appear in italics in the white section of the question box.
- Required Indication:** Question will be marked as (Required) if a response is needed.

Adding Personnel



Study Personnel Page 2 of 17

If the contact you are attempting to add is not already... [Add Note](#)

[New Contact Link](#)

Please enter the email address for the Primary Coordinator. [Add Note](#) [View Audit](#)

Please enter the email address for each coordinator involved in this study. [Add Note](#) [View Audit](#)

[Add Contact](#)
No answer provided.

Please enter the email for the Primary Sub-Investigator. [Add Note](#) [View Audit](#)

Please add the email addresses for other Sub-Investigators. [Add Note](#) [View Audit](#)

[Add Contact](#)
No answer provided.

Please enter the email for any Research Assistant(s). [Add Note](#) [View Audit](#)

[Add Contact](#)
No answer provided.

1. All personnel being added to an application must have an IRBManager contact and user login.
 - a. If they do not, use the link at the top of the page “New Contact Link.”

Page 1 of 1

New Contact Last Name (Required) [Add Note](#) [View Audit](#)

New Contact Degree (Required) [Add Note](#) [View Audit](#)

PhD, MD, DO, etc.

New Contact Email (Required) [Add Note](#) [View Audit](#)

New Contact Organization (Required) [Add Note](#) [View Audit](#)

New Contact Mailing Address (Required) [Add Note](#) [View Audit](#)

New Contact Mailing Address (City) (Required)

New Contact Mailing Address (State) (Required)

New Contact Mailing Address (Zip) (Required)

New Contact Phone (Primary) (Required) [Add Note](#) [View Audit](#)

Indicate if the contact is a Resident, Student, or N/A (Required) [Add Note](#) [View Audit](#)

☐ N/A
☐ Resident
☐ Student

After you have submitted the New System Contact Form return to the Submission Form and enter the email address of the newly submitted contact. [Add Note](#)

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After you have submitted the New System Contact Form and enter the email address of the newly submitted contact.

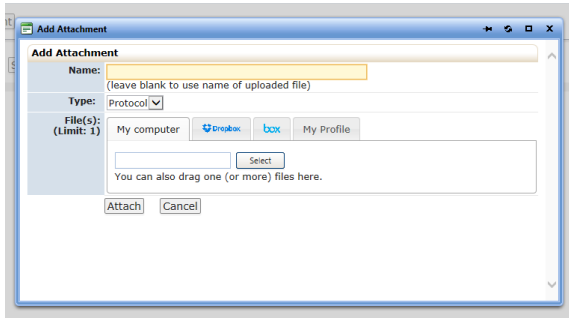
- b. To add a user that you know exists as a contact in IRBManager, simply enter their email address for them in the appropriate Role (Primary Coordinator, Sub-Investigators, Research Assistants, etc.) and select “Add Contact.” This can be done for multiple personnel.

Attaching Documents

All documents requiring IRB review should be submitted to the IRB via the attachments section of the xForm.

To attach a document:

1. Click “Add Attachment” on specified attachment questions. The following window will pop up:



2. Enter name for the attachment. If you want to use the name of the uploaded file, leave this field blank. You **should not** add the file extension to the file name (ex: .pdf). IRBManager will automatically assign the file extension for you.
3. Select the type of attachment using the drop down menu (i.e. Informed Consent Form, Protocol, etc.)
4. Click the “Select” button to locate the file on your computer, Drop Box, box, or My Profile. You can attach multiple documents under the Attachment Type designated.
5. Click “Attach” to finish the process.

Submitting an xForm

When the form is ready to submit, go to the “Check and Submit” page. Error messages will appear if there are any required questions that need to be answered. Please contact the IRB office if you need assistance.

Once ready to submit, click “Submit” the xForm will automatically notify the PI for review and signature. Be sure to review your form before submitting to the IRB. Once you submit a form to the IRB, it will be locked for IRB review.

Submitting Revisions to an xForm

Revisions may be requested by IRB staff for administrative purposes before the submission can be assigned for review, or may be requested by an IRB reviewer.

To Respond to Administrative Revisions/Requirements Needed

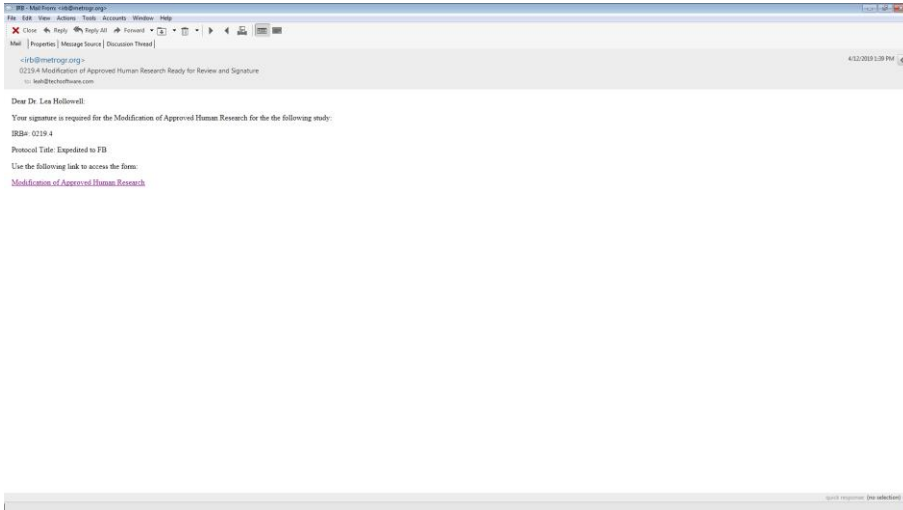
1. You will receive an electronic notification if your form is returned for administrative purposes. This means that more information is required before the form can be assigned for review.
2. Your application will be sent back to a data entry stage so that you can make the necessary revisions. You can get the form by either clicking on the link from the email notification. You can quickly find any sections that require updates by clicking the “View Questions with Notes” button at the bottom of the xForm or using the drop down menu and choosing “Check and Submit Form” to show the sections requiring changes.
3. Unless the revisions are purely administrative, the PI will need to sign off on the revised application/xForm. If the revisions are administrative, please notify the IRB when they are resubmitted so the IRB staff can override the PI Signature.

Instructions for Signatories on xForms

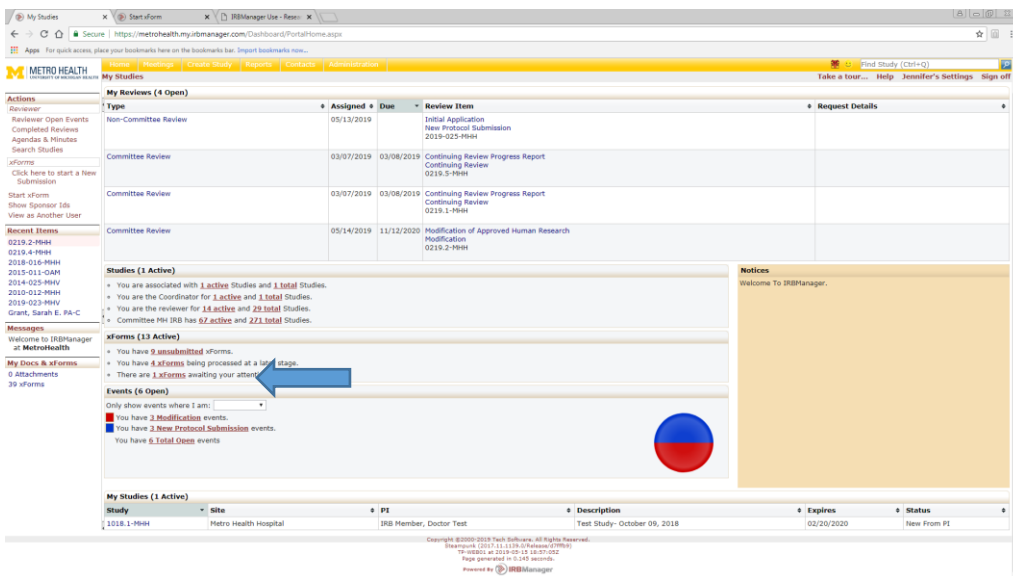
Notification Emails and Checking Notifications

IRBManager will send automatic notification to the PI that a signature is required, as well as provide a link to the form for quick access.

Example:



In addition to accessing the form through the email notification, users may login to their IRBManager account and access the “You have xForms awaiting your attention” link from the xForms section of their dashboard. This will provide a page of all the forms requiring their action.



PI Signature Stage

When the PI access the form in PI signature, they have the following options: