



Broward Health Institutional Review Board

Guide to IRBManager for Researchers

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1. ABOUT IRBMANAGER

IRBManager is an online submission, workflow, and data management system for Broward Health's Institutional Review Board. All submissions to the IRB must be submitted via IRBManager. IRBManager is a fully web-based system, which means that users can log in anywhere they have internet access. All persons participating in research at Broward Health must have an IRBManager account. The application forms (called xForms) provided within this system allow users to submit new studies for review as well as submit other applications for continuing review, amendments, reportable/non-reportable events, and final reports. Once these forms are completed, they are electronically routed through the required review process.

1.1. DEFINITIONS

Dashboard – Home page screen. Your Dashboard allows you to access and review all information relevant to projects you have submitted.

Event – An action in IRBManager, such as a New Study Application, Progress Report, Amendment. A study can have multiple “events” throughout its lifetime (Initial Review, Progress Report, Amendment).

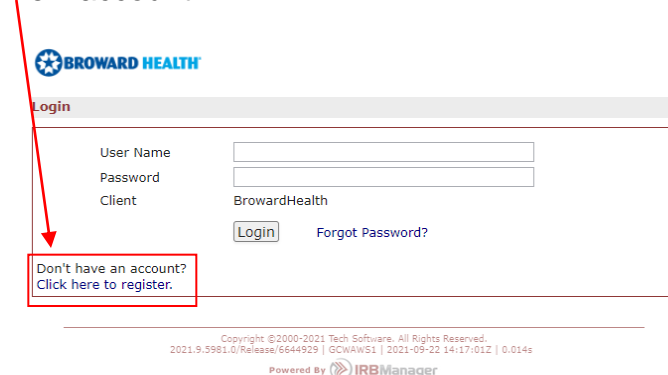
xForm – When you begin a new event in IRBManager, you will start with a xForm. xForms are the applications forms used to document the submissions being sent to the IRB for review.

2. CREATING A NEW ACCOUNT AND LOGGING INTO IRBMANAGER

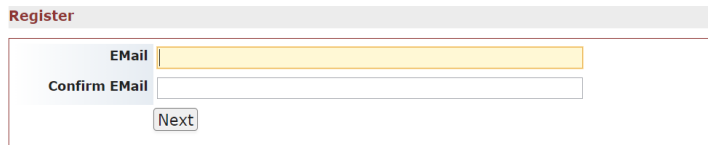
IRBManager can be accessed here: <https://browardhealth.my.irbmanager.com/>

2.1. CREATING A NEW IRBMANAGER ACCOUNT

If you do not have an IRBManager account, you can request access by registering for a new account.



When prompted by the next screen, you **MUST** enter your Broward Health email address if you are an employee of Broward Health. If you are an affiliate of Broward Health and do not have a Broward Health email address, you **MUST** use your professional email address. **This email address will be used as your primary point of contact with the Broward Health IRB.**



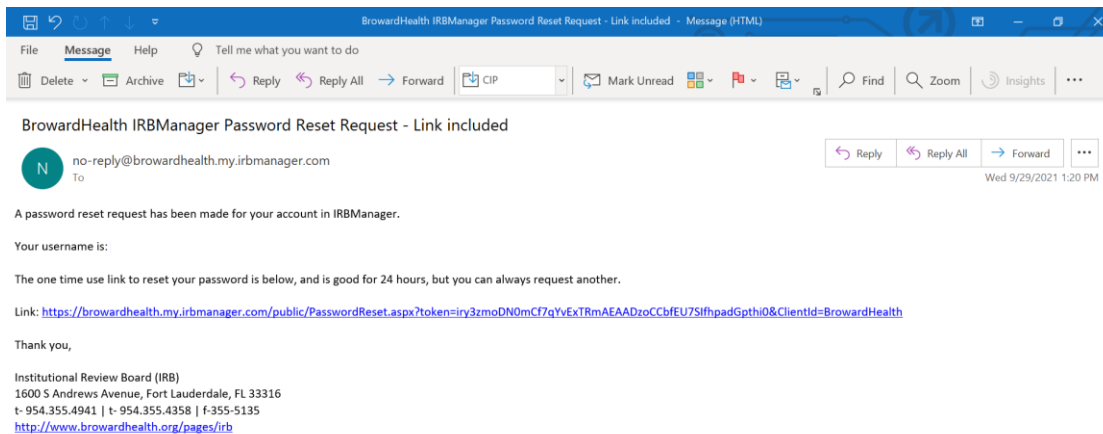
Register

EEmail

Confirm EEmail

Next

Clicking “Next” will generate an automatic email from no-reply@browardhealth.my.irbmanager.com. The subject line will read “Broward Health IRBManager Password Reset Request – Link included”, even if you are registering for the first time.



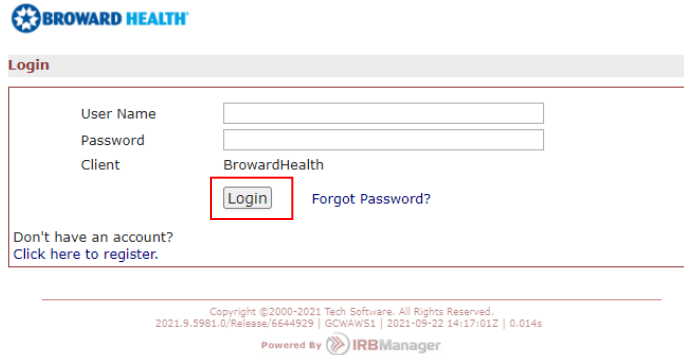
Follow the link. It will return you to the IRBManager login and prompt you to create a username and password. **Note:** Your username must be the email address you used to register.

After choosing a password and confirming the password, click “Reset Password”. You will once again be returned to the login screen. IRBManager will prompt you to use your new login credentials you have just created.

2.2. LOGGING INTO IRBMANAGER

1. Go to: <https://browardhealth.my.irbmanager.com/>
2. Enter your username and password
 - Your username is the email address used to create the IRBManager account
 - Your password is specific to IRBManager and is the one used when creating the IRBManager account
3. Click Login

Note: IRBManager will lock your account after three incorrect password attempts. Resetting your password will unlock your account.



BROWARD HEALTH

Login

User Name

Password

Client BrowardHealth

[Forgot Password?](#)

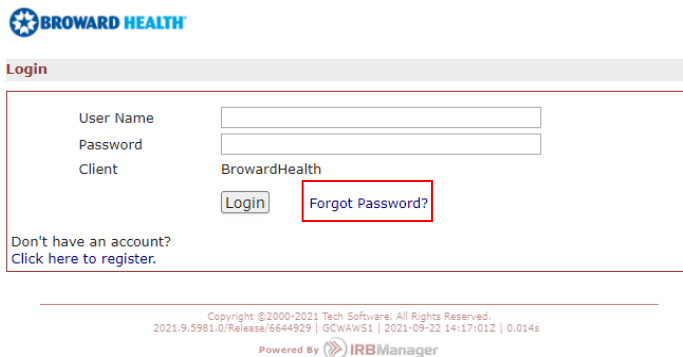
Don't have an account?
[Click here to register.](#)

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2021.9.5981.0/Release/6644929 | GCWAW51 | 2021-09-22 14:17:01Z | 0.014s

Powered By **IRBManager**

2.3. RESETTING YOUR PASSWORD

If you forget your password, click on the “Forgot Password?” link to reset your password. **Note:** If you do not use the link within 24 hours, it will expire. If you have any issues receiving the email, please click on the “spam” or “junk” folders within your email account.



BROWARD HEALTH

Login

User Name

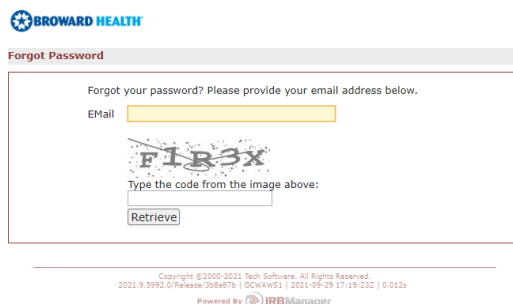
Password

Client BrowardHealth

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

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2021.9.5981.0/Release/6644929 | GCWAW51 | 2021-09-22 14:17:01Z | 0.014s

Powered By **IRBManager**



BROWARD HEALTH

Forgot Password

Forgot your password? Please provide your email address below.

Email

F1B3X

Type the code from the image above:


Copyright ©2000-2021 Tech Software. All Rights Reserved.
2021.9.5992.0/Release/3086076 | GCWAW51 | 2021-09-29 17:19:23Z | 0.012s

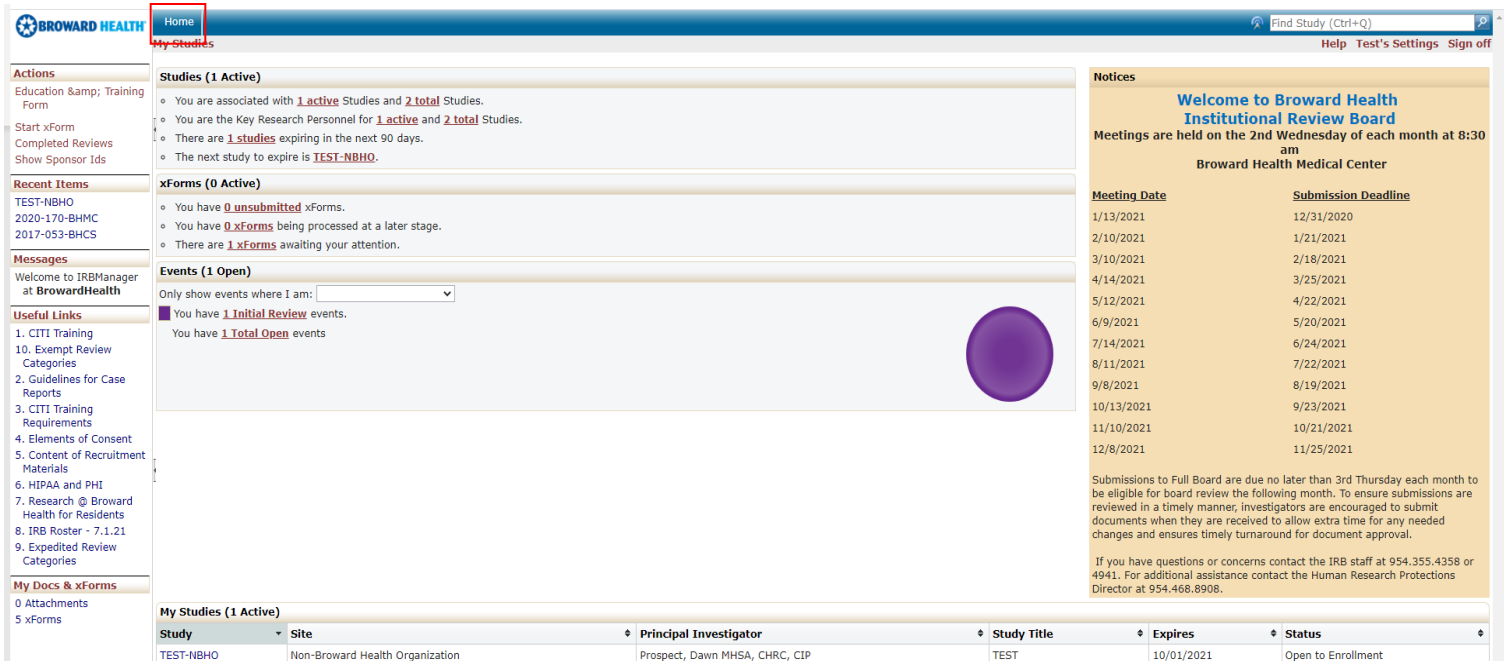
Powered By **IRBManager**

Anyone associated with a research study **MUST** meet specific educational and training requirements, based on their particular role in a study. Current Education and Training documentation must be maintained on file with the IRB. This must be submitted via the [Education and Training Form](#), see below.

3. NAVIGATING THE IRBMANAGER DASHBOARD (HOME PAGE)

The IRBManager dashboard, displays information relevant to all studies associated with a user. The main dashboard area displays studies, xForms and events that are associated with a user. Clicking on the links under the Studies, xForms or Events tabs will open more detailed summaries with links to each form. It also provides a schedule of the IRB meetings and submission deadlines for the current year and useful links.

The  button is used to return to the dashboard, from any location within the system.



Home

My Studies

Studies (1 Active)

- You are associated with **1 active** Studies and **2 total** Studies.
- You are the Key Research Personnel for **1 active** and **2 total** Studies.
- There are **1 studies** expiring in the next 90 days.
- The next study to expire is **TEST-NBHQ**.

xForms (0 Active)

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

Events (1 Open)

Only show events where I am:

- You have **1 Initial Review** events.
- You have **1 Total Open** events

My Studies (1 Active)

Study	Site	Principal Investigator	Study Title	Expires	Status
TEST-NBHQ	Non-Broward Health Organization	Prospect, Dawn MHSA, CHRC, CIP	TEST	10/01/2021	Open to Enrollment

Notices

Welcome to Broward Health Institutional Review Board

Meetings are held on the 2nd Wednesday of each month at 8:30 am
Broward Health Medical Center


Meeting Date	Submission Deadline
1/13/2021	12/31/2020
2/10/2021	1/21/2021
3/10/2021	2/18/2021
4/14/2021	3/25/2021
5/12/2021	4/22/2021
6/9/2021	5/20/2021
7/14/2021	6/24/2021
8/11/2021	7/22/2021
9/8/2021	8/19/2021
10/13/2021	9/23/2021
11/10/2021	10/21/2021
12/8/2021	11/25/2021

Submissions to Full Board are due no later than 3rd Thursday each month to be eligible for board review the following month. To ensure submissions are reviewed in a timely manner, investigators are encouraged to submit documents when they are received to allow extra time for any needed changes and ensures timely turnaround for document approval.

If you have questions or concerns contact the IRB staff at 954.355.4358 or 4941. For additional assistance contact the Human Research Protections Director at 954.468.8908.

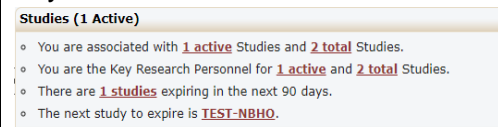
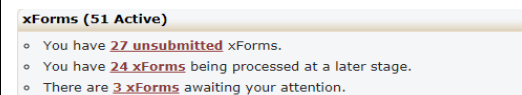
3.1. Left Side

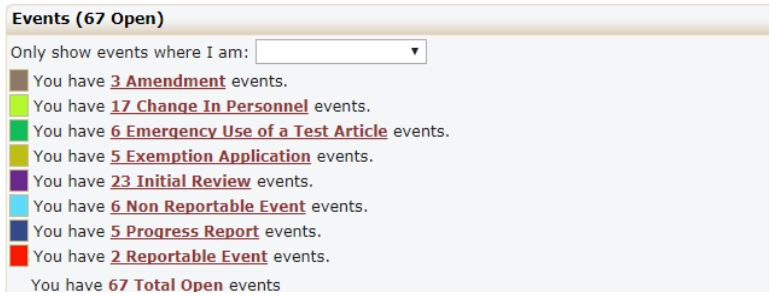
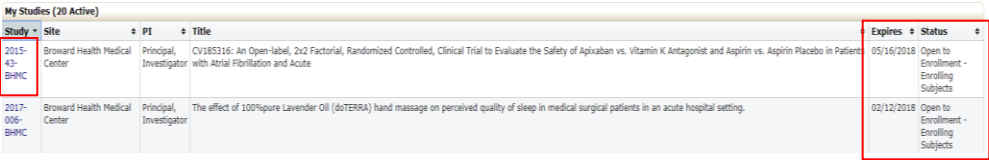
The left side of the screen includes a menu of the following:

	<p>Actions</p> <p>The options in this section will change depending on the page being viewed. Some pages allow for the viewing of attachments, xForms and sending an email.</p> <p>Recent Items</p> <p>Displays up to 7 items that were recently viewed.</p> <p>Messages</p> <p>Displays important messages from the IRB Office.</p> <p>Useful Links</p> <p>Provides access to Guidance Documents, Form Templates and the current IRB roster.</p> <p>My Docs and xForms</p> <p>Attachments – Clicking on “Attachments” displays attachments associated with a particular user e.g. CITI certificates and CV.</p> <p>xForms – Displays xForms (application forms) associated with a particular user across the entire system.</p>
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3.2. Center

Information and status updates pertaining to IRB applications on which the user is listed, will be displayed in the center of the screen.

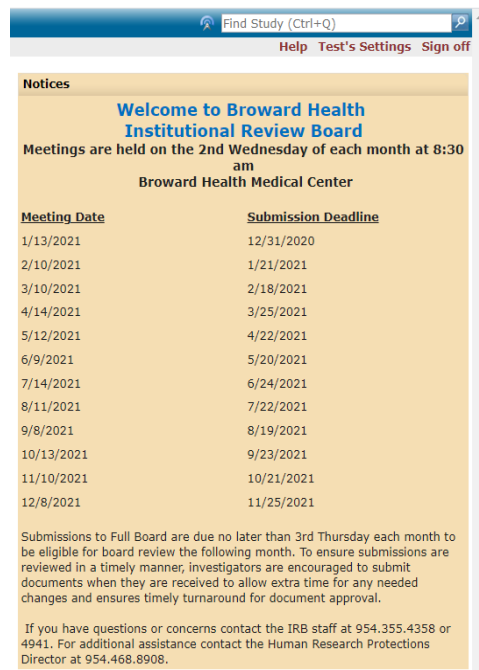
<p>Studies</p>	<p>Displays a summary of the active and total studies on which the user is listed, the role of the user on each study, and studies expiring in the next 90 days.</p> 
<p>xForms</p>	<p>Displays the xForms currently active for the user and a summary of each form.</p> 
<p>Events</p>	<p>This section shows submissions open by name of the event (Initial submission, Progress Report, Amendment, etc.) Clicking on any of the links</p>

	<p>will take you directly to that form.</p> 
<p>My Studies</p>	<p>Displays the active studies on which the user is a member of the study team. It also displays the expiration date (if applicable) and the enrollment status. Clicking on the study number (in blue) provides additional detail about the study.</p> 

3.3. Right Side

The right side menu includes the following:

<p>Find Study</p>	<p>Used to search for a specific study.</p>
<p>Help</p>	<p>For assistance, please contact the IRB Office at irb@browardhealth.org.</p>
<p>Settings</p>	<p>Enables the user to change their account information.</p>
<p>Sign Off</p>	<p>This option is to sign out of IRBManager.</p>



Find Study (Ctrl+Q)

Help Test's Settings Sign off

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6/9/2021	5/20/2021
7/14/2021	6/24/2021
8/11/2021	7/22/2021
9/8/2021	8/19/2021
10/13/2021	9/23/2021
11/10/2021	10/21/2021
12/8/2021	11/25/2021

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4. GETTING STARTED

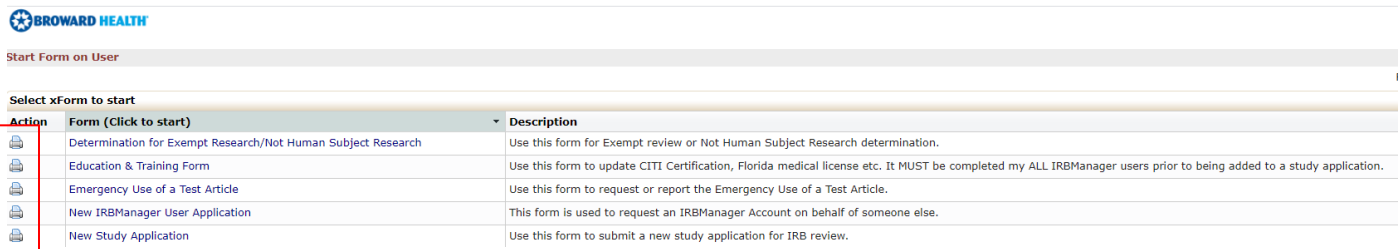
4.1. SMART FORMS:

The applications in IRBManager are “smart forms”, where the questions are tailored to the specifics of the study. The questions are asked in different formats, such as short answer, check boxes, drop down menus, attachments, etc.

- IRBManager allows users to view all available question options by following the steps below:
- On the Dashboard under “Actions”, click “Start xForm”



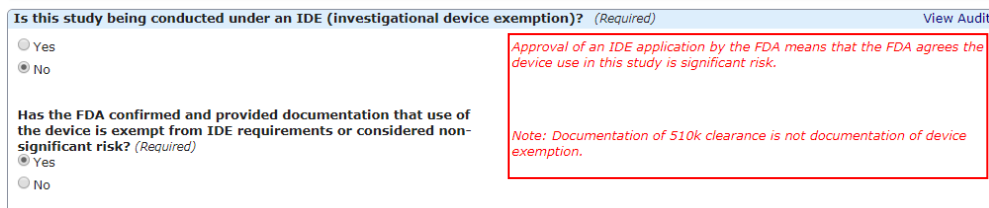
- Click on the **printer** icon located next to the applicable form.



- A sample of the form will be displayed, showing all of the possible questions.

4.2. FORM GUIDANCE AND NAVIGATION

- Guidance for most questions can be found to the right of a question.



The image shows a screenshot of a form question. The question is: "Is this study being conducted under an IDE (investigational device exemption)? (Required)". There are two radio buttons: "Yes" and "No", with "No" selected. To the right of the question is a red box containing the following text: "Approval of an IDE application by the FDA means that the FDA agrees the device use in this study is significant risk." Below this is another red box containing the text: "Note: Documentation of 510k clearance is not documentation of device exemption." A "View Audit" link is visible in the top right corner of the form.

OR by hovering the mouse over “Show Help” (where available)

the study of...
 he FDA for use...
 ssionate use...

Drug - A substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease OR (other than food) intended to affect the structure or any function of the body of man.
 Biological Product - A substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.
 Dietary Supplement - A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients.
 Medical Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, OR intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
 Food - Articles used for food or drink (or for components of such articles) and intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.
 Cosmetic - Articles (except soap) intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying promoting attractiveness, or altering the appearance (and any component of any such articles) AND intended for use to affect the structure or function of the body or to prevent, treat, mitigate, cure, or diagnose a disease.

ication by the f...
 is significant r...

- Some questions provide specific form templates to complete and attach.

HIPAA Authorization Form: (Required)

HIPAA Authorization Form Template
 Spanish HIPAA Authorization Form Template

- The “Add Note” option is available for some questions, to provide information to anyone that will be viewing the form. It can also be used to respond to revisions required by the IRB Office. See [Data Entry \(after changes required\)](#).

Study Title: (Required)

test

- The buttons located on the bottom of each section are used to navigate through the application. All work completed thus far in IRBManager is saved each time click the [Next] , [Previous], or [Save for Later] buttons are clicked.

- View Attachment Questions
- View Questions with Notes
- View Changed Responses
- View as PDF

Previous	Moves the application to the previous section.
-----------------	--

Next	Moves the application to the next section.
Save for Later	Saves the application in its current state and allows returning at a later time for completion.
More	Shows the below options
View Attachment Questions	Shows questions that require/have attachments.
View Questions with Notes	Shows questions which contain notes.
View Changes Responses	Shows questions where responses were changed
View as PDF	Creates a PDF version of the form.

- While completing the IRB application, IRBManager will automatically alert to any “issues” detected during form progression. The “issues” will be listed at the top of the screen for review and correction.
- Example:
 - The following issues exist. Click on an issue to jump there.
 - 1. How subjects will be identified - Required.
 - 2. Sources of Information for Identification - Required.
 - 3. Initial Contact of Potential subjects - Required.
 - 4. Recruitment Circumstances - Required.
 - 5. Recruitment materials - Required.
- The application cannot be progressed to the next page using the “Next” button, or be submitted, if there are “required” questions on a page which have not been answered.

The screenshot shows the top of the application with a 'Collaborators' button, a 'SITE INFORMATION' dropdown menu, and a 'Page 4 of 9' indicator. Below this, a message states 'The following issues exist. Click on an issue to jump there.' with a list item: '2.1 Research Feasibility Form - Required.' The main form area contains two sections: '1. Primary Research Site: (Required)' with a dropdown menu showing 'Broward Health Medical Center' and buttons for 'Show Help', 'Add Note', and 'View Audit'; and '2. Will Broward Health resources/services be needed to conduct research or procedures that require IRB review? (Required)' with radio buttons for 'Yes' (selected) and 'No'. A red box highlights the 'Yes' radio button. At the bottom, there is a section for '2.1 Research Feasibility Form: (Required)' with an 'Add Attachment' button and footer text: 'Research Feasibility Form' and 'Research Feasibility Form - Residents and Fellows'.

- Other areas of the application can be accessed by jumping to the section using the drop down menu at the top of the page.

The following issues exist. Click on an issue

- 2.1 Research Feasibility Form - Required

1. Primary Research Site: (Required)
Broward Health Medical Center

2. Will Broward Health resources/services be used? (Required)
=> 2.1 Research Feasibility Form - Required
 Yes
 No

2.1 Research Feasibility Form: (Required)
Add Attachment

3. Broward Health resources or services needed to conduct research or procedures that require IRB oversight: (Required)

Broward Health Patients
 Broward Health Pharmacy
 Broward Health - Other

Broward Health Records
 Broward Health Laboratory

Broward Health Employees
 Broward Health Facility

4.3. PROVIDING OTHERS ACCESS TO AN APPLICATION

When an application is created, only the creator (submitter) has access to edit, manage and submit the application. Others can be granted access to the application by being added as a collaborator. Collaborators can view, edit, manage, and/or submit an application depending on the level of access granted.

- Click on the [Collaborators] button located on the top of the page within the application.

- Insert the email address of the collaborator.

Add

Email [Text Field]

Access [Dropdown: Edit, View Only, Edit, Edit and manage, Edit, manage and submit]

Note for Collaborator [Text Area]

CC Me

[Add]

Current Collaborators

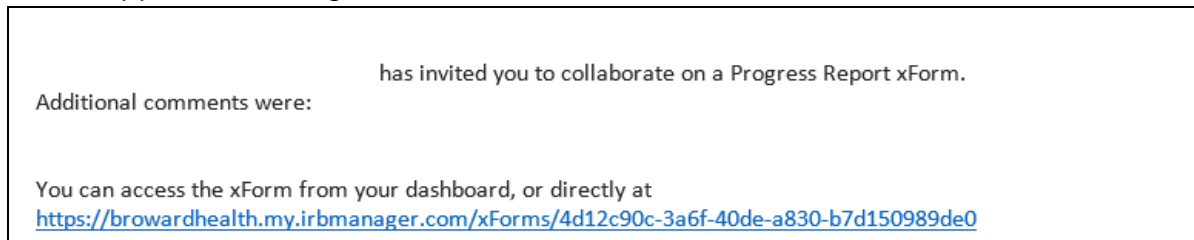
Action	Collaborator	Permission	BGR
[Search]	Prospect, Dawn MHSa, CHRC, CIP	Author	

- Select the access for the collaborator.

View Only	Allows the collaborator access to see the application only
-----------	--

Edit	Allows the collaborator to view and edit the application only
Edit and Manage	Allows the collaborator to edit the application and invite additional collaborators
Edit, Manage and Submit	Allows the collaborator to edit and submit the application and invite additional collaborators

- Click [Add]
 - The collaborator will receive an email inviting them to collaborate on the application along with a link to the form.



- Collaborators can be removed by accessing the “Collaborators” menu and clicking on the red “X” next to the collaborator’s name.

5. COMPLETING APPLICATION FORMS (xFORMS)

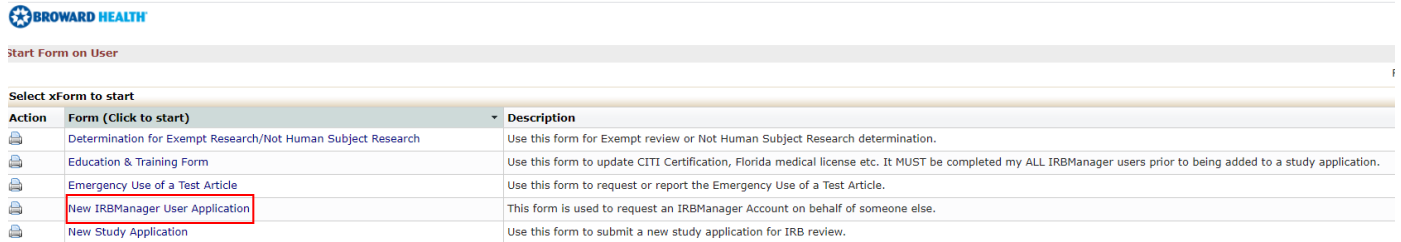
5.1. xFORMS

- All application forms (xForms) are created by clicking on “Start xForm” at various locations within IRBManager.
- Initial Review Applications ([Determination for Exempt Research/Not Human Subject Research](#) and [New Study Application](#)) and non-study specific forms ([Education & Training Form](#) and [New IRBManager User Application](#)) are available from the Dashboard.
- Applications for ongoing studies ([Progress Report](#), [Amendment](#), [Change in Personnel](#), [Reportable Event](#), [Non-Reportable Event](#)) are available within that particular study (see instructions below).



5.2. NEW IRBMANAGER USER APPLICATION

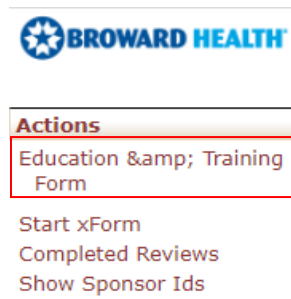
The new IRBManager User Application is used to request a new IRBManager account on behalf of someone else. After the submitter (creator of the form) submits the application, the New User is sent an email from IRBManager with their username and temporary password, along with a link to access IRBManager and the IRBManager User Guide. When completing the form, the submitter will have the option to submit an Education and Training Form on behalf of the New User. If the submitter does not have access to the New User's Education and Training documentation, an email is sent to the New User prompting them to submit the Education and Training Form.



5.3. EDUCATION AND TRAINING FORM

Each IRBManager user is required to have an Education and Training Form on file prior to participating on a research study. An Education and Training Form is also required to submit any updated Training Information e.g. expired CITI training and Professional Licenses.

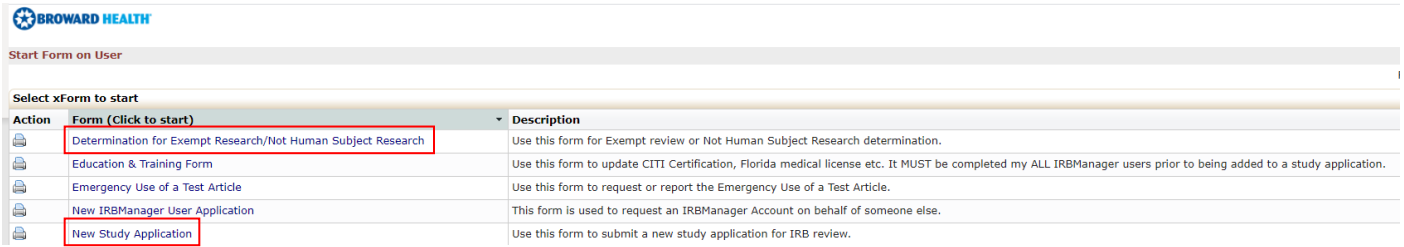
- From the Dashboard, click “Education & Training Form”, under “Actions” OR “Start xForm”








- Documents Required:
 - CITI Certification
 - Professional License (if applicable)
 - CV/Resume
- Complete the form using the instructions provided within.
- When the form is processed by the IRB Office, an email will be sent to the submitter and person whose information was updated (if different).

5.4. INITIAL REVIEW APPLICATION

An initial review application can be submitted to the IRB using the Determination for Exempt Research/Not Human Subject Research Form **OR** the New Study Application Form, depending on the nature of the study.



Action	Form (Click to start)	Description
	Determination for Exempt Research/Not Human Subject Research	Use this form for Exempt review or Not Human Subject Research determination.
	Education & Training Form	Use this form to update CITI Certification, Florida medical license etc. It MUST be completed by ALL IRBManager users prior to being added to a study application.
	Emergency Use of a Test Article	Use this form to request or report the Emergency Use of a Test Article.
	New IRBManager User Application	This form is used to request an IRBManager Account on behalf of someone else.
	New Study Application	Use this form to submit a new study application for IRB review.

- The Determination for Exempt Research/Not Human Subject Research application should be used to determine whether a study qualifies for Exempt Review, or Not Human Subjects Research. Guidance on whether an activity is Human Subjects Research is available [here](#). Guidance on Human Subjects Research activities which qualify for exemption are available [here](#).
 - Documents Required (as applicable to a study):
 - Research Feasibility Form – Template available in IRBManager
 - External Site permission documentation
 - Recruitment Materials
 - Protocol
 - Participant materials – Surveys, Questionnaires etc.
 - Data Collection Sheet – Template available in IRBManager
 - Study Information Sheet – Template available in IRBManager
 - HIPAA Authorization Form - English and Spanish Templates available in IRBManager
- The New Study Application should be used when submitting studies that may qualify for Expedited Review, studies that require Full Board Review, Expanded Access/Compassionate Use, Humanitarian Use Devices and requests for Reliance on an External IRB.
 - Documents Required (as applicable to a study):
 - Informed Consent documents
 - Research Feasibility Form – Template available in IRBManager
 - External Site permission documentation
 - Recruitment Materials
 - Protocol
 - IND Documentation

- IDE Documentation
- Investigational Brochure
- Device Manual
- HDE Documentation
- Investigational Drug Services Form
- Executed Reliance Agreement
- Local Context Questionnaire
- External IRB Approval Letter
- Participant materials – Surveys, Questionnaires etc.
- Data Collection Sheet – Template available in IRBManager
- HIPAA Authorization Form - English and Spanish Templates available in IRBManager

5.5. EMERGENCY USE OF A TEST ARTICLE APPLICATION

An Emergency Use of a Test Article application must be submitted either prior to or within 5 days of Emergency use of an Investigational Drug or Device.

- Documents Required:
 - Sponsor/Manufacturer Documentation
 - Independent Physician Assessment/Certification
 - FDA Documentation
 - Informed Consent Document (if applicable)



Start Form on User

Select xForm to start

Action	Form (Click to start)	Description
	Determination for Exempt Research/Not Human Subject Research	Use this form for Exempt review or Not Human Subject Research determination.
	Education & Training Form	Use this form to update CITI Certification, Florida medical license etc. It MUST be completed by ALL IRBManager users prior to being added to a study application.
	Emergency Use of a Test Article	Use this form to request or report the Emergency Use of a Test Article.
	New IRBManager User Application	This form is used to request an IRBManager Account on behalf of someone else.
	New Study Application	Use this form to submit a new study application for IRB review.

Note: If the report is prior to the use of an Investigational Article, the submitter and Treating Physician will receive an email reminder with a link to submit the required follow up report within 5 business days of the article's use.

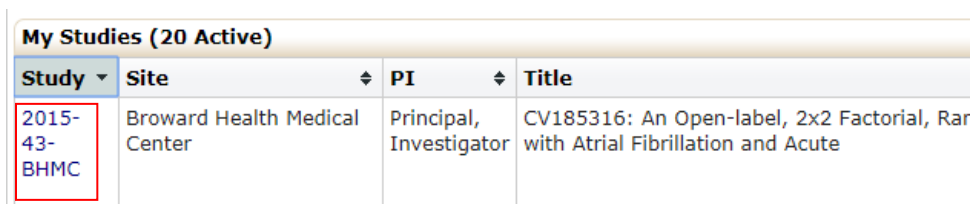
5.6. PROGRESS REPORT

A Progress Report application is required to update the IRB on the progress of a study, extend IRB approval **OR** to close out a study.

Note: If there have been changes to the research personnel, a [Change in Personnel Application](#) must be submitted **AND** approved by the IRB prior to starting the Progress Report xForm.

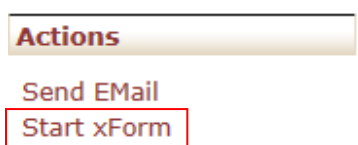
Documents Required (as applicable to a study):

- Informed Consent documents (clean or previously stamped)
 - DSMB/DSMC Report
 - Medical Device Report
 - Non-Reportable Event Summary Sheet – Template available in IRBManager
 - External IRB approval letter (External IRB studies)
 - Copies of revised protocols (External IRB studies)
 - Sponsor Closeout documentation (Industry funded studies)
- From the Dashboard, under the section titled “My Studies”, click on the study for which the Progress Report is required.

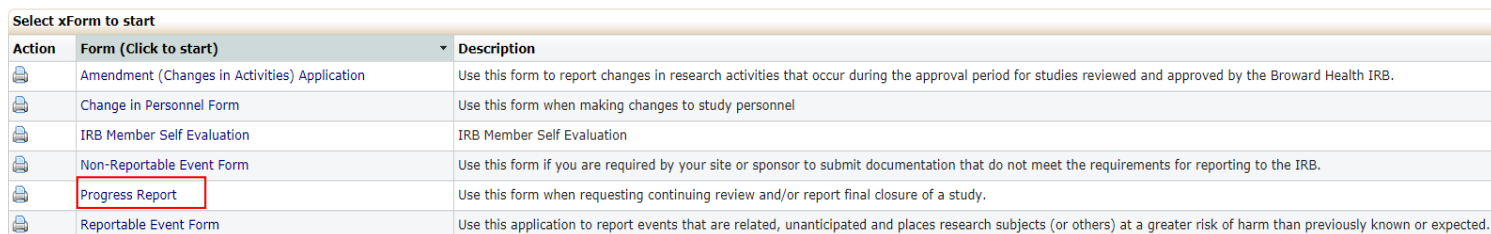


Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- On the left side of the screen, under “Actions”, click on “Start xForm”



- Click “Progress Report”



Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes to study personnel
	IRB Member Self Evaluation	IRB Member Self Evaluation
	Non-Reportable Event Form	Use this form if you are required by your site or sponsor to submit documentation that do not meet the requirements for reporting to the IRB.
	Progress Report	Use this form when requesting continuing review and/or report final closure of a study.
	Reportable Event Form	Use this application to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

- Complete each section of the Progress Report application and click “Submit”. See [“Form Stages”](#) to view the stages of the form.

5.7. AMENDMENT (CHANGES IN ACTIVITIES) APPLICATION

An Amendment Application is required to to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.

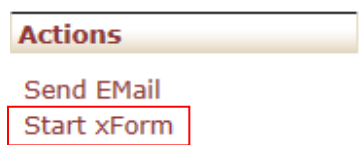
Note: Users will not be allows to create multiple amendment applications for one study at the same time, to avoid the potential for overlapping information.

Note: If there have been changes to previously IRB approved documents, you must submit a track changed copy of these documents in addition to a clean copy e.g. informed consent documents. Any changes to these documents must be made to the versions that were previously approved by the IRB.

- From the Dashboard, under the section titled “My Studies”, click on the study for which the Amendment is required.

My Studies (20 Active)			
Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- On the left side of the screen, under “Actions”, click on “Start xForm”



- Click “Amendment (Change in Activities) Application”

Select xForm to start		
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes to study personnel
	IRB Member Self Evaluation	IRB Member Self Evaluation
	Non-Reportable Event Form	Use this form if you are required by your site or sponsor to submit documentation that do not meet the requirements for reporting to the IRB.
	Progress Report	Use this form when requesting continuing review and/or report final closure of a study.
	Reportable Event Form	Use this application to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

- Complete each section of the Amendment application and click “Submit”. See “[Form Stages](#)” to view the stages of the form.

5.8. CHANGE IN PERSONNEL APPLICATION

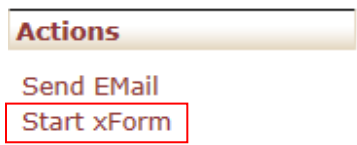
A Change in Personnel application is required when making changes to study personnel.

Note: If any of the changes in personnel affect the study documents, these must be revised and submitted (a track changed and clean copy).

- From the Dashboard, under the section titled “My Studies”, click on the study for which the Change in Personnel is required.

My Studies (20 Active)			
Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- On the left side of the screen, under “Actions”, click on “Start xForm”



- Click “Change in Personnel Form”

Select xForm to start		
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes to study personnel
	IRB Member Self Evaluation	IRB Member Self Evaluation
	Non-Reportable Event Form	Use this form if you are required by your site or sponsor to submit documentation that do not meet the requirements for reporting to the IRB.
	Progress Report	Use this form when requesting continuing review and/or report final closure of a study.
	Reportable Event Form	Use this application to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

- Complete each section of the Change in Personnel application and click “Submit”. See [“Form Stages”](#) to view the stages of the form.

5.9. REPORTABLE EVENT FORM

- A Reportable Event form is required to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.
- From the Dashboard, under the section titled “My Studies”, click on the study for which the Reportable Event is required.

My Studies (20 Active)			
Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- On the left side of the screen, under “Actions”, click on “Start xForm”



- Click “Reportable Event Form”

Select xForm to start		
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes to study personnel
	IRB Member Self Evaluation	IRB Member Self Evaluation
	Non-Reportable Event Form	Use this form if you are required by your site or sponsor to submit documentation that do not meet the requirements for reporting to the IRB.
	Progress Report	Use this form when requesting continuing review and/or report final closure of a study.
	Reportable Event Form	Use this application to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

- Complete each section of the Reportable Event form and click “Submit”. See [“Form Stages”](#) to view the stages of the form.

5.10. NON-REPORTABLE EVENT APPLICATION

- A Non-Reportable Event Form is used if required by a site or sponsor to submit events/documentation that do not meet the requirements for reporting to the IRB.
- From the Dashboard, under the section titled “My Studies”, click on the study for which the Non-Reportable Event is required.

My Studies (20 Active)			
Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- On the left side of the screen, under “Actions”, click on “Start xForm”



- Click “Non-Reportable Event Form”

Select xForm to start		
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes to study personnel
	IRB Member Self Evaluation	IRB Member Self Evaluation
	Non-Reportable Event Form	Use this form if you are required by your site or sponsor to submit documentation that do not meet the requirements for reporting to the IRB.
	Progress Report	Use this form when requesting continuing review and/or report final closure of a study.
	Reportable Event Form	Use this application to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

- Complete each section of the Non-Reportable Event Form and click “Submit”. See [“Form Stages”](#) to view the stages of the form.

6. FORM STAGES

6.1. CHECKING ON THE STATUS OF AN APPLICATION

- From the IRBManager Dashboard, click on xForms “being processed at a later stage”. The form stages and parties responsible for action at each stage, are available [below](#).

xForms (51 Active)

- You have **27 unsubmitted** xForms.
- You have **24 xForms** being processed at a later stage.
- There are **3 xForms** awaiting your attention.

Status: Being Processed At A Later Stage

Form	Identifier	Owner	Stage	As Of
New Study Application		Initial Review	Principal Investigator Interests and Signature (3rd time)	4 hours ago
Amendment (Changes in Activities) Application	Change in study title, design, methods, or procedures Addition, deletion or change in questionnaires or other study instruments Revised informed consent process or consent/assent forms	Amendment	Protocol Amendment Data Entry (2nd time)	09/09/2021 at 10:16 AM ET
Progress Report		Progress Report	Principal Investigator Interests and Signature (2nd time)	09/08/2021 at 7:32 AM ET

6.2. DATA ENTRY:

Party Responsible for Action: Submitter

The submitter creates and completes the application. In this stage, the submitter is the only one with access to edit the application. Others can be granted access by being added as a collaborator, see [Provide Others Access to My Application](#).

Once all of the required questions have been answered, IRBManager will allow advancement to the submission screen. **Note:** The application form can only be edited in this stage. Once submitted, the application form will be “locked” and cannot be edited unless it is returned to the submitter by someone further along the approval chain.

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

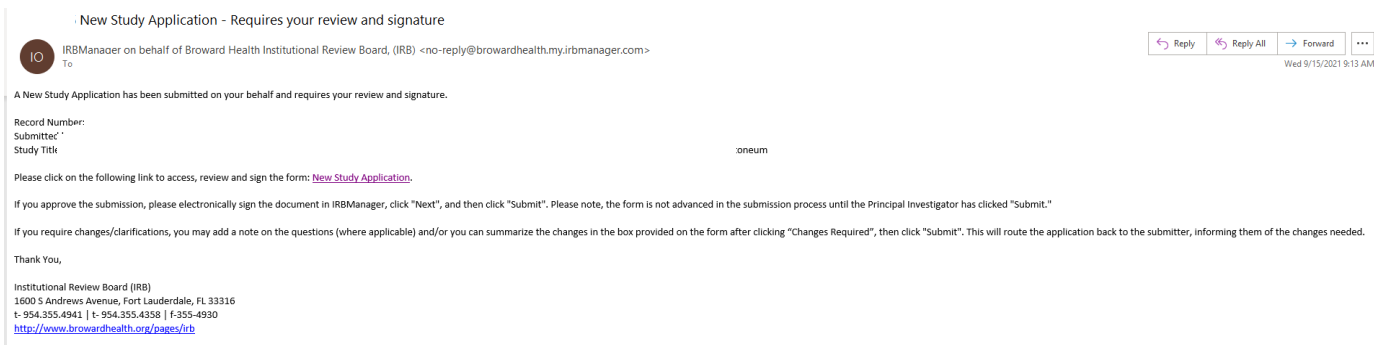
[Save for Later](#) [Print](#) [Submit](#)

Note: The “submit” button must be clicked to advance the application form to the next stage in the review chain. If any action other than submit is chosen, the form will remain in your list of unsubmitted xForms and will not route through the submission process.

6.3. PRINCIPAL INVESTIGATOR INTERESTS AND SIGNATURE:

Party Responsible for Action: Principal Investigator

If the application form was completed by someone other than the Principal Investigator (PI), the PI will receive an email from IRBManager indicating that their review and signature is required. The submitter also receives an email notifying them that the submission is awaiting signature by the PI.



Clicking on the link in the email will take the PI to the new study application. The PI is responsible for reviewing the application and ensuring that it is complete and the information is accurate.

After reviewing the application, click on the “Next” button on the bottom of the screen and determine whether the application is Ready to Submit or there are Changes Required.

After reviewing the submission on the previous page, is it ready for submission to the IRB? (Required) [Add Note](#) [View Audit](#)

Ready for submission

Changes Required

[Previous](#) [Next](#) [Save for Later](#) [More >](#)

- If “Ready to Submit”:
 - Complete the outside interest disclosure and certify that that the information is true and complete.

A screenshot of the IRBManager "Outside Interest Disclosure" form. The form title is "New Study Application -- Outside Interest Disclosure". It includes a "Collaborators" field and a "Next" button. The main question is: "1. Do you, or any of your immediate family members (i.e. spouse and/or dependent children) have any of the following financial, professional, or other interests in entities which could be affected by this research project?" The list of interests includes: Scientific Advisory Board Membership, Other Advisory Role, Service in Management Role (e.g. Director, Officer or similar position of decision-making authority), Payment for protocol or study design (paid directly to you), Other payments related to the protocol, that are not included in the research agreement budget (e.g. enrollment bonuses, finder's fees etc.), Stock or options, Honoraria, and Proprietary Interests (Including but not limited to patents, trademarks, copyrights, licensing agreements). Below the list, there is a "(Required)" label and two radio button options: "I have an outside interest to disclose" and "I do not have an outside interest to disclose". A "3. Certification: (Required)" section follows, with a checkbox for "The information on this form is true and complete to the best of my knowledge." At the bottom, there are navigation buttons: "Previous", "Next", "Save for Later", and "More >".

- Read the Principal Investigator Assurance Statement and electronically sign the document by entering your password.

Principal Investigator Assurance Statement:

- Research Involving Human Subjects:** I acknowledge and accept primary responsibility for protecting the rights and welfare of human research subjects, and that each rights and welfare take precedence over the goals and requirements of the research. I hereby represent that I have reviewed the following documents and agree to conduct my research in compliance with: (1) the Belmont Report, (2) the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations, (3) the Federal Health Assurance applicable to this research study, and (4) the Broward Health IRB policies and procedures governing human subject research.
- Conflict of the Study:** This research study or project will be performed in the manner described in this application and in accordance with Broward Health IRB policies and procedures, applicable laws, regulations and guidelines. I hereby advise from beginning this proposed research study prior to its review and receipt of written approval by the Broward Health IRB to begin research. I understand that any modifications from the procedure detailed herein must be submitted to the IRB and approved by the IRB prior to implementation unless necessary to eliminate apparent immediate hazards to subjects.
- Protected Health Information:** I hereby agree that I will not reuse or disclose to any other person protected health information obtained or accessed by virtue of this research except as authorized by the subject, or permitted or required by law and shall notify my research staff to also comply with this section.
- Informed consent:** I agree to obtain, document, and maintain records of informed consent (or legally authorized representative), unless an applicable waiver has been granted by the IRB, as required under HHS or FDA regulations, applicable laws and Broward Health IRB policies and procedures, and as stipulated by the IRB.
- Training:** I hereby assure that all investigators/key research personnel working with human subjects described in this application are individually competent and have a working knowledge of the Belmont Report, applicable federal regulations regarding human subject research and HIPAA and Broward Health IRB policies and procedures. I agree to complete and receive any investigator/key research personnel participating in this research study under my direction and control to complete any and all educational training required by Broward Health IRB prior to initiating this research study. **Note: No submission will receive that this approval until the Broward Health IRB Office has received documentation that all investigators/key research personnel have completed required training.**
- Conflict of Interest:** All investigators/key research personnel are required to comply with Broward Health's policies regarding conflict of interest in research. All investigators/key research personnel listed on this submission are required to have completed their conflicts of interest disclosure.
- Expenses/Findings:** If funded by an external source, I assure that this application accurately reflects all procedures involving human subjects as described in the grant/contract prepared to the funding agency. I also assure that I will notify the Broward Health IRB and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.
- Continuing Obligations:** It is understood that it is the responsibility of the Broward Health IRB to conduct continuing review of research as intervals appropriate to the degree of risk, as indicated by the IRB approval. I also understand that on continuing review a condition, it is my responsibility to provide timely and accurate information when pertinent or requested, and to notify the Broward Health IRB in a timely manner when my study has been revised, amended or modified in any way, stated or not, suspended, completed, or otherwise is no longer active.

By entering my password, I am certifying the accuracy of the information contained in this application.

To sign, enter password for Director@browardhealth.org

- If “Changes required”, enter feedback for the submitter in the text box. Alternatively, the textbox can be used to direct the submitter to review the notes on the xForm.

Submission Status

After reviewing the submission on the previous page, is it ready for submission to the IRB? (Required)

Ready to submit

Changes Required

Required changes: (Required)

Previous Next Save for Later More

- Click “Next” and “Submit” regardless of the submission status. The application will either be returned to data entry for revisions, and an email sent to the submitter (if submission status is changes required), or forwarded on for review (if submission status is ready to submit). **Note:** The “submit” button must be clicked to advance the application to the next stage. If any action other than “submit,” is chosen, the application will be saved and remain unsubmitted.

Form Completed

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

Go Back Save for Later Print **Submit**

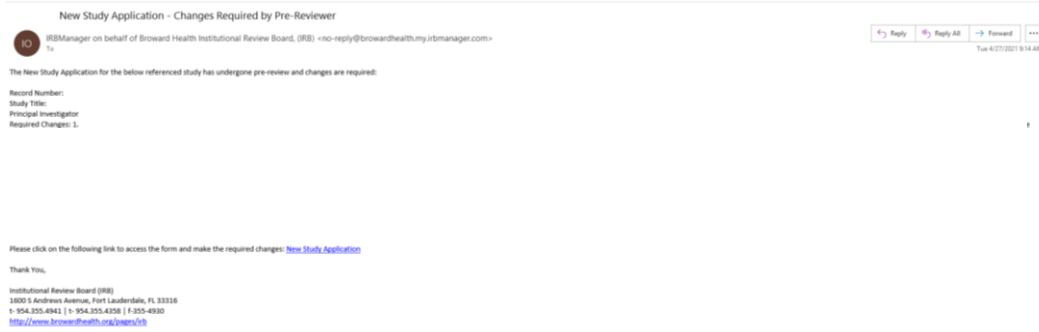
If the PI does not sign the form within 3 business days, a reminder email is sent to the Principal Investigator and submitter (if not the PI).

6.4. PRE-REVIEW:

Party Responsible for Action: IRB Office

The application has been submitted to the IRB Office. A pre-review is being conducted to determine if the application is complete and ready for further review. An email is sent to the IRB Office and the submitter notifying them that the study is ready for Pre-Review.

If there are changes required by the Pre-Reviewer, the submitter will receive an email notifying them of the required changes.



The application form will return to “Data Entry” and can be edited at this stage.

6.5. DATA ENTRY (AFTER CHANGES REQUIRED):

Party Responsible for Action: Submitter

- Click on the link in the “changes required” email to access the application.
- Alternatively, once logged into IRBManager, IRB application which needs attention can be located under the xForms heading on the dashboard and click on **“#xForms awaiting your attention.”**

- Next, select the application which needs attention from the list.
- Look for any question that needs attention by looking for a blue comment box, as shown below.

Important notes:

- When replacing a previously submitted item with a new version, click on the **green arrows**. This will avoid a duplicate of the documents uploaded in IRBManager.
- When deleting a previously submitted item, click on the **red x**.



- A list of questions which need to be addressed can also be found by clicking on **“More – View Questions with Notes”** located at the bottom of the screen.



- When each of the questions with notes have been addressed, the application may be re-submitted.
- The application will be sent to the PI for their signature. After the PI has signed the submission, it will return to the IRB Office for Pre-Review.

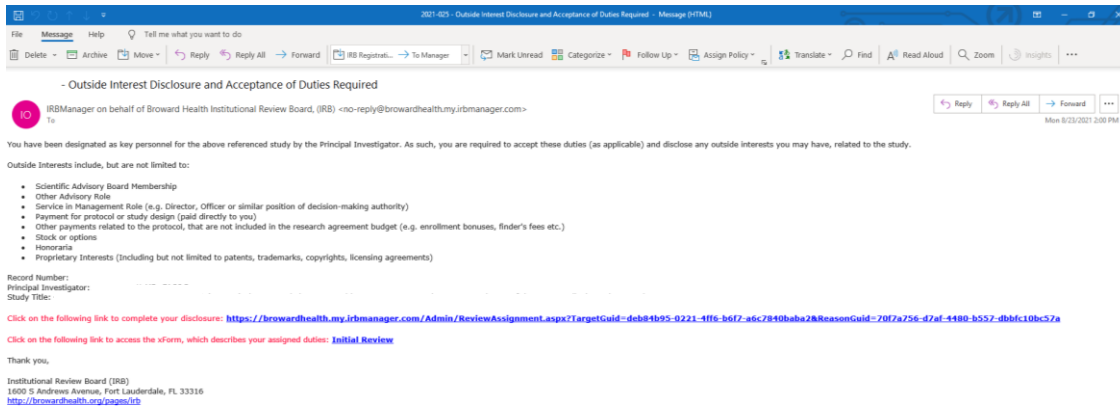
6.6. OUTSIDE INTEREST DISCLOSURE AND ACCEPTANCE OF DUTIES

Party Responsible for Action: Sub-Investigator(s) and/or Key Research Personnel

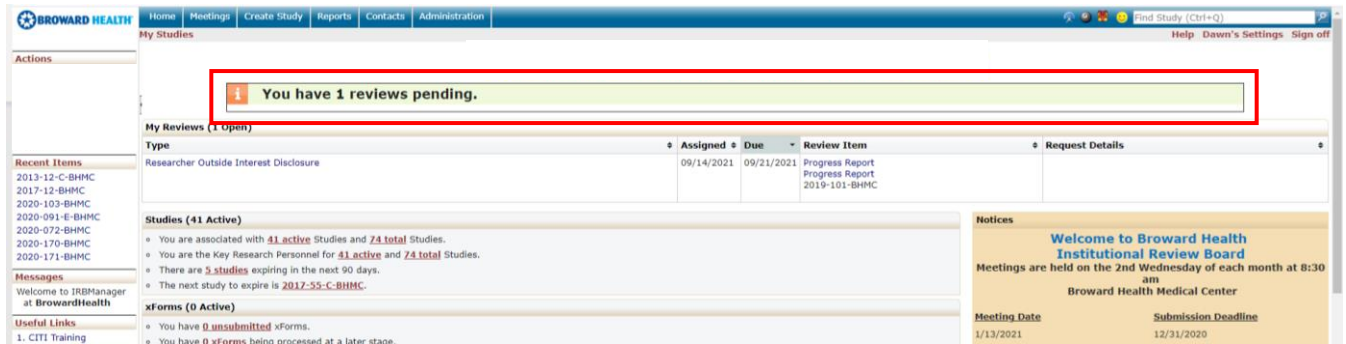
Important Notes:

- This stage is available in the New Study Application, Amendment (if reporting a change in previously disclosed outside interests), Change in Personnel forms (if adding new persons to the study) and Progress Reports. If there are persons designated as sub-investigators and/or key research personnel, the form will then be routed to the outside interest disclosure & acceptance of duties stage. Each person listed as sub-investigator or key research personnel will receive an email notification that they have been designated as members of the study team and request that they accept these duties and disclose whether or not they have an outside interest. The submitter will also receive an email that the submission is pending Outside Interest Disclosure and Acceptance of Duties.
- The key research personnel/sub-investigators must click on the link in the email to complete and submit the Outside Interest Disclosure Form. A link is also provided to view the application on which they are listed.

- The submission will remain in this stage until all sub-investigators and key research personnel have submitted their Outside Interest Disclosure Form.



- Alternatively, the persons listed as key research personnel/sub-investigators can access the submissions for which Outside Interest Disclosure is required, via the dashboard. The required reviews will appear on the top of the screen upon login.



If all persons listed as key research personnel/sub-investigator do not complete and submit their Outside Interest Disclosure within 5 business days, the submitter will receive a status email notification that it is not complete.

6.7. OUTSIDE INTEREST REVIEW AND COI DETERMINATION

Party Responsible for Action: Corporate Compliance

If the Principal Investigator, a sub-investigator or key research personnel discloses an outside interest, the submission is routed to a member of Corporate Compliance for review.

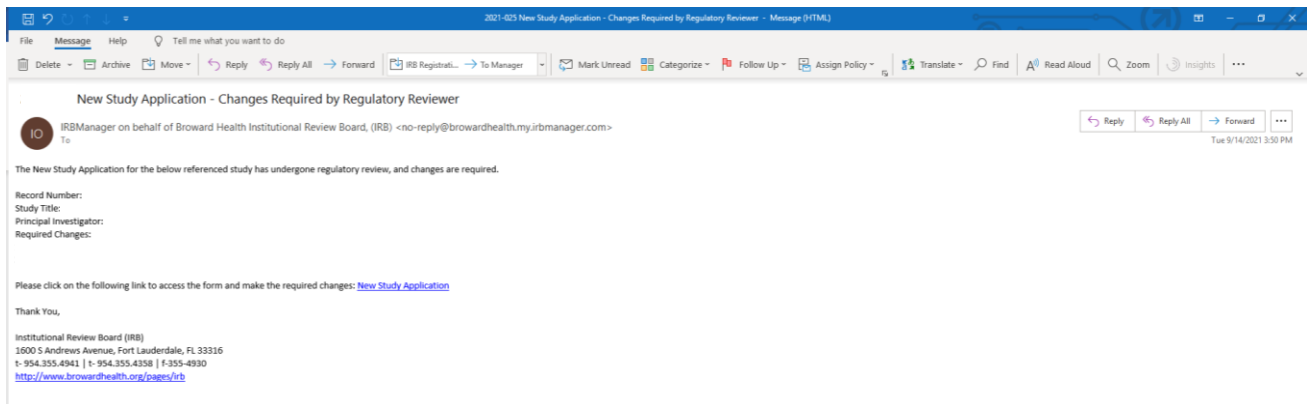
The submitter will also receive an email that an outside interest has been disclosed and the submission is pending review by Corporate Compliance.

The Conflict of Interest Reviewer reviews the submission and enters the determination on whether or not a conflict of interests exists. If it is determined that a conflict exists, a copy of the management plan will be sent via email to the Principal Investigator and the Individual with the identified conflict.

6.8. REGULATORY REVIEW

Party Responsible for Action: IRB Office

- The application is being reviewed to ensure that it meets the requirements of the regulations. The review level is determined at this stage. An email is sent to the IRB Regulatory Reviewer and the submitter notifying them that the study is ready for Regulatory Review.
- If there are changes required by the Regulatory Reviewer, the submitter will receive an email notifying them of the required changes.



- The application form will return to “Data Entry” and can be edited at this stage. Refer to: [Data Entry \(after changes required\):](#)

6.9. FACILITATED REVIEW (EXTERNAL IRB STUDIES ONLY)

Party Responsible for Action: IRB Office

- The application is being reviewed to ensure that it meets the requirements of the for reliance on an External IRB.

6.10. POST FACILITATED REVIEW (EXTERNAL IRB STUDIES ONLY)

Party Responsible for Action: IRB Office

- The application is awaiting issuance of a determination letter

6.11. POST EXPEDITED REVIEW

Party Responsible for Action: IRB Office

- The submission has been deemed eligible for expedited review and is being reviewed by an IRB Member – no action required by the study team at this time.

6.12. POST FULL BOARD REVIEW

Party Responsible for Action: IRB Office

- The submission requires review by the Full Board and is awaiting review at an IRB meeting. The submitter and PI will receive an email notifying them of the scheduled meeting date.

7. RETURNING TO AN APPLICATION IN PROGRESS

- Applications which have not been submitted, will automatically be saved, or they can be saved using the “Save for later” option.
- To return to an application in progress, from the dashboard, click on “**You have #unsubmitted xForms.**”

The screenshot shows a dashboard titled "My Studies". It is divided into two main sections: "Studies (20 Active)" and "xForms (51 Active)".

Studies (20 Active)

- You are associated with **20 active** Studies and **38 total** Studies.
- You are the PI for **20 active** and **36 total** Studies.
- You are the Sub-Investigator for **0 active** and **1 total** Studies.
- You are the Study Coordinator for **0 active** and **1 total** Studies.

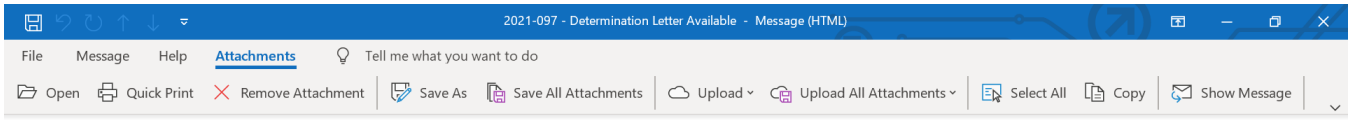
xForms (51 Active)

- You have **27 unsubmitted** xForms.
- You have **24 xForms** being processed at a later stage.
- There are **3 xForms** awaiting your attention.

8. POST IRB REVIEW

8.1. ACCESSING IRB DETERMINATION LETTERS, WATERMARKED DOCUMENTS AND INVOICES (AS APPLICABLE)

- After the IRB has made a determination on a submission, the determination letter, a copy of IRB policy GA-025-085 – Research Personnel Responsibilities (initial submission approvals only) and Invoice (if applicable) will be provided to the individual assigned as the Primary Key Research Personnel and Principal Investigator via an email from IRBManager. The email also contains instructions to access the watermarked documents (if applicable).



- Determination Letter Available

no-reply@browardhealth.my.irbmanager.com
To

GA-025-085 - Research Personnel Responsibilities - 4.6.21.pdf 142 KB
Exemption Determination Letter.pdf 186 KB

The Broward Health IRB has completed its review of the above referenced study, and the determination letter is attached. Also attached is policy GA-025-085 - Research Personnel Responsibilities.

Record Number:
Study Title:
Principal Investigator:

Please review the letter and use the documents that were reviewed and approved for your research as applicable.

If Applicable: To access the IRB approved and watermarked documents, click on the following link: [Exemption Application](#), click on the attachments link on the left side of the page and click on "Attachments."

If you have any questions, please contact the IRB at 954-355-4941 or 954-355-4358.

Broward Health Institutional Review Board (IRB)
1600 S Andrews Avenue, Fort Lauderdale, FL 33316
t- 954.355.4941 | t- 954.355.4358 | f-355-5135
<http://www.browardhealth.org/pages/irb>

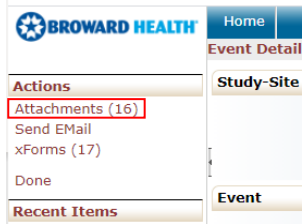
- These documents are also available in IRBManager.
- From the dashboard, click on the study for which the documents are to be accessed.

My Studies (20 Active)			
Study	Site	PI	Title
2015-43-BHMC	Broward Health Medical Center	Principal, Investigator	CV185316: An Open-label, 2x2 Factorial, Rar with Atrial Fibrillation and Acute

- Under “Events”, click on the event for which you wish to view the attachments

Events (7)		
Event	Att	F
Amendment (#119)	7	
Amendment (#117)	5	

- Click on “Attachments” on the left side of the screen.



- Click on “Attachments” – Center of the screen

- The watermarked documents will be labelled “Approved – Date of IRB approval” under attachments. **Note:** The IRB watermarks informed consent documents, data collection sheets and non-standardized questionnaires. These watermarked documents must be used when conducting the study.
- The determination letter and invoice (if applicable) can be viewed by clicking on “Generated Docs”

Name	Attached	Type
	11/24/2020 2:16 PM ET	FDA Documentation
	11/24/2020 2:16 PM ET	Investigator Brochure
	11/24/2020 2:16 PM ET	Investigational Drug Service Form
	11/24/2020 2:16 PM ET	Research Feasibility Form
	11/24/2020 2:16 PM ET	Protocol
	11/24/2020 2:16 PM ET	Survey /Questionnaires
	11/24/2020 2:16 PM ET	Survey /Questionnaires
	11/24/2020 2:16 PM ET	Subject Diary
	11/24/2020 2:16 PM ET	Survey /Questionnaires
Approved 01/04/21 Informed Consent Document #1 dated 09/29/20	11/24/2020 2:16 PM ET	Informed Consent Document
Approved 01/04/21 Optional Donation Informed Consent Document #1 dated 09/29/20	11/24/2020 2:16 PM ET	Informed Consent Document
HIPAA Authorization Form	11/24/2020 2:16 PM ET	HIPAA Authorization Form

Name	Attached	Type	Tags
Full Board - Conditional Approval	12/11/2020 4:54 PM ET	IRB Determination Letter	Full Board - Conditional Approval
Full Board - Approval	01/05/2021 7:58 AM ET	IRB Determination Letter	
Invoice - Initial Review.pdf	01/05/2021 8:12 AM ET	IRB Invoice	Initial Review - Invoiced

9. WITHDRAWING AN IRB APPLICATION

To withdraw a submitted IRB application, contact the IRB Office via email irb@browardhealth.org or phone 954-355-4941 or 954-355-4358.

10. HELP AND SUPPORT

If you have any questions or problems using IRBManager, please contact the IRB Office at 954-468-8908, 954-355-4941, 954-355-4358 or irb@browardhealth.org.