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).

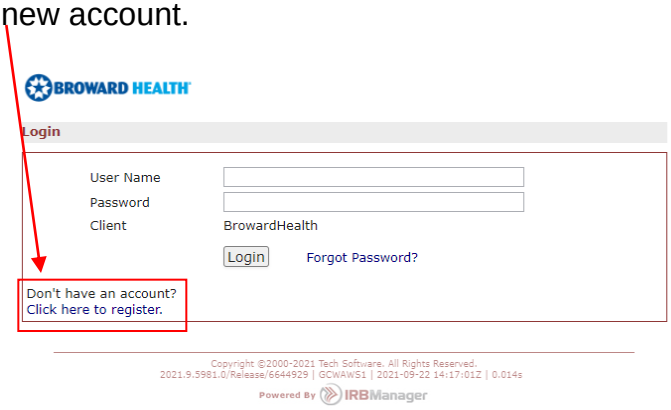
xForm – When you begin a new event in IRBManager, you will start with a xForm. xForms are the applications forms used to document the submissions being sent to the IRB for review.

2. CREATING A NEW ACCOUNT AND LOGGING INTO IRBMANAGER

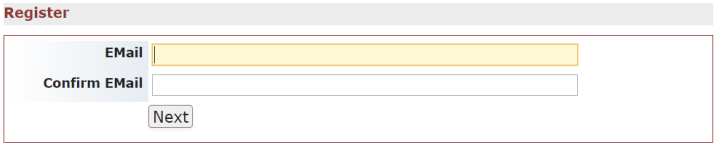
IRBManager can be accessed here: https://browardhealth.my.irbmanager.com/

2.1. CREATING A NEW IRBMANAGER ACCOUNT

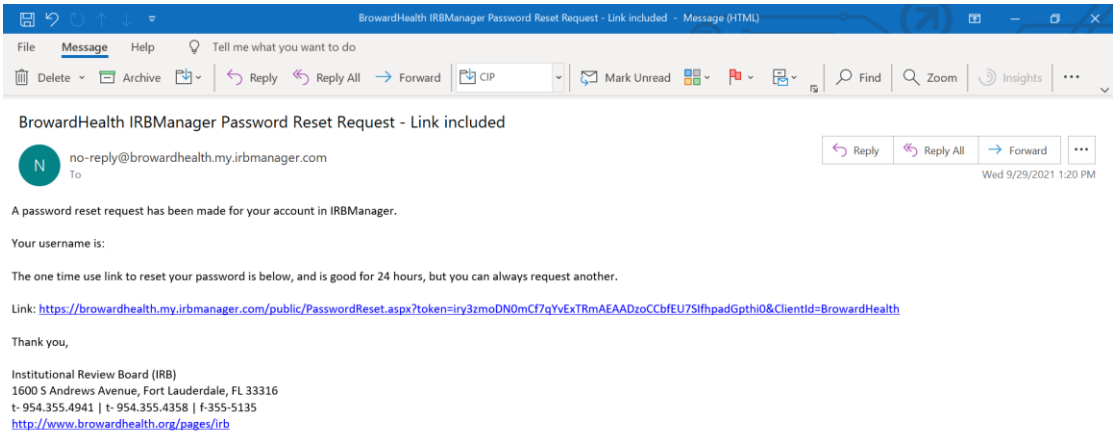
If you do not have an IRBManager account, you can request access by registering for a new account.



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.



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.

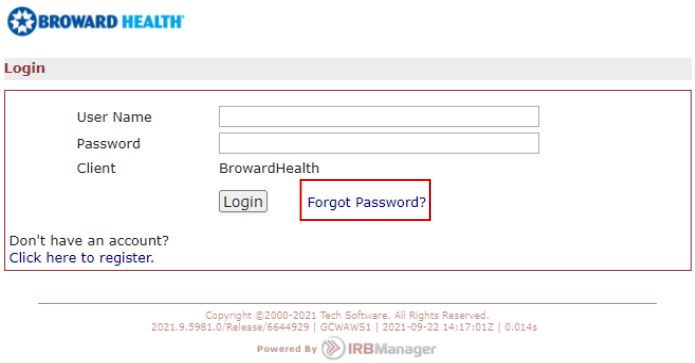
2.2. LOGGING INTO IRBMANAGER

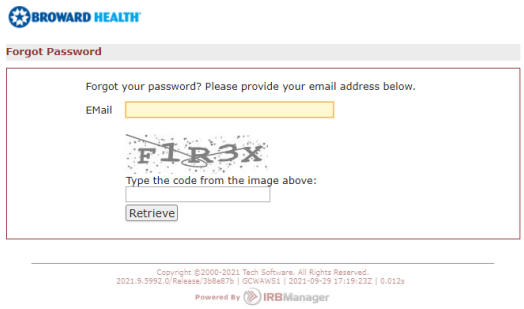
1. Go to: https://browardhealth.my.irbmanager.com/
2. Enter your username and password
    - Your username is the email address used to create the IRBManager account
    - Your password is specific to IRBManager and is the one used when creating the IRBManager account
3. Click Login

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

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.





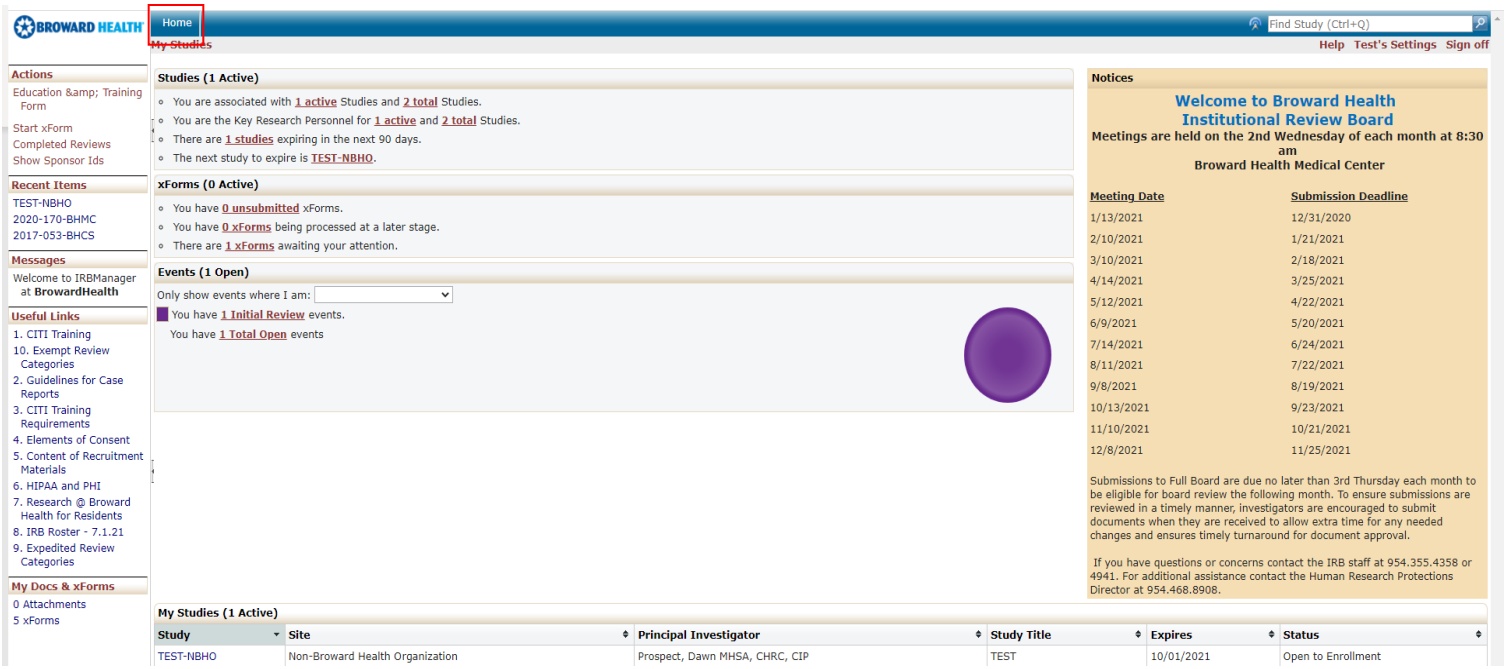
Anyone associated with a research study MUST meet specific educational and training requirements, based on their particular role in a study. Current Education and Training documentation must be maintained on file with the IRB. This must be submitted via the Education and Training Form, see below.

3. NAVIGATING THE IRBMANAGER DASHBOARD (HOME PAGE)

The IRBManager dashboard, displays information relevant to all studies associaeted with a user. The main dashboard area displays studies, xForms and events that are associated with a user. Clicking on the links uder 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.



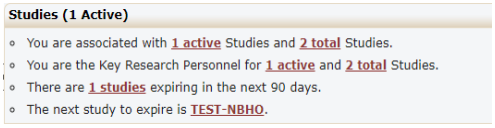
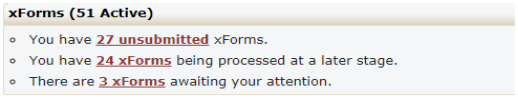
3.1. Left Side

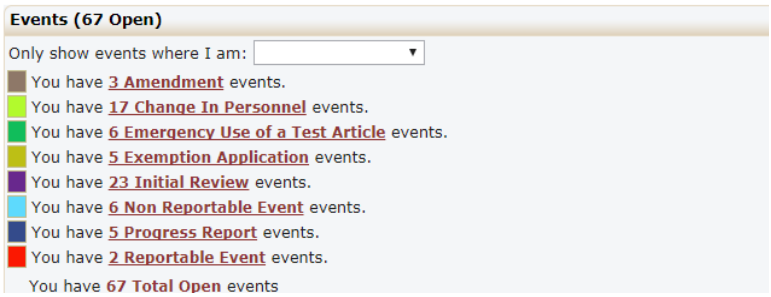
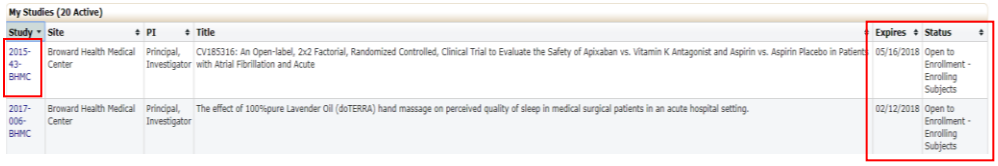
The left side of the screen includes a menu of the following:

	Actions 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. Recent Items Displays up to 7 items that were recently viewed. Messages Displays important messages from the IRB Office. Useful Links Provides access to Guidance Documents, Form Templates and the current IRB roster. My Docs and xForms **Attachments** – Clicking on “Attachments” displays attachments associated with a particular user e.g. CITI certificates and CV. **xForms** – Displays xForms (application forms) associated with a particular user across the entire system.

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.

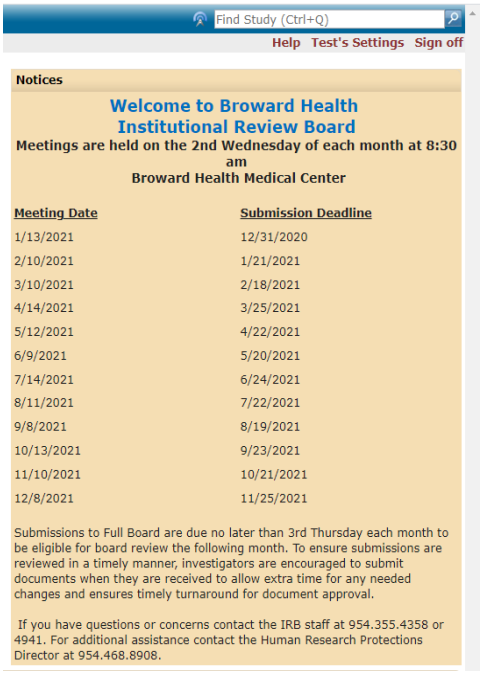
Studies	Displays a summary of the active and total studies on which the user is listed, the role of the user on each study, and studies expiring in the next 90 days. 
xForms	Displays the xForms currently active for the user and a summary of each form. 
Events	This section shows submissions open by name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

	will take you directly to that form. 
My Studies	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. 

3.3. Right Side

The right side menu includes the following:

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



4. GETTING STARTED

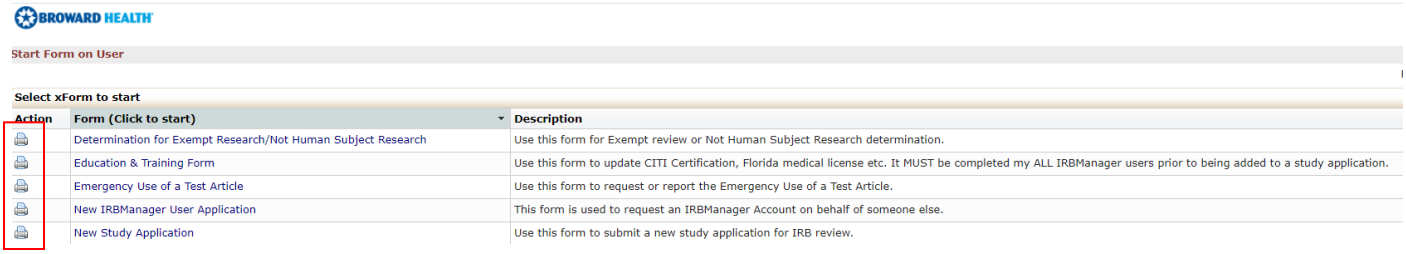
4.1. SMART FORMS:

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”

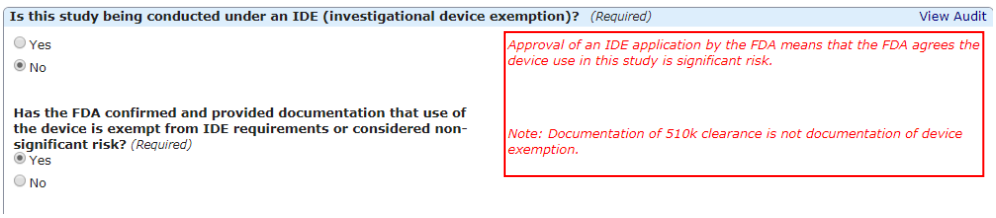
- Click on the **printer** icon located next to the applicable form.



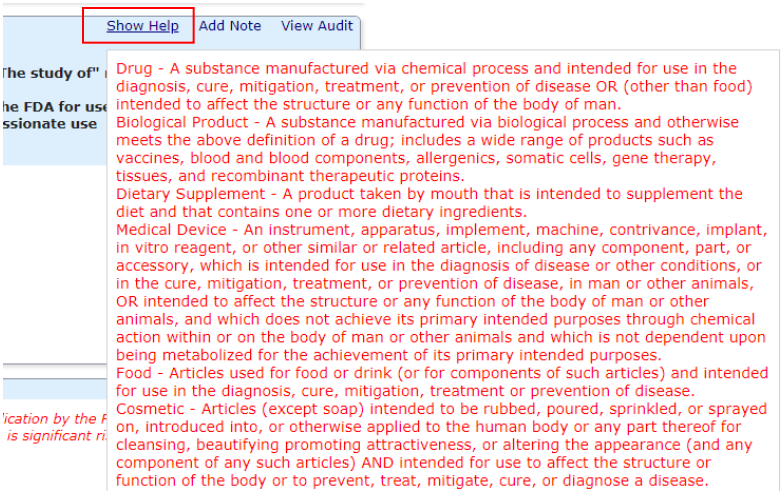
- A sample of the form will be displayed, showing all of the possible questions.

4.2. FORM GUIDANCE AND NAVIGATION

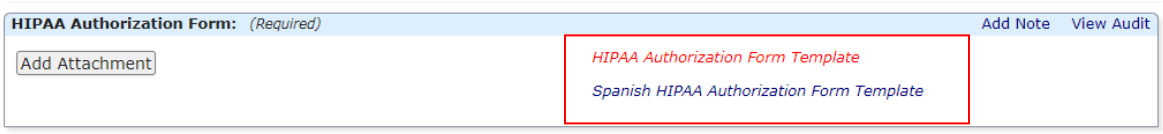
- Guidance for most questions can be found to the right of a question.



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

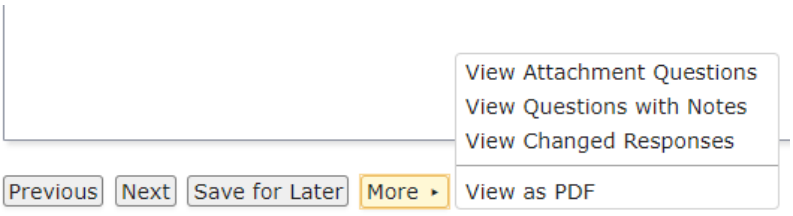


- Some questions provide specific form templates to complete and attach.



- 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)].

- 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.



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.

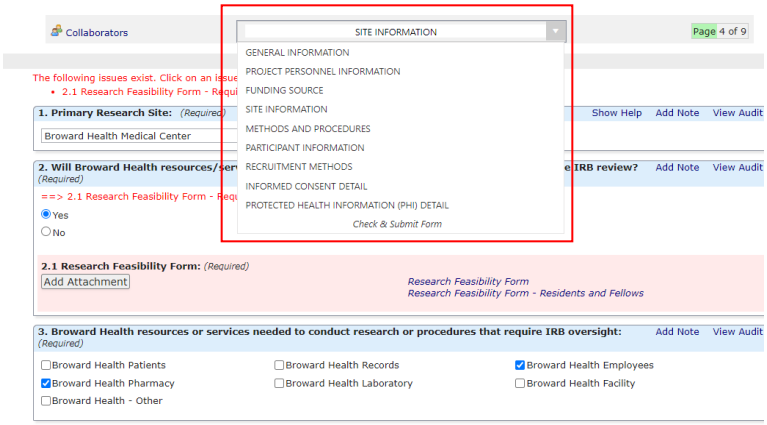
- While completing the IRB application, IRBManager will automatically alert to any "issues" detected during form progression. The "issues" will be listed at the top of the screen for review and correction.
- Example:

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.

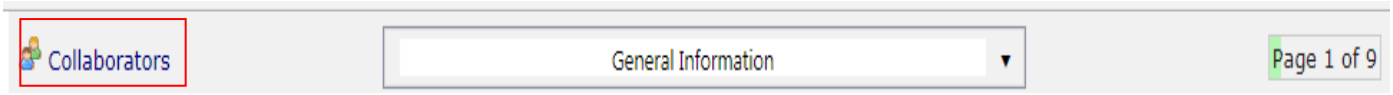
- Other areas of the application can be accessed by jumping to the section using the drop down menu at the top of the page.



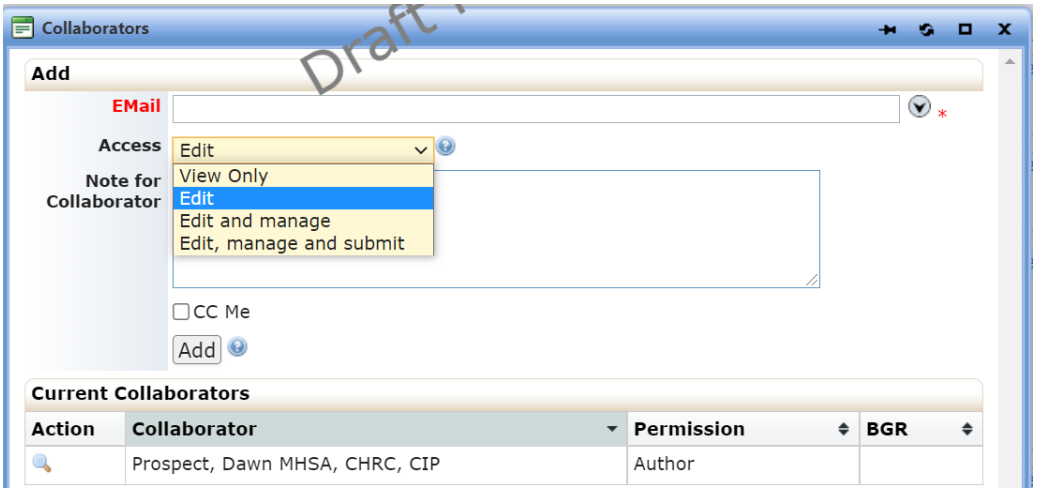
4.3. PROVIDING OTHERS ACCESS TO AN APPLICATION

When an application is created, only the creater (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.

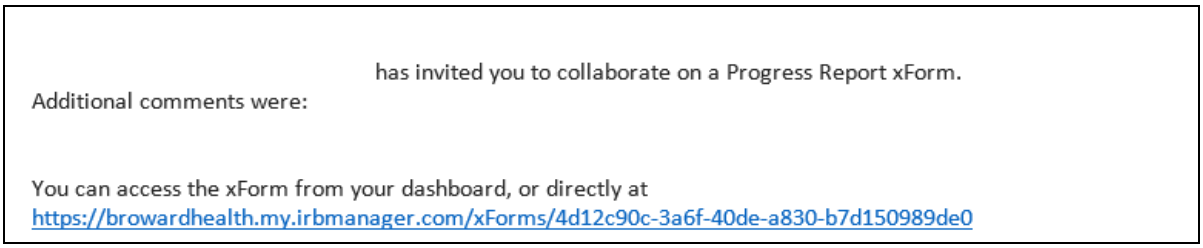


- Select the access for the collaborator.

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

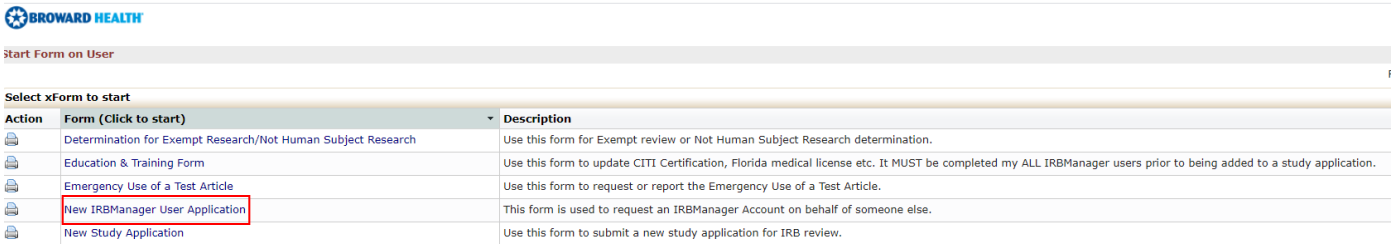
- All application forms (xForms) are created by clicking on “Start xForm” at various locations within IRBManager.

- 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

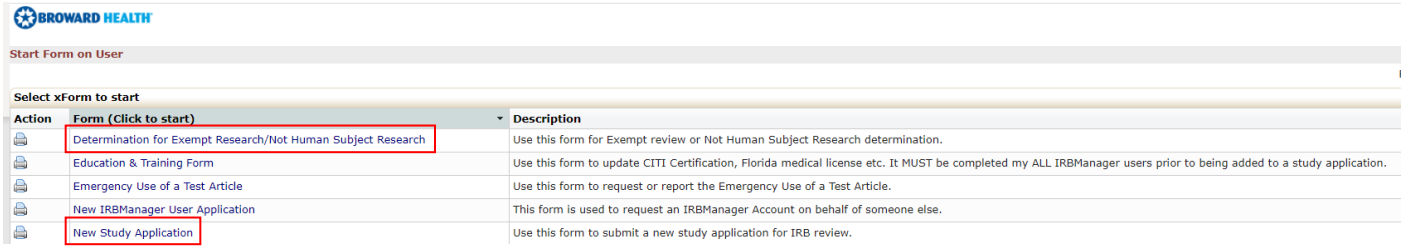
Each IRBManager user is required to have an Education and Training Form on file prior to participating on a research study. An Education and Training Form is also required to submit any updated Training Information e.g. expired CITI training and Professional Licenses.

- 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 with 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.



- 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.

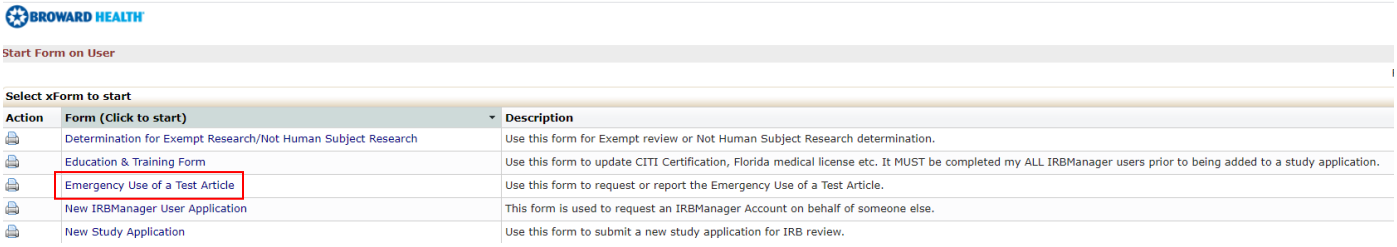
    - Documents Required (as applicable to a study):
        - Informed Consent documents
        - Research Feasibility Form – Template available in IRBManager
        - External Site permission documentation
        - Recruitment Materials
        - Protocol
        - IND Documentation

- 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)



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

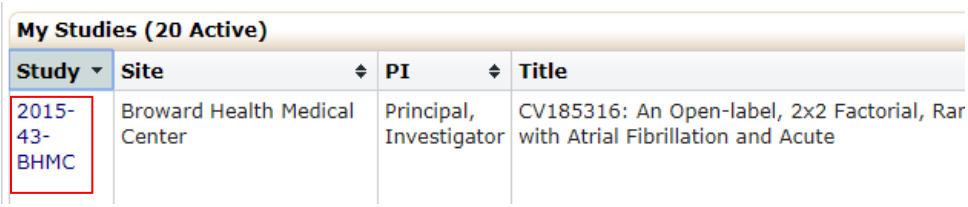
A Progress Report application is required to update the IRB on the progress of a study, extend IRB approval **OR** to close out a study.

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):

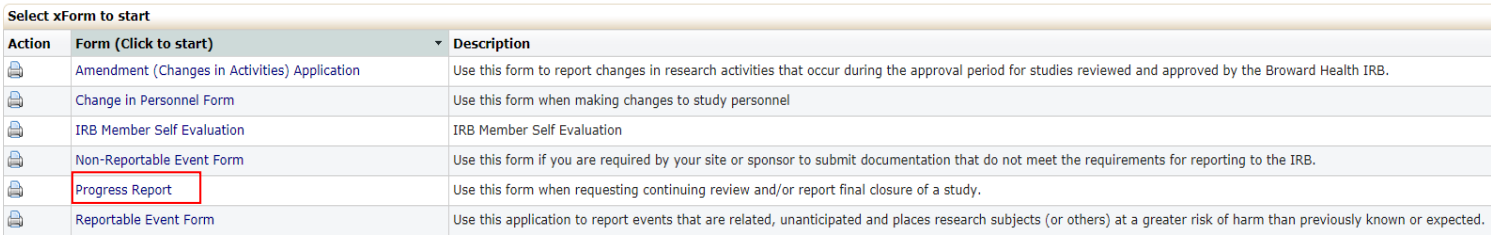
- Informed Consent documents (clean or previously stamped)
- DSMB/DSMC Report
- Medical Device Report
- Non-Reportable Event Summary Sheet – Template available in IRBManager
- External IRB approval letter (External IRB studies)
- Copies of revised protocols (External IRB studies)
- Sponsor Closeout documentation (Industry funded studies)

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



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

- Click “Progress Report”



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

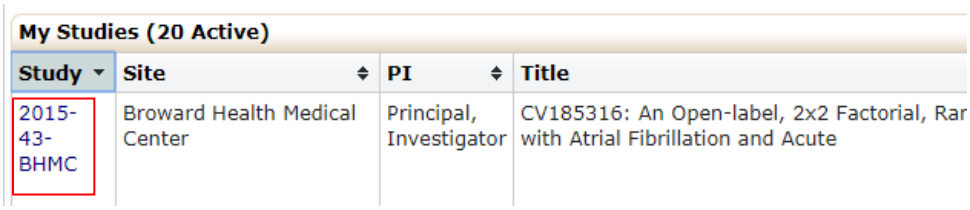
5.7. AMENDMENT (CHANGES IN ACTIVITIES) APPLICATION

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.

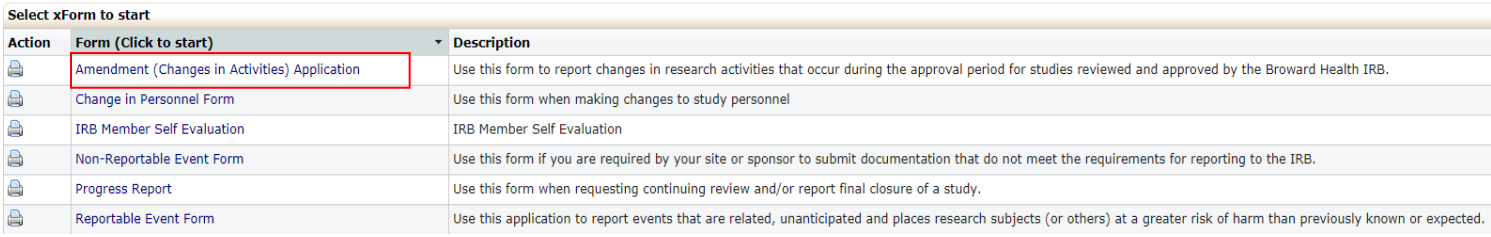
Note: If there have been changes to previously IRB approved documents, you must submit a track changed copy of these documents in addition to a clean copy e.g. informed consent documents. Any changes to these documents must be made to the versions that were previously approved by the IRB.

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



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

- Click “Amendment (Change in Activities) Application”



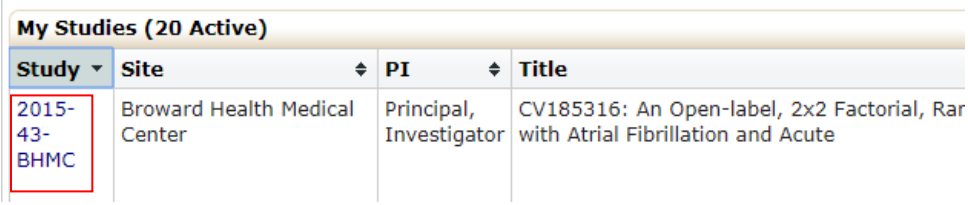
- Complete each section of the Amendment application and click “Submit”. See “Form Stages” to view the stages of the form.

5.8. CHANGE IN PERSONNEL APPLICATION

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

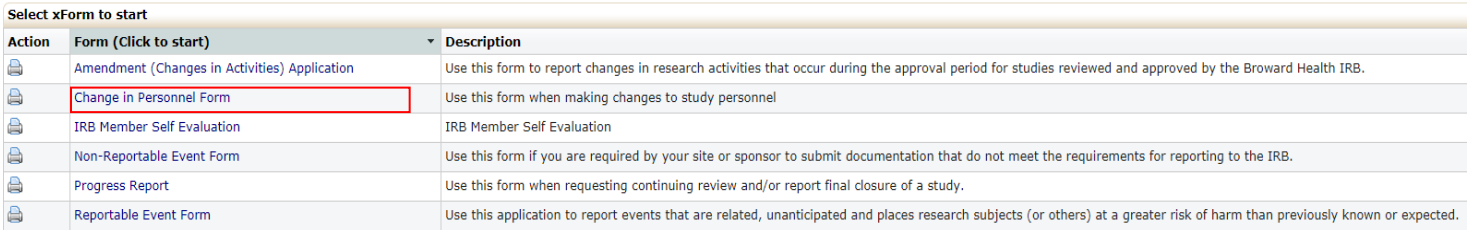
Note: If any of the changes in personnel affect the study documents, these must be revised and submitted (a track changed and clean copy).

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



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

- Click “Change in Personnel Form”

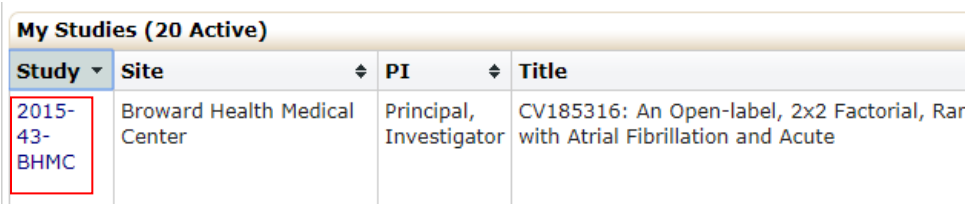


- Complete each section of the Change in Personnel application and click “Submit”. See “Form Stages” to view the stages of the form.

5.9. REPORTABLE EVENT FORM

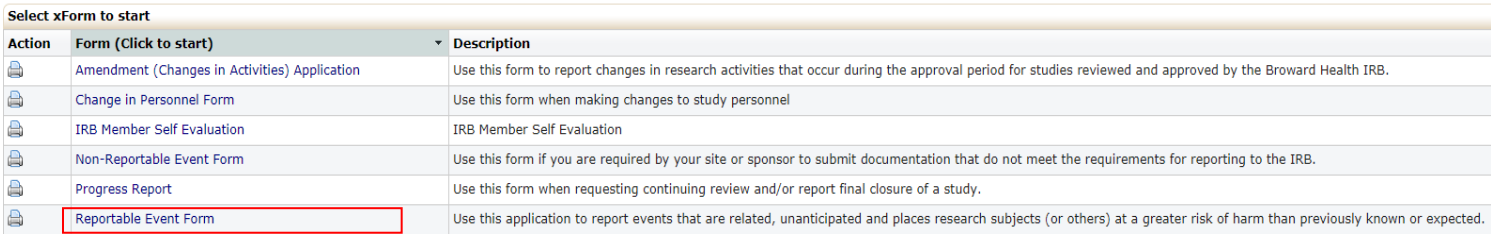
- A Reportable Event form is required to report events that are related, unanticipated and places research subjects (or others) at a greater risk of harm than previously known or expected.

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



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

- Click “Reportable Event Form”


Select xForm to start

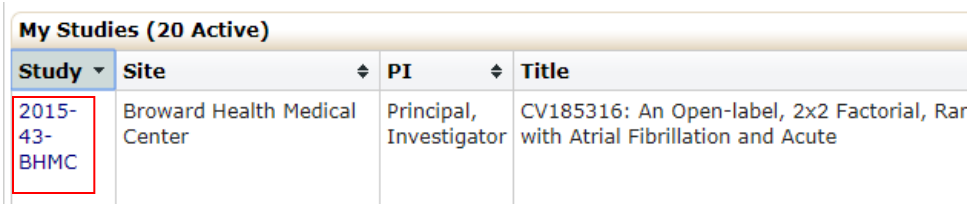
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes 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.

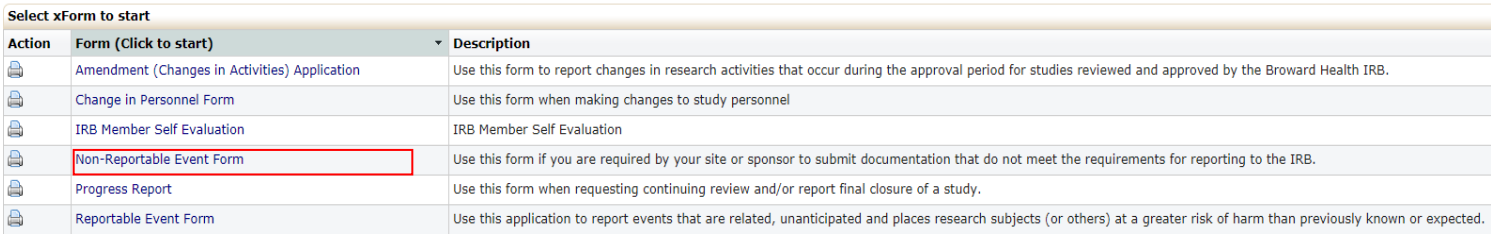
- From the Dashboard, under the section titled “My Studies”, click on the study for which the Non-Reportable Event is required.


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

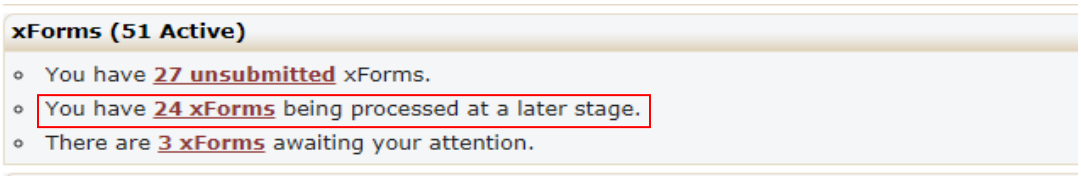
Action	Form (Click to start)	Description
	Amendment (Changes in Activities) Application	Use this form to report changes in research activities that occur during the approval period for studies reviewed and approved by the Broward Health IRB.
	Change in Personnel Form	Use this form when making changes 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.

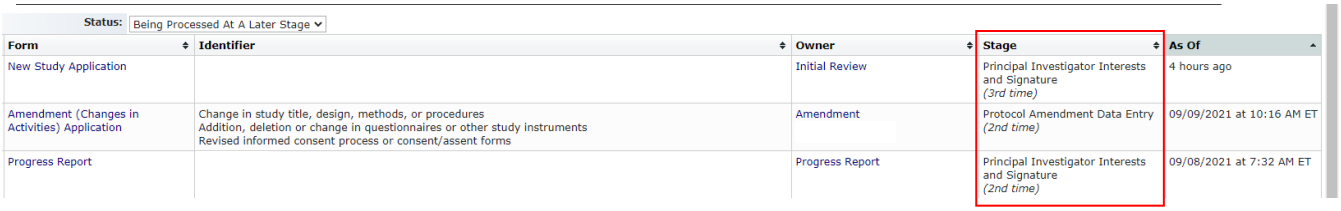
- Complete each section of the Non-Reportable Event Form and click “Submit”. See “Form Stages” to view the stages of the form.

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.



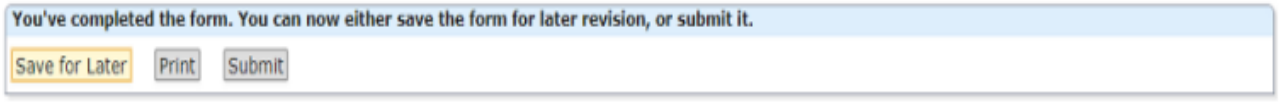


6.2. DATA ENTRY:

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.

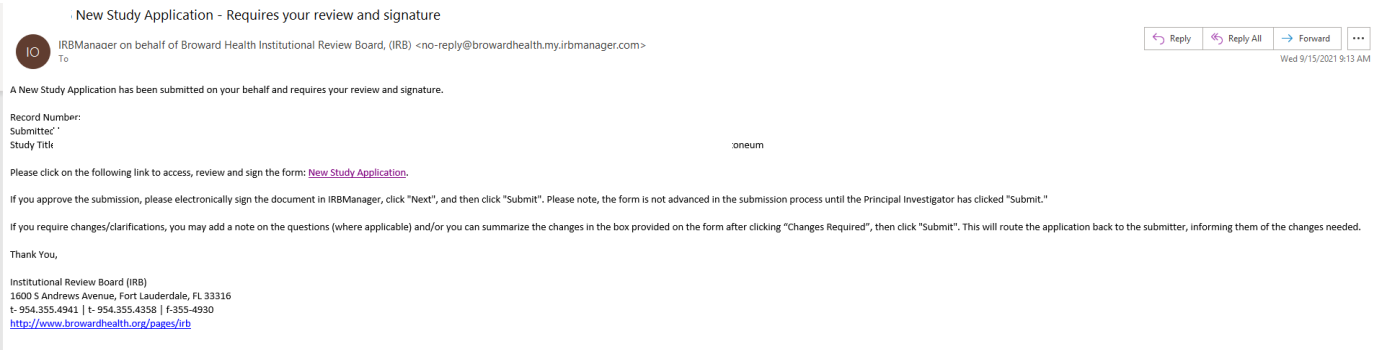


Note: The “submit” button must be clicked to advance the application form to the next stage in the review chain. If any action other than submit is chosen, the form will remain in your list of unsubmitted xForms and will not route through the submission process.

6.3. PRINCIPAL INVESTIGTOR 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.



New Study Application - Requires your review and signature

IO IRBManager on behalf of Broward Health Institutional Review Board, (IRB) <no-reply@browardhealth.my.irbmanager.com>
To

Reply | Reply All | Forward | ...
Wed 9/15/2021 9:13 AM

A New Study Application has been submitted on your behalf and requires your review and signature.

Record Number:
Submitted
Study Title oneum

Please click on the following link to access, review and sign the form: New Study Application.

If you approve the submission, please electronically sign the document in IRBManager, click "Next", and then click "Submit". Please note, the form is not advanced in the submission process until the Principal Investigator has clicked "Submit."

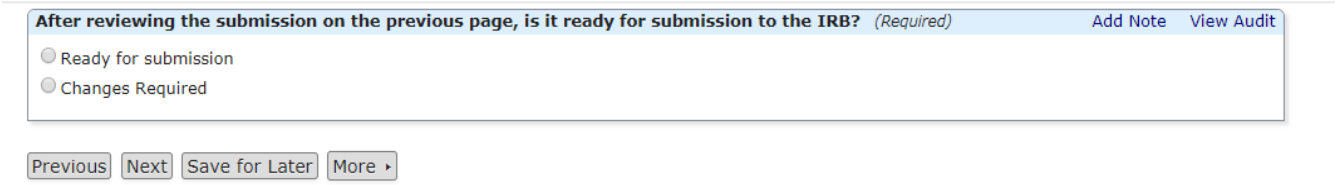
If you require changes/clarifications, you may add a note on the questions (where applicable) and/or you can summarize the changes in the box provided on the form after clicking "Changes Required", then click "Submit". This will route the application back to the submitter, informing them of the changes needed.

Thank You,

Institutional Review Board (IRB)
1600 S Andrews Avenue, Fort Lauderdale, FL 33316
t- 954.355.4941 | t- 954.355.4358 | f-355-4930
http://www.browardhealth.org/pages/irb

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.

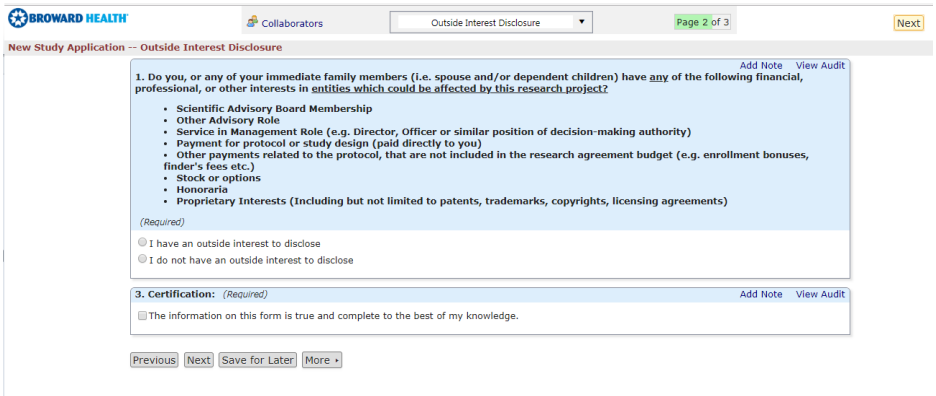


After reviewing the submission on the previous page, is it ready for submission to the IRB? *(Required)* Add Note View Audit

- 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.



BROWARD HEALTH | Collaborators | Outside Interest Disclosure | Page 2 of 3 | Next

New Study Application -- Outside Interest Disclosure

Add Note View Audit

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?

- **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**
- **Proprietary Interests (Including but not limited to patents, trademarks, copyrights, licensing agreements)**

(Required)

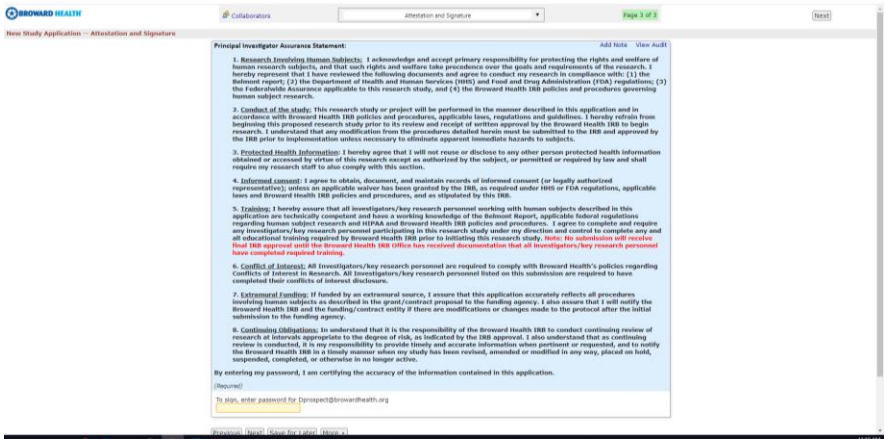
- I have an outside interest to disclose
- I do not have an outside interest to disclose

3. Certification: *(Required)* Add Note View Audit

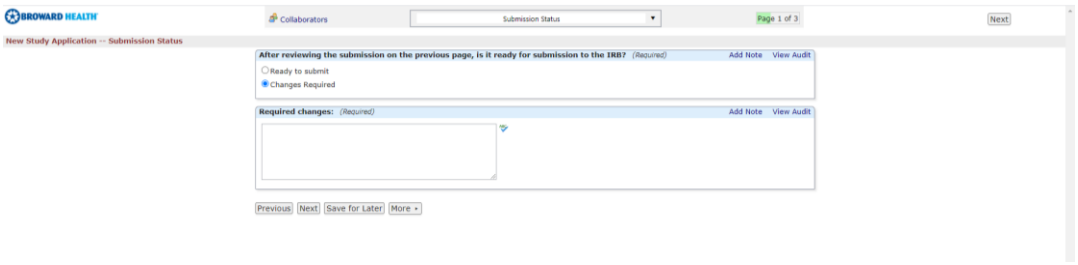
- The information on this form is true and complete to the best of my knowledge.

Previous | Next | Save for Later | More ▸

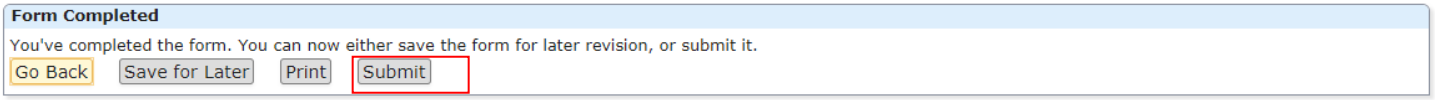
  - Read the Principal Investigator Assurance Statement and electronically sign the document by entering your password.



- 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.



- 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.



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.


New Study Application - Changes Required by Pre-Reviewer

IRBManager on behalf of Broward Health Institutional Review Board, (IRB) <no-reply@browardhealth.my.irbmanager.com>

The New Study Application for the below referenced study has undergone pre-review and changes are required:

Record Number:
Study Title:
Principal Investigator
Required Changes: 1.

Please click on the following link to access the form and make the required changes: New Study Application

Thank You,

Institutional Review Board (IRB)
1600 S Andrews Avenue, Fort Lauderdale, FL 33316
t- 954.355.4941 | t- 954.355.4358 | f-355-4930
http://www.browardhealth.org/pages/irb

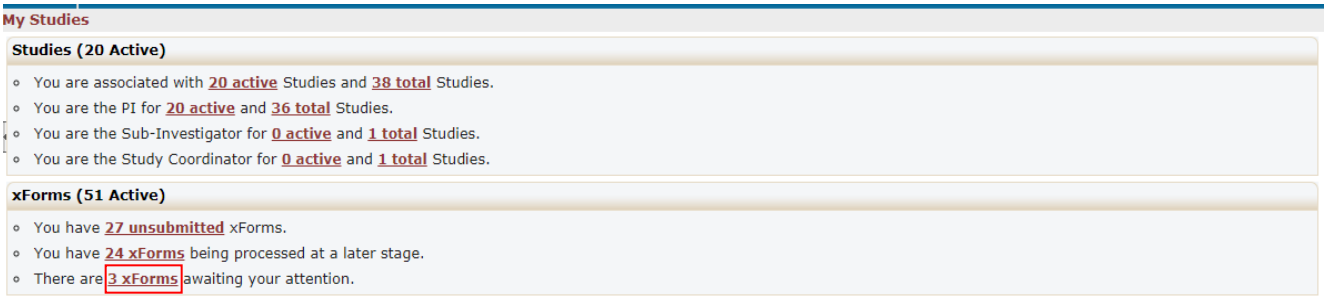
The application form will return to “Data Entry” and can be edited at this stage.

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.**


My Studies

Studies (20 Active)

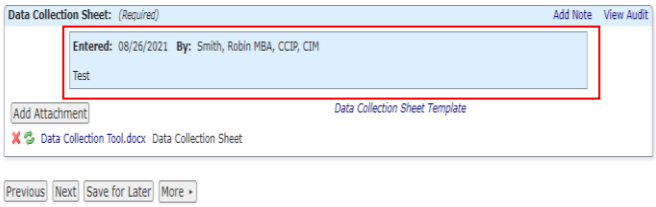
- You are associated with 20 active Studies and 38 total Studies.
- You are the PI for 20 active and 36 total Studies.
- You are the Sub-Investigator for 0 active and 1 total Studies.
- You are the Study Coordinator for 0 active and 1 total Studies.

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.

- 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.


Data Collection Sheet: (Required) Add Note View Audit

Entered: 08/26/2021 By: Smith, Robin MBA, CCIP, CIM

Test

Add Attachment Data Collection Sheet Template

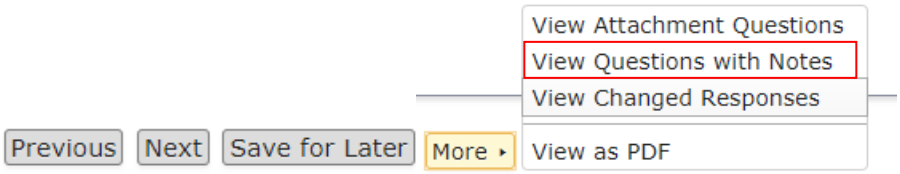
Data Collection Tool.docx Data Collection Sheet

Previous Next Save for Later More ›

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 click 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.

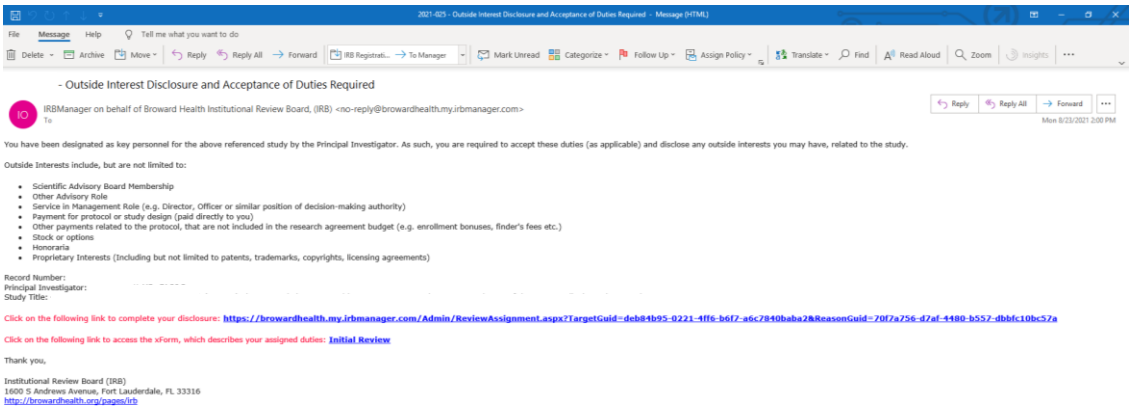
6.6. OUTSIDE INTEREST DISCLOSURE AND ACCEPTANCE OF DUTIES

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

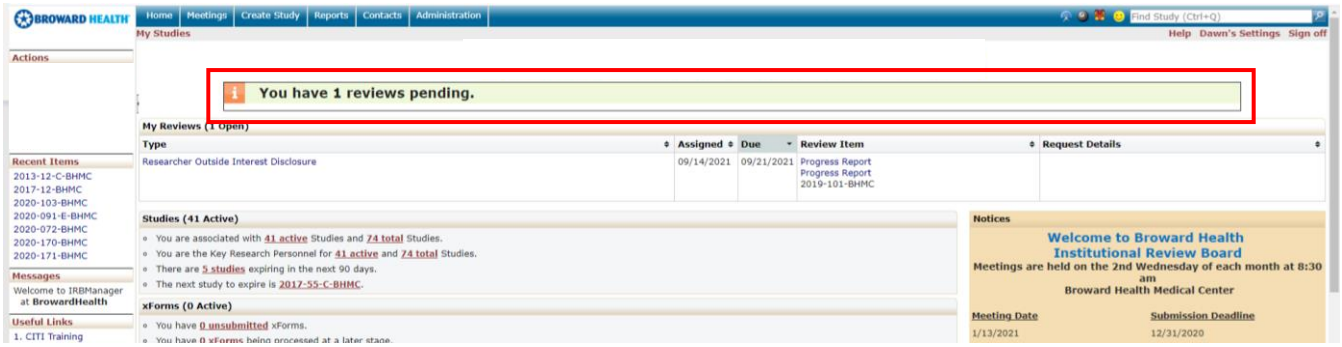
Important Notes:

- 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.

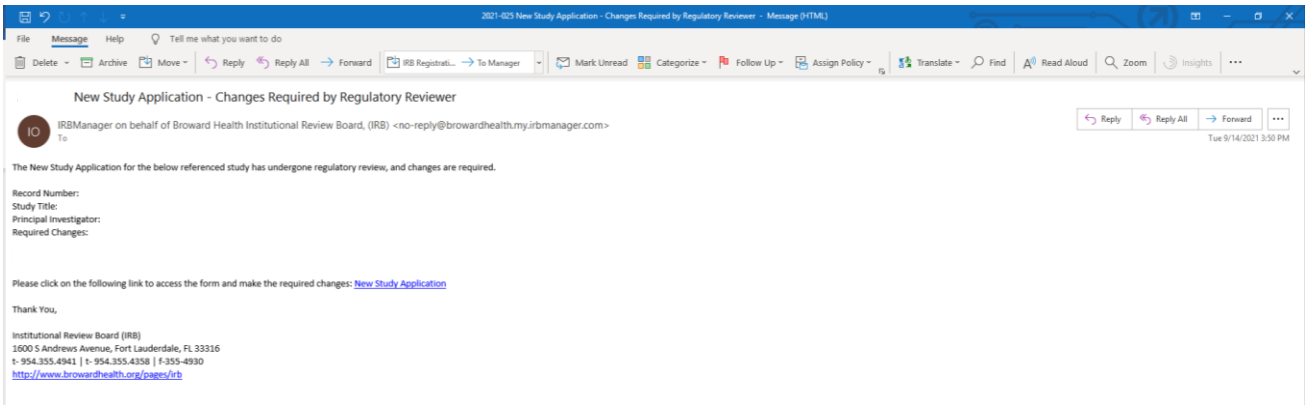
The Conflict of Interest Reviewer reviews the submission and enters the determination on whether or not a conflict of interests exists. If it is determined that a conflict exists, a copy of the management plan will be sent via email to the Principal Investigator and the Individual with the identified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

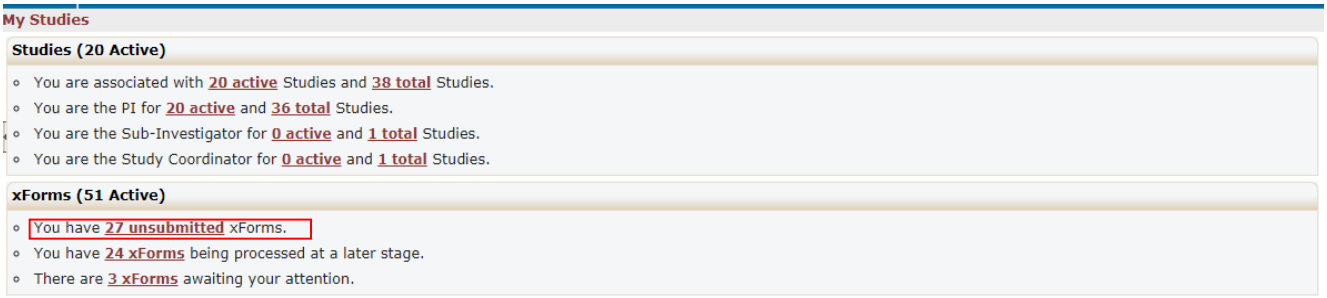
6.12. POST FULL BOARD REVIEW

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

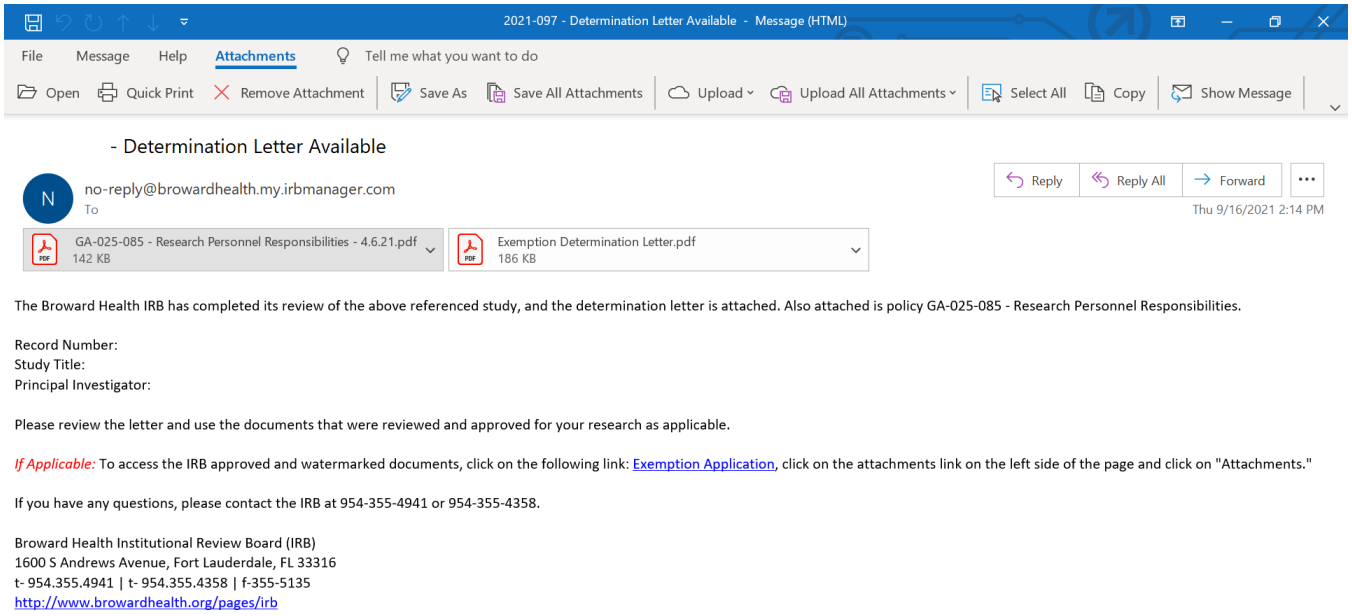
- Applications which have not been submitted, will automatically be saved, or they can be saved using the "Save for later" option.
- To return to an application in progress, from the dashboard, click on "**You have #unsubmitted xForms."**



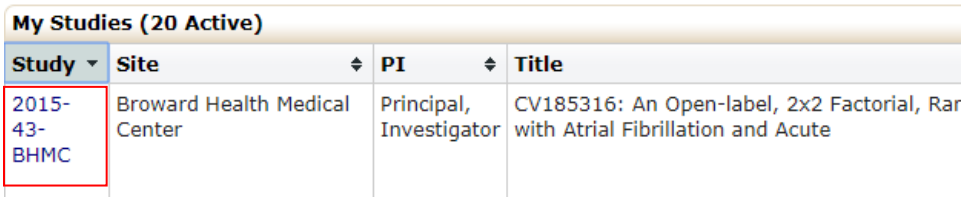
8. POST IRB REVIEW

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

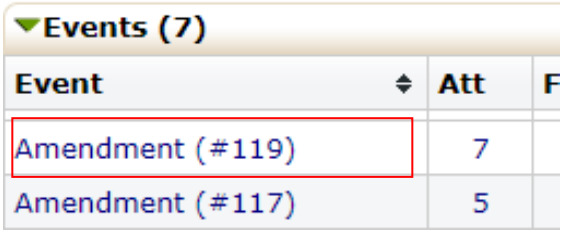
- After the IRB has made a determination on a submission, the determination letter, a copy of IRB policy GA-025-085 – Research Personnel Responsibilities (initial submission approvals only) and Invoice (if applicable) will be provided to the individual assigned as the Primary Key Research Personnel and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



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



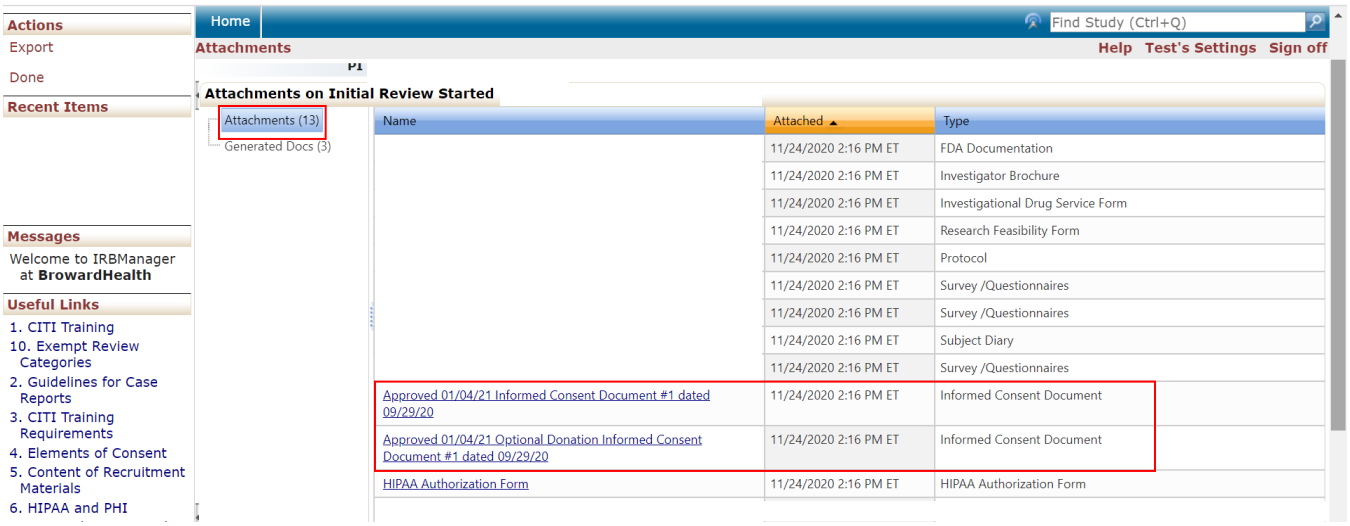
- Under “Events”, click on the event for which you wish to view the attachments

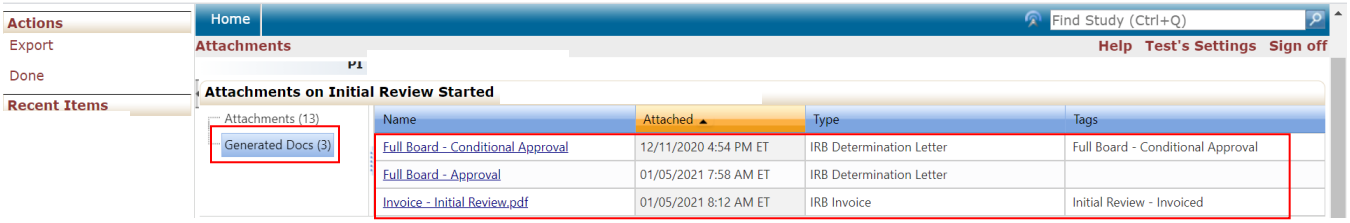


- Click on “Attachments” on the left side of the screen.

- 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”





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.