IRBManager User Guide
# Table of Contents

1.0 IRBManager ......................................................... 4
   1.1 What is IRBManager? ........................................... 4
   1.2 How do I access IRBManager? .............................. 4
      1.2.1 First Time Users ......................................... 5
      1.2.2 Users currently listed on ongoing studies ............. 6
2.0 Navigating the Home Page - Dashboard ............................ 8
   2.1 Actions .......................................................... 9
   2.2 Recent Items ................................................... 9
   2.3 My Documents and Forms .................................... 9
   2.4 Studies .......................................................... 9
   2.5 xForms .......................................................... 10
   2.6 Events ........................................................... 11
   2.7 My Studies ....................................................... 11
   2.8 Top Headings ..................................................... 12
      2.8.1 Change Password .......................................... 13
      2.8.2 Change Your Profile ...................................... 13
      2.8.3 My Phone Numbers ........................................ 13
      2.8.4 My Address ................................................ 14
      2.8.5 Log-In Information ....................................... 14
      2.8.6 Email Signatures ........................................... 14
3.0 Navigating the Study Protocol Page .................................. 15
   3.1 Study ............................................................. 15
   3.2 Study-Site ....................................................... 16
   3.3 Contacts ........................................................ 16
   3.4 Events ........................................................... 16
4.0 Event Details ........................................................... 17
   4.1 Study Site ......................................................... 17
   4.2 Event ............................................................. 17
   4.3 Steps ............................................................. 18
   4.4 Actions in the Event Details ................................... 18
1.0 IRBManager

1.1 What is IRBManager?

IRBManager is an electronic management system that serves as the “front door” for the submission, tracking and retention of research protocols. Users can fill out and submit forms directly in IRBManager and all forms, attachments, and documents submitted with a participating study will be accessible via IRBManager.

IRBManager is a fully web-based system that is accessible inside and outside of the Broward Health network.

1.2 How do I access IRBManager?

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

OR

www.browardhealth.org/pages/irb
1.2.1 First Time Users

If this is your first time doing research at Broward Health OR you are not listed on an ongoing study, you will need to register for an IRBManager account.

Note: You MUST use your Broward Health email address when registering for an IRBManager account. If you do not have a Broward Health email address, you MUST use your professional email address.
1.2.2 Users currently listed on ongoing studies/forgotten passwords

If you are currently listed on an ongoing study AND this is your first time logging into IRBManager OR if you have forgotten your password, click here.

Note: If you DO NOT have a Broward Health email address and are unsure which email address is associated with your IRBManager account, please contact the IRB Office. DO NOT create a new account.
After logging in for the first time, you **MUST** complete the Education and Training Form. The Education and Training form enables you to upload your CITI certificate, Medical License, etc. Submissions will not be reviewed unless the Education and Training forms have been completed by everyone on the study team.
2.0 Navigating the Home Page – DashBoard

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

- Access forms by clicking “Start xForm” to see a full list and description of all available forms. Please note that certain forms (e.g. Progress Report) can only be completed for an active protocol in IRBManager. These forms are not available from the Dashboard.
- “Show Sponsor’s study ID” – allows you to see protocols listed by Sponsor study ID rather than IRB numbers. Just click on the “Show local study ID” link to toggle your view from IRB numbers to Sponsor study IDs (and vice-versa). Note: If the study has multiple sponsors, the Sponsor study ID numbers view will only show one line for each sponsor, so a study may have multiple listings in this view.

2.2 Recent Items

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

2.3 My Documents and Forms

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

2.4 Studies:

This shows the studies you are associated with (as principal investigator, sub-investigator, study coordinator, or key research personnel) and shows studies you are the Principal Investigator on.

![Studies (20 Active)](image)

**Note:** By clicking on the underlined link, you will be taken to a separate screen showing the studies with which you are associated.
2.5 xForms
The xForms tab shows the forms currently active at this time for the user. An xForm is also referred to as a submission.

In this view of the Dashboard:

- "You have 27 unsubmitted xForms" = the user has 27 xForms (submissions) stated, but has not yet submitted them for further processing. (The user may have clicked “save for later” or just closed a form before pressing the “submit” button at the end of the form.)

  **Note:** By clicking on the underlined link, “27 unsubmitted,” the user can go straight to the unsubmitted xForms.

- "You have 3 xForms being processed at a later stage” = the user currently has 3 forms being processed. In this case, the user has successfully submitted the forms, and forms are currently under review at a later stage in the processing cycle (IRB Office processing).

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

- “There are 3 xForms currently awaiting your attention” = the user has 3 forms that require their attention and will not be processed to the next stage until the user addresses and submits the form. This will appear if someone else sends a form to the user. (For example, the Principal Investigator will see this when the study coordinator sends the form to them for review and approval. A study coordinator would see this if the IRB Office returned a form for clarifications, etc.).

  **Note:** By clicking the underlined link, “3xForms,” the user can go straight to that xForm that needs attention.
2.6 Events

- The events section of the Dashboard shows the submissions open by submission type.
- This section shows all open events and the submission name, such as a Progress report, initial review, reportable event and amendment.

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

2.7 My Studies

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

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

- Studies can be sorted by record number
- Site can be sorted alphabetically
- PI is sorted alphabetically
- Study title can be sorted alphabetically
- Expiration dates are sorted by numerical date
- Status is grouped and sorted alphabetically
2.8 Top Headings

**Find Study toolbar** – Search bar to find existing studies. Studies can be searched by record number, site, PI name, Title, expiration date, or status.

**Take a tour** provides an overview of the sections on the Dashboard.

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

**Investigator’s Settings** – allows the user to edit their profile settings. “Investigator” will be replaced with your first name.

**Sign off** – click to log off IRBManager.
Under My Settings you can:

2.8.1 Change your password

1. Enter old password.
2. Enter new password. Your new password must be at least 6 characters long and contain characters from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. I, @, #, ~).
3. Click “Update.”

2.8.2 Change your profile

1. Click on “Change my Profile” link.

2. Update your name, degree, specialty or email address.
3. Click “Update.”

2.8.3 My Phone Numbers

1. Click on “My Phone Number” link.
2. Click the “hand holding a piece of paper” icon.

3. Update your phone number.
4. Click “Update Phone.”

2.8.4 My Address
1. Click on “My Address(es) link.
2. Click on the “hand holding a piece of paper” icon

3. Update your address
4. Click “Update Address”

2.8.5 Log-In Information
1. Lists the time and date of the last 25 times the user logged into IRBManager.

2.8.6 Email Signatures
1. Click on “Email Signature” link.
2. Enter your signature (see below)
3. Click “Save.”
3.0 Navigating the Study Protocol Page

From the home page, you can access the study details for each of your studies. Click on the blue study code (record number) link to access the specific study.

3.1 Study

This section notes all of the basic information about the protocol, such as:

- Record Number
- Sponsor
- Committee (if there is more than one IRB then this notes the IRB the study was reviewed at)
• Sponsor ID or Acronym of the study
• Agent type (methodologies used the study)
• Study Title
• Year of first review
• IRB of Record
• Risk Assessment
• Comments (a summary of the study)

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

### 3.2 Study-Site

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

- Status (open to enrollment, closed to enrollment, closed etc.)
- Initial approval date
- Principal Investigator name
- Expiration date for continuing review
- Comments

### 3.3 Contacts

This section lists the contacts associated with the study.

### 3.4 Events

This table lists the events associated with the study.
This section lists all the IRB “events” or submissions that have been or are being conducted for this protocol. The event line contains the following sections:

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

**Note:** You can click on any blue event link in this section to view information specific to the event. After clicking on the blue link, it will take you to the event details (see below).

### 4.0 Event Details

Event Details are specific to the event or submission

#### 4.1 Study Site

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

#### 4.2 Event

The event section shows specific details about the submission you are viewing.
These include:

- Type (Initial Review, Progress Report, Amendment, etc.)
- Instance (documents or information related to the event)
- Committee (Broward Health IRB)
- Action/Acknowledgement date (the date the event was completed)

### 4.3   Steps

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Planned</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receive study progress report</td>
<td>10/24/2017</td>
<td>10/24/2017</td>
</tr>
<tr>
<td>Office Staff Pre-Review</td>
<td></td>
<td>10/24/2017</td>
</tr>
<tr>
<td>Send for full board review</td>
<td>10/31/2017</td>
<td></td>
</tr>
</tbody>
</table>

### 4.4   Actions in the Event Details

Actions in the event details screen are as follows:

- Attachments – shows the attachments related to the event detail
  - Generated Docs – shows documents generated by the IRB Office for the study (e.g. approval documents associated with the study)
- Send Email – allows user to email the IRB Office directly from IRBManager
- xForms – shows the form used to submit the event

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

“Generated Docs” Button: Shows all of the documents that have been generated by the IRB Office for this submission.

4.4.2 xForms
Shows the application associated with the event. This application is the application completed by the study team.

5.0 xForms (Application Forms)

5.1 How to Open an xForm

1. Opening a New xForm for a New Study (New Study Application)

On the Dashboard, click “Start xForm” under the “Actions” menu on the left side of the screen.
This will open a new screen with a list of all application forms available and a description of each form. Click on the name of the form you wish to complete. Note that only certain forms are available from the dashboard (including new study application, conflict of interest form etc.) Forms that can only be completed once a study is already approved (such as a progress report) are not available from the dashboard; these must be opened within a study (see below).

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

2. Opening a new xForm for an Existing study (Progress Report, Amendment, Reportable Event, etc.)

In order to complete an event (submission) for an active study, such as a Progress Report, Amendment or Change in Personnel, you must first go to the study. Active studies can be found in the “My Studies” section on the bottom of the Dashboard (see section 4.2.D above).

Once you are in the study, you click on the Start xform button under the “Actions” menu on the left. This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete.
3. **Opening an Existing Unsubmitted Form**

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

- The “xForms” link under the “My Documents and xForms” menu on the left side of the dashboard (see section 3.0)
- The you “You have _unsubmitted xForms” link from the “xForms” section in the middle of the Dashboard (see section 2.5)

5.2 **Completing an xForm**

1. **General Instructions**

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

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

   Note that some information in the form may be automatically generated. For example, when completing a Progress report, the system will automatically populate study details (such as study title, Principal Investigator, etc.) on the top of the form.

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

2. **Navigation Buttons at the Top of Each Page**

   The top of each xForm page will contain a header that looks as follows:
The person originally opening a form is initially the only individual who will initially have access to the form. In order to allow others access to the form, these other users must be added via the “Collaborators” function located in the upper left of the header.

Note that collaborators on a study (e.g. sub-investigators, research coordinators, key research personnel, etc.) are added by responding to the study personnel questions in the application xForm; adding a collaborator to your study does not automatically give them access to the form itself.

Upon clicking on the “Collaborators” link, a pop-up window will appear.

- Enter the email address of the user you would like to grant access to the form. **Note:** the user must already have a contact established within IRBManager to be added as a collaborator. If you need to add a contact, you can do this by completing the “New IRBManager User Application” xForm.
- Select the access rights you wish to grant.
  - “View only” will give the user view only rights.
  - “Edit will allow the user to make edits only.”
“Edit and manage” will allow the user to make edits and add other collaborators.

“Edit, manage and submit” will allow the user to make edits, add other collaborators and submit.

- Add a note for the collaborator (optional). Text entered in this box will be included in the email sent to the collaborator.
- Click Add. This will automatically send an email to the collaborator with instructions to access the form.

### 5.2.2.2 Page Titles Drop-down Menu

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

### 5.2.2.3 Page Numbers

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

### 5.2.2.4 Next Button

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

### 5.2.3 Navigation Buttons on the Bottom of Each Page

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

```plaintext
Next  Save for Later  View Attachment Questions  View Questions with Notes  PDF
```

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

- Previous – saves your progress on the current page and takes you to the previous page within the form.
- Next – saves your progress on the current page and takes you to the next page in the form.
- Save for later – saves your current progress
• View Attachment Questions – shows only the questions in the form that have “add attachment” buttons [Available to IRB reviewers only]
• View Questions with notes – shows only those questions where a note has been added via the “Add note” feature (section 15.2.4 below) [Available to reviewers only]
• PDF Allows you to save the form as a PDF file. If you plan to close the form following selecting this PDF button, ensure you save for later.

5.2.4 “Add Note” Feature
Select sections of the xForm includes an “Add Note” button on the right-side of the section title.

<table>
<thead>
<tr>
<th>IRB of Record: (Required)</th>
<th>Add Note</th>
</tr>
</thead>
</table>

This feature allows the user to enter reminders to themselves and/or comment/questions to an individual further down the review chain (Principal Investigator, IRB Office, etc.

Clicking on this button brings up the following note box:

```
Enter Note:  

OK Cancel
```

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

5.2.5 Attaching Documents
Attachments can be added to xForms wherever an “Add Attachment” button is found.

![Add Attachment]

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

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

5.3 Submitting an xForm

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

You may either submit the form, or press the browser’s back button to return to the previous page in the form.

**You must click the “submit” button to advance the form to the next person/office in the review chain.** If you choose any other action other than “submit,” the form will remain in your list of unsubmitted xForms and will not reach the IRB Office. The form will automatically route to the next person in the chain.

Note: Clicking “submit” is equivalent to mailing a paper version of the form to the next person/office in the chain. Once submit is pressed, you will not have the opportunity to make any changes to the form unless it gets returned to you by someone further down the approval chain (Principal Investigator, IRB Office, etc.)

If an application form is submitted by someone other than the PI, the form will be routed to the PI. Only the PI can submit the form forward to the IRB.

5.4 Signatures

All of the xForms require the Principal Investigator to electronically sign the form and attest to the accuracy of the information provided within the form, as well as other compliance stipulations. This electronic signature is equivalent to a paper signature.
When the submission has been routed to the Principal Investigator for review, at the end of the form is a signature box to enter their IRBManager password.

6.0 Principal Investigator Review

If the Principal Investigator is not the submitter, all forms will be routed to him/her for signature before being routed to the IRB Office.

6.1 Principal Investigator viewing of application

Principal Investigators can access the application via one of two methods.

6.1.1 Via Email

The Principal Investigator will receive an email similar to the one below:

The link in the email will take the Principal Investigator directly to the form.

6.1.2 Via Dashboard

Alternatively, the Principal Investigator can access the protocol from the xForms section in the middle of their Dashboard, under the “There are _xForms awaiting your attention.”

Clicking on the underlined link will open a screen with all xForms awaiting attention by the Principal Investigator.
To open the form, click on the form name in blue. **Note:** If the Principal Investigator has xForms awaiting their attention for other reasons (such as their role as an IRB member), the forms needing approval can be filtered by clicking the “Show forms requiring approvals ONLY” checkbox in the upper right of the screen.

### 6.2 Application Review

#### 6.2.1 Reading the Application

Upon clicking open the form, the Principal Investigator will see the entire application as submitted by the submitter.

To review the protocol, simply scroll through the page.

Additional features to aid in the review process:

- **“Hide Help Text”** – this hides the form instructions the submitter viewed when filling out the form. When this is checked, all responses from the submitter will still be visible.
- **Page Name Drop-Down menu at top of page** – Use this to jump to a particular section of the form.
- **“Add Note” button** – This feature allows you to enter a note that will be viewable to the submitter (if the form is returned for changes) and/or the IRB when the form is submitted.

#### 6.2.2 Completing Principal Investigator Review

Once you have finished reading the application, click “next” either at the top of the page or at the very bottom of the page. This will take you to the attestation and signature page.

If you approve the application:

1. Select that the protocol is ready for submission.
2. Read the attestation and electronically sign the form by entering your IRBManager password.
3. Click “Next” to take you to the submissions page.
4. Click “Submit”. **Note:** You must click “Submit” for the form to be moved forward in the review process.
If you require changes to the application:

1. Select that changes are required
2. Enter the changes you want the submitter to make in the text box. All text entered in this box will be sent to the submitter via email. Note: If you made your comments via the “Add Note” feature, inform the submitter of this in the text box so that they know to look for the notes when they open the application again to make changes.
3. Click “Next” to take you to the submission page.
4. Click “Submit”. **Note: You must click “Submit” for the form to be routed back to the submitter.**
5. The submitter will receive an email indicating you require changes. Once the submitter has made changes, the form will be routed back to the Principal Investigator again for approval.

6.3 Post-Principal Investigator Approval
The Principal Investigator will be copied on all emails from the IRB, including final decision notifications.

**Note:** If the IRB needs to return the form for any reason, the Principal Investigator signature process will need to be repeated upon re-submission of the form by the submitter.

6.4 Conflict of Interest Disclosure and Acceptance of Duties
Each person listed on the application must accept the responsibilities assigned to them by the Principal Investigator and sign a conflict of interest disclosure statement.

After approval by the Principal Investigator, each person listed on the application will receive an email similar to the one below.
6.4.1 Click on the link provided to access the Conflict of Interest and Acceptance of duties form.

6.4.2 If there is a conflict of interest to be disclosed, follow the instructions on the page to provide this information.

**Note:** The submission will not be routed to the IRB Office for review until each person listed on the application has submitted the conflict of interest and acceptance of duties certification.

7.0 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.