IRBManager User Guide
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About IRBManager

IRBManager is a web-based IRB application, submission, tracking and management system. This system allows researchers to securely submit their IRB applications for processing by the IRB Office.

LOGGING INTO YOUR IRBMANAGER ACCOUNT

1. Go to: https://browardhealth.my.irbmanager.com/
2. Enter your username and password
3. Click Login

If this is your first time doing research at Broward Health, you must request access to IRBManager by completing a request for a new account.

**Note:** If you are an employee of Broward Health, you **MUST** use your Broward Health email address when registering for an IRBManager account. If you are an affiliate with Broward Health and do not have a Broward Health email address, you **MUST** use your professional email address.
**HOME PAGE**

After you log into IRBManager, you will be directed to IRBManager’s home page. Depending on your role(s) (i.e. researcher, IRB Member, IRB Administrator), within IRBManager, you will see slightly different menus.

You can return to the home page at any point by clicking the Home button.

![Home button](Home_button.png)

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**Left Side**

On the left side of the screen you will see a menu which includes the following:

<table>
<thead>
<tr>
<th>Sections</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Actions</strong></td>
<td>Depending on the page you are viewing, the sections in this category will change. On some pages you will be able to add an attachment or an xForm, or send an email. [Done] will typically take you to the previous page.</td>
</tr>
<tr>
<td><strong>Recent Items</strong></td>
<td>Will display any recently viewed items.</td>
</tr>
<tr>
<td><strong>Messages</strong></td>
<td>Will display important messages from the IRB Office.</td>
</tr>
<tr>
<td><strong>My documents and forms</strong></td>
<td><strong>User attachments</strong> – will display any attachments not associated with a specific event or study within IRBManager. <strong>xForms</strong> – allows you to start a new IRB application and will also display any application that you are associated with.</td>
</tr>
</tbody>
</table>
Information and status updates pertaining to your applications will be displayed in the center of the screen.

<table>
<thead>
<tr>
<th><strong>Center</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Information and status updates pertaining to your applications will be displayed in the center of the screen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Studies</strong></th>
<th>Summary information about your studies.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>xFoms</strong></td>
<td>List of forms that have not been submitted and forms that have been submitted.</td>
</tr>
<tr>
<td><strong>Events</strong></td>
<td>Open events on your studies. The events section on the dashboard shows that submissions open by name of the event (Initial submission, Progress Report, Amendment, etc.)</td>
</tr>
<tr>
<td><strong>My Studies</strong></td>
<td>Your active studies.</td>
</tr>
</tbody>
</table>
Right Side

The right side menu includes the following:

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Find Study</td>
<td>Will enable you to search for a specific study.</td>
</tr>
<tr>
<td>Take a tour...</td>
<td>Will provide you with a high level tour of IRBManager.</td>
</tr>
<tr>
<td>Help</td>
<td>For assistance, please contact the IRB Office at <a href="mailto:irb@browardhealth.org">irb@browardhealth.org</a>.</td>
</tr>
<tr>
<td>Settings</td>
<td>Enables you to change your account information.</td>
</tr>
<tr>
<td>Sign Off</td>
<td>Sign off will sign you out of IRBManager.</td>
</tr>
</tbody>
</table>

STUDY/PROTOCOL PAGE

From the Home page, you can view all studies you are involved with by clicking on the study number (in blue) under the section “My studies”.

<table>
<thead>
<tr>
<th>Study</th>
<th>Site</th>
<th>PI</th>
<th>Title</th>
<th>Expires</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-43</td>
<td>BWHC</td>
<td>Principal Investigator</td>
<td>A Randomized, 2x2 Factorial, Controlled Clinical Trial to Evaluate the Safety of Acipimox vs. Aspirin and Acipimox vs. Aspirin Placebo in Patients with Atrial Fibrillation and Atrial Fibrillation</td>
<td>05/04/2016</td>
<td>Open to Enrollment - Recruiting Subjects</td>
</tr>
<tr>
<td>2017-0002</td>
<td>BWHC</td>
<td>Principal Investigator</td>
<td>The effect of Lavender Oil (Lavender Oil) on the Quality of Sleep in Medical Surgical Patients in an Acute Hospital Setting</td>
<td>06/24/2019</td>
<td>Open to Enrollment - Recruiting Subjects</td>
</tr>
</tbody>
</table>
VIEWING ALL AVAILABLE QUESTION OPTIONS

If you wish to view all available options in the IRB Application form, you can complete the following steps below.

1. Once signed into IRBManager, under the heading “Actions”, click on “Start xForm”.

![Actions menu]

2. Click on the printer icon located next to the applicable form.

![Form selection]

3. This will open the form and display all available options for each question.

STARTING A NEW IRB APPLICATION

You can start a new IRB application by following the instructions below.

1. From the home page, click on “Start xForm” under the section “Actions” located on the left-hand side of the screen.
2. Next, you will choose the application that you wish to complete.

Guidance for most questions can be found next to the question.

OR by hovering your mouse over “Show Help”

When you are completing the IRB application, IRBManager will provide you with any “issues” that it detects with the form as you progress. The “issues” will be listed at the top of the screen for your review and correction.

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 buttons locate on the bottom of each section will help you navigate through the application. Your work in IRBManager is saved each time you click the buttons [Next], [Previous], or [Save for Later] located on the bottom of the page.

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous</td>
<td>Takes you to the previous section.</td>
</tr>
<tr>
<td>Next</td>
<td>Will move to the next section. If there are any required questions which have not been answered you will not be able to proceed to the next section until the questions have been answered.</td>
</tr>
<tr>
<td>Save for Later</td>
<td>Saves your progress and allow you to return at a later time to complete the application.</td>
</tr>
<tr>
<td>View Attachment Questions</td>
<td>Views attachments.</td>
</tr>
<tr>
<td>View Questions with Notes</td>
<td>View questions which contain notes.</td>
</tr>
<tr>
<td>PDF</td>
<td>Creates a PDF of your form.</td>
</tr>
</tbody>
</table>

STARTING A NEW APPLICATION FOR SUBMISSION

Things to consider:
- All Principal Investigators, Sub-Investigators and Key Research Personnel must have an IRBManager account before being listed anywhere in the application.
- Application questions are asked in different formats, such as short answer, check boxes, drop down menus etc.
- The [Add Note] link allows you to leave notes for the reviewer or IRB Office on a specific question (s).

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

**Note:** 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.)

**Submitting an application on behalf of a Principal Investigator (PI)**

If someone other than the PI submits the application xForm, the PI will receive an email informing them that they need to review and approve the submission in order for the application to be submitted to the IRB Office for review. Only the PI can submit the form forward to the IRB.

After the PI reviews the xForm and attachments, they can save the form for later, print a copy, return the submission to the submitter to make changes, or accept the application and submit to the IRB by entering their password in the “Submit” box.

**Approval of the submitted application by the PI**
1. Once the PI has reviewed the application and made any notes where applicable, they will click on the [Next] button located on the bottom of the screen.

2. The PI review screen will be displayed, allowing the PI to either sign off on the application or sent the application back to the submitter for revisions.

3. On the PI review screen, you would select “Ready for Submission” in order to approve the application and allow the application to progress to the next stage.

4. The Outside Interest Disclosure Screen will appear. You are required to disclose any Outside Interests that you may have that could be. Click [Next]

5. On the next screen you will be required to enter your IRBManager password in order to sign off on the application.

6. Click [Next]

7. Click [Submit] in order to complete your sign off, approval, and review of the application.

CHECKING ON THE STATUS OF YOUR APPLICATION

If you wish to check on the status of your IRB application, please follow the instruction below.

1. Once logged into IRBManager, from the home page, click on your xForms “being processed at a later stage”.
2. You can check the status of your IRB application by looking at the “stage” column next to your application.

<table>
<thead>
<tr>
<th>Initial Application Stage</th>
<th>Stage Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Entry</td>
<td>Application has been started by the submitted. It has not yet been submitted to the IRB. -or- Application has been returned by the Principal Investigator, or IRB Office for revision</td>
</tr>
<tr>
<td>Principal Investigator COI and Signature</td>
<td>Awaiting Principal Investigator sign off on IRB application, if someone other than the principal investigator is submitting the protocol (e.g regulatory team)</td>
</tr>
<tr>
<td>Pre-Review</td>
<td>Application is submitted to the IRB Office. A pre-review is conducted to determine if the application is complete and ready to be reviewed.</td>
</tr>
<tr>
<td>Outside Interest Disclosure &amp; Acceptance of Duties</td>
<td>Awaiting outside interest disclosure and acceptance of study duties by everyone listed as a sub-investigator and key research personnel on the study.</td>
</tr>
<tr>
<td>Outside Interest Review and COI Determination</td>
<td>A member of the study team has disclosed an outside interest and the submission is awaiting review by Corporate Compliance on whether or not it constitutes a conflict of interests.</td>
</tr>
<tr>
<td>Regulatory Review</td>
<td>The application is being reviewed to ensure that it meets the requirements of the regulations. The review level is determined at this stage.</td>
</tr>
<tr>
<td>Facilitated Review</td>
<td>For submissions where an external IRB is the IRB of record – the submission is undergoing review by an IRB member.</td>
</tr>
<tr>
<td>Post Facilitated Review</td>
<td>For submissions where an external IRB is the IRB of record – review has been completed by an</td>
</tr>
</tbody>
</table>
IRB member and pending additional actions by the IRB Office.

Post Expedited Review

The submission has been deemed eligible for expedited review – Submission has been sent to the expedited reviewer. IRB Office is awaiting completion of the review.

Full Board Review

The submission requires Full Board review and is awaiting review at a Committee meeting.

IRB Member Verification of Conditions

The submission was approved with conditions, the conditions were addressed by the study team and now awaiting final approval by an IRB member.

Post Full Board Review

The submission has been reviewed by the Full Board and the submission is awaiting processing by the IRB Office.

Expiration Date(s)

If you wish to check the expiration of your IRB approved studie(s), you can do so from the home page. Expiration dates are listed at the bottom of the home page next to the title of the study. The Principal Investigator and the person listed as Primary Key Research Personnel will receive continuing review reminders at 90, 60 and 30 days prior to the study’s expiration date.

<table>
<thead>
<tr>
<th>My Studies (20 Active)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study #</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>2015-45-EPIC</td>
</tr>
<tr>
<td>2017-026-BHPC</td>
</tr>
</tbody>
</table>

Expires | Status |
--------|--------|
05/16/2016 | Open to Enrollment - Enrolling Subjects |
02/12/2016 | Open to Enrollment - Enrolling Subjects |

RETURNING TO YOUR APPLICATION IN PROGRESS

1. Click on “You have #unsubmitted xForms.”

2. Next, you will click on the form in order to pick back up with completing the application.
REVISING YOUR SUBMITTED APPLICATION

1. After you have submitted your application, you may be notified by the Principal Investigator and/or the IRB Office that revisions are required.

2. You will receive notification via email when revisions are needed to your IRB application. You can click the link in the email, which will take you directly to the form.

3. Alternatively, once logged into IRBManager, you can click the IRB application which needs attention under the xForms heading and click on “#xForms awaiting your attention.”

4. Next, you will select the application which needs attention from the list.

5. You can easily locate any question which needs attention by looking for any blue box as shown below.

6. You can see a list of questions which need to be addressed by clicking on “More – View Questions with Notes” located at the bottom of the screen.
7. Once you have addressed each of the questions, you may resubmit the application.

**SUBMITTING A PROGRESS REPORT**

You will submit a progress report form in order to extend your IRB approval OR to close out your study. Please follow the instructions below in order to complete this process.

1. From the Dashboard, under the section titled “My Studies”, click on the study you wish to complete a progress report.

   ![Study Details]

2. Next you will see the details pertaining to the study you selected displayed.
3. On the left hand side of the screen, under heading “Actions”, click on “Start xForm”.

4. Next, click on “Progress Report”, in order to start your Progress Report for the study that you are within.

5. Work through each section of the Progress Report.
6. After you have addressed each section of the Progress Report, you must click on the [Submit] button to move the submission to the next stage in the review process.
7. You will be notified via email of any revisions and once the progress report has been approved.
SUBMITTING AN AMENDMENT

You will submit an amendment form if you need to make any changes to your IRB approved study. Please follow the instructions below in order to complete this process.

1. From the Dashboard, under the section titled “My Studies”, click on the study you wish to complete an amendment.

2. Next you will see the details pertaining to the study you selected displayed.
3. On the left hand side of the screen, under heading “Actions”, click on “Start xForm”.

4. Next, click on “Amendment (Changes in Activities) Application”, in order to start your Amendment for the study that you are within.

5. Work through each section of the Amendment Form.
6. After you have addressed each section of the Amendment Form, you must click on the [Submit] button to move the submission to the next stage in the review process.
7. You will be notified via email of any revisions and once the amendment has been approved.

SUBMITTING A REPORTABLE EVENT

You will submit a reportable event pertaining to an unanticipated problem or adverse event that has occurred as part of your research project.
1. From the Dashboard, under the section titled “My Studies”, click on the study you with to complete a reportable event.

2. Next you will see the details pertaining to the study you selected displayed.
3. On the left hand side of the screen, under heading “Actions”, click on “Start xForm”.

4. Next, click on “Reportable Event Form”, in order to start your Reportable Event for the study that you are within.

5. Work through each section of the Reportable Event Form.
6. After you have addressed each section of the Reportable Event Form, you must click on the [Submit] button to move the submission to the next stage in the review process.
7. You will be notified via email of any revisions and once the Reportable Event has been acknowledged.

WITHDRAWING AN IRB APPLICATION

If you need to withdraw your already submitted IRB application, you will need the contact the IRB Office via email irb@browardhealth.org or phone 954-355-4941 or 954-355-4358.

ACCESSING YOUR APPROVED STAMPED DOCUMENTS

You can access stamped documents and any IRB Office generated documents such as approval letters and stamped consent forms by following the instructions below.
1. From the Dashboard, click on the study you wish to access approved and stamped documents.

2. Next, under the heading “Events” located on the bottom of the screen, you will see details pertaining to the study you selected displayed. Click on the # next to the heading you wish to view the attachments. For Example: Amendment (#119) show in the image below has 7 attachments. You can click on “7” to view these attachments.

3. From the attachments screen, you can download each attachment listed for your review.

4. Attached documents will be listed under “Attachments” and any IRB Office generated documents (e.g. Determination letters and Invoices) will be listed under “Generated Docs”.
PROVIDE OTHERS ACCESS TO MY APPLICATION

If you wish for someone else (other than the submitter) to make changes to the application, you must add them as a collaborator with edit rights.

Add a Co-PI or unnamed personnel
You may add a collaborator at any time during the application writing/editing stage. Adding a collaborator will allow those added to help you write/edit the form. Collaborators can edit, manage, and/or submit an application depending on the level of access granted. Collaboration can allow co-investigators or others associated with the application to assist the author of the form.

1. You may collaborate with other people by clicking on the [Collaborators] button located on the top of the page within the application.

2. Next, start typing the email address of the person you wish to collaborate with on your application.

3. Select the access level you wish the collaborator to have on your application.

<table>
<thead>
<tr>
<th>Access Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>View Only</td>
<td>Can only view the application</td>
</tr>
<tr>
<td>Edit</td>
<td>This will allow the person to edit the application</td>
</tr>
<tr>
<td>Edit and Manage</td>
<td>This will allow the person to edit the form and</td>
</tr>
<tr>
<td>Invite new collaborators</td>
<td>invite new collaborators</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Edit, Manage and Submit</td>
<td>This will allow the person to edit the form, invite new collaborators, and submit the application.</td>
</tr>
</tbody>
</table>

4. Click [Add] in order to add the person to your collaborators list. Once you click [Add], the person added will receive an email informing them that they have been added to the list of collaborators for your application.

```
has invited you to collaborate on a Progress Report xForm.
```

Additional comments were:

You can access the xForm from your dashboard, or directly at
https://browardhealth.my.irbmanager.com/xforms/4d12c90c-3a5f-40de-a830-b7d150989de0

**Remove Collaborator(s)**

You can remove collaborators at any time by selecting the [Collaborators] link at the top of each page of the application and then clicking the red X under the heading “Action” in order to remove the collaborator.

**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.