

e Protocol-Investigator-FAQs

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Who can log in?

Anyone with a User ID login to eProtocol. Access to specific protocols is based on this ID. As an investigator or administrator, you will only be able to see protocols that you are listed on.

What computer/browser should I use?

- To access eProtocol, you will need a computer with an internet connection.
- Supported browsers: Mozilla Firefox, Internet Explorer or Safari
- Turn OFF pop-up blockers to use eProtocol.

What is My Dashboard?

My Dashboard is an integrated homepage for eProtocol that will allow researchers to see all of their protocols.

How do I see my protocols?

Once logged in to eProtocol, you will see all the protocols in which you are listed as personnel.

If you don't see a protocol on your homepage, that means you are not listed on that protocol.

If you need to be listed on a protocol, but currently are not, contact the person in your group/lab who handles eProtocol and ask them to add you. They will need to submit a revision to add you as personnel.

Why won't my protocol open? aka How do I allow pop-ups?

If you click to open your protocol and nothing happens, check your pop-up blockers.

Browser settings may need to be adjusted as well as Toolbar settings. Please see the instructions below. You may need to follow more than one set of instructions before you will be able to open your protocol.

Pop-up instructions for:

- Internet Explorer
- Safari
- Firefox
- Yahoo Toolbar
- Google Toolbar

Internet Explorer: allowing pop-ups

- 1. Start Internet Explorer.
- 2. On the **Tools** menu, click **Pop-up Blocker** and select **Turn Off Pop-up Blocker**.
- 3. When Pop-up Blocker is correctly turned off, it will show **Turn On Pop-up Blocker**.

Safari: allowing pop-ups

- 1. Start Safari.
- 2. On the **Safari** menu, look to see if **Block Pop-up Windows** is checked. If so, click this line once to turn off pop-up blocking.
- 3. When Pop-up Blocker is correctly turned off, it will show **Block Pop-up Windows** as unchecked.

Firefox: Allowing Pop-ups

- 1. Start Firefox
- 2. On the Tools Menu, choose "Options..."
- 3. In the Options menu, click "Content"
- 4. Next to "Block pop-up windows, click "Exceptions..."
- 5. In the Allowed Sites Pop-ups menu, Add eprotocol-hrpp.mclaren.org and click "Allow."
- 6. Then hit "Close" to close this window. Hit "OK" in the Options window.

Yahoo Toolbar: allowing pop-ups

- 1. On the Yahoo Toolbar, click the pop-up blocker icon to see if **Enable Pop-up Blocker** is checked. If so, click this line once to turn off pop-up blocking.
- 2. When Pop-up Blocker is correctly turned off, it will show **Enable Pop-up Blocker** as unchecked.

Google Toolbar: allowing pop-ups

- 1. On the Google Toolbar, look to see if the pop-up blocker icon is shown as **blocked**. If so, click this button once to turn off pop-up blocking.
- 2. When Pop-up Blocker is correctly turned off, the button will show **Pop-ups okay**.

When will my protocol be reviewed?

Most new studies take between 4-6 weeks to be approved. Please factor in this review time when you're getting started. Contact the panel staff at any time with questions.

How do I create a new protocol?

There are two ways you can create a new protocol: from scratch or from a copy of an existing protocol.

Create a new protocol from scratch

To create a new protocol, simply click on the CREATE PROTOCOL button in the upper right-hand corner of your HOME page. You will need to enter basic information (such as Protocol Title, Personnel Information) before your application form will be generated, protocol number assigned, and the initial information that you have entered is saved. Once you have your protocol application number, you may continue to complete the application, or exit the system and return at a later time to complete.

If after entering the title, personnel info, nothing happens when you click CREATE, then you have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See <u>instructions</u> for allowing pop-ups in your browser.

Create a new protocol from an existing protocol

To create a new protocol from an existing protocol, find the protocol you would like to clone, and click on more actions. Select Clone protocol from the dropdown menu. This will copy the entire contents of the protocol into a new form and assign a new protocol number. You will need to go through every page very closely to update information for the new protocol.

How do I submit a protocol?

From the eProtocol homepage, click on the protocol number and choose to open in edit mode. In the protocol left-hand menu, click "Submit Protocol."

eProtocol will automatically check to make sure that all parts of the application form are complete. If the application is complete, a small window will open thanking you for submitting your protocol. If the application is not complete, then a window will open indicating the portions of the application that remain to be completed. Navigate to those areas and answer the questions before attempting to submit again.

Once a protocol is submitted, you will not be able make edits or additions, unless requested as part of the review.

How do I resubmit a returned protocol?

From your eProtocol homepage, click on the protocol number to open the protocol. Then in the left hand menu, choose "Return Notes."

A small window will open with information on the reason your protocol was returned and instructions on how to proceed. Usually we'll list changes you need to make, and then ask you to submit your protocol again.

How do I revise a protocol? or How do I submit a modification to my protocol?

Before you begin a revision/modification, you should consider the date that the current protocol approval will expire. Keep in mind that once a revision is submitted, you will not be able to start a renewal application until the revision has been reviewed and approved. If the expiration date of your protocol is near, you should start a <u>Continuing Review application</u> instead. As part of the renewal application, you may include any proposed changes to the protocol.

On your eProtocol homepage, find your protocol in the Active Protocols section. Click on the protocol ID and choose "Start Modification" option in the small window that comes up. Your protocol should open in edit mode. If nothing happens – <u>check your pop-up blockers</u>.

You can make any changes as needed. You can save this form and return to it later, it will be listed under your Action Items.

When you are ready to submit your revision, click Submit Protocol in the left-hand menu.

How do I add someone to the protocol?

All changes to the protocol, including personnel changes must be submitted as part of a revision/modification or renewal/continuing review.

Once you've started the revision or renewal, go to the personnel info section.

For the Principal Investigator or Admin Contact, click on the binocular to choose a new person. You can't clear these sections, because we require someone to always be listed in these roles.

Under the top four spots, there is a link "Click here to add Other Personnel." Anyone entered as "Other Personnel" will have view access to the protocol, but will not be able to make changes.

How do I renew a protocol? or How do I submit a Continuing Review?

On your eProtocol homepage, find your protocol in the Active Protocols section. Click on the protocol ID and choose "Start Continuing Review" option in the small window that comes up. Your protocol should open in edit mode. If nothing happens – check your pop-up blockers.

You can make any changes as needed. You can save this form and return to it later, it will be listed under your Action Items. When you are ready to submit your renewal/continuing review, click "Submit Protocol" in the left-hand menu of the protocol form.

How do I submit a report?

On your eProtocol homepage, go to the Active Protocols section, and find the correct protocol. Click on the protocol ID and choose "Report Form" option in the small window that comes up. Your Report should open in edit mode. If nothing happens – <u>check your pop-up blockers</u>.

Where is my approval letter?

From the eProtocol homepage, go to the Active Protocols section, find the protocol you want, and Click on the protocol ID. To find approval letters, open the protocol in view mode. Click on "Event History" from the left hand menu. This will show you a list of activities for your protocol, oldest to newest. Find the activity you are looking for, and click "Approval Letter."

How do I close a protocol?

From your eProtocol homepage, go to the Active Protocols section. Find the protocol you would like to close, and click on Protocol ID. Select "Final Report Form", from the options that are displayed.

Regular Protocols will see a Final Report option. Choose this, complete the form, and submit it to the IRB.

Expedited and Exempt protocols will see a Close Protocol option. Choose this, and your protocol will be marked as closed.

I logged in with my username and password but I cannot find the eProtocol site. What happened?

Always start with this URL: https://eprotocol-hrpp.mclaren.org. Do not bookmark the subsequent URLs you may see in the login process.

I saved the eProtocol site as a Favorite/Bookmark, but now I get an error message. What happened?

If your saved Bookmark does not work, you can make changes to it. Here are the instructions for Internet Explorer:

- Open your browser. Click on Favorites, Organize Favorites.
- Click on the bookmark/favorite you want to edit. Right click and select Properties.
- Make sure the URL is listed as https://eprotocol-hrpp.mclaren.org. Click Apply and then OK.

The page doesn't load or won't advance to the next section. What do I do?

If the page appears 'stuck', you can Refresh or Reload the page. Right click with your mouse and select Refresh or Reload (depending on your browser). If the page continues to freeze, close the protocol and then reopen. You should also clear the browser history.

What general guidelines can you offer when I use this system?

- **Turn off your pop-up blocker. Disable Yahoo/Google toolbars. **
- Avoid using your browser's BACK button. Use the links inside the window.
- SAVE your changes. Every time you click Next or Previous, the system saves your work. If you are working in a specific section for an extended time, it is a good idea to click the SAVE button.
- Sign Out when done log off and close your browser window.

How can I input text from a document into the eProtocol form?

You can copy and paste plain text from a document into the text boxes, but the formatting will not transfer (such as bold, italics, tables, indenting). It is recommended to first paste into Notepad, and then copy and paste into the eProtocol text box.

You can copy and paste symbols and special characters from a word processing program into the eProtocol text boxes.

When copying text from a PDF file, it is recommended to first paste into Notepad, and then copy and paste into the eProtocol text box.

If you have tables or diagrams, use the Add feature to attach the file in the Attachments section.

I have tables and diagrams that need to be included in my protocol. How do I do this?

Under the Attachments section, you can attach any kind of document to your protocol. If you have tables or diagrams, save in a document and attach in the Attachments section.

Keep in mind that the reviewers will need the appropriate software to open your attachments so it is recommended that you limit your attachments to commonly used software programs (Microsoft Word, Adobe PDF, etc.).

How can I print out the form?

Open the protocol in View or Edit Mode. On the left side of the screen, you will see your navigation menu. Click on the 'Print View' option. The system will ask if you want only the protocol or the protocol with comments. You can also select specific sections to print. Click your selection. The protocol information will be converted into a PDF file. You can print and/or save this pdf file on your desktop.

Note: After the protocol is reviewed and commented on by the office/reviewers, the other two options—Protocol with Comments and Comments only—will be enabled.

For Internet Explorer Users: If the pdf file will not open, try this: Hold down the Ctrl and Alt keys, then click on Print View. Keep holding these two keys until the pdf file opens.

You should have Adobe Reader version 6 or newer to view the pdf file.

Once my protocol is submitted, how can I keep track of the status?

You will receive e-mail notifications when the status of your protocol changes. For example, when it is submitted, you will receive an e-mail confirmation. If the office or committee has questions or needs clarification, you will receive an e-mail notification.

You can also keep track of the status of your protocol by logging in to the system. The status of all the protocols you have created and submitted will be available on your Investigator homepage (dashboard). Make sure you click on the appropriate committee tab to view your protocols and disclosures.

How can I view previous versions of my protocol?

Open your protocol. Click on Event History. You will see links for each unique version of your protocol (including reviewer comments) as it has progressed through the review cycle(s).

How do I view the Reviewer Comments?

When reviewer comments are first sent to you, you will click on the 'Comments Received' link. You will need to respond to each comment, revise the protocol as appropriate, and resubmit the protocol.

You can also use the Print View feature to view Reviewer Comments. Open the protocol and click on Print View. You will see three options: Protocol Only, Protocol with Comments, and Comments Only.

Note: After the protocol is reviewed and commented on by the office/reviewers, the other two options—Protocol with Comments and Comments only—will be enabled.

How do I know which sections I need to revise based on the reviewer comments?

When you click on 'Comments Received', each comment will reference a specific section of the protocol. In the comment box, the reviewer should indicate the specific section that you need to revise. As you make revisions to the protocol, the system will keep track of all your revisions and when the protocol is submitted, the reviewers will be able to view the revised sections.

How do I get a copy of my Approval Letter?

When your protocol is approved, you will receive an e-mail notification. Log-in to the system and your 'Approved Protocols' will be listed on the Investigator homepage (dashboard). Click on the ID link and select View Mode. Click on Event History. You can view and print the Approval Letter from this page. Your approved protocols will always appear on your Investigator homepage (dashboard) so you can access your Approval Letters at any time.

How to create a new Protocol by cloning an existing protocol?

Yes, on the Investigator homepage (dashboard) there is a 'Clone Protocol' button. Click this button and then select the protocol that needs to be cloned (copied). All the content will be copied into a new protocol with a unique ID number.

Where can I get Technical Help?

Call MHCC or Antheliohealth at NNN-NNN-NNNN.

Troubleshooting

How do I delete a revision, renewal or report that was started on accident?

On your eProtocol homepage, Click 'Delete Protocol'. Find the protocol activity and click on Delete. This will only delete this activity, and will not affect your approved protocols.

I need to renew my protocol, but I've already started a revision, what do I do?

If you haven't submitted your revision, you should delete the revision, and submit a renewal instead.

Make a list of any changes you've made in your revision. You'll need to re-enter these into a renewal form.

If you have already submitted a revision, contact IRB and ask their advice. Depending on how far along the revision is, they will be able to come up with the best option for you.

I already submitted my protocol, but I need to make another change, what do I do? Contact IRB staff and let them know what the change is. They will see where your protocol is in the review cycle, and can let you know the best way to include this change.