Greenville Hospital System eIRB Quick Reference Guide for Investigators and Study Staff

Logging in

How to log in to the eIRB system

1 Go to http://eirb.healthsciencessc.org
2 Click on the link to eIRB.
3 Enter *ghs* – and your *User name*: and *Password*:
4 Click *Log In* to enter the site.

Your Personal Workspace

 Your Personal Workspace, otherwise known as *My Home*, displays all the eIRB study submissions associated to you.

 If you are not already at your home page, click *My Home* at the top right of your screen.

The Study Workspace

 When you open an existing study application, amendment, or continuing review from your Personal Workspace, you will be taken to its workspace.
 The Study Workspace is the area where all activities associated with the study will be performed.

Creating a New Application

How to create a new application

 Applications for new research studies must be submitted by the Principal Investigator (PI). Study coordinators and/or Student co-Investigators (co-Is) may complete, but not submit applications.
1 Click the *Create New Study* button to initiate a new IRB Application.
2 Begin by filling out the first page of an application.
3 Click *Continue* to advance to the next page of the application.
4. Click on HIPAA Research Authorization button choice under section 3.0 "How will PHI be accessed for the research study"

- Under Section 2.0 "Summarize the procedures to be used when obtaining authorization" - use the following language:

  "GHS ORCA approved HIPAA authorization language included in local consent form submitted with this application"

5 When you are finished, click Save to save your changes and then Exit to exit the application form and return to the Study Workspace.

Adding Key Study Personnel

How to add study team members

1 Start a new application or create an amendment for an already approved study.
2 Click the *Select (*or *Add)* button beside the study team member to be added - Principal Investigators, Study Coordinators, Co-Investigators, other team members.
3 Filter the list to find the team member you want to add.
4. Select the team member to be added by clicking the radio button beside his/her name.
5 Click *OK*.

How to Add Study Team Members not in the Pick List

 If a study team member does not appear in the pick list for a particular role then they have not been assigned this role in eIRB.
 You may request a role by contacting the IRB coordinator at 455-3145 or email jwinter@ghs.org

CITI Certification

 An IRB application cannot be approved until all study team members have current Human Subjects Protection Education (CITI) certification dates in the eIRB system.

 If a study team member has not completed the CITI training, instructions for research education requirements can be found at www.ghs.org under Clinical Trials choose Research Compliance, Under the heading ***Research Training before Conducting Human Subject Research*** - Click CITI Training Course.

Uploading Documents

How to upload documents to your application

1 Click the *Add* button and a new window will appear.
2 Enter a *title* for the document you are uploading.
3 Click *Browse*… and select the file you want to attach.
4 Click *Open*.
5 Click *OK*.

Biosketches

How to attach a biosketch to an application

 Any person designated as PI, study coordinator or co-I must have a biosketch or CV on file in the eIRB.
1 At the end of the application in the *General Comments* section you can upload any additional forms to the application.
2 Click the *Upload Files* button.
3 Click *Browse*… and select the file you want to attach.
4 Click the *Add* button to upload a new biosketch document for this team member.

Informed Consent Documents

How to upload an original informed consent

 Informed Consent templates, and sample consent/assent forms can be found at www.ghs.org under Clinical Trials choose Research Compliance.
1 Save the Informed Consent template to your computer or network drive.

2 Open the Informed Consent template and modify the body of the template as required for your study.
3. Click on the link to *watermark* your template form(s). Follow the instructions detailing how to watermark a document. The consent form cannot be uploaded and accepted until this task has been performed.
4 Save the document.
5 Back in the eIRB application, use the *Add* button to attach the original Informed Consent in the *Consent Forms* section.

How to edit informed consent documents

 An application can not be edited while it is under review.
1 Re-open the original Informed Consent document on your computer or network drive.
2 Turn on change tracking and modify the body of the document as needed.
3 Save the redlined copy.
4 Turn off change tracking, accept all changes, and save a clean copy of the document.
5 Once back in the eIRB application, use the *[Edit]* link to attach the revised clean copy in the Consent Forms section.
6 Use the *Add* button to attach the redline copy in the *Redline Consent Forms* section.

Editing and Deleting Study Documents

How to edit documents that have previously been uploaded

 An application can not be edited while it is under review.
1 Open the document on your computer or network drive.
2 Make the necessary changes.
3 Save the document.
4 Back in the eIRB application, select the checkbox beside the name of the currently uploaded document.
5 Use the *[Edit]* button to upload the revised copy.

How to edit documents that have previously been uploaded

1 Select the check box in front of the name of the document to be deleted.
2 Click the *Delete* button.

Submitting an Application

How to submit an application

 The *Submit Application* activity can only be performed by the PI.
 Once the PI submits the application, an email will be sent to study team members (co-investigators and study coordinator) notifying them of the submission.
 After submission, the study team will not have access to edit the application unless it is returned with changes requested by eIRB.
 The Submit Application activity is performed from the Study Workspace.
1 From the Study Workspace, click the Submit Application button.
2 Complete all questions on the *Submit Application* screen.
3 Click *OK* at the bottom of the *Submit Application* window.

Viewing Reviewers Concerns

How to view reviewer concerns

 When IRB Administrator or Board concerns are sent to the study team, the application will be returned to the Personal Workspace Inbox of all study team members with an indication in the History log that concerns have been added.
 An email will also be sent to study team members alerting them that concerns need to be addressed.
1 Use the link in your Personal Workspace Inbox or on your email to enter the Study's Workspace.
2 Click the *Concerns* tab to see what concerns have been added.

Responding to Reviewer's concerns

How to respond to reviewer concerns

1 Use the *Jump To:* link to go to the section of the application where concerns have been added.
2 Make the necessary changes.
3 Once the changes have been made on the application, use the *Click here to respond* link at the top of the page to summarize your response to the reviewer.
4 Select the appropriate category and give your response.
5 Click *OK*.
6 When finished, *Save* and *Exit* the application form and return to the Study Workspace.
7 Click the *Submit Response to Reviewe*r button to return the application to the reviewer

Amendments

How to create an amendment request

 Amendments can be submitted for approved active studies only.
 Only one amendment can be in process at a time for each study.
1 Navigate to the Study Workspace of the approved active study.
2 Click the *New Amendment* button on the left to start a new amendment submission.
3 Complete the required information on each page of the Amendment Request form.
4 When you reach the *Summary of Amendment Changes* screen, click the *Click here to continue* link.
5 Click *Continue*.
6 Click *Continue* to return to the Amendment Workspace.
7 After making all changes to the amended study, click the *Submit Amendment* button on the left.
8 Click *OK*.

Continuing Review

How to create a continuing review

- Study team members will receive an email reminder that their application is due for a continuing review 60 and 30 days prior to the study expiration date.
- Continuing reviews can be submitted for approved active studies only.
- A continuing review can not be created while an amendment is in progress.
- Scheduled continuing review applications should be submitted at least twenty-one days before the approval is to expire.
- Only IRB-requested changes can be made at the time of continuing review. Study team initiated changes must be filed before or after the continuing review via amendment.
- If you do not need an extension of IRB approval, click on the *Study Team Close* button, found in the Study Workspace to close your study.

1 Navigate to the Study Workspace of the approved active study.
2 Click the *New Continuing Review* button on the left to start a new continuing review submission.
3 Complete the required information on each page of the *Action Requested at Continuing Review* form.
4 Click *Finish* at the end of the continuing review.
5 Click *Submit Scheduled Continuing Review* button on the left.
6 Click *OK*.

Printing an Application

How to print an application

- The print version of the study includes only the required application sections. Detailed information is printed at the end of the document.

1 Navigate to the Study Workspace.
2 Click the *Print-Friendly Application* button.

- You can also open the study application and click the *Print* button at the top of the screen to print specific pages of the application.

3 Click *Print* to open the Print dialog box.
4 Select a printer and click *Print*.