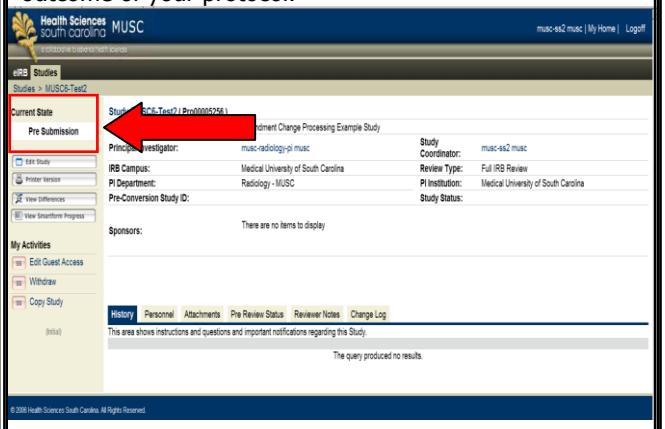
eIRB Quick Reference Guide for Protocol Workspace Navigation

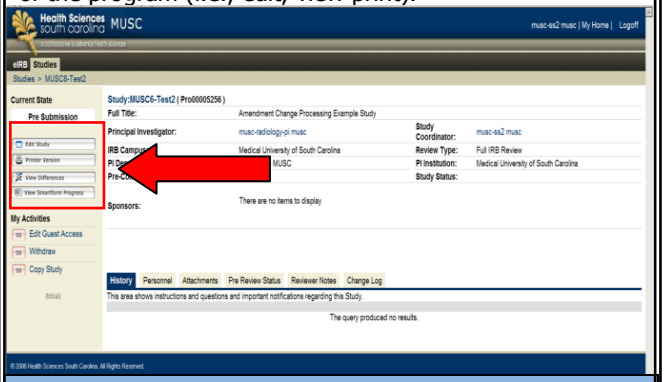
Current State

The stage of study development within the system, where the protocol is in the review process, and the review outcome of your protocol.



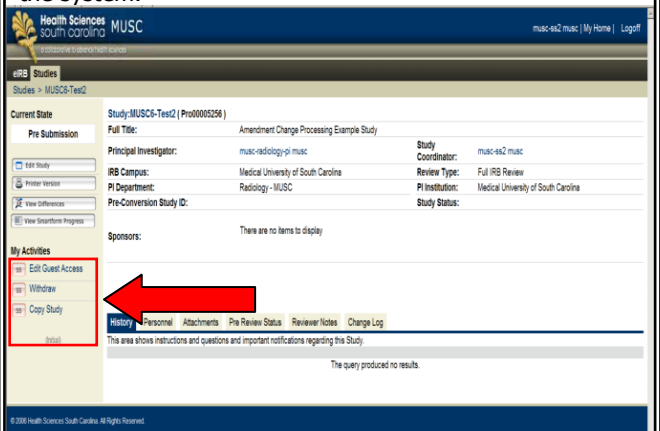
Tools

Your buttons that, when clicked, activate certain functions of the program (i.e., edit, view print).



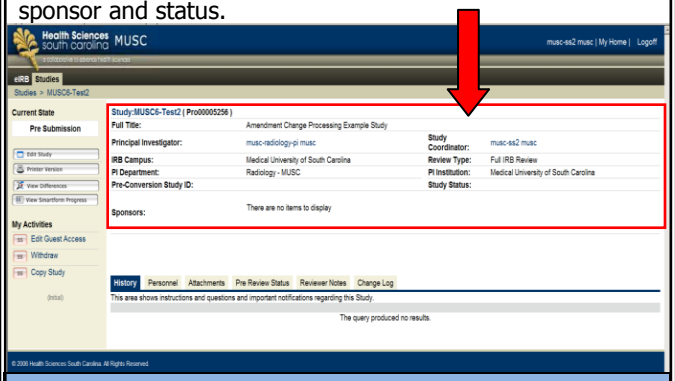
My Activities

Actions that can be taken within the submission process. The types of actions you are able to perform are specific to the state of the protocol and your permission rights in the system.



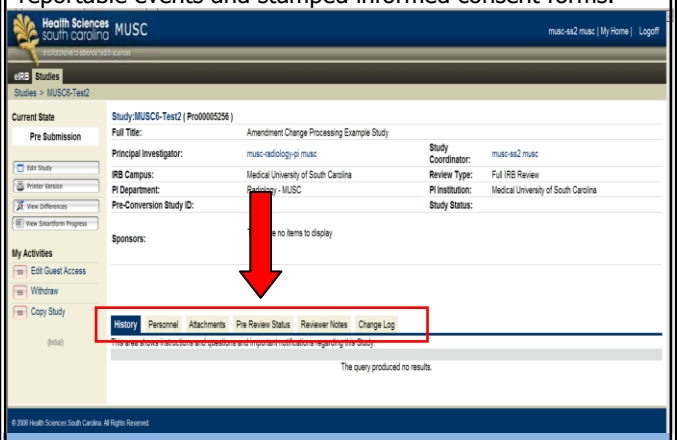
Protocol Details Synopsis

A synopsis of the protocol details, including IRB study number, title, PI name, institution and department, IRB Campus, study review type, study coordinator and study sponsor and status.

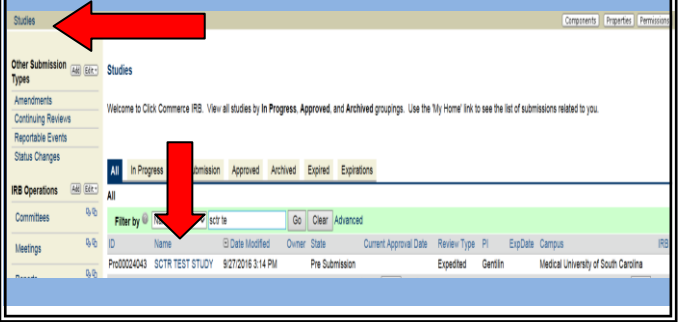


Protocol Details Tabs

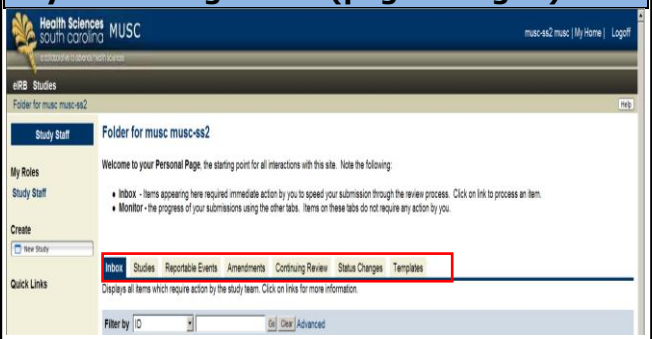
Protocol detail tabs will include history of protocol activities, study personnel, attachments and pre-IRB approval information and post-IRB approval amendments, continuing reviews, study status changes, reportable events and stamped informed consent forms.



The **Protocol Workspace** can be accessed in the system by locating the study at log in from the 'Studies' tab and clicking on the hyperlinked name of the study.



My Home Page Tabs (page at log in)



Inbox = studies that require some action on your part *(for instance, new studies or amendments to finish that have not yet been submitted to IRB)*.

Studies = all your studies in the system.

Reportable Events = reported safety events, deviations and safety committee reports entered into the system.

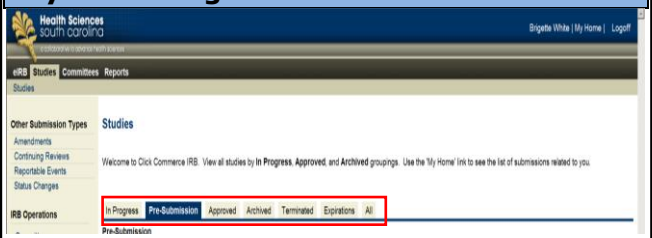
Amendments = all changes in process entered in for all studies.

Continuing Review = the continuing reviews entered in the system for all studies.

Status Changes = the changes in study enrollment status reported outside of a continuing review

Templates = study template you have created as copies to model future submissions.

My Home Page>>Studies Link Tabs



All = all of your studies that are within the system

In Progress = new studies that have been completed by the study teams/PI and sent to Department for review or that require action after submission BUT prior to IRB approval

Pre-Submission = studies not yet sent to IRB (available for IRB view)

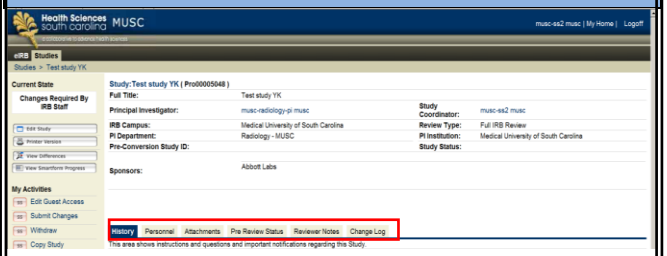
Approved = studies that are currently IRB approved

Archived = studies that are in a closed state (i.e., completed, withdrawn, expired, terminated, suspended, disapproved)

Expired = studies that have expired with IRB

Expirations = studies that will expire in 60 days

Pre- IRB Submission Protocol Tabs



History = all activities associated with review of submission.

Personnel = study team members on the application

Attachments = all documents uploaded as part of submission.

Pre-review status* = approval status of any other committee approvals needed (i.e., department approval, radiation safety, co-I approvals, etc.)

Reviewer Notes = all notes, comments, recommendations from IRB reviewers

Change Log* = all changes to an activity (study, amendment, etc.) performed by the study team after the activity is returned from the IRB.

**These tabs will no longer be available after IRB approval.*

Post IRB Approval Protocol Tabs

History = all study activities.

Personnel = study team members you have indicated as participating in the study.

Amendments = all amendments entered in for the study

Continuing Review = all renewals entered in for the study

Status Changes = the changes in study enrollment status entered in outside of a continuing review

Reportable Events = reported safety events, deviations and safety committee reports entered into the system.

Attachments = all uploaded documents and currently approved (excluding informed consent)

Stamped ICF = the current approved consent

Coop Review Status = approval details for studies that undergo a cooperative review among HSSC IRBs

Reviewer Notes = all notes, comments, recommendations from IRB reviewers

Central IRB = external site documentation for studies approved with the local IRB serving as the central IRB