



The Basics of Study Management For Principle Investigators

Version 8.02

Included:

1. Reviewing the study
2. Signoff

Chapter 1: Reviewing the Study

Once the Study Coordinator has setup the study and prepared the Initial Review Submission Form then they are able to trigger a notification sent to the Principle Investigator of the study. As the Principle Investigator, you can then log in to iRIS. Notice that you will have a new Incomplete Task (due to this notification to signoff) titled "Submission Routing Signoff."

Incomplete Tasks	Complete Tasks	Not Opened Correspondence	Previously Opened Correspondence
127 result(s) found... 1 - 20			
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Open	Task Type	Received
		Submission Routing Signoff	02/09/2009 02:58 PM PST
<div style="border: 1px solid black; padding: 5px;"> Admin Administrator as Principal Investigator review and apply signoff Study Title: test42345 Principal Investigator: Admin Administrator Submission Type: Initial Review Submission Form Reference Number: 000405 Study Number: test123325 </div>			

Click the Open icon. This will bring you directly to the Submission Signoff page. This page will contain all the associated submission forms like the Application, Initial Review Submission Form, and any associated Consent forms or Study Documents. Each of these can be opened or printed, so that you can thoroughly review the submission before approving or denying it.

Submission Signoff Sheet [Back](#)

[Save Signoff](#)

Study Title: test42345
 Submission Reference Number: 000405

[Print selected item\(s\)](#)

Print	Open	Type	Document Name	Version	Date Submitted into Workflow
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Submission Form	Initial Review Submission Form	Version 1.0	02/09/2009 02:58 PM PST
Submission Attachments below:					
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Application	Application	Version 1.0	02/09/2009 02:58 PM PST
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consent (English)	test	Version 2.0	02/09/2009 02:58 PM PST

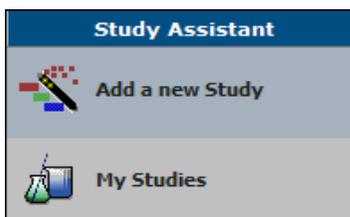
Comments: [Click here to add comments.](#)

Admin Administrator as Principal Investigator
 do you Approve or Deny this submission?
 Approve Deny

This form requires your electronic signature.
 Please enter your User ID & Password:
 User ID:
 Password:

[Save Signoff](#)

Should you need to open the study itself to obtain more information about the study before approving it, you can locate your study in the My Studies List found under your Study Assistant



This lists all of the studies you have a role on along with basic information about each study. Use the filters to narrow the list to the study you need to open.

My Studies Back

Display my studies by: Filter my studies by study status: All Most Recently Used: Find by IRB Number: Find Find by Study Number: Find

2 result(s) found... 1 - 2

Click to open	Study Status	IRB Number	IRB Expiration	Principal Investigator	Study Title/ Study Number	Copy Study	Delete Study
 Open	Draft			Administrator, Admin	test42345 test123325	 Copy	 Delete
 Open	Pending - Submitted for Initial Review	GH-08-00140		Administrator, Admin	designated department reviewer role designated department reviewer	 Copy	

Once you've located the Study in the list, click the Open icon. This will bring you to the Submissions tab of the Study.

Study Number: test123325 **Submissions** Back
 PI: Administrator, Admin Study Status: Draft Study Title: test42345
 Expiration Date:

Submissions | Study Management | Subject Management

Protocol Items	Submission Forms	Outstanding Submission(s)								
<ul style="list-style-type: none">  Application  Informed Consent  Other Study Documents  Contract Documents  Grants.Gov Application  Miscellaneous  Study Correspondence  Submissions History  Forms  Attachment A  FDA 1572  HIPAA Waiver of Authorization 	<ul style="list-style-type: none">  Adverse Event Form  Continuing Review Submission Form  Contract Submission Form  Protocol Deviation  Feasibility Form  Financial Disclosure  Grant Submission Form  Inactivation Form  Initial Review Submission Form  Questionnaire  Study Closure Form 	<table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td></td> <td>000405</td> <td>Click on the hyperlink to edit/view the submission.  Initial Review Submission Form</td> <td> Send Submission</td> </tr> </tbody> </table>	Track Location	Ref Number	Request Type	Process Submission		000405	Click on the hyperlink to edit/view the submission.  Initial Review Submission Form	 Send Submission
Track Location	Ref Number	Request Type	Process Submission							
	000405	Click on the hyperlink to edit/view the submission.  Initial Review Submission Form	 Send Submission							

From here you will have access to any information pertaining to the study. The Study Application and Initial Review Submission form are found within their corresponding link (shown above circled in red).

Chapter 2: Signoff

Submission Signoff Sheet Back

Study Title: test42345
Submission Reference Number: 000405

Print selected item(s)

Print	Open	Type	Document Name	Version	Date Submitted into Workflow
<input type="checkbox"/>		Submission Form	Initial Review Submission Form	Version 1.0	02/09/2009 02:58 PM PST

Submission Form(s):

Submission Attachments below:

Print	Open	Type	Document Name	Version	Date Submitted into Workflow
<input type="checkbox"/>		Application	Application	Version 1.0	02/09/2009 02:58 PM PST
<input type="checkbox"/>		Consent (English)	test	Version 2.0	02/09/2009 02:58 PM PST

Comments: [Click here to add comments.](#)

Admin Administrator as Principal Investigator
do you Approve or Deny this submission?

Approve Deny

This form requires your electronic signature.
Please enter your User ID & Password:

User ID:
Password:

Save Signoff

The signoff screen allows you to either Approve the submission or Deny it. Either outcome requires your electronic signature which is simply your User ID and Password.

Comments can be added to the Submission Signoff screen.

If you approve the Submission, it will proceed to further signature queues (if there are any assigned), or it will proceed to the appropriate Review Board queue. If you deny the Submission, it will return to the Study and will not proceed further in the workflow to any signature queues or review board queues.