The Basics of Study Management
For Principle Investigators
Version 8.02

Included:
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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.”

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.

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.

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

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

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.