Human Subjects Protocol Management Quick Reference Guide For View-Only Users

Accessing the Module

1. Using your browser, go to https://www.pennera.upenn.edu
2. Select LOGON in the left navigation bar.
3. Enter your PennKey username and password.
4. Select Protocols in the left navigation menu, and from the expanded menu, select Human Subjects.

Protocol Search

From the Human Subject Protocols main page, type the protocol number, if known, in the Open By Number field and click the [Go] button. Otherwise, click the [Show] icon to the right of All Status and search for a protocol using other criteria:

1. By Sponsor
   Click the [Set] button next to the Sponsor field. From the pop-up window, choose the first letter in the sponsor’s name and then scroll to find the sponsor that you want. This method of searching is also applicable to all other fields with an adjacent [Set] button. When searching for an investigator, use the Filter by Position drop-down listing to narrow search results by University affiliation or position.

2. By Date Range
   A range of dates may be entered into any of the date range fields provided that a specific range does not exceed 90 days.

3. By Review Board
   Select the IRB Review Board number, then enhance your search by adding criteria such as Agenda Date Range, Approval Date Range, Approval From Date Range, Approval To Date Range, or Submission Date Range.

4. By Protocol Status
   Click the checkbox next to each of the protocol status types you wish to include in your search results. By default, all fields are checked, with the exception of “Terminated”. Other than the protocol number field, all search parameters may be used in combination.

     Once you have entered all of your search criteria, click the [Go] button to generate your search results.

Search Results

All search results will display on either the Browse Results or All Status search page. Both pages display the same information. From either page, click the [View] icon under HSM to be directed to the Summary page for the protocol that you wish to see. To begin a new search, click [Done] in the top toolbar to close all pop-up windows, and then click the [Back] icon to return to the All Status or Human Subject Protocols main page where you can enter new search criteria.

Summary Page

The Summary page is the first page you see upon opening a protocol and contains basic information relevant to a specific protocol including Protocol Number, Submission Date, Original Meeting Date, Board Name, Reviewers, Review Category, Full Title, Short Title, Objectives & Purposes, and Other Information.

A Protocol Information Box containing the Protocol Number, Personal Investigator, Department, and Title can be found in the top toolbar of the page. This box remains visible while a protocol is being worked on.

In addition, multiple sections or “pages” of information are available from the Summary page, including:

- Associated Departments,

Several sections are not used on the Summary page at this time: Devices, Drugs, Keywords, Methods, and Procedures.

For more details on these pages and their individual fields, see “Summary Menu” in the “Menus” section of the Human Subjects Protocol Management Manual.

Attached Documents

The Attachments page on the expanded Summary menu displays information pertaining to any electronic documents attached to a protocol’s record. Each attachment is associated with a specific review or amendment.

To open a new browser window in which the document can be viewed, click the [View] icon next to a listed document (if any).

Review Record

A review record contains information relevant to the specified review period of a given protocol.

Multiple sections or “pages” of information are available in the review record, including:

- Pre-Review, Compliance Information, Investigators, Department, Post Review, Attachments, Communications.
- Compliance Information is not currently used within the review records.

For more information, see “Creating a Protocol Review Record” in the Human Subjects Protocol Management Manual.

Viewing Review Records

To see a protocol’s review record(s), select Reviews in the left navigation menu after opening the protocol. Then, click the [Edit] icon next to a listed document (if any) to view that
Note: To open a protocol review record from a search results page, click the [View] icon under HSM, and then select Reviews in the left navigation menu.

### Amendment Record
To see a protocol’s amendment information (if any), select Amendments in the left navigation menu (accessible after displaying the protocol’s Summary page).

Amendment records have the same general format as review records, but contain information about changes to the protocol.

For more information on the pages and individual fields in a protocol’s amendment record, see “Adding Amendments to a Protocol” in the Human Subjects Protocol Management Manual.

### Adverse Event Info
To see a protocol’s Adverse Event information (if any), start at the protocol Summary page, and then select Adverse Events in the left navigation menu.

Note: Adverse Event information is imported nightly into PennERA from the PennAEs reporting module.

For more information on the pages and individual fields relating to AE’s in PennERA, see “Viewing Adverse Event Information” in the Human Subjects Protocol Management Manual.

### Completing a Search
When finished with a specific protocol, click the [Done] icon in the top toolbar. You can then click the [Back] icon to begin a new search, or click the Log Out icon to end your session in the PennERA HS Module.

### Notes Regarding Data
There may be discrepancies between Review Decisions and Protocol Status on Converted Records (labeled “Conversion” in the list of Reviews).

Information from Penn Protocol Manager (PPM) that did not have designated equivalent data placeholders in HSM were placed in “Provisions/Comments” field.

For the PennERA Help Line number, documentation & online technical support, please go to https://ww.pennera.upenn.edu and click on “Help”