Human Subjects
Electronic Research
Application
Quick Reference Guide

Accessing the Module

1. Using your browser, go to https://medley.isc-seo.upenn.edu/hsProtocol/jsn/fast.do
2. Enter your PennKey username and password.

Finding Submissions

To view a listing of submissions that are in draft mode and have not yet been submitted, select Manage drafts from the menu, and at the next page click the edit icon (pen/paper) to complete the application.

To search/sort for a submission using other criteria:

1. By Type
   Click the [Type] column heading. This will sort your submission listing by type. The four types are Protocol, Continuing Review, Modification and Unanticipated Problem.

2. By Principal Investigator
   Click the [Principal Investigator] column heading. This will sort your submission listing by PI.

3. By Submission Date
   Click the [Submission Date] column heading. A range of dates may be entered into the date range fields provided that a specific range does not exceed 90 days.

4. By Title
   Click the [Title] column heading. This will sort your submission listing by Short Title.

5. By Status
   Click the [Status] column heading. This will sort your submission listing by departmental approval status.

Other than draft versions of submissions, Submissions submitted within the last 90 days can also be viewed by selecting, Recent under Submissions History.

Protocol Creation

From the HS–ERA main page, click Create under My Submissions. Select Initial Review and begin your application.

Basic Information

The Basic Info page contains the basic information relevant to a specific protocol including Protocol Title, Short Title, Description, and Submission Type. This information is usually contained in the IRB facesheet.

A Protocol Information Box containing the Protocol Number and Status can be found on this page once assigned. These fields remain invisible until a protocol is submitted.

Personnel

The Personnel page contains information relevant to the individuals participating in the research of the protocol. This includes the Principal Investigator, Study Contact, Other Investigator and Key Personnel.

A Human Subjects Training Information Box detailing whether training was obtained and its expiration date and whether a Conflict of Interest exists among any of the participants can also be found on this page.

Biomed/Soc Behavioral

The More (Bio/Soc) page contains information related to the submission type selected for the research. This selection was made on the Basic Info page.
This page also contains information on the other reviewing entities that may be required to review your application. Electronic notifications are driven by this page and are sent to the appropriate reviewing body as necessary.

**Sponsors**

The Sponsors page contains information relevant to the sponsors of a protocol. It is here where a funding sponsor, regulatory sponsor, industry sponsor and IND holder would be identified.

If the research project is funded by or associated with a grant or contract, it will also detail the proposal # that it is linked to.

**Sites**

The Sites page is where all sites containing PIs participating in the research, in addition to Penn and CHOP, are added.

If the study is an Industry Sponsored or NCI study, or is a cooperative group trial, a communications plan is also detailed here.

**Protocol**

The Protocol page contains information related to the details of the study. The information recorded here is the equivalent to the Protocol summary document required by the IRB.

Information found on this page includes the Abstract, Objectives and Study Design.

**Populations**

The Populations page contains information relevant to the participants taking part in the research. Information detailing the Target Populations, Accrual and Subject recruitment are recorded here.

**Procedures**

The Procedures page contains information detailing the study procedures used, its Subject Confidentiality and how Data Protection was maintained.

**Consent**

The Consent page details how informed consent was obtained from the subjects.

If no informed consent was required, this area also describes any requests for waiver of consent.

**Risk/Benefit**

The Risk/Benefit page explains the risks and benefits involved in a research study.

In this section, the details of how the study benefits and risks were assessed are described and how data and safety monitoring was handled.

**Confirmation**

The Confirmation page is the last page to complete prior to submitting an application.

In this section, any documents that were not uploaded previously are attached to the application.

It is also the page where the submitter gives his/her electronic signature to sign-off on the submission by clicking I Accept.

**Attachments**

Attachments can be uploaded throughout the application where the Upload button is displayed.

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

**Continuing Review**

A request for continuing review application is submitted when
an approved protocol is up for renewal. It contains information relevant to the specified review period of a given protocol.

From the HS–ERA main page, click Create under My Submissions. Select Continuing Review and begin your application.

To see an existing continuing review submission, select Type on the Submission listing screen under Submission History then Recent. Select a submission with the type Continuing Review.

Once a continuing review is submitted, it is electronically routed to the PI (if the submitter is not the PI). The approval by the department chair is only required if the PI is the submitter.

View (eyeglasses) icon next to a listed submission.

**Modifications**

From the HS–ERA main page, click Create under My Submissions. Select Modification and begin your application.

To see an existing modification, select Type on the Submission listing screen. Select a submission with the type Modification.

Modifications have the same general format as Initial reviews, but contain information about changes to the protocol.

Once the submitter completes the request for modification, a copy of the original initial review is opened up for changes. Any piece of data on the application can be modified except the project title, short title and the PI. For these changes, they must be detailed in the modification description box in the form.

Once a modification is submitted, it is electronically routed to the PI (if the submitter is not the PI). The approval by the department chair is only required if the PI is the submitter.

**Unanticipated Problems**

From the HS–ERA main page, click Create under My Submissions. Select Unanticipated Problem and begin your application.

To see an existing unanticipated problem/adverse event, start at the submission listing page, and select Type in the column headings. Note: Unanticipated Problem/Adverse event information is no available via the PennAEs reporting module. This application has been retired.

Once an unanticipated problem is submitted, it is electronically routed to the PI (if the submitter is not the PI). The approval by the department chair is only required if the PI is the submitter.

When finished with a specific submission, click the I Accept icon on the submitter’s Assurance Screen. Once this is done, your submission is electronically routed for departmental approval. You can then click the Create link to begin a new submission, or click the Log Out icon to end your session in the HS–ERA module.

For HS–ERA documentation or support, please go to https://medley.isc-seo.upenn.edu/hsProtocol/isp/fast.do and click on Help. Support is also available by clicking on the Help email link within the application.