

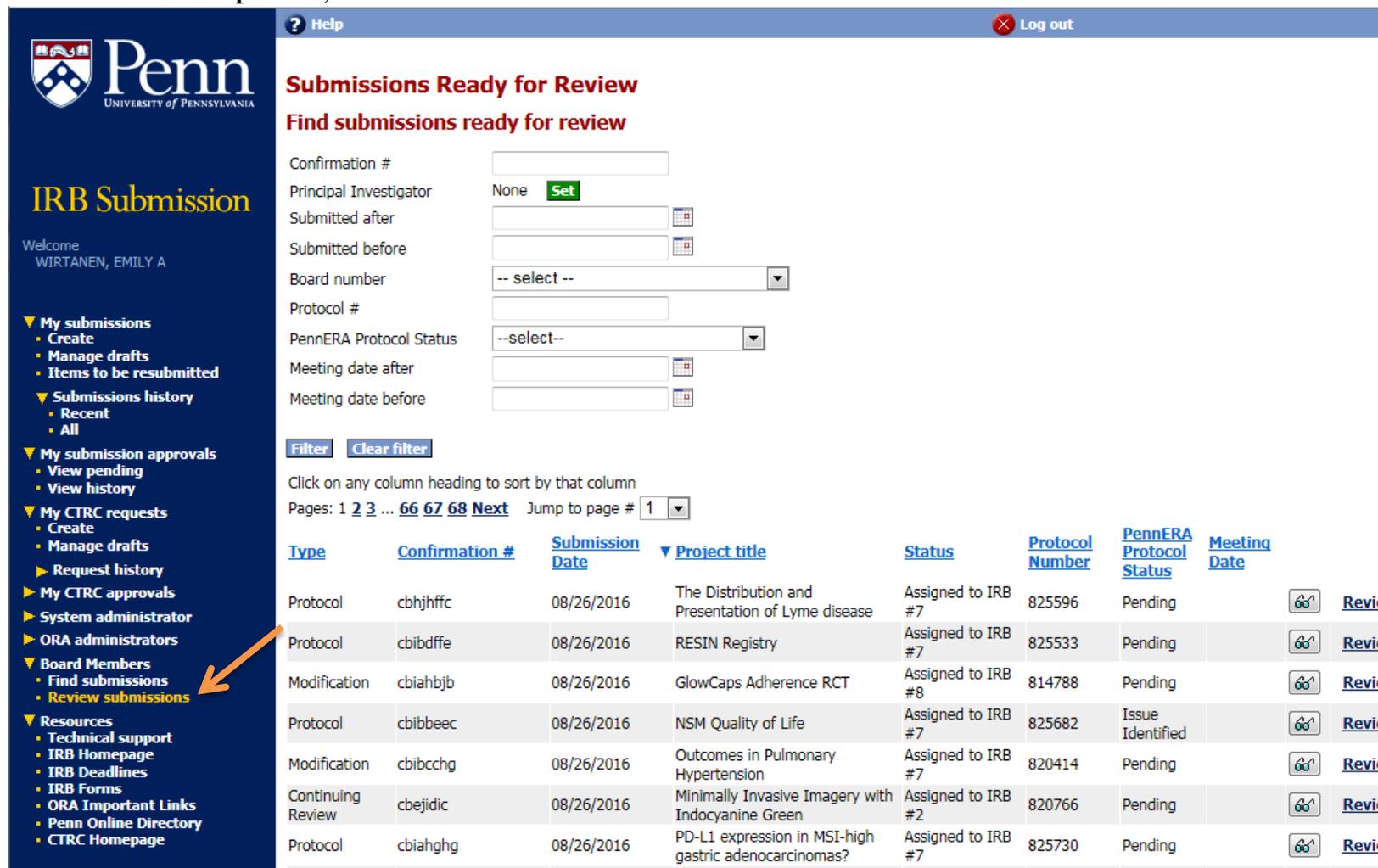
HS-ERA (Human Subjects Electronic Research Application) is Penn’s online IRB submission system. The system was developed in 2008 and became mandatory in 2011. HS-ERA serves as the electronic file as well as the protocol summary and face sheet for each protocol. The first half of the application contains face sheet information such as study personnel and sponsor. The latter portion of the application contains information that would be included in a Protocol Summary. In order to streamline the review process, researchers are allowed to include references to a full protocol in cases where they would otherwise be copy/pasting the information.

## HS-ERA Instructions:

The Human Subjects Electronic Research Application (HS-ERA) is available to all researchers at Penn with a valid PennKey and Password.

1. Go to <https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do>
2. Authenticate with your PennKey and PennKey password.
3. The Human Subjects Electronic Research Application (HS-ERA) home page will appear.

To locate a protocol, click on “Review Submissions” under “Board Members” on the left side of the screen...



The screenshot shows the HS-ERA web application interface. On the left is a dark blue sidebar with the Penn logo and navigation menu. The main content area has a search filter and a table of submissions.

**IRB Submission**

Welcome WIRTANEN, EMILY A

- ▼ My submissions
  - Create
  - Manage drafts
  - Items to be resubmitted
- ▼ Submissions history
  - Recent
  - All
- ▼ My submission approvals
  - View pending
  - View history
- ▼ My CTRC requests
  - Create
  - Manage drafts
- ▶ Request history
- ▶ My CTRC approvals
- ▶ System administrator
- ▶ ORA administrators
- ▼ Board Members
  - Find submissions
  - Review submissions
- ▼ Resources
  - Technical support
  - IRB Homepage
  - IRB Deadlines
  - IRB Forms
  - ORA Important Links
  - Penn Online Directory
  - CTRC Homepage

**Submissions Ready for Review**

Find submissions ready for review

Confirmation #

Principal Investigator None

Submitted after

Submitted before

Board number -- select --

Protocol #

PennERA Protocol Status --select--

Meeting date after

Meeting date before

Click on any column heading to sort by that column

Pages: 1 2 3 ... 66 67 68 Next Jump to page # 1

Type	Confirmation #	Submission Date	Project title	Status	Protocol Number	PennERA Protocol Status	Meeting Date	
Protocol	cbjhffc	08/26/2016	The Distribution and Presentation of Lyme disease	Assigned to IRB #7	825596	Pending		<a href="#">Revi</a>
Protocol	cbibdfe	08/26/2016	RESIN Registry	Assigned to IRB #7	825533	Pending		<a href="#">Revi</a>
Modification	cbiahbjb	08/26/2016	GlowCaps Adherence RCT	Assigned to IRB #8	814788	Pending		<a href="#">Revi</a>
Protocol	cbibbec	08/26/2016	NSM Quality of Life	Assigned to IRB #7	825682	Issue Identified		<a href="#">Revi</a>
Modification	cbibcchg	08/26/2016	Outcomes in Pulmonary Hypertension	Assigned to IRB #7	820414	Pending		<a href="#">Revi</a>
Continuing Review	cbejdic	08/26/2016	Minimally Invasive Imagery with Indocyanine Green	Assigned to IRB #2	820766	Pending		<a href="#">Revi</a>
Protocol	cbiahghg	08/26/2016	PD-L1 expression in MSI-high gastric adenocarcinomas?	Assigned to IRB #7	825730	Pending		<a href="#">Revi</a>

Type in the Protocol number then click the “Filter” button (pressing “Enter” on your keyboard will bring you to a different screen- if this happens click the back button). Click the blue column headings (submission date, type, etc) to sort the submissions. To open a submission to, click “Review” on the far right side.

## Find Submissions

### Find submissions created using this system

Confirmation #

Principal Investigator None

Assigned To None

Submitted after

Submitted before

Board number -- select --

Protocol # 811685

PennERA Protocol Status --select--

Meeting date after

Meeting date before

Click on any column heading to sort by that column

Pages: 1 2 3 4 Next

Type	Principal Investigator	Submission Date	IRB Received Date	Title	Status	Penn ERA Protocol Board	Confirmation Number	Protocol Number	PennERA Protocol Status	Meeting Date		Review
Modification	MANDELL, DAVID S	12/18/2014	12/18/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bhbaejdc	811685	Approved			<input type="button" value="Review"/>
Modification	MANDELL, DAVID S	12/05/2014	12/05/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bhabbeda	811685	Approved			<input type="button" value="Review"/>
Continuing Review	MANDELL, DAVID S	11/03/2014	11/03/2014	Clinical Algorithm	Assigned to IRB #8	IRB #8	bggbgjcj	811685	Approved	11/24/2014		<input type="button" value="Review"/>

To see the review history of a particular submission, click the eyeglasses button next to “Review”. The eyeglasses view is strictly an overview of the actions by the IRB staff as it relates to the submission (comments regarding the review, the review decision, and decision letter). On this page there will be a listing of hyperlinks in the middle of the page. Example:

Assigned to IRB #5, created on 11/27/2013 (beccadef) [IRB Administrator = LESAGE, STEPHANIE G]  
[Returned by ORA, created on 11/21/2013 \(bebgfgcd\) \[IRB Administrator = DAVISON, CHRISTINE M\]](#)  
[Returned by ORA, created on 09/27/2013 \(bdggheec\) \[IRB Administrator = DAVISON, CHRISTINE M\]](#)  
[Returned by ORA, created on 09/12/2013 \(bdfcebfd\) \[IRB Administrator = DAVISON, CHRISTINE M\]](#)  
[Returned by ORA, created on 07/23/2013 \(bdafhhig\) \[IRB Administrator = DAVISON, CHRISTINE M\]](#)

This example list of links indicates that the submission was returned to the study team 4 times by the IRB staff before a decision was made. You can see that each time a submission is returned to the IRB, it is given a new confirmation code (in parentheses). Clicking these hyperlinks will take you to the eyeglasses view of each edition of the submission. To review any of these submissions in their entirety (i.e. the application content and changes made by the study team), the confirmation code that corresponds to the submission should be entered on the “Find Submissions Page” in the same way you would search for a protocol.

If a submission was received and a decision was made without returning it to the study team, this area will not have any hyperlinked entries but will look like this:

**Revision History:** Assigned to IRB #5, created on 01/31/2014 (behfgjdb) [IRB Administrator = DAVISON, CHRISTINE M]

There are instances where the decision made by the IRB results in a new submission being required to make the requested edits. In these cases the submission that contains the response will not be hyperlinked in this fashion.

**The following screen shots are examples of the automatic viewing options for the different types of submissions as they appear in HS ERA, with an overview of the information contained within.**

<p><b>Protocol Application Form</b></p> <p>You may view the entire protocol application form:</p> <p><a href="#">Clean protocol application</a> (shows printer-friendly version)</p> <p><a href="#">Protocol application w/ tracked changes</a> (shows printer-friendly tracked v</p> <p><i>OR</i></p> <p>You may view the protocol application form by section:</p> <p><b>IRB Facesheet</b></p> <table border="0"> <tr> <td><b>Basic Info</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Personnel</b></td> <td><a href="#">show clean</a></td> <td></td> </tr> <tr> <td><b>Bio</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Sponsors</b></td> <td><a href="#">show clean</a></td> <td></td> </tr> <tr> <td><b>Sites</b></td> <td><a href="#">show clean</a></td> <td></td> </tr> </table> <p><b>Protocol Summary</b></p> <table border="0"> <tr> <td><b>Protocol</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Populations</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Procedures</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Consent</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> <tr> <td><b>Risk/Benefit</b></td> <td><a href="#">show clean</a></td> <td><a href="#">show tracked</a></td> </tr> </table> <p><b>Documents</b></p> <p><a href="#">show attached documents</a>                      <a href="#">show new documents</a></p> <p><b>Comments</b></p> <p><a href="#">show comments</a></p> <p><b>IRB Correspondence</b></p> <p><a href="#">show IRB correspondence</a></p> <p><b>Ancillary Committee Correspondence</b></p> <p><a href="#">show Ancillary Committee correspondence</a></p> <p><b>IRB Review History</b></p> <p><a href="#">show IRB review history</a></p>	<b>Basic Info</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Personnel</b>	<a href="#">show clean</a>		<b>Bio</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Sponsors</b>	<a href="#">show clean</a>		<b>Sites</b>	<a href="#">show clean</a>		<b>Protocol</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Populations</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Procedures</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Consent</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<b>Risk/Benefit</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>	<p><b>This is an Initial Protocol Application submission that was returned for edits before approval</b></p> <ul style="list-style-type: none"> <li>• Clicking “Show Clean” will expand each individual section for review of content. The linked button will change to show “hide clean” to collapse that section when you are finished viewing it. “Show tracked” will expand and show tracked changes to that section if any changes were made</li> <li>• Clicking “Clean Protocol Application” will show the entire application in a seamless screen to scroll through instead of viewing each section individually.</li> <li>• Clicking “Show Attached Documents” will expand a list of the documents previously uploaded before the submission was returned. “Show new documents” will show the most recent documents</li> <li>• Clicking “Show Comments” will show the comments from IRB staff and reviewers as they appear in the eyeglasses view previously mentioned</li> <li>• Clicking “Show IRB Correspondence” will show the decision letter and also may contain communications from other review entities</li> <li>• Clicking “Show IRB review history” will show the decision made, the name of the person who made the decision and the date and time the decision was entered</li> </ul>
<b>Basic Info</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>																													
<b>Personnel</b>	<a href="#">show clean</a>																														
<b>Bio</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>																													
<b>Sponsors</b>	<a href="#">show clean</a>																														
<b>Sites</b>	<a href="#">show clean</a>																														
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<b>Consent</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>																													
<b>Risk/Benefit</b>	<a href="#">show clean</a>	<a href="#">show tracked</a>																													

NOTE: The Comments, IRB Correspondence, Ancillary Committee Correspondence and IRB Review History sections are the same for all types of submissions and are not included in the next screen shot examples.

<p><b>Modification form</b> <a href="#">show</a></p> <p><b>Protocol Application Form</b></p> <p>You may view the entire protocol application form:</p> <p><a href="#">Clean protocol application</a> (shows printer-friendly version)</p> <p><a href="#">Protocol application w/ tracked changes</a> (shows printer-friendly tracked ve</p> <p><i>OR</i></p> <p>You may view the protocol application form by section:</p> <p><b>IRB Facesheet</b></p> <p><b>Basic Info</b> <a href="#">show clean</a></p> <p><b>Personnel</b> <a href="#">show clean</a></p> <p><b>Bio</b> <a href="#">show clean</a></p> <p><b>Sponsors</b> <a href="#">show clean</a></p> <p><b>Sites</b> <a href="#">show clean</a></p> <p><b>Protocol Summary</b></p> <p><b>Protocol</b> <a href="#">show clean</a></p> <p><b>Populations</b> <a href="#">show clean</a></p> <p><b>Procedures</b> <a href="#">show clean</a></p> <p><b>Consent</b> <a href="#">show clean</a></p> <p><b>Risk/Benefit</b> <a href="#">show clean</a></p> <p><b>Documents</b></p> <p><a href="#">show previously submitted documents</a> <a href="#">show new documents</a></p>	<p><b>This is a modification submission.</b></p> <ul style="list-style-type: none"><li>-Clicking “Show” next to “Modification Form” will expand the sections that the submitter must complete when creating the submission before they alter any sections of the overall application. These are the fields that differ for each submission type.</li><li>Clicking “Show Clean” will expand each individual section for review of content. The linked button will change to show “hide clean” to collapse that section when you are finished viewing it</li><li>To review the documents relevant to this submission, click “show new documents.” Clicking “ show previously submitted documents” is typically only useful for Initial Protocol Reviews that were returned and re-submitted.</li></ul>
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The above screen shot is of the automatic viewing option for a Modification submission, but the overall layout is similar for all submission types.

Important tips:

-Modifications and response submissions have a tracked change function highlighted above. Not all modification submissions or response submissions will have track changes.

-Clicking “Show” next to “Modification Form” will expand the sections that the submitter must complete when creating the submission before they alter any sections of the overall application. These are the fields that differ for modifications, continuing reviews, reportable events etc...

-To review the documents for a submission, click “show new documents.”

- “Previously submitted documents” is typically only useful for Initial Protocol Reviews that were returned and re-submitted.

- Click “Show comments” to see notes from the IRB administrators, members, and reviewers.

-Click “Show IRB correspondence” to see the uploaded IRB approval letter for that submission.

-The automatic viewing option allows you to expand and collapse each section of the application. If you would like to see the entire HS-ERA application on one screen, click “Clean Protocol Application” or “Protocol application w/ tracked changes.”