Human Subjects and Animal Use Frequently Asked Questions

How can I get help?

Q1. If I have a problem with HS or AU (formerly Lab Animals), how can I get help?

Logging on

Q2. What URL should I use to access PennERA’s HS and AU modules? How do I log in?
Q3. What browsers are supported for this software?
Q4. What browser settings are needed to use the PennERA software?
Q5. What do I do if I get the “Page not found” error?
Q6. How long before I get timed out and what do I do?
Q7. Can I log in from more than one window?
Q8. When retrieving a previous page do I click the Back button on my browser?

Finding Information

Q9. How do I find a particular protocol if I don’t know the protocol number?
Q10. How do I search for terminated protocols?
Q11. What canned reports are available?
Q12. Why would I use the Calendar?
Q13. What should I do if, when opening a protocol, I don’t see the entire page?
Q14. Why are Provisions and Comments not in date order on the Summary page?
Q15. How can I find the correct address for a PI?
Q16. What to do if you find a problem in the protocol data?

Entering Data

Q17. How do I enter a new protocol when there is no sponsor specified on the IRB face sheet?
Q18. What sponsor do I pick if it is listed as “in-house”?
Q19. Where do I enter Award ID#?
Q20. Where do I enter the Grant Title?
Q21. What do I enter for Full Title?
Q22. What is the difference between the Full Title and the Short Title?
Q23. Why do I have to select a Department for some PIs?
Q24. How do I process a new protocol that has an Initial Review before getting assigned to a board?

Q25. Where should Miscellaneous/Internal Comments go in PennERA?

Q26. What is the best way to enter dates?

Q27. (Human Subjects) What do I enter into Termination Date?

Q27. Why is my data not saved?

Entering Data – Lab Animals Only

Q28 Lab Animals – What do I put into Planned/Actual Termination Date?

Q29. Lab Animals – Where Do I enter Pain Category?

Sending Email

Q31. How do I send email to a PI?

Q32. How do I indicate the version of a letter or document?

Q33. How do I save email in PennERA?

Q34. When email is sent to a PI from the PennERA software, who is the sender?

Q35. I need a new letter template to be created. What do I do?

Q36. How do I generate a letter?

Q37. How do I make changes to a generated letter?

Agendas and Minutes

Q38. Agenda Troubleshooting

Q39. Minutes Troubleshooting

Q40. What should I enter into Description vs. Provisions vs. Comments?

Q41 Reviewer does not show up on Agendas/Minute

Investigator and Sponsor Maintenance

Q42. What should I tell a PI who needs to update their contact information?

Q43. What do I do if I can’t find the PI in the Personnel pick list?

Q44. What do I do if the sponsor I need is not found in the list?
How can I get help?

Q1. If I have a problem with HS or AU (formerly Lab Animals), how can I get help?
A1. Go to the PennERA website at https://www.pennera.upenn.edu, and click Help in the left navigation menu. The PennERA Help page lists links to reference materials and technical support as well as the phone number for the PennERA Help Line.

Logging on

Q2. What URL should I use to access PennERA's HS and AU modules? How do I log in?
A2. Use the following instructions to log into HS or AU:
   a. Open up Internet Explorer, type in the following URL, and click “Go”:

   https://www.pennera.upenn.edu

   Please bookmark this URL. If you are using Internet Explorer, click on “Favorites” - “Add to Favorites”. To use the bookmark next time, click on “Favorites” and then select this bookmark from the list.

   b. Click on “Logon” in the left navigation menu.

   c. At the PennKey Authentication page, enter your PennKey and PennKey password. In approximately 30 seconds (this is a time-sensitive process), you will see a message saying “successfully authenticated click continue”.

   If you do not see this message, it could be that you took too long to type in your Pennkey and password or your password may not be valid.

   Click on the “PennKey and password” link for help at: https://rosetta.upenn.edu/cgi-bin/websec/websec_authform?app=websecapp-register&login=demo

   If you are still having trouble, contact your LSP for help. If you don't know who that is, LSP listings are at http://www.upenn.edu/computing/view/support.

   d. Once you’re authenticated your PennKey and password, you will see the PennERA Portal page. Click on Protocols in the left navigation menu and then select either Human Subjects or Animal Use Browsers and Browsers Settings.
Q3. What browsers are supported for this software?
A3. Internet Explorer, Netscape, and Mozilla Firefox are currently supported. For more information about supported browsers and the current versions supported at Penn, click on http://www.upenn.edu/computing/product

Q4. What browser settings are needed to use the PennERA software?
A4. From Internet Explorer:

Tools > Internet Options... > click on Settings... button > check “Every Visit to Page” >Advanced tab, and uncheck “show Friendly Http error messages”

and allow pop-ups:

Tools > Pop-up blocker > Turn off Pop-up Blocker

Q5. What do I do if I get the “Page not found” error?
A5. First, check to make sure your browser settings are correct (see Q4 and A4). If they are correct and you are still getting this error, you’ll need to complete a Remedy Web form. The form is available at the PennERA website at https://www.pennera.upenn.edu (click Help in the left menu and then click on the web form on the Help page) and from within the HS & AU modules (click on the Support icon in the top toolbar).

When completing the form, include a detailed description of how you got the error (what you typed, the protocol number, etc.).

Q6. How long before I get timed out and what do I do?
A6. 500 minutes of inactivity will cause you to be “timed out”. The application will send you to the logon screen. When you see this, you should just click on the main URL: https://www.pennera.upenn.edu

and log in again.

Remember to click SAVE or Done so you don’t loose any work:

✔ before you leave your computer
✔ before you switch to other tasks

It’s actually better to click on “Done” so that you do not lock a protocol thereby preventing others from editing it.
Q7. Can I log in from more than one window?
A7. Yes. You can open up multiple windows of the application and consequently be working in one protocol and viewing another in the event that you should receive a phone inquiry.

Q8. When retrieving a previous page do I click the Back button on my browser?
A8. No. You must click the Back icon that’s located in the top toolbar of the PennERA application to return to a previous page. Remember to click the Save icon before using the Back icon or else the changes to the page will not be saved or updated.

Finding Information

Q9. How do I find a particular protocol if I don’t know the protocol number?
A9. From the main page, click the Show icon to access the page where you can enter one or more selections (search criteria) to find protocols that match all of the criteria you entered. After entering your criteria, click Go. The application will retrieve a list of protocol numbers that meet your criteria.

If you are not sure about the PI or exact title of a recently entered protocol, try entering a submission date within 90 days of today’s date and click Go. This will give you a complete list of everything that has been recently entered.

Q10. How do I search for terminated protocols?
A11. To view a list of all terminated protocols, select Terminated & Disapproved Protocols from the Protocols menu, and then click the Go button next to Show All. You can then browse the list for the protocols that you want.

To restrict your search results to terminated protocols that meet certain criteria, use the selections under Or Apply Filters and at the bottom of this page uncheck all the protocol statuses except Terminated and Disapproved.

Q11. What canned reports are available?
A11. “Canned reports” will be available from the InfoView website:

http://zinc.isc-seo.upenn.edu/wi/

Your username is whatever you use when you log into your computer. Your initial password is “change1me”. Click on Corporate Documents from the left navigation menu to see a list of reports that will be available to you.
In PennERA, you can find additional canned reports under:

**Administration > (HS or AU) > Task Management > Reports**

Please note that access to these reports is permissions-based. Please see your HS/AU Modular Administrator if you do not have access.

**Q12. Why would I use the Calendar?**

A12. It provides a quick way to keep track of the number of protocols that are new submissions or that are changed or are expiring.

To see a listing, click on the **Range** drop-down arrow to select **Today's Calendar** or **This Week's Calendar** and click the **Apply** button. The listing will appear at the bottom of the Calendar page. You can use the small calendar to select a date outside of today’s or this week's date.

**Q13. What should I do if, when opening a protocol, I don’t see the entire page?**

A1. Click on the **Maximize** the browser window button (the middle button in the upper-right corner of the browser window).

**Q14. Why are Provisions and Comments not in date order on the Summary page?**

A14. A portion of the review notes is in date sequential order from most recent to oldest. But at the point just prior to conversion: 11/17/03, the review notes coming from InfoEd were loaded at the bottom of each of these sections going from oldest to newest review records, so it appears to be a jumbled up section of dates for both Provisions and Comments.

**Q15. How can I find the correct address for a PI?**

A15. In order for the correct address and contact information to be present when we select a given PI, the PI must have previously updated his/her contact information in the Online Directory. If this has not been done, contact the PI and instruct the PI on how to complete this step as it can only be completed by that individual.

Go to U@Penn at [http://medley.isc-seo.upenn.edu/penn_portal/u@penn.php](http://medley.isc-seo.upenn.edu/penn_portal/u@penn.php) and select **My directory information** under “Personal Resources, Health & Welfare.” Log in using your PennKey username and password. Edit as necessary, save changes and log out.

**Q16. What to do if you find a problem in the protocol data?**

A16. If you think you have found data that was not properly converted or entered, please complete a Remedy Web Form available on the PennERA website at [https://www.pennera.upenn.edu](https://www.pennera.upenn.edu) (click on “Help” in the left menu) or from within the HS & AU modules (click on the “Support” icon in the top toolbar).
Please complete all the fields on the form, and in the Description text box, include a detailed note of the problem including the protocol number, meeting date, if relevant, etc.

**Entering Data**

**Q17. How do I enter a new protocol when there is no sponsor specified on the IRB face sheet?**
A17. Using the Sponsors page, click the Add New button. When the Sponsors pick list displays, click “N” and select “No Sponsor Number” from the drop-down list.

**Q18. What sponsor do I pick if it is listed as “in-house”?**
A18. Using the Sponsors page, click the Add New button. When the Sponsors pick list displays, click “U” and select “University of Pennsylvania”.

**Q19. Where do I enter Award ID#?**
A19. Award ID numbers are entered in the Funding ID Number field located on the Sponsors page.

**Q20. Where do I enter the Grant Title?**
A20. Enter the Grant Title into ERA as the Short Title. The Short Title must match exactly with the title as known by the sponsor. This is especially important for ORS as they must verify that all protocols of a particular proposal have been approved by ORA and therefore qualify for funding from the sponsor. The short title does have a limited number of characters. If you enter too many characters, it is possible that the title will be cut off at the end.

**Q21. What do I enter for Full Title?**
A21. Enter the Full Title as supplied by the PI. In order for the protocol to be assigned an Institutional Protocol number, the Full Title must be entered when the protocol is first created and logged. The Protocol Index Card (located in the top toolbar) is populated from this field. Additionally, the Full Title shows up in important places within the HS and AU modules in such places as the agendas and minutes. The Full Title accommodates an unlimited number of characters.

**Q22. What is the difference between the Full Title and the Short Title?**
A22. The Full title is the title provided by the Principal Investigator on the protocol submission. The Short title is the grant title and contains a length limitation on the number of characters it can be.
Q23. Why do I have to select a Department for some PIs?
A23. In PennERA HS or AU, PI’s or other personnel may be listed with multiple departments. Please make sure to check with the PI to find out which of his/her departmental affiliations is responsible for the work being done on the protocol. The Associated Department is very important because whatever you select here will also be copied down into the “associated department” for the whole protocol. The Associated Department determines access within the Protocol Status Report, which is widely used by the university.

Q24. How do I process a new protocol that has an Initial Review before getting assigned to a board?
A24. In order to capture communications with a PI, it may be necessary to create an Initial Review before the protocol has been assigned to a board. Enter your communication notes via the Review Activities link. Retrieve your protocol, click on Reviews to access the Pre Review page. The Review Activities link is on the Pre Review page right under the Description box.

Q25. Where should Miscellaneous/Internal Comments go in PennERA?
A25. All miscellaneous text, notations, and internal comments should be entered in the Review section of each protocol via the Review Activities link. Retrieve your protocol, click on Reviews to access the Pre Review page. The Review Activities link is on the Pre Review page right under the Description box. 

Click the link to choose what kind of notation you wish to make: incoming correspondence, outgoing correspondence, incoming/outgoing phone message, interoffice correspondence, etc. You have a blank text field in which you can type your notation and save it by clicking Add. It keeps a running list of communication notes there.

Q26. What is the best way to enter dates?
A26. The quickest way is by typing 6 digits, e.g., 111803, or 8 digits, e.g., 11182003. You can also use slashes or dashes to separate the month, day, and year, but this is not required.

Q27. (Human Subjects) What do I enter into Termination Date?
A27. When a Human Subjects protocol is terminated, please enter the date of termination into the Termination Date field located in the Additional Information section on the Summary page. Do this before changing approval status to Terminated (so you can see the value in Approved To while you are entering Termination Date).

Q27. Why is my data not saved?
A27. After entering your information (e.g., either a protocol or review or amendment), click on the application’s Save icon in the top toolbar. Do not click on the browser Back button or else
you will lose your information. You may, however, use the Back button provided by the application.

**Entering Data - Lab Animals Only**

**Q28 Lab Animals - What do I put into Planned/Actual Termination Date?**
A28. Enter the anticipated 3-year Termination Date into the Planned/Actual Termination Date field on the Summary page.

When an Animal Use protocol is terminated, please enter the actual Termination Date into the Planned/Actual Termination Date field on the Summary page. Do this before changing approval status to Terminated (so you can see the value in Approved To while you are entering Termination Date).

**Q29. Lab Animals - Where Do I enter Pain Category?**
A29. You should enter Pain Category only into the Procedures of a group of a Species. Once we get the next version of the LA agendas and minutes, the Max Pain Category entered in any Procedure should be displayed on the agendas and minutes.

Note that the PPM Pain Categories data has been converted into a UDF (user defined field) called **Pain Cat at 11-2003**. This is historical data only.

**Sending Email**

**Q31. How do I send email to a PI?**
A31. In the Review or Amendment screen, click on the Communications Left Navigation bar. Create or build your letter. Once the letter appears in the list of dated letters, you may view the letter by clicking on the Eye Glasses icon and then close the document once you are sure the letter was created correctly.

Now click **Edit**, then click **Add New Player by Role** (or Select New Addressee By Name for when you wish to email someone by name) select role of person, such as PI. It will give you a pop up screen with the name of the PI and click **Select**. Next choose the checkbox Email and To so that it indicates to whom you are sending the document and click Save. Next you must indicate who is sending the document, usually it will be yourself. Select **Select New Addressee By Name** and select your name from the pick list. Next choose the checkbox From and click Save. A list of letters will appear and the word SEND will be underlined to the left of your document’s name. Click **Send** to send the document by email.
Q32. **How do I indicate the version of a letter or document?**

A32. See the Naming Convention Document on the ORA server at 

G:\IRB\upload-download_holdingfile\NamingUploads_Definition-of-Terms_090204.doc

For Human Subject or for Animal Use, go to

G:\IACUC\upload-download_holdingfile\NamingUploads_Definition-of-Terms_090204.doc

**Q33. How do I save email in PennERA?**

A33. You have two options for saving email:

1) Open your email application, highlight the text that you want, and press Ctrl C. Open the protocol, and click on the Review Activities link. When the pop-up window appears, paste the text into the Comments box, and then complete the Status and Date fields. (To access the Review Activities link: Retrieve your protocol, click on Reviews to access the Pre Review page. The Review Activities link is on the Pre Review page right under the Description box.)

2) Using the Save As command within your email application, save the email message to a location on your hard drive. Open your protocol, and click the Add Documents link on the Attachments page via Reviews or Amendments. You can then save the email by using the application’s upload function.

**Q34. When email is sent to a PI from the PennERA software, who is the sender?**

A34. The sender is configurable. The user decides from who the email should be sent.

**Q35. I need a new letter template to be created. What do I do?**

A35. Please contact your HS or LA Administrator with your request. She/He will get it reviewed and approved and uploaded. However, this will probably not happen the same day you make your request. While you are waiting for your letter template to be approved and uploaded, you can use the **miscellaneous letter** template.

**Q36. How do I generate a letter?**

A36. From the Review or Amendment screen, make sure the PI is correct. Some letters (e.g., miscellaneous letter) pull text from the **Comments** field (in the Post Review section at the button of the screen. Make sure **Comments** have been entered in the **Post-review** section of the **Review** or the **Amendment** (only if the letter you will use needs to pull from comments). Click the **[Build Letter]** button from the Review or Amendment screen.
NOTE: If you try to generate a letter and nothing happens — no window pops up -- it could be that you had a letter window opened before and forgot to close it, so it is BEHIND your other browser window. If you think this is the case, find the letter window, close it and then try again to generate your letter.

**Q37. How do I make changes to a generated letter?**

A37. View the letter and save the letter to your desktop. Then edit the document from your desktop and save final changes.

Attach document by uploading the revised version into PennERA by clicking on the REPLACE icon in the Attachments page. The new document will replace existing document.

**Agendas and Minutes**

**Q38. Agenda Troubleshooting**

A38. If you’re having problems with generating agendas, check the following:

- **Agenda yes/no radio buttons** within any of the review/amendment/Adverse Event left navigation menu must be set to **yes**. You may leave the agenda date blank if you do not yet have a date to which you wish to assign the record.

- The Agenda date of the review/amendment/Adverse Event must be correct (For Full Board: agenda date=meeting date, for expedited/designated/exempt review: agenda date will be prior to the review/meeting date).

- The Board assigned to the protocol and responsible for the review/amendment must be correct and match.

- Reviewers must have sequence numbers assigned to their names - reviewers are pulled from review/amendment section, not from the protocol Summary page.

- PI pulls from the review/amendment/Adverse Event, not from the protocol Summary page.

**Q39. Minutes Troubleshooting**

A39. If you’re having problems with minutes, check the following:

- The Agenda date of the review/amendment/Adverse Event must be correct (For Full board: agenda date=meeting date, for expedited/designated/exempt review: agenda date will be prior to the review/meeting date).
PennERA Human Subjects / Animal Use Frequently Asked Questions

- The Board of the Protocol and of the review/amendment/Adverse Event must be correct.

- Reviewers must have sequence numbers – reviewers are pulled from review/amendment, not from the protocol summary screen.

- PI pulls from the review/amendment/Adverse Event not from the protocol Summary screen.

Q40. What should I enter into Description vs. Provisions vs. Comments?

A40. Use the following guide for deciding how to complete each field:

- Whatever you enter into the **Description** field at the top of a Review/Amendment will appear as agenda notes on your agenda and on your minutes.

- Whatever you enter into the **Provisions** field at the bottom of a Review/Amendment will appear as review notes on your minutes.

- Please note that you NO LONGER need to copy/paste agenda notes (from description) into the Provisions field. If you do, duplicated text will appear on your minutes.

- Whatever you enter into the Comments field at the bottom of a Review/Amendment/Adverse Event may be pulled into a letter, depending on which letter you generate. Please do NOT use **Comments** for internal notes and to track various communications with the PI. For internal notes and to track communications, click on the **Review Activities** link (at the bottom of the Pre Review page of the Review/Amendment) and make your notes there.

Q41 Reviewer does not show up on Agendas/Minute

A41. There may be reviewers set in the protocol Summary but none set in the amendment(s) or review meeting(s) of the protocol. In order to have reviewers show up in the agenda/minutes you must add the reviewer(s) to the amendment(s) or review meeting(s).

To add a reviewer(s) to an amendment or review, click on the **Set Reviewers** button from the amendment or review meeting. **Do not set the reviewer from the Summary page.**
Select the reviewer(s) you want added to the review/amendment and be certain there is a sequence number associated with each of the reviewer’s names listed under the Active Reviewers section. Once the above step has been completed click on the Save button.

Investigator and Sponsor Maintenance

Q42. What should I tell a PI who needs to update their contact information?
A42. To update their contact information, an investigator must go into the Genius-Smarts section of InfoEd at

https://www.pennera.upenn.edu

and edit their individual profile as follows:
Click on Genius/Smarts icon to get into the Genius/Smarts module. 
Click Edit Existing Profile
Click General
Make changes (to name, email address, street address, fax number, etc.) 
Save changes
Log out (at bottom of screen)

Q43. What do I do if I can’t find the PI in the Personnel pick list?
Q43. You’ll need to contact the PI and ask if there is a co-investigator, a faculty sponsor, or a Department Chair that you can use as a substitute PI just to get the protocol assigned a protocol number during the time that it will take the real PI to get. Also, ask the PI if they have a Penn ID number and a PennKey. If not, then refer them to the PennERA website at https://www.pennera.upenn.edu so that they can fill out a Penn Community Request for Access form to get a Penn ID# and then instructions to get a PennKey.

Enter the PI’s name into the Full Title of the Protocol and note that you will have to correct this protocol record once the PI is available in the Penn Community which will then be loaded into the Personnel pick list nightly.

Q44. What do I do if the sponsor I need is not found in the list?
A44. You’ll need to request a new sponsor code to be created in the PennERA Sponsor data. Your request must include the Sponsor’s name, phone number, department, and any relevant information such as sponsor name & address, EIN (Entity Identification Number) &/or DUNS # to help uniquely identify the sponsor. Please make this request through your HS/LA administrator.