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Printing a Submission

Q28. Can I print a submission?

Q29. Can I print a PDF version of my submission?
How can I get help?

Q1. If I have a problem with HS-ERA, how can I get help?
A1. Go to the HS-ERA website at https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do, and click Help in the top of the screen. The PennERA Help page at https://www.pennera.upenn.edu also lists links to reference materials and technical support as well as the phone number for the PennERA Help Line.

Q2. How do I schedule an orientation/demo of the system for my department/school?
A2. To schedule an orientation/demo for your department/school, send a request to hsera_help@lists.upenn.edu.

Logging on

Q3. What URL should I use to access HS-ERA’s electronic module? How do I log in?
A3. Use the following instructions to log in:
   a. Open up Internet Explorer, type in the following URL, and click “Go”:
      
      https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do

   b. 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.

   c. Once you’ve authenticated your PennKey and password, you will see your HS-ERA home page.
Q4. What browsers are supported for this software?
A4. Internet Explorer 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

Q5. How long before I get timed out and what do I do?
A5. 60 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://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do and log in again.

Access

Q6. Who will have access to my submission?
A6. As the submitter of an application, you will automatically have edit access to an application until it is submitted if you are not the PI. Anyone named on the application as the PI, Study Contact or Other Investigator will also have edit access. If you would like to retain edit access after an application is submitted and you are not listed as any of the 3 roles described, you should name yourself as the Study Contact of the protocol.

Finding Information

Q7. How can I locate a particular submission? Can I sort my list of submissions on the screen?
A7. Yes. Submissions are ordered by default in date descending order. You may also sort them by type, PI, title, creation date or date of last update.

Q8. How do I find a particular submission, as an administrator, if I don’t know the confirmation number or protocol number?
A8. From the “Find Submissions” screen, 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 “Filter”. The application will retrieve a list of submissions that meet your criteria.

If you are not sure about the PI or confirmation number of a recently entered protocol, try entering a submission date range. This will give you a complete list of everything that has been entered during this timeframe.
Q9. What do I do if I can’t find the PI in the Personnel pick list?
Q9. 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.

Q10. What do I do if the sponsor I need is not found in the list?
A10. 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 pennerahelp@pobox.upenn.edu.

Q11. What should I do if, when opening a protocol, I don’t see the entire protocol’s information?
A11. Not all protocols will appear with its full information. Protocols that were not originally created in HS-ERA will provide basic information retrieved from PennERA. Only protocols created within this application will provide the full details of the protocol.

Q12. How can I find the correct address for a PI?
A12. 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 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.

Q13. How do I get the status of a submission?
A13. Every submission is applied 2 different statuses. To see the status of departmental review, click “Submissions History”, then click on “Recent”. This will give you a listing of all
applications submitted within the last 90 days and their current status. To find the status of an application submitted more than 90 days ago, click on “All”.

To get the IRB review status, click on the eyeglasses then click on “View Protocol Details”. If the IRB has made a decision regarding your submission, the information will appear on the “Basic Info” screen.

Entering Data

Q14. What is the difference between the Full Title and the Short Title?
A14. 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.

Q15. How do I enter a funding sponsor of a protocol when there is no sponsor?
A15. 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.

Q16. What sponsor do I pick if it is listed as “in-house”?
A16. Using the Sponsors page, click the Add New button. When the Sponsors pick list displays, click “U” and select “University of Pennsylvania”.

Q17. Why is my data not saved?
A17. After entering your information (e.g., either a protocol or continuing review, amendment or unanticipated problem), click on the application’s “Save Draft” icon at the top or bottom of the screen. Do not click on the browser Back button or any other link on the screen or else you will lose your information. You may, however, use the “Previous” or “Next” button provided by the application.

Q18. What is the yellow “i” icon for?
A18. The “i” icon is the information icon. Clicking on this icon will give additional information about a subject in the protocol application questionnaire. Use this icon when you are unsure what a question is asking.
Submitting an Application

Q19. How do I submit an unanticipated problem for a protocol that was originally submitted on paper?
A19. From the Protocol Submission Type Menu, select “Unanticipated Problem”. In the box title, “Protocol Number”, enter the institution number of your protocol as assigned by the IRB. The system will retrieve basic information from PennERA about your protocol. You can then complete the application for an unanticipated problem.

Q20. Can I use this application to apply for continuing review of protocols originally submitted on paper?
A20. Continuing review and Modification submissions can be created for protocols originally created within this application only. Any protocol initially submitted on paper must also have any subsequent submissions submitted on paper.

Q21. How is my submission routed for electronic signature?
A21. If you are the submitter of an application and you are not the PI, the submission will first be routed to the PI for approval. Once he/she gives approval, it is routed to the department chair. If the submitter is the PI, it is routed to the department chair only. If the submitter is the department chair, it is routed to the dean. The submission must pass each level of approval before it is sent to the IRB.

Q22. If an electronic notification is sent to another reviewing entity to review my application, do I still need to submit to them?
A22. Members of the other reviewing entities will have view access to review your IRB application. However, if additional information is required, you should follow the guidelines in place for that specific reviewing entity.

Q23. I would like to send a copy of my investigational brochure to the IRB but the application did not ask for it, what should I do?
A23. Any documents that you would like to submit to the IRB with your application can be uploaded once you’ve completed the required sections of your application. On the Submitter’s Assurance screen, click the “Upload” button to attach your documents.
Q24. I made a mistake on my application but I have already submitted, how do I correct it?
A24. Once an application has been submitted for approval, it can no longer be edited. You will need to contact the approver in the route for your application and ask them to reject it. Once rejected, the application will be returned to you where you can make changes and re-submit.

Receiving Notifications

Q25. When email is sent to a PI from the HS-ERA software, who is the sender?
A25. The sender is hsera_help@lists.upenn.edu.

Q26. How do I know if the IRB has received my application?
A26. Once an application has been submitted and has received departmental approval, you will receive an electronic notification stating that your application has been received by the IRB. Your submission will also appear in the system with a status of “Approved and Submitted to ORA”.

Q27. What other electronic notifications can I expect to receive from the system?
A27. You will receive notifications when a departmental approval/rejection has been given to your application as well as when the IRB has received it.

Printing a Submission

Q28. Can I print a submission?
A28. Yes. To print a submission, click on the eyeglasses next to the submission to be printed. Then, click on the “Printer Friendly” button in the upper right-hand corner. You can now use your browser’s print functionality to print your document.

Q29. Can I print a PDF version of my submission?
A29. No. Currently, the application does not allow for PDF generation. This functionality will be available in Release 2 of the software.