HS-ERA Frequently Asked Questions

I am ready and excited to create a submission in the HS-ERA system!

Q: I do not have access to the HS-ERA system in general. How do I get access?

A: Your Business Administrator will most likely need to add a research affiliation to your Penn Community profile (where your payroll information is managed). If this is completed and the problem persists, then please email the HS-ERA help desk (hsera_help@lists.upenn.edu) and provide a valid Pennkey and PennCard ID number.

Q: I cannot find the HS-ERA system. How do I find the URL address?

A: Go the Office of Regulatory Affairs website (http://www.upenn.edu/regulatoryaffairs). In the blue navigation bar to the left of the screen, click “IRB”. In the third blue horizontal bar on the top of the screen, click “Forms Page”. You will find the link in the table under “Electronic Submissions”.

![Image of HS-ERA website](http://example.com/hsera.png)
**I am ready to create a new submission!**

Q: I am a coordinator but my name is not in the list of Study Personnel. How can I add myself?

A: You will need to submit a request to the HS-ERA help desk ([hsera_help@lists.upenn.edu](mailto:hsera_help@lists.upenn.edu)) with your name, department, and PennCard ID number.

Q: How can I update my contact information in the system?

A: You can do this by updating the Online Penn Directory.
   1. Go to the Penn Directories ([http://www.upenn.edu/directories/](http://www.upenn.edu/directories/)).
   2. Click “Update Directory Listings”.
   3. Log in with your Penn Key and Password.
   4. Update your address details in the “Manage Penn Profile” section.
   5. If more than one address is listed for an investigator/coordinator in the Penn Profile section, the individual must choose the address they would like to use as the “Primary” address.

Note: The Primary Address must be complete (including street address, city, state, etc) to pull into Penn ERA/HS-ERA. If the address is missing an element (like city or state), then Penn ERA will default to the PAYROLL address for this individual, which may be outdated.
Q: HS-ERA does not reflect my current human subject training expiration date. How do I fix this?

A: Please email the HS-ERA help desk (hs era_help@lists.upenn.edu) with your current human subject training certificate. We will update knowledgelink so that your current expiration date is updated in HS-ERA.
Q: My sponsor is not in the list of Funding Sponsors. How can I add this?

A: You will need to submit a request to the PennERA help list (pennerahelp@lists.upenn.edu) with the Sponsor’s name, address, contact info and contact person.
Q: I have a grant that is funding my project, so I clicked “Yes” under the “Project Funding” section of the H-SERA application. However, when I click “set” to select my proposal, it is not listed. How do I link my grant proposal to my protocol?

A: You need the eight digit grant number. You can get this number from your Business Administrator. If the grant number is unavailable at the time of initial submission, you should select “pending” for project funding. When you obtain the eight digit grant number, you will have to create a modification to add the grant number and upload the grant application.
I have created and submitted a new submission.

Q: Why has the submission not been received by the IRB when it has been submitted a while back?

A: It’s most likely because it is awaiting the PI or the Department Chair’s approval. To check the status of a submission, click “Recent” under the “Submissions history” menu option. It will indicate what is still pending, under “Status”.

![Image of IRB Submission webpage]
Q: My PI is having trouble approving a study I submitted for his/her review. How can I help?

A: Provide your PI with the following instructions:


2. In the blue navigation bar to the left of the screen to locate the submission, click “View pending” under the “My submission approvals” menu option.

3. After reviewing the submission, click “Submit a decision” and either certify (click the green “approve” button) or reject (click the red “reject button).
Q: Why is the submission pending approval by someone else other than my Department Chair?

A: It’s most likely because the “Responsible Org” designation was incorrectly selected within the application or the routing setup is outdated. If you have already checked and confirmed that the correct “Responsible Org” has been selected, you will need to submit a request to the HS-ERA help desk (hsera_help@lists.upenn.edu) with the PI’s name, submission title, confirmation code, and the name of the Department Chair to whom you would like this study to be re-routed.
Q: Can an email notification be re-sent if the PI or Department Chair did not receive notification the first time around?

A: No, the notification is automated within the system and cannot be re-sent. They will need to be manually notified that the submission is awaiting their approval and provided with the following instructions:

2. In the blue navigation bar to the left of the screen to locate the submission, click “View pending” under the “My submission approvals” menu option.
3. After reviewing the submission, click “Submit a decision” and either certify (click the green “approve” button) or reject (click the red “reject button).

Q: My protocol has been returned to me with stipulations. Where can I find my submission to edit it?

A: When a protocol is returned with stipulations, a draft version of the submission will be opened for you to edit. In the blue navigation bar to the left of the screen, click “Items to be resubmitted” under the “My submission approvals” menu option to edit the draft version.

Note: Do not delete this draft version that has been re-opened to you for editing or the link will be broken and you will need to recreate the draft manually. You should only delete a draft if you have decided to no longer submit this action to the IRB.
I would like to create a modification for this study.

Q: If I was the original submitter of a protocol, why am I no longer able to edit?

A: It’s most likely because you were not listed as either the PI, study contact, or other investigator within the study personnel section of the application. One of the above people will need to create a modification adding you as a study contact.

Q: I have access to the general HS-ERA application. How do I get access to individual protocols?

A: Someone who currently has edit access to the protocol (i.e. individuals listed as PI, study contact, or other investigator) will need to create a modification request to add you onto the application and submit for each respective protocol.

Note: Individuals listed as “key study personnel” will only have view access.

Q: When I have to make modifications to the protocol, do I also have to modify the online application?

A: Yes. The revisions you made to the online application will show as track changes to the IRB administrator.

Q: I have revised the consent form document. Should I delete the currently uploaded consent form from the online application?

A: Yes, when submitting a new modification to the protocol, you should delete any documents that are not associated with this specific modification. Previously reviewed and approved documents are saved with the submission with which they were sent.
I would like to create a request for continuing review for this study.

Q: The documents that automatically uploaded into my continuing review submission are not the most recently approved documents. Can I delete these documents and upload the currently approved documents?

A: Yes, you should review each document that automatically uploads into your CR submission and remove any that are not the most recently approved documents. Then you should upload the most current document versions.
The study is over!

Q: What do I need to do to close a trial?

A: You will need to create a continuing review request by clicking “Create” under the “My submissions” menu option and then clicking “Continuing Review”. Then check off for study closure within the application.
But I still have so many questions…

Q: My PI did not approve my submission draft. When I go into “Items to be resubmitted”, there is no edit button. How do I edit the protocol?

A: When your PI clicked the “reject” button, he/she was automatically routed back to the submission. Please let the PI know that after the protocol is rejected, he/she should then click “Save draft” to re-open the draft for you to edit.

Note: If your PI has already rejected and logged out, then you will need to email a request to the HS-ERA help desk (hsera_help@lists.upenn.edu) with the PI’s name, submission title, confirmation code, and the request to unlock the protocol.
Q: If a protocol was originally submitted via paper submission, can I submit a modification or continuing review via HS-ERA?

A: No. If your initial submission was submitted via paper, then all subsequent actions must be submitted via paper. Similarly, if your initial submission was submitted via HSERA, then all subsequent actions must be submitted via the HS-ERA system.

Note: You can submit reportable events via the HS-ERA system for both paper studies and HS-ERA studies. However, if you need to submit a modification as a result of the reportable event action, then you must submit this modification according to how the initial submission was submitted (paper or HS-ERA).

Thanks from your friends at the IRB!