Institutional Review Board
3800 Spruce Street
First Floor Suite 151
Philadelphia, PA 19104-6006
Phone: 215-573-2540

Reliance Agreement Guidance:

How to Apply for External IRB Review

This document provides step by step instructions on how to submit a request for the Penn IRB to rely on an External IRB using the HS-ERA submission system. It is expected that this document will be most helpful to research staff that will be submitting reliance agreement requests to the Penn IRB. However, Penn Investigators, other research support staff, and individuals affiliated with other IRBs may find the information in this guidance document to be helpful.

If you have more general questions about the Reliance Agreement Process, please view the Reliance Agreement Guidance: External IRB Review FAQ

This document will not be helpful to individuals who are asking Penn to serve as the IRB of Record for other sites.

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Note regarding this guidance document

The following is a description of the most common way that reliance agreements are executed at Penn. It does not apply to all requests. If you believe that the following steps are not applicable to your study, it is recommended you discuss the request with the Penn IRB prior to creating your first submission.

Step 1: Preliminary conversation with the Penn IRB Points of Contact (optional)

If you already know that Penn is willing to rely on an external IRB for your study, then you should skip this step and move on to Step 2. If you are not sure that Penn will rely on an external IRB, you should contact the IRB via phone or email to discuss the request. Please reach out to one of the individuals listed as a reliance agreement point of contact on the IRB website.

You should have the following before contacting the IRB:

- A copy of the study protocol. This can be a draft document if the central IRB has not yet reviewed and approved the study.
- The name of the external IRB that will serve as the IRB of Record
- The name of the Penn Principal Investigator

The IRB contact will review the information provided and let you know if we are willing to rely on the external IRB. You should then continue to work with that IRB contact as you draft your reliance agreement request. The contact will be able to answer any questions you may have as you work through the process.

Step 2: Compiling Required Documents

In order to complete its review, the Penn IRB will need to review the documents listed below. It is recommended that you compile the following documents before submitting to the Penn IRB:

- The Study Protocol
- The Investigator's Brochure, Package Insert, or Device Brochure (if applicable)
- The IRB Authorization Agreement that will be signed by the Penn IRB and the External IRB *(This document may not be required. The IRB of Record determines how the reliance agreement will be documented. If you are not sure if this document is required it is recommended you contact the Penn IRB for assistance.)*
- The completed and signed PI Assurance Form
- The Informed Consent Form
- The Protocol Supplement for Requests to Rely on an External IRB

Step 3: Creating an application through HS-ERA

1. Log in to HS-ERA
2. On the left-hand side of your screen, click the "Create" link under "My Submissions"
3. On the "Protocol Submission Type – Choose" screen, click the "Initial Review" link
4. On the "New Initial Review: Choose" screen, click the "Reliance agreement request" link

Step 4: Completing the "Basic Info" Page

- The Protocol Title should be the full title as listed on the Protocol and Consent form. This is the title that will be listed in your acknowledgement letter.
- The Short Title should be an acronym or an abbreviated title that the IRB staff can use when referring to the study in external communications.

- Brief Description of the protocol – Please begin this section by stating that you are requesting a reliance agreement with an external IRB (you may include the name of the central IRB but this is not required). Then provide a brief description of the study.

Step 5: Completing the "Personnel" Page

- Please complete this page as you normally would for any other IRB application
- Remember that only those listed as PI, Study Contact, and Other Investigator can edit the application and create submissions for the study in the future.
- Please identify any significant financial interest as you normally would for any other IRB application.
- Please note that, per the terms of an IRB reliance agreement, Penn's Conflict of Interest Standing Committee and the Penn IRB will conduct the financial interest review per standard institutional policies and practices. However, you may be required to share information about the disclosure and the management plan with the Central IRB. Investigators should review the central IRB's conflict of interest review policies and make themselves aware of their obligations.

Step 6: Completing the "HRPP" Page:

- This page is identical to the Bio page that appears in the standard IRB biomedical application. Please complete this page as you normally would for any other IRB application
- Please note that ancillary committee reviews are still required for studies where an external IRB is serving as the IRB of Record. Please make sure that you answer the Ancillary Review committee questions appropriately and follow up with the ancillary committees regarding their review if you have any questions about their processes.

Step 7: Completing the "Sponsor" Page:

- Please complete this page as you normally would for any other IRB application.
- Please make sure you complete the Department budget code section. For industry sponsored studies, the IRB does charge a one-time initial administrative review fee to execute a reliance agreement. For Federally Funded and Internally Funded research, no fee is charged for the execution of a reliance agreement where Penn is relying on an external IRB.
- For FDA regulated research, please make sure you identify both the funding and regulatory sponsor for the project.

Step 8: Uploading Documents to the "Confirmation" Page:

- Please upload all the documents you are submitting as part of the reliance agreement request.
  This must include the following:
  - The Study Protocol
  - The Investigator's Brochure, Package Insert, or Device Brochure (if applicable)
  - The IRB Authorization Agreement that will be signed by the Penn IRB and the External IRB *(if applicable)*
  - The completed and signed PI Assurance Form

- The Informed Consent Form
- The Protocol Supplement for Requests to Rely on an External IRB

Step 9: Editing the Informed Consent Form

1. The sponsor or lead site will likely provide you with a consent form template that has been approved by the Central IRB. You can edit this template consent form. You do not need to use the Penn template consent.
2. The template consent form will have several placeholder sections where you can input Penn specific information. Please complete all those fields.
3. Please make sure the consent form has the appropriate Penn template language that applies to your research. For additional information on what template language may be applicable please see the Reliance Agreement Guidance: Requirements for External Consent Templates.

Step 10: Completing the Protocol Supplement for Reliance Agreements

1. Go to the Forms Page of the IRB Website
2. Download the document titled "Protocol Supplement for Requests to Rely on an External IRB"
3. Please follow the instructions within the form to complete the document.
4. When completed, please ensure that all the blue text has been removed and then upload the completed form to the HS-ERA application.

Step 11: Completing the IRB Authorization Agreement

1. Please check with the central IRB or the lead site to see how they prefer to document the reliance agreement. The central IRB may request that a protocol specific IRB authorization agreement be executed and request that you complete their preferred template. An authorization agreement may not be necessary if the agreement is being conducted under the SMART IRB agreement or another Master Agreement between Penn and the central IRB. If you are not sure how to document the reliance agreement, it is recommended that you contact the Penn IRB for assistance.
2. If the central IRB provides you with a template IRB authorization agreement form to complete, you should use this form. If this is the first time you are executing an agreement with this Central IRB we recommend that you reach out to the Penn IRB before submitting in HS-ERA to see if there are any issues with using the Central IRB'sagreement template.
3. If the central IRB or lead site is willing to use Penn's IRB Authorization Agreement, you should go to the Forms page of the IRB website and download the document titled "IRB Authorization Agreement."
4. Whichever version of the form you use, it will require you to provide some information about the Penn IRB. Below are the commonly requested fields and the information you should input:
   a. Institution Name: University of Pennsylvania
   b. Federalwide Assurance Number: FWA00004028
   c. IRB Registration Number(s): IRB00000038; IRB00000039; IRB00000040; IRB00000041; IRB00000042; IRB00000043; IRB00000044;IRB00002997
      - Note: you should include all 8 of these numbers in the form.

d. Office Name: University of Pennsylvania Institutional Review Board

e. Address: 3800 Spruce St. First Floor Ste. 151 E, Philadelphia, PA 19104

f. Phone: 215-573-2540

g. Fax: 215-573-9438

5. The form will also ask you to identify and provide contact information for a Signatory Official. Please leave these fields blank. The Penn IRB will complete these fields.
6. There may be other fields requesting information about the study and the Principal Investigator. Please complete these fields.
7. If the form requires the PI signature, please upload a signed copy of the form to the HS- ERA application.

Step 12: Completing the PI Assurance Form

1. Go to the Forms Page of the IRB website
2. Download the form titled "Principal Investigator Assurance."
3. Review the document as it outlines the investigator responsibilities if Penn is relying on an external IRB.
4. Have the PI sign and date the form.
5. Upload the completed form to your HS-ERA application.

Step 13: Completing the "Confirmation Page"

After uploading all the documents previously described, click the "I accept" button to complete the submission. The submission will be routed to the PI then the Department Chair associated with the chosen Responsible Org for approval before it will be received by the IRB.

Step 14: Penn IRB Review of your HS-ERA Application

1. Your application will be assigned to a member of the Penn IRB's Reliance Agreement Team. They will assign a Penn IRB Protocol Number to your study.
2. The IRB will review the submission to determine the following:
   a. Whether we are willing to rely on the External IRB identified.
   b. The application is complete and contains the required documents.
   c. The consent form includes applicable required Penn template language.
   d. All applicable institutional policies and state and local requirements have been incorporated into the study.
3. If there are any issues identified, the application will be returned to you in HS-ERA with a list of concerns for you to address. You will be notified of this via email. Once you address the issues and resubmit, the application will be reassigned to the IRB staff who screened the first submission.
4. Once all the issues have been addressed the IRB will formally acknowledge the submission and sign the IRB authorization agreement. An acknowledgment letter and signed agreement will be provided.

Step 15: Submission to the External IRB

1. Please consult with the External IRB (also referred to as IRB of Record/Central IRB/Single IRB) or the lead site to determine if any applicable ancillary committee reviews (RRSC, CTSRMC, CAMRIS, etc.) should be completed before you submit your revised documents for review and approval.
2. You should submit the study documents to the external IRB for their review and approval. The central IRB, CRO, or lead site team should be able to help you through this process.
3. Once the documents have been approved, the central IRB should provide you with a copy of the IRB authorization agreement that is now signed by both IRBs, their approval letter, and the stamped consent form.

Step 16: Forwarding external approval to the Penn IRB

1. Create a modification to the reliance agreement request in the HS-ERA system.
2. Upload the documents provided by the Central IRB.
3. Submit the modification to the Penn IRB.
4. The Penn IRB will acknowledge receipt of the documents and change the status of your protocol to Approved. This will allow you to complete the remaining steps in the site initiation process and begin enrolling subjects.

I have other questions. Where do I go?

Please contact any member of the IRB Reliance Agreement Team with any questions or issues you may have with the reliance agreement process. For complete information see the IRB website.