Penn | Human Research Protections Program
University of Pennsylvania

Institutional Review Board
Phone: 215-573-2540

Reliance Request 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 eIRB 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 submission.

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 whether 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 move forward.

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 Informed Consent Form

Creating an application through eIRB

Detailed instructions and guidance on how to navigate the eIRB system are posted on the How to Submit an Initial Page of the Penn IRB website. In addition, you should review the eIRB Researcher Training Module for step by step instructions. This document will not provide step by step instructions on how to complete the eIRB website. However the following sections of this document will identify some key fields that you should be aware of as they are specific to the reliance agreement process.

Completing the "Research Team" Panel

- Please use the "Add Researcher" button to identify the Penn Personnel who make up the study team team.
- Please note that any member of the study team, regardless of Project Role, can be given edit access. Selecting the Edit permission option allows the individual to update the application and create submissions for the study in the future.
- Identifying study team members as Study contact means that they will be notified of IRB actions and copied on IRB correspondence regarding this protocol
- Please note that Penn's Conflict of Interest Standing Committee and the Penn IRB will conduct a financial interest review per standard institutional policies and practices. However, if a significant financial interest is present and related to this research, 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.

Completing the "Review Type Determination" Panel:

- The Review Type Determination Panel of the eIRB application is where you will indicate that you are asking Penn to rely on an external IRB. Please select "Yes" to the "Is this a request to rely on an external IRB" field.
- Select "Add IRB of Record" to designate the IRB that you are asking Penn to rely on. If the IRB does not appear in the list select the "Can't find Relying Site – add new Relying Site" option. Complete the name and country fields. You do not need to list IRB Contact Name or Email.
- If Penn does not have a Master Agreement already executed with the central IRB, please update the "Reliance Agreement" field by uploading a copy of the IRB Authorization Agreement form that the central IRB would prefer to use to document the reliance agreement.

Completing the "Protocol Description" Panel:

- Please answer "Yes" to the "Is there a standalone protocol…" question.
- All reliance agreement applications should have a standalone protocol document uploaded to their application. If you received a protocol document from the sponsor or lead study site, please upload it to the "Research Protocol" phase. If a standalone protocol is not available, please upload a copy of the IRB application submitted to the central IRB. Please contact the IRB if you have any questions about how to complete this field.

Completing the "Recruitment" and "Clinical Trials" Panels:

- Please provide a Penn specific recruitment plan in your eIRB application. The standalone protocol document is unlikely to provide Penn specific details in its description of recruitment strategies across all study sites.

Completing the "Informed Consent" Panel:

- If you will be enrolling subjects, please upload a copy of the consent form that has been edited to include institutionally required language. Please see the "Editing the Informed Consent Form" section below for additional information.

Completing the "Risks and Benefits," "Privacy & Confidentiality," and "Connected Project" Panels:

- Please provide a Penn specific confidentiality plan in your eIRB application. The standalone protocol document is unlikely to provide Penn specific details in its description of confidentiality measures implemented across all study sites.

Completing the "Human Research Protections program (HRPP)" Panel:

- 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

Uploading Documents to the "Additional Documents" Panel:

- Please upload any other documents you are submitting as part of the reliance agreement request. **This may include the following:**
    - The Investigator's Brochure, Package Insert, or Device Brochure (if applicable)
    - Other Participant Materials (such as recruitment materials)
    - Any Local Context Forms provided by the central IRB
- The following documents should have been uploaded to the application in the panels detailed above. Please make sure that these documents are included in your application prior to submission:
    - The Standalone Protocol Document
    - The IRB Authorization Agreement that will be signed by the Penn IRB and the External IRB (if applicable)
    - The Informed Consent Form

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.

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's agreement 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 agreement 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; IRB00008395; IRB00000015
        - Note: you should include all 10 of these numbers in the form.
    d. Office Name: University of Pennsylvania Institutional Review Board
    e. Address: 3600 Civic Center Blvd, 9th Floor, 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 application.
8. In some circumstances, the IRB of Record may request that a Local Context Form be completed by the study team and/or the Penn IRB. Please complete as many fields in this form as you can. If you are unsure how to answer certain questions, you can leave them blank. Please include this form in your HS-ERA application. The Penn IRB will review your answers, complete any blank fields, and sign the form as part of the review process.

Submitting the Application

After uploading all the documents previously described, click the "Submit for Approval" button to complete the submission. If any required fields were left blank or errors were identified you will see a red text box with

details on what additional requirements need to be met. If there are no errors to address, 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.

Penn IRB Review of your eIRB Application

1. Your application will be assigned to a member of the Penn IRB's Reliance Agreement Team.
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 eIRB with a list of concerns for you to address. You will be notified of this via a notification within eIRB and via email. You will also receive a task in eIRB to update your record. 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 issue a Reliance Accepted review decision. As needed, the IRB will sign the IRB authorization agreement. A Reliance Accepted letter and signed agreement will be provided. The initial submission will be returned to you for response.

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. The initial submission will have been returned to you in the eIRB system.
2. Upload the documents provided by the Central IRB.
3. Re-submit the updated application to the Penn IRB.
4. The Penn IRB will acknowledge receipt of the documents and change the status of your protocol to Approved Relying. 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.