Relying on an External IRB

A guide on the process for submitting and finalizing an IRB authorization agreement.

When is the agreement appropriate?

Under certain circumstances, the Penn IRB may rely on an external IRB to provide initial IRB review and ongoing regulatory oversight in order to avoid duplicative IRB reviews.

- The Penn IRB is willing to rely on an external IRB under the following scenarios:
- CHOP is willing to serve as the IRB of Record through a Penn/CHOP Agreement
- Study is a Phase III industry sponsored protocol and a Central IRB has been designated
- Study is a federally funded, multi-site clinical trial and the lead site is serving as the Central IRB
- Multi-site study where Penn is not enrolling subjects but is engaged in other research related activities and the lead site is willing to serve as the IRB of Record.

The Penn IRB is willing to consider relying on an external IRB for other protocols that do not fit these scenarios. These determinations will be made on a case by case basis.

The following slides describe the steps you should take to put an agreement in place.
Step 1: Preliminary Discussion

If you would like the Penn IRB to rely on an external IRB, you should first contact the Penn IRB to see if we are willing to put an IRB Authorization Agreement in place.

Contact Tracy Ziolek, Megan Kasimatis Singleton, or Patrick Stanko for this initial discussion. Contact information is available on the IRB website.

The only material needed at this time is a copy of the clinical protocol. If a protocol is not available, provide the IRB with another written summary of the study. This document can be submitted via email. You do not need to complete a formal electronic or paper submission at this time.

After this review the IRB will provide you with the following information:
- Confirmation of whether or not we are willing to rely on an external IRB
- Instructions on how to complete the next steps

Occasionally, the external IRB may require that the Penn IRB sign a form indicate their willingness to defer to the external IRB. This form is different than an IRB Authorization Agreement. The Penn IRB will sign this form and provide a signed copy for you to give to the external IRB.

Step 2: Formal submission of the agreement

The IRB strongly recommends that you submit your formal request for a reliance agreement electronically through the HS-ERA system. This will allow your application to be shared with other ancillary committees that may need to review the protocol. If you are unable to submit through HS-ERA or would prefer not to use the system, a paper submission process is available.

Instructions for Electronic Submissions:
- You should create a standard expedited or convened IRB application using the HS-ERA system. As you move through the pages, you should complete the first half of the application (from the Basic Description Page to the Sponsor Page) in the same manner you would for any other IRB application.
- You do not need to provide protocol specific information to answer the questions that are on the second half of the application (from the Protocol through the Risk/Benefit pages). You only have to indicate that the application is a request to execute a reliance agreement with an external IRB.

Instructions for Paper Submissions:
- You should go to the Forms Page of the IRB Website and download the “Request Form/Facesheet for External IRB Reliance Agreements.” You will complete this form and have it signed by the Principal Investigator and the Department Chair. It will take the place of the electronic application.
Step 2: Protocol Documents

In addition to the completed application form, you will need to provide additional study documents. They can be uploaded on the confirmation page of the HS-ERA application or provided as attachments to the Paper Facesheet.

You should include the following documents:
1. the protocol,
2. any investigator’s brochure or operations manual for the drug/device,
3. any recruitment materials that will be used at Penn.

Step 2: The Informed Consent Form

You will also need to include a copy of the consent form. You can use External IRB’s approved consent form template but you should revise the form to include the Penn required template language such as:
1. Penn contact information,
2. Penn’s HIPAA language,
3. the EMR language,
4. language about local and state law requirements (e.g. reportability of infectious diseases if you will test for HIV, hepatitis, etc.),
5. research related injury language.

Note: You are NOT required to re-format the central IRB’s consent template so that it aligns with the UPenn informed consent form template.
Step 2: Authorization Agreements

You will also need to upload the IRB authorization agreement that will be used to execute the reliance agreement. On the forms page of the IRB website, you can download the IRB Authorization Agreement Form and use that template to put the agreement in place. If the central IRB has an Authorization Agreement Form they would like you to use, then you can upload that document in place of the Penn Template.

In addition, you should download and complete IRB Authorization Agreement (IAA): Addendum 1 – Principal Investigator Assurance document. This form outlines the PI’s requirements while the study is ongoing.

Step 2: Submission to IRB

Once these materials are prepared you should submit them to the IRB staff. The IRB will conduct an administrative review. IRB staff will contact you with any questions or requests for revisions. The submission will not be scheduled for a convened IRB meeting.

After this review the IRB will provide you with the following information:
• A signed copy of the IRB Authorization Agreement
• Instructions on how to complete the next steps
Step 3: Finalizing the Agreement

HS-ERA and PennERA will not indicate that the study is approved until the IRB authorization agreement has been signed by both IRBs and the external IRB has given you an approval letter with a stamped consent form. While this process is underway, the external IRB or central site may send you additional documents for acknowledgment by our IRB.

This could include:
- A copy of the IRB authorization agreement (and any necessary addendums) that has been signed by the external IRB.
- Revised consent forms or other study documents
- Other notifications that need to be acknowledged by the Penn IRB.

You can submit these documents to the Penn IRB as modifications. The IRB will review these documents and provide you with acknowledgment letters.

Step 3: Finalizing the Agreement (Continued)

Once the study has been approved by the external IRB, please submit a copy of that external IRB approval letter. Once that letter has been acknowledged by the IRB, the IRB will update the protocol status from acknowledged to approved and align the expiration dates with the dates provided in the external IRB approval letter.

Note: The Penn IRB will not issue an approval letter or a stamped consent form for these protocols. Those documents will be issued by the external IRB.
Step 4: Ongoing correspondence

Most modifications and other reports will not need to be submitted to the Penn IRB for review. However you will have to submit the following to the Penn IRB:

- Continuing review approval letters from the external IRB.
- Notifications of any reportable events that have occurred at Penn.
- Notifications of any deviations that are referred to the convened external IRB for review.
- Penn Personnel Changes.
- Notifications of potential conflicts of interest.
- Modifications to the research related injury section of the informed consent form.

You can submit these notifications to the Penn IRB as modifications. The IRB will review these documents and provide you with acknowledgment letters.

Special provisions for when Penn is not an enrollment site

If Penn will not be enrolling subjects but is still engaged in research, we are willing to rely on the lead site IRB. In this scenario, you should consider the following:

1. Please submit a cover letter to the IRB that details the specific roles the study team will complete for this project.
2. A revised consent form is not required. You can submit the blank template consent from the lead site.