

## Reliance Agreement Guidance:

### SMART IRB Agreement FAQ

This document is designed to answer questions frequently asked about the SMART IRB Master Reliance Agreement and how it is implemented at Penn. It is expected that this document will be most helpful to Investigators and research staff that are executing reliance agreements between Penn and other academic centers. However, other research support staff and individuals affiliated with other IRBs may find the information in this guidance document to be helpful.

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## **1. What is the SMART IRB agreement?**

SMART IRB is an initiative developed under an award from the National Center for Advancing Translational Sciences of the National Institutes of Health to support single IRB review for multi-site human subjects research. The SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) is a master IRB authorization agreement that has been signed by over 400 institutions. It sets terms and conditions upon which any of the participating institutions can rely on each other's IRBs.

This agreement was created to facilitate reliance agreements by avoiding circumstances where IRBs needed to review and negotiate the terms of every reliance agreement for every protocol. The SMART IRB agreement avoids that step because the participating IRBs have already signed the agreement and accepted its terms.

Additional information about the SMART IRB agreement can be found here: <https://smartirb.org/>

## **2. Has Penn signed onto the SMART IRB agreement?**

Yes. The Penn IRB signed onto the SMART IRB agreement and it is currently in use at Penn. We have used the SMART IRB agreement to execute reliance agreements both when Penn has served as the IRB of Record and when Penn has agreed to rely on other external IRBs.

## **3. Who else has signed onto the SMART IRB agreement?**

Over 400 participating institutions have signed the SMART IRB authorization agreement. The majority of these institutions are academic centers and hospitals that conduct human subjects research. A searchable list of institutions that have signed the agreement is available here: <https://smartirb.org/participating-institutions/>

## **4. How is the SMART IRB different from other IRB Authorization Agreements?**

The agreement includes specific terms and conditions for how the reliance agreement will operate and the responsibilities of both the IRB of Record and the Relying Site IRBs. This allows Reliance Agreements to be executed in a more streamlined fashion.

Typically, when a new reliance agreement is put in place, the IRBs have to negotiate terms and responsibilities. In some circumstances, the agreement may need to be reviewed by an institution's Office of General Counsel. This can slow down the reliance agreement process for your protocol.

However, this negotiation is not required if you use the SMART IRB agreement because the terms and responsibilities are already set and agreed to by all the sites that have signed onto the agreement. All that is needed is verification that the IRBs involved agree to apply the SMART IRB agreement to your protocol.

## When Penn is relying on an external IRB

### 5. How does Penn use the SMART IRB to rely on other external sites?

The Penn IRB does not automatically apply the SMART IRB agreement to requests to rely on external IRBs. The decision about whether or not to use the SMART IRB agreement is typically made by the lead research team in consultation with the IRB of Record.

If the lead site and the IRB of Record have determined they want to use the SMART IRB agreement, the research team or the IRB may do any of the following:

- Reach out to the Penn IRB directly to determine if Penn will rely using the SMART IRB agreement
- Reach out to the Penn investigators and request that the Penn team contact the Penn IRB about relying per the SMART IRB agreement
- Send requests to the Penn IRB via the SMART IRB Online Reliance System or SMART IRB Exchange.

If any of the above actions occur, it is important that you remember the following:

- The Penn IRB will likely be willing to rely on the IRB of Record per the SMART IRB agreement
- Both the Penn IRB and the Penn research team need to be aware of the request before it moves forward
- Additional action will likely be needed after the reliance agreement is reached

The specific steps that will be taken to finalize the agreement are going to depend on how the lead team and the IRB of Record want to proceed. The Penn IRB will be flexible and work with all parties to make this process as smooth as possible. Therefore, it's important that the Penn research team and the Penn IRB reliance agreement team be in close contact to make sure that everyone is aware of the steps that need to be taken.

Please remember that if you receive a request to use the SMART IRB, you should reach out to the Penn IRB reliance agreement team to determine the appropriate next steps. If the Penn IRB receives a request directly, they will reach out to the Penn research team to make sure they are aware of the request.

### 6. Does my HS-ERA reliance agreement application look different if I'm using SMART IRB?

It is important to remember that if Penn agrees to rely on another IRB using the SMART agreement, you still need to create a reliance agreement application in HS-ERA. You would create this application the same way you create any request to rely on an external IRB.

The only difference in the process is that if the SMART IRB agreement is being used, an IRB authorization agreement document should not be included in your application. In place of the IRB authorization agreement you should include documentation that the SMART IRB agreement is being used.

### 7. How do I document that Penn is relying on another site per the SMART IRB?

The use of the SMART IRB agreement can be documented in multiple ways. Here are some of the common ways that the use of the SMART IRB agreement has been documented:

- The team used the SMART IRB Online Reliance System and that system disseminated an email to all sites confirming that a reliance was fully executed in that system.

- The team used the SMART IRB Exchange System and that system disseminated an email to all sites confirming that a reliance was fully executed in that system.
- A form was signed by both IRBs to indicate that they agree to execute the reliance agreement per the terms of the SMART IRB agreement
- A letter was drafted by the Penn IRB to indicate that they agree to rely on the IRB of Record per the SMART IRB agreement.

Any of these documents can be considered documentation of the use of the SMART IRB agreement. If you have received one of these documents or something similar, you should include it in your HS-ERA reliance agreement application in place of an IRB authorization agreement.

If none of the above documents have been given to you, you can still complete your HS-ERA application. In that application you should make it clear that you are asking Penn to rely on the IRB of Record per the terms of the SMART IRB agreement.

Once the IRB has completed its administrative local review, you will be provided with an acknowledgment letter clearly stating that the SMART IRB agreement will be used.

## **8. What is the electronic SMART IRB reliance system?**

There are two online platforms that have been developed to assist researchers and IRBs with executing reliance agreement using the SMART IRB agreement. They are:

- The SMART IRB Online Reliance System: <https://smartirb.org/reliance/>

\*And\*

- The SMART IRB Exchange: <https://trialinnovationnetwork.org/smart-irb-exchange-partner-institutions/>

The Penn IRB has accounts on both of these platforms and responds to requests to use these systems to execute reliance agreements.

Additional information on how these systems function is available on the system's corresponding website.

## **9. Do I have to do anything in the electronic SMART IRB registration system?**

Probably not. These systems are designed to improve communication between the lead study team, the IRB of Record, and the Relying IRBs. If you are at site that is relying on another IRB, you will likely not need to use the system.

However, if you are designated as an investigator or point of contact for Penn, you will likely receive email correspondence from these systems. You should keep this correspondence in your research records.

If action is needed, you will likely be prompted within the email or in a separate communication.

## When Penn is the IRB of Record

### 10. How do I know if I should use the SMART IRB agreement?

The Penn IRB is willing to use the SMART IRB agreement to execute reliance agreements with any other participating institution. If you are conducting a multi-site trial and you plan to ask academic centers to rely on Penn, you should first check to see if they have signed onto the SMART IRB agreement.

A searchable list of institutions that have signed the agreement is available here: <https://smartirb.org/participating-institutions/>

If any of the participating sites have signed onto the SMART IRB agreement, you should encourage those teams to use SMART IRB to execute their reliance on the Penn IRB.

### 11. Does Penn prefer using the SMART IRB agreement?

Yes. The Penn IRB would rather use the SMART IRB agreement than Penn's template IRB authorization agreement. However, we will still use the template agreement if that is the lead investigator's preference or if the relying sites do not want to use the SMART IRB agreement.

### 12. How do I use the SMART IRB agreement?

The easiest way for new studies to use the SMART IRB agreement is to create an account with either of the electronic online reliance agreement systems. These systems make it easier to contact the relying sites' IRBs and request their review of the reliance agreement request.

If you do not want to use the online systems, you can ask the relying sites' IRBs directly if they are willing to use the SMART IRB. It is recommended that you have the local site investigators reach out to their IRBs but this can also be done by the Penn point of contact.

### 13. What is the electronic SMART IRB reliance system?

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In order to use these systems, a member of the lead research team must register the study within the system and then submit a request. The Penn IRB cannot initiate use of this system.

#### **14. Do I have to use the electronic SMART IRB reliance system?**

You do not have to use the electronic systems. If you do not want to use the electronic systems, the reliance agreement can be documented on paper. This can be done by asking the relying IRB to draft a letter indicating that they are willing to rely on Penn per the SMART IRB agreement.

It is recommended that if you do not use the online system, that you work closely with the Penn IRB reliance agreement team as there may be questions about the process from the Relying Site's IRB.

#### **15. Do all relying sites have to agree to use the SMART IRB agreement to rely on Penn?**

No. There is no requirement that all sites rely on Penn in the same manner. Some sites may want to use the SMART IRB agreement. Other sites may prefer to use their own template agreement. The Penn IRB is flexible and will work with research teams and IRBs to negotiate an agreement that can be fully executed.

#### **16. What happens after a reliance agreement has been reached?**

A study site is not yet approved even after a reliance agreement has been reached. A relying site is not fully approved until all of the following have been done:

- The Penn IRB granted full approval of the protocol
- The relying site IRB completed their local context review
- The Penn IRB approved the addition of the relying site to the study and stamped the site's informed consent form (if applicable)

If you have any questions about how to obtain approvals for relying sites, please see the Reliance Agreement Guidance: Penn as Central IRB FAQ guidance on the Penn IRB website.