How to use this Reliance Instruction Template for Your Study

**[Delete this page and save your tailored reliance instruction for your sites.]**

# **Reliance Instructions**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Title** | | | |
| **Lead Study Site:** | List Institution Here | | |
| **Single IRB Institution:** | List Single IRB Institution Here | | |
| **STUDY POINTS OF CONTACT (POCs)** | | | |
| **Primary Study POC** | Name | Email | Phone# |
| sIRB POC | Name | Email | Phone# |

# **NEXT STEPS FOR RELYING ON THE sIRB**

* **The coordinating center/lead study team** should have shared the approved study materials needed to complete the steps below.

**1. Site completes reliance-related agreements**

**The site investigator/study team** **should share these instructions with their HRPP/IRB to initiate the completion of the resources in the table below, if not already complete for their site:**

**2. Site PI/Study team submits to local HRPP** (after lead site approval)

|  |  |
| --- | --- |
| **SINGLE IRB RESOURCES** | **Status** |
| **SMART IRB Agreement:** A national, master reliance agreement supporting single IRB review. | [**Check your site’s status here**](https://smartirb.org/participating-institutions/)  The HRPP/ IRB can follow the steps to join SMART IRB [here](https://smartirb.org/join/). |
| **IRB Reliance Exchange (IREx):** A single IRB documentation and communication portal. | [**See if your site is a member here**](https://IRBExchange.org/p/participants)  If not, a **human research protections administrator or IRB director/manager can initiate your site’s access** [**here**](https://redcap.vanderbilt.edu/surveys/?s=W98HMCHAPT)**.** |

1. **Local Submission: S**eek guidance from your HRPP/Research Office/IRB regarding what is required to be submitted to your local HRPP in order to rely on the sIRB for this study. Most IRBs require a local submission to complete their local documentation (step 3).
2. **Consent Forms:** Please carefully review all informed consent documents. You will need to insert your site-specific information into the sections indicated. Modifications to these documents should be limited to only those sections; please do not make any other changes to these forms.

**3. Local HRPP documentation in IREx** [(Relying HRPP IREx Quick Guide)](https://www.irbexchange.org/p/wp-content/uploads/2019/02/IREx_PSiteHRPP_QuickGuide.pdf)

1. **Confirm your site’s engagement: Log into IREx and ‘register’ the FWA that is engaged in research for this study. *This is not an indication of reliance.* After registration you will be able to access the study page.**
2. **Confirm your site’s Institutional Profile: This information helps the sIRB know how best to work with your site and provide proper review in the context of your specific participant population.**
3. **Indicate Reliance to the sIRB: The Study-Specific Reliance Plan (SSRP) is the sIRB’s plan for handling HIPAA, auditing, and reporting, as well as other flexible parts of the reliance agreement. Accept the SSRP to indicate your site’s willingness to rely on the sIRB.**
4. **Complete the Human Research Protections (HRP) Survey. Document your local considerations for your site and provide** information about your institution’s requirements (e.g., applicable state or local laws, regulations, etc.) that would affect the conduct or approval of the research at your site.
5. **Review PI Survey (optional).** Review the information and procedures provided by your PI about the study conduct are aligned with local site policies.

**4. Site PI documentation in IREx**

Site investigators and study teams receive an email from IREx after their HRPP confirms their site’s participation and lists them in IREx. Once access to IREx is granted, login to do the following [(IREx Quick Guide)](https://www.irbexchange.org/p/wp-content/uploads/2018/12/IREx_PS-StudyTeam_QuickGuide.pdf):

1. **Complete PI Survey**: This survey asks about the conduct of the study at your site.
   1. The PI or Coordinator can complete the PI Survey. Upload a clean copy of the site-specific consent form in the PI Survey, if applicable.
   2. The PI will need to attest to the information in the PI Survey once it is complete and if edits are made prior to sIRB initial approval.
2. **Add / Edit Study Team** **Access**: The PI or Coordinator can remove or give access to additional study team members at their site. Enter contact information, press **+Add Contact,** and press **Save** to continue.

**WHAT HAPPENS NEXT?**

1. Once the PI Survey is completed and your local HRPP has completed their steps\*,the Primary Study POC will submit your site’s information to the sIRB for review.
2. You will receive an email from IREx when the sIRB has issued approval for your site, at which point you can log into IREx to download your approved documents (e.g., stamped consents).
3. Verify with your local IRB that you are approved to begin the research study. \*\*

**IMPORTANT**: \*If the study team participating in research engages multiple FWAs, documentation for each FWA (steps 3 and 4 above) is completed separately. The sIRB may also review and issue approval of the study at each FWA separately. The Relying Site HRPP should communicate with the research team if they should not begin the study activities until multiple or all FWAs engaged by the team have completed the process.

\*\*Your local HRPP may require that you send or submit the approval letter and other approved documents before you can begin the study at your site. Please check with your local HRPP regarding the process for using reliance at your site.