**HOW TO USE AND TAILOR THESE TEMPLATE RELIANCE INSTRUCTIONS**

**HOW TO USE THE INSTRUCTIONS:**

1. **These instructions should be a collaborative effort between the sIRB for the study and the study’s lead study team or coordinating center.**
2. **These instructions are designed to be disseminated as follows:** 
   1. TO: participating site study teams;
   2. BY: the study’s lead study team or coordinating center; along
   3. WITH: key study documents (e.g., protocol, consent forms), as these have to be submitted to the local HRPP to kick off the reliance process.
3. **Disseminate these instructions to sites:**
   1. AFTER participating sites have been added to the study in IREx—otherwise they will not be able to access the study; and
   2. AFTER (ideally) the protocol and consents for the lead site have approval by the sIRB.

**HOW TO TAILOR THE INSTRUCTIONS TO YOUR STUDY:**

1. Fill in the information under “STUDY INFORMATION”.
2. **Fill in or delete all the pink text.**
3. Consider tailoring the status of the agreements for sites, by indicating “complete” or “incomplete”.
4. In 2b, indicate how informed consent documents are handled and tailored to the site.
5. If local considerations are NOT being captured in IREx, delete steps 3.d. and 4.b.
6. **DELETE THIS PAGE; THESE SHOULD ONLY BE TWO PAGES ☺**

**STUDY INFORMATION:**

**Study:**

**Lead Study Site:**

**Lead Study PI:**

**Coordinating Center:**

**Central/Single IRB:**

**sIRB Name** will serve as the single IRB of Record (“sIRB”) using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement ("[SMART IRB](https://smartirb.org/) Agreement”)  to establish reliance with all participating sites. **sIRB Name** is also using the [IRB Reliance Exchange platform (“IREx”)](https://IRBExchange.org/p/) to capture all sIRB documentation (e.g., cede decisions and local considerations) and facilitate communications between the sIRB and participating site study teams and Human Research Protection Programs/Offices (HRPPs).

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| **STUDY POINTS OF CONTACT (POCs)** | | | |
| **Primary Study** |  |  |  |
| sIRB |  |  |  |
| IREx | [admin@IRBExchange.org](mailto:admin@IRBExchange.org) | | |

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

# The steps below must be completed before the sIRB can begin to review for your site. These steps may involve actions from multiple offices and individuals at your institution**. It is the responsibility of the Site PI/study team to work with research administration officials at your institution to ensure these steps are completed.**

1. **Site PIs/study teams should SHARE THIS INSTRUCTION SHEET with their HRPP or IRB to facilitate the execution of the SMART IRB agreement and initiate IREx access, which are required to rely on the sIRB.**

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| **SINGLE RESOURCES** | **Status** |
| **SMART IRB Agreement:** A national, master reliance agreement supporting single IRB review. Access [these FAQs](https://smartirb.org/sites/default/files/faq.pdf) if you have questions about eh eligibility requirements or key provisions. | [**Check your site’s status here**](https://smartirb.org/participating-institutions/)  If you are not listed, review the agreement and sign the joinder [here](https://smartirb.org/join/). |
| **IRB Reliance Exchange (IREx): ):** A single IRB documentation and communication portal.To access IREx, your institution has to have an account on IREx. The human research protections administrator or IRB director/manager must initiate an institution's access.  **[Note: A portal agreement is no longer required to join IREx.]** | [**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 institution’s access** [**here**](https://redcap.vanderbilt.edu/surveys/?s=W98HMCHAPT)**.**  **Send questions to** [admin@IRBExchange.org](mailto:admin@IRBExchange.org) |

1. **Site PIs/study teams prepare and submit to your local HRPP, as instructed.** 
   1. **S**eek guidance from the 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.
   2. Consent form process: **Insert instructions for the informed consent documents here**. Example: “Please carefully review all informed consent documents. You will need to insert your site specific information into the highlighted sections of these documents. **Modifications to these documents should be limited to the highlighted sections only; please do not make any other changes to these forms.”**
   3. Submit the consent forms and these reliance instructions to your HRPP for their review.

**Note to PIs/Study Teams: many HRPPs require a local submission before the following steps can be completed.**

1. **Your HRPP will complete the steps below in IREx. Please share these instructions with your HRPP.** 
   1. **Confirm your site’s engagement: Login to IREx and search for the study on dashboard. Click on the study title and ‘register’ the FWA(s) that is(are) engaged in research for this study. This is not an indication of reliance.**

**Important: if your site is listed wrong or if you need to list an additional FWA that is engaged for your site, please contact the sIRB POC listed above.**

* 1. **Indicate willingness to rely on [sIRB Name]:** To indicate that your institution will rely on the sIRB, click the steps in the Getting Started Action List. The actions include providing your local study personnel, your local IRB #, key dates (optional), and accepting the Study-Specific Reliance Plan (SSRP). The SSRP is the sIRB’s plan for handling HIPAA, auditing and reporting, as well as other flexible parts of the reliance agreement.
  2. **Complete or confirm the information in your Institutional Profile. In order to participate as a relying site, sections 1, 2 and 3 of the Institutional Profile, must be completed. Information collected in these sections help the sIRB know how best to work with your site and provide proper review in the context of your specific participant population.**

**\*\*delete all of 3.d. if not capturing local considerations in IREx\*\***

* 1. **Provide your local context.**
     1. **Complete the study-specific local context. In order for the sIRB to complete the IRB review for your site, your institution must provide** the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution, as well as upload the informed consent documents with your local site information for this study.
     2. **Review the information provided by your local study team in the PI Survey regarding the conduct of the study at your site, if necessary.** Your local study team will provide information about the conduct of the study at your site (e.g., consenting, recruitment, and DSMB plan). You will be asked to review and confirm the procedures in IREx to ensure they are permissible at your institution.

1. **Study Teams are provided access to IREx.**

Site PIs 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:

* 1. Add other study team members at your institution, if needed.
  2. **\*\*delete this step if not capturing local considerations in IREx\*\*** Complete the PI survey, which asks about the conduct of the study at your site. The PI survey can be completed before or after your HRPP completes the local context survey.

# You will receive an email from IREx when the sIRB has issued approval for your site. **IMPORTANT**: 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 institution.