

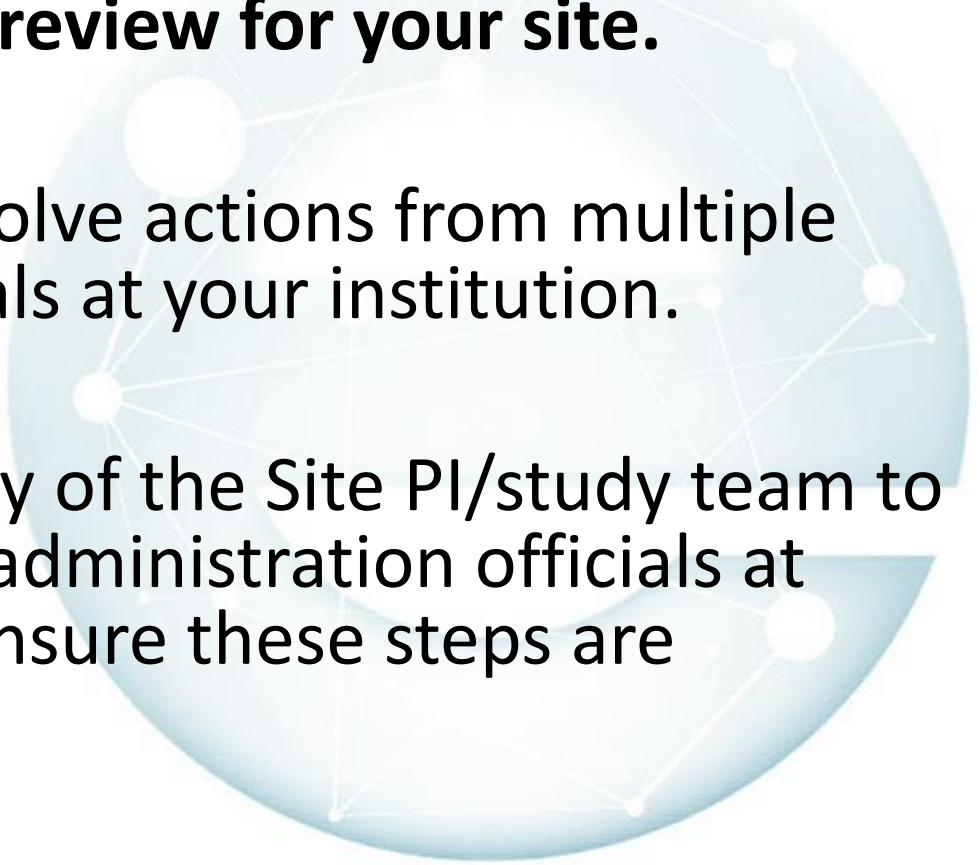
Participating Site Instructions for Relying on VUMC as the Single IRB via IRB Reliance Exchange (IREx)

The EFFORT Trial

Single IRB of Record

- Vanderbilt University Medical Center (VUMC) will serve as the single IRB of Record (“sIRB”) using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (“[SMART IRB Agreement](#)”) and the [sIRB Letter of Indemnification \(LOI\)](#) to establish reliance between all participating sites and Vanderbilt.
- The VUMC sIRB also use the [IRB Reliance Exchange platform \(“IREx”\)](#), a web-based platform hosted by Vanderbilt, to track site progress towards initial approval, which includes documenting reliance arrangements; capturing site-specific local considerations from participating sites; capturing and disseminating IRB approval notifications; and facilitating communications.

Next Steps for Relying on VUMC as the sIRB

- **The following steps must be completed before VUMC 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.
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STEP 1

- Site PIs/Study Teams should share this information with their human research protection program (HRPP) or IRB, who can facilitate the execution of the agreements (found on next slide), as necessary.
- Your institution must execute all of these agreements to rely on VUMC for this study.

E.g. Virtua Voorhees

(component of Virtua Hlth, Inc. FWA 00002656)

sIRB Agreement

Status

SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.

- To view the SMART IRB agreement: <https://smartirb.org/agreement/>
- To join SMART IRB: <https://smartirb.org/join/>.
- Access [these FAQs](#) if you have questions about the eligibility requirements or key provisions.

Not complete

Vanderbilt CIRB Letter of Indemnification (LOI) for the SMART IRB Agreement.

- View and download the [sIRB Letter of Indemnification](#)
- Send questions and executed agreements to admin@IRBExchange.org

Not complete

IRB Reliance Exchange Portal Access Form: This authorizes use of a web-based platform hosted by Vanderbilt, as described above.

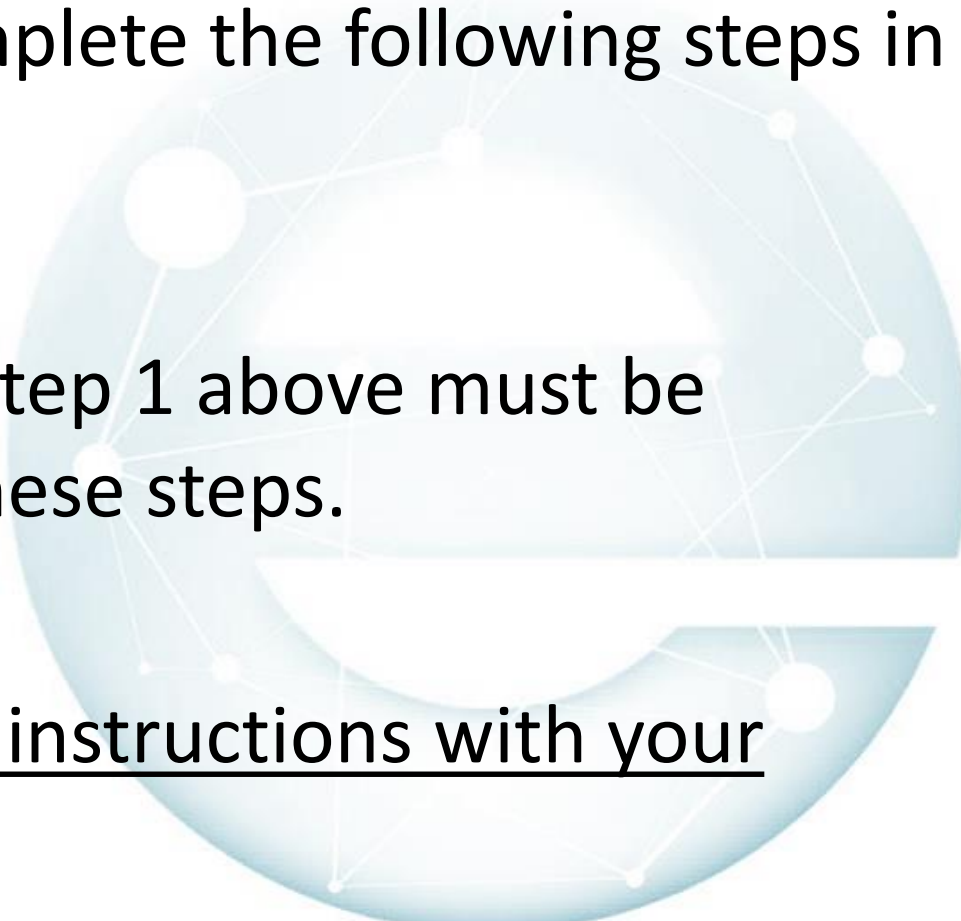
- View the IRB Reliance Exchange Portal Agreement [here](#)
- Send questions and executed agreements to admin@IRBExchange.org

Not complete

STEP 2

- Site PIs/study teams prepare and submit to your local HRPP, as instructed.
 - a) Seek guidance from the HRPP/Research Office/IRB regarding what is required to be submitted to rely on VUMC for this study.
 - a) Submit to your local IRB as instructed.

STEP 3

- Your HRPP will complete the following steps in IREx.
 - All agreements in step 1 above must be completed to do these steps.
 - Please share these instructions with your HRPP.
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a) Confirm your site's engagement: [Login to IREx](#) and search for the study on the 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 in incorrectly or if you need to list an additional FWA that is engaged for your site, please contact the VUMC sIRB POC listed above who will update IREx.

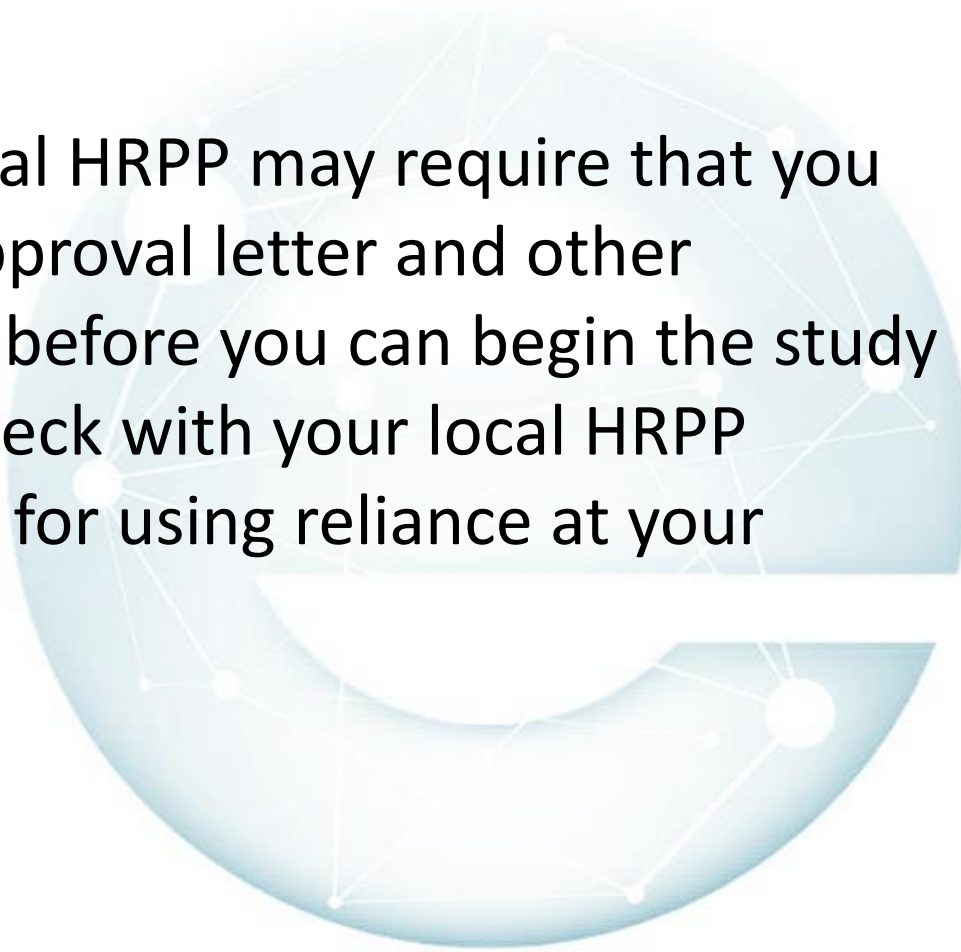
b) Indicate willingness to rely on VUMC: To indicate that your institution will rely on VUMC, click the steps in the Getting Started Checklist. The actions include providing your local study personnel, your local IRB #, key dates (optional), and accepting the Study-Specific Reliance Plan (SSRP). The SSRP is VUMC's plan for handling HIPAA, auditing and reporting, as well as other flexible parts of the reliance agreement.

c) Provide your local context.

- **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 VUMC know how best to work with your site and provide proper review in the context of your specific participant population.
- **Complete the study-specific local context survey. In order for VUMC 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 confirm the local site information for the customizable sections of the ICF for this study.
- **Review the information provided by your local study team in the PI Survey regarding the conduct of the study at your site.** 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 the procedures to ensure they are permissible at your institution.

STEP 4

- **Site PIs are provided access to IREx by their local HRPP in Step 3 and login to complete the PI survey.**
 - Site PIs and study team members receive an email from **IREx** after the HRPP confirms the site's participation (Step 3a above). Once access to **IREx** is granted, login to do the following:
 - a) Add other study team members at your institution, if needed.
 - b) 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 their local context survey.

- **You will receive an email from IREx when VUMC 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.
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Contacts

- The Project Leaders at the coordinating center will be your main contacts for the sIRB process for the EFFORT Study:
 - Jennifer Korol (Jennifer.Korol@kingstonhsc.ca)
 - Alfonso Ortiz (laor@queensu.ca)
- As you progress through the sIRB process, your local HRPP or IRB may need to communicate with representatives from VUMC or IREx:
 - VUMC – Tyler Hubbard (tyler.hubbard@vumc.org; (615)875-8716)
 - IREx – Linda Tan (admin@IRBExchange.org; (615)343-2863)

STEP 1 Site PIs/study teams should share this information with their human research protection program (HRPP) or IRB.

STEP 2 Site PIs/study teams prepare and submit to your local HRPP, as instructed.

STEP 3 Site HRPP will complete the necessary information in IREx.

STEP 4 Site PI/study teams are provided access to IREx by their local HRPP. Site PI/study team logs into IREx to complete the PI survey.

STEP 5 Site PI/study team will receive an email from IREx when VUMC has issued approval for your site.