

SMART IRB EXCHANGE

Using the IRB Exchange as the Lead Study Team

IRB Exchange (“Exchange”) was developed by Vanderbilt to support IRBs, Human Research Protection Programs (HRPPs), coordinating centers, and study teams implement single IRB (sIRB) review for a multisite study. The Exchange’s web-based portal can be used to support the reliance process and exchange of information for the *life of a study*—from initial IRB approval to study close.

Lead Study Teams Use Exchange To:

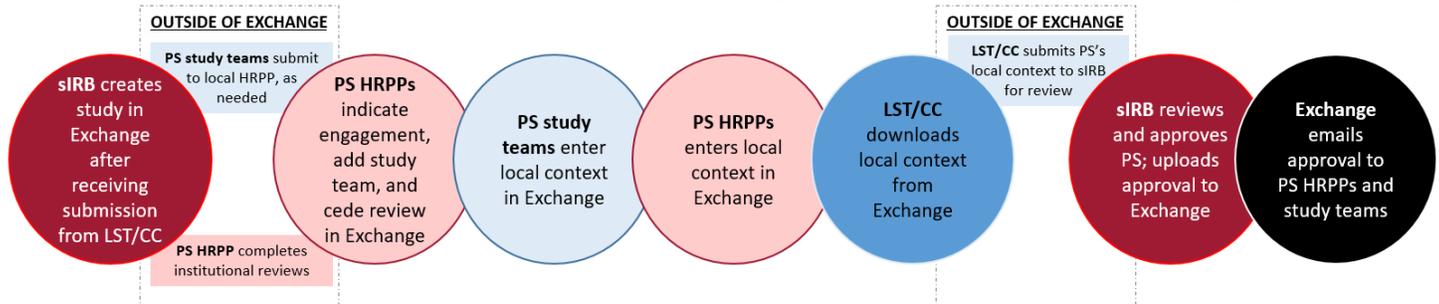
- ✓ Track participating site progress towards initial IRB approval
- ✓ Streamline and centralize the capture of participating sites’ local considerations/context
- ✓ Centrally manage participating site approval documents
- ✓ Facilitate communications to participating sites
- ✓ Automate notifications to participating sites

HOW DO I USE EXCHANGE TO SUPPORT THE SINGLE IRB PROCESS?

Lead Study Teams (LSTs) primarily use Exchange to track the sIRB approval progress of the other participating sites in their trial or study. **The LST does not submit or upload any information to Exchange.** As shown on the reverse, LSTs use Exchange’s study-specific **Status Summary** dashboard to track and monitor each site’s (1) progress completing the required agreements; (2) cede/reliance decisions; (3) the completion of local context (optional); and (4) each site’s approval status. LSTs also use Exchange to send reminders of outstanding action items to a site’s study team.

GENERAL SINGLE IRB WORKFLOW

PS = Participating Site; LST = Lead Study Team; CC = Coordinating Center



As shown in the diagram, even when using a sIRB each participating site study team must contact and likely submit to their local HRPP to initiate the sIRB process at their institution. Before the sIRB can review for a participating site, the sIRB has to collect information from that site’s HRPP and the PI. The Exchange offers tools to help track whether each required step has been completed. This is described in detail on the next page.

HOW DO I GET MY STUDY IN EXCHANGE?

The sIRB for your study will decide whether Exchange will be used to support the sIRB process for your study. Prior to a study being created in Exchange, here’s what needs to happen:

- An IRB agrees to serve as sIRB for your study.
- The sIRB prepares instructions for Participating Sites and educates you or the Coordinating Center on the sIRB process.
- You (or the CC) submit the study for review to the sIRB’s local submission system.
- You (or the CC) disseminate the reliance instructions along with the study materials (e.g., protocol, template ICF) to PS study teams
- The sIRB creates the study in Exchange.** [You will get access to Exchange when the sIRB creates the study.]

WHAT HAPPENS AFTER MY STUDY IS IN EXCHANGE?

- You will receive an email with a temporary password and a link to login to the Exchange.
- Login and change your password using the under “Your Profile” at the top of the screen. Then click

[Change Password](#)



- To access your study, use the search feature on the dashboard.
- Add other study team members from your site to the Exchange by using the site-specific info button (see image) and selecting [Edit Study Team Contacts](#). Each person added will receive an email with a temporary password to login.

HOW DO I USE THE STATUS SUMMARY DASHBOARD?

The Status Summary dashboard is used to track the actions required for each participating site to reach CIRB approval.

Have the required agreements been signed?

Institution-level agreements are required to use a sIRB. The system tracks site sign on to the following:

- SMART IRB:** A check indicates that the [SMART IRB reliance agreement](#) has been signed
- IRB EXCHANGE:** A check indicates that the [Exchange Portal Access Form](#) has been signed.

Has the site's HRPP made a RELIANCE DECISION?

Before the sIRB can review for a site, the HRPP has to indicate they are willing to cede review to the sIRB. **NOTE: Many HRPPs will not indicate this decision until they have received a submission from their local study team.**

- **Incomplete** means the HRPP has not logged into Exchange for this study.
- **Pending** means the HRPP has started the reliance process
- **Complete** means the HRPP has ceded review.

Has the site's HRPP and PI completed the local context requirements? (Optional)

Note: If you do not see the local context column, this information is being collected outside of the Exchange. Ask the sIRB for guidance.

A sIRB may use the Exchange to capture the information it needs to review for each participating site. This information is called local context or local considerations and is provided by the participating site's HRPP and the participating site PI. In Exchange, there are three components of local context, which can be completed concurrently by the respondents:

- Institutional Profile:** Completed by the HRPP, this includes institutional-level information about the site.
- Local Context:** Completed by the HRPP, this includes applicable local requirements for this study at the site.
- PI Survey:** Completed by the PI, this includes information about conduct of the study at the site. *Note: this survey may require sign off by the HRPP (as indicated in the picture above. If so, the Exchange emails the site's HRPP liaison).*

You will receive an email from Exchange when the local context is complete for each site. If you are expected to submit the local context information to the sIRB on behalf of participating sites, you or the coordinating center can use [Export Survey Data](#) and submit it to the sIRB's local IRB submission system for review.

Has the site received approval from the sIRB?

Sites that have been approved by the sIRB will be listed as **Approved**. You can view the site's approval by click on the Approved button or going to the Relying Site Approvals tab. The Exchange sends an email to the participating site's HRPP and study team contacts when approval is uploaded by the sIRB.

HAVE A QUESTION FOR YOUR HRPP/IRB?

You can view your site's HRPP liaisons from the main Exchange Dashboard.

Site	SMART IRB	SMART IRB Exchange	Reliance Decision	Local Context	Approval Status (current version)
Alliance University	✓	✓	Incomplete	0 / 3 Surveys Complete	Approval Not Ready
Denver College	✓	✓	Complete	0 / 3 Surveys Complete	Not Approved
Morris State Medical Center	✓	✓	Complete	3 / 3 Surveys Complete	Not Approved
University of the South	✓	✓	Complete	2 / 3 Surveys Complete	Not Approved

Institutional Profile
 Local Context
 PI Survey (Awaiting HRPP Validation)
 Email study personnel

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