

SMART IRB EXCHANGE

The [SMART IRB Exchange](#) is a web-based platform supporting single IRB review of multisite studies. IRBs use the platform to initiate the reliance process for a study; track the review status; capture approved documentation; and facilitate communication between IRBs. Access to the SMART IRB Exchange is granted after the SMART IRB Exchange Operator Agreement has been executed by an institutional official.

GENERAL SYSTEM FEATURES

create a user

First Name ▲ Required

Last Name ▲ Required

Email ▲ Required

Phone

Site Duke University Health Systems, Inc. (aahrpp) (ctsa) (smart-irb)

Role
 Liaison
 User

User Status
 Active
 Inactive

1. User Access

Exchange administrators create an initial user account for one IRB point of contact (POC) identified at an institution. The identified liaison can add and remove access for others at their institution, as needed. Study team members, such as PIs and coordinators, are added on a study-by-study basis.

2. The Institutional Profile

Each partner institution completes an institutional profile that captures the following:

- 1) General HRPP demographics;
- 2) Local context information;
- 3) Investigator submission requirements when relying on another IRB (e.g., local submission and reporting requirements); and
- 4) An IRB's preferences when serving as the IRB of record for a study (e.g., preferred method for handling HIPAA-related issues, reporting to external agencies, and auditing).

Institutional Profile

View Profile: The University of Utah

ABOUT THE INSTITUTIONAL PROFILE
This information will be visible to other regulatory personnel (e.g., IRB staff and members) in SMART IRB Exchange. This information will provide the first ever central repository for IRBs to identify a potential collaborator for a study (e.g., Reviewing IRB), as well as to learn best practices for supporting single IRB review. This information can be edited at any time!

Section 1: GENERAL HRPP INFORMATION

Institution	The University of Utah
Federalwide Assurance (FWA) #	FWA00003745
FWA Expiration Date	2018-09-20
Do you have an internal IRB?	Yes
Are you AAHRPP accredited?	Yes

Section 2: LOCAL CONTEXT

In what state is your institution located?	UT
Age of majority in your state?	18
How does a minor become emancipated in your state?	<input type="checkbox"/> By judicial petition with age limitations <input checked="" type="checkbox"/> By judicial petition <input checked="" type="checkbox"/> By married <input checked="" type="checkbox"/> By joining the armed forces <input type="checkbox"/> Temporarily while in policy custody to consent to medical treatment

STUDY-SPECIFIC SYSTEM FEATURES

The Reviewing IRB initiates use of the Exchange by creating the study. At this time, the Reviewing IRB indicates the sites that are participating in the study and allowed to rely on the Reviewing IRB. Only the indicated sites will have access. Similarly, for industry-sponsored studies, access is limited to a restricted list of sites, which must be confirmed by the sponsor and set up by the SMART IRB Exchange Administrator. Next, Relying Sites use the Exchange to do the following:

1.

Initiate reliance on the Reviewing IRB. Relying Site point of contacts receive an email when a Reviewing IRB indicates their site is part of a study. Next, the Relying Site POC logs into the Exchange to indicate whether they will rely on the Reviewing IRB. Confirmation letters are sent to both sites to formally document reliance.

The screenshot shows a form titled "Primary Contacts" with two columns: "Primary Investigator" and "Coordinator". Each column has fields for "First Name", "Last Name", and "Email", all marked as "Required".

2.

Document local study team contacts.

Relying Sites enter their primary study contacts (e.g., PI and study coordinator), who will receive study-specific notifications about new approvals; amendments to the study; and impending annual reviews.

3.

Capture site-specific approval documents. After the Reviewing IRB grants approval for a site, the site point of contacts and study team members can login to access their study approvals. Approval documents may include the study protocol, approved consent documents, IRB minutes (redacted, after all personal identifiers are removed), and other IRB approved documents.

The screenshot displays the "Relying Site Approvals" section of the SMART IRB Exchange. It shows a list of versions for a study, with the current version (1.1) highlighted. The interface includes a "Documents" section with a table of files, including the study protocol, determination letters, and consent forms.

Type	Name	Size
Protocol of [1.1]	PROTOCOL_v1.1.docx	12 KB
Determination Letter	DETERMINATION LETTER_Initial Review.docx	12 KB
Consent Forms - Consent Document	CONSENT FORM - Adult.docx	12 KB
Consent Forms - Consent Document	CONSENT FORM Spanish.docx	12 KB
Consent Forms - Consent Document	CONSENT FORM.docx	12 KB

The SMART IRB Exchange is not:

1. **A submission system.** Each study will have a point of contact at the Reviewing IRB to facilitate submission from Relying Site study teams to the Reviewing IRB's IT platform.
2. **An event and problem reporting mechanism.** Investigators will receive a study-specific instruction sheet that details how and when to contact, submit to, and report to the Reviewing IRB. This information will not be stored in the Exchange.



CONTACT US | EMILY SHEFFER, PROJECT MANAGER | admin@SMARTIRBExchange.org | 615.343.2384