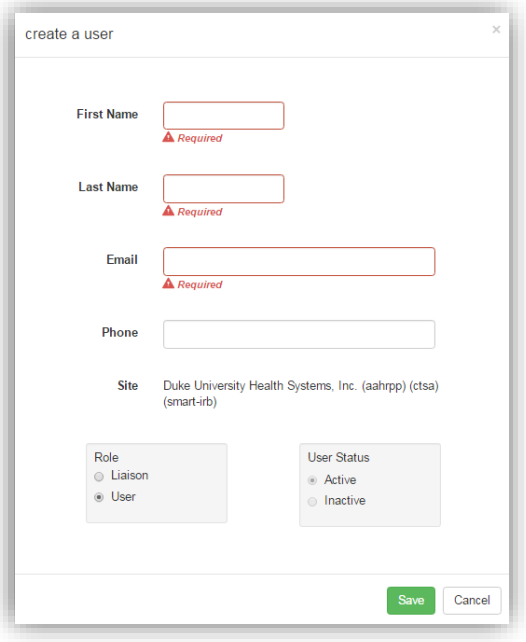
SMART IRB EXCHANGE

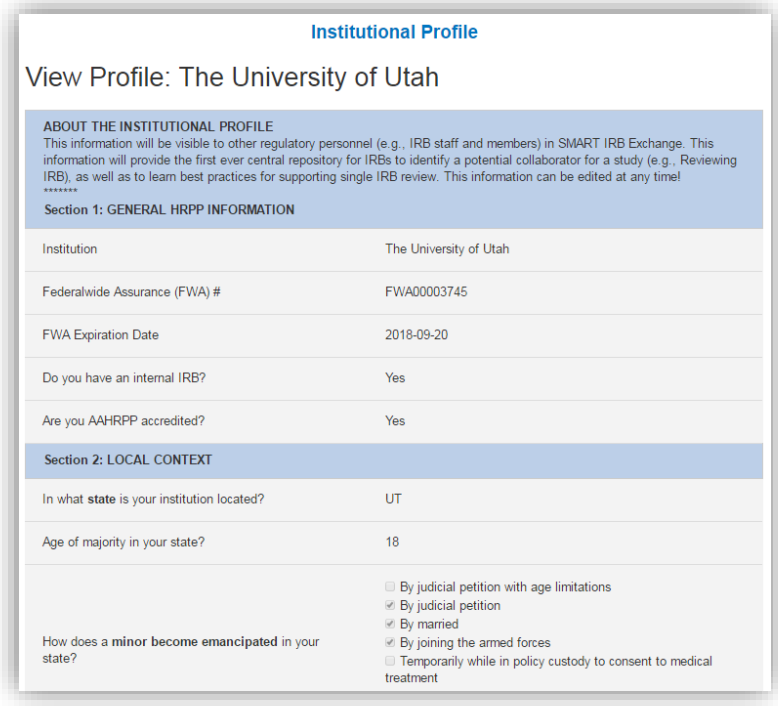
The SMART IRB Exchange is a web-based platform supporting single IRB review of multisite studies. IRBs use the platform to initiate the reliance process for a study; track the review status; capture approved documentation; and facilitate communication between IRBs. Access to the SMART IRB Exchange is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

GENERAL SYSTEM FEATURES



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

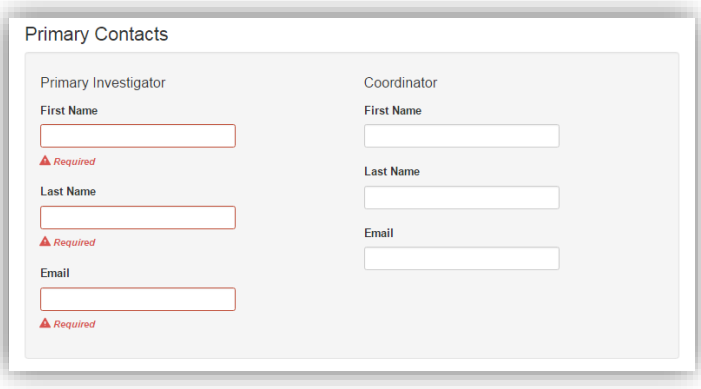
Each partner institution completes an institutional profile that captures the following:

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).

STUDY-SPECIFIC SYSTEM FEATURES

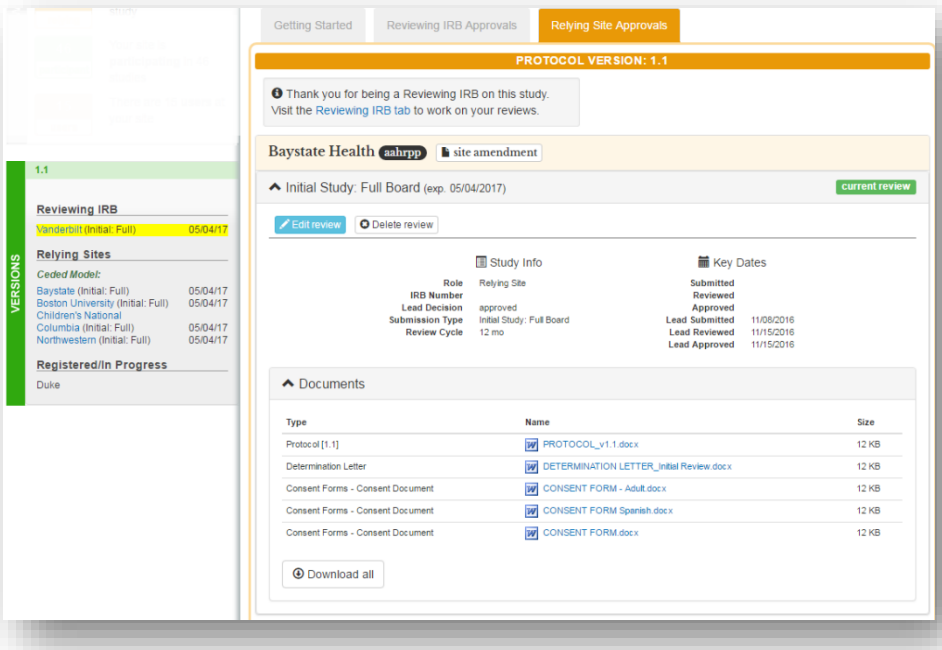
The Reviewing IRB initiates use of the Exchange by creating the study. At this time, the Reviewing IRB indicates the sites that are participating in the study and allowed to rely on the Reviewing IRB. Only the indicated sites will have access. Similarly, for industry-sponsored studies, access is limited 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.



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 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.

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