

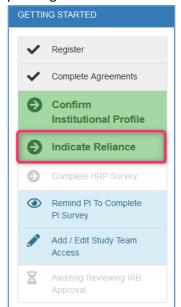
RELYING HRPP STUDY-SPECIFIC RELIANCE PLAN (SSRP) QUICK GUIDE

WHAT IS THE SSRP?

The Study-Specific Reliance Plan (SSRP) is used to document how the flexible elements of the SMART IRB Agreement will be implemented. The SSRP aligns with the <u>SMART IRB Implementation Checklist and Documentation Tool</u> and includes parts of the IRB review (e.g., SOPs and HIPAA determinations and actions), as well as institution-level decisions around insurance and indemnification. *Reviewing IRBs* use the SSRP to outline their plans for operationalizing these flexible elements for a study. *Relying Institutions* must agree to the terms of the SSRP to indicate reliance on the Reviewing IRB.

HOW DOES THE RELYING HRPP VIEW AND ACCEPT THE SSRP FOR A STUDY?

After the relying HRPP has registered for a study and completed agreements, they can view and accept the SSRP by pressing **Indicate Reliance** on the GETTING STARTED checklist. Click the green **Accept SSRP** button to accept the SSRP.





WHAT IF THE RELYING HRPP WISHES TO REQUEST CHANGES TO THE SSRP?

Relying Institutions may request changes to the SSRP. The Reviewing IRB contact information is available under Request Changes button (screenshot above), and the Relying HRPP can contact the Reviewing IRB to request changes. These communications occur outside of IREx.

Workflow for Changing the SSRP:

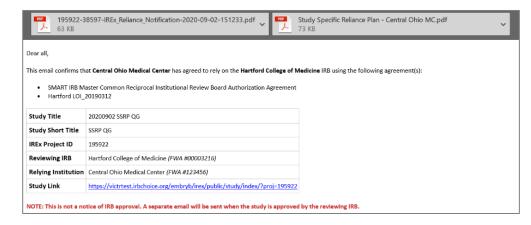
- 1. Relying Institution emails/calls the Reviewing IRB to request a change to the SSRP.
- 2. The Reviewing IRB will edit a site's SSRP in IREx from the Status Summary page.
- 3. **IREx** will notify the Relying HRPP that changes were made.
- 4. The **Relying Institution** can log in, press **Indicate Reliance** on the GETTING STARTED checklist, and accept the revised SSRP.
- 5. IREx will send a Notification of Reliance email to the Reviewing IRB and Relying Institution.

If the Relying Institution requests changes after they have accepted the SSRP, the Reviewing IRB can still follow the workflow above. The original date of reliance and the "Updated" date the revised SSRP was accepted will be noted in IREx.

WHAT HAPPENS AFTER RELYING INSTITUTIONS ACCEPT THE SSRP AND INDICATE RELIANCE?

IREx sends a Notification of Reliance email to the Reviewing IRB and Relying Institution. The email attachments include a PDFs of the

- (1) Letter/Notification of Reliance
- (2) SSRP



They can also be downloaded from the study page by clicking the My Site Info button.

