The Study Specific Reliance Plan (SSRP)

Overview
The Study-Specific Reliance Plan (SSRP) is used to document how the flexible elements of the SMART IRB Agreement will be implemented. These flexible elements include 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 in order to indicate reliance on the Reviewing IRB.

How does the SSRP work?
The SSRP is generated from an institution’s responses to the last section of the Institutional Profile (IP) if the institution indicated it is willing to serve as the Single IRB (sIRB) for others. When these questions are completed, here’s how it works:

NOTE: If a sIRB has responded no in the last section of the IP, the SSRP will be empty after the study is created. The SSRP can be completed for that specific study; however, the answers do not get pushed to the IP. Additionally, answering the questions in the IP after creating a study will not be pushed to the SSRP for a specific study.

As the Reviewing IRB, how do I create an SSRP for a study?
1. On the Institutional Profile, be sure you have indicated “Yes” that your institution is willing to serve as the Reviewing IRB for other institutions and that you have completed all the questions in that section. If you have answered No, change your answer to Yes to complete the required questions.
2. From the dashboard, press Create a Study and from the Getting Started checklist, Complete IREx Setup.
3. Next, select “Confirm SSRP” on the Getting Started checklist.
4. Review the responses in the SSRP and press “Submit”. If the SSRP is blank, complete the SSRP and consider completing the questions in your IP so that they appear automatically next time you create a study.
   a. SSRP responses can be edited for a study without changing the IP responses.
   b. Changes can be made for a specific site after that site has registered for the study.

Can I make changes for a Relying Institution after I confirm the study’s SSRP?
Yes! Relying Institutions may request changes to the SSRP. These conversations occur outside of IREx. If your institution is amenable to the requests, follow these steps to make changes for a Relying Site:
1. From the Status Summary, click “Started” under Reliance Decision (see image →).
2. Change your responses and press Submit.

The Relying Institution will be notified of the changes and you both will receive an email when the Relying Institution accepts the SSRP.