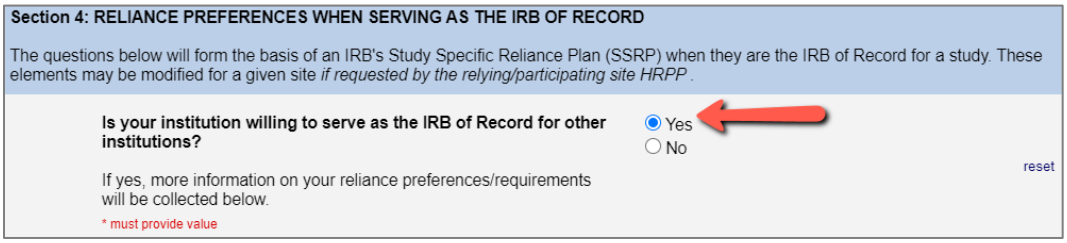
IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)

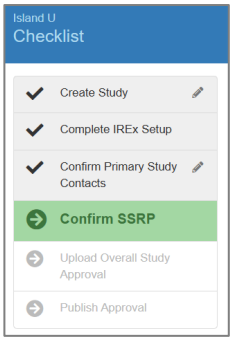
The Study-Specific Reliance Plan (SSRP) is used to document how the flexible elements of the SMART IRB Agreement will be implemented. The SSRP aligns with the SMART IRB Implementation Checklist and Documentation Tool and includes parts of the IRB review (e.g., SOPs and HIPAA determinations and actions), 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 in order to indicate reliance on the Reviewing IRB.*

HOW DOES THE REVIEWING IRB COMPLETE THE SSRP FOR A STUDY?

1. **Before creating the study**, complete Section 4 of the Institutional Profile (IP). Reviewing IRBs indicate their general preferences for items on the SSRP by completing Section 4 of the IP, "Reliance Preferences When Serving as the Reviewing IRB of Record". Be sure you have indicated "**Yes**" – that your institution is willing to serve as the Reviewing IRB for other institutions. Respond to all the questions in that section. These responses will pre-populate on the SSRP for the Reviewing IRB after a study is created.



2. Create the study and use the IREx Checklist to **Complete IREx Setup** and **Confirm Primary Study Contacts**.
3. Next, select **Confirm SSRP** on the Checklist.
   a. The SSRP will have prepopulated responses if the sIRB completed the last section of the Institutional Profile (IP) and responded "Yes" when asked if their institution is willing to serve as the Reviewing IRB for others.
   b. If the SSRP is blank, the sIRB answered "No" or has not completed their IP. **Tip:** The answers provided on a study's SSRP do not propagate to the IP. Additionally, answering the questions in the IP *after* creating a study *will not* change or populate answers on the SSRP for an existing study.

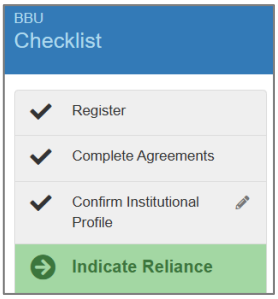


4. Review or complete the responses in the SSRP and press "**Submit**".
   a. Changes made to the study's SSRP will not change your institution's responses on the IP.
   b. After sites have registered for the study, the Reviewing IRB is able to make changes for individual sites, if needed.

Tip: If the sIRB is using a reliance agreement other than the SMART IRB Agreement, there is no SSRP to confirm. Reviewing IRBs will not have this step available on their Checklist.

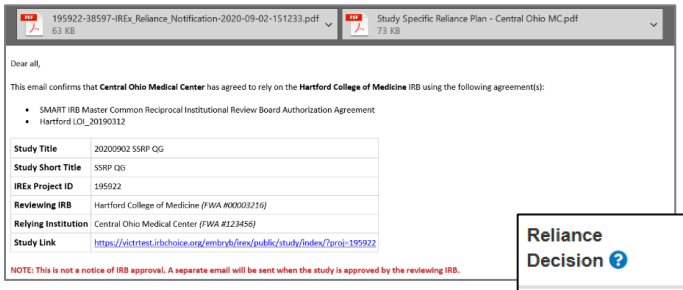
HOW DOES THE RELYING HRPP VIEW AND ACCEPT THE SSRP FOR A STUDY?

Relying HRPPs can view and accept the SSRP by pressing **Indicate Reliance** on the IREx Checklist. This step is actionable after the Relying HRPP has registered for a study, verified the local study team, completed agreements, and completed the Institutional Profile.

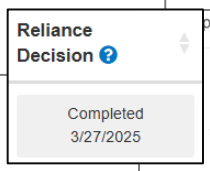


Tips: (1) Relying Institutions may request changes to the SSRP. The Reviewing IRB contact information is available under **Request Changes**, but the discussion with the Reviewing IRB occurs outside of IREx (via phone or email); **(2)** If the sIRB is using a reliance agreement other than the SMART IRB Agreement, Relying Institutions will still indicate reliance; they will indicate reliance based on the agreement being used.

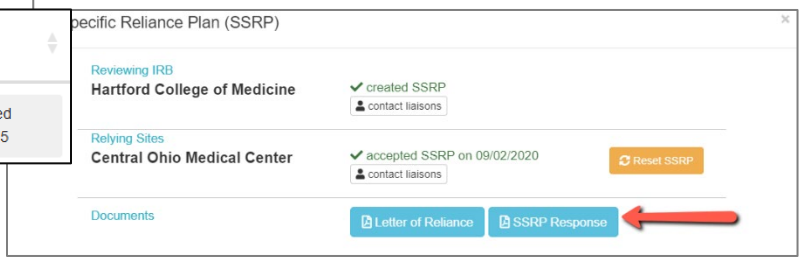
WHAT HAPPENS AFTER RELYING INSTITUTIONS ACCEPT THE SSRP AND INDICATE RELIANCE?

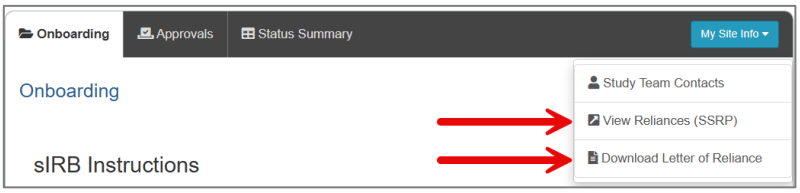


IREx sends a Notification of Reliance email to the Reviewing IRB and Relying Institution. The email contains a PDFs of the (1) Letter/Notification of Reliance and (2) site-specific SSRP, which can also be downloaded from the study page in IREx.



Reviewing IRBs access PDFs for specific sites, by clicking on the site's **Reliance Decision** button on the **Status Summary** tab.





Relying Institutions access the PDFs from the **My Site Info** menu.

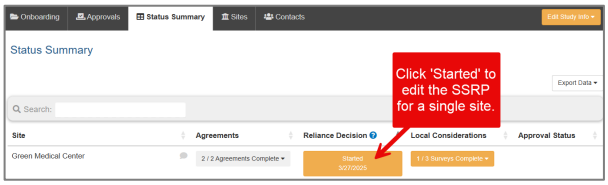
CAN THE REVIEWING IRB MAKE CHANGES FOR A RELYING INSTITUTION ON A STUDY?

Yes! Changes can be made to a site's SSRP before or after the SSRP has been accepted using the steps outlined below:

Editing the SSRP BEFORE it has been accepted

If the Reviewing IRB and Relying Institution agree on changes to the SSRP:

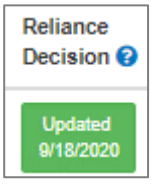
1. The **Reviewing IRB** can edit a site's SSRP from the Status Summary by clicking **Started** under the Reliance Decision column.
2. The **Reviewing IRB** then makes the changes discussed and presses **Submit.** *IREx will notify the Relying HRPP that changes were made.*
3. The **Relying Institution** can log in, press **Indicate Reliance** on the IREx Checklist, and accept the revised SSRP.
4. IREx will send a Notification of Reliance email to the Reviewing IRB and Relying Institution.



Editing the SSRP AFTER it has been accepted

If the Reviewing IRB and Relying Institution agree to change the SSRP after it has been accepted:

1. The **Reviewing IRB** accesses the site's accepted SSRP from the **Status Summary** tab by clicking **Completed** under Reliance Decision.
2. The **Reviewing IRB** presses **Reset SSRP** and makes the needed changes before pressing **Submit.** *The Relying Institution will be notified of the changes made to the SSRP.*
3. Next, the **Relying Institution** logs in, presses **Indicate Reliance** on the IREx Checklist, and accepts the revised SSRP.
4. After the revised SSRP is accepted, the Reviewing IRB and Relying Institution receive an email with a PDF of the revised SSRP. **Tip:** The original date of reliance is not reset in this instance. The date the revised SSRP was accepted will be noted as an "Updated" Reliance Decision on the Status Summary tab. The dates the SSRP was Reset and Updated are also noted in the Status Summary tab export.



THE STUDY-SPECIFIC RELIANCE PLAN

Notification of Acceptance or Declination of Ceded Review	☐Reviewing IRB Will Provide Notification ☐Another Party Will Provide Notification ☐Reiewing IRB Determination Mandated by External Group
Standard Operating Procedures ('SOPs')	☐SMART IRB SOPs Apply ☐Reviewing IRB SOPs Apply ☐Using other SOPs as mandated by an external group ☐Using other SOPs (not otherwise mandated)
HIPAA Determinations and Actions	☐Reviewing IRB will provide determination ☐Relying Institution(s) or 3rd Party will provide determination ☐Relying Institution(s) will make any HIPAA determinations or perform any HIPAA Actions as the Reviewing IRB does not as a matter of policy or otherwise, review requests for HIPAA waivers/alterations ☐Ceded Research does not fall under HIPAA Privacy Rule regulations, OR Relying Institution is NOT HIPAA Covered Entity
HIPAA Authorization Language and Consent Forms	☐Not applicable – HIPAA does NOT apply, or the Relying Institution is NOT a HIPAA Covered Entity ☐Relying Institution will provide Reviewing IRB with its own HIPAA language to be inserted into the informed consent documents OR provide a separate HIPAA Authorization. ☐Reviewing IRB will Provide and Insert HIPAA Authorization Language into the Informed Consent Document(s) on behalf of the Relying Institution ☐Reviewing IRB will Provide separate HIPAA Authorization Form on behalf of the Relying Institution
Conflicts of Interest	☐Relying Institution(s) will perform conflict of interest analyses under their policies ☐Reviewing IRB will perform conflict of interest analyses under its policies ☐Relying Institution(s) and Reviewing IRB have agreed on an alternative plan for conflict of interest analyses
IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance)	☐Reviewing IRB will provide notifications directly ☐Reviewing IRB will provide notifications through another party
IRB-Initiated Audits/Investigations	☐Reviewing IRB will conduct any IRB-intitiated, for-cause audits or investigations ☐Relying Institution(s) will conduct any IRB-initiated, for-cause audits or investigations ☐Reviewing IRB and Relying Institution(s) will jointly conduct any IRB-initiated, for-cause audits or investigations ☐Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis
IRB-Initiated External Reporting	☐Reviewing IRB will draft and submit reports to external recipients ☐Relying Institution(s) will draft and submit reports to external recipients ☐Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties ☐Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis
Congruence of Federal Grant Applications/Contract Proposals	☐Reviewing IRB will review congruence ☐Another party will review congruence
Financial Agreements	☐Reviewing IRB/Institution will not charge Reyling Institution(s) for costs of review ☐Reviewing IRB/Institution will charge the Relying Institution(s) for costs of review

Quality Assurance/Quality Improvement ['QA/QI']Function/Program	☐QA/QI program access required ☐QA/QI program access not required
Insurance	☐Insurance required ☐Insurance not required
Indemnification	☐SMART IRB Version 3.0 Indemnification required ☐Indemnification agreements not required ☐One or more Participating Institutions require an indemnification agreement

The SSRP aligns with the SMART IRB Implementation Checklist and Documentation Tool