

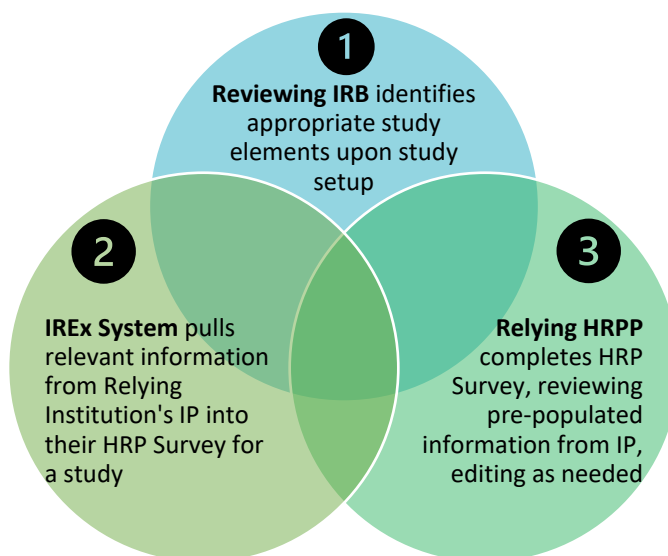
AUTOMATING LOCAL CONSIDERATIONS OVERVIEW

OVERVIEW

Section 6.6 of the SMART Reliance Agreement requires that relying institutions identify local considerations and communicate them to the Reviewing IRB for *each study* using a single IRB. While this local input is crucial for the Reviewing IRB to consider, the *documentation process for Relying Institutions* and the *review process for Reviewing IRBs* are onerous.

To streamline the process, the IREx platform **matches** Reviewing IRB-informed study elements with information from the Institutional Profile (IP) to **populate** a study-specific worksheet for Relying HRPP to review and submit. This automated process minimizes reporting of duplicative or contradictory information from Relying HRPPs and simplifies the review for Reviewing IRB.

HOW DOES IREx AUTOMATE LOCAL CONSIDERATIONS?



- (1) When creating a study in IREx, the Reviewing IRB will be prompted to select study elements that apply to the study during the setup process.

Confirm Study Elements

Study-specific Consent and Protocol Elements

In the list below, select element(s) that are relevant to this study to help Relying Institutions identify potential aspects that may need particular attention. The list is not exhaustive. Select the "Other" element to include additional questions on the HRP and/or PI Surveys.

Relying HRPPs remain responsible for communicating all their pertinent local review information to you, as the sIRB, even if a relevant study element is not marked in this list.

Federally Regulated Study Elements

☐ Assent
 ☐ Children
 ☐ Drugs/devices
 ☐ EFIC
 ☐ Genetic Testing
 ☐ HIPAA applies to this study
 ☐ Other vulnerable populations (e.g., students)
 ☐ Pregnant women
 ☐ Prisoners
 ☒ Study has a consent form
 ☐ Waiver or alteration of informed consent

Other Elements Related to State Laws/Local Policies

☐ Drug or device that could impact billing
 ☐ Drug storage or distribution
 ☐ Individuals with impaired decision making
 ☐ Investigational biosafety review
 ☐ Involves radiation of any kind
 ☐ Is federally funded
 ☐ Mandatory reporting (e.g., testing for infectious disease, abuse/neglect)
 ☒ Non-English speaking individuals
 ☐ Pregnancy testing or collecting pregnancy status
 ☒ Other (e.g., Future Use of Data, Standard of Care, etc.)

You must add a Study Element or Question to at least one Survey (up to five additional elements per survey). Leave blank if not applicable.

HRP Survey

Write the Study Element or Question as it should appear on the HRP Survey.

Please provide information about any policies and/or required consent language about future use of data or specimens.

PI Survey

Write the Study Element or Question as it should appear on the PI Survey.

- (2) IREx will pull relevant information about the selected study elements from the Relying Institution's IP into their HRP Survey.
- (3) After a Relying HRPP registers for a study and opens their HRP Survey, they will see pre-populated information from their IP about the study elements and can confirm or edit the information, as needed.

Note: Any edits made in the HRP Survey do NOT change the IP. To change answers in their IP, HRPPs should click **Profile** from the homepage, and **Edit Institutional Profile**.

KEY ELEMENTS RELEVANT TO LOCAL REVIEW	
Age of majority in your state? <small>* must provide value</small>	18
Does your institution have a posted policy for the following? <ul style="list-style-type: none"> Consent Process for those with Impaired Decision-Making Capacity Use of short forms for non-English speaking individuals Translation of consent forms for non-English speaking individuals We do not have a posted policy/guidance for any of these <small>NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</small> <small>* must provide value</small>	<input checked="" type="checkbox"/> Consent Process for those with Impaired Decision-Making Capacity <input checked="" type="checkbox"/> Use of short forms for non-English speaking individuals <input checked="" type="checkbox"/> Translation of consent forms for non-English speaking individuals <input type="checkbox"/> We do not have a posted policy/guidance for any of these
If your site will enroll non-English speakers, does your site allow the use of a short form? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
How many times can the short form be used before needing a fully translated consent? You can also indicate no limit. <small>* must provide value</small>	No limit
Does your site require a Translator/Witness to sign the short form? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>
Please insert your policy language related to the consent of non-English speakers. <small>* must provide value</small>	<div>Our site allows a short form consent process for individuals with limited English proficiency.</div> <div><small>Expand</small></div>
Does your site require a Translator/Witness to sign the full English consent document? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <small>reset</small>

CAN THE STUDY ELEMENTS BE MODIFIED TO ACCOMMODATE CHANGES IN THE STUDY?

Yes! The Reviewing IRB may modify the Study Elements up until the Overall Study / Lead Site Initial Approval is published in IREx. Once the Initial Approval is uploaded, the selected Study Elements are 'locked' and unable to be edited. This will prevent changes to study elements after a Relying HRPP has begun their documentation process.

Study Elements can also be edited when a Study-Wide Amendment is created – the **Confirm Study Elements** step will reappear on the Reviewing IRB's Checklist. The elements initially chosen will carry over and will already be checked. The step will also appear on the Study Manager's Checklist for the first time, allowing them to make edits. The person uploading the approval can check new elements that apply and/or uncheck elements that no longer apply to the study. The **Confirm Study Elements** step must be confirmed even if no changes are made before the Study-wide Amendment can be uploaded.

Note: Changes to the Study Elements will also update the relevant questions on the HRP Survey. This will not change a Relying site's already confirmed HRP Survey, but if requested by the Reviewing IRB, Relying HRPPs editing an already confirmed HRP Survey will display the updated questions.

DOES THE REVIEWING IRB HAVE TO INDICATE STUDY ELEMENTS?

Yes. To continue to standardize local considerations documentation processes across institutions using IREx, sIRBs must choose at least one Study Element when capturing local considerations in IREx.