

## BENEFITS OF USING IREx TO CAPTURE LOCAL CONSIDERATIONS

For Single IRBs	For Lead Study Teams/ Coordinating Centers	For Relying Site HRPPs
<ul style="list-style-type: none"> <li>Standardize questions and align with national sIRB initiatives</li> <li>Minimize need for external study teams to submit directly to the sIRB's submission system</li> <li>Ensure sign off by the Relying Site HRPPs</li> </ul>	<ul style="list-style-type: none"> <li>Track site progress</li> <li>Centralize site documentation of local considerations</li> <li>Enable pre-screening to catch errors or missing information and facilitate edits</li> <li>Provide user-friendly exports to streamline submission to the sIRB</li> </ul>	<ul style="list-style-type: none"> <li>Reduces duplicative submission of site-specific/institutional local considerations</li> <li>Verify information submitted by your local study team to the sIRB</li> <li>Provides a historical record of local considerations submitted on a study-by-study basis</li> </ul>

## WHAT DO I NEED TO KNOW BEFORE USING IREx TO CAPTURE LOCAL CONSIDERATIONS?

- Local considerations consist of THREE components in IREx:
  - Site-specific Information – The Institutional Profile (IP):** each HRPP completes an IP one time. The IP captures information about the FWA, legal components, and overarching state laws or institutional policies affecting *all research* at a site.
  - Study-specific Information from the HRPP – The Human Research Protections Survey (HRP Survey):** For each study, the site's HRPP must communicate any applicable state or local laws, regulations, institutional policies, standards, relevant consent language, or other local factors, including local ancillary reviews, relevant to the study being reviewed.
  - Study-specific Information from the PI – The PI Survey:** For each study, PIs are asked to provide information about the conduct of the study and any procedures that differ from the protocol. This information must be verified by the site's HRPP.
  - Note:** For Exception from Informed Consent Studies (EFIC), the **Community Consultation Plan Summary of Results** is also a part of each site's local considerations, for a total of FOUR local considerations components in IREx.
- After creating a study, the Reviewing IRB sets up the study using **Complete IREx Setup** on the IREx checklist. After indicating you will collect local considerations in IREx, please indicate how site consents are being handled:
  - (Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.** Select this option if sites will provide their locally required language in the consent form or a template the sIRB provides. Using this option, the study team enters their required language into the consent; submits it to their HRPP for sign off; and the HRPP will upload the consent to the HRP survey in IREx for sIRB review.
  - Exception From Informed Consent (EFIC).** Select this option if the study is an EFIC study.
  - A consent form generator will be used to build consents for sites.** Select this option if sites will provide their locally required language and consents will be created for the sites by the Coordinating Center, Lead Study Team, or sIRB, which may require significant resources depending on the number of sites and consents. In this option, the site HRPP and PI enter their required language into the HRP and PI surveys in IREx, rather than directly into a consent. The consent is then generated and submitted for sIRB review.
- Submitting local considerations in IREx is NOT a submission to the sIRB.** IREx is a mechanism to centrally capture and track local considerations from sites. However, after a site completes the local considerations, the IREx Study Manager (i.e., the lead coordinator or coordinating center) receives an email from IREx that local considerations is complete. The Study Manager then exports the information and submits it to the sIRB for review.

