Using the Exchange to Capture Local Context from Participating Sites

One of the biggest challenges to relying on a single IRB (sIRB) is ensuring the Participating Site’s Human Research Protection Program (HRPP) is aware of the study, has completed the appropriate institutional reviews, and communicates all relevant local considerations to the sIRB. As of February 2018, the IRB Exchange can be used to capture local context from participating sites.

**BENEFITS OF USING EXCHANGE TO CAPTURE LOCAL CONTEXT**

**For Single IRBs**
- Standardize local context questions and align with national sIRB initiatives
- Minimize need for external study teams to submit directly to sIRB’s submission system
- Ensure sign off by the relying HRPP

**For Lead Study Teams/Coordinating Centers (LSTs/CCs)**
- Centralize site-specific tracking and documentation on a study-by-study basis
- Facilitate follow up with site PIs regarding outstanding action items
- Provide user-friendly exports to streamline submission to the sIRB

**For Relying HRPPs**
- Reduces duplicative submission of site-specific/institutional local context
- Verify information submitted by your local study team to the sIRB
- Provides a historical record of local context submitted on a study-by-study basis

**WHAT DO I NEED TO KNOW BEFORE USING EXCHANGE TO CAPTURE LOCAL CONTEXT?**

1. **The Exchange captures local context in three components, which are tracked on the Status Summary Dashboard (see image):**
   a. **Site-specific Information:** Each HRPP completes site-specific information in the Institutional Profile. This includes information about its FWA, legal components, and over-arching state laws or institutional policies that affect all research at the site.
   b. **Study-specific Information from the HRPP:** For each study, the participating institution’s HRPP must communicate any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to the study being reviewed.
   c. **Study-specific Information from the PI:** For each study, each site PI is asked to provide information about the conduct of the study and any procedures that differ from the protocol. This information is available to the participating site’s HRPP and must be verified if any procedures differ at the site.

2. **The current local context module available in Exchange assumes each participating site is generating their own ICF.** The local context surveys in Exchange do not collect sites’ locally required language for the informed consent form (ICF). Instead, it assumes participating site study teams edit the ICF(s) to include their local language; submit it to their local HRPP for verification; and then the local HRPP uploads the site’s ICF(s) to the Exchange as part of local context.

3. **Submitting local context in Exchange is NOT a submission to the sIRB.** The Exchange is a mechanism to centrally capture and track local context from each participating site. However, after a site completes the local context information, the LST or CC will receive an email from the Exchange that local context is complete. The LST/CC will then export the information and submit it to the sIRB for review. See the high-level local context workflow above.