Prior to Lead Site Approval

1. **Single IRB** receives submission & reviews for lead site
   Single IRB creates study in IREx
2. **Lead Study Team** adds relying sites to IREx
3. **Single IRB** approves lead site

IREx

Relying sites execute required agreements (SMART IRB Agreement) and join IREx (one-click Terms of Use), if not already members

After Lead Site Approval

3. **Lead Study Team** uploads lead site approval to IREx & grants site access
4. **Relying study team** includes local language in ICF and submits to local HRPP
   Relying HRPP assesses local considerations based on consent and protocol
   - **Relying HRPP** documents reliance on Single IRB and local considerations in the HRP Survey in IREx
   - **Relying study team** completes PI Survey in IREx, listing site differences from protocol + local ICF
5. **Lead Study Team** screens site's documentation in IREx, exports from IREx, and submits site to Single IRB
   Single IRB reviews & approves site
   Lead Study Team uploads site's approval to IREx

Site HRPP and Study Team notified of Single IRB approval in IREx

Key: Actions taken in IREx; IRB Reliance Exchange (**IREx**); Informed Consent Form (**ICF**); Human Research Protections Program (**HRPP**)

Lessons Learned

1. **To avoid requesting revisions and delay site onboarding,** approve the lead site first, before asking sites for local HRPP documentation.
2. **To minimize onboarding time,** use the SMART IRB Agreement and ask sites to execute any incomplete agreements while the lead site is being reviewed.
3. **To standardize the process and centralize documentation,** use IREx and identify a lead study team member to communicate and coordinate the Single IRB process to sites.
4. **To streamline Single IRB review of sites,** allow limited editing of the informed consent to only designated sections.
5. **To avoid bottlenecks in Single IRB review,** encourage the lead study team to pre-screen the HRP & PI Surveys before submitting the site to the Single IRB for review.