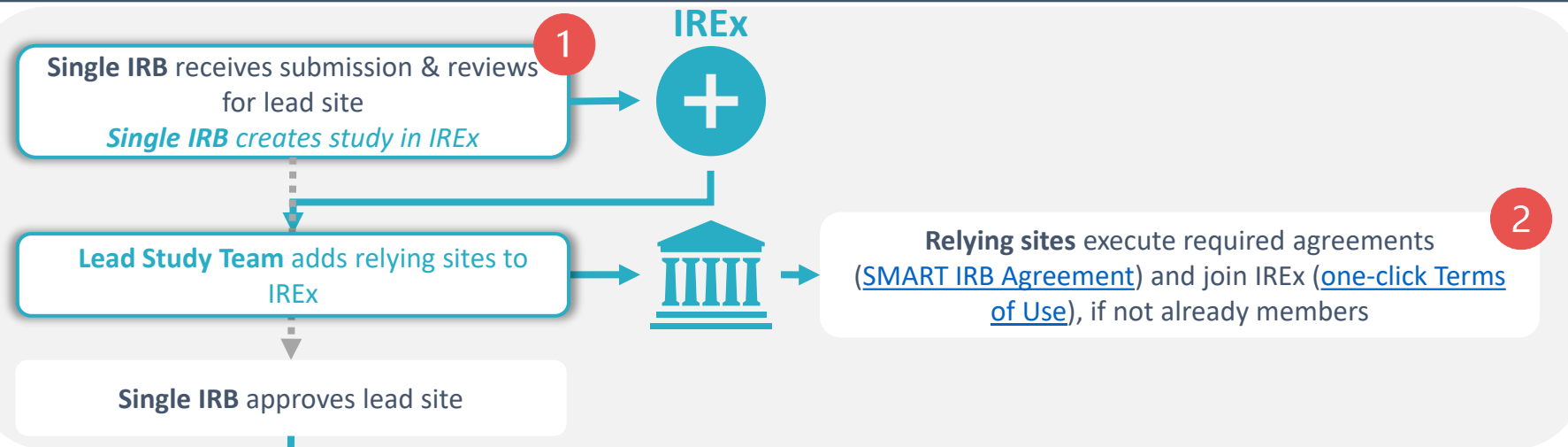
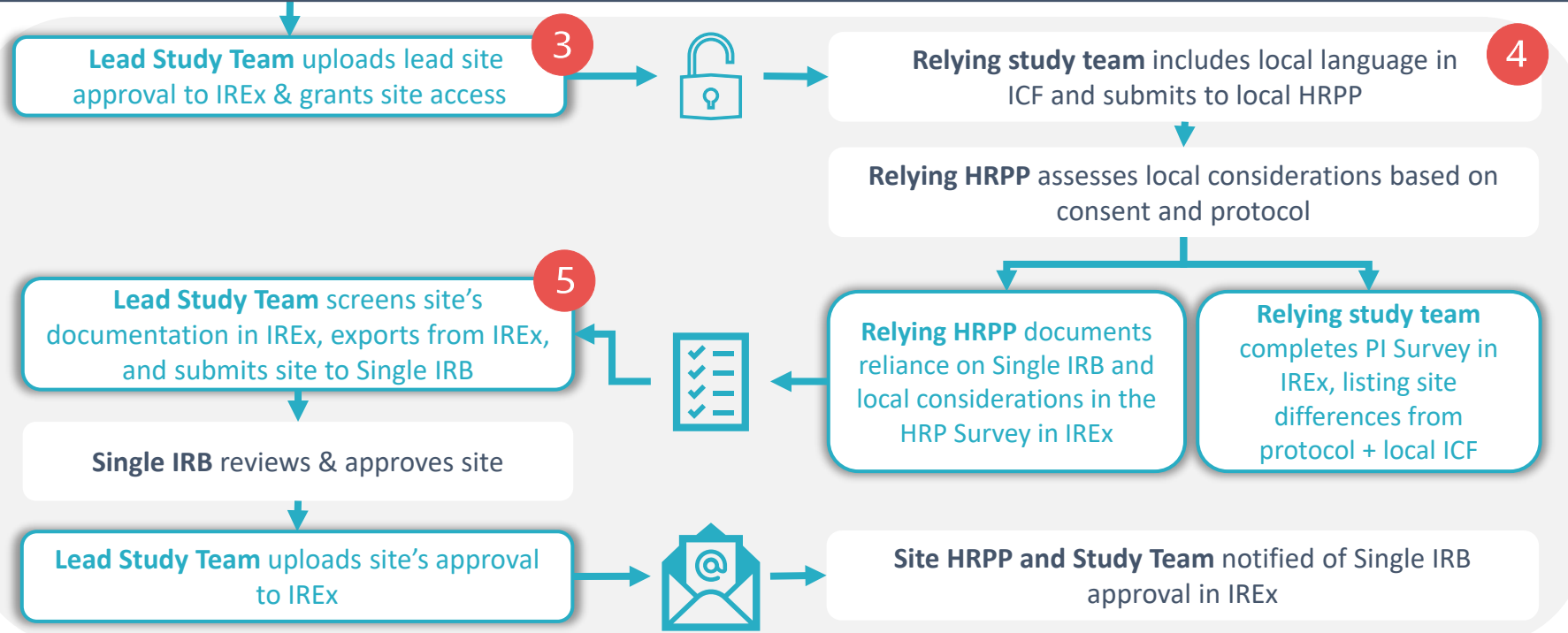


Prior to Lead Site Approval



After Lead Site Approval



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.