NCI-CIRB Local Submissions – Study Team Guidance

Action	Steps to Take
Initial Study Start-Up	Create a New Study Application • Indicate CIRB as IRB of Record • Attach SSW and CR • Route to PI for Signature NOTE: Department Chair and Business Admin signature are not required. Ancillary approvals do not need to be submitted to the IRB. *The study may not begin enrollment until acknowledged by JOHRP.
Add/Remove Study Personnel	Utilize the Adding/Removing study personnel form • PI Signature is required • All study personnel must be approved by the IRB prior to working on the study.
Change of PI	Utilize the IRB Reliance Form Follow Up to report a change of PI. • Signature of the new PI is required. • The submission should be made in real time. The follow-up form should be submitted to JOHRP no more than one month after approval by CIRB. • Approval from CIRB should be attached.
Continuing Review	Utilize the External IRB - Annual Update and Check-In Form. • Attach the approval from CIRB • Report amendments that have occurred • Report deviations that have occurred The continuing review should be submitted promptly to JOHRP in order for the expiration date to be updated locally and review of personnel training, COI deviations, etc.
Amendments	Amendments made to a protocol do not need to be reported to JOHRP throughout the approval period. Instead, all amendments made within the approval period should be itemized in the External IRB Annual Update and Closure form.
Final Report	Utilize the External IRB - Annual Update and Check-In Form. • Attach the closure approval from CIRB • Report amendments that have occurred • Report deviations that have occurred The study closure/final report/end of oversight notification should be submitted promptly to close out the local record.
Changes to Information contained in the Master Application	Utilize the IRB Reliance Form Follow Up

Obtain Approved HIPAA Consent Document	**The Regulatory Coordinator updates the HIPAA consent template to include the unique study ID and emails it to Compliance for review, approval, and stamping.** • **The compliance team that approves our HIPAA consents includes: Doreen Kornrumpf, Geraldine Hagan, and Erin Galbally.**