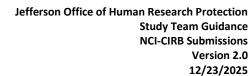


NCI-CIRB Local Submissions - Study Team Guidance

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
	NOTE: Department Chair and Business Admin signature are not required. Ancillary approvals do not need to be submitted to the IRB.
	Anchiary approvais do not need to be submitted to the ikb.
	*The study may not begin enrollment until acknowledged by JOHRP.
Add/Remove Study	Utilize the Adding/Removing study personnel form
Personnel	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	Utilize the IRB Reliance Form Follow Up
contained in the Master	
Application	3





Obtain Approved HIPAA	The Regulatory Coordinator updates the HIPAA consent template to include
Consent Document	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.