

Regulatory Study Close-Out

Approval Date: 01SEP2022

1. On close-out day, fill out the IRB Study Termination Form (see policy for how this is completed). File all correspondence accordingly and send IRB Termination Form to CRA for their records.
2. Go to Delegation of Authority Log and enter the end date for each staff member. Have PI sign-off after end dates have been entered. Staff do not need to complete any signatures.
3. Ensure IP Accountability Logs are complete and that each item is accounted for and signed off for destruction per site SOPs or returned to Sponsor with CRA sign-off or documentation.
4. Complete all logs in Dynamic Documents Binder (IP Logs, Monitoring Visit logs, etc.). Be sure to finish pagination, sign where applicable and have PI sign where applicable. Single cross-out through any empty forms or log lines remembering to sign and date when you do. Upload all logs that do not have PHI on them into CRIO and file under the correct folder. There is typically a NTF from study start in CRIO that designated where they were stored for the duration of the study for these items. Keep the NTF there.
5. Upload Protocol Deviation logs from Dropbox. PI should sign final copy before uploading to CRIO.
6. Complete charge sheet with study name, date of closure, CRA name who conducted the closeout, and type of visit (remote or on-site) to the site billing specialist.

Policy Manual

