Policy Manual

Regulatory Study Start-up

Approval Date: 01SEP2022

1. Upon receipt of regulatory binder. Upload all material under CRIO appropriate tab. Keep all logs as paper (IP log, Monitor Sign-in Sheet, Subject Log, etc.)
2. Use provided Delegation of Authority Log (DOA) and enter tasks exactly as written by Sponsor. If numbers are used, enter task as 01-09, 10, 11,…. If there are blinded and unblinded tasks assign as 00U and 00B if there is nothing on sponsor delegation log to specify. Footnotes cannot be uploaded so keep a copy of the original DOA and read through carefully. If necessary, the footnote language can be added to the task. Make sure all staff review before signing off. Have PI and all study staff sign off before study start.
3. The Initial Approval Letter will arrive from the IRB. File this under IRB Correspondence (YYYYMMDD Initial Approval expires YYYYMMDD). Mark the expiration when uploading to CRIO and turn on a reminder for one month prior.
4. Download all items listed on Approval Letter from IRB website. The Protocol and Investigator's Brochure (IB) will come directly from the study sponsor. File all items under the appropriate folder in CRIO.
5. File the ICF in CRIO eRegulatory and in Dropbox. Notify all site staff that ICF is available. ICF is filed in CRIO by approval date by IRB (YYYYMMDD ICF Main or YYYYMMDD ICF PreScreen, etc.).
6. File all SIV documentation including attendance logs, slides, etc. under Monitoring > Site Initiation Documentation.
7. Add Note to Files (NTF) in CRIO for locations of logs kept in the paper Dynamic Documents Binder (monitoring logs, IP Accountability, etc.). NTF templates for this are found in Dropbox under Care Institute > Templates > NTF.
8. Items not included, such as local lab values (local lab reference ranges, CV of lab director, etc.) that are not provided by Sponsor are uploaded to labs. For pregnancy tests or drug screens provided by site upload the package insert and file under a Sub-Folder titled Lab Manual.

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