Policy Manual

Scanning and Attaching SUBJECT Documents into CRIO

Approval Date:04APR2023

1. All SUBJECT SPECIFIC documents should be scanned into CRIO and attached to the appropriate visits. Subject specific documents include but are not limited to: ICFs, lab reports, ECG tracings, subject questionnaires, past medical records, medial records release forms, and correspondence from Sponsor dealing directly with subject (do NOT file general study correspondence that affects all subjects into a subject chart).
2. Once scanned save the document into a temporary file in Dropbox for filing.
3. Attach that document to the correct subject and subject visit in CRIO being sure to add proper Category and Custom Name so that the document type and content is easily identified without having to open it.
4. If there are any protected health information (PHI) on the document use CRIO's redacting tool to obscure this information. This ensures that all PHI is not visible to CRAs who may be off-site when viewing these documents.
5. PRIOR TO E-SIGNING IT IS RESPONSIBILITY OF THE STAFF MEMBER UPLOADING TO LOOK AT EACH AND EVERY PAGE THAT WAS UPLOADED TO CRIO AND TO ENSURE IT IS A COMPLETE AND ACCURATE COPY OF THE ORIGINAL.   eSignatures are equivalent to wet-ink signatures and is the staff members attestation that they have completed the above policy.
6. Once the document is VERIFIED AS COMPLETE AND ACCURATE and eSigned then all documents other than the following are shredded: ICFs, Patient Registration Forms, Medical Records Release forms. These three documents are filed into the patient tracking binder by subject number.

Policy Manual