

## *CRIO eRegulatory Naming Conventions & Date Usage*

Approval Date: 31OCT2017

Revision Date: 16OCT2019 Updated for CRIO

Revision Date: 11DEC2021

Revision Date: 08NOV2022 Updated Training Log CRIO Location

1. Upload any documents that need to go into the regulatory with the below general format:
  - a. YYYY-MM-DD\_NAME or CONTENT OF DOCUMENT
  - b. Please use correct spelling, punctuation, capitalization, and date with uppercase in the month format.
2. Email/Correspondence
  - a. Use the date of the MOST RECENT email if there is a string of emails. Do not upload email chain until the issue is resolved. Use subject line as title unless it is too long or if it doesn't actually pertain to the email subject matter. Add additional information in the "comments" section if clarification is needed.
3. IRB Approvals
  - a. Use the date of the ACTUAL APPROVAL. Do not use the date version on the media (flyer, brochure, ICF, etc) but, rather, the date the IRB actually approved the media.
  - b. Use date at the top of the Letter of Approval document.
4. FDA Form 1572s, Protocol Signature Pages and Investigator Brochures
  - a. Use the date of signature by PI
5. Training Logs
  - a. Since dates of individual trainings can often vary depending on when each staff member reviewed material and/or when the trainer spoke with the employee use the date the trainer signs the training log.
  - b. All individual training logs for staff will be located in the individual staff member's blue training folder which is under each study. If there are any general training logs, they will be kept under the study specific training folder.
6. Monitoring Letters
  - a. Use the date at the top of the monitoring letter but, if received AFTER that date, please make a comment of the date received in the comments section of the box.
  - b. Because the date leads the document name in CRIO there is a single date for each monitoring letter- one for the Confirmation Letter and one for the Follow-up Letter.
  - c. The PI must sign the Follow-up letter (either wet-ink or electronically) to acknowledge review of any findings and action items.
  - d. If there is a significant delay for the Follow-up Letter being sent by the CRO, the date of receipt of letter will be noted explaining the late signature of the PI.
7. Supply requests and receipts
  - a. Use the date of request or receipt of supplies

# *Policy Manual*

