CRIO eSource Validation

Approval Date: 11FEB2019
Revision Date: NA

1. Check the order of events to ensure that study procedures are completed in the following order UNLESS DICTATED OTHERWISE IN THE PROTOCOL
    a. Informed Consent/Reconsent
    b. Demographics
    c. Medical History
    d. Concomitant Medications
    e. Patient Reported Outcome (PROs) Questionnaires
    f. Vitals
    g. ECG
    h. Blood/Urine Collection
    i. Physical
2. Using the eCRF completion guidelines and ensure the following FOR EACH page:
    a. For datapoints make check if date or date AND time need to be collected
    b. Make sure terms match that found in the eCRF (ie. Death vs Fatal or
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.
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.
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.
7. Supply requests and receipts
    a. Use the date of request or receipt of supplies