SOP#: CDMS-4 **Site eCRF Development, Review and Approval Process**

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NCI Clinical Director Signature: William L. Dahut -S

Digitally signed by William L. Dahut -S
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Purpose: To describe the process for the development, maintenance, review and approval of electronic case report forms (eCRFs) in the CCR's clinical research database. SOPs set forth standards for practice of clinical research at this institute.

Step 1: IRB Approved protocol is submitted to the Clinical Analysts (CA)

- After the protocol has initial approval the IRB (with/without recommendations/stipulations), QC Manager will assess build prioritization with CCR Management input
- An eCRF protocol specification worksheet is completed
  - Specifications are customized from the standard eCRFs to reflect the protocol's objectives, study design, study calendar, treatment schema, and reporting requirements
  - All data *must* be collected if specified in the protocol
  - Data that will not be analyzed or used for regulatory compliance *should not* be captured in a CRF

- If there is protocol data required but no standard eCRF is available, the CA will search the Common Data Element (CDE) repository for possible CDE(s) that could be used and as needed request additional information from the PI. If no CDE is available, the CA will work with NCI Center for Bioinformatics and Information Technology (CBITT) for appropriate curation and storage in the NCI global library.
- The CA will decide whether a database build meeting is necessary based on protocol clarity, clinical team experience with the specific database and the need for new eCRFs or customization of standard eCRFs.

Step 2: Clinical Research Team and CA review the specifications worksheet

- The protocol specification worksheet is reviewed with clinical research team including the PI, research nurse and data manager. This can be done via email or at a build meeting.
- All changes made will be incorporated into the specification worksheet and submitted to programmers to build the eCRF in RAVE

Step 3: Database programmers build the protocol eCRFs

- The programmers will use the final specification worksheet and any additional eCRFs that were needed to develop the eCRFs
- All eCRF templates are Common Data Element (CDE) compliant
- Each protocol will include a PI sign off eCRF in the off-study section of the database.

Step 4: Clinical research team conduct User Acceptance testing

- CA will email the research team when the database is available for testing.
- All changes required by team during testing is documented and submitted to the database programmers via an excel spreadsheet.
- eCRF changes are completed by the programmers.

Step 5: Sponsor review of eCRF if applicable

- Sponsor staff will review the final draft eCRFs and submit any requested changes to the IT Manager
- The CA will submit Sponsor database change documentation to research team for review and approval
- Disapproved Sponsor requests will be reviewed by CCMG or OCD
- Changes requested beyond the scope of standard eCRF builds will be reviewed and approved by CCMG or submitted to OCD for approval

Step 6: Finalization of eCRFs

- Once the database has been finalized by the research team and, if applicable, the sponsor, Office of Information Technology (OIT) will submit to CBITT for final approval.

Step 7: eCRFs are opened for use

- CA emails team and pertinent staff that the protocol eCRFs have been activated in the clinical research database for use by the data managers and clinical research team.

Step 8: eCRFs added or modified due to protocol Amendment

- CA will review all IRB approved amendments to assess if changes will be needed to the clinical research database.
- Should the protocol amendment require changes in the database, this SOP will be repeated starting at Step 1.

Note: Protocol Database Development Documentation Maintenance (Steps 1-7)

All steps in the eCRF Development, Review and Approval Process are documented. Documentation includes:

- Build Specification

- Clarifications and Questions about the protocol (indicating which ones could impede build)
- Screenshots showing changes to standard eCRFs
- Mocked new eCRFs required in the protocol
- Meetings agenda's and minutes
- Studies' specific Team Testing checklists with the sites feedback and sites approval of eCRFs
- The C3D database maintains information related to eCRFs versions:
    - Original protocol eCRFs set
    - Documentation of each eCRFs versions controls which contains: information about eCRF changes, date/time of eCRF version creation (original or modified), list of retired eCRFs and currently active eCRFs.