Standard Operating Procedure

eCRF Development in Oncore

Biostatistics and Data Management Core
Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. eCRF Developer uses all relevant sections of the protocol to determine what to collect. These items could include the following, but this list is not comprehensive (just a sample of items):
    a. Study Objectives
    b. Study Endpoints
    c. Schedule of Events
    d. Statistical section (with possible assistance from biostats)
    e. Patient safety
    f. Other sections (eg. schema, cohort tables, etc.)
2. Pre-SRC submission, the eCRF Developer begins the database build in preparation for the Pre-SRC Protocol Review Meeting.
3. eCRF Developer meets with the Statistician and Statistical Data Manager to review the database prior to the Database Review Meeting.
4. eCRF Developer creates draft eCRFs and sends to the study team for review. This could be in the form of screen snapshots. Although the drop down lists may not be included, it would allow the team to see the overall structure of the database and what is being collected.
5. Study team* reviews the draft eCRFs **before** the Database Review meeting for **at least** the following:
    a. All data noted in the Schedule of Events with the exception of data arising from standard-of-care procedures that are not related to the study objectives. Also, with the exception of data from the Schedule of Events captured in REDcap.
    b. All data needed to complete the statistical analyses planned for the study objectives and study endpoints. This would include data that is needed to verify the responses for the study subjects, such as tumor measurements for solid tumor studies, or relevant lab data for hematological cancers must be included in the main database or be made available to the statistician through other HIPPA compliant electronic means (such as a supplemental REDCap database), so responses can be verified.
    c. All data related to patient safety.

    Note: Additional Database Review Meetings may be planned, if necessary.

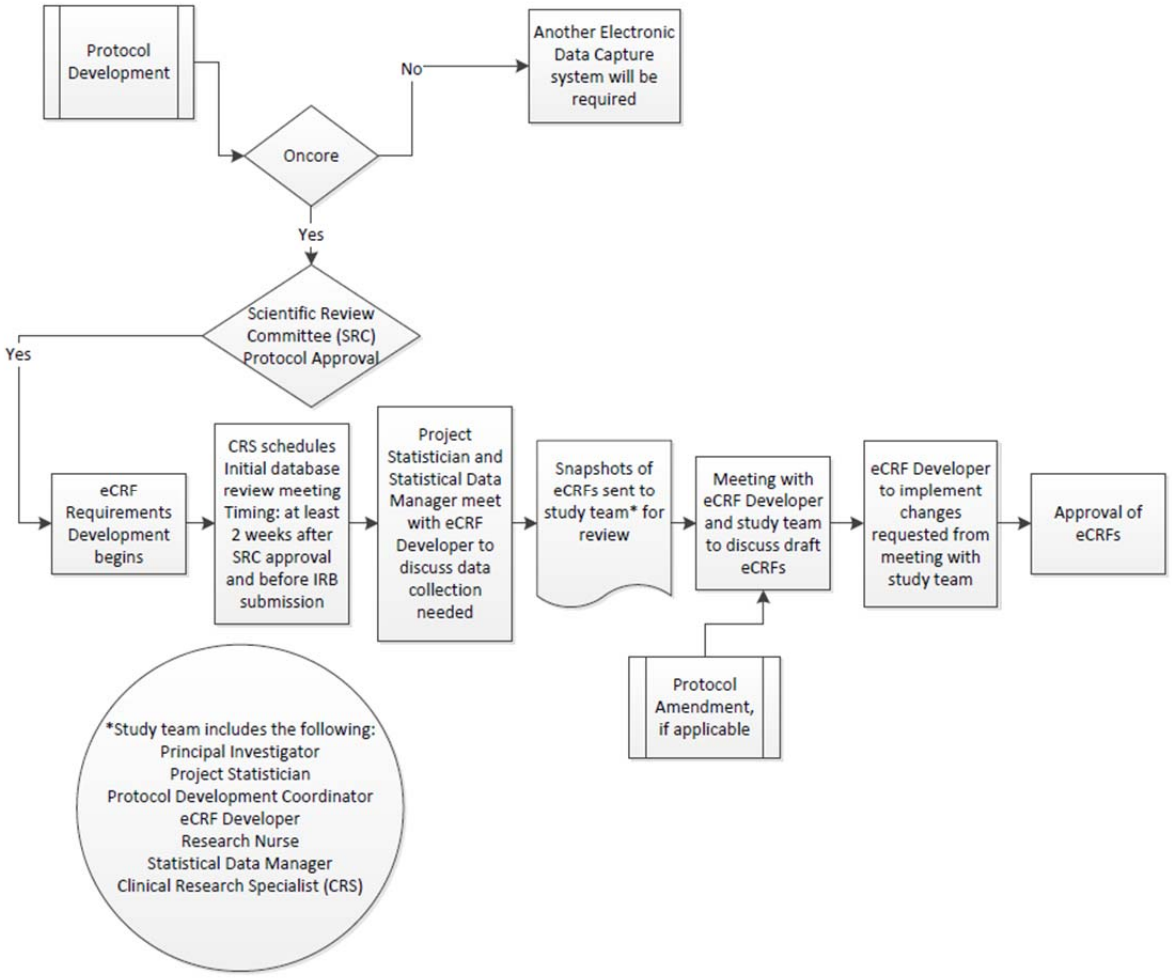
6. eCRF Developer requests CRS to schedule the Database Review meeting. Note: The time of this meeting would be at least 2 weeks after SRC approval, and should always be **before** IRB submission.
7. eCRF Developer and study team has the Database Review meeting to go over the eCRFs and provide comments. Note: It is strongly recommended to include the Protocol Development Coordinator and the Budget Managers in this meeting.

8. eCRF Developer makes changes and sends updated forms for approval.
9. Approval of the eCRFs is document by the appropriate people (Statistician, and PI)
10. Final database is available in appropriate location (eg. OnCore, REDCap)
11. After the 1st subject enrolls in the trial, accrual is suspended until a certain time point. The data is entered into the database and members of the study team (eCRF developer, PI, statistician, statistical data manager) assess everything from the clinical/operational and data collection perspectives. If everything is okay, then the trial is reopened to accrual.
12. If Protocol Amendment, then re-review and approval will be needed.

Note: Regardless of what is included in the electronic database, it is the CRS' responsibility to ensure that all data from the Schedule of Events is available through the appropriate source documents.

Note2: It is the responsibility of the PI that ALL data is collected in the Medical Record.

The figure below depicts the eCRF development process.



*Study Team: PI, Project Statistician, Protocol Development Coordinator, eCRF Developer, RN, DM, CRS (or study coordinator)