

Young Investigators' Guide to Research Mentoring

Operationalizing Protocols

Create A Regulatory File/Binder: This should contain: final COMIRB approval notice, COMIRB-approved versions of the protocol and consent form, signed 1572, investigators' CVs and medical licenses, COMIRB correspondence, protocol related correspondence, list of protocol personnel and copies of COMIRB certification, test article dispensing log, SAE/AE documentation, case report forms or source documents, investigator brochures, IND, safety updates and Manual of Operations (if relevant).

Create Source Documents And A Database: Create separate source documents for each visit. Make these as simple and as user friendly as possible. Narrative sections ought to be kept to a minimum. List all procedures and information to be collected in the chronological order of collection. Libraries of such forms are available from the GCRC. Construct the database to replicate the order of the source documents. Include in the column information reference ranges for all measures and lab tests where appropriate. Contact the Bioinformatics Manager at 303-764-8373 for assistance.

Create A Subject File/Binder: This should contain all documents related to a single subject; demographic collection forms, source documents in order of visit, lab results, all questionnaires, measures etc. There should be a special sheet or section that lists the subject safety measures and labs, and these results should be highlighted and notations made regarding when they were reviewed and by whom. Construct these files in batches and label with subject study numbers.

Create Written Procedures: This should include procedures for reviewing subject safety measures with details on how frequently and by whom each of the measures are reviewed and acted upon. This should also include procedures for assuring data integrity such as data entry methods, frequency and method of data verification procedures.

Conduct A Protocol Operationalizing Meeting: Include in this meeting all members of the research team; study personnel, consulting and support personnel as relevant. e. g. PI, study coordinator, research pharmacist, GCRC in-patient nurse, respiratory therapist, et al. Review standard operating procedures for the informed consent process, data collection and entry. Review safety issues and contingency procedures.

Conduct Protocol With Mock Subjects: If at all possible schedule a time to run a mock subject through the entire protocol. This can be done with a staff member as the goal is to discover any logistical difficulties or quirks that should be resolved before actual eligible subjects are enrolled and participate in the protocol. Do all data entry from these mock subjects on a pilot basis as well. Have a debriefing meeting with study staff to assess the piloting of the protocol. Make changes to procedures and logistics as necessary.

Office of the Research Subject Advocate
Pediatric General Clinical Research Center
University of Colorado Health Sciences Center

Conduct Protocol With the First 3-5 Subjects: Conduct the protocol on the first few subjects and have a debriefing meeting with the entire research team after the first few have completed the initial or more important visits. A protracted protocol should have such meetings after the first few subjects complete each of several phases in a protocol.

Ongoing Protocol Assessment Meetings: There should be regularly scheduled protocol assessment meetings. In general the more that is asked of a subject and the quicker the rate of enrollment the more frequently the meetings should be held. Most protocols should have monthly assessment meetings with the key staff. This might include only the PI and the study coordinator or, in more complicated protocols more individuals should be involved. Each meeting should review accrual rate, data collection and entry, recruitment and retention issues, and discussions of any problems encountered, changes needed and how to bring them about.

Review With Your Mentor When And To Whom SAEs Must Be Reported: You should download the standard IRB form and have blank copies in your regulatory binder. An event need not be clearly related to the conduct of the study before one must report it. e. g. A subject falls and breaks her leg on the stairs coming to the visit location.