

Mentoring the Young Investigator (YI)

Operationalizing Protocols

- Review The Regulatory File/Binder With the YI:** The YI should have a list of regulatory binder contents which he/she received from the GCRC. Provide the YI with contact information for those who can help fill in any missing bits.
- Review The Protocol Source Documents And Database:** Both the source documents and the database should be user-friendly enough for you to clearly see what data must be collected and how it should be recorded.
- Review The Subject File/Binder:** This should contain all documents related to the subject and should contain a special sheet or section that lists safety measures and labs.
- Review Written Procedures:** The procedures should detail the steps involved in subject safety monitoring and the data verification and integrity methods.
- Attend A Protocol Operationalizing Meeting:** This meeting should include all members of the research team and should review standard operating procedures for the informed consent process, data collection and entry as well as safety issues and contingency procedures.
- Use Of Mock Subjects:** When possible the YI should conduct the protocol with mock subjects. This will maximize the likelihood that all subjects enrolled will yield usable data. Meet with the YI to review results.
- Conduct Of The Protocol With the First 3-5 Subjects:** Encourage the YI to conduct the protocol with the first few subjects and then convene a meeting of the research team to evaluate performance and discuss possible changes.
- Ongoing Protocol Assessment Meetings:** Review the YI's plans for ongoing protocol assessment meetings and plan to attend the first few of these at least, and then on a regular and on-going basis.
- Review With The YI When And To Whom SAEs Must Be Reported:** He/she should have blank copies of the standard COMIRB form in the regulator binder. Discuss the difference between SAEs and AEs as well as the role of relatedness. 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. Check with the RSA if there are any questions about these issues.