

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

Mentoring the Young Investigator (YI)

Protocol Writing and Submission

- Meet With YI About The Nature of Clinical Research;** review research-treatment distinction, brief regulatory overview, teach YI to use tracking changes function in Word, and a reference manager software, and how to perform literature searches and create a database.
- Meet With YI About His/Her Research Idea;** purpose, understanding of design issues, background, significance, scientific questions, reasons for questions, population to be studied.
- Provide YI With Protocol Writing Resources;** on-line resources (NIH, PHS, GCRC), names of local experts, references for pivotal work in field.
- Meet With YI To Review And Critique Protocol Draft;** examine and discuss all sections prompting the YI to articulate issues that arose in writing each section.
- Provide YI With Information about Additional Resources and Expertise;** contact information for experts in DSMPs, DSMBs, HIPAA, FDA, informed consent, data handling, biostatistics et al.
- Meet With YI to Review And Critique The Full Protocol Draft;** examine and discuss each section of the protocol, use NIH or PHS format
- Instruct YI To Personally Contact GCRC Core Managers (RSA, Biostatistics, Bioinformatics, Administrative Manager);** encourage early protocol submission for pre-review.
- Meet With YI Post-GCRC Pre-Review;** based upon readiness for submission, advise YI to proceed or delay
- Meet With YI Prior To The Review Meeting;** Discuss the review process, what to expect from reviewers, expected turn-around time et al.
- Attend Review Meeting With YI;** This is required by the GCRC.
- Meet With YI Post-Review Meeting;** debrief and discuss YI's experience of the review process and what is now required.
- Meet With YI To Review And Assess Adequacy of Responses to Reviewers;** advise YI to proceed with submission of revisions, or delay.
- Protocol Approval or Disapproval;** Proceed to protocol initiation, or regroup.