Proposal for the IND/IDE Seminar Series for Fall 2010

1-1.5 hr lectures will be taking place at CC main conference room on Fridays 12-2pm

**August 27, 2010.** Overview of the investigator responsibilities under IND, IND exemptions (CC best practices)
- Definitions of Drug, Device, Comb product
- 21 CFR 312
- Overview of Drug dev and IND process
- CDER org chart and where to call (website)
- Botanicals – special category
- Cancer Center – Clinical Trials Support Unit (CTSU) Best Practices
  i. Protocol Development
  ii. IND exemptions – CC consultative process
  iii. Submit Protocol, Informed Consent Document, and other study materials to UC Davis IRB
  iv. Conduct a protocol initiation meeting
  v. Post study on clinicaltrials.gov

**September 3, 2010.** IND filing, timelines, paperwork and reports
- UC Davis IND webpage
  http://www.ucdmc.ucdavis.edu/ctsc/investigators/IND/
- IND filing timelines
- Pre-IND meeting, timelines, information package. minutes
- IND cover letter w/examples
- IND table of content
- Completing Form 1571
- Completing Form 1572
- Binders and where to send
- What happens after submission
- Amendments
- Annual reports – table of contents, when to send
- Withdrawing of IND
  b. Inactive status of IND

**September 10, 2010.** Monitoring and special considerations for multi-center trials
- Basic Principles
  o Investigator’s Responsibilities
  o Sponsor’s Responsibilities
  o Monitor’s Responsibilities
- Study Initiation Visit, Periodic Monitoring Visits, Study Termination/CLOSEOUT
Safety Reporting
Record Retention
Communicating with other sites
Other

September 17, 2010. IDE filing and performing studies under IDE regulations

September 24, 2010. GLP/GMP regulations and why it is important
   Definitions: GLP, GTP, GMP
   How GLP studies should be conducted
   How GTP compares with GMP
   GMP facilities and operations
   What can be GMP manufactured at UC Davis
   How an investigator at UC Davis can have a product GMP manufactured and quality controlled so an IND will have an appropriate clinical grade product
   IND support of cellular and stem cell products for the investigator by the UC Davis GMP facility.

October 1, 2010. FDA Audits – DVD