SUMMARY OF 2012 LECTURES FOR: CLINICAL TRIALS DESIGN & CONDUCT [CTSC 5102S]

Time: Thursdays, 4:30-7:30pm
Location: Clinical Research Center, Room 105, Acute Care Building, RWJUH, New Brunswick
[ Parking at 125 Paterson Street deck ]

Course Directors:  Vivien Hsu, MD, hsvm@umdnj.edu
Sunanda Gaur, MD, gaursu@umdnj.edu

Week 1 (Jan 19)
• Lessons learned; Overview of ethics/regulations- Dr. Hsu
• How do I design a clinical trial -Dr. Stevens or Mark
• Discuss project

Week 2 (Jan 26)
• How do I select statistical test (s) for my research study (2 hrs)- Dr Yen-Hong Kuo
  (Power analysis, sample size calculations, analysis of study results)
• Approach to data analysis/statistics for non-statistician- Dr Yen-Hong Kuo

Week 3 (Feb 2)
• How do I design an observational study?
• How do I use/design Questionnaires for my study ?
• Endpoints; how/when can biomarkers be used in clinical trials? -Dr. Peter Schafer

Week 4 (Feb 9)-
• How do I write a clinical protocol- provide samples – Mark Sturgill
• How do I write a consent form –provide samples (2 hrs) –Susan Rood
  (Include consenting process , phone & web based consents, language barier)

Week 5 (Feb 16)
• Phase 1-4 trials; drug development (2 hrs) - Dr. Stevens
• Multi-centered trials - Dr. Mahmood Loglimar-Adham

Week 6-FIRST DRAFT OF PROTOCOL due (Feb 23)
• How do I complete the IRB application process? -McCloskey
• FDA function in clinical trials – Eileen Duffy (Pharm D)
• IRB function /Code of Federal Regulations-Bistak
**Week 7- FIRST DRAFT of ICF due (March 1)**

- PK/PD (2 hrs) - *Mark Sturgill*
- Lab processing of phase 1 studies - *Galina*

**Week 8-FIRST DRAFT OF IRB APPLICATION due (March 8)**

- Role of research pharmacist- *Dr. Goodin*
- Role of CRO in research - *Dr. Ladd*
- Return protocols & Q/A session to discuss protocol – *Drs. Hsu/Gaur*

**Week 9 (March 22)**

- Pediatric study design- challenges in clinical trials - *Dr. Gaur*
- Role of PI and other key members in clinical trials - *Dr. Hsu*
- ROLE PLAY in consenting process & Q/A session for ICF – *Drs. Hsu/Gaur*

**Week 10 (March 29)**

- QOL tools - *Dr. Moorthy*
- Other questionnaires used in clinical trials/ HAQ/MD & patient assessment tools- *Dr. Hsu*
- Q/A session for IRB & ICF forms- *Drs. Hsu & Gaur*

**Week 11: regulatory process (April 5)**

- Implementation of clinical trial protocol, source documents etc/ SAE reporting- *McCloskey*
- SOP- *McCloskey*
- Normal vs. Disease population in Phase 1 trials- *McCloskey*

**Week 12 (Project due- April 12)**

- How do I develop a budget? – *Sherri*
- Compliance (2 hrs- regulations from the site perspective)- *Cathy Whalen*

**Week 13 (April 19)**

- How to run a registry – review of different types(?Dr. Tishfield)
- Pharmacogenomics – *Dr. Conney*
- Challenges in running a CRC; funding – *Drs. Hsu & Gaur*

**Week 14-15: (April 26 & May 3)**

- Mock IRB - *Drs. Gaur, Hsu, Duffy, Sturgill, Rood*