

PRACTICAL ASPECTS OF CLINICAL TRIAL DESIGN

CTSC 5102S (3 credits)

Thursday evenings, 4:30-7:30pm

RWJMS Clinical Academic Building, Room 3403, New Brunswick, NJ

Course Directors: Vivien Hsu, M.D. and Sunanda Gaur, M.D.

Date/Lecturer	Week	Topic	Readings
9/10/09	1	<p><u>Historical Perspectives & Overview</u></p> <ul style="list-style-type: none"> a. Lessons from the past, the codes b. Regulations impacting clinical trials (<i>important for those who are not taking the Ethics and Regulations course</i>) c. History of pediatric regulations, economic aspects <p><u>Concepts in Study Design (An Overview)</u> -- (<i>for those not taking biostatistics</i>)</p> <ul style="list-style-type: none"> a. Types of clinical studies (e.g. prospective vs retrospective, cohort, case control, etc.) b. Bias in clinical studies – purpose of randomization, stratification, blinding 	To be assigned
9/17/09	2	<p><u>Concepts in Study Design (continued)</u> – (<i>for those not taking biostatistics</i>)</p> <p>Basic statistics for study design (power analysis, sample size calculation, etc.)</p>	
9/24/09	3	<p><u>Clinical Trials Process</u></p> <ul style="list-style-type: none"> a. Types and Phases of Clinical Trials (i.e. crossover, parallel, various phases) b. Identifying steps in drug development process, IND c. Issues related to drug development in children d. Defining key components of clinical trial and key members of research team 	
10/01/09	4	<p><u>Unique Considerations in Pediatric Trial Design (kids are not small adults....)</u></p> <ul style="list-style-type: none"> a. Pharmacokinetic & pharmacodynamics in children – its impact on study design b. Mathematical methods, novel approaches to pediatric clinical trial design, neonatal drug studies c. Extrapolation of efficacy: Pediatric Study Decision Tree <p><i>INTRODUCE PROJECT – WRITING IRB PROPOSAL</i></p>	
10/08/09	5	<p><u>Participant Protection in Clinical Trials</u></p> <ul style="list-style-type: none"> a. Informed consent process (Peds and Adults) – OSCE video b. IRB function c. GCP and FDA regulations – how to write an ICF 	

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10/15/09	6	<u>Presentations of Research/Writing an IRB application</u> a. Students present their research idea with outline of proposed study b. How to write an IRB application	
10/22/09	7	<u>Policies and Procedures</u> a. SOPs for conducting clinical trials b. Safety measures for biological drugs and chemotherapy	
10/29/09	8	<u>Overcoming Barriers to Participation in Clinical Trials</u> a. Subject Selection b. Risks, referrals, minorities, costs c. Ethical Issues: 1. Children as research volunteers 2. Rights of children and parents 3. Consent/Assent issues 4. Child who is ward of the state d. Subject recruitment & retention – pediatric & adult populations	
11/05/09	9	<u>Phase I Trials</u> a. Normal vs disease population b. Laboratory specimen processing (PK/PD studies) c. Pediatric issues in Phase I trials <i>PROJECT DUE – IRB Proposal Distributed to Ethics Course</i>	
11/12/09	10	<u>Budgeting for Trials & Budget Negotiation</u>	
11/19/09	11	<u>Research Pharmacy</u>	
11/26/09	12	<i>NO CLASS – Thanksgiving</i>	
12/03/09	13	<u>Adverse Events/Safety Assessment</u>	
12/10/09	14	<u>Regulatory Process</u>	

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		a. Preparation & implementation of clinical protocol (i.e. clinical trial agreements, IRB, FDA, and Sponsor requirements) b. Monitoring c. Source documents <i>TAKE HOME FINAL EXAM</i>	
12/17/09	15	<u>Data Management</u> a. Data and clinical report form completion b. Adverse event reporting c. Data collection, entry and storage <i>FINAL EXAM DUE MONDAY, DECEMBER 21, 2009</i>	

Required Textbooks:

A Step-By-Step Guide to Clinical Trials (2001) by Marilyn Mulay, Jones and Barlett Publishers, Inc.

Available on Amazon at http://www.amazon.com/Step-Step-Guide-Clinical-Trials/dp/0763715697/ref=si3_rdr_bb_product

Clinical Trials: Design, Conduct, and Analysis (Monographs in Epidemiology and Biostatistics, Vol 8) (1986) by Curtis

Meinert, Oxford University Press, Inc.

Available on Amazon at http://www.amazon.com/Clinical-Trials-Monographs-Epidemiology-Biostatistics/dp/0195035682/ref=si3_rdr_bb_product

Assignments for Evaluation:

- 1) PROJECT- DEVELOPMENT OF PROTOCOL & CONSENT DOCUMENTS (50%)
- 2) FINAL TAKE HOME EXAM (40%)
- 3) COMPLETION OF CITI TRAINING (10%)