

**PRACTICAL ASPECTS OF CLINICAL TRIAL DESIGN/CONDUCT**

CTSC 5102S (3 credits)

Thursdays, 4:30-7:30pm,

Conference Room, CRC

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

Date	Week	Topic	Speaker	Readings
9/8/2009 --R	1	<p><b><u>Course Overview and Requirements</u></b> (combined with Ethics class on 9/8/09-- Room CAB 3403)</p> <p><b><u>Historical Perspectives and Overview</u></b></p> <ul style="list-style-type: none"> <li>a. Lessons from the past, ethical codes</li> <li>b. Regulations impacting clinical trials</li> </ul>	<p>offered 9/8/09 with Ethics class</p> <p>Drs. Leibowitz/Moorman/ Donna Hoagland</p>	
9/17/2009	2	<p><b><u>Concepts in Study Design (An Overview)</u></b> – (for those not taking biostatistics)</p> <ul style="list-style-type: none"> <li>a. Types of clinical studies (eg., retrospective vs. prospective, cohort, case control, etc.)</li> <li>b. Bias in clinical studies - purpose of randomization, stratification, blinding</li> <li>c. Basic statistics for study design (power analysis, sample size calculation, etc.)</li> </ul> <p><a href="#">CITI certificate due</a></p>	<p>Anna Petrova, M.D.,MPH. Anna Petrova, M.D.,MPH Anna Petrova, M.D.,MPH</p>	
9/24/2009	3	<p><b><u>Clinical Trials Process</u></b></p> <ul style="list-style-type: none"> <li>a. Defining key components of a clinical trial and key members of the research team (<a href="#">bring protocol examples</a>)</li> <li>b. Introduce student project ( <b><u>Introduce student project, refer to UMDNJ IRB website for assistance in preparing protocol and IRB application Further discussion on project will occur on 10/15 session</u></b>)</li> <li>c. Phases of clinical trials- <a href="#">cost and time to bring a new drug to market!</a></li> <li>d. Identifying steps in the drug development process, IND</li> </ul>	<p>a &amp; b)Vivien Hsu/Sunanda Gaur</p> <p>c) Dr. Randall Stevens</p> <p>d) Dr. Randall Stevens</p>	
10/1/2009	4	<p><b><u>Pharmacokinetic Considerations in Clinical Trial Design</u></b></p> <ul style="list-style-type: none"> <li>a. Review of basics in Pharmacokinetics</li> <li>b. Pharmacokinetics/Pharmacodynamics in children - How children differ from adults</li> <li>c Use of adult pK data to design pediatric studies</li> </ul>	<p>Mark Sturgill, Pharm.D</p>	

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10/8/2009	5	<p><b><u>Challenges in conducting Clinical trials in children</u></b></p> <p>a. Pediatric regulations</p> <p>b. Subject selection, risks, referrals, minorities, costs</p> <ol style="list-style-type: none"> <li>1. Children as research volunteers</li> <li>2. Rights of children and parents</li> <li>3. Consent/Assent issues</li> <li>4. Child who is ward of the state</li> </ol> <p><b><u>Adults: Subject recruitment and retention:</u></b></p> <p>fair subject selection, coercion, exploitation; how to work with IRB–</p>	<p>Sunanda Gaur, M.D. Lisa Cerrachio, R.N. Vivien Hsu, MD</p>	
10/15/2009	6	<p><b><u>Completing an IRB Application and Packet - Hands-on work on student projects (focus on study design)</u></b></p>	<p>Vivien Hsu, M.D., Sunanda Gaur, M.D., Marc Sturgill, Pharm.D., Anna Petrova, M.D., Ph.D.</p>	
10/22/2009	7	<p><b><u>Participant Protection in Clinical Trials</u></b></p> <p>a. video on ICF process- pediatrics and adults/Role Play</p> <p>b. GCP and FDA regulations</p> <p>c. IRB function</p>	<p>Sunanda Gaur/Vivien Hsu Susan Torok Root</p>	
10/29/2009	8	<p><b><u>Completing an IRB Application and Packet</u></b> – Hands-on work on student projects (focus on writing a Consent Form and completing an IRB Application)</p>	<p>Deborah McCloskey, R.N. et al Lisa Cerrachio, R.N. Stephanie Farias, R.N.</p>	
11/5/2009	9	<p><b><u>Policies and Procedures</u></b></p> <p>a. SOPs for conducting clinical trials</p> <p>b. Overview of Investigational drug services and role of research pharmacist.</p>	<p>Deborah McCloskey, R.N. Susan Goodin Pharm.DBCOP.</p>	

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11/12/2009	10	<u><b>Phase I Clinical Trials</b></u> a. Normal vs. disease populations b. Laboratory specimen processing (PK/PD studies) c. Bioequivalence Studies	Deborah McCloskey, R.N. Galina Solodkin Marc Sturgill, Pharm.D.	
11/19/2009	11	<u><b>a) Budgeting for Trials &amp; Budget Negotiation</b></u>  <u><b>b) Designing and Managing multi-centered trials</b></u> <u><b>c) Validating biomarkers; pitfalls of using biomarkers; QTc in safety monitoring</b></u> Student project due (distributed to Ethics Course mock IRB vs. Clinical Trial Design faculty IRB)	a) Sherry Gzemsky b& c) Dr. Brookman	
11/26/2009	12	<i>NO CLASS (Thanksgiving holiday)</i>		
12/3/2009	13	<u><b>1 Adverse Drug Reaction/Safety Assessment</b></u> <u><b>2 Practical Solutions in conducting clinical trials</b></u> * Case Studies * Challenges in operating a Clinical Research Center	Deborah McCloskey, R.N. Lisa Cerrachio, R.N. Drs. Vivien Hsu & Sunanda Gaur	
12/10/2009	14	<u><b>Regulatory Process &amp; Data Management</b></u> a) Implementation of clinical protocol (CTA, IRB, FDA, Sponsor requirements), b) source documents, clinical trial monitoring, data & clinical report form completion, c) data collection, entry, storage. <b>Take</b> <u><b>Home final exam (due Monday, December 21, 2009)</b></u>	Deborah McCloskey, R.N. Lisa Cerrachio, R.N. ?Pat Dalton	
12/17/2009	15	<u><b>1. Pharmacogenomics</b></u> <u><b>2.Course Feedback and Assessment</b></u>	pending speaker	

**Suggested Reading:**

1) **A Manager's Guide To The Design and Conduct of Clinical Trials (2nd edition,2006)** by Phillip Good,

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2) **Good Clinical Practice Reference Guide** by FDA- revised yearly (Clinical Research Resources, LLC) **FDA.Gov**

3) **Principles and Practice of Clinical Research** by John Gallin (2nd Edition 2007)

4) **Common Terminology Criteria for Adverse Events (CTCAE)** available at the following link: **<http://CTEP.cancer.gov>**

**Assignment for Evaluation:**

1. Project – Development of protocol, consent documents, and IRB application (50%)
2. Final take-home examination (40%)
3. Completion of CITI training (10%)

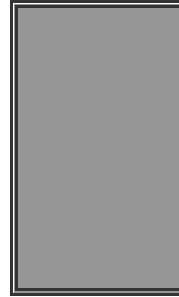
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Gaur/Hsu

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