# Methods in Clinical Research Core Curriculum 2010

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**Place:** Tulane Medical School  
1430 Tulane Avenue, **ROOM 7062**

**Lecture I:** What is Clinical Research? Why Do Clinical Research?  
**Date & Time** Tuesday, April 13, 2010 4:00-4:30 p.m.  
**Instructor:** David Mushatt, M.D.  
**Description:** This lecture will discuss the importance of research including why do research and how to do it.

**Lecture I:** Reporting of Adverse Events  
**Date & Time** Tuesday, April 13, 2010 4:30-5:00 p.m.  
**Instructor:** David Mushatt, M.D.  
**Description:** The reporting of adverse events encompasses reporting any serious side effects from the medication or the protocol to the IRB. Ways to go about reporting such events will be discussed.

**Lecture II:** Overview of the Program: Clinical and Translational Research Education and Commercialization Program  
**Date & Time** Tuesday, April 20, 2010 4:00-4:30 p.m.  
**Instructor:** Gina Currera, MeD.  
**Description:** This lecture will introduce you to the services that the CTRECP Program has available to both Tulane and LSU residents, fellows, faculty, researchers, etc.

**Lecture II:** The Tulane/LSU Clinical Trials Navigator  
**Date & Time** Tuesday, April 20, 2010 4:30-5:00 p.m.  
**Instructor:** Barbara Kurth, Ph.D.
**Description:**  This lecture will outline what the Clinical Trials Navigator can assist Principal Investigators with as well as define the different types of trials.

**Lecture III:**  Design of Clinical Trials  
**Date & Time** Tuesday, April 27, 2010  4:00-5:00 p.m.  
**Instructor:** Patricia Kissinger, Ph.D.  
**Description:**  The lecture will describe the basic study design of Phase I, Phase II, Phase III, and Phase IV trials. Sampling and randomization procedures. Importance of compliance and follow-up on generalizability. Importance of reliability and validity of measurements. Describe some of the common data analysis issues (e.g. survival analysis, intent-to-treat).

**Lecture IV:**  Biostatistics-1  
**Date & Time** Tuesday, May 4, 2010  4:00-5:00 p.m.  
**Instructor:** Leann Myers, Ph.D.  
**Description:**  The lecture will provide an introduction to probability distributions, hypothesis testing, interpretation of p-values, one-sided and two-sided tests, the chi-square test for comparing two proportions, the independent t-test for comparing two means and the paired t-test.

**Lecture V:**  Biostatistics-2  
**Date & Time** Tuesday, May 11, 2010  4:00-5:00 p.m.  
**Instructor:** Leann Myers, Ph.D.  
**Description:**  The lecture will cover the issues of power and sample size calculation for comparing two means and two proportions and interpretation of regression equations.

**Lecture VI:**  Introduction to Epidemiologic Studies  
**Date & Time** Tuesday, May 18, 2010  4:00-5:00 p.m.  
**Instructor:** Patricia Kissinger, Ph.D.  
**Description:**  The lecture will focus on the discussion of three types of descriptive studies - correlational, case report/case series, and cross-sectional. Two types of analytic studies: case-control, cohort. Intervention studies: clinical trials, community trials. Describe strengths and limitations of each type of design and methods of reducing bias. Measures of association and confidence intervals. Identify the design of several studies.

**Lecture VII:**  The Importance of a Career Mentor  
**Date & Time** Tuesday, May 25, 2010  4:00-5:00 p.m.
Instructor:  
Description: This lecture will outline the importance of Mentoring in Clinical Research. The types of mentoring and the characteristics that make for a good mentor will also be discussed.

Lecture VIII: Data and Safety Monitoring Plans  
Date & Time  Tuesday, June 1, 2010  4:00-4:30 p.m.  
Instructor: Mary Meyaski-Schluter, MSN  
Description: The lecture will provide a basic background into Data and Safety Monitoring: their purpose and the reason behind them. Will also include the components that are required in a DSMP.

Lecture VIII: Ethical and Regulatory Issues in Human Research  
Date & Time  Tuesday, June 1, 2010  4:30-5:00 p.m.  
Instructor: Jim Outland  
Description: The lecture will summarize rules and regulations pertaining to human research at Tulane Medical Center. In addition, it will provide tips on how to prepare a successful IRB application. The lecture will be supplemented with handouts covering ethical and legal issues of human research.

Lecture IX: Introduction to Grant Writing/Manuscript Preparation  
Date & Time  Tuesday, June 8, 2010  4:00-5:00 p.m.  
Instructor: Paula Gregory, Ph.D.  
Description: This lecture will outline a framework for writing proposals and manuscripts for clinical research studies. Peer review process at federal agencies and how to obtain information about funding sources.