

## INTRODUCTION TO CLINICAL RESEARCH

Fall Semester, 2006

(1 credit hour)

Hearing and Speech (AUD 805)

MD/PhD Students (GSMC 803)

Nursing (NRSB 803)

Graduate Preventive Medicine (PRVM 803)

2<sup>nd</sup> Year Medical Student (IDSP 850)

4<sup>th</sup> Year Medical Student (IDSP 950)

**Time:** 5:00 pm - 6:30 pm, Thursday

**Place:** Wahl Hall East Auditorium; except for classes 9/21 and 10/19 which will be held in Lied Auditorium

**Co-Instructors:** Richard J. Barohn, MD  
Professor and Chair Department of Neurology  
GCRC Program Director, GH04 Delp, MS 3037  
(913) 588-6094/0970; email: [rbarohn@kumc.edu](mailto:rbarohn@kumc.edu)

Jeffrey M. Burns, MD  
Assistant Professor, Department of Neurology  
GCRC Assistant Director, Director of Education, GH04 Delp, MS 3037  
(913) 588-0682  
email: [jburns2@kumc.edu](mailto:jburns2@kumc.edu)

### Course Description:

The course will provide a comprehensive overview to clinical research. The student will gain an understanding of how to develop clinical research questions including protocol design and the factors that should be considered in initiating a clinical research study. This will include biostatistical considerations, the recruitment of study participants, regulatory issues, and data management, and defining measures and instruments. Students will gain knowledge of how to define clinical research among the various institutional entities involved with clinical research at The University of Kansas Medical Center such as the Research Institute (RI), General Clinical Research Center (GCRC) and the Human Subjects Committee (HSC). Additionally, one component of the course will focus on how to apply for funding (grantsmanship), critical appraisal of research studies, and how to present research data.

The target audience for the course is broad and includes faculty involved in the K-30 program, students pursuing a masters in clinical research, clinical fellows in the school of medicine, doctoral students (medical and graduate, MD/PhD, MD/MPH, etc.), post-doctoral fellows, medical residents, and faculty at KUMC and KU-Lawrence.

**Prerequisites:** Permission from the instructor

### Course Objective:

Upon completion of the course students will be able to:

- Discuss principles of clinical research study design and protocol development
- Describe ethical and regulatory issues in conducting research involving human subjects
- Discuss biostatistical significance including data management and defining measures and instruments
- Describe the process of applying for funding
- Describe how to present research data

**Course Format:** Lecture and discussion

The course is composed of 12 to 14 lectures and discussion (1 ½ hours each) organized into three components over a period of one semester.

**Grading Policy:**

Students will be evaluated on their attendance and participation in the course and upon submission of an outline of a clinical research project which addresses the key components of clinical research discussed in the course. A letter grade will be assigned to each student based on their evaluation.

Participation and Attendance	75%
Clinical Research Project	25%

The students will be evaluated on the scale of Superior, High Satisfactory, Satisfactory, Low Satisfactory and Unsatisfactory.

Superior	90-100%
High Satisfactory	80-89%
Satisfactory	70-79%
Low Satisfactory	60-69%
Unsatisfactory	59% or below

Students will be evaluated on their attendance and participation in the course and upon submission of an outline of a clinical research project that demonstrates a working knowledge of study design issues (outcome measures, data management, biostatistical considerations) as well as ethical and regulatory issues. A letter grade will be assigned to each student based on their participation and their ability to apply principles of clinical research design to clinical research protocol development.

**Course Readings:**

An instructional packet of readings will be provided to the students. Readings will be selected from a variety of sources and will be pertinent to each topic discussed.

**Topic Outline and Textbook Reading Assignment**

**I. Overview of Clinical Research/Mentorship (Key instructor Richard Barohn, MD)**

1. Who/What/Why/Where of Clinical Research
  - Clinical research defined
  - RI, GCRC, HSC
  - Research Coordinators
  - Mentorship
2. Developing Clinical Research Questions/Hypothesis
3. Types of Clinical Research Designs
  - Clinical Trials
  - Observational
  - Descriptive
  - Case Studies
4. Ethics of Clinical Research

**II. Protocol Design (Key Instructor Matt Mayo, PhD)**

5. Designing a Clinical Research Protocol
6. Research subjects
  - Identify
  - Recruit
  - Consent
7. Study organization and management/Forms
8. Outcomes, co-variants, sample size, analytic plans
9. Measures/Instruments
10. "Putting it all together"
  - How I got my Investigator-Initiated research off the ground at KUMC

**III. Data Presentation and Appraisal (Key Instructor Lauren Aaronson, PhD)**

11. Grantsmanship/RI Funding
12. Critically Appraising Research-A Consumer's Perspective
13. Writing a Clinical Research Paper and Submitting to a Journal
14. Effective Data Presentation: Platforms & Posters
  - Organize/Present Project Data

**Tentative Lecture Schedule** (Thursday, August 24th-1<sup>st</sup> Day of Classes)

<u>Date</u>	<u>Instructor</u>	<u>Subject</u>
Aug. 17 <sup>th</sup>		<b>No Class Scheduled</b>
Aug. 24th	Barohn	Who/What/Why/Where of Clinical Research
Aug. 31st	Ellerbeck	Developing Clinical Research Questions/Hypothesis
Sept. 7th	Choi	Types of Clinical Research Designs
Sept. 14th	Menikoff	Ethics of Clinical Research
Sept. 21st	Mayo	Designing a Clinical Research Protocol <b>*Class will be held in Lied Auditorium</b>
Sept. 28th	Blackwell	Research subjects
Oct. 5th	Smith	Study organization and management/Forms
Oct. 12th	Gronseth	Critically Appraising Research-A Consumer's Perspective
Oct. 19th	Mayo	Outcomes, co-variants, sample size, analytic plans <b>*Class will be held in Lied Auditorium</b>
Oct. 26th	Liow	Clinical Research in a Community Setting
Nov. 2nd	Aaronson	Grantsmanship / RI Funding
Nov. 9th	Lyons	Measures/Instruments
Nov. 16th	Montello	Writing a Clinical Research Paper and Submitting to a Journal
Nov. 23rd		<b>NO CLASS – THANKSGIVING BREAK BEGINS</b>
Nov. 30th	Radel	Effective Data Presentation: Platforms & Posters
Dec. 7 <sup>th</sup>	Weir	Conduct of First-IN-Man Trials <i>LAST DAY OF CLASSES</i>
<i>*Dec. 11<sup>th</sup></i>		<i>FIRST DAY OF FINALS</i>
Dec. 14th	Burns	Putting it all together: How I got my research off the ground at KUMC <b>Research outline due by email</b>
<i>*Dec. 15<sup>th</sup></i>		<i>LAST DAY OF FINALS</i>

*\*Note to Instructor: Grades due by Dec. 27<sup>th</sup>*

**Learning assistance, academic performance enhancement, and psychological services at KUMC are free, confidential, and available at Student Counseling & Educational Support Services by calling 913-588-6580 or visiting G116 Student Center.**

**Any student in this course who needs an accommodation because of a disability in order to complete the course requirements should contact the instructor or the Equal Opportunity / Disability Specialist (913) 588-7813, TDD (913) 588-7963 as soon as possible.**