

INTRODUCTION TO CLINICAL RESEARCH AND PROPOSAL DEVELOPMENT

Fall 2009

Course Director: Matthew Karafa, PhD

Office: JJN3-01

Time: Thursdays, 9am-12pm.

karafam@ccf.org

Phone: (216) 445-9556

Sept 10th – Dec 12th

Course Description

This course is designed to provide you with an overview of skills necessary to plan and conduct clinical research. The goals of the 15-week course are to learn the basic skills necessary to develop and describe a clinical research project and apply these skills by working with a research mentor to develop a project proposal, which can be submitted for funding. Special emphasis will be placed on identifying clinical research resources at the Cleveland Clinic, components of a written research proposal, study design and statistical considerations, ethical and legal considerations of clinical research, and specific methodologies such as cost-benefit studies, analyses of large data sets, outcomes research, and qualitative methods in clinical research. Students and faculty will devote the last session of the course to conducting a mock-NIH review of their proposals. **CME Credit will be offered.**

Course Objectives

1. Identify and utilize clinical research resources at the Cleveland Clinic Foundation.
2. Explain the elements of a successful clinical research program.
3. Explain basic principles of clinical research design, data collection, and analysis to answer specific clinical research questions.
4. Develop a comprehensive research proposal to answer a clinical research question.
5. Explain the legal and ethical considerations of conducting clinical research.
6. Explain the principles and processes of scientific review of research proposals.
7. Develop skills in transferring clinical research knowledge into clinical practice.
8. Improve ability to edit manuscripts for accuracy, clarity, and conciseness

Course Requirements

Requirement	Points
Research question(s) prefaced by a brief review of the literature substantiating that a problem exists-1 page	10
Full written literature review on the clinical problem, what's known, what's been done, what's the gap in the literature, and how your proposed research will address this gap (background & significance-2-3 pages.	15
Specific aims and hypotheses (1 page)	10
Student power point presentations on methods section of their proposal	15
Full proposal (15-20 single spaced pages)	40
Participation in mock NIH proposal review session with faculty where each student gets to be a reviewer and reviewee!	10

Textbooks

Designing Clinical Research, 2nd Edition. Hulley, Stephen B. and Cummings, Steven R. (editors). Baltimore: Williams and Wilkins. 2000 [ISBN: 0-781-72218-7] . Other text, chapters, and articles to be used in the preparation for each session will be provided by the instructor prior to the session.