

# INTRODUCTION TO THE PRINCIPLES



# AND PRACTICE OF CLINICAL RESEARCH

from the National Institutes of Health Clinical Center

October 14, 2014 to March 9, 2015

This course will be offered live at the NIH Clinical Center, Building 10, Lipsett Amphitheater, classes will be held at 5:00 pm, please check the Clinical Center IPPCR website for a course schedule: <http://clinicalcenter.nih.gov/training/training/ippcr.html> .

This course will also be offered remotely for students who register at an approved remote site. Registered remote sites can choose to view the lectures live via web broadcasting or archived online on the course website <https://ippcr.nihtraining.com/> . A certificate will be awarded upon successful completion of the course, which is based on receiving a passing grade on an open-book final examination. This course will be of interest to physicians and all other health professionals planning a career in clinical research.

## Topics

- Choosing a Research Question
- Design of Epidemiologic Studies and Study Development
- Using Secondary Data and Meta Analysis
- Opportunities for Innovation in Clinical Research
- Measures
- Participant Selection
- Issues in Randomization
- Overview of Hypothesis Testing
- Sample Size and Power
- Conceptual Approach to Survival Analysis
- Designing and Testing Questionnaires
- Economic Analysis in Clinical Research
- Quality of Life
- Inclusion of Women and Minorities in Clinical Trials
- Researching an Ethics Question
- Legal Issues in Clinical Research
- Information Resources for Clinical Research
- Community Based Participatory Research
- Scientific Conduct
- Protocol Mechanics
- Concepts in the Management of Projects
- Data Management in Clinical Trials
- Quality Control in Clinical Trials
- FDA Product Regulation
- The Clinical Researcher and the Media
- Data and Safety Monitoring Boards
- Evaluation of a Protocol Budget
- NIH Peer Review Process
- Technology Transfer
- Evaluation of Alternative and Complementary Therapies
- Ethical Principles in Clinical Research
- Design of Case Report Forms
- Mock Institutional Review Boards
- Clinical Research from a Patient's Perspective
- Health Disparities Research
- Basic Data Representation

## Course Objectives

- To become familiar with the basic biostatistical and epidemiologic methods involved in conducting clinical research.
- To understand the principles involved in the ethical, legal, and regulatory issues in clinical human subjects research, including the role of IRBs.
- To become familiar with the principles and issues involved in monitoring patient-oriented research.
- To understand the infrastructure required in performing clinical research and to have an understanding of the steps involved in developing and funding research studies.

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There is no charge for the course; however, the textbook, Principles and Practice of Clinical Research, Third Edition is suggested as supplemental information for the course. For additional information on the course and registration, please visit the course website <http://clinicalcenter.nih.gov/training/training/ippcr.html> or email course coordinator, Daniel McAnally at [daniel.mcanally@nih.gov](mailto:daniel.mcanally@nih.gov) or call 301-496-9425. Registration will open on Friday, August 15<sup>th</sup>, 2014 and close on Monday, October 6<sup>th</sup>, 2014.