INTRODUCTION TO THE PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH (IPPCR) COURSE

NIH Clinical Center

From the National Institutes of Health Clinical Center
October 13, 2015 to March 22, 2016

This course will be of interest to physicians, scientists, medical students, nurses, public health professionals, and all other health professionals planning a career in clinical research.

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 course assessment.

Topics

- Overview of Clinical Study Design
- Design of Epidemiologic Studies
- Clinical Research from the Patient's Perspective
- Dissemination and Implementation Research
- Measures
- Study Participant Selection
- Issues in Randomization
- Overview of Hypothesis Testing
- Sample Size and Power
- Conceptual Approach to Survival Analysis
- Designing and Testing Questionnaires
- Technology Transfer
- Quality of Life
- Inclusion of Women and Minorities in Clinical Trials
- Ethical Principles in Clinical Research
- Legal Issues in Clinical Research
- Information Resources for Clinical Research
- Scientific Conduct
- Health Disparities and Community-Based Participatory Research
- Choosing a Research Question and Implications for Efficient Clinical Trails
- History of Clinical Research: A Merging of Diverse Cultures
- Using Large Datasets for Population-Based Healthcare
- Secondary Data/Meta-Analysis
- Data and Safety Monitoring Committees
- Research with Vulnerable Participants
- Developing Protocols and Manuals of Operating Procedures
- The Clinical Researcher and the Media
- FDA Product Regulation
- Evaluation of a Protocol Budget
- NIH Peer Review Process
- Electronic Health Records and Clinical Data Interchange
- Quality Management in Clinical Research
- Clinical Trial Registration and Results Reporting
- Data Management & Case Report Form Development
- Mock Institutional Review Boards
- Pharmaceutical Development: Management of Projects
- Health Disparities Research

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.

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 the course coordinator, Daniel McAnally at daniel.mcanally@nih.gov or call 301-496-9425.