Course Number: 640
Course Title: Introduction to Clinical Research and Informatics Applications in Research
Course Credit: 2 credits
Prerequisite: MD, PhD, or equivalent doctoral degree or permission of instructor
Placement in Curriculum: Spring Semester (first semester)

Course Description: This course provides instruction in developing a clinical research question and creating a concise protocol that includes a literature review, study design, subject recruitment and sampling, instruments and other measurement approaches, sample size, consent form, budget and timetable and use of bioinformatics. Each trainee reviews and supports the work of colleagues. The course closely follows the textbook Designing Clinical Research, by S. Hulley.

Course Objectives: In this course, students will:

- acquire the skills for designing and interpreting clinical research, including appropriate informatics;
- produce a complete concise draft of a research protocol;
- help others in the class to develop these skills and protocols;
- provide feedback that will improve the course and its materials; and in time, contribute to the field by teaching these skills to others.

Learning Outcomes

At the conclusion of the course students will be able to:

use of informatics to design and interpret clinical research
prepare a first draft of a research proposal
collaborate with other researchers on protocol development
possess the skills to contribute to the field by teaching basic research skills to others
Topical Outline:

General Sessions

Getting Started: the anatomy of clinical research
Conceiving the Research Question
Choosing the Study Subjects: Specification, Sampling, and Recruitment
Planning the Measurements: Precision, Accuracy and Informatics
Getting Ready to Estimate Sample Size: Hypotheses and Underlying Principles
Estimating Sample Size and Power: The Nitty-gritty
Designing an Observational Study: Cohort Studies
Designing an Observational Study: Cross-sectional and Case-control Studies
Enhancing Causal Inference in Observational Studies
Designing an Experiment: Clinical Trials I
Designing an Experiment: Clinical Trials II
Designing Studies of Medical Tests
Research Using Existing Data: Secondary Data Analysis, Ancillary Studies, and Systematic Reviews and informatics
Addressing Ethical Issues
Designing Questionnaires and Data Collection Instruments
Data Management and informatics
Implementing the Study: Pretesting, Quality Control, and Protocol Revisions
Community and International Studies
Writing and Funding a Research Proposal

Teaching Methods

Discussions of interest emerging from the previous week
Illustrations of selected aspects of the readings from current week
Review of assigned protocol assignments
Weekly Exercises
Critique of Protocols
Submission of protocol by email

Required Texts:


Learning Experiences:

Lecture, discussion, critique, literature searchers and analysis, protocol development

Evaluation:
<table>
<thead>
<tr>
<th>Activity</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Critiques of protocols</td>
<td>10%</td>
</tr>
<tr>
<td>Submission of completed protocol</td>
<td>75%</td>
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<tr>
<td>Exercises</td>
<td>10%</td>
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<tr>
<td>Evaluation</td>
<td>5%</td>
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