

Demystifying Cancer Clinical Trials

Proposed Pre-Work on ILEARN

I. Getting Started: Introduction to the Clinical Research Life Cycle (October 14, 2016)

- i. Clinical Research Lifecycle (Under Research Coordinator Education course)
- ii. Clinical Trial Lifecycle (Under Research Coordinator Education course)

II. PI Initiated Clinical Trials – Study Design (November 18, 2016)

- i. Developing a Study Protocol (Under Research Design and Data Analysis course)
- ii. Introduction to Study Design (Under Research Design and Data Analysis course)
- iii. How Many Subjects Do I Need: Calculating Sample Size and Power (Under Research Design and Data Analysis course)
- iv. Pitfalls in Statistical Analysis (Under Research Design and Data Analysis course)
- v. Concepts of Hypothesis Testing (Under Research Design and Data Analysis course)
- vi. Why Studies Fail: Bias and Confounding (Under Clinical Research course)

If you have questions from your session II pre-work, consider attending the drop-in hours for statistical support on Wednesday mornings from 8-9 am; 35 Kneeland St., 10th Floor.

III. Clinical Trials (December 16, 2016)

- i. Principal Investigator IRB Responsibilities (Under Regulatory Affairs course)
- ii. Working with the IRB: Common Myths and Successful Strategies Best Practices in Clinical Trial (Under Regulatory Affairs course)
- iii. Data Safety and Monitoring Boards (Under Regulatory Affairs course)
- iv. What you need to know about DSMBs (But were afraid to ask), (Under Regulatory Affairs course)
- v. Research Ethics of Clinical Investigation (Under Clinical Research course)
- vi. Research Data Management (Under Clinical Research course)