BMTRY 781
Methods in Clinical Cancer Research
Spring 2019

Instructor: Elizabeth Goodwin Hill, PhD
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Class hours

General schedule: Tuesday and Thursday 12 – 2pm, March – April 2019
Students should make every effort to attend HCC's Protocol Review Committee at 8am on:

- Friday, March 8th
- Friday, March 29th
- Friday, April 19th

Class will be cancelled either Tuesday or Thursday of the corresponding week to accommodate.

Class location: Education Library, Room 119 (or outside enjoying the weather while we discuss various topics)
Class website: http://people.musc.edu/~hille/BMTRY781/
Office hours: By appointment

Description: Didactic lectures will cover the following topics:

- "Stat 101" review
- Endpoints vs. objectives
- Phase I trials
  - Algorithmic designs
  - Model-based designs
  - Hybrid designs
  - Relevant operating characteristics in Phase I
  - First-in-human
  - Multiple agents
- Phase II trials
  - Futility, efficacy and safety monitoring
  - Simon two-stage designs
  - Predictive probability designs
  - Randomized Phase II designs
  - Phase II with a safety lead-in
  - "Pick the winner" designs
  - Phase I/II
- Phase III trials
- Additional topics (as time and interest allows)
  - Basket/Umbrella trials
  - Platform trials
  - Phase I/III trials and other efforts at 'speeding up' the approval process
  - Cluster-randomized trials
  - Pragmatic trials
  - Feasibility studies
  - Pilot studies
  - PRC/IRB review
  - Informed consent
  - Patient advocacy

Textbooks: No textbook. Reading material (primarily found on the web) will be provided as necessary. This will include journal articles in clinical trial and cancer research journals. Suggested textbooks for reference include:

- *Clinical Trials: A Methodologic Perspective* (Piantadosi)
- *Clinical Trials in Oncology, Third Edition* (Green, Benedetti, Smith and Crowley)
- *Principles of Anti-Cancer Drug Development* (Hidalgo, Eckhardt, Garrett-Mayer, Clendennin)

Prerequisites: eligible students must satisfy at least one of the following criteria:

(1) The student is a Paul Calabresi K-12 training grant scholar.

(2) The student is enrolled in a masters or PhD program in the Dept. of Public Health Sciences and instructor permission

Student assessment: P/F – come to class, read the assigned readings, participate in discussions, and you'll be fine.

Course Objectives: At the end of the course, students should be able to:

(1) Understand the key statistical design components required for designing, activating and implementing a cancer clinical trial.

(2) Effectively review and critique the statistical design aspects of a clinical trial protocol and published cancer clinical trials research.