*BMTRY 781*

***Methods in Clinical Cancer Research***

Spring 2019

**Instructor**: Elizabeth Goodwin Hill, PhD

 Professor of Biostatistics

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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.