

MTR/REG 510 - Introduction to Clinical & Translational Research

Fall 2017

Instructor Information

Course Director

Emma Meagher, MD

Email

emma@upenn.edu

Class Location & Time

Maloney 8030 - M/W 4:00-5:30PM

Course Coordinator

Anna Greene

Email

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Office Location

Maloney 8035

General Information

Description

This introductory course lays the foundation for understanding practical aspects of conducting clinical research in an academic environment. The course is divided into two modules: Module 1: Research Methods, Protocol Development, and Trial Execution and Module 2: Regulatory Environment for Clinical Trials. The first module introduces clinical research, clinical protocols, study design and execution and biostatistics that underlie such studies. The second module covers ethical considerations in clinical research, study oversight, and the regulatory environment for clinical research. Upon completion, students should have a strong foundation in the fundamentals of clinical research.

Objectives

By the end of the course, students will:

- Understand the concept of clinical research
- Know the methodical approach in designing a research protocol
- Understand numerous study designs and best practices for their use
- Understand sources of bias and confounding in studies
- Distinguish between Phase 0-III trials
- Understand ethical principles for research
- Learn the basics of clinical study oversight
- Understand the regulatory environment for conducting clinical studies

Evaluation and Due Dates

Evaluation Methods:

Students will be graded based on class attendance, participation, a midterm and final exam.

33% - Attendance/Participation

33% - Midterm Exam

33% - Final Exam

Academic Policies:

Attendance:

Students are expected to attend all classes. If for any reason a student will not be in class, they should contact the Course Coordinator prior to class to alert them of the absence and make arrangements to make up course content. Please remember to sign the attendance sheet in class to indicate your presence.

Academic Integrity:

As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

Course Management: Canvas

All course materials and assignments will be managed on Canvas. Log in with Pennkey and password at <https://canvas.upenn.edu>.

Student Disabilities Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the Office of Student Disabilities Services (SDS). Please make an appointment to meet with me as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235. The office is located in the Weingarten Learning Resources Center at Stouffer Commons 3702 Spruce Street, Suite 300. All services are confidential.

Course Schedule

Date	Topic	Location	Lecturer
<i>Module 1: Research Methods, Protocol Development, and Trial Execution</i>			
8/30	Introduction to Clinical Research	MALB 8030	Meagher
9/6	Basic Pharmacology I (Online)		Meagher
9/11	Overview of Clinical Research Methods	SCTR 10-146AB, 4:15PM	Meagher
9/13	Clinical Trial Protocol Development Part I	MALB 8030	Meagher
9/18	Basic Pharmacology II (Online)		Meagher
9/20	Clinical Trial Protocol Development Part II	MALB 8030	Meagher
9/25	Basic Pharmacology III (Online)		Meagher
9/27	Overview of Drug Development and Trial Design Part I	MALB 8030	Meagher
10/2	Basic Pharmacology IV (Online)		
10/4	No Class		
10/9	Overview of Drug Development and Trial Design Part II	SCTR 10-146AB, 4:15PM	Meagher
10/11	Trial Execution: Study Start-Up, Enrollment, Study Close-Out	MALB 8030	Fluharty

10/16	Understanding the Construct of a Clinical Trial Budget	MALB 8030	Appleson
10/18	Key Statistical Concepts in Clinical Trials	MALB 8030	Vachani
10/23	Midterm Exam	MALB 8030	
<i>Module 2: Regulatory Environment for Clinical Trials</i>			
10/25	Human Subjects Protection I	MALB 8030	Meagher
10/30	Human Subjects Protection II: Case Studies	MALB 8030	Meagher
11/1	Good Clinical Practice I	MALB 8030	Grace
11/6	Good Clinical Practice II	MALB 8030	Grace
11/8	HIPAA (Online)		Heagerty
11/13	HIPAA Case Studies	MALB 8030	Steinfeld
11/15	Conflict of Interest		Rosenthal
11/20	Intellectual Property	MALB 8030	Langenberger
11/22	No Class - Thanksgiving		
11/27	Trial Oversight: Monitoring and Auditing (Online)	MALB 8030	Shank
11/29	Funding Clinical Research: Grants & Contracts	MALB 8030	Steinbugler
12/4	FDA Regulation in Academic Studies	MALB 8030	Meagher
12/6	Final Exam	MALB 8030	