MTR/REG 510 – Introduction to Clinical & Translational Research

Fall 2018

Instructor Information

Course Director	Email	Class Location & Time
Emma Meagher, MD	emma@upenn.edu	Maloney 8030 – M/W 4:00-5:30PM

Course Coordinator	Email	Office Location
Anna Greene	acgreene@upenn.edu	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: Trial Design and Execution and Module 2: Regulatory Environment for Clinical Trials. The first module introduces clinical research, clinical protocols, study design and execution and the drug development process. 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 and translational research
- Know the methodical approach to 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, quizzes and a final exam.

25% – Attendance/Participation
50% – Quizzes
25% – Take Home 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. Students are allowed two absences before it may affect their attendance grade.

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.

Course Evaluations:
Course & Lecture evaluations are completed via OASIS throughout the semester. These are a required part of course participation. Students can access evaluation forms with their Pennkey and password and will also receive emails when forms are available: http://gme-evals.med.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
	Module 1: Trial Design and Execution		
9/5	**Introduction to Clinical Research**	MALB 8030	Meagher
9/10	**Overview of Clinical Research Methods**	MALB 8030	Meagher
9/12	**Clinical Trial Protocol Development Part I**	MALB 8030	Meagher
9/17	**Clinical Trial Protocol Development Part II**	MALB 8030	Meagher
9/19	**Basic Pharmacology I (Online)**	Online	Meagher
9/24	**Basic Pharmacology II (Online)**	Online	Meagher
9/26	**Basic Pharmacology III (Online)**	Online	Meagher
10/1	**Basic Pharmacology IV (Online)**	Online	Meagher
10/3	**Overview of Pharmacology - Bringing it all together**	MALB 8030	Meagher

10/8	**Overview of Drug Development and Trial Design I**	MALB 8030	Meagher
10/10	**Overview of Drug Development and Trial Design II**	MALB 8030	Meagher
10/15	**Trial Execution: Study Start-Up, Enrollment, Study Close-Out Part I**	MALB 8030	Fluharty
10/17	**Trial Execution: Study Start-Up, Enrollment, Study Close-Out Part II**	MALB 8030	Fluharty
10/22	**Understanding the Construct of a Clinical Trial Budget**	MALB 8030	Steider
10/24	**Good Clinical Practice I**	MALB 8030	Lundin
10/29	**Good Clinical Practice II**	MALB 8030	Lundin
	Module 2: Regulatory and Funding Environment for Clinical Trials		
10/31	**Human Subjects Protection I**	MALB 8030	Meagher
11/5	**Human Subjects Protection II: Case Studies**	MALB 8030	Meagher
11/7	**HIPAA (Online)**	Online	Heagerty
11/12	**HIPAA Case Studies**	MALB 8030	TBD
11/14	**FDA Regulation in Academic Studies**	MALB 8030	Meagher
11/19	**Trial Oversight: Monitoring and Auditing (Online)**	Online	Shank
11/21	**No Class - Thanksgiving**		
11/26	**Intellectual Property**	MALB 8030	Langenberger
11/28	**Funding Clinical Research: Grants & Contracts I**	MALB 8030	Steinbugler
12/3	**Funding Clinical Research: Grants & Contracts II**	MALB 8030	Steinbugler