Center for Clinical and Translational Science
Education Resources

CTSC 5020
Regulatory Issues in Clinical Research

Faculty: Nathan P. Staff, M.D. and Alexandra J. Greenberg, Ph.D., MPH
Credits: 1
Quarter: Fall
Prerequisites: None
This course is required for the CTS Postdoctoral Master's Degree and Predoctoral programs.

Overview
This online course is designed to introduce students to regulatory issues pertaining to clinical research. Topics will expose students to the various external and internal regulatory agencies and how they affect investigator's research responsibilities. Some of the agencies explored include the Institutional Animal Care and Use Committees, the U.S. Food and Drug Administration, and Mayo Clinic's Institutional Review Board (IRB). Content experts will present online lectures and students will engage in activities and discussion based on the topics presented. Students will have the opportunity to attend an IRB meeting and present a review of a newly submitted research protocol.

Objectives
- To express a basic understanding of regulatory terms, concepts and theories that affect research
- To employ knowledge, in course discussions, of how regulations apply to investigators and their research
- To identify the appropriate course of action in relation to questions associated with regulatory issues

Evaluation
The final course grade will be a weighted average of the module quizzes and the review of a protocol for an IRB meeting.

Students are expected to spend approximately two to four hours per week on this 1-credit course.

For specific dates and times this course is provided, please see the quarterly detailed course schedule.