

CLINICAL AND TRANSLATIONAL RESEARCH (CCTR)

CCTR 520. Fundamentals of Research Regulation. 2 Hours.

Semester course; 2 lecture hours. 2 credits. Focuses on the regulations that govern translational and clinical research. There will also be a series of discussions on the influence of international policies and research guidelines on the conduct of research. Topics include, but are not limited to, the history and current role of the FDA and the OHRP within the research arena; informed consent regulations relevant to federally funded research i.e., the common rule; informed consent regulations relevant to investigations conducted in support of a new drug application or an expanded marketing indication; good clinical practice guidelines; international conference on harmonization (ICH) conduction of research guidelines; HIPAA rules and regulations relevant to the conduction of research on human subjects; fiscal accountability/responsibility; and clinical trial registration and results reporting guidelines.

CCTR 630. Design Implications in Clinical Trials. 3 Hours.

Semester course; 3 lecture hours. 3 credits. This course focuses on designing intervention studies to achieve research objectives by selecting appropriate study samples, end points and trial designs. Specific topics include efficacy versus effectiveness trials and critiquing clinical trial protocols, with emphasis on evaluating strengths and weaknesses of trial design.

CCTR 631. Adaptive Clinical Trials. 1 Hour.

Semester course; 1 lecture hour. 1 credit. Prerequisite: CCTR 630 or BIOS 571. This course is intended for the research scientist who is interested in advancing innovative trial designs and wishing to incorporate adaptations, modifications and changes to the clinical trial process. The goal is to enhance comprehension and methodologic skills in designing adaptive clinical trials for clinical investigators. The course provides an overview of the theoretical framework and key concepts of adaptive design methods in clinical trials. The design and implementation process are discussed through real-world examples. The feasibility, validity, integrity and efficiency of the trial designs will be stressed through comparisons between traditional fixed and adaptive trials. Graded as pass/fail.

CCTR 640. Team Science: Theories and Practice. 2 Hours.

Semester course; 2 lecture hours (delivered online). 2 credits. In this seminar-style course, students will keep current by participating in presentations, discussion and writing on the topic of the science of team science. This course is designed to introduce students to research in the social sciences and to help build skills in critical-thinking, leading discussions, writing and providing succinct presentations. Teamwork is difficult and it is pervasive. Whether engaging in collaborative research or collaborating with others within a chosen profession, students will better understand how to be more effective at being team members as well as leading a team.

CCTR 690. Research Seminar in Clinical and Translational Sciences. 1 Hour.

Semester course; 1 lecture hour. 1 credit. The course will include student presentations and discussion of research topics and published papers of current interest within the broad field of the biomedical and biobehavioral sciences, focusing on interdisciplinary and systems-related research. Students will be required to make an oral presentation on their research the final semester they enroll in the course for credit. Students will keep current on new findings in the biomedical and biobehavioral sciences and, through presentations and the constructive critiques of course participants, will develop verbal research communication skills. Graded as S/U/F. M.S. students will be enrolled for three semesters; Ph.D. students for four semesters.

CCTR 691. Special Topics in Translational Research. 1-6 Hours.

Semester course; variable hours. 1-6 credits. Restricted to graduate students in clinical and translational sciences programs or by permission of instructor. Translational research improves the "bench-to-bedside" trajectory of health research and is a rapidly evolving field. This course provides exposure opportunities to learn about the latest issues surrounding translational research in various disciplines. Graded S/U/F.

CCTR 692. Special Topics in Translational Research. 1-6 Hours.

Semester course; variable hours. 1-6 credits. Restricted to graduate students in clinical and translational sciences programs or by permission of instructor. Translational research improves the "bench-to-bedside" trajectory of health research and is a rapidly evolving field. This course provides exposure opportunities to learn about the latest issues surrounding translational research in various disciplines.

CCTR 697. Directed Research in Clinical and Translational Sciences. 1-15 Hours.

Semester course; 1-15 research hours. 1-15 credits. May be repeated for credit. Research leading to the M.S. or Ph.D. degree and elective research projects for other students. Graded S/U/F.

CCTR 700. Master's Capstone Project. 3 Hours.

Semester course; 3 lecture hours. 3 credits. This course is the final "capstone" product for which a student should enroll after successfully completing 27 credits of didactic course work and directed research hours. Enrollment requires the approval of the program director and student's adviser. Students may select one of two options: 1) and NIH-style grant application demonstrating knowledge of the translational and clinical processes and the regulatory environment in which research is conducted or 2) a scientific research article to be submitted to a peer-reviewed journal. Students will demonstrate that they are able to integrate the core competencies of the master's program into problem resolution as evidenced by the development of a sound, well-written research project grant proposal or research article. Graded as S/U/F.

CCTR 702. Statistics for Genetic Studies I. 3 Hours.

Semester course; 3 lecture hours. 3 credits. Restricted to students in the psychiatric, behavioral and statistical genetics track of the clinical and translational sciences doctoral program or by permission of instructor. Teaches students statistical methods for multidisciplinary research, specifically presenting the mathematical components that underlie statistical analysis and including probability theory, statistical distributions, inference and linear models.

CCTR 703. Statistics for Genetic Studies II. 3 Hours.

Semester course; 3 lecture hours. 3 credits. Restricted to students in the psychiatric, behavioral and statistical genetics track of the clinical and translational sciences doctoral program or by permission of instructor. Builds upon the quantitative statistical methods from CCTR 702. Students will learn the mathematical components that underlie statistical analysis with a focus on maximum-likelihood methods and structural equation modeling. These components provide the necessary foundation for clinical and translational research and the advanced statistical genetic methods for understanding how genetic and environmental factors impact the development of psychiatric and substance abuse disorders.

CCTR 801. Clinical Practicum. 2 Hours.

Semester course; 2 practicum hours. 2 credits. Designed to equip students with knowledge of the translational and clinical research processes and the environments in which research is conducted. Through participation in these practica, the student will observe and develop an appreciation for the role of clinical or translational scientists in the design, conduction and analysis aspects of human research, including data collection, analysis or monitoring; case management of protocol participants; recruitment and enrollment of human subjects; protection of subjects and subjects' rights; development of informed consent documents; preparation of adverse event experience reports; construction or monitoring of case report forms; grant and budget development; report preparation; and education of other health care professionals, patients or families regarding clinical and translational studies, protocol development and program administration. Graded as S/U/F.

CCTR 802. Research Practicum I. 1 Hour.

Semester course; 1 lecture hour. 1 credit. Designed to equip students with knowledge of the translational and clinical research processes and the environments in which research is conducted. Through participation in these practica, the student will observe and develop an appreciation for the role of clinical or translational scientists in the design, conduction and analysis aspects of human research, including data collection, analysis or monitoring; case management of protocol participants; recruitment and enrollment of human subjects; protection of subjects and subjects' rights; development of informed consent documents; preparation of adverse event experience reports; construction or monitoring of case report forms; grant and budget development; report preparation; and education of other health care professionals, patients or families regarding clinical and translational studies, protocol development and program administration. Graded as S/U/F.

CCTR 803. Research Practicum II. 1 Hour.

Semester course; 1 lecture hour. 1 credit. Designed to equip students with knowledge of the translational and clinical research processes and the environments in which research is conducted. Through participation in these practica, the student will observe and develop an appreciation for the role of clinical or translational scientists in the design, conduction and analysis aspects of human research, including data collection, analysis or monitoring; case management of protocol participants; recruitment and enrollment of human subjects; protection of subjects and subjects' rights; development of informed consent documents; preparation of adverse event experience reports; construction or monitoring of case report forms; grant and budget development; report preparation; and education of other health care professionals, patients or families regarding clinical and translational studies, protocol development and program administration. Graded as S/U/F.

CCTR 898. Dissertation Research in Clinical and Translational Sciences. 1-10 Hours.

Semester course; variable hours. 1-10 credits. Students will be required to complete a minimum of 15-30 credits under this course number directed toward completion of a dissertation. Prerequisite: admission to candidacy. Dissertation research with a strong interdisciplinary focus, as facilitated by the composition of the research advisory committee. Graded as S/U/F.