

# Clinical & Translational Research (CLTR)

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## **CLTR 6500 Research Ethics Human Subjs. 3 Credits**

This interactive case-based course explores ethical considerations and issues pertaining to scientific research, especially biomedical research with human subjects. Issues regarding scientific integrity, ethical research design and implementation, and research involving special populations are analyzed. Certification of training in the protection of human subjects is accomplished during progression through the material. The foundational principles of the Belmont Report underlying the responsible conduct of research are explored fully in the core content areas of human subjects, conflicts of interest and commitment, collaborative science, data acquisition, management, sharing, and ownership, publication practices and responsible authorship, mentor/trainee responsibilities, peer review, and research misconduct. The course is designed to help participants become comfortable with the language and literature of research ethics through the analysis stakeholder interests and perceptions using case studies presenting moral dilemmas in research ethics. This course is especially helpful to clinical investigators and members of Institutional Review Boards (IRB) as the application of federal regulations to particular cases is probed in depth. This is an online course that requires meetings in addition to lecture time. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a major in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

## **CLTR 6501 Intro to Biostats in Clin Res 3 Credits**

This course provides a foundation for current and future thinking in terms of practical aspects of the importance of biostatistics in conducting clinical research and thereafter translating its findings. One purpose of this course is to make the student aware of the complexities of the relationships between biostatistics and clinical research, particularly as they pertain to decision making. This course provides students a scientifically oriented perspective on the types of information that is integral for the proper design and conduct of clinical research. The goal is to improve students' conceptual understanding of the differences and similarities among the different inferential tests, and the appropriate use of statistical tests. Assessments target articulation of arguments and decisions involving, or based on, fundamental aspects of biostatistics in the context of medical research. Each of the modules are enhanced by examples using PRISM software (GraphPad). This is an online course that requires meetings in addition to lecture time. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

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*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

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Enrollment is limited to Graduate level students.

## **CLTR 6502 Clin. Research Administration 3 Credits**

This course prepares students to implement successful clinical investigations. Specifically, this course teaches how to establish a clinical research practice, understand and apply the federal and local regulations governing clinical research, develop, implement and financially-manage a protocol. As well, it addresses assurance of study quality, private and reliable data systems, intellectual property, and the identification and resolution of problems and risks. Student performance is evaluated by periodic quizzes covering content from several lectures, class participation, and a final examination. This is an online course that requires meetings in addition to lecture time. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a major in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 6503 Core Clin Translational Res. 0.5 Credits**

This course anchors the entire Clinical and Translational Research (CTR) curriculum and supplements both coursework and mentored research by bringing together all students along with CTR Scholars in GHUCCTS faculty and research development programs to: 1) share issues and challenges in design and execution of CTR; 2) host presentations by outstanding clinical investigators; 3) host presentations by outstanding translational investigators; and 4) provide the forum for an interdisciplinary CTR journal club and stimulate cross-disciplinary approaches and collaborations. This is a 2 semester course. Meets 4th Thursday of every month. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a major in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 6504 Project Dev. in Clinical Res 1 Credit**

This interactive course focuses on applying knowledge experimental design, biostatistics, and research ethics to trainee specific proposal. We will use, as examples, obesity/metabolic syndrome; age-related neurocognitive impairment; asthma. Students will work in groups to identify a researchable question and study hypothesis, and consider alternative approaches to study design, participant recruitment, and data collection. This is an online course that requires meetings in addition to lecture time. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

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Enrollment is limited to Graduate level students.

**CLTR 6505 Soc Behav Aspects of Pub Hlt 3 Credits**

This course focuses on aspects of the social and behavioral sciences (e.g., psychology, sociology, and anthropology) that are applicable to public health will be reviewed and their applications defined through case studies and presentations by public health leaders. The objective of this course is to develop public health professionals who can address the health needs of individuals, groups, and health systems within an interdisciplinary framework. Attendance and active participation in classroom discussions are required of all students. The classroom format will center around discussion of the following issues: A.What are the theories that underlie health behaviors? B.What are the social, economic, and cultural issues related to health behavior? C.What are effective and ineffective interventions to address health behavior? D.What policies and systems are needed to optimally implement the interventions? E.How are interventions, policies, and systems best evaluated? F.How can intervention strategies be improved? This is an online course that requires meetings in addition to lecture time. All non-CLTR students must request instructor/dept. approval. The Registration Team will be able to help with the "add/drop".

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

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Enrollment is limited to Graduate level students.

**CLTR 6506 Study and Clin Trials Design 2 Credits**

This course builds upon the introductory statistics concepts and skills developed in the first term, extending them to practical application in study and clinical trial design and interpretation. Topics include structural aspects of clinical trials, protocol design, randomization and blinding, issues of error, bias and hypothesis testing, selecting and working with trial outcome variables, issues in safety versus efficacy trials, power and sample size calculations, secondary subgroup and exploratory analysis.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 6507 Epidemiologic Methods 3 Credits**

Principles of Epidemiology is a course designed to provide a comprehensive introduction to Epidemiology. Epidemiology is a scientific method of studying the causes, transmission, incidence and prevalence of health and disease in human populations. The course consists of a series of lectures, problem sessions, homework assignments, and journal club. The lectures will review and reinforce topic areas of discussion. Epidemiology will be taught from a research and practical perspective by faculty who are actively involved in scientific research and public health professionals who are actively involved in public health practice.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a program in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 6508 Capstone Project 3-6 Credits**

Each student will complete and present a mentored capstone project, which includes a poster presentation and research paper. Students will submit a 1-page abstract to the program director the semester prior to their capstone registration. Each project must be approved by the student's advisor and by the Program Director prior to being undertaken, preferably by the first half of the term of study, and will be presented in a final term, program-wide poster/discussion session. Capstone projects can take several forms, individualized to the student's research activities and goals, but based in a clear and evaluable manner on the competencies developed in the MS CTR course of study, including: 1. Critical review of the literature 2. Development of clear and testable hypotheses 3. selection of appropriate methods and of a rigorous (data) analysis plan 4. attention to human subjects research ethics considerations 5. Clarity of presentation and of responses to questions.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a major in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 6509 Independent Project 1-3 Credits**

Each student will complete and present a mentored independent study project, which will be submitted to and approved by the student's advisor and by the Program Director prior to being undertaken, preferably by the first half of the second term of study, and will be presented in a final term, program-wide poster/discussion session. independent study can take several forms; individualized to the student's research activities and goals, but based in a clear and evaluable manner on the competencies developed in the Graduate Certificate in CTR course of study. This includes: 1) critical review of the literature, 2) development of clear and testable hypotheses, 3) selection of appropriate methods and of a rigorous (data) analysis plan, 4) attention to human subjects research ethics considerations, and 5) clarity of presentation and of responses to questions.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 6511 Capstone Proposal**

The purpose of this course is for students to choose a capstone project, create an initial plan with specific deliverables identified, and receive approval. This course covers review of key concepts necessary for success in the Capstone (CLTR508) course, including a detailed capstone proposal (project type/format, detailed mentorship plan, tentative schedule of mentor meetings, project timeline, and final proposal in the form).

*Level:* Graduate

*Prerequisites:* (CLTR 504 or CLTR 6504)

*Grading:* Pass/Fail Default

*Course registration restrictions:*

Enrollment is limited to students with a program in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 6700 Aspects of Drug Development 3 Credits**

The objectives of this course are to complement the biostatistics, and study design courses, by focusing on specific challenges in drug development trials. Detailed focus on regulatory requirements, interactions with study sponsors, and review of successful and failed trials as guides to study design, implementation and oversight.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 7800 Intro: Comm Engagement in Res 3 Credits**

This course introduces students to principles of community engagement in research and offers the necessary foundation for conducting research with diverse communities. Topics include: defining community engagement and its guiding principles; role of community engagement in translational research; community–academic research partnerships; and ethics in community engagement; and research resources for further study and skill development.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to students with a program in Clinical/Translation Research, Clinical/Translation Research, Clinical/Translation Research or Clinical/Translation Research.

Enrollment is limited to Graduate level students.

**CLTR 7802 Elim of Racial Ethnic Disparities 3 Credits**

There is convincing evidence that most racial and ethnic minorities in the United States experience health disparities as compared with the majority of the population. These disparities differ in several minority groups but they all result in limiting the length and quality of life of many members of this group. The public health profession has taken as one of its major challenges the need to eliminate these health disparities within the next decade.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 7803 Global Health in Research 2 or 3 Credits**

This course is designed to introduce students to the practice of global health research, with a focus on but not limited to the conduct of research in developing countries. This is both a principles course, in which mastery is obtained through class lectures, readings, discussions, and research groups regarding health research, and a skills course in which mastery is obtained through the development of research proposals, the structured review of peer-reviewed health research articles, and the completion of the online CITI course for the protection of human subjects. The course emphasizes the scientific method as a mode of inquiry applied to quantitative, qualitative and mixed method research. It considers particular issues related to global health research, including: the use and interpretation of secondary data; cultural, linguistic, socioeconomic and other considerations in study design, data collection instruments, study methods, and analysis and interpretation of data; involvement of donors in funding and conduct of health research; opportunities for and considerations in collaborative global health research; and ethical issues and related to global health research.

*Level:* Graduate

*Grading:* Main Campus (UGrad, Grad)

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 9991 Continuous Registration**

*Level:* Graduate

*Grading:* No Grade

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 9993 Continuous Registration**

*Level:* Graduate

*Grading:* No Grade

*Course registration restrictions:*

Enrollment is limited to Graduate level students.

**CLTR 9994 Continuous Registration**

*Level:* Graduate, Undergraduate

*Grading:* No Grade

*Course registration restrictions:*

Enrollment is limited to Graduate level students.