CLINICAL & TRANSLATIONAL SCI (CTSC)

CTSC 5005 Foundations of Clinical and Translational Science (1 Credit)
A. Windebank, S. Naik (Summer, Fall, Winter, Spring) The Foundations of Clinical and Translational Research course is a comprehensive multi-module program designed to provide participants with a solid foundation in the principles, methods, and practical applications of clinical and translational research. Through a combination of engaging lectures and case studies, participants will gain the skills and knowledge needed to engage in impactful research that bridges the gap between bench and bedside.
Grading: Sat / Unsat

CTSC 5010 Clinical Research Proposal Development (2 Credits)
A. Rule (Fall, Spring) – The goal of this course is to systematically teach the process by which one takes a conceptual idea for a clinical research project and converts it into a research proposal or grant application. It is expected that students will already have begun to formulate their research question and refine their research project. Students will use their own research question to build a proposal for a research project that they intend to conduct in the future. By the end of the course, students will have a proposal for an important, valid, feasible research project that can serve as the foundation for a Certificate or Master's thesis research project or a grant application.
Prerequisites: (CTSC 5300, or CTSC 5370)
Grading: Standard Letter

CTSC 5011 Independent Clinical Research Proposal Development (1 Credit)
L. Roberts (Summer) – The goal of this online course is to systematically teach the process by which one takes a conceptual idea for a clinical research project and converts it into a research proposal or grant application. It is expected that scholars will already have begun to formulate their research question and refine their research project. Scholars will use their own research question to build a proposal for a research project that they intend to conduct in the future. By the end of the course, scholars will have a proposal for an important, valid, feasible research project that can serve as the foundation for a Master's thesis research. NOTE:#This course is offered #to Mayo CTSC MD/MS program scholars only.#Scholars admitted to other CTS programs should take CTSC 5010 – Clinical Research Proposal Development.
Prerequisites: CTSC 5370 may be taken concurrently, or CTSC 5300 may be taken concurrently, and CTSC 5600 may be taken concurrently
Grading: Standard Letter

CTSC 5020 Regulatory Issues in Clinical Research (1 Credit)
N. Madigan, T. Armbrust (Winter, Summer) This online course is designed to introduce students to regulatory and legal issues pertaining to clinical research. Topics will expose students to the various external and internal regulatory agencies including, Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) and U.S. Food and Drug Administration (FDA), with a focus on how the agencies affect investigator's research responsibilities. Students will view lectures by content experts and engage in activities that include, but are not limited to, analyzing an actual IRB protocol, reviewing regulatory documents and attend an IRB Overview/IRB Meeting session. Evaluation will be based on completion of online modules, assessments and attending one IRB Overview/ IRB Meeting session.
Grading: Standard Letter

CTSC 5025 Introduction to Regulatory Science (1 Credit)
A. Windebank, D. Witter (Summer) - As medical treatments and technologies continue to advance at an unparalleled pace, there is a need to develop new scientifically based standards and metrics to assess the safety, efficacy, and quality of diagnostic and therapeutic products. Development of techniques and measurements to assess these characteristics of clinical products is known as "regulatory science." In this online course, participants will learn about focus areas of regulatory science, as defined by the FDA's "Advancing Regulatory Science" report. Lectures will focus on concepts for the evaluation of innovative therapeutics such as; digital health, artificial intelligence, precision medicine, advanced manufacturing, regenerative biotherapeutics, and use of real-world evidence in regulatory decision making. #Students will leave with a firm understanding of FDA-regulated product lifecycle management, including the navigation of federal requirements for the clinical use of novel investigational products such as exosomes, 3D printed products, bacteriophages, and engineered cellular therapies. Evaluation will include attendance and participation in class discussion, online quizzes, and a final paper determining what methods of safety, efficacy, and quality assessment would be necessary from a regulatory standpoint for a new treatment or technology. CTSC 5020 and CTSC 6120 are complimentary courses.
Grading: Standard Letter

CTSC 5040 Introduction to the Principles of Current Good Manufacturing Practices (cGMP) (1 Credit)
A. Windebank, C. Schmidt, H. Wang (Summer) – This course is a broad introduction to the principles of current good manufacturing practices (cGMP). Through a series of presentations by content experts students will learn how to apply these principles to individual types of manufacturing areas.
Grading: Standard Letter

CTSC 5070 Introduction of Community Engagement - What Every Researcher Should Know (1 Credit)
K. Boehmer (Spring) - Health disparities are differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist when specific population subgroups are compared. To effectively address the disproportionate burden of diseases experienced by health disparity (HD) populations, it is important that the targeted community is part of the solutions for the problem(s) identified for their community. Thus, community based participatory research (CBPR) has become the focal approach for researchers to discover practical solutions to achieve health equity. This course will introduce students to an approach to conducting CBPR, including development of research questions; study designs and data collection methods; analysis and interpretation; and dissemination. The course will explore the concept of community engagement (the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people), expand students' skills of identifying and engaging with appropriate partners for CBPR.
Grading: Standard Letter

CTSC 5100 Academic Publishing (1 Credit)
M. Hassan Murad (Fall, Winter, Spring, Summer) - As researchers, academicians, clinician-researchers, medical educators, or faculty in a higher education institution, we are expected to publish the results of our research or scholarly activities. Publication disseminates information to relevant stakeholders in the form of a journal article manuscripts. Therefore, learning about the process of academic publishing (also called scholarly or scientific publishing) is critical for communicating knowledge to peer-reviewers who will evaluate the credibility of the work, and to the end users. The target audience for this course are individuals who desire to publish an article in an academic or scientific journal. This includes novel basic science findings, clinical or translational research manuscripts, review articles, case reports, medical education articles that describe teaching methodology and outcomes, published quality improvement projects or any other scholarly activity worthy of dissemination. The course covers the whole process of academic publishing, including decisions about what to publish, learning the unique writing style called academic or scholarly writing style, crafting the appropriate narrative or massage based on target audience, choosing the right journal, preparing a manuscript, choosing a title, avoiding pitfalls such as plagiarism and publication bias, authorship considerations, going through the submission and peer review process, learning about galley proofs and communicating with the media, and anticipating post publication activities such as letters to the editor and corrections.
Grading: Sat / Unsat, Test-Out/Waivers

CTSC 5110 Grant Writing in the Sciences (1 Credit)
M. Sherman (Fall) – The goal of this course is to provide a basic primer on grant writing, to help students learn about resources and approaches for developing grants, and to initiate the development of skills in grant planning and preparation. Throughout the course, students will be offered mentorship and guidance on developing research activities and career planning as well as fostering a collegial environment amongst students to provide peer support. This course is not intended to convey information primarily, but rather to help you develop perspectives and learn about available resources and strategies.
Grading: Sat / Unsat

CTSC 5115 Elevating Grant Writing in the Sciences: Strategies for Competitive Proposals (2 Credits)
M. Sherman (Winter) - This interactive, synchronous course provides an in-depth primer on NIH grant writing, with a focus on developing foundational knowledge and skills for grant planning, preparation, and review. Through live sessions, students will engage in guided discussions, collaborative exercises, and faculty-mentored activities that emphasize the interpretation of NIH guidelines and critique of real-world examples. Rather than simply conveying information, this course aims to foster critical perspectives, peer learning, and strategic thinking for research and career development. Students will also explore institutional and national resources available to support their grant writing efforts.
Grading: Standard Letter

CTSC 5201 Independent Study in Clinical and Translation Research (1 Credit)
F. Enders (Summer, Fall, Winter, Spring) Students work independently, according to a written agreement outlined on the proposal form, under the general supervision of a pre-identified faculty mentor. Independent study offers flexibility to meet individual student needs, interests, and styles of learning, while allowing students to meet the curriculum requirements for program completion. An independent study is the equivalent of a course. Thus, the proposed project should be just as rigorous in scope and content as a regularly offered graduate level course. The reading load and the research paper/project produced should be comparable to the reading load and research paper/project that students are expected to complete in a regularly offered course. The difference between a regularly scheduled course credit and that of an independent course credit is that a student can pursue (under the direction of a faculty member who is an expert in the subject matter area) a highly focused and in-depth independent study project in which the student can devote complete attention.
Grading: Sat / Unsat

CTSC 5210 Ethical Issues in Regenerative Medicine (1 Credit)
M. McGowan, N. Madigan (Summer) - The ethical, legal/policy, and social (ELS) issues surrounding regenerative medicine, including its clinical translation, continues to receive significant attention by the public, professionals, and policy-makers. Research scientists and clinicians need to be cognizant of ELS quandaries surrounding the field of regenerative medicine along with understanding ELS implications for their own research or practice. This course meets learner demands for obtaining a richer understanding of the norms and practices related to contemporary regenerative medicine technologies. More specifically, this course will provide a deeper understanding of several ELS issues of regenerative medicine including stem cell research and therapies, gene editing, chimeras and organoids, and the Food and Drug Administration's Expanded Access Program and federal Right-to-Try law. Learners will gain a greater appreciation for a variety of views and be able to communicate the ELS ramifications of regenerative medicine to patients, research participants, and the public.
Grading: Standard Letter

CTSC 5241 Research in Pediatric Populations: Study Design (1 Credit)
R. Jacobson (Fall) - This course focuses on determining the appropriate study design given the balance of benefits and risk to the research participants, given the problems presented by pediatric research participants. Topics include research ethics, human participants regulation, institutional responsibility, and investigator responsibility. This course along with its companion (CTSC 5242: Research in Pediatric Populations: Implementation) addresses the special concerns and challenges faced by investigators when conducting observational or experimental research involving infants, children, and teenagers. Both this course and CTSC 5242 are taught independently. Neither is required nor strongly recommended before taking the other. Both courses concern institutional review board (IRB) interaction. The IRB provides the basis for institutional responsibility for the application of US regulation of research. The US regulation determines what study designs will work in children based on the potential benefits and risks posed by the research.
Grading: Standard Letter

CTSC 5242 Research in Pediatric Populations: Implementation (1 Credit)
R. Jacobson (Spring) This course focuses on the successful implementation of a study protocol to carry out or execute a pediatric research study given the problems presented by pediatric research participants. Topics include research funding, protocol registration, institutional (IRB) approval, parent and patient recruitment, research participant remuneration, and data collection. This course along with its companion (CTSC 5241: Research in Pediatric Populations—Study Design) addresses the special concerns and challenges faced by investigators when conducting observational or experimental research involving infants, children, and teenagers. CTSC 5241, taught in the fall, concerns the ethical and regulatory issues with regard to pediatric study protocols that affect their design. CTSC 5242, taught in the spring, focuses on the successful implementation, rather than the successful design, of a study protocol Both this course and CTSC 5241 are taught independently. Neither is required nor strongly recommended before taking the other.
Grading: Standard Letter

CTSC 5250 Science Beyond the Lab: Intersections of Science, Society and Policy (1 Credit)
A. Kumbamu (Winter) - This course is intended to provide an overview of the contemporary culture of science and its implications for science production and translation, socio-political relations in the scientific community, and the general public. Students will be introduced to various structural, institutional and policy aspects that influence and are influenced by their research. In addition to social and policy aspects, students will also learn about dynamics of professionalism and ethics in science production and translation. The importance of scientists' engagement with various social institutions, policy makers and institutions (civic engagement), and the public communication of science will be discussed in this course.
Grading: Standard Letter

CTSC 5261 Theoretical and Historical Foundations of Biomedical Ethics (2 Credits)
A. Barwise (Fall) - This introductory course explores foundational topics, events, and principles in biomedical ethics, emphasizing the historical cases that have shaped contemporary ethical standards in medicine. Through a multidisciplinary lens—incorporating medical, legal, philosophical, and ethical perspectives—students will examine landmark cases and their lasting impact on clinical practice and policy. Learners will gain familiarity with key terminology, ethical theories, and decision-making frameworks used in biomedical ethics. The course fosters critical thinking and ethical reasoning through the analysis of real-world and hypothetical case studies. Topics include clinical ethics, end-of-life decision-making, physician aid in dying, human research ethics, organ transplantation, resource allocation, and genetics. By engaging with current and emerging ethical challenges, students will be equipped to thoughtfully assess the implications of rapidly evolving medical technologies and contribute meaningfully to ethical discourse in healthcare settings.
Grading: Standard Letter, Test-Out/Waivers

CTSC 5262 Health Policy and Biomedical Ethics (1 Credit)
A. Barwise (Winter) – The COVID-19 pandemic brought to the forefront the essential interactions between public health, policy, and ethical decision-making. This course is designed to illustrate how biomedical ethics research and normative analyses in bioethics can advance our thinking about particularly complex situations at the intersection of clinical practice and health policy. This course will showcase several high visibility areas that highlight the impact biomedical ethics has on the direction and evolution of medicine & public policy. This course is open to all students and may be of particular interest to learners interested in related forms of translational research. This course involves prep-work.
Grading: Standard Letter

CTSC 5263 Ethical Issues in Population Health (1 Credit)
R. Jacobson (Spring) - The contemporary emphasis on population health raises ethical questions about the needs of the community versus the needs of the individual patient. This course will give learners an introduction to population health and the ethical issues that its management and its research methodologies raise.
Grading: Standard Letter

CTSC 5300 Foundations of Epidemiology (1 Credit)
K. Fischer (Fall, Winter, Spring, Summer) – This standalone asynchronous course provides an overview of basic epidemiologic terminology and methodology used in clinical research. Topics include: foundational concepts (experiments, causality, bias and error, and reliability and validity); descriptive studies (incidence, prevalence, time, place, and person); bias and causal inference; confounding, mediation, and interaction; and case-control, cohort, and clinical trial studies. Upon completion of this course, scholars will be equipped to understand and interpret epidemiologic studies in the literature, and to contribute to research teams in which an epidemiologist is involved. NOTE: This course is targeted towards CTS PhD and KL2 scholars, as well as scholars in MCGSBS tracks other than CTS. For those seeking more detailed coursework aimed at preparing them to lead their own epidemiologic or clinical research studies, take CTSC 5370 Introduction to Epidemiology and CTSC 5390 Advanced Applied Epidemiology.
Grading: Standard Letter

CTSC 5340 Ethical Issues in Individualized Medicine (1 Credit)
R. Sharp (Fall) – Advances in medicine and technology are allowing researchers to analyze genome sequencing to understand more nuanced relationships between genes and disease. This course will examine the ethical implications of this emerging capacity to analyze genetic information and apply it to patient care. Topics will include non-invasive prenatal testing; DNA biobanking; broad data sharing and consent; managing incidental findings; return of uncertain research results; genetic screening; and direct-to-consumer genetic testing. Multiple case examples from the Mayo Clinic Center for Individualized Medicine will be used to facilitate discussion. Using these case studies, several cross-cutting ethical issues will be examined in greater detail, including privacy and confidentiality, the right not to know genetic information, who has access to genetic information, and the acceptability of genetic exceptionalism. This course is targeted toward scholars conducting research in the field of individualized medicine and/or scholars seeking more advanced bioethics training.
Grading: Standard Letter

CTSC 5350 Ethical Issues in Artificial Intelligence and Information Technologies (1 Credit)
B. Barry, M. McGowan (Winter) – Applications of artificial intelligence (AI) and information technologies (IT) in medicine and healthcare are growing exponentially each year, and with them, concerns about the ethical, legal, and social implications (ELSI) of such technologies on our current health structures. Due to the predicted scoping and disruptive impact of AI, many members of the medical community have expressed interest in understanding the technologies themselves and being able to critically evaluate them for ELSI considerations. This class will serve as an introduction to current and future uses of IT and AI in biomedical research and healthcare and the already understood and documented ELSI associated with them. Additionally, this class will give learners the opportunity to engage in current hot-topic discussions about emerging applications of the technology and develop a tool kit to critically evaluate any future applications. Specifically, learners will be introduced to the processes of developing AI tools and implementing them into practice and asked to view them through various ethical lenses including bias, transparency, privacy and confidentiality, and distinctions between research and practice.
Grading: Standard Letter

CTSC 5370 Introduction to Epidemiology (2 Credits)
M. Hassan Murad, T. Rajjo (Winter, Summer) - This course is the first in a series of two courses about the principles and application of epidemiologic methods. This first course, Introduction to Epidemiology (CTSC 5370), is an introduction to epidemiologic concepts and study design methodology. The second course, Advanced Applied Epidemiologic Methods (CTSC 5390), concentrates on application of these methods. Thus, the two course series equates to a typical 4-credit graduate level introductory epidemiology course. This course will focus on developing common terminology to discuss epidemiologic concepts. We will begin by focusing on the foundational concepts for all study designs including topics such as incidence, prevalence, and sampling. Next, we will compare and contrast cross-sectional studies, case-control studies, cohort studies, and randomized trials. Finally, we will address practical issues related to the collection and assessment of quality for research data.
Grading: Standard Letter

CTSC 5390 Advanced Applied Epidemiological Methods (2 Credits)
M. Hassan Murad, K. Mohammed, Z. Wang (Fall) - This course will provide students with the knowledge and skills required to interpret and critically appraise research studies published in the medical literature and improve their ability in the future to design such studies. This applied approach is different from that learned in the introduction to epidemiology course, in that it requires more critical thinking and will lead to acquiring appraisal skills. For each type of study discussed in this class, the instructors will explain the general terminology, underlying epidemiologic underpinnings, and provide guidelines on how to read and appraise the articles, and reflect on designing your own. The students will use standard appraisal worksheets. All students are expected to participate in the discussion.
Prerequisites: CTSC 5370, and CTSC 5600, or CTSC 5590
Grading: Standard Letter

CTSC 5400 Introduction to Bioinformatics Concepts and Core Technologies for Individualized Medicine Approaches (1 Credit)
V. Sarangi (Winter) – The purpose of this course is to orient researchers and clinicians in the field of Individualized Medicine and familiarize them with the key 'omics' technologies and bioinformatics approaches being employed in clinical and preclinical initiatives. The course combines lectures and practical exercises to introduce students to the core conceptual and practical elements of high throughput data generation, processing, and analysis. Individuals will gain understanding of available technologies and data types and be familiarized with use-cases, user-friendly analytical approaches and available online tools and resources.
Grading: Standard Letter, Test-Out/Waivers

CTSC 5410 Molecular Variant Evaluation (2 Credits)
M. Ellingson, A. Pickart, S. Brunker (Winter) - This course aims to provide the foundational knowledge and skills used to assess the clinical significance of molecular DNA variants and formulate recommendations for the classification of these variants. Hands-on application of the tools and processes via online modules in conjunction with class discussions will provide experiential education and prepare students for analysis of molecular variants and their contribution to human genetic variation and disorders. Students will learn and apply concepts related to molecular variant nomenclature, genetic variation within the general population, calculation of allele frequencies, utilization of computational tools as well as reported occurrences of variants in the literature and online databases. Critical evaluation of the literature and functional studies, together with standard published guidelines will be used to recommend a variant classification and creation of interpretive comments. Previous college-level coursework in Genetics and Molecular Biology is strongly recommended.
Grading: Standard Letter

CTSC 5420 Genomic Data Exploration with Graphical User Interfaces (1 Credit)
K. Kalari (Summer) - This course is designed to introduce user-friendly tools for laboratory- and clinical-based investigators to explore genomics data. This course will leverage open-source tools (free) for graphically exploring data from BAM, VCF, BED, and other standard file types. As these tools expect highly specific inputs, the course will also cover the details regarding file formats and nomenclature types that you need to be aware of while exploring genomic data. We will highlight common pitfalls when analyzing genomic data regarding poor data quality & structural variants, inconsistent annotation sources, and poor experimental design. Upon completing this course, the student will have a basic understanding of navigating through the different tools so that they can explore their own data and data in the public domain. CTSC 5400 is strongly recommended.
Grading: Standard Letter

CTSC 5500 Genomic Analysis of Complex Traits (1 Credit)
N. Larson, B. Coombes (Winter) This course will introduce students to fundamental concepts of population- and clinic-based genetic studies, including study design principles and analytical approaches used for the purpose of understanding complex disease etiology and prognosis. Topics covered will include quality control and analysis of large genome-wide association studies as well as next-generation DNA sequencing data and rare-variant analyses. Students will also be exposed to advanced topics, including biological pathway analysis, gene-environment interactions, and polygenic risk scores. Through a combination of lectures and interactive discussions, students will be equipped with fundamental knowledge for collaborative research in human genomics.
Prerequisites: (CTSC 5300, or CTSC 5370), and CTSC 5600
Grading: Standard Letter

CTSC 5590 Foundations of Statistics in Clinical and Translational Research (1 Credit)
J. Aakre, H. Kosiorek (Summer, Fall, Winter, Spring) - This asynchronous course introduces basic statistical methods utilized in clinical and translational research through the use of real-world clinical examples. Course materials use published research studies and emphasize statistical reasoning and concepts. Topics covered include data visualization, descriptive statistics, estimation, and inference. Statistical techniques covered include parametric and non-parametric tests for binary, categorical, and continuous data, as well as diagnostic tests. For each statistical technique, we'll identify what research questions it can address. This course does NOT teach the use of statistical software. This course does not serve as a pre-requisite for CTSC 5602, CTSC 5603, CTSC 5610, CTSC 5611, CTSC 5640, CTSC 5641, CTSC 5650; CTSC 5600 is the pre-requisite for these courses. At the end of this course, students will be able to: • Understand and interpret results from basic statistical methods. • Recognize key statistical ideas like variability, distribution, and statistical significance. • Identify and choose basic statistical methods for different types of data. • Think critically about statistical arguments made in scholarly publications.
Grading: Sat / Unsat, Test-Out/Waivers

CTSC 5600 Introduction to Statistics in Clinical and Translational Research (3 Credits)
J. Aakre, K. King (Summer, Winter) — This hybrid (synchronous and asynchronous) course introduces basic statistical methods used in a variety of clinical study designs. Course materials use published research studies and emphasize statistical reasoning and concepts. Topics covered include data visualization, descriptive statistics, estimation, and inference. Statistical techniques covered include parametric and non-parametric tests for binary, categorical, and continuous data, as well as diagnostic tests. For each statistical technique, we'll identify what research questions it can address, how to verify that assumptions are adequately met and identify the limitations of the conclusions. This course does NOT teach the use of statistical software. Students interested in learning statistical software should enroll concurrently in CTSC 5602 (Introduction to Statistical Software - BlueSky) or CTSC 5603 (Introduction to R Programming). At the end of this course, students will be able to: • Interpret the results of a variety of basic statistical techniques, including both exploratory and inferential methods. • Recognize, define, and differentiate fundamental concepts of statistics, such as variability, distribution, association, causation, sampling, experimentation, confidence, and significance. • Determine appropriate statistical methods for different types of data and study Designs. • Assess and defend statistical arguments such as those in scholarly publications. Identify and apply appropriate statistical methods for given research questions, including test statistics, confidence intervals, and p-values.
Grading: Standard Letter

CTSC 5602 Introduction to Utilizing Statistical Software in Clinical and Translational Research (1 Credit)
J. Aakre, E. Lundt (Winter, Summer) — This course introduces statistical software for introductory statistical methods including descriptive statistics, estimation, and inference; students also participate in in-person discussion of the pros and cons of methods used in the literature. The focus of the course is on determining the correct statistical method for a given situation, introducing the corresponding method in the BlueSky statistical software, and correctly interpreting the results of the BlueSky analysis. BlueSky is a Gui interface to R.
Prerequisites: CTSC 5600 may be taken concurrently
Grading: Standard Letter

CTSC 5603 Introduction to R Programming in Clinical and Translational Research (1 Credit)
K. King (Summer) This course introduces statistical software for introductory statistical methods, including descriptive statistics, estimation, and inference. Students also participate in in-person discussion of the pros and cons of methods used in the literature. The focus of the course is determining the correct statistical method for a given situation, implementing the corresponding method in the R statistical software, and correctly interpreting the results of the R analysis.
Prerequisites: CTSC 5600 may be taken concurrently
Grading: Standard Letter

CTSC 5610 Statistics in CTR: Linear Regression Concepts, Interpretation, and Statistical Software (3 Credits)
S. Winham (Fall) This course provides an introduction to methods for statistical modeling and introduces some extensions of these methods such as logistic regression and Cox regression. Specific topics covered include simple linear regression and multiple linear regression. General concepts taught include graphical methods, descriptive statistics, and statistical inference. Particular attention is given to verification of model assumptions, interpretation, and generalization of results. Additionally, it provides a broad overview of basic statistical regression methods, especially the underlying concepts, reasoning, and methods of linear models. Note: A grade of 'B' or higher is required in CTSC 5600 and CTSC 5602 or CTSC 5603 to ensure success in this course. Specifically, knowledge of basic univariate and bivariate statistics will be assumed as well as familiarity with the Bluesky statistical software package.
Prerequisites: CTSC 5600, and CTSC 5602, or CTSC 5603
Grading: Standard Letter

CTSC 5611 Statistics in Clinical and Translational Research: Linear Regression Concepts and Interpretation (2 Credits)
S. Winham (Spring) - This course provides an introduction to methods for statistical modeling and introduces some extensions of these methods such as logistic regression and Cox regression. An emphasis is placed on reading the literature. Specific topics covered include simple linear regression and multiple linear regressions. General concepts taught include understanding and interpreting published research results using linear regression. Particular attention is given to understanding model assumptions, interpretation, and generalization of results. Additionally, it provides a broad overview of basic statistical regression methods, especially the underlying concepts, reasoning, and methods of linear models. This course is similar in content to CTSC 5610, however, no statistical software will be used and a larger emphasis will be placed on reading and interpretating the scientific literature. Unlike CTSC 5610, the labs for this course will allow students to explore regression using practice problems but not conduct analyses. *Note: CTS Master's Scholars are required to take CTSC 5610 and not eligible to register for CTSC 5611 as an elective.
Prerequisites: CTSC 5600
Grading: Standard Letter

CTSC 5640 Statistics in Clinical and Translational Research: Logistic Regression with Statistical Software (1 Credit)
B. Coombes, K. King, S. Jenkins (Winter) – Logistic regression is often used as an analytic tool for medical studies with binary endpoints. Evaluation will include computer laboratory sessions, individual homework assignments, and a final exam. #In this course, we will: Identify appropriate occasions to use logistic regression and describe how logistic regression may be used to estimate the magnitude of association for a predictor versus a binary outcome variable using an odds ratio. Interpret odds ratios for binary, categorical, and continuous predictor variables, describe how the odds ratio may be influenced by confounding variables and/or interactions among variables, and how logistic regression may be used to adjust for the presence of confounders and to test for the presence of interaction. Explore the assessment of statistical significance, model building, and model assessment strategies in the presence of several risk variables. Apply the use of logistic regression in score development and validation with the associated receiver-operator characteristic (ROC) curve. #From this course, students will learn how to use statistical software (BlueSky) to perform logistic regression and select appropriate models depending on research questions. Evaluation will include computer laboratory sessions, individual homework, and a final exam.
Prerequisites: CTSC 5600, and CTSC 5602, and CTSC 5610
Grading: Standard Letter

CTSC 5641 Observational Studies & Causal Inference (1 Credit)
S. Savitz, V. Thao (Spring) – Randomized controlled trials (RCTs) are the gold standard for generating evidence to guide medical care. However, RCTs are time-consuming, expensive to conduct, and their results may not apply to patients in routine clinical practice. Further, there are many factors of interest that cannot be feasibly randomized. Observational research methods can overcome some of the challenges of RCTs to inform care delivery. The major limitation of observational research designs is that they are not randomized and observed findings may be due to differences in the underlying populations. To address this limitation, advanced statistical approaches have been developed to conduct causal inference in non-randomized settings. This course will introduce some of these statistical approaches like propensity score matching, fixed and random effect modeling, difference-in-differences, instrumental variables, and regression discontinuity models to generate causal evidence at a faster pace and lower cost. CTSC 5640 Advanced Statistics in Clinical and Translational Research: Logistic Regression with Statistical Software is recommended but not required.
Prerequisites: CTSC 5600, and (CTSC 5610, or CTSC 5611)
Grading: Standard Letter

CTSC 5650 Advanced Statistics in CTS Research: Survival Analysis with Statistical Software (1 Credit)
N. Foster (Spring) – This course will introduce students to methods for summarizing and analyzing time-to-event data, which commonly occur in clinical trials and epidemiological studies. Basic quantities (e.g., survival function, hazard function) and their relationships will be introduced. Non-parametric approaches (such as the Kaplan-Meier method) and parametric approaches (e.g., Exponential) for estimating these quantities for a given data set of event times will be covered. Associated tests (such as the log-rank test) to compare event times originating from multiple groups will be discussed. The widely used semi-parametric Cox proportional hazards regression model will be introduced and related topics including variable selection, assumption testing, and model building will be covered, along with real life examples.
Prerequisites: CTSC 5600, and CTSC 5602, and CTSC 5610
Grading: Standard Letter

CTSC 5710 Practical Data Collection (1 Credit)
J. Larson (Fall) – This course introduces the general principles and practical exercise of data management in medical research including laboratory experiments, cohort observational studies, and clinical trials. While these principles can be used for any data collection system, in this course, students will learn how to apply these principles in REDCap as it is Mayo Clinic endorsed free alternative to Excel and Access. Students will be allowed to use their own data and research studies to complete some of the assignments. Evaluation will be based on in-class short quizzes, in-class exercises, and take-home assignments.
Grading: Standard Letter

CTSC 5715 Publication Quality Tables and Figures (1 Credit)
J. Larson, C. Mester (Winter) – This course introduces sound practical data presentations by tables and graphs which are aimed to deliver the appropriate inferences regarding data in an efficient yet objective manner. This course will utilize the R software to generate reproducible summary statistics and figures via programming. Evaluation will be based on in-class assignments and take-home assignments. This course involves learning how to program within R as opposed to using a graphical user interface (GUI) like the one used by the BlueSky software. By learning how to program within R directly, you will be able to generate code to make analysis repeatable.
Prerequisites: CTSC 5600, and (CTSC 5602, or CTSC 5603, or CTSC 5610)
Grading: Standard Letter

CTSC 5720 Clinical Trials Design and Conduct (1 Credit)
N. Foster (Summer, Winter) This course will focus on the statistical considerations and practical issues involved in the design and analysis of clinical trials. The foundations of and practical considerations involved in drug development in humans will be presented. The Phase I-III paradigm for clinical trials will be discussed, including issues about aims, endpoints, statistical power, early stopping rules, and analytic techniques. There will be a focus on several case studies of clinical trials. Issues about subject selection, study design, masking treatment assignment, outcome measures, goals, and post hoc analyses will be reviewed.
Prerequisites: CTSC 5600 may be taken concurrently, or CTSC 5590 may be taken concurrently
Grading: Standard Letter

CTSC 5740 Systematic Reviews and Meta-Analysis (2 Credits)
C. West, M. Murad, Z. Wang (Winter) – By the end of this problem-based course, the learner will be comfortable with the methods of evidence synthesis and will have completed a systematic review/meta-analysis, from protocol to journal-ready manuscript, in a topic of their choice. The small group tutorials include expert faculty to discuss key concepts and troubleshoot the students' reviews in progress. Each session will represent a step in conducting a systematic review. A series of selected readings for each session will help students prepare to participate in discussions. Hands-on activities include developing thorough and systematic search strategies, in coordination with Mayo Library experts, and learning how to use meta-analysis statistical software. Evaluation will be based on the methodological quality of the final systematic review/meta-analysis.
Prerequisites: CTSC 5600, or CTSC 5590, and CTSC 5300, or CTSC 5370
Grading: Standard Letter

CTSC 5761 Evidence-Based Medicine for Clinical Researchers (1 Credit)
I. Hargraves, M. Murad Z. Wang (Spring) – Course participants will learn the principles of evidence-based medicine (EBM) through applying the GRADE framework (Grading of Recommendations, Assessment, Development and Evaluation), to research in their own field. By teaching these appraisal and decision-making principles, this course helps researchers design and produce evidence that warrants high certainty and fulfills the needs of evidence users (patients, clinicians, and policy makers). Students will benefit the most from this course if they have conducted clinical research and participated in designing a study.
Prerequisites: (CTSC 5300, or CTSC 5370), and (CTSC 5600, or CTSC 5590)
Grading: Standard Letter

CTSC 5770 Diagnostic Testing Strategies (1 Credit)
C. West (Spring) – This course is designed to enable students to apply a knowledge of diagnostic testing strategies to common medical problems using a Bayesian framework (e.g., pre-test probabilities, test operating characteristics/likelihood ratios and post-test probabilities). Students interested in diagnostic test performance for the purposes of clinical decision-making or research on existent or emerging technologies should enroll in this course. The first 5 sessions will introduce material in a discussion format. Subsequent sessions will be organized around student driven presentations on clinical or clinically relevant research topics of interest to them. For the presentations, students will review the relevant background for the clinical or research problem, the prevalence of the disease in question, the operating characteristics of the diagnostic test/tool/technology (sensitivity/specificity, likelihood ratios, etc.), and the range of post-test probabilities that might be expected to result from the application of various diagnostic strategies. An illustrative case of potential application will be used to frame the discussion and potential impact of applying the test to a care or research scenario. The course grade will be based on the presentation and a take-home written assignment.
Prerequisites: (CTSC 5600, or CTSC 5590)
Grading: Standard Letter

CTSC 5810 Qualitative Research Design, Methods, and Analysis (1 Credit)
K. Boehmer (Fall) – This course provides an overview and comparative analysis of selected qualitative research methodologies, methods, and analytic strategies. Focus is on developing rigorous qualitative designs that contribute to the development of health care knowledge for all populations. This application-based course will provide numerous examples from the qualitative research field as well as practical, hands-on experience for the participant.
Grading: Standard Letter

CTSC 5815 Qualitative and Mixed Methods Research for Translational Science (2 Credits)
K. Boehmer, J. Griffin, J. Ridgeway (Spring) – Qualitative and mixed methods are increasingly recognized for their potential to assist in the development of successful interventions in practice, and the translation of scientific knowledge into next-phase research or practice; An understanding of quantitative and qualitative methods is an important prerequisite to learning these skills, but more specific learning is required to understand the nuances of mixed methods research and the ways in which methods can be combined to support research translation. In this course, students will begin by examining applications of qualitative methods and mixed method designs and exploring the clinical and translational research questions that these methods are best designed to answer. They will then incorporate their own translational science interests to evaluate an existing clinical program, or to develop a mixed methods grant/IRB proposal. The course will use readings, discussion, student presentations, and writing to accomplish its learning objectives. A textbook is required for this course. CTSC 5810 or previous qualitative methods coursework or experience as well as quantitative methods coursework or experience (e.g. survey methods) are both strongly recommended.
Grading: Standard Letter

CTSC 5820 Introduction to Survey Research (1 Credit)
K. Yost (Spring) – This course provides an overview of survey research. It is intended to familiarize students with the theory and application of survey research in data collection. The overall goal of this course is to provide students with a foundation that will allow them to conduct a survey or be aware of the issues to consider in the design and implementation of a survey. Specific topics covered are question writing, questionnaire design, scale development, reliability and validity, sampling, sample size estimation, survey types, statistical analysis, and presentation of results. No prior survey research experience is required or expected.
Prerequisites: (CTSC 5600, or CTSC 5590)
Grading: Standard Letter

CTSC 5900 Introduction to Health Services Research (1 Credit)
M. Gionfriddo (Winter) - This course provides an overview of health services research. Different questions relevant to health services research will be discussed, including common methods to address. By the end of the course learners should have an introductory understanding of health services research and be able to create a proposal for a health services research project.
Grading: Standard Letter

CTSC 5910 Economic Evaluation in Health Care (1 Credit)
V. Thao, J. Moriaty (Fall) – Cancelled for Fall 2025; next offering Fall 2026. In a world of rising health care costs and fixed budgets, economic evaluation plays an increasingly important role in technology assessment and payment decisions. This course will present basic concepts, theory, and methods associated with economic evaluation in health care. Specific topics include: decision trees, Markov models, cost-effectiveness analysis, outcomes measurement and analysis (clinical outcomes, costs, health-related quality of life), guidelines and reference standards, and the use of economic models in decision-making. This course will be presented in the form of lectures and computer labs. Class discussion/interaction will be encouraged.
Grading: Standard Letter

CTSC 5940 Secondary Data Analysis (1 Credit)
M. Jeffery, M. Rank (Fall) – Secondary data analysis takes advantage of data originally collected for other purposes in order to answer distinct health services research questions. There are many secondary data sources readily available, yet they are typically underutilized. As such they provide a rich opportunity for empirical investigation and subsequent publication. This course provides the student an introduction to secondary data analysis using publicly available data sources. Data sources covered in this class include survey data, administrative data (hospital, outpatient, and administrative claims), clinical electronic data, and cancer and clinical registry data. Note: No data analysis will be completed. However, by completing this class you will grasp not only what is possible but also how to proceed with a secondary data analysis project idea.
Prerequisites: (CTSC 5600, or CTSC 5590)
Grading: Standard Letter

CTSC 6100 Mechanisms of Human Disease (3 Credits)
D. Mukhopadhyay,#J. Grande, A. Windebank (Spring) – This course is designed to introduce students to the basic organization, histology, and function of major organ systems and provide an appreciation for pathophysiological conditions leading to disease and therapeutic interventions. Lecture topics will focus on five different systems: renal, immunologic, cardiovascular, gastroenteric, and endocrine with emphasis given to the importance of each system's structure and function. Students will have the opportunity to review case studies including imaging, pathology, and treatments. By the end of the course, students will have gained skills in cross-disciplinary communication, specifically with those in the medical field.
Grading: Standard Letter, Test-Out/Waivers

CTSC 6110 CTS Works in Progress (1 Credit)
M. Walther-Antonio (Fall, Winter, Spring, Summer) – The CTS Works in Progress (WIP) forum offers an engaging and dynamic learning environment designed to empower clinical and translational science students in predoctoral programs to effectively present their research while emphasizing the challenges they've overcome, demonstrating the translational potential of their findings, and enhancing their communication skills. The course aims to foster a deeper understanding of how translational research progresses from concept to implementation, promoting an appreciation of the intricacies involved in moving research beyond the bench. The course structure is tailored to accommodate a variety of projects and embodies a commitment to pushing the boundaries of knowledge in Clinical and Translational Science, with the goal of positively impacting the landscape of healthcare through innovative research and its practical applications. Emphasis is placed on developing critical thinking skills, honing presentation abilities, and cultivating a growth-oriented mindset. In addition to receiving feedback from peers and instructors, participants will engage in discussions that explore common challenges, innovative solutions, and best practices for advancing works in progress.
Grading: Sat / Unsat

CTSC 6120 Case Studies in Translation (2 Credits)
A. Windebank, E. Enninga (Winter, Summer) The course will explore the process by which fundamental discoveries move from the first demonstration of an experimental observation to a widespread use in medicine and public health. Examples will be chosen to represent the different classes of discovery that lead to improved human health. Scholars will gain insight into the various stages of the translational science process, including basic research, clinical trials, regulatory approval, commercialization, and societal impact. *Note CTSC 5020: Regulatory Issues in Clinical Research, 5025: Introduction to Regulatory Science, CTSC 5040: Introduction to Current Good Manufacturing Practices (cGMP) are not pre-requisites for this course. Students interested in FDA regulations are encouraged to take CTSC 5040: Introduction to Current Good Manufacturing Practices (cGMP).
Grading: Standard Letter

CTSC 6130 CTS Journal Club (1 Credit)
D. Fairweather (Fall, Winter, Spring, Summer) – The CTS Journal Club is an engaging and interactive course designed to provide participants with an in-depth understanding of the latest research developments in the field of Clinical and Translational Science (CTS). This course aims to foster critical thinking, promote evidence-based practice, and facilitate lively discussions among participants. Throughout the course, participants will explore a wide range of peer-reviewed journal articles that cover a variety topics in CTS. The selected articles will reflect current trends, breakthrough discoveries, and emerging methodologies relevant to clinical research, translational medicine, and public health.
Grading: Sat / Unsat

CTSC 6160 Genomic Analysis and Data Interpretation for Rare and Undiagnosed Diseases (2 Credits)
E. Klee, L. Schimmenti, F. Pinto e Vairo (Spring) - Analysis of genomic data from patients suffering from genetic disorders is now an essential skill for physicians and scientists in the clinical and translational arena. #Patients who suffer from rare and undiagnosed disease are sometimes referred to as “medical mysteries”. #To find a diagnosis for a medical mystery patient, sequencing of the entire coding region of the genome (exome sequencing), or the entire genome (genome sequencing), is employed. Currently, there is a shortage of individuals who possess the bioinformatics and genetics knowledge to analyze the sequencing data and identify potentially pathogenic variants leading to a diagnosis for medical mystery patients. #This course is designed to give students the essential skills to take exome or genome sequence data from real patients and identify a pathogenic sequence variant that leads to a diagnosis. In this course, students will be provided with clinical data from an actual medical odyssey patient from the Mayo Clinic. The cases have been previously solved by the Translational Omics Program (TOP) team through a Genomic Odyssey Board (GOB) within the Center for Individualized Medicine and identified to have pathogenic sequence variants that are consistent with their medical phenotype. Students will be given raw exome sequencing data and the medical phenotype of the patient only. Students will also be introduced to the use of RNA seq and other Omic approaches as complementary tests to the DNA sequencing for identifying or clarifying variants of interest. The results of the sequencing data will not be revealed to the student who will then “solve” the medical mystery and demonstrate an understanding of how arriving at a diagnosis for a patient is an example of precision medicine and will improve the medical management of the patient. To “solve” their assigned medical mystery, students will be taught a series of genomic data analysis skills over the course of 11 weeks. #Students will take the raw sequencing data from the patient and in some situations, first degree relatives, analyses the data and by the end of the course, have sufficient sophistication to be able to solve their case. Students will give both an oral presentation and written description of their process of phenotype and sequence analysis during the last week of the course. This presentation and written description will count toward most of the points for the class.
Grading: Standard Letter

CTSC 6170 The Science of Team Science - Strategies for Success (1 Credit)
H. Billings, K. Turkowski (Fall) – This course offers practical guidance about engaging in team science to pursue complex research questions, work effectively with team members, and assess team performance in order to produce high-impact outcomes. Students will explore the basic principles of teamwork and multidisciplinary collaboration in order to accelerate translational research and strengthen the alignment of discovery science with the clinical practice.
Grading: Standard Letter

CTSC 6900 Thesis Proposal (2 Credits)
F. Enders (Summer, Fall, Winter Spring) - This course facilitates the development and submission of the Clinical and Translational Science (CTS) PhD thesis proposal, structured in the format of an NIH F30/F31 grant proposal.* The course is designed to assess the student's readiness for doctoral candidacy by requiring the articulation of a testable scientific hypothesis, a well-contextualized and methodologically sound research plan, and a personalized training and career development strategy. The proposal must demonstrate the student's capacity for independent scientific thinking, familiarity with translational science principles, and ability to lead interdisciplinary team science efforts. Proposal evaluation by a faculty review panel follows NIH peer review guidelines, including structured critique and scoring.
Grading: Sat / Unsat