**CLINICAL AND TRANSLATIONAL SCIENCE**

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Graduate Study in Clinical and Translational Science

The Center for Clinical and Translational Science (CCTS) at Creighton University is committed to the cutting-edge multidisciplinary clinical and translational research in a manner that builds upon current science strengths to help bring about an era of personalized medicine. The Center is an innovative resource to support and advance education, collaboration and research in clinical and translational science by pooling existing strengths and expertise together. The goal is to increase the number, quality and diversity of clinical and translational researchers and promote research and intellectual exchange among diverse professionals that elicit novel approaches to area health care priorities and fostering long-term, bi-directional relationships with academic and community partners. An integral part of this commitment is to identify, educate, and create a mentored environment to develop and enrich the career of next generation of clinical and translational researchers to become independent investigators, and engage the community in clinical research efforts.

Program Goals

Successful scholars in the CTS program will be mentored and supported to write independent research grant applications. Scholars will be enrolled either as full-time or part-time scholars. The CTS graduate program will provide a structured course curriculum. Since the stature comes with recognition of qualifications, successful scholars will earn either a Graduate Certificate, an MS, or a Ph.D. in Clinical and Translational Science. The graduates of the CTS program will:

1. Demonstrate the competence and knowledge in applied biostatistics, federal policies in clinical research and disparity in global health issues as they pertain to the community;
2. Demonstrate an ability to combine critical thinking, disciplined research, and effective problem-solving both within their field of study and beyond, for use in the service to others;
3. Demonstrate the knowledge of scientific integrity, ethics, and moral values to maintain responsible conduct of research in the field of clinical and translational science following Catholic and Jesuit mission;
4. Demonstrate competency in written and oral communication of their acquired knowledge and research findings in relation to public health issues to scientific and non-scientific audience;
5. Demonstrate deliberate reflection for lifelong personal and professional career in their field of expertise; and
6. Demonstrate an ability to interact and coordinate with a diverse group of colleagues and the ability to respond effectively to the questions and feelings of others.

The MS and Ph.D. graduates will have gained the ability to identify important clinical questions, ability to independently conduct clinical and translational research, develop research protocols, generate pilot data, conduct clinical investigations, ability to critique and interpret findings to non-specialists in their field, analyze and write the results in a publishable form and develop and submit grant proposals.

The Ph.D. graduates will also have mastered the art of writing and publishing critical review articles and original research articles in scholarly journals, and gained knowledge of and expertise in independently developing and conducting original research in clinical and translational science.

Each scholar will select a Graduate Advisory Committee. It will be comprised of four members of the CTS faculty and other qualified faculty within the Health Sciences and other schools at Creighton. The committee members will be selected by the scholar in consultation with the major advisor and in consultation with the Program Director of the CTS program. The Participant Advisory Committee of each scholar will set up educational goals, will provide information about opportunities for conferences, networking and communication, and will provide information about clinical research opportunities and assist the scholar in identifying a focus area.

The scholar will meet in person with his/her major advisor at least once a week. Progress of the scholar will be evaluated at least once every quarter by the scholar's graduate advisory committee. The purpose of such meetings will be to evaluate the scholar's progress and the effectiveness of the CTS graduate program. A written report of each advisory committee meeting will be maintained in the file of the scholar.

Admission Requirements

1. A minimum of bachelor's degree or equivalent, with satisfactory completion of course work in both the biological and chemical sciences.
2. A minimum GPA of 3.0 on a scale of 4.0 is required.
3. The applicant is required to submit results from the Graduate Record Examination (GRE) prior to admission. GRE scores in the 50th percentile or above for the verbal and quantitative parts of the examination are preferred. A minimum score of 3.5 is required for the analytical writing component.
4. The scores of the MCAT, DAT, USMLE or other Health Professional Entrance Examination may be considered in lieu of GRE.
5. GRE will not be required from applicants who hold a professional degree, such as MD, Pharm D, DDS, or Master of Science in Nursing (MSN) or equivalent.
6. The Graduate School requires all students from countries in which English is not the native language to demonstrate competence in English by a minimum of 90 on the Internet-based Test (iBT) TOEFL (Test of English as a Foreign Language) examination at the graduate level.

Each applicant's "Personal Statement" together with prior academic preparation and Letters of Reference will be carefully reviewed by an internal committee chaired by the Program Director, Devendra K. Agrawal. Highly motivated scholars will be selected and the final recommendation to the Dean of Graduate School will be made for their enrollment in the Graduate Certificate, Master of Science, or Ph.D. in Clinical and Translational Science. Selection will be based on:

1. The quality of the applicant's academic and/or clinical record,
2. Quality of applicant's letters of recommendation,
3. Potential for development into an independent clinical and translational researcher focused on patient-oriented clinical research,
4. Commitment to a career in patient-oriented clinical research whether in academia or in a pharmaceutical industry, and interest
in disseminating clinical trial outcomes to health-related fields that serve the general community.

**Degrees in Clinical and Translational Science**

- Ph.D., Clinical and Translational Science (http://catalog.creighton.edu/graduate/graduate-programs-courses/clinical-translational/clinical-translational-science-phd)
- M.S., Clinical and Translational Science (http://catalog.creighton.edu/graduate/graduate-programs-courses/clinical-translational/clinical-translational-science-ms)
- M.D./M.S. (Dual Degree) - Clinical and Translational Science (http://catalog.creighton.edu/graduate/graduate-programs-courses/clinical-translational/clinical-translational-science-md-ms)

**Certificate in Clinical and Translational Science**

- Clinical and Translational Science Certificate (http://catalog.creighton.edu/graduate/graduate-programs-courses/clinical-translational/certificate-clinical-translational-science)

**Courses**

**CTS 601. Biostatistics and Analysis of Clinical Data**

- Evidence-based Practice. 3 credits.

The focus of CTS 601 will be on descriptive, parametric and nonparametric bivariate inferential statistics used in medicine and foundational to the empirical “evidence” supporting evidence-based practice. Didactic lectures, class discussions, individual and group projects using empirical data, and presentations to peers will develop analytical skills for evaluating the published empirical research in medicine and related health care disciplines. Emphasis is on identifying the appropriate research design, statistical tests, and interpretation of results, given a specific practice-based question. Course material provides an applied perspective, with examples presented through statistical analytical printouts from actual studies and critiques of selected articles from peer-reviewed journals. Upon successful completion of CTS 601, students will be able to: (1) Interpret descriptive and inferential statistical analyses and apply them to evidence-based practice, (2) Integrate theoretical concepts and knowledge from scientific inquiry, probability theory, and statistical reasoning in the design and critique of empirical research, and (3) Evaluate a focused area of clinical practice by conducting a systematic review of the empirical literature and developing a research proposal and protocol.

**CTS 701. Intermediate Biostatistics: Correlational and Multivariate Regression Analyses of Clinical Data.** 3 credits. FA

**CTS 702. Federal Policies in Clinical and Translational Research.** 2 credits. FA

This class will provide a comprehensive overview of the history of Federal Regulations that Govern Human Subject Research. These will include: (1) Research Ethics, (2) Federal and State Regulations, (3) OHRP and FDA Documents, (4) Institutional Review Board Functions and Operations, and (5) Informed Consent. The program objective will be to: (i) provide a Historical Perspective of the Development of the IRB System and Federal Regulations, (ii) discuss the Relevant Ethical Principles and their Application, (iii) cover all Federal and State Regulations (DHHS, FDA, HIPAA), (iv) analyze guidance documents (OHRP, FDA), (v) Provide an overview of IRB functions and operations (exempt/expedited/convened review, IRB requirements, risk/benefit analysis, vulnerable populations, subject recruitment, advertising), (vi) explore Informed Consent (required elements, practical considerations, proper documentation, helpful hints, common errors), and (vii) case Studies and Discussion (to braid together the course content with real-life work experiences).

**CTS 705. Community Engagement in Clinical and Translational Research.** 2 credits. SU

This two-credit hour course focuses on the definitions, concepts, Best Practices, and challenges of Community Engagement in Clinical and Translational Research. Learning strategies will include: didactic and seminar classes, independent reading and assignments, local and national speakers with expertise in Community Engagement and Clinical and Translational Research, case studies, audiovisuals, etc. The student will: (1) Demonstrate a knowledge of the history, rationale, and the emerging emphasis of Community Engagement in Clinical and Translational Research, (2) Identify the resources and organizations furthering community engagement, (3) Demonstrate an understanding of definitions, concepts, Best Practices, and challenges of community engagement, (4) Compare and contrast community engagement in several countries, (5) Apply Best Practices of community engagement to one’s own student research project, and (6) Demonstrate an appreciation for the value of Community Engagement in Clinical and Translational Research.

**CTS 708. Health Disparity in Global Health.** 3 credits. SP

The global health issues are extremely critical due to transmission of infectious diseases across the world, emergence of resistance to current antibiotic therapies, threat of bioterrorism, and health disparity between and within nations. Thus, it is critical to understand the social and environmental factors that contribute to diseases and develop preventive measures. Upon completion of this course, the CTS scholar will be able to understand: (1) health inequalities, (2) socio-economic risk factors, (3) maternal and child health, (4) the health of special populations, (5) HIV/AIDS, Malaria and tuberculosis, (6) globalization and emerging infectious diseases, and (7) global health payers and players and their role in understanding cultural issues.

**CTS 709. Clinical Research Design and Methods.** 2 credits.

An overview of the research designs available for clinical investigation: Strengths and weaknesses of controlled trials, cohort studies, and case control studies; the problem of response heterogeneity; bias and its sources; the problem of lost sampling units; randomization and its importance; the weaknesses of systematic reviews and of evidence-based medicine.
CTS 712. Bioinformatics and Information Technology in Clinical Medicine. 2 credits.
This course will introduce the scholars to Bioinformatics, which uses computer databases to store, retrieve and assist in understanding biological information. Genome-scale sequencing projects have led to an explosion of genetic sequences available for automated analysis. These gene sequences are the codes, which direct the production of proteins that in turn regulate all life processes. The CTS graduate program scholars will be shown how these sequences can lead to a much fuller understanding of many biological processes allowing pharmaceutical and biotechnology companies to determine for example new drug targets or to predict if particular drugs are applicable to all patients.

CTS 713. The Discipline of Scientific Writing and Preparation of Competitive Grant Applications. 3 credits.
The course will entail lectures on how to write a scientific paper and a proposal for funding with adherence to conventions of the literature and expectations of individual journals and funding agencies. Emphasis will be placed on writing clear English, and sequence of information. Course topics will include those in the recommended literature: (1) Writing a scientific paper and speaking at scientific meetings, second edition, Communicating in Science, by Vernon Booth, Cambridge University Press, 1993, (2) The Elements of Style, by W. Strunk and E.B. White, and (3) Writing a Scientific Paper, Chapter 1. The ACS Style Guide, A manual for Authors and Editors, Second Edition, J.S. Dodd, Editor, 1997, American Chemical Society. The lecture topics will be demonstrated in class discussions of papers selected from the literature. Students will be expected to participate in discussions and write individual critiques of the papers.

CTS 715. Applied Pharmacokinetics and Pharmacodynamics for Clinicians. 3 credits. FA
This course will prepare the clinician for individualized optimization of drug dosage based on a thorough understanding of pharmacokinetic and pharmacodynamic principles. The clinical application of pharmacokinetics to specific drugs will be discussed through the presentation and solution of problems commonly encountered in the clinical practice setting. The process of using drug concentrations, pharmacokinetic, and pharmacodynamic criteria to optimize therapy in individual patients will be illustrated and reinforced through discussions of pertinent drugs and case examples. Finally, principles and the underlying mechanisms of drug-receptor interaction will be discussed.

CTS 716. Molecular Med & Molecular Gen. 2 credits.
The overall objective of this course is to familiarize the student with current aspects of molecular medicine in the clinical setting. The course will consist of 16 lecture sessions. Two thirds of these sessions will cover classical Medelian molecular genetics, modern genetic testing and genetic diseases. The remaining lectures will cover the genetic aspects of cell inflammation, cell death and neoplasia. These lectures will be presented by members of the Departments of Pathology and Biomedical Sciences. Also, each student will be assigned a separate genetic disease and will "present" it to the class- similar to the way one would do it at a clinical grand round conference.

CTS 718. Medical Anthropology Research Strategies. 1 credit.

CTS 719. Drug Discovery & Translation of Research Innovation to Commercial Entities: Academic Entrepreneurship. 3 credits.
The relationship between academic centers, medical centers and corporate entities has become increasingly important in bringing a collaborative approach to new biotechnologies along with existing pharmaceutical remedies into clinical practice. This relationship has become part of a complex innovation ecosystem comprised of entrepreneurs, universities, corporate partners and others in a collaborative/competitive environment. This course will consist of a concise view of basic drug discovery process with an emphasis on biotechnologies, medicinal chemistry and molecular modelling in translational science. It will describe various models for translating biotechnology and medicinal chemistry innovations into commercial products, including university startups/spin outs and university/corporate partnerships. The course will also cover critical issues in the intellectual property management and disclosure, patents, and it will contain discussion of ethical dilemmas in academic corporate relationships. Issues related to the FDA regulatory process will be explored to assist investigators in determining whether the potential product is considered a drug, a biological therapeutic, or a biologic. Finally, NIH funding mechanisms via the STTR and SBIR will be explored and include eligibility considerations, new NIH funding opportunities, and enhancements to the program.

CTS 747. Cellular and Molecular Mechanisms of Transmembrane Signaling. 3 credits.
This course consists of lectures covering topics related to transmembrane signaling, including overviews of biological signals, intracellular and extracellular receptors, signaling pathways involving both heterotrimeric and monomeric G-proteins and their regulatory pathways, adenylate and guanylate cyclase, inositol-triphosphate, intracellular Ca2+, diacylglycerol, serine, threonine and tyrosine kinases, phosphatases and other regulatory mechanisms. Examples are discussed with clinical implications on the receptors for catecholamines, histamine, growth hormones, cytokines, IgE, light (photoreceptors), and odor (odorant receptors). Additional topics that are discussed include: molecular insight into the basis of diversity in ion channels, lymphocyte-induced signal transduction, toll-like receptors, and mechanisms underlying phagocytosis, apoptosis and smooth muscle contraction and relaxation as well as mechanisms underlying the activation of key transcriptional factors in transmembrane signaling pathways. Each student is assigned to write a comprehensive review on a recent topic related to cellular and molecular mechanisms of transmembrane signaling. Formal oral presentations and critical discussions of the aforementioned subjects will familiarize students with the nature and extent of research literature, the analysis of research papers, and the collation and presentation of scientific information. Individual student presentations and their active participation in the discussion are key aspects of this course.

CTS 791. Seminars in Clinical and Transitional Science. 1 credit.
Regular seminars will be held on various topics related to clinical and translational research, including issues in clinical research design and conduct, community engagement in clinical research, research methodologic issues, Web-based Technology: Implications for Data Collection in Clinical Research, gene and stem cell therapy, nanotechnology, etc. Seminars will be held at least once a week. Outside qualified speakers will be invited.
CTS 795. Directed Independent Study. 2-3 credits.
In this course, each scholar will be supervised by faculty members; will pursue in-depth reading and discussions on current research topics of interest to scholars. The purpose is to provide an environment whereby the student is introduced to scientific research methods and can improve critical thinking and reading skills as well as exchanging scientific information.

CTS 797. Directed Independent Research. 2-6 credits.
Original investigation under supervision and guidance of individual faculty members. The course will require laboratory work and conferences. The CTS scholars will work with established investigators in the area of clinical and translational science.

CTS 799. Master’s Thesis. 1-6 credits.
Review of literature and research design; writing of the thesis. The scholars must register for this course in any term when engaged in formal preparation of the Master’s thesis. However, six credit hours are the maximum applicable towards the degree.

CTS 895. Directed Independent Study. 2-3 credits.
In this course, each scholar will be supervised by faculty members; will pursue in-depth reading and discussions on current research topics of interest to faculty and students. The purpose is to provide an environment whereby the student is introduced to scientific research methods and can improve critical thinking and reading skills as well as exchanging scientific information. This course can be taken every semester up to a maximum of 12 credit hours.

CTS 897. Directed Independent Research. 2-6 credits.
Original investigation under supervision and guidance of individual faculty members. The course will require laboratory work and conferences. The CTS scholars will work with established investigators in the area of clinical and translational science. At Creighton University, there are many faculty who have funded projects from NIH, Department of Defense, Veterans Administration Merit Grant, American Heart Association, Department of Health, Nebraska, and pharmaceutical industries. Currently, Creighton University faculty have about 31 NIH-funded projects, 2 DoD funded projects, more than 200 pharmaceutical industry-funded projects, 12 Nebraska Department of Health and Human Services funded projects, and many more. Thus, the CTS graduate students will have choice to select research projects in many different disciplines of clinical research. This course can be taken every semester, up to a maximum of 40 credit hours.

CTS 899. PhD Dissertation. 6-12 credits.
This course consists of the review of literature and research data and formal composition of the Doctoral Dissertation. The scholars must register for this course in any term when engaged in formal preparation of the Doctoral dissertation. When taken in a student’s final semester, it culminates in the defense of the Doctoral dissertation before the Graduate Advisory Committee. Repeatable to a maximum of 12 credit hours. Six credit hours are the maximum applicable towards the degree. P: CTS 897.