

# CLINICAL SCIENCES (CLSCI-DN)

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## CLSCI-DN 7016 Practicum in Clinical Research Center I (3 Credits)

*Typically offered Fall*

This is a practicum related to clinical research that gives the students experiential training in the various components of conducting clinical research. Practicum I covers basic knowledge of the procedural and regulatory component of clinical research, including participating as an observer in meetings of the different committees in charge of supervising the entirety of the research process, from IRB meetings to DSMB meetings, among others. Students will work with mentors and participate in various clinical research activities that can range from IRB applications, subject recruitment, data collection, data entry and editing, monitoring of studies, data analysis, and report writing.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7021 Practicum in Clinical Research Center II (3 Credits)

*Typically offered Spring*

This is the second level of the clinical research practicum that is offered in the spring semester of the MS program and offers students additional practical training in clinical research. Students will work with selected mentors (same as in the practicum I or a different mentor) and participate in various clinical research activities under supervision, that can range from protocol review and advanced regulatory training to shadowing study team members in a clinical environment.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7030 Fund of Clin Trials I (3 Credits)

Fundamentals of Clinical Trials I is a foundational course introducing students to randomized controlled trials (RCTs). The course covers basic elements of an RCT, formulation of research questions, study populations, power and sample size, randomization and masking, study recruitment and enrollment, industry and regulatory issues, safety and adverse events, compliance and monitoring, and data analysis.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7035 Fund of Clinical Trials II (3 Credits)

*Typically offered Spring*

The second course in the Clinical Trials sequence, Fundamentals of Clinical Trials II is a more advanced treatment to the design, conduct, and analysis of clinical trials. Topics include the FDA and US regulatory authorities, pharmaceutical research and industry, drug development and discovery, toxicology testing, pre-clinical requirements for human testing, safety reporting in clinical trials, phases of clinical trial development and design, IRB and ethics committees, trial monitoring, and multi-center trials.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7040 Biostatistics I (3 Credits)

*Typically offered Spring*

Biostatistics is a rigorous, 15-week course consisting of 13 lectures, a midterm, and a final exam. It covers basic probability, descriptive and inferential statistics, and the role of biostatistics in the practice of clinical research. Specific attention will be given to common probability distributions in clinical research and medicine, t-tests, Analysis of Variance, multiple linear and logistic regression, categorical data analysis, and survival analysis. Statistical topics are presented conceptually with little derivation, and applications are demonstrated using common statistical software.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7050 Federal Regulations & Federal Agencies (2 Credits)

*Typically offered Fall*

This course will introduce the regulatory and legal underpinnings that dictate the conduct of human clinical trials and drug and device development in the United States. Topics include US laws and regulations, penalties and debarment, good laboratory practice, toxicology testing, HIPAA regulations, the Declaration of Helsinki, INDs, NDAs, and FDA criteria, drug nomenclature, and regulations regarding medical devices.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7060 Fund of Data Mgmt I (2 Credits)

This is an introductory course for the management and manipulation of clinical data. The course will cover technical aspects of data management such as data collection, data entry, discrepancy review, data validation, and data cleaning. This course is essential for individuals who desire a basic hands-on understanding of the data flow process within data management in various research studies (observational as well as experimental). Students will apply data management skills in SAS.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

## CLSCI-DN 7080 Bioethical Issues & Irb Skills (2 Credits)

This course explores issues about ethics, ethical reflection, and case studies that apply ethical principles and moral reflection to health care research using human participants. This course goes beyond the subjects at an introductory level and facilitates the development of independent effort in the resolution of ethical dilemmas. Moreover, students will gain knowledge about federal regulations and key documents that guide human subjects research in the U.S. and globally. Given that the students enrolled in the course provide a diversity of experience and career focus, the course will develop several lines of thought. There will be issues relate directly to the ethical aspects of research design, recruitment, and enrollment of subjects into projects. The course will use a textbook and case studies as vehicles to deepen understanding and perspectives about the use of human participants. The course includes special topics like confidentiality, decision-making, informed consent, using confidential information in research, and requirements of the Health Insurance Portability and Accountability Act (HIPAA).

**Grading:** Dental Graded

**Repeatable for additional credit:** No

**CLSCI-DN 7090 Scientific Writing (3 Credits)**

This course will allow students in the Clinical Research program to gain the basic skills needed to be competent in writing a scientific paper or protocol for a clinical trial study. The course will focus on skills to write for scientific audiences and summarize a clinical research study, consisting of 1) an opening series of class presentations and discussions on the key component parts of a scientific protocol, grant, or paper as well as on grant writing and reviewing skills; 2) sessions in which students acquire skills in evaluating and formally reviewing written protocols or grants; and, 3) sessions which focus on skills in selecting a research topic and writing a protocol or paper for a scientific/research audience.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

**CLSCI-DN 8925 Epidemiology (3 Credits)**

Epidemiology is the study of the distribution and determinants of health and disease in different human populations and the application of methods to improve disease outcomes. As such, epidemiology is the basic science of health. This course is designed to introduce students in all fields of health and medicine to the background, basic principles, and methods of epidemiology. Topics include historical developments, principles of epidemiology, measures of mortality, study design, selection and information bias, confounding, effect modification and causal inference, screening, and outbreak investigations.

**Grading:** Dental Graded

**Repeatable for additional credit:** No

**CLSCI-DN 8926 Evidenced-Based Healthcare (3 Credits)**

*Typically offered January term*

Evidence-based healthcare is the integration of the current best evidence, with clinical judgment, and patient values and circumstances to improve health. This course uses lectures and case-base discussion learning to deliver the theory and practice of evidence-based care implementation. The course will include introductory reviews of PICO development (Patient, Intervention, Comparators, and Outcomes), MEDLINE databases, study design and causality, critical appraisals of RCTs, Systematic Reviews, online research resources such as EBD, TRIP, DARE, and Cochran, Dissemination and Implementation Research, meta-analysis, literature reviews, and surveillance & assessment systems.

**Grading:** Dental Graded

**Repeatable for additional credit:** No