

# Clinical Trials and Regulatory Affairs

This section presents the requirements for programs in:

- **M.Sc. Clinical Trials and Regulatory Affairs**

## Program Requirements

### M.Sc. Clinical Trials and Regulatory Affairs (4.5 credits)

#### Requirements:

##### 1. 0.0 credit in:

HLTH 5101 [0.0] Statistical Software and its Application to Health Sciences Primer (must be completed within two weeks of first semester)

HLTH 5811 [0.0] Clinical Trials Primer (must be completed within two weeks of first semester)

##### 2. 4.0 credits in: 4.0

HLTH 5812 [0.5] Clinical Trials 1: Introduction

HLTH 5813 [0.5] Clinical Trials 2

HLTH 5814 [0.5] Assessment and Patient Safety for Clinical Trials

HLTH 5815 [0.5] Principles of Data Management and Analysis in Clinical Trials

HLTH 5816 [0.5] Government Regulatory Processes

HLTH 5817 [0.5] Government, Research Organizations, and Industry

HLTH 5818 [0.5] Ethics, Community and Patient Engagement

HLTH 5819 [0.5] Clinical Trials Protocols, Operations and Management

##### 3. 0.5 credit from: 0.5

BIOC 4708 [0.5] Principles of Toxicology

CHEM 4305 [0.5] Environmental Chemistry and Toxicology

HLTH 5150 [0.5] Statistics for Health Sciences

HLTH 5151 [0.5] Principles of Epidemiology

HLTH 5350 [0.5] New Health Technologies

HLTH 5700 [0.5] Special Topics in Biostatistics and Epidemiology

HLTH 5704 [0.5] Special Topics in the Science of Disease

STAT 5602 [0.5] Analysis of Categorical Data

STAT 5603 [0.5] Reliability and Survival Analysis

##### Total Credits 4.5

### M.Sc. Clinical Trials and Regulatory Affairs (practicum pathway - 6.0 credits)

#### Requirements:

##### 1. 0.0 credit in:

HLTH 5101 [0.0] Statistical Software and its Application to Health Sciences Primer (must be completed within two weeks of first semester)

HLTH 5811 [0.0] Clinical Trials Primer (must be completed within two weeks of first semester)

##### 2. 4.0 credits in: 4.0

HLTH 5812 [0.5] Clinical Trials 1: Introduction

HLTH 5813 [0.5] Clinical Trials 2

HLTH 5814 [0.5] Assessment and Patient Safety for Clinical Trials

HLTH 5815 [0.5] Principles of Data Management and Analysis in Clinical Trials

HLTH 5816 [0.5] Government Regulatory Processes

HLTH 5817 [0.5] Government, Research Organizations, and Industry

HLTH 5818 [0.5] Ethics, Community and Patient Engagement

HLTH 5819 [0.5] Clinical Trials Protocols, Operations and Management

##### 3. 0.5 credit from: 0.5

BIOC 4708 [0.5] Principles of Toxicology

CHEM 4305 [0.5] Environmental Chemistry and Toxicology

HLTH 5150 [0.5] Statistics for Health Sciences

HLTH 5151 [0.5] Principles of Epidemiology

HLTH 5350 [0.5] New Health Technologies

HLTH 5700 [0.5] Special Topics in Biostatistics and Epidemiology

HLTH 5704 [0.5] Special Topics in the Science of Disease

STAT 5602 [0.5] Analysis of Categorical Data

STAT 5603 [0.5] Reliability and Survival Analysis

##### 4. 1.5 credits in: 1.5

HLTH 5820 [0.5] Clinical Trials Practicum

##### Total Credits 6.0

## Admission

### M.Sc. Clinical Trials and Regulatory Affairs - Practicum pathway:

- 4-year (honours) bachelor degree or equivalent professional degree in a related discipline
- minimum B+ (77%) average over last 2 years of study (or last 20 one-term courses)
- one undergraduate course in statistics or equivalent (desirable)

### M.Sc. Clinical Trials and Regulatory Affairs - Non-practicum pathway:

- in addition to the admission requirements listed above, non-practicum pathway applicants must possess two years of experience in clinical trials.

Applicants must submit their transcripts, a professional resume, two or three letters of recommendation, a statement of intent outlining their career goals and their alignment with the learning outcomes and degree level expectations of the program, and provide information about relevant work experience.

## **Health Sciences (HLTH) Courses**

### **HLTH 5100 [0.5 credit]**

#### **Fundamentals of Research Methods**

Experimental design, statistical analysis and interpretation of results in health science research, principles and methods of epidemiology, fundamentals of research ethics.

Includes: Experiential Learning Activity

Prerequisite(s): university-level statistics.

### **HLTH 5101 [0.0 credit]**

#### **Statistical Software and its Application to Health Sciences Primer**

Introduction to statistical softwares used to analyze health research data. Data management topics include data entry, manipulation, and elementary statistical analyses using SAS, SPSS, Stata and R. Other topics include privacy/maintaining security of health datasets. For students without strong backgrounds in biostatistics/data handling.

Includes: Experiential Learning Activity

### **HLTH 5150 [0.5 credit]**

#### **Statistics for Health Sciences**

Statistical methods commonly used in analyses of health data. This applied course covers topics related to descriptive and graphical methods, tests of hypotheses in both paired and independent samples, linear regression, survival analysis, and logistic regression.

Includes: Experiential Learning Activity

Lecture three hours a week, lab/workshop three hours a week.

### **HLTH 5151 [0.5 credit]**

#### **Principles of Epidemiology**

Introduction to epidemiologic concepts and methods.

Different types of epidemiological study designs.

Fundamental concepts of: definitions and measures of disease frequency and effects, causality, bias, sample size, confounding and interaction.

Includes: Experiential Learning Activity

### **HLTH 5201 [0.5 credit]**

#### **Fundamentals of Policy I: Policy Analysis**

Policy analysis and policy processes with an emphasis on the stages of the policy process, as well as the influences of institutions, ideas and interests.

### **HLTH 5202 [0.5 credit]**

#### **Fundamentals of Policy II: The Health Sector**

Canadian health policies and programs with emphasis on the economics, politics and public administration of the healthcare sector.

### **HLTH 5300 [0.5 credit]**

#### **Knowledge Translation**

The application of knowledge translation in the formulation of policy and the development of skills required to maximize the impact of scientific findings through real world programs and policies and communication skills for diverse audiences.

Precludes additional credit for NEUR 5801.

Also offered at the undergraduate level, with different requirements, as HLTH 4701, for which additional credit is precluded.

### **HLTH 5350 [0.5 credit]**

#### **New Health Technologies**

Overview of new and emerging health technologies, including medical and assistive devices, diagnostics and screening, genetics, reproduction, tissue regeneration, imaging, and health informatics. Health technology assessment methods and issues. Regulatory, ethical and social implications; considerations in the developing world.

Includes: Experiential Learning Activity

Also offered at the undergraduate level, with different requirements, as HLTH 4102, for which additional credit is precluded.

### **HLTH 5401 [0.5 credit]**

#### **Interdisciplinary Problems in Health**

Development of an understanding of the scope and interdisciplinary nature of issues that impact the health of Canadians is the focus of this course.

Precludes additional credit for HLTH 5903.

### **HLTH 5402 [0.5 credit]**

#### **Biological and Social Fundamentals of Health**

What comprises a healthy body and mind? This course addresses the psycho-social and biological mechanisms that may interact to determine health outcomes. The course examines complex relationships between social, environmental, and biological factors underlying some of the most important and emerging health concerns today.

### **HLTH 5403 [0.5 credit]**

#### **Host-Pathogen Interactions**

Advanced cellular and molecular mechanisms governing host-pathogen interactions and their contribution to disease. Exploration of immune signaling and recognition, virulence factors, antimicrobial resistance and research techniques used in this field.

Prerequisite(s): Permission of the department.

Also offered at the undergraduate level, with different requirements, as HLTH 4304, for which additional credit is precluded.

**HLTH 5504 [1.0 credit]****Interdisciplinary Health Research Project - Group**

Student teams will collaborate on a research project that addresses a real-world health concern, supervised by a cross-disciplinary team of faculty. Students must be continually registered in this course throughout their degree program (five terms.).

Includes: Experiential Learning Activity

Precludes additional credit for HLTH 5502 (no longer offered), HLTH 5503(no longer offered), HLTH 5505.

**HLTH 5505 [1.0 credit]****Interdisciplinary Health Research Project – Individual**

An independent research project that addresses a real-world health concern, supervised by a faculty member and advised by a cross-disciplinary team of experts. Students must be continually registered in this course throughout their degree program (five terms).

Includes: Experiential Learning Activity

Precludes additional credit for HLTH 5502(no longer offered), HLTH 5503(longer offered), HLTH 5504.

Prerequisite(s): permission of the Faculty supervisor and the Department of Health Sciences.

**HLTH 5506 [1.0 credit]****Field Research and Placement**

This practicum supports students in gaining relevant and practical experience through applying course learning at approved organizations.

Includes: Experiential Learning Activity

Precludes additional credit for HLTH 5801.

Prerequisite(s): Completion of two terms of the MSc HSTP program, permission of the department and at the discretion of the practicum supervisor.

Schedules may vary depending on the field placement site, but students are required to spend a minimum of 32 weeks over summer, fall and winter in the second year.

**HLTH 5507 [1.0 credit]****Interdisciplinary Health Research Project**

Research project that addresses a real-world health concern, supervised by a faculty member and advised by a cross-disciplinary team of experts. Students must be continually registered in this course throughout their degree program (five terms).

Includes: Experiential Learning Activity

Precludes additional credit for HLTH 5504, HLTH 5505.

Prerequisite(s): Permission of the Faculty supervisor and the Department of Health Sciences.

**HLTH 5600 [0.25 credit]****Special Topics in Biostatistics and Epidemiology**

Selected topics in biostatistics and epidemiology, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

Includes: Experiential Learning Activity

**HLTH 5601 [0.25 credit]****Special Topics in Health Policy and Administration**

Selected topics in health policy and administration, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5602 [0.25 credit]****Special Topics: Social and Behavioural**

Selected topics in the social and behavioural sciences, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5603 [0.25 credit]****Special Topics in Environmental Health**

Selected topics in environmental health, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5604 [0.25 credit]****Special Topics in the Science of Disease**

Selected topics in the science of disease, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5605 [0.25 credit]****Special Topics: Engineering, Design and Computer Science**

Selected topics in applications of engineering, design or computer science in health, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5700 [0.5 credit]****Special Topics in Biostatistics and Epidemiology**

Selected topics in biostatistics and epidemiology, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

Includes: Experiential Learning Activity

**HLTH 5701 [0.5 credit]****Special Topics in Health Policy and Administration**

Selected topics in health policy and administration, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5702 [0.5 credit]****Special Topics: Social and Behavioural**

Selected topics in the social and behavioural sciences, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5703 [0.5 credit]****Special Topics in Environmental Health**

Selected topics in environmental health, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5704 [0.5 credit]****Special Topics in the Science of Disease**

Selected topics in the science of disease, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5705 [0.5 credit]****Special Topics: Engineering, Design and Computer Science**

Selected topics in applications of engineering, design or computer science in health, focusing on areas of specific relevance to the health sector, not available in regular program offerings. These courses are designed to provide depth of expertise and/or specific skills relevant to the workplace.

**HLTH 5800 [0.5 credit]****Directed Studies in Health: Science, Technology and Policy**

One-to-one instruction in selected aspects of specialized Health: Science and Technology subjects not covered by other graduate courses. Students may not take this course from their project supervisor(s), and are limited to one directed studies course per program.

Prerequisite(s): permission of the director of Health: Science, Technology and Policy.

**HLTH 5801 [0.5 credit]****Health: Science, Technology and Policy Practicum**

This practicum supports students in gaining relevant and practical experience through applying course learning at approved organizations. Students are responsible for arranging the placement with an external partner where the practicum will be held, preparing a learning contract, and completing a field-based project deliverable.

Includes: Experiential Learning Activity

Precludes additional credit for HLTH 5506.

Prerequisite(s): Completion of two semesters of the MSc in HSTP program, permission of the department and at the discretion of the practicum supervisor. Students may not be supervised by their MSc research supervisor(s) and are limited to one practicum per program.

**HLTH 5811 [0.0 credit]****Clinical Trials Primer**

Overview of the vast area of clinical trials of drugs and devices, and principles of informed consent, regulatory requirements, rigorous documentation, analysis, and reporting. Students will also work on certificates in biomedical ethics, good clinical practice, and others, for example from CITI Canada.

**HLTH 5812 [0.5 credit]****Clinical Trials 1: Introduction**

Fundamentals of trials of health products and different phases and types of clinical trials. Investigator vs. sponsor-initiated trials, different regulatory agencies, the use of randomization, blinding, registration regulatory requirements, rigorous documentation, and common trials.

**HLTH 5813 [0.5 credit]****Clinical Trials 2**

Other trial designs, recruitment of patients, data collection and quality control, interim monitoring, audits, inspections, timelines. Includes a four to six-week placement at a clinical or regulatory site, CRO, or similar institution involved in clinical trials.

Includes: Experiential Learning Activity

**HLTH 5814 [0.5 credit]****Assessment and Patient Safety for Clinical Trials**

The importance of efficacy and safety measurements, biosamples, pharmacokinetics, pharmacodynamics, drug mechanism of action, reporting of harm, Data and Safety Monitoring Board, pharmacovigilance, consideration of special populations. Good clinical practice, good medical practice, and good laboratory practice.

Includes: Experiential Learning Activity

**HLTH 5815 [0.5 credit]****Principles of Data Management and Analysis in Clinical Trials**

Randomization, biomarkers, endpoints, estimands, sample size requirements, random error and bias, multiple testing correction, intent-to-treat versus per-protocol, equipoise and stopping rules for trials, database development, validation and reporting/transferring, development of statistical analysis plans, considerations around missing data.

**HLTH 5816 [0.5 credit]****Government Regulatory Processes**

Regulatory agencies (Health Canada, US Food and Drug Administration, European Medicines Agency) will be compared. Harmonization efforts of national drug approval agencies, timelines for an investigational New Drug Application including labeling, accelerated approval, breakthrough designation, orphan drugs, and biologics licence application.

**HLTH 5817 [0.5 credit]****Government, Research Organizations, and Industry**

Overview of regulatory requirements of pharmaceutical companies, contracting research organizations, and communication with regulatory agencies. Negotiation and collaboration between sectors, incentives such as FDA priority review vouchers, project management, manufacturing and distribution, phase IV post-marketing and continued monitoring, pharmacovigilance and post-marketing changes.

**HLTH 5818 [0.5 credit]****Ethics, Community and Patient Engagement**

Patient engagement, equipoise, informed consent, ethics board, monitoring, reporting/release of data in the literature, compassionate/expanded access; patient foundations, liaisons and advocates. Engaging with Indigenous communities and special populations. Considerations around translational research, generics, biosimilars, and labeling.

**HLTH 5819 [0.5 credit]****Clinical Trials Protocols, Operations and Management**

Clinical protocols, electronic case report forms and guidelines, data management plan, monitoring plan, pharmacy manual, standard operating procedures, manual of operating procedures, delegation of authority logs and training logs. Leadership, logistics, budgeting.

**HLTH 5820 [0.5 credit]****Clinical Trials Practicum**

Capstone credit course required for students in the practicum pathway. Experiential learning at a clinical site, regulatory site, CRO, or similar institution involved in clinical trials. Students will demonstrate the knowledge and skills gained and will present on their experience, efforts and lessons learned.

Includes: Experiential Learning Activity

**HLTH 5901 [0.5 credit]****Advanced Topics in Interdisciplinary Health Sciences**

Discussion of current health problems and exploration of innovative interdisciplinary solutions. Development of skills required to perform critical analyses of health research to evaluate the quality, interpret the findings, and assess the impact of health sciences literature across disciplines.

Precludes additional credit for HLTH 5903.

**HLTH 5902 [0.5 credit]****Seminars in Interdisciplinary Health Sciences for MSc**

Development of scientific communication skills through attendance at interdisciplinary seminars and by the student presenting a seminar on their own thesis research. Topics have specific or broad relevance to health sciences. Graded SAT/UNS.

**HLTH 5903 [0.5 credit]****Current Topics in Interdisciplinary Health Sciences**

Exploration of current health challenges and opportunities, and the role of interdisciplinary approaches to understand health and disease. Development of skills required for communication, collaboration, literature appraisal. Includes student, faculty, and invited seminar speakers.

Precludes additional credit for HLTH 5401, HLTH 5901.

Prerequisite(s): Permission of the Department of Health Sciences.

**HLTH 5905 [0.0 credit]****Final Research Seminar Presentation for MSc**

Final seminar of MSc thesis research. Seminar presentation should occur within one month of the final oral thesis defence.

Includes: Experiential Learning Activity

**HLTH 5909 [4.0 credits]****MSc Thesis**

Includes: Experiential Learning Activity

**HLTH 6902 [0.5 credit]****Seminars in Interdisciplinary Health Sciences**

Development of scientific communication skills through attendance at interdisciplinary seminars and by the student presenting a seminar on their own thesis research. Topics have specific or broad relevance to health sciences. Graded SAT/UNS.

**HLTH 6903 [0.5 credit]****Grant Proposals and Ethics**

Advanced course in writing successful grant proposals in Tri-Council (CIHR, NSERC, SSHRC) formats. Ethics associated with conducting health sciences research, including the preparation of ethics proposals for human and animal studies in health sciences research.

Includes: Experiential Learning Activity

**HLTH 6904 [0.0 credit]****Mid-Program Defence**

Departmental seminar and Graduate Advisory Committee meeting on PhD research including results to date and future research aims and directions, and on field-specific knowledge.

Includes: Experiential Learning Activity

**HLTH 6905 [0.0 credit]****Final Research Seminar Presentation**

Final seminar of PhD thesis research. Seminar presentation should occur within one month of the final oral thesis defence.

Includes: Experiential Learning Activity

**HLTH 6909 [0.0 credit]****PhD Thesis**

Includes: Experiential Learning Activity