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	
HLTH 5821 [0.5]	Effective Communication in Clinical Research and Regulatory Environments	
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	
HLTH 5821 [0.5]	Effective Communication in Clinical Research and Regulatory Environments	
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 [1.5]	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
Individualized instruction in selected aspects of specialized Health Sciences subjects not covered by other graduate courses. Students are permitted to only take this course once per program. Their project supervisor(s) may supervise if the research to be conducted is different from their thesis/project research.
Prerequisite(s): permission of the department.

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.

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 [1.5 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 5821 [0.5 credit]
Effective Communication in Clinical Research and Regulatory Environments
This course equips students with the skills to convey complex information in decision-based discussions and explain complex regulatory environments, preparing them for impactful roles in clinical trial research.

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. 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 5906 [0.0 credit]
Research Seminar Presentation for MSc
Seminar of MSc thesis research. Seminar presentation should occur after two terms in the MSc, and prior to enrolment in the second year.
Prerequisite(s): permission of the department.

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. 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 6906 [0.0 credit]
Research Seminar Presentation for PhD
Seminar of PhD thesis research. Seminar presentation should occur after two terms in the PhD in Health Sciences, and prior to enrolment in the second year.
Prerequisite(s): Permission of the department.

HLTH 6909 [0.0 credit]
PhD Thesis
Includes: Experiential Learning Activity