

HLTH 5812 for Fall 2026

Clinical Trials 1

Course Instructor: Scott Sawler

Email:

Student Hours: by appointment

Office Location: Online Via Zoom

Class Location:

Class Times:

Department/Unit: Health Sciences

Topics Covered and Learning Outcomes

Important dates and deadlines can be found here: <https://calendar.carleton.ca/academicyear/>, including class suspension for fall, winter breaks, and statutory holidays.

Course level learning outcomes:

- Explain the purpose, phases, and principal types of clinical trials and place individual studies within a health-product development program.
- Translate a clinical question into the basic architecture of a trial: population, intervention, comparator, outcomes, timing, and design.
- Apply foundational design concepts - including randomization, allocation concealment, blinding, controls, and bias reduction - to assess trial validity.
- Evaluate participant eligibility, recruitment, representativeness, outcome selection, follow-up, and common threats to interpretability.
- Differentiate the roles and accountabilities of sponsors, investigators, institutions, CROs/service providers, ethics boards, and regulators.
- Explain foundational ethics, informed-consent, GCP, and Canadian clinical-trial regulatory requirements and compare them at a high level with U.S. and EU approaches.
- Identify the purpose of essential trial records, registration, results disclosure, and transparent protocol and trial reporting.
- Read a protocol, registry entry, and published trial critically and communicate a proportionate conclusion about what the evidence does and does not support.

Core reference set

These sources form the recurring reference base for the course. Assigned excerpts should be identified in Brightspace before each class; students are not expected to read every source in full every week.

- ICH. E6(R3), Guideline for Good Clinical Practice, consolidated final version adopted 16 June 2026. [Link](#)
- ICH. E8(R1), General Considerations for Clinical Studies (2021). [Link](#)
- Health Canada. Food and Drug Regulations, Part C, Division 5 - Drugs for Clinical Trials Involving Human Subjects. [Link](#)
- Health Canada. GUI-0100, Guidance Document: Part C, Division 5 of the Food and Drug Regulations, Version 4 (14 August 2026). [Link](#)
- TCPS 2 (2022), Chapter 11: Clinical Trials. [Link](#)
- World Medical Association. Declaration of Helsinki, revised October 2024. [Link](#)
- SPIRIT 2025 statement: updated guideline for protocols of randomised trials. [Link](#)
- CONSORT 2025 statement: updated guideline for reporting randomised trials. [Link](#)

- Health Canada. Guidance on the registration of clinical trials and public disclosure of results, effective 29 July 2026. [Link](#)

Course-wide additional reading

- ICH. E9, Statistical Principles for Clinical Trials - as a conceptual reference; detailed statistical methods are taught in HLTH 5815. [Link](#)
- ICH. E10, Choice of Control Group and Related Issues in Clinical Trials. [Link](#)
- CIOMS. International Ethical Guidelines for Health-related Research Involving Humans (2016). [Link](#)
- WHO. International Clinical Trials Registry Platform and WHO Trial Registration Data Set. [Link](#)
- FDA-NIH Biomarker Working Group. BEST (Biomarkers, Endpoints, and other Tools) Resource. [Link](#)

Lecture	Topic	Organizing question
1	Clinical Trials as an Evidence System	Why do we conduct clinical trials, and how do trials fit within health-product development and clinical evidence?
2	From Research Question to Trial Protocol	How is a clinically important question translated into a protocol that can be conducted and evaluated?
3	Trial Phases and Development Programs	What question is each phase of development intended to answer, and how does evidence accumulate across a program?
4	Common Trial Designs and Comparison Strategies	Which basic trial design best answers the research question while producing an interpretable comparison?
5	Randomization, Allocation	How do trial design safeguards create a fair comparison and reduce systematic error?
6	Concealment, Blinding and Bias	Who should be enrolled, and how do eligibility and recruitment choices affect ethics, feasibility and generalizability?
7	Participants, Eligibility, Recruitment and Representativeness	What should a trial measure, when should it measure it, and what makes an outcome meaningful?
8	Outcomes, Endpoints, Follow-up and Clinical Meaning	Who is accountable for what in a clinical trial?
9	Roles, Responsibilities and Trial Governance	What makes human participation in a clinical trial ethically acceptable?
10	Ethics and Informed Consent in Clinical Trials	How do regulatory authorization and GCP govern whether a drug trial may proceed and how it must be conducted?
11	Regulatory Foundations and Good Clinical Practice	How does a trial create a traceable public and regulatory record from protocol to results?
	Essential Documentation, Registration and Results Transparency	

Student Expectations

- Preparation: complete the assigned readings or extracts before class and arrive able to explain the week's core concepts in your own words.
- Participation: contribute to case discussions, design exercises, and critique of published trials. Questions, disagreement, and uncertainty are welcome when expressed respectfully and supported by reasoning.
- Attendance: consistent attendance and punctual participation are expected because much of the learning occurs through live discussion and applied exercises. Students who miss a class are responsible for obtaining the material and any announced changes.
- Evidence discipline: distinguish what a trial was designed to show from what its results actually support. Avoid causal, safety, or generalizability claims that go beyond the design and data.
- Source use: use primary or authoritative sources where reasonably available. Do not cite a secondary summary when the underlying protocol, registry record, guideline, regulation, or trial report is the material source.
- Professional writing: written work should be concise, structured, accurately referenced, and transparent about assumptions and uncertainty.
- Academic integrity: submitted work must reflect the student's own understanding and comply with Carleton University's Academic Integrity Policy and any assessment-specific collaboration rules.
- Course materials: course slides, cases, assignment materials, and recordings are for enrolled students and should not be distributed outside the course without permission.
- Respectful learning environment: ideas may be challenged; individuals will be treated with respect. Diverse disciplinary and professional perspectives are expected to strengthen discussion.

Lecture-by-Lecture Content

The following material is designed to be transferred directly into the weekly syllabus schedule or Brightspace modules. "Primary references" are authoritative or foundational sources; "additional reading" is recommended enrichment and may be selectively assigned.

Lecture 1: Clinical Trials as an Evidence System

Why do we conduct clinical trials, and how do trials fit within health-product development and clinical evidence?

Introduces the clinical-trial ecosystem, core terminology, the logic of prospective experimentation, the relationship between research and care, and the progression from exploratory evidence to confirmatory evidence. The lecture establishes a common vocabulary for the rest of the course without moving into advanced statistical methods or operational detail.

Learning objectives

- Explain the purpose of clinical trials and distinguish interventional research from routine clinical care and observational research.
- Describe how clinical trials contribute to evidence about efficacy, safety, dose, use conditions, and benefit-risk.
- Use core trial terminology accurately, including intervention, comparator, outcome, participant, protocol, sponsor, investigator, and trial phase.
- Place a clinical trial within the broader lifecycle of health-product development and evidence generation.

Primary references

- ICH. E8(R1), General Considerations for Clinical Studies (2021). [Link](#)
- ICH. E6(R3), Guideline for Good Clinical Practice, consolidated final version adopted 16 June 2026. [Link](#)
- World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants, revised October 2024. [Link](#)

Additional reading

- Health Canada. Clinical trials and drug development resources. [Link](#)
- World Health Organization. Clinical trials: questions and answers. [Link](#)

Lecture 2: From Research Question to Trial Protocol

How is a clinically important question translated into a protocol that can be conducted and evaluated?

Moves from the research question to objectives, hypotheses, intervention and comparator definitions, participant population, outcomes, visit schedule, analysis concepts, and oversight. Students learn the architecture of a protocol and the importance of pre-specification, without attempting the detailed protocol-writing and operational planning taught later in the program.

Learning objectives

- Translate a broad clinical question into a structured trial objective and testable primary question.
- Identify the core elements of a clinical-trial protocol and explain how they fit together.
- Differentiate primary and secondary objectives and distinguish exploratory from confirmatory purposes.
- Explain why prospective specification and version control matter for scientific credibility, ethics, and oversight.

Primary references

- Chan AW et al. SPIRIT 2025 statement: updated guideline for protocols of randomised trials. *BMJ*. 2025;389:e081477. [Link](#)
- ICH. E8(R1), General Considerations for Clinical Studies. [Link](#)
- ICH. E6(R3), Good Clinical Practice - protocol and trial-design principles. [Link](#)

Additional reading

- Chan AW et al. SPIRIT 2025 explanation and elaboration. BMJ. 2025;389:e081660. [Link](#)
- Health Canada. GUI-0100, clinical trial application and protocol expectations. [Link](#)

Lecture 3: Trial Phases and Development Programs

What question is each phase of development intended to answer, and how does evidence accumulate across a program?

Examines Phase I through Phase IV, including first-in-human and early clinical pharmacology work, dose-finding, proof-of-concept, confirmatory trials, and post-authorization studies. The emphasis is on the purpose and evidentiary role of each phase rather than on advanced design methodology.

Learning objectives

- Differentiate Phase I, II, III, and IV trials by their principal purpose, population, and typical evidence contribution.
- Explain why development is iterative rather than a simple linear sequence.
- Distinguish exploratory evidence from confirmatory evidence and identify common transitions between phases.
- Recognize how product characteristics, disease context, prior evidence, and uncertainty can alter a conventional development program.

Primary references

- ICH. E8(R1), General Considerations for Clinical Studies. [Link](#)
- U.S. FDA. The Drug Development Process: clinical research and investigational new drugs. [Link](#)
- Health Canada. How drugs are reviewed in Canada. [Link](#)

Additional reading

- ICH. E4, Dose-Response Information to Support Drug Registration. [Link](#)
- ICH. E5(R1), Ethnic Factors in the Acceptability of Foreign Clinical Data. [Link](#)

Lecture 4: Common Trial Designs and Comparison Strategies

Which basic trial design best answers the research question while producing an interpretable comparison?

Introduces the main design families students should recognize in an introductory course: parallel-group, crossover, factorial, cluster-randomized, single-arm, superiority, non-inferiority, and equivalence approaches. Adaptive, basket, umbrella, platform, master-protocol, and advanced comparative-effectiveness methods are deliberately outside the scope of this course.

Learning objectives

- Distinguish common parallel, crossover, factorial, cluster, and single-arm designs and identify their basic strengths and limitations.
- Differentiate superiority, non-inferiority, and equivalence questions at a conceptual level.
- Select a basic design that aligns with a stated research question, intervention, disease context, and feasible comparator.

- Identify design choices that can threaten interpretability or create avoidable bias.

Primary references

- ICH. E8(R1), General Considerations for Clinical Studies. [Link](#)
- ICH. E10, Choice of Control Group and Related Issues in Clinical Trials. [Link](#)
- Hopewell S et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. BMJ. 2025;389:e081123. [Link](#)

Additional reading

- CONSORT. Extensions for trial designs (consult the applicable extension when reading cluster, crossover, factorial, or non-inferiority trials). [Link](#)
- ICH. E9, Statistical Principles for Clinical Trials - introductory design concepts. [Link](#)

Lecture 5: Randomization, Allocation Concealment, Blinding and Bias

How do trial design safeguards create a fair comparison and reduce systematic error?

Explains random sequence generation, allocation concealment, stratification at a conceptual level, open-label and blinded designs, masking of different trial actors, and common sources of selection, performance, detection, attrition, and reporting bias. Statistical implementation is reserved for HLTH 5815.

Learning objectives

- Explain the purposes of randomization and allocation concealment and why they address different risks.
- Differentiate open-label, single-blind, double-blind, and assessor-blind arrangements without relying on ambiguous labels.
- Identify common sources of bias across enrollment, treatment, outcome assessment, follow-up, analysis, and reporting.
- Evaluate whether the design safeguards in a published trial are adequate for the clinical question.

Primary references

- ICH. E9, Statistical Principles for Clinical Trials - randomization and bias concepts. [Link](#)
- CONSORT 2025 statement - randomisation, allocation concealment, and blinding items. [Link](#)
- ICH. E6(R3), Good Clinical Practice - trial design and conduct principles. [Link](#)

Additional reading

- Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. Lancet. 2002;359:515-519. [Link](#)
- Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet. 2002;359:614-618. [Link](#)

Lecture 6: Participants, Eligibility, Recruitment and Representativeness

Who should be enrolled, and how do eligibility and recruitment choices affect ethics, feasibility and generalizability?

Examines inclusion and exclusion criteria, recruitment pathways, screening, underrepresentation, vulnerable or special populations, retention, and the relationship between internal validity and applicability. The lecture treats recruitment as a design and ethics issue rather than as an operational marketing exercise.

Learning objectives

- Develop eligibility criteria that are linked to the scientific question, participant safety, and interpretability.
- Explain how overly restrictive eligibility can affect recruitment, representativeness, and generalizability.
- Identify ethical concerns in recruitment, screening, incentives, and inclusion of populations who may be vulnerable or underrepresented.
- Assess whether a trial population is appropriate for the intended clinical use of the intervention.

Primary references

- World Medical Association. Declaration of Helsinki, revised 2024. [Link](#)
- TCPS 2 (2022), Chapter 11: Clinical Trials. [Link](#)
- ICH. E8(R1), General Considerations for Clinical Studies - study population and representativeness. [Link](#)

Additional reading

- CIOMS. International Ethical Guidelines for Health-related Research Involving Humans (2016). [Link](#)
- SPIRIT 2025 statement - participant population, recruitment and patient/public involvement items. [Link](#)

Lecture 7: Outcomes, Endpoints, Follow-up and Clinical Meaning

What should a trial measure, when should it measure it, and what makes an outcome meaningful?

Introduces clinical outcomes, biomarkers, surrogate endpoints, patient-reported outcomes, composite outcomes, primary and secondary endpoints, measurement timing, follow-up, missing observations as a design concern, and the distinction between statistical and clinical meaning. Detailed estimands, sample-size calculations, multiplicity, and missing-data methods belong in HLTH 5815.

Learning objectives

- Differentiate outcomes, endpoints, biomarkers, surrogate endpoints, and patient-reported outcomes.
- Explain why a primary endpoint should align with the research question, population, intervention, comparator, and follow-up period.

- Identify limitations of composite and surrogate endpoints and recognize when clinical interpretation requires caution.
- Assess whether the timing and method of outcome measurement are appropriate for the clinical question.

Primary references

- ICH. E8(R1), General Considerations for Clinical Studies - endpoints and study objectives. [Link](#)
- FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource. [Link](#)
- CONSORT 2025 statement - outcomes and harms reporting items. [Link](#)

Additional reading

- SPIRIT 2025 statement - outcomes, assessment schedule and harms specification. [Link](#)
- ICH. E9(R1), Addendum on Estimands and Sensitivity Analysis - optional orientation only. [Link](#)

Lecture 8: Roles, Responsibilities and Trial Governance

Who is accountable for what in a clinical trial?

Maps the responsibilities of sponsors, sponsor-investigators, investigators, qualified investigators, institutions, CROs/service providers, research ethics boards, regulators, monitors, and other oversight bodies. Students learn that tasks may be transferred or delegated, but accountability must remain visible and documented.

Learning objectives

- Differentiate the principal responsibilities of the sponsor, investigator, institution, CRO/service provider, REB/IRB, and regulator.
- Explain the sponsor-investigator model and how it differs from a conventional industry-sponsored trial.
- Distinguish delegation of trial tasks from transfer or retention of accountability.
- Map a basic governance structure for a hypothetical multicentre trial and identify likely escalation points.

Primary references

- ICH. E6(R3), Good Clinical Practice - investigator and sponsor responsibilities. [Link](#)
- Health Canada. GUI-0100, Part C, Division 5 clinical trial responsibilities. [Link](#)
- Food and Drug Regulations, Part C, Division 5. [Link](#)

Additional reading

- U.S. eCFR, Title 21 Part 312 - sponsor and investigator responsibilities. [Link](#)
- TCPS 2 (2022), Chapter 11: Clinical Trials. [Link](#)

Lecture 9: Ethics and Informed Consent in Clinical Trials

What makes human participation in a clinical trial ethically acceptable?

Addresses scientific validity, favorable risk-benefit, independent ethics review, informed and voluntary consent, ongoing consent, privacy, vulnerable situations, placebo ethics, post-trial considerations, and the difference between regulatory authorization and ethics approval.

Learning objectives

- Apply foundational ethical principles to common clinical-trial scenarios.
- Explain the elements of valid informed consent and recognize circumstances requiring additional safeguards.
- Distinguish the functions of regulatory authorization, REB/IRB review, institutional authorization, and participant consent.
- Analyze an ethical tension involving placebo use, vulnerable participants, risk, or access without treating any single principle as absolute.

Primary references

- TCPS 2 (2022), Chapter 11: Clinical Trials. [Link](#)
- World Medical Association. Declaration of Helsinki, revised 2024. [Link](#)
- ICH. E6(R3), Good Clinical Practice - informed consent and participant protection. [Link](#)

Additional reading

- CIOMS. International Ethical Guidelines for Health-related Research Involving Humans (2016). [Link](#)
- TCPS 2 (2022), Chapter 3: The Consent Process. [Link](#)

Lecture 10: Regulatory Foundations and Good Clinical Practice

How do regulatory authorization and GCP govern whether a drug trial may proceed and how it must be conducted?

Provides an introductory regulatory map of Canadian drug clinical-trial authorization under Part C, Division 5, with orientation to the U.S. IND and EU Clinical Trials Regulation systems. The lecture focuses on authorization, GCP, amendments, safety information, records, and inspection-readiness at a foundational level; detailed regulatory strategy is developed in HLTH 5816.

Learning objectives

- Describe the basic Canadian clinical-trial authorization framework for drugs under Part C, Division 5.
- Explain the relationship among law, regulatory guidance, GCP, ethics review, and institutional requirements.
- Identify the main regulatory events that can require an amendment, notification, safety report, suspension, or discontinuance.
- Compare the basic purpose of a Canadian CTA, U.S. IND, and EU clinical-trial authorization without assuming the systems are identical.

Primary references

- Food and Drug Regulations, Part C, Division 5. [Link](#)
- Health Canada. GUI-0100, Version 4, issued and implemented 14 August 2026. [Link](#)
- ICH. E6(R3), consolidated final version adopted 16 June 2026. [Link](#)

Additional reading

- U.S. FDA. Investigational New Drug (IND) Application. [Link](#)
- European Commission. Clinical Trials Regulation (EU) No 536/2014. [Link](#)

Lecture 11: Essential Documentation, Registration and Results Transparency

How does a trial create a traceable public and regulatory record from protocol to results?

Connects protocol versions, consent materials, investigator information, essential records, trial registration, public disclosure of results, and transparent reporting. It introduces documentation discipline without duplicating the detailed TMF, data-management, monitoring, and operational content taught later in the program.

Learning objectives

- Explain why essential records must allow reconstruction and evaluation of trial conduct and decisions.
- Identify major document families created before, during, and after a clinical trial.
- Describe current Canadian policy expectations for trial registration and summary-results disclosure and distinguish a registry from Health Canada's search portal.
- Use SPIRIT and CONSORT to assess whether a protocol or trial report contains the information needed for transparent interpretation.

Primary references

- Health Canada. Guidance on the registration of clinical trials and public disclosure of results, effective 29 July 2026. [Link](#)
- WHO. Trial Registration Data Set (TRDS), Version 1.3.1. [Link](#)
- ICH. E6(R3), Good Clinical Practice - essential records and documentation principles. [Link](#)
- SPIRIT 2025 and CONSORT 2025 statements. [Link](#)

Additional reading

- WHO. Trial registration and the International Clinical Trials Registry Platform. [Link](#)
- CONSORT 2025 explanation and elaboration. BMJ. 2025;389:e081124. [Link](#)

Lecture 12: Reading and Critiquing a Clinical Trial: Course Integration

Can the trial's design, conduct, reporting and evidence support the conclusion being claimed?

A capstone lecture that integrates the entire course through structured appraisal of a published randomized trial and, where available, its protocol and registry record. Students trace the question through design, population, comparison, bias safeguards, outcomes, governance, ethics, registration, and reporting, and learn to state conclusions proportionately.

Learning objectives

- Critically appraise a published clinical trial using a structured, reproducible approach.
- Link claims in a publication to the corresponding design choices, outcomes, participant flow, protocol, and registry record.
- Identify material limitations without overstating their implications or dismissing a study on the basis of minor imperfections.
- Communicate a concise conclusion about what the trial supports, what remains uncertain, and what evidence would be needed next.

Primary references

- CONSORT 2025 statement. [Link](#)
- SPIRIT 2025 statement. [Link](#)
- ICH. E8(R1), General Considerations for Clinical Studies. [Link](#)

Additional reading

- CONSORT 2025 explanation and elaboration. [Link](#)

Selected trial, protocol and registry record assigned by the instructor.

Assessments

Component	Grade Value	Date
Assignment 1	30%	After week 2
Assignment 2	30%	After week 5
Assignment 3	30%	After week 8
In Class Participation	10%	Throughout

Late and Missed Work Policies

Late Work

Insert statement about late work penalties (indicate percentage and/or grade point deduction, as well as the maximum number of days something may be submitted after the initial deadline), and course-related policy regarding use of the [academic considerations form](#).

Missed Work

Short-term (5 days or less): Insert statement about course-related policy for missed work, and a link to the [academic considerations form](#). You may state whether there is a limit to the number of times the student can submit the form for your course.

Long-term (> 5 days): Insert statement about course-related policy for [longer-term accommodation](#).

We strongly encourage you to use the Academic Considerations Form for any circumstances where you either require or permit students to hand in late or missed work so that a record is captured in the Registrar's Office of how often students use the form. The link to the form is at the end of the URL above: <https://sarms.carleton.ca/registrar/academic-consideration>

Learning Material(s) and Other Course/Lab-Related Resources

Students are not required to purchase textbooks or other learning materials for this course.

Academic Accommodations and Regulations

Carleton is committed to providing academic accessibility for all individuals. You may need special arrangements to meet your academic obligations during the term. The accommodation request processes, including information about the Academic Consideration Policy for Students in Medical and Other Extenuating Circumstances, are outlined on the Academic Accommodations website (<https://students.carleton.ca/course-outline/>).

Statement on Generative Artificial Intelligence (GenAI) Usage:

Generative artificial intelligence (GenAI) tools may be used in this course as research-support, drafting-support, and professional productivity tools, subject to the limitations below. Their use does not transfer responsibility for regulatory analysis, legal interpretation, evidentiary judgment, or professional recommendations from the student to the AI system.

Permitted uses may include using GenAI to:

- brainstorm regulatory questions or analytical frameworks;
- organize research or develop an initial outline;
- identify issues that warrant further investigation;
- summarize material for the student's own preliminary understanding, provided the original source is subsequently reviewed;
- compare ways of structuring an argument or communicating a regulatory conclusion;
- improve the clarity, organization, or concision of student-authored material; and
- simulate questions, counterarguments, or regulatory-review perspectives for learning purposes.

Students may not rely on GenAI as the authority for a statement of law, regulation, regulatory policy, guidance, scientific evidence, or agency practice. Regulatory conclusions must be supported by the underlying legislation, regulations, guidance, regulatory decisions, case law, scientific literature, or other appropriate primary and authoritative sources.

Where GenAI materially contributes to graded work, students must disclose its use. The disclosure should identify the tool and describe its role with sufficient specificity to distinguish the student's work from the assistance provided by the tool. For example: *"ChatGPT was used to identify potential*

counterarguments and to review the organization of the memorandum. The statutory interpretation, source research, analysis, conclusions, and final wording were completed and verified by the author." More detailed disclosure requirements may be specified for individual assignments.

The rationale for permitting limited GenAI use is that regulatory professionals increasingly work in environments where AI-assisted research, drafting, information retrieval, and analysis are available. Competent regulatory practice therefore includes knowing how to use these tools efficiently while recognizing their limitations. A central objective of HLTH 5816, however, is the development of independent regulatory judgment: students must be able to identify the governing authority, distinguish law from guidance and policy, assess evidence and uncertainty, develop a defensible position, and communicate the basis for that position. GenAI may assist that process but may not substitute for it.

Students are responsible for the accuracy, currency, traceability, originality, and professional defensibility of all submitted work. AI-generated statements must be independently verified, particularly where they concern legislation, regulations, government guidance, regulatory decisions, dates, jurisdictional differences, or scientific evidence.

The following uses are not permitted unless expressly authorized by the instructor:

- submitting GenAI-generated regulatory analysis, legal interpretation, recommendations, or conclusions as the student's own work;
- citing a GenAI tool as the substantive authority for a regulatory or legal proposition;
- using citations, quotations, cases, guidance documents, regulatory decisions, or scientific references generated by AI without verifying the underlying source;
- using GenAI during an examination, quiz, or individually assessed exercise where its use has not been authorized;
- fabricating or altering evidence, regulatory records, quotations, references, data, or government positions;
- entering confidential, proprietary, personal, client, patient, sponsor, or otherwise protected information into a public GenAI platform; or
- using GenAI in a manner that prevents meaningful assessment of the student's own regulatory reasoning and professional judgment.

Failure to disclose material GenAI use when disclosure is required may constitute a breach of academic integrity.

Statement on Academic Integrity

Students are expected to uphold the values of academic integrity, which include fairness, honesty, trust, and responsibility. Examples of actions that compromise these values include but are not limited to plagiarism, accessing unauthorized sites for assignments or tests, unauthorized collaboration on assignments or exams, and using Generative Artificial Intelligence (GenAI) tools when course assessment instructions indicate such use is not permitted.

Misconduct in scholarly activity will not be tolerated and will result in consequences as outlined in Carleton University's Academic Integrity Policy. A list of standard sanctions in the Faculty of Science can be found here.

Additional details about this process can be found on the Faculty of Science Academic Integrity website.

Students are expected to familiarize themselves with and abide by Carleton University's Academic Integrity Policy.

Student Rights & Responsibilities

Students are expected to act responsibly and engage respectfully with other students and members of the Carleton and the broader community. See the 7 Rights and Responsibilities Policy for details regarding the expectations of non-academic behaviour of students. Those who participate with another student in the commission of an infraction of this Policy will also be held liable for their actions.