HLTH 5814 for Fall 2026

Assessment and Patient Safety for Clinical Trials

Course Instructor: Mary Zhang

Email: _____

Note: If you have or question or would like to talk with me, you can send an email or approach me after lecture.

Best Ways to be in Touch: in class, or via email.

Student Hours: upon email request

Office Location: Remote

Class Location: Online

Class Times: Tuesdays 18:05 to 20:55

Prerequisites: N/A

Preclusions: N/A

Department/Unit: Health Sciences/ Clinical Trials

Topics Covered and Learning Outcomes

Topics to be Covered

Week	Topic/Content	Readings/Prep for Class
1-Sep. 8	**Fall Orientation**	
2-Sep.15	Course Overview & Introduction to Clinical Research and Patient Safety	History of clinical trial safety; ethics codes; major safety failures.
3-Sep.22	Ethical & Regulatory Foundations of Safety	Regulatory frameworks, global regulatory systems (ICH, FDA, EMA, Health Canada), GCP/GxP, Division 5, protocol structures.
4-Sep.29	Foundations of Efficacy, Safety, and Benefit–Risk	Defining efficacy/safety/tolerability, phases of development, risk–benefit analysis, signal detection.
5-Oct.6	Scientific Foundations of Safety and Risk Planning: Pharmacologic Principles & Mechanistic Understanding	PK/PD, Mechanism of Action, biomarkers, preclinical predictors.
6-Oct.13	Designing Protocols for Safety: Prospective Safety Planning	Protocol safety design, safety endpoints, stopping rules, DSMPs, IBs.
7-Oct.20	AE Classification, Grading, Ecpectedness & Causality	AE classification (CTCAE, ICH E2A), expectedness, causality (Naranjo, WHO-UMC), MedDRA.
8-Oct.27	**Fall Break**	
9 - Nov.3	Non-Serious AEs & Real-World Data	Non-serious AEs, RWD, Health Canada AE reporting, NHP/vaccine safety.
10-Nov.10	Advanced AE Subtypes & Regulatory Thresholds	ADRs, TEAEs, AESIs, SAEs, SUSARs; regulatory consequences, ISS, devices.
11-Nov.17	Communication: Safety Reporting Channels	Communication with regulators, REBs, participants, GUI-0100, lay summaries.
12-Nov.24	Oversight Structures: Operational Oversight & Quality Systems (Monitoring and Compliance)	Sponsor, IRB, DSMBs, centralized/RBM, QMS, audits, CAPAs, decentralized trials.
13-Dec.1	Post-Market Safety: Long-term Surveillance	Pharmacovigilance systems, DSURs, RMPs, signal detection, Canada Vigilance.
14-Dec.8	Special Populations: Vulnerable Populations, Access and Ethics	Pediatric, geriatric, pregnant populations; expanded access and compassionate use.

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

Course Level Learning Outcomes

This course examines how safety is assessed, monitored, and managed throughout the lifecycle of clinical trials.

1. Describe the historical evolution of clinical trial safety oversight and its impact on current practices.
2. Apply ethical principles and regulatory frameworks that govern clinical trial safety.
3. Evaluate methodologies used to assess the efficacy and safety of investigational therapies.
4. Examine contemporary approaches to pharmacovigilance, risk management, and risk communication.
5. Analyze real-world case studies to identify safety challenges and propose evidence-based solutions.
6. Demonstrate critical thinking and practical skills through lectures, readings, assignments, case studies, and group discussions.

Assessments

Grade Breakdown

COMPONENT	GRADE VALUE	DUE DATE
ASSIGNMENT 1	12% (8%+4%)	Week 3
ASSIGNMENT 2	12% (8%+4%)	Week 9
ASSIGNMENT 3	12% (8%+4%)	Week 11
FINAL PROJECT – CLINICAL TRIAL PROTOCOL (SAFETY)	30%	Week 14
IN-CLASS PRESENTATION & DISCUSSION	4 x 6%	
PARTICIPATION/ENGAGEMENT	10%	

There are three assignments (case studies) during the term:

- Assignment 1: Operationalizing Ethics into Safety Oversight
- Assignment 2: Adverse Event Classification
- Assignment 3: CIOMS Report

Assignment Format

Each assignment consists of two components:

- **Written Component (2/3 of the assignment grade):** Submit your written work through Brightspace by the specified deadline as above.
- **Oral Component (1/3 of the assignment grade):** Participate in in-class discussion(s) and feedback of your submission, demonstrating your understanding of the topic and responding to questions.

Late and Missed Work Policies

Late Work

Assignments submitted after the deadline without prior approval will incur a penalty of 10% of the assignment grade **per day**, including weekends, for up to five (5) days. Assignments submitted more than five (5) days after the deadline will not be graded and a zero (0) will be recorded unless formal academic consideration has been approved in accordance with university policy using the academic considerations form.

Students who experience short-term, unforeseen circumstances (such as illness, injury, or family emergency) that affect their ability to meet course requirements may request academic consideration through Carleton Central, unless arrangements have been made with me directly. Requests should normally be made within three business days, and remedies (e.g., extensions, deferrals, make-up work) will be determined fairly while maintaining academic integrity.

Missed Work

Short-term (5 days or less): If you miss a class (i.e., 3h of lecture) or graded deliverable (i.e., assignment, presentation, etc.) due to illness or other short-term, unforeseen circumstances, you may request academic consideration by submitting the online form through academic considerations form. Requests should normally be submitted within three business days of the missed requirement. In this course, students may use the Academic Consideration form up to **two times** during the term. Remedies (e.g., extensions, make-up assignments, or redistribution of marks) will be determined fairly while maintaining academic standards.

Long-term (> 5 days): must be arranged through the appropriate Carleton University processes using the longer-term accommodation form.

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

- Students are not required to purchase textbooks or other learning materials for this course
- Foundational texts and references include:
  - ICH Guidelines: E2A–E2F, E6(R3), E8(R1).
  - Health Canada Guidance: GUI-0100; Division 5 Regulations.
  - Selected peer-reviewed journal articles provided throughout the course.
- Required, recommended and web-based online resources for this course are available to access through the learning management system: Brightspace.
- Required readings will be provided weekly via Brightspace and include academic articles, ICH and Health Canada guidance, and selected case studies.

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 are outlined on the Academic Accommodations website (https://students.carleton.ca/course-outline/).

Statement on Chat GPT/Generative AI usage

AI use in this course: Students may use AI tools for ideas, clarifying challenging concepts or getting started on projects. Some acceptable uses include:

- Sounding board (e.g. generating essay topics with ChatGPT, using Microsoft Word's Smart Lookup or Copilot to find inspiration and related topics)
- Creating outlines (e.g. using AI to structure an essay or presentation flow, using Microsoft Word's Outline View with AI suggestions)
- Providing definitions or explanations of complex concepts (e.g. using AI to explain a difficult theory or to find relevant information)

Documenting use of AI: It is necessary to document your use of AI in this course, using the following guidelines:

- Clearly identify and cite AI-generated text (e.g. "The following paragraph was generated by ChatGPT/Microsoft Word's Researcher tool/Copilot")
- Review, edit and ensure accuracy and originality of final submissions
- AI-generated content should **not exceed 30%** of the total assignment length

Why have I adopted this policy? This policy supports the use of AI as a supplementary tool, helping students develop ideas and structure their work while emphasizing the importance of transparency and personal engagement with the content. AI can be used for inspiration and foundational support and can encourage students to critically assess and refine AI-generated material.

As our understanding of the uses of AI and its relationship to student work and academic integrity continue to evolve, students are required to discuss their use of AI in any circumstance not described here with the course instructor to ensure it supports the learning goals for the course.

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 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 artificial intelligence tools such as ChatGPT when your assessment instructions say it 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 and 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.

Student Concerns

If a concern arises regarding this course, **your first point of contact is me**: Email and I will do my best to address your concern. If I am unable to address your concern, the next points of contact are (in this order):

Note: You can also bring your concerns to Ombuds services.