



Carleton
UNIVERSITY

Department of
**Systems and
Computer Engineering**

SYSC 4201

Ethics, Research Methods and Standards for Biomedical Engineering Winter 2024

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Calendar Description

Ethical theories, ethical decision-making, biomedical research ethics: informed consent, confidentiality, privacy, research ethics boards; research methods: hypothesis formulation, data collection, sampling bias, experimental design, statistical literacy; regulations for design, manufacture, certification of medical devices; impact of technology and research (social, political, financial).

Includes: Experiential Learning Activity

Lectures three hours a week, problem analysis one and a half hours per week.

<http://calendar.carleton.ca/undergrad/courses/SYSC/>

Prerequisites

ELEC 3605 or SYSC 3203.

Prior Knowledge

Students should have knowledge of:

- Foundation in mathematics including calculus, algebra, and probability.
- Foundation in written and oral communication skills.

Course Objectives

The objectives of this course are for students to:

- Gain an understanding about normative ethics and applied ethics through a case study analysis.
- Gain an understanding about research ethics and the research process through engaging in a research project.
- Increase their statistical literacy.
- Gain an understanding about medical device regulations.
- Discuss issues regarding biomedical engineering technology and society.

Learning Outcomes

By the end of this course, students should be able to:

- Justify a course of action in an ethical dilemma.
- Evaluate the ethics of research involving humans.
- Explain the purpose and results of statistical analysis, including common misinterpretation and misapplication of statistics.
- Describe the regulatory process for medical devices.
- Discuss the impact of biomedical technology with a multidisciplinary audience.
- Design an appropriate research methodology to investigate a research question.

List of Topics

- Ethical theories
- Common versus particular moralities
- Ethical decision making
- Moral status
- History of research ethics
- Research involving humans
- Informed consent
- Confidentiality and privacy

- Research ethics
- Research methods
- Proposal feedback sessions
- Introduction to statistics
- Plagiarism
- Graphs
- Bivariate data
- Probability
- Receiver Operating Characteristic Curve
- Research Design
- Normal Distribution
- Sampling Distributions
- Estimation
- Hypothesis testing
- Type I and Type II Errors
- Testing Means
- Medical Device Regulations (Health Canada)
- Medical Device Evaluation (Health Canada)
- Technology and society

Graduate Attributes (GAs)

The Canadian Engineering Accreditation Board requires graduates of undergraduate engineering programs to possess 12 attributes. Courses in all four years of our programs evaluate students' progress towards acquiring these attributes. Aggregate data (typically, the data collected in all sections of a course during an academic year) is used for accreditation purposes and to guide improvements to our programs. Some of the assessments used to measure GAs may also contribute to final grades; however, the GA measurements for individual students are not used to determine the student's year-to-year progression through the program or eligibility to graduate.

| Graduate Attribute | Learning outcome(s) |
|--|---------------------|
| 3.1: Investigation: Applied: Complex problem assessment | 2, 4 |
| 3.2: Investigation: Applied: Design of experiment | 4 |
| 3.3: Investigation: Applied: Experimental procedure | 4 |
| 3.4: Investigation: Applied: Data reduction methods and results | 3, 4 |
| 3.5: Investigation: Applied: Interpretation of data (synthesis) and discussion | 3, 4 |
| 6.1: Individual and Team Work: Applied: Personal and group time management | 6 |
| 6.2: Individual and Team Work: Applied: Group culture; group dynamics | 6 |

| | |
|---|---------|
| 6.3: Individual and Team Work: Applied: Leadership: initiative and mentoring, areas of expertise, and interdisciplinary teams | 6 |
| 7.1: Communication Skills: Applied: Instructions | 6 |
| 7.2: Communication Skills: Applied: Professional documents: writing, design notes, drawings, attributions, and references | 6 |
| 7.3: Communication Skills: Applied: Oral and written presentations | 1, 2, 6 |
| 7.4: Communication Skills: Applied: Technical reading | 6 |
| 7.5: Communication Skills: Applied: Note-taking skills | 6 |
| 10.1: Ethics and Equity: Developed: Equitable practice | 2 |
| 10.2: Ethics and Equity: Developed: Professional, accountable and ethical conduct | 1, 2 |

Accreditation Units (AUs)

For more information about Accreditation Units, please visit:

<https://engineerscanada.ca/>.

The course has 46 AUs divided into:

| Math | Natural Science | Complementary Studies | Engineering Science | Engineering Design |
|------|-----------------|-----------------------|---------------------|--------------------|
| | | 60% | 40% | |

Textbook (or other resources)

The mandatory course materials are:

- Beauchamp TL, Childress JF, Principles of Biomedical Ethics, 5th edition, Oxford University Press, 2001. (available online via Carleton Library)
- Frize, Monique, Ethics for Bioengineers, 1st Edition, Morgan & Claypool, 2012. (available online via Carleton Library)
- Walliman, Nicholas, Research Methods – the basics, Routledge, New York, 2011. (available online via Carleton Library)
- Online Statistics: An Interactive Multimedia Course of Study (<http://onlinestatbook.com/> web version 2.0)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>)

All of these resources are available to students online for free (some via the Carleton University Library). If you decide to purchase some of these, there may be updated versions (e.g., Principles of Biomedical Ethics has an 8th edition from 2019). For the purposes of this course, the dated versions suffice, and I've prioritized free access to the resources over the updates.

Evaluation and Grading scheme

| Element | Notes | Grading Scheme |
|-----------------------|--|----------------|
| TCPS 2: CORE Tutorial | Students must complete this tutorial to pass the course. | 0% |
| GBA+ | Students must complete this tutorial to pass the course. | 0% |
| Research Project | A complete Ethics Closure Form must be submitted to pass the course. Participation in the 3 min poster presentation is mandatory. | 35% |
| Quizzes | For full marks, students must complete all quizzes. | 15% |
| Discussion Sessions | Lab sessions will be synchronous discussion sessions. Specific guidelines for each session regarding the requested deliverables will be posted on the course page. | 10% |
| Participation | For full marks, students must attend all guest lectures. | 5% |
| Final Exam | E-proctored exam (details will be available closer to the scheduled exam date) | 35% |

a) Final Exam: **Final exams are for evaluation purpose and will not be returned to students.** Students will be provided access to the lectures for the Final exam.

b) Deferred Final Examinations

Students who are unable to write the final examination because of a serious illness/emergency or other circumstances beyond their control may apply for accommodation by contact the Registrar's office. Consult the Section 4.3 of the University Calendar (<https://calendar.carleton.ca/undergrad/regulations/academicregulationsoftheuniversity/examinations/>)

c) Exam format and e-proctoring

Engineering Courses shall have on campus and proctored final examinations. The final exam may be in electronic format (ie. Student will write the exam on campus and use either their computer or a university-owned computer).

e-Proctoring: Please note that tests and examinations in this course will use a remote proctoring service provided by Scheduling and Examination Services. You can find more information at <https://carleton.ca/ses/e-proctoring/>.

d) Additional requirement(s):

Students must obtain **TCPS 2: CORE Tutorial and GBA+ certificate** to pass the course.

e) Self-Declaration form and Deferred Term work

Calendar language (Section 4.4

<https://calendar.carleton.ca/undergrad/regulations/academicregulationsoftheuniversity/examinations/#deferred-term-work>):

Students who claim illness, injury or other extraordinary circumstances beyond their control as a reason for missed term work are held responsible for immediately informing the instructor concerned and for making alternate arrangements with the instructor and in all cases this must occur no later than three (3) days after the term work was due. The alternate arrangement must be made before the last day of classes in the term as published in the academic schedule.

Consult with the instructor no later than 3 days after any missed course work or midterm examination.

Breakdown of Course Requirements

Lectures: Learning resources will be assigned each week; students are expected to review and understand these materials. Weekly lecture sessions on the respective module materials will happen at the allocated class time. Class time will be spent providing students with an overview of the topics, answering student questions, and discussing the material from the learning resources when suitable. This course relies on student engagement in completing all assigned readings, attending lectures, and bringing questions to the class, and participating in the proposed activities.

Research Project (35%): The project work required in this course should be completed in groups of 6-7 students and it will be divided into four components:

- Research Proposal (10%)
- Research Ethics Board (REB) application for ethics review & Ethics Closure Form (not marked, but mandatory to pass the course. REB must be submitted prior to starting to collect data)

- Research Project Final Report (15%)
- Poster & 3-min presentation (10%)

Quizzes (15%): Quizzes will take place in the lab sessions, according to the course schedule. All quizzes will be individual, online, and timed. Students will have a predefined amount of time and one attempt to complete each quiz. Quizzes will be available on Brightspace and will be moderated by the TAs. These quizzes are intended to help you to stay on track by revising and understanding specific concepts covered in the course material. As such, you should be able to answer these questions confidently.

Discussion Sessions (10%): Discussion sessions will take place in the lab sessions. Students are required to check the course page frequently for up-to-date information. Full marks (100) for the discussion are given when students receive an Excellent. Criteria for part marks will be communicated. Zero marks (0) are given when students are absent. There are 6 Discussion Sessions, the session with the lowest mark will be dropped.

Guest lectures (5%): For full marks, students must attend all guest lectures. Information about the guest lectures will be announced on Brightspace.

Final Exam (35%): The final examination is for evaluation purposes only and will not be returned to students. You will be able to make arrangements with the instructor or with the department office to see your marked final examination after the final grades have been made available. **Please note that the examinations in this course will use a remote proctoring service provided by Scheduling and Examination Services. You can find more information at <https://carleton.ca/ses/e-proctoring/>**

Tentative Week-by-Week Breakdown

| Week # | Content |
|---------|---|
| Week 1 | <ul style="list-style-type: none"> • Meet & greet, course introduction • What is research and why do we conduct research • Research Process and Research Proposal |
| Week 2 | <ul style="list-style-type: none"> • Research Ethics (Part 1 - overview) • Informed Consent • Confidentiality and privacy • Self-experimentation & Experimental Design, Data |
| Week 3 | <ul style="list-style-type: none"> • Introduction to Statistics • Sampling and Sampling Bias • Correlation and Causation (bivariate data) • Probability • Normal Distributions |
| Week 4 | <ul style="list-style-type: none"> • Sensitivity, specificity, precision, and recall • Receiver Operating Characteristic Curve • Central limit theorem, t-distribution • Degrees of freedom |
| Week 5 | <ul style="list-style-type: none"> • Logic of Hypothesis • Type I and Type II errors • Misconceptions in hypothesis testing |
| Week 6 | <ul style="list-style-type: none"> • Statistical errors • Power, graphs and data presentation • Data Visualization |
| Week 7 | Reading week |
| Week 8 | <ul style="list-style-type: none"> • Research Ethics (Part 2) • Introduction to Ethics • Normative and non-normative ethics |
| Week 9 | <ul style="list-style-type: none"> • Common morality and particular moralities • Moral dilemmas • Ethical theories |
| Week 10 | <ul style="list-style-type: none"> • Teleological and Utilitarianism • Deontological and Kantian ethics • Rights-based • Fairness or Justice and Rawlsian ethics |
| Week 11 | <ul style="list-style-type: none"> • Virtue-based and Aristotelian ethics • Principlism, Moral status |
| Week 12 | <ul style="list-style-type: none"> • Technology and Society |
| Week 13 | <ul style="list-style-type: none"> • Medical Device Regulations and Evaluations • Engaging with indigenous communities |
| Week 14 | <ul style="list-style-type: none"> • 3-minute project presentations |

Copyright

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Advising and Counselling Services

a) Engineering Academic Advising

The Engineering Academic Support Service: <https://carleton.ca/engineering-design/current-students/undergrad-academic-support/> assists undergraduate engineering students with course selection, registration, and learning support from first-year through to graduation.

Academic Advisors Contact: <https://carleton.ca/engineering-design/current-students/undergrad-academic-support/undergraduate-advisors/>

b) Student Mental Health Service

As a University student you may experience a range of mental health challenges that significantly impact your academic success and overall well-being. Carleton's Wellness Services Navigator <https://wellness.carleton.ca/navigator/> is designed to help students connect with mental health and wellness resources. If you need to talk to someone, please reach out for assistance: <https://carleton.ca/health/emergencies-and-crisis/>.

Learning and Working Environment

The University and all members of the University community share responsibility for ensuring that the University's educational, work and living environments are free from discrimination and harassment. Should you have concerns about harassment or discrimination relating to your age, ancestry, citizenship, colour, creed (religion), disability, ethnic origin, family status, gender expression, gender identity, marital status, place of origin, race, sex (including pregnancy), or sexual orientation, please contact the Department of Equity and Inclusive Communities at equity@carleton.ca

We will strive to create an environment of mutual respect for all through equity, diversity, and inclusion within this course. The space which we work in will be safe for everyone. Please be considerate of everyone's personal beliefs, choices, and opinions.

Academic Integrity and Plagiarism

a) Please consult the Faculty of Engineering and Design information page about the Academic Integrity policy and our procedures: <https://carleton.ca/engineering-design/current-students/fed-academic-integrity> Violations of the Academic Integrity Policy will result in the assignment of a penalty such as reduced grades, the assignment of an F in a course, a suspension or, expulsion.

b) One of the main objectives of the Academic Integrity Policy is to ensure that the work you submit is your own. As a result, it is important to write your own solutions when studying and preparing with other students and to avoid plagiarism in your submissions. The University Academic Integrity Policy defines plagiarism as “presenting, whether intentionally or not, the ideas, expression of ideas or work of others as one’s own.” This includes reproducing or paraphrasing portions of someone else’s published or unpublished material, regardless of the source, and presenting these as one’s own without proper citation or reference to the original source.

Examples of violations of the policy include, but are not limited to:

- any submission prepared in whole or in part, by someone else;
- Using another’s data or research findings without appropriate acknowledgement;
- Submitting a computer program developed in whole or in part by someone else, with or without modifications, as one’s own;
- Failing to acknowledge sources of information through the use of proper citations when using another’s work and/or failing to use quotations marks; and
- Unless explicitly permitted by the instructor in a specific course, the use of generative AI and similar tools to produce assessed content (such as text, code, equations, images, summaries, videos, etc.).

Academic Accommodations

You may need special arrangements to meet your academic obligations during the term. For an accommodation request the processes are as follows:

Pregnancy obligation: write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For accommodation regarding a formally-scheduled final exam, you must complete the Pregnancy Accommodation Form ([click here](#)).

Religious obligation: write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For more details click [here](#).

Academic Accommodations for Students with Disabilities: The Paul Menton Centre for Students with Disabilities (PMC) provides services to students with Learning Disabilities (LD), psychiatric/mental health disabilities, Attention Deficit Hyperactivity Disorder (ADHD), Autism Spectrum Disorders (ASD), chronic medical conditions, and impairments in mobility, hearing, and vision. If you have a disability requiring academic accommodations in this course, please contact PMC at 613-520-6608 or pmc@carleton.ca for a formal evaluation. If you are already registered with the PMC, contact your PMC coordinator to send me your Letter of Accommodation at the beginning of the term, and no later than two weeks before the first in-class scheduled test or exam requiring accommodation (if applicable). After requesting accommodation from PMC, meet with me to ensure accommodation arrangements are made. Please consult the PMC website for the deadline to request accommodations for the formally-scheduled exam (if applicable).

Survivors of Sexual Violence: As a community, Carleton University is committed to maintaining a positive learning, working and living environment where sexual violence will not be tolerated, and where survivors are supported through academic accommodations as per Carleton's Sexual Violence Policy. For more information about the services available at the university and to obtain information about sexual violence and/or support, visit:
<https://carleton.ca/equity/sexual-assault-support-services>

Accommodation for Student Activities: Carleton University recognizes the substantial benefits, both to the individual student and for the university, that result from a student participating in activities beyond the classroom experience. Reasonable accommodation will be provided to students who compete or perform at the national or international level. Write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist.
<https://carleton.ca/senate/wp-content/uploads/Accommodation-for-Student-Activities-1.pdf>