Carleton University acknowledges the location of its campus on the traditional, unceded territories of the Algonquin nation.

**Instructor Information and Office hours**

Dr. Adrian D. C. Chan  
Pronouns: he/him/his  
Email: adrian.chan@carleton.ca  
Office: Canal Building 6201  
Office Hours: Students can find me immediately after class for quick questions. If you wish to meet, please send me an email with dates/times that you are available over the next 2-3 days and I will find an amiable time to meet. You can specify an order of preference but please provide as many options as possible to avoid us going back and forth. Note that I am usually on campus between 8:00-16:00 Mondays to Friday.

**TA Information and Office hours**

Mohamed Abdelazez mohamedabdelazez@cmail.carleton.ca  
Curtis Lacelle curtislacelle@cmail.carleton.ca

**Calendar Description**

[http://calendar.carleton.ca/undergrad/courses/SYSC/](http://calendar.carleton.ca/undergrad/courses/SYSC/)

SYSC 4201 [0.5 credit]

Ethics, Research Methods and Standards for Biomedical Engineering

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.

Prerequisite(s): ELEC 3605 or SYSC 3203.

Students who have not satisfied the prerequisites for this course must either withdraw from the course or obtain a prerequisite waiver by visiting the Engineering Undergraduate Academic Support Office.
**Assumed Knowledge**

Students are expected to have the following knowledge coming into the course:

- 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:

1. gain an understanding about normative ethics and applied ethics through a case study analysis
2. gain an understanding about research ethics and the research process through engaging in a research project
3. increase their statistical literacy
4. gain an understanding about medical device regulations
5. discuss issues regarding biomedical engineering technology and society

**Learning Outcomes**

By the end of the class, students should be able to:

1. justify a course of action in an ethical dilemma
2. evaluate the ethics of research involving humans
3. explain the purpose and results of statistical analysis, including common misinterpretation and misapplication of statistics
4. describe the regulatory process for medical devices
5. discuss the impact of biomedical technology with a multidisciplinary audience
6. design an appropriate research methodology to investigate a research question

**Graduate Attributes (GA’s)**

The Canadian Engineering Accreditation Board requires graduates of engineering programs to possess 12 attributes at the time of graduation. Activities related to the learning outcomes listed above are measured throughout the course and are part of the department’s continual improvement process. Graduate attribute measurements will not be taken into consideration in determining a student’s grade in the course. For more information, please visit: [https://engineerscanada.ca/](https://engineerscanada.ca/).

<table>
<thead>
<tr>
<th>Graduate Attribute</th>
<th>Learning Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 - Investigation: Complex problem assessment</td>
<td>2,4</td>
</tr>
<tr>
<td>3.2 - Investigation: Design of experiment</td>
<td>4</td>
</tr>
<tr>
<td>3.3 - Investigation: Experimental procedure</td>
<td>4</td>
</tr>
<tr>
<td>3.4 - Investigation: Data reduction methods and results</td>
<td>3,4</td>
</tr>
<tr>
<td>3.5 - Investigation: Interpretation of data (synthesis) and discussion</td>
<td>3,4</td>
</tr>
</tbody>
</table>
### Textbooks (or other resources)

There is no need for students to purchase any textbooks for this course. Resources were selected so that they are readily available online (or only particular excerpts are used from the book, and sufficient information will be provided within the class).

The main resources for this course are:

- Online Statistics: An Interactive Multimedia Course of Study (http://onlinestatbook.com/webversion 2.0)

Additional resources for this course are:

- Internet Encyclopedia of Philosophy (http://www.iep.utm.edu/)
- Ropella, Kristina, Introduction to Statistics for Biomedical Engineers, Morgan & Claypool, 2007. (available online via Carleton Library)
Evaluation and Grading Scheme

<table>
<thead>
<tr>
<th>Element</th>
<th>Note</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCPS 2: CORE Tutorial (students must complete this tutorial to pass the course)</td>
<td>due last day of class (recommended to be completed end of January)</td>
<td>0%</td>
</tr>
<tr>
<td>Ethics Video</td>
<td>two attempts, best mark used (one due mid February one due mid March)</td>
<td>15%</td>
</tr>
<tr>
<td>Research Project (a complete ethics closure form must be submitted to pass the course)</td>
<td>proposal and REB application due end of January; paper due mid March; presentation beginning of April</td>
<td>35%</td>
</tr>
<tr>
<td>Quizzes (averaged across all the quizzes, after your lowest quiz mark is dropped)</td>
<td>Weekly</td>
<td>10%</td>
</tr>
<tr>
<td>Journals</td>
<td>Bi-weekly</td>
<td>5%</td>
</tr>
<tr>
<td>Final Exam</td>
<td></td>
<td>35%</td>
</tr>
</tbody>
</table>

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.

Tentative Week-by-Week breakdown

Week 1 (Jan 7 and Jan 9)
- Course introduction
- Introduction to ethics
- Ethical theories
- Common versus particular moralities

Week 2 (Jan 14 and 16)
- Research and library resources (Heather Macdonald)
- Ethical decision making
- Moral status

Week 3 (Jan 21 and 23)
- History of research ethics
- Research involving humans
- Informed consent
- Confidentiality and privacy
- Research ethics (Alisha Seguin)

Week 4 (Jan 28 and Jan 30)
- Research methods
- Proposal feedback sessions
Week 5 (Feb 4 and Feb 6)
- Introduction to statistics
- Plagiarism
- Graphs

Week 6 (Feb 11 and Feb 13)
- Bivariate data
- Research methods

Reading Week (Feb 17 to 21)

Week 7 (Feb 25 and Feb 27)
- Probability
- Receiver Operating Characteristic Curve
- Research Design
- Normal Distribution
- Sampling Distributions

Week 8 (Mar 3 and Mar 5)
- Estimation
- Hypothesis testing
- Type I and Type II Errors

Week 9 (Mar 10 and Mar 12)
- Testing Means

Week 10 (Mar 17 and Mar 19)
- Medical Device Regulations (Health Canada)
- Medical Device Evaluation (Health Canada)

Week 11 (Mar 24 and Mar 26)
- Technology and society

Week 12 (Mar 31 and Apr 2)
- ERMSBE Conference

Week 13 (April 7)
- ERMSBE Conference

**General Regulations**

**Attendance:** Students are expected to attend all lectures and lab periods. The University requires students to have a conflict-free timetable. For more information, see the current *Undergraduate Calendar, Academic Regulations of the University, Section 2.1.3, Course Selection and Registration and Section 2.1.7, Deregistration.*
**Health and Safety**: Every student should have a copy of our Health and Safety Manual. A PDF copy of this manual is available online: [http://sce.carleton.ca/courses/health-and-safety.pdf](http://sce.carleton.ca/courses/health-and-safety.pdf)

**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 (3.0) working 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. For more information, see the current Undergraduate Calendar, Academic Regulations of the University, Section 4.4, Deferred Term Work.

**Appeal of Grades**: The processes for dealing with questions or concerns regarding grades assigned during the term and final grades is described in the Undergraduate Calendar, Academic Regulations of the University, Section 3.3.4, Informal Appeal of Grade and Section 3.3.5 Formal Appeal of Grade.

**Academic Integrity**: Students should be aware of their obligations with regards to academic integrity. Please review the information about academic integrity at: [https://carleton.ca/registrar/academic-integrity/](https://carleton.ca/registrar/academic-integrity/). This site also contains a link to the complete Academic Integrity Policy that was approved by the University's Senate.

**Plagiarism**: Plagiarism (copying and handing in for credit someone else's work) is a serious instructional offense that will not be tolerated.

**Academic Accommodation**: You may need special arrangements to meet your academic obligations during the term. You can visit the Equity Services website to view the policies and to obtain more detailed information on academic accommodation at [http://www.carleton.ca/equity/](http://www.carleton.ca/equity/). For an accommodation request, the processes are as follows:

- **Pregnancy or Religious obligation**: Please contact your instructor 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 see [https://carleton.ca/equity/wp-content/uploads/Student-Guide-to-Academic-Accommodation.pdf](https://carleton.ca/equity/wp-content/uploads/Student-Guide-to-Academic-Accommodation.pdf)
- **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*). **Requests made within two weeks will be reviewed on a case-by-case basis.** After requesting accommodation from PMC, meet with me to ensure accommodation arrangements are made. Please consult the PMC
website (www.carleton.ca/pmc) 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/sexual-violence-support/](https://carleton.ca/sexual-violence-support/).

- **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 must be provided to students who compete or perform at the national or international level. Please contact your instructor 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, see [https://carleton.ca/senate/wp-content/uploads/Accommodation-for-Student-Activities-1.pdf](https://carleton.ca/senate/wp-content/uploads/Accommodation-for-Student-Activities-1.pdf)

**Parental/Caretaking Accommodations**

Based on my commitment to students who are parents or the primary caretaker for a young child, the following is my own classroom policy:

- Nursing or bottle-fed babies are welcome in class anytime, and you are welcome to feed your baby during class. If class lasts for more than 1.5 hours, you are welcome to take a break to pump.
- For older children, I understand that illnesses and unforeseen disruptions in childcare happen. It is acceptable to bring a child to class during emergencies like these as long as the child does not distract other students and it does not become a regular occurrence.
- When babies and children come to class, I recommend that you sit close to the door so that if your little one needs special attention and is disrupting learning for other students, you may step outside until their need has been met.

You do not need to request prior permission for any of the points above. Please communicate with me if we need to discuss other accommodations related to parenting/caregiving.

**Copyright on Course Materials:** The materials created for this course (including the course outline and any slides, posted notes, labs, project, assignments, quizzes, exams and solutions) are intended for personal use and may not be reproduced or redistributed or posted on any web site without prior written permission from the author(s).