

MIMG C234 / C134: Ethics and Accountability in Biomedical Research – ONLINE Syllabus and Requirements, Spring Quarter 2021

C234 is a graduate-level course covering topics of scientific integrity and ethics. This or an equivalent course is required of first-year PhD students in the UCLA Graduate Programs in Bioscience and other departments in bioscience disciplines. This course satisfies the requirements for training in Responsible Conduct of Research for predoctoral and postdoctoral trainees supported by federal training grants or individual fellowships. C134 is offered to senior-level undergraduates with faculty-supervised research experience (199 or equivalent) and instructor permission (request PTE). Course grading is P/F (undergrad) or S/U (graduate). **Postdocs email instructor to join class (LTalton@mednet.ucla.edu).**

ONLINE Class Meetings (in response to COVID-19 mandates)

C234 is offered in two online sections during Spring quarter. Each student is expected to attend their registered section unless they have secured prior permission from the instructor. All class sessions will begin in a common Zoom meeting, see CCLE for the links to join Zoom meeting

Section	Day	Time	Location	Dates	Course Website
1	Tuesday	12:00PM - 2:00PM	Zoom meeting	March 30 - June 1	ccle.ucla.edu
2	Friday	10:00AM - 12:00PM	Zoom meeting	April 2 - June 4	ccle.ucla.edu

Contact Information:

<p>Email Dr. Talton for:</p> <ul style="list-style-type: none"> Setting up phone or video chat appointments Bringing up issues/concerns 	<p>You can reach Lynn Talton at: LTalton@mednet.ucla.edu</p>
<p>Email Course Assistant for:</p> <ul style="list-style-type: none"> Requesting to switch sections for a week Planning to be absent, requesting make-up Turning in make-up assignments Turning in case assignment 	<p>You can reach the course assistant at: GradPostdoc@mednet.ucla.edu <i>(not monitored as frequently on evenings or weekends)</i></p>
<p>Dr. Talton's: Office Hour Options</p>	<ul style="list-style-type: none"> I will login to class meetings early and linger on a bit at the end to provide an opportunity for students to ask questions You can Email and set up a time for an individual call or Zoom meeting

Class Requirements: (Explicit requirements are detailed on pages 5-6)

In order to receive a passing grade, or an equivalent record of completion (postdocs), all students must:

- Attend and participate in every class meeting online (either Tuesday or Friday)
- If you must miss a class, make up approved absence with a written assignment (maximum 2/quarter)
 - If you get sick or are caring for a sick family member and won't be able to participate in the course for longer than two sessions, contact Dr. Talton when possible to discuss alternate options.
- Complete the written case-study assignment by the deadline and submit by email.

Reading assignments will be posted on course website, including selections from:

- On Being a Scientist: A Guide to Responsible Conduct in Research*, National Academy of the Sciences
- Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty*, Burroughs Wellcome Fund, Howard Hughes Medical Institute
- Additional articles: links to articles will be provided through the course website.

Outline of Discussion Topics for each of the 2-hour classes

Meeting	Topic and Assignments	Planned Speakers or Activities
<p>Tuesday class March 30</p> <p style="text-align: center;">or</p> <p>Friday class April 2</p>	<p style="text-align: center;">Introduction</p> <p>Introduction: Review class organization, reading and small group discussion assignments and discuss course written assignment.</p> <p>Begin discussion of the importance of ethics and integrity in scientific research, using case-studies.</p>	<p style="text-align: center;">In class Discussion: Case-Studies in Research Ethics</p>
<p>Tuesday class April 6</p> <p style="text-align: center;">or</p> <p>Friday class April 9</p>	<p style="text-align: center;">Mentor/Mentee Responsibilities and Laboratory Safety for Researchers</p> <p>Arguably, the mentor relationship is the most critical relationship of a trainee's career. We will discuss potential mentorship issues and strategies for handling different dilemmas. We will also consider laboratory safety for researchers. What is the division of responsibility between research trainees and PIs for setting and upholding laboratory safety measures?</p> <p style="color: red; text-align: center;">Before class, please prepare to discuss your assigned perspectives in Case-Study Discussion Week 2 – Mentorship and Lab Safety</p> <p>Reading Assignment:</p> <ul style="list-style-type: none"> • <i>Compact Between Biomedical Graduate Students & Their Research Advisors</i>, AAMC • <i>Lab Duties and Responsibilities</i>, UCLA Environmental Health and Safety • R. Van Noorden. (2011). A Death in the Lab. <i>Nature</i>, 472: 270-271. 	<p style="text-align: center;">Small-Group Discussion: Mentorship and Laboratory Safety Case-Studies</p>
<p>Tuesday class April 13</p> <p style="text-align: center;">or</p> <p>Friday class April 16</p>	<p style="text-align: center;">Authorship and Collaborative Research</p> <p>Authorship is often the yardstick by which we measure academic success. What are appropriate guidelines for determining authorship and how do you handle conflict around authorship? Research collaborations are critical to modern interdisciplinary research. How are collaborations with colleagues, funding agents and industry handled ethically?</p> <p style="color: red; text-align: center;">Before class, please prepare to discuss your assigned perspectives in Case-Study Discussion Week 3 – Authorship & Collaborative Research</p> <p>Reading Assignment:</p> <ul style="list-style-type: none"> • ICMJE (2018) - <i>Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research</i>: Selection: Authorship and Contributorship Requirements (2-3) • <i>On Being a Scientist</i> - Authorship & Allocation of Credit (35-38) <i>Making the Right Moves</i> - Setting up Collaborations (201-210) 	<p style="text-align: center;">Small-Group Discussion: Authorship and Collaborative Research Case-Studies</p>

Meeting	Topic and Assignments	Planned Speakers or Activities
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Publication and Peer Review

What is the process for determining which articles get published and by which journals? Is it fair? What is the editor’s role? Are journals doing enough to prevent plagiarism and data manipulation?

Tuesday class
April 20

or

Friday class
April 23

A major tenet of academic research is the peer review process. Can this process ever really be unbiased and how does it affect publications and grant applications? How can you be a responsible peer reviewer?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion Week 4 – Publication and Peer Review**

Reading Assignment:

- *Council of Science Editors’ White Paper on Promoting Integrity in Scientific Journal Publications*
 - Selection 1: Editorial Responsibilities (pgs. 8-15)
 - Selection 2: Peer Review (pgs. 31-35)

Speaker:
Dr. Paul Weiss,
Editor-in-Chief,
ACS Nano

Small-Group Discussion:
Publication and Peer Review Case-Studies

Conflicts of Interest and Dual Use Research of Concern

Everyone has biases, but when reporting research results we try to present them as truthfully as possible. When do you need to disclose your conflicts of interest and under what circumstances are biases too strong to be managed?

Tuesday class
April 27

or

Friday class
April 30

Dual Use Research of Concern is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health and safety. How can we promote important scientific progress while minimizing the risk of misuse of findings?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion Week 5 – Conflicts of Interest and DURC**

Reading Assignment:

- *On Being a Scientist* - Competing Interests (43-47)
- Dual Use Research of Concern (DURC) Summary Sheet

Small-Group Discussion:
Conflicts of Interest and Dual Use Research of Concern Case-Studies

Managing Data, Intellectual Property and Technology Transfer in a University Setting

Who owns the data that you produce at UCLA? What are your responsibilities in terms of managing or protecting that data? When and how are you allowed to share the data?

Tuesday class
May 4

or

Friday class
May 7

What are the intellectual property policies at UCLA (and most institutions) that may apply to trainees and how do they protect the interests of the researcher, university, and funding source? What should trainees consider about future potential commercialization when planning their research? What is technology transfer and how does it apply to intellectual property?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion Week 6 – Managing Data and IP**

Reading Assignment:

- *Making the Right Moves* - Data Management and Lab Notebooks (Ch. 8)
- *Making the Right Moves* - Understanding Technology Transfer (Ch. 11)

Speaker:
Ragan Robertson,
Business Development Officer and Information Systems Officer, UCLA Technology Development Group

Small-Group Discussion:
Managing Data, IP and Tech Transfer Case-Studies

Meeting	Topic and Assignments	Planned Speakers or Activities
<p>Tuesday class May 11</p> <p>or</p> <p>Friday class May 14</p>	<p style="text-align: center;">Research Misconduct</p> <p>In what ways is it inappropriate to manipulate data? How do you avoid inadvertently mishandling your data? What constitutes misconduct and how do you respond if you see evidence of such behavior?</p> <p style="text-align: center; color: red;">Before class, please prepare to discuss your assigned perspectives in Case-Study Discussion Week 7 – Research Misconduct</p> <p>Reading Assignment:</p> <ul style="list-style-type: none"> • <i>On Being a Scientist</i> - Misconduct Selections Treatment of Data, Mistakes and Negligence, Research Misconduct, Responding to Suspected Violations of Professional Standards (8-23) and Discussion of Case Studies (51-53) 	<p style="text-align: center;">In class Discussion: US Dept of HHS-ORI “The Lab” interactive movie on research misconduct</p> <p style="text-align: center;">Small-Group Discussion: Research Misconduct Case-Studies</p>
<p>Tuesday class May 18</p> <p>or</p> <p>Friday class May 21</p>	<p style="text-align: center;">Animal Welfare and Human Subjects in Biomedical Research</p> <p>Bioscience research often involves human or animal subjects. What are the current ethical standards of the US scientific community regarding the protection of humans and animals in research? How do investigators decide when use of these subjects is required? What policies are in place at UCLA to protect the subjects and ensure that the research complies with US, CA, and UCLA policies?</p> <p style="text-align: center; color: red;">Before class, please prepare to discuss your assigned perspectives in Case-Study Discussion 8 – Animal and Human Subject Welfare</p> <p>Reading Assignment:</p> <ul style="list-style-type: none"> • <i>N.H. Steneck. (2007). ORI: Intro to the Responsible Conduct of Research</i> <ul style="list-style-type: none"> ○ Selection 1: <i>Protection of Human Subjects</i> (35-45) ○ Selection 2: <i>Welfare of Laboratory Animals</i> (51-61) 	<p style="text-align: center;">Small-Group Discussion: Animal and Human Subject Welfare Case-Studies</p> <div style="border: 2px solid red; padding: 5px; text-align: center; color: black;"> <p>Submit Case-Study Writing Assignment by email to GradPostdoc@mednet.ucla.edu by <u>May 18</u> (Tues class) or <u>May 21</u> (Fri class)</p> </div>
<p>Tuesday class May 25</p> <p>or</p> <p>Friday class May 28</p>	<p style="text-align: center;">Wellness, Discrimination and Support</p> <p>Graduate students and postdocs may experience issues of discrimination, concerns about wellness, and need for support during their training. These experiences could be personal or as a mentor or colleague to the affected individual. How can you help? How can students, postdocs and faculty access support for these situations? In what ways can UCLA help foster resilience in research trainees?</p> <p style="text-align: center; color: red;">There will be no assigned perspectives for this class, discussions will take place in the large group and participation in discussion will be voluntary. Case-Study Discussion Week 9 – Special Cases</p>	<p style="text-align: center;">Guests: Kaitlyn Loughran Graduate Student & Postdoc Case Manager, Grad Division</p>
<p>Tuesday class June 1</p> <p>or</p> <p>Friday class June 4</p>	<p style="text-align: center;">Student-Prepared Case-Study Discussion and Course Wrap-up</p> <p>The best student case-studies submitted for the written assignment will be used for the last class case-study discussion.</p>	<p style="text-align: center;">In class Discussion: Student Submitted Case-Studies</p>

Course Description

This course introduces standard and acceptable practices in the biomedical and life sciences research, with emphasis on responsibilities in research activities such as record keeping, data treatment, authorship, peer review, mentoring, laboratory safety and participation in research that engages human or animal subjects. Additional topics include, misconduct, collaborative research, conflicts of interest, ownership of data and other intellectual property, and potential problems stemming from use of data from human genetic or stem cell experiments.

The course consists of ten online lecture-discussion sessions of two hours each. Classes will begin with a brief introduction of the topic by instructor or an invited expert speaker, followed by a large group discussion. The class will then break into smaller groups for in depth discussion of case studies assigned for the day, led by a faculty discussion leader. Students and faculty discussion leaders will be sorted into breakout groups within Zoom and can send requests to the course leader to join their group for questions, etc.

Case-Study Discussion Groups

Discussions groups will take place during class time. Pre-assigned small groups of students will join a faculty facilitator for case discussions in a Zoom breakout group. The facilitators are faculty volunteers who will be different each week. During these discussions, each student will be assigned 1-2 points-of-view from one of the case-studies to present to the group.

Discussion Attendance

You will be assigned to a specific discussion group. Your group will remain the same throughout the quarter. Dr. Talton will take attendance during discussion groups based on Zoom logins. If you do not appear in the login record for the main class and the discussion group, you will be responsible for completing a **Case-Study Discussion Make-up Assignment**, as described below.

Individual Discussion Assignment

You will be assigned to present the perspective of one of the people described in one or more of the week's case-studies. You may incorporate foundation material from the readings into your presentations as appropriate. The student representing the first listed perspective will briefly summarize the case and identify the problem(s) revealed by the case description. The class members representing the other perspectives will then briefly state their views, using the questions at the end of the case as a guide.

The faculty facilitators will then invite comments from others and attempt to develop a group consensus view on how the problem presented in the case can or should be resolved.

Case-Study Written Assignment (due by May 18 [Tues] or May 21 [Fri])

Each student will be required to write one original case-study during the quarter. This is your opportunity to contribute to the course and create a case-study very relevant to your research experience. This will be a 2-3 page written assignment consisting of a written case scenario, some thought questions for readers who might take on different roles or perspectives in the scenario, and a facilitator guide for the case discussion leader, including background information on the included ethical issues. Background can be gleaned from the assigned readings, class discussion, or additional research.

A document template for the assignment will be provided on the course website. The Case-Study Written Assignment should be clearly labeled with the student's name and submitted as an email attachment to GradPostdoc@mednet.ucla.edu by May 18 (members of the Tuesday class) or May 21 (members of the Friday class). Submissions will be accepted by email until 11:59pm on the assigned due date.

6-8 of the best student case-studies submitted will be selected to be used for the class case-study discussion on the last day of the quarter.

Options for a Missed Class

Participation in all of the case-study discussions and classes is a requirement for passing the course. If you must miss a class, you have two options for making up the assignment:

1. Attending the alternate class day

- a. You may attend the other class with prior approval of the instructor.
- b. For approval, email: GradPostdoc@mednet.ucla.edu
 - i. State your name and usual session (Tues/Fri)
 - ii. Give your reason for absence
 - iii. Request a temporary assignment to the alternate class
- c. We will respond with a temporary case-study assignment for that week.

2. Preparing the Case-Study Discussion Make-up Assignment

- a. For the first missed discussion, students will be asked to submit make-up case reports for **three** of the week's case studies, including the case assigned to you for that day. The second absence will require make-up case reports from **ALL** of the missed week's case studies. Students who miss two or more classes may be required to repeat the course.
- b. Each written case report should begin with a summary of the problem revealed by the case description and explore possible solutions to the dilemma presented there. It should be prepared in Microsoft Word format in Arial, 11-point font. Each written case report should be one, single-spaced page in length, headed with the case identifier and include your name, the class date of the discussion, and your Discussion Group (A,B,C, etc.) Written reports should be emailed to GradPostdoc@mednet.ucla.edu with the subject line: "Case Study Make-Up Assignment" and are due **no later than one week** after the date of the missed class.

Course Learning Objectives

Topics	Learning Outcomes
Mentoring Responsibilities and Relationships	Students should be familiar with the expectations for both the mentor and mentee in the training relationship. Students should have learned strategies for approaching this understanding, including IDPs, compacts and conversational tools.
Safe Laboratory Practices	Students should understand policies promoting and protecting laboratory safety at UCLA, and the role of the mentee and mentor in creating a culture of safety.
Data: acquisition, tools; management, sharing and ownership	Students should understand how to appropriately record, label and store data and use tools that redundantly back up data and facilitate sharing. Students should understand the chain of data ownership and their responsibility to make their data usable by others.
Intellectual Property	Students should understand the basics of intellectual property around data, publications and inventions, including: sharing appropriate credit, managing university IP and transferring technology between labs, companies and funders.
Conflicts of Interest	Students should be able to describe several types of personal, professional and financial conflicts of interest that are common in research institutions and in collaborations or relationships with industry or other outside funding sources. Students should also know how potential conflicts of interest are reviewed, and the types of mitigation plans that may result.
Research Misconduct and Handling Misconduct	Students should be able to describe common types of research misconduct and to avenues for reporting potential misconduct or negligence.
Authorship	Students should understand how authorship is determined in their work groups as well as the scientific community standards for contributions that merit authorship. They should know how to discuss authorship with mentors and collaborators and support appropriate attribution of credit in their projects.
Collaborative Research	Students should be able to demonstrate how to set up a collaboration using a collaboration agreement, and the factors that should be considered within. They should know how to address changes in the agreement as research progresses and evolves and how to participate as a trainee in a larger collaboration. Special topics include protecting the research and education mission in collaborations with industry and the role of authorship in collaborations.
Responsible Publication	Responsible publication includes appropriate citation, avoiding plagiarism, following appropriate guidelines for images, being clear with readers and reviewers regarding originality, the strength of effects, sharing lines of evidence that do not support hypotheses in addition to those that do, appropriate use of statistical evaluation of data, methodology that promotes rigor, and data sharing. Students should be able to recognize and advocate for these practices in their projects.
Peer Review	Students should understand the strengths and weaknesses of the peer review process, the confidentiality required of reviewers, how to appropriately assist in a review with a mentor, when to disclose conflicts of interest in a review, and who to approach with peer review issues or concerns.
Human Subjects and Live Vertebrate Animal Subjects	Students should understand the oversight of Vertebrate Animal and Human Subject Research and the guiding ethical principles of both types of research.
Broader Ethical Issues in Scientific Research Practice	Throughout the course, students will discuss the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research. Students should be able to argue ethical opinions on the current status and the likely future directions of these issues as technologies and guardrails evolve.