MIMG C234 / C134: Ethics and Accountability in Biomedical Research
Syllabus and Requirements, Spring Quarter 2020

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).

Class Meetings
C234 is offered in two 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 the lecture room, (see schedule-pg.10 and map-pg.9). Classes with discussion meetings will include smaller breakout groups moving to nearby conference rooms during class time.

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<tr>
<th>Section</th>
<th>Day</th>
<th>Time</th>
<th>Lecture Room</th>
<th>Dates</th>
<th>Course Website</th>
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<tr>
<td>1</td>
<td>Tuesday</td>
<td>12:00PM - 2:00PM</td>
<td>CHS A2-342</td>
<td>March 31 - June 2</td>
<td>ccle.ucla.edu</td>
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<td>2</td>
<td>Friday</td>
<td>10:00AM - 12:00PM</td>
<td>CHS A2-342</td>
<td>April 3 - June 5</td>
<td>ccle.ucla.edu</td>
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Contact Information:

Email Dr. Talton for:
- Setting up appointments
- Bringing up issues/concerns

You can reach Lynn Talton at: LTalton@mednet.ucla.edu

Email Course Assistant for:
- Requesting to switch sections for a week
- Planning to be absent, requesting make-up
- Turning in make-up assignments
- Turning in case assignment

You can reach the course assistant at: GradPostdoc@mednet.ucla.edu
(not monitored on evenings or weekends)

Dr. Talton’s:
- Office Phone 310-825-1391
- Office Location Geffen Hall, Suite 300 (Room 300W)
- Office Hours Before class or Email and set up a time

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

1. Attend and participate in every class discussion meeting
2. Complete the written case-study assignment
3. Make up approved absences with a written assignment (maximum 2)
   - Multiple and unapproved absences will result in a No Pass grade

Explicit requirements are detailed on pages 5-6.

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

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<th>Meeting</th>
<th>Topic and Assignments</th>
<th>Planned Speakers or Activities</th>
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<td><strong>Tuesday class</strong>&lt;br&gt;March 31&lt;br&gt;or&lt;br&gt;Friday class&lt;br&gt;April 3</td>
<td><strong>Introduction</strong>&lt;br&gt;Introduction: Review class organization, reading and small group discussion assignments and discuss course written assignment.&lt;br&gt;Begin discussion of the importance of ethics and integrity in scientific research, using case-studies.</td>
<td><strong>In class Discussion:</strong>&lt;br&gt;Case-Studies in Research Ethics</td>
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<td><strong>Tuesday class</strong>&lt;br&gt;April 7&lt;br&gt;or&lt;br&gt;Friday class&lt;br&gt;April 10</td>
<td><strong>Mentor/Mentee Responsibilities and Laboratory Safety for Researchers</strong>&lt;br&gt;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?&lt;br&gt;Before class, please prepare to discuss your assigned perspectives in <strong>Case-Study Discussion Week 2 – Mentorship and Lab Safety</strong>&lt;br&gt;<strong>Reading Assignment:</strong>&lt;br&gt;• <em>Compact Between Biomedical Graduate Students &amp; Their Research Advisors, AAMC</em>&lt;br&gt;• <em>Lab Duties and Responsibilities, UCLA Environmental Health and Safety</em>&lt;br&gt;• R. Van Noorden. (2011). A Death in the Lab. <em>Nature</em>, 472: 270-271.</td>
<td><strong>Small-Group Discussion:</strong>&lt;br&gt;Mentorship and Laboratory Safety Case-Studies</td>
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<td><strong>Tuesday class</strong>&lt;br&gt;April 14&lt;br&gt;or&lt;br&gt;Friday class&lt;br&gt;April 17</td>
<td><strong>Managing Data, Intellectual Property and Technology Transfer in a University Setting</strong>&lt;br&gt;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?&lt;br&gt;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?&lt;br&gt;Before class, please prepare to discuss your assigned perspectives in <strong>Case-Study Discussion Week 3 – Managing Data and IP</strong>&lt;br&gt;<strong>Reading Assignment:</strong>&lt;br&gt;• <em>Making the Right Moves - Data Management and Lab Notebooks</em> (Ch. 8)&lt;br&gt;• <em>Making the Right Moves - Understanding Technology Transfer</em> (Ch. 11)</td>
<td><strong>Speaker:</strong> Ragan Robertson, Business Development Officer and Information Systems Officer, UCLA Technology Development Group&lt;br&gt;<strong>Small-Group Discussion:</strong> Managing Data, IP and Tech Transfer Case-Studies</td>
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### 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?

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 4 – Conflicts of Interest and DURC**

#### Reading Assignment:
- *On Being a Scientist* - Competing Interests (43-47)
- Columbia Center - RCR Training Portal
  - Course 1: Conflicts of Interest
- Dual Use Research of Concern (DURC) Summary Sheet

### Research Misconduct

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?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion Week 5 – Research Misconduct**

#### Reading Assignment:
- *On Being a Scientist* - Misconduct Selections
  - *Selection 1*: Treatment of Data, Mistakes and Negligence, Research Misconduct, Responding to Suspected Violations of Professional Standards (8-23)
  - *Selection 2*: Discussion of Case Studies (51-53)

### Authorship and Collaborative Research

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?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion Week 6 – Authorship & Collaborative Research**

#### Reading Assignment:
- ICMJE (2018) - *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research*: Selection: Authorship and Contributorship Requirements (2-3)
- *On Being a Scientist* - Authorship & Allocation of Credit (35-38)
- *Making the Right Moves* - Setting up Collaborations (201-210)
**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?

A major tenet of academic research is the peer review process. Can this process ever really be unbiased and how does it affect publications, presentations, 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 7 – 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)

**Animal Welfare and Human Subjects in Biomedical Research**

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?

Before class, please prepare to discuss your assigned perspectives in **Case-Study Discussion 8 – Animal and Human Subject Welfare**

**Reading Assignment:**
  - Selection 1: Protection of Human Subjects (35-45)
  - Selection 2: Welfare of Laboratory Animals (51-61)

**Wellness, Discrimination and Support**

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?

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**

**Student-Prepared Case-Study Discussion and Course Wrap-up**

The best student case-studies submitted for the written assignment will be used for a class case-study discussion on the last day of the quarter.

**In class Discussion:** Student Submitted Case-Studies
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 lecture-discussion sessions of two hours. Case-study discussion 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. Classes will begin promptly, so be seated and prepared to start before class time.

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 nearby conference room. The facilitators are faculty volunteers that 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 and advised of the room to which your group will move during your discussion. Your group will remain the same throughout the quarter, though the meeting room may change. Dr. Talton will rotate among the discussion groups, and while there, she will pass around a sign-in sheet on which you must provide your signature to indicate your presence in the discussion. If you do not sign the sheet, 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 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 case discussants 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 19 or May 22)
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 textbooks, 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 19 (members of the Tuesday class) or May 22 (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 Case-Study Discussion
Participation in all of the case-study discussions 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, usual session (Tues/Fri) and usual discussion group
      ii. Give your reason for absence
      iii. Request a temporary assignment to the alternate class
   c. We will respond with a temporary discussion group/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

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<th>Topics</th>
<th>Learning Outcomes</th>
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<td>Mentoring Responsibilities and Relationships</td>
<td>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.</td>
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<td>Safe Laboratory Practices</td>
<td>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.</td>
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<td>Data: acquisition, tools; management, sharing and ownership</td>
<td>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.</td>
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<td>Intellectual Property</td>
<td>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.</td>
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<td>Conflicts of Interest</td>
<td>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.</td>
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<td>Research Misconduct and Handling Misconduct</td>
<td>Students should be able to describe common types of research misconduct and to avenues for reporting potential misconduct or negligence.</td>
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<td>Authorship</td>
<td>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.</td>
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<td>Collaborative Research</td>
<td>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.</td>
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<td>Responsible Publication</td>
<td>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.</td>
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<td>Peer Review</td>
<td>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.</td>
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<td>Human Subjects and Live Vertebrate Animal Subjects</td>
<td>Students should understand the oversight of Vertebrate Animal and Human Subject Research and the guiding ethical principles of both types of research.</td>
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<td>Broader Ethical Issues in Scientific Research Practice</td>
<td>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.</td>
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Map to Moss Auditorium
CHS A2-342

To find Moss Auditorium (CHS A2-342):
- From the intersection of Charles Young Drive S and Tiverton Ave (★).
- Walk south on Tiverton Ave until you pass under a building extension over the road.
- Turn right and go between the dental school and dental clinic entrances and enter the center doors labeled “David Geffen School of Medicine.”
- Inside to the right, take the elevator or stairs down one level to A-level.
- Turn left out of the elevator stairs, and walk south until you reach A2-342 (Moss Auditorium).
Map to the CHS Conference Rooms
(class will always start in the lecture hall, but will later divide into smaller discussion groups on Weeks 2-8 (April 7-May 22) – see schedule pg. 10)
### Tuesday Section

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<tr>
<td>Group 3</td>
<td>Stay in A2-342 CHS</td>
<td>17-256 CHS Sunset</td>
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### Friday Section

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**Note:**
- EVERY GROUP MEETS AT 14-214U CHS FROM 1:00 – 1:30 ON TUESDAY & FRIDAY AT THE START OF EACH WEEK.
- GROUPS THEN BREAKS INTO SMALL GROUPS & MOVES TO THEIR RESPECTIVE ROOMS AS SHOWN ABOVE.