

The Responsible Conduct of Research (RCR): A Short Course for
Investigators
1 Credit Hour or ½ Credit Hour

Course Logistics

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Course Time: Winter term 2018; dates and times to be announced.

COURSE DESCRIPTION

In response to a perceived increase in the frequency of cases of scientific misconduct, the National Institutes of Health (NIH) introduced its first policy on the responsible conduct of research (RCR) in 1989. Since this time, the NIH has required that all grant awardees receive training in RCR, and other federal science agencies such as the National Science Foundation (NSF) have followed suit. More broadly, scientific research raises many ethical issues, and it is important that investigators are aware of and able to critically think through the ethical dimensions of their work and that the public's trust in science is preserved.

This short course in the responsible conduct of research (RCR) will introduce students to major ethical and policy issues in research. Priority will be given to those issues covered in the federal definition of "scientific misconduct" and in the NIH's model curriculum on RCR. These issues include data fabrication, data falsification and plagiarism; responsible authorship, publication and mentorship practices; conflicts of interest; data management; and the use of human participants and animal subjects in research. As well, broader ethical issues in scientific research will be touched upon, for example as relates to changes in the way science is funded and structured and evolving social views regarding researchers' responsibilities to both humans and animal involved in research.

COURSE STRUCTURE

The course exists in two forms: a 1-credit course, which will be the default standard for doctoral students around the university, and a shorter, ½ credit course, which can be elected by doctoral programs with permission from the Graduate College and Office of Research. The 1-credit course will involve student attendance of eight 1-hour lectures, as well as an additional 2 hours of RCR instruction to be delivered by students' doctoral programs. The 1/2-credit course will involve 5 hours of contact time, with programs choosing either 5 classroom lectures or 4 classroom lectures and supplementary training. Students will be notified by their programs of whether they are registered for the 1 or ½-credit option.

All lectures will be 50 minutes in length. Course sections will meet once per week and will be capped at approximately 60 students each.

COURSE OBJECTIVES

Upon completion of this course, students will be able to:

1. Consider their role as scientists in society and the kinds of ethical considerations that are implicated in scientific activity.
2. Understand the changing nature of science and the ways in which science is shaped by social values.
3. Understand the federal definition of "scientific misconduct," factors driving the prevalence of misconduct, the processes for investigating misconduct, and the penalties for committing misconduct.
4. Understand relevant governmental and non-governmental policies regarding authorship, data retention and sharing, financial conflicts of interest, and the use of human participants and animal subjects in research.
5. Consider broader ethical issues, beyond policies *per se*, regarding each of the aforementioned areas.

COURSE CONTENT AND TEACHING METHODS

Course materials: Materials that will be available on Blackboard:

- PowerPoint slide presentations
- Required course readings
- Additional readings

Required text: Nicholas Steneck, *An Introduction to the Responsible Conduct of Research*. Bethesda, MD: Office of Research Integrity, National Institutes of Health, 2007. (Available for free and posted on BlackBoard.)

Other Required readings: As posted under "materials by week" on Blackboard

Optional readings: As posted under “materials by week on Blackboard”

EVALUATION METHODS

This is a pass/fail course. In order to pass the course, students must attend or make up all in-classroom sessions (absence policy elaborated below) and earn a grade of 75% or higher on the final quiz. In addition to the classroom portion of the course, students must also complete relevant supplementary training with their home programs and have this training documented with the Graduate College in order to receive a passing grade.

Evaluation Method	Proportion of Final Grade
Final quiz	Mandatory grade of 75% or higher to pass
Attendance	Mandatory to pass course

Grading Scale

The course is pass/fail. Students will need to receive a grade of 75% on the quiz in order to pass.

ATTENDANCE POLICY

In order to ensure compliance with funding agency requirements, attendance at this course is considered mandatory, and attendance will be taken at all sections. Students are strongly encouraged to make the required efforts to attend all class sessions for the course section in which they are registered. If for some reason an absence is unavoidable, students should contact Dr. Rossi and arrange to make up the missed lecture by attending a different class section, if at all possible. If the student cannot attend in-class make-up lecture, then s/he will be required to view an online, streamed version of the in-class lecture in order to make up for the missed content. Outside of exceptional circumstances, students who miss more than 2 hours of in-class lecture will fail the course. If there is an exceptional circumstance requiring substantial absences, students should contact Dr. Rossi to make alternate arrangements, which might include taking the course in a later term.

ADD/DROP POLICY

The Drexel University course add & drop policies are available here:

http://www.drexel.edu/provost/policies/course_add.asp

http://drexel.edu/provost/policies/course_drop/

Please note that this course is generally considered a required course for doctoral students, and that modification of the course schedule should be confirmed with the student's doctoral program director.

<u>LECTURE SCHEDULE</u>		
Lecture #	Topics & relation to course objectives	Readings/Assignments
<i>Lecture 1: An Introduction to the Responsible Conduct of Research (RCR)</i>	<ul style="list-style-type: none"> • Course Introduction • Science and ethics: framing the relationships • History of RCR: problems, policies, and education • Why act ethically in research? Perspectives from philosophy. 	<ul style="list-style-type: none"> • Gary Comstock. "Introduction." In <i>Research Ethics</i>. (14 pages). • Alok Jha. (September 13, 2012). "False Positives: Fraud and Misconduct Are Threatening Scientific Research." <i>The Guardian</i>. Available at: https://www.theguardian.com/science/2012/sep/13/scientific-research-fraud-bad-practice
<i>Lecture 2: Research Misconduct</i>	<ul style="list-style-type: none"> • <i>Federal policy on research misconduct: definition, examples, penalties, & process.</i> • <i>Misconduct: its extent and factors influencing it</i> • <i>Some considerations regarding misconduct & whistleblowing.</i> 	<ul style="list-style-type: none"> • Steneck "Chapter 2: Research Misconduct." • Drexel University Policy on Research Misconduct. Available at: http://drexel.edu/research/resources/forms-and-policies/Policies/Research%20Misconduct/ • Optional: Lutz Bornmann. (2013). "Research Misconduct: Definitions, Manifestation, and Extent." <i>Publications</i> 2013, 1, 87-98; doi:10.3390/publications1030087
<i>Lecture 3: Conflicts of Interest in Research</i>	<ul style="list-style-type: none"> • <i>A motivating case example</i> • <i>Conflict of Interest: definitions, conceptual distinctions</i> • <i>Financial COI in research: types, extent, federal policies, Drexel Policy</i> • <i>Nonfinancial COI in</i> 	<ul style="list-style-type: none"> • Steneck, "Chapter 5: Conflicts of Interest," in <i>An Introduction to the Responsible Conduct of Research</i>, pp. 67-82. • Josephine Johnston. (2008). "Conflicts of Interest." in <i>The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns</i>, ed. Mary Crowley

	<p><i>research: sources, possible ways to manage</i></p>	<p>(Garrison, NY: The Hastings Center, 2008), 31-34. Available at: http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2156</p> <ul style="list-style-type: none"> • Optional: Brian D. Wright, et al. (March 19, 2014). "Technology transfer: Industry-funded academic inventions boost innovation." <i>Nature</i> 507, 297–299. Available at: http://www.nature.com/news/technology-transfer-industry-funded-academic-inventions-boost-innovation-1.14874 • Optional: Howard Brody. (2011). "Clarifying Conflict of Interest." <i>The American Journal of Bioethics</i>, 11:1, 23-28
<p><i>Lecture 4: Authorship & Publication</i></p>	<ul style="list-style-type: none"> • <i>Some recent controversies regarding scientific authorship & publication</i> • <i>Scientific publication: definition, purposes, goals</i> • <i>What does it mean to be an "author" on a scientific paper?</i> • <i>Bylines: authorship guidelines by discipline and points of debate</i> • <i>Problematic authorship practices</i> • <i>Peer review: ethical considerations & guidelines</i> 	<ul style="list-style-type: none"> • Fred Barbash. (July 11, 2014). "An Obscure Academic Journal. A Memorable Peer Review Scandal." <i>The Washington Post</i>. Available at: http://www.washingtonpost.com/news/morning-mix/wp/2014/07/11/the-most-brazen-peer-review-scandal-anyone-can-remember/ • Tom Spears. (August 20, 2014). "Respected Medical Journal Turns to Dark Side." <i>The Ottawa Citizen</i>. Available at: http://ottawacitizen.com/technology/science/respected-medical-journal-turns-to-dark-side • Vijaysree Venkatramen. (April 16, 2010). "Conventions of Scientific Authorship." <i>Science</i>. Available at: http://www.sciencemag.org/careers/2010/04/conventions-scientific-authorship • Bernard Lo. (2009). "When Authorship Turns Sour," <i>CTSI Research Ethics Blog</i>. (See comments as well). Available at: https://accelerate.ucsf.edu/blogs/et

		<p>hics/when-authorship-turns-sour</p> <ul style="list-style-type: none"> • Nicholas Steneck, "Chapter 9: Authorship & Publication," in Steneck, N. <i>An Introduction to the Responsible Conduct of Research</i>. Bethesda, MD: National Institutes of Health, 2007, pp. 133-145. • Optional: Kevin Strange. (2008). "Authorship: Why Not Just Toss a Coin?" <i>J Physiol Cell Physiol</i>. 2008 Sep; 295(3): C567–C575. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2544445/
Lecture 5: Ethical Issues in Data Management	<ul style="list-style-type: none"> • Federal definition of "data" and components of data management • Ethical and pragmatic reasons to ensure good data management • Data ownership: regulatory considerations • Considerations for data collection: authorization, appropriate methods, attention to detail, recording. • Data storage: preservation & limiting access to sensitive information. • Data Analysis: Current issues in scientific research, points to consider • New regulatory initiatives to improve rigor & reproducibility • Additional case discussion if time 	<ul style="list-style-type: none"> • Jonah Lehrer. (December 13, 2010). "The Truth Wears Off: Is There Something Wrong with the Scientific Method?" <i>The New Yorker</i>. Available at: http://www.newyorker.com/magazine/2010/12/13/the-truth-wears-off?currentPage=3 Janet D. Stemwedel. (2008). "Should Researchers Share Data?" <i>Adventures in Ethics & Science</i> [online resource]. Available at: http://scienceblogs.com/ethicsandscience/2008/03/03/should-researchers-share-data/ • Nicholas Steneck. (2007). "Chapter 6: Data Management Practices," in <i>An Introduction to the Responsible Conduct of Research</i>, pp. 87-102. • Optional: Psychonomic Society. (2012). "Psychonomic Society Guidelines on Statistical Issues." [online resource]. Available at: http://www.psychonomic.org/statistical-guidelines • Optional: John Ioannidis. (2005). "Why Most Published Research Findings Are False." <i>Plos One</i> 2(8): e124. • Optional: Jennifer A. Thomson.

		<p>(2007). "How to Start and Keep a Laboratory Notebook." <i>iP Handbook of Best Practices</i>. (OK to skim)</p> <p>Available at:</p> <p>http://www.iphandbook.org/handbook/ch08/p02/</p>
<p><i>Lecture 6: Mentoring in Research</i></p>	<ul style="list-style-type: none"> • <i>Opening Case Study</i> • <i>Definitions: What is a mentor? How is mentorship different from supervision?</i> • <i>The relationship between mentoring and ethical research</i> • <i>Mentoring and role delineation—who is responsible for what?</i> • <i>Considerations when choosing a mentor</i> • <i>Things to clarify with your advisor or mentor</i> • <i>Toxic mentoring: what is it, how common is it, and how to deal with it.</i> • <i>Mentorship: larger institutional issues</i> 	<ul style="list-style-type: none"> • Comstock, "Mentor Inclusively," in <i>Research Ethics</i>. (10 pages). • National Institutes of Health, Office of Intramural Training and Education. (n.d.). "Evaluating Potential Mentors." Available at: https://www.training.nih.gov/evaluating_potential_mentors • "Advisor/Student." <i>Science Professor</i> [online resource]. Available at: http://science-professor.scientopia.org/2011/02/07/advisorstudent/ • Drmellivora [pseudonym]. "Toxic Academic Mentors." <i>Tenure She Wrote</i> [online resource]. Available at: https://tenureshewrote.wordpress.com/2013/08/12/toxic-academic-mentors/ • William Neaves. (2012). "The Roots of Research Misconduct." <i>Nature</i> 488: 121-122.
<p><i>Lecture 7: Research with Human and Animal Subjects</i></p>	<ul style="list-style-type: none"> • <i>IRBs and IACUCs: What Do They Do?</i> • <i>Working with the IRB and IACUC: Points to Consider</i> • <i>Why not self-regulate? Arguments for committee review.</i> • <i>Current controversies; science and society</i> 	<ul style="list-style-type: none"> • Steneck. (2007). "Chapter 3: The Protection of Human Subjects," in <i>An Introduction to the Responsible Conduct of Research</i>, pp. 35-50. • Steneck. (2007). "Chapter 4: The Welfare of Laboratory Animals," pp. 51-62.

Drexel University Policy on Plagiarism

(taken directly from

http://www.drexel.edu/provost/policies/academic_dishonesty.asp#plagiarism)

Plagiarism is the inclusion of someone else's words, ideas, or data as one's own work. When a student submits work for credit that includes the words, ideas, or data of others, the source of that information must be acknowledged through complete, accurate, and specific references, and, if verbatim statements are included, through quotation marks as well. By placing his/her name on work submitted for credit, the student certifies the originality of all work not otherwise identified by appropriate acknowledgments. Plagiarism covers unpublished as well as published sources. Examples of plagiarism include, but are not limited to:

- Quoting another person's actual words, complete sentences or paragraphs, or an entire piece of written work without acknowledgment of the source
- Using another person's ideas, opinions, or theory, even if it is completely paraphrased in one's own words without acknowledgment of the source
- Borrowing facts, statistics, or other illustrative materials that are not clearly common knowledge without acknowledgment of the source
- Copying another student's essay test answers
- Copying, or allowing another student to copy, a computer file that contains another student's assignment, and submitting it, in part or in its entirety, as one's own
- Working together on an assignment, sharing the computer files and programs involved, and then submitting individual copies of the assignment as one's own individual work

Students are urged to consult with individual faculty members, academic departments, or recognized handbooks in their field if in doubt regarding issues of plagiarism.

Drexel University Policy on Cheating

(taken directly from

http://www.drexel.edu/provost/policies/academic_dishonesty.asp#cheating)

Cheating is an act or an attempted act of deception by which a student seeks to misrepresent that he or she has mastered information on an academic exercise that he/she has not mastered. Examples include, but are not limited to:

- Copying from another student's test paper
- Allowing another student to copy from a test paper
- Unauthorized use of course textbook or other materials, such as a notebook to complete a test or other assignment from the faculty member
- Collaborating on a test, quiz, or other project with any other person(s) without authorization

- Using or processing specifically prepared materials during a test such as notes, formula lists, notes written on the students clothing, etc. that are not authorized
- Taking a test for someone else or permitting someone else to take a test for you

Disability Statement: Students with disabilities requesting accommodations and services at Drexel University need to present a current accommodation verification letter (AVL) to faculty before accommodations can be made. This must be done prior to the midterm exam. AVL's are issued by the Office of Disability Services (ODS). For additional information, contact ODS at www.drexel.edu/edt/disability, 3201 Arch St., Suite 210, Philadelphia, PA 19104, 215.895.1401 (V) or 215.895.2299 (TTY).