

## About the Coursemaster



### Contact Information:

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Preferred method of contact: e-mail. I will respond to emails as promptly as possible, usually within 24 hours.

### Teaching Assistant: TBD

**In-Person Office Hours:** By appointment. Contact us by email and we can set up a time to meet.

**Welcome:** Welcome to Ethical and Regulatory issues in clinical research! We are looking forward to a semester of exploring key ethical issues arising in clinical research together. The class provides a unique opportunity for you to not only learn the fundamental elements of ethical conduct of research but also to reflect on the ethical implications of your own work in a constructive and supportive environment.

**Coursemaster Biography:** I am Associate Professor in Health Care Ethics with a secondary appointment in the School of Public Health and Social Justice at Saint Louis University. I also am Adjunct Associate Professor of Medicine at Washington University's Center for Clinical and Research Ethics. I am trained originally as a philosopher with a focus on philosophy of science, but did my postdoctoral work in empirical research ethics. Since completing my education, I have conducted both empirical and theoretical research on research ethics, focusing on community-engaged research, research with vulnerable populations, IRB policy, the ethics of biobanking, and public deliberation on bioethics issues.

### Teaching Philosophy:

This class is interactive and discussion-based. Your participation and engagement with the material is essential, so please be prepared to take part in class discussions, respectfully share your opinions and views with the group, and critically assess different opinions about ethical issues. We each bring expertise to this area based on our experience and disciplinary backgrounds, which is a benefit to the class as a whole, and this class is an opportunity for us to explore the issues together. We will have guest lectures from speakers for certain topics. A

large part of class time will be spent discussing and doing in-class activities to illustrate and apply key themes from course materials so please come prepared to participate and reflect.

## About This Course

### Required Texts:

Shamoo A., and Resnik D. *Responsible Conduct of Research 3rd Edition*. Oxford: Oxford University Press, 2015

All other course readings will be available through Blackboard at <https://bb.wustl.edu>.

### Course Description:

The principal goals of this course are to prepare clinical and translational researchers to critically evaluate and identify ethical issues in clinical research and the situational factors that give rise to them, to identify ethics and regulatory compliance resources, and to foster ethical problem-solving skills. The course aims to deliver practical guidance for investigators through discussion and activities in critical areas of clinical research ethics. An additional aim of the course is to enable participants to recognize the different ways in which research participants may be vulnerable and the ethical issues raised by including and excluding vulnerable participants.

### Goals of the Course:

By the end of the course, participants will be able to:

- Understand the regulatory framework that governs human subjects research and the distinction between compliance and ethics
- Identify major ethical concerns in the conduct of clinical research, including situational factors that may give rise to ethical concerns
- Apply ethical problem-solving skills in clinical and translational research

**Course requirements:** Coursework is divided into two categories: homework and in-class work. There is no final exam for this course.

### Homework

Readings: There are readings for each class that provide important background for the topics we will discuss in class. You are expected to do the readings for each class and come prepared to use that information in discussion.

#### Journals (total of 7 due)

- Bi-weekly, each student will choose **ONE** of the journal prompts provided and write a 1 page double-spaced written response to it. The thoughts you articulate in the response paper will help you contribute to the class discussion, which will touch on these topics, and are essential elements of class participation.
  - *Note:* There are a couple of journal assignments that ask you to identify the URL of a policy. This is REQUIRED in addition to whichever type of journal entry you choose.
- Journals should be submitted under “Journals” on Blackboard, or in the day’s folder under the journal icon by 11.59PM Sunday night before the class.
- Assignments less than 24 hours late will receive partial credit. Assignments turned in more than 24 hours late receive NO credit.
- If you miss a journal one week, no matter the reason, you can make it up the next week (when you would normally not be assigned a journal).

#### Weekend Reads Project:

- Through Blackboard, you will have access to a link to “Weekend Reads” on Blackboard. Weekend Reads contain links to current stories and examples of real world ethical issues and misconduct posted on Retraction Watch. You are encouraged to review and read the headlines every week. You must choose

one Weekend Reads article that has come out during the semester, and write a 2-4 page (double-spaced) analysis of it. This should include:

- 1) A summary of the article (What happened?)
- 2) What do you think were the major causes of the situation?
- 3) Could this situation have been prevented? If so, how?
- 4) How does this case relate to the readings/discussion in this course?
- 5) What are some implications of this situation for research ethics? In other words, what can be learned from this case?
  - This project is due by the start of the last day of class, but can be turned in at any point during the semester.

### **In-class work (you may miss 2 classes and corresponding in-class work without penalty)**

#### Quizzes:

- At the **beginning** of each class, I will administer a short True/False quiz (5 pts) related to the readings due for that day. The quizzes are designed to ensure that everyone has done the readings, which are essential for class discussion and activities. There are no makeups for the quizzes (including if you arrive late to class and miss the quiz).
  - Note: I will not count 10 pts toward your total quiz grade, which will create a buffer for two missed quizzes, or lost points on quizzes where you may not have done as well as you had hoped.

#### Group Activities:

- Every class, there will be in-class activities that you will do in small groups and write-up on a provided worksheet. The product of these activities will be turned in to Blackboard at the end of class and graded as V+ (6 pts); V (4 pts); V- (2 pts).
- You are allowed to miss 2 classes with no makeup of the Activities required. If you miss more than two classes, then you must complete the requirements under “Make-Up Classes” below.
- At the end of the semester, you will also be evaluated by your group members to evaluate your contribution, and this will constitute a large part of your participation grade.

### **Make-Up Classes**

Note: After your two allowed absences, you must “make up” the classes that you miss in order to pass the class. This requires

- 1) Watching/Listening to the recording of the class
- 2) Doing the class activities that you missed on your own, writing them up on the Activity Worksheet, and turning it in on Blackboard. This must be turned in by the start of the next class to get credit.
- 3) As noted above, you cannot make up quizzes, and missing more than 2 classes will impact your quiz grade, regardless of any make-up work.

### **Participation and Decorum:**

You are expected to do your best to attend and ACTIVELY participate in all classes in this course. Each class attended with participation will contribute to your participation grade. Your success in this course will heavily depend on your ability to communicate, engage and participate in all course activities.

It is vitally important that our classroom environment promote the respectful exchange of ideas. This entails being sensitive to the views and beliefs expressed during discussions. Your success in this course depends on your ability to communicate, engage and participate in all course activities, including timely completion of assignments.

### **Technology Requirements:**

As this course utilizes Blackboard extensively, you are expected to have access to reliable internet access. In-class activities can be written up and submitted to Blackboard using a laptop. If you have computer problems, it is your responsibility to address these or utilize the CRTC Computer Lab. Problems with your computer or other technology issues are not an excuse for delays in meeting expectations and missed deadlines for the course. If you have a problem, get help in solving it immediately.

**Technology Usage During Class:**

Please be respectful of your fellow classmates and the instructor by only using your laptop or other electronic devices for in-class activities and learning purposes. Please turn off cell-phones during class and do not use them for non-course related activities during class. It is distracting to everyone when individuals use laptops or cell phones for non-class activities. The class is discussion based, so please refrain from using or checking electronic devices during class.

**Blackboard:**

All the class materials, as well as the assignments and communications will be done through Blackboard at <https://bb.wustl.edu>. There are tabs for each of the different items on Blackboard, including:

- **Main Page:** holds a folder for each class, in order. In each class folder are the readings that aren't in the textbook and a link to turn in that class's journal entry. It also holds the most up-to-date syllabus.
- **Activity sheets:** holds a folder where one member of your group will download and submit your In-class Activity sheet at the end of each class.
- **Journals:** holds a link to all the journals for the class.
- **Weekend Reads Project Tab:** where you can turn in your Weekend Reads Project at any time during the semester.
- **Makeup Activity Tab:** where you can turn in makeup activities.
- **My Grades:** a running account of your grades for the class.
- **Tools:** other tools, like email and other functions, for Blackboard.

**Time Requirements**

For face-to-face courses in the CRTC program it is expected that you will be in class 1 hour per week for each credit of the course a week plus travel time (i.e. this is a 2 credit course so that is 2 hours a week). In addition it is assumed you will be doing homework and reading assignments that take at least double that time. You should anticipate your time commitment for this course to be at least 5-6 hours a week.

**Course Schedule** (subject to modification)

| Dates                 | Topic  | Readings Due  |
|-----------------------|--|---|
| <b>Week 1</b><br>8-27 | What is research ethics?   | <ul style="list-style-type: none"> <li>• S&amp;R Ch.1 (1-10; 17-26)</li> <li>• PR Wolpe "Reasons Scientists Avoid Thinking about Ethics"—Wolpe</li> </ul> |
| 9-3                   | Labor Day – No Class<br>Enjoy!                                       |   |
| <b>Week 2</b><br>9-10 | What is the appropriate relationship between scientists and society? | <ul style="list-style-type: none"> <li>• S&amp;R Ch.12 (283-297)</li> </ul>   |

|                          |   |   |
|--------------------------|---|---|
| <b>Week 3<br/>9-17</b>   | What is research wrongdoing and what causes it?                               | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 2 (28-40; 46-48)</li> <li>• Locate and skim Washington University Research Integrity Policy</li> </ul>   |
| <b>Week 4<br/>9-24</b>   | How is human subjects research regulated and why?                             | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 11 (236-263)</li> <li>• The Belmont Report</li> </ul>  |
| <b>Week 5<br/>10-1</b>   | How do we ethically enroll participants in research?                          | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 11 (263-265)</li> <li>• Horng and Grady "Misunderstanding in Clinical Research"</li> <li>• Applebaum et al. "Voluntariness of Consent to Research"</li> </ul>  |
| <b>Week 6<br/>10-8</b>   | How do we protect AND give access to more vulnerable populations in research? | <ul style="list-style-type: none"> <li>• S&amp;R Ch.11 (268-277)</li> </ul>   |
| <b>Week 7<br/>10-15</b>  | How do we ethically collect, analyze and interpret data?                      | <ul style="list-style-type: none"> <li>• Resnik, DB. "Statistics, Ethics, and Research: An Agenda for Education and Reform"</li> </ul>  |
| <b>Week 8<br/>10-22</b>  | How do we legally and ethically protect and manage our data?                  | <ul style="list-style-type: none"> <li>• Ch.8: Data Management and Laboratory Notebooks" Making the Right Moves: A Practical Guide to Scientific Management; Burroughs Wellcome Fund at <a href="http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch8.pdf">http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch8.pdf</a></li> <li>• Wilson and Schreier et al. "Research Records and the Resolution of Misconduct Allegations at Research Universities"</li> </ul> |
| <b>Week 9<br/>10-29</b>  | How do we identify and ethically manage conflicts of interest and commitment? | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 9 (194-205)</li> <li>• WUSTL School of Medicine COI Policy at <a href="http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx">http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx</a></li> </ul>   |
| <b>Week 10<br/>11-5</b>  | How do we legally and ethically own, share, and use data?                     | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 8 (74-78; 100-117; 183-188)</li> <li>• Locate and skim Washington University Intellectual Property Policy</li> </ul>   |
| <b>Week 11<br/>11-12</b> | How is authorship ethically determined, and what is appropriate peer review?  | <ul style="list-style-type: none"> <li>• S&amp;R Ch. 6-7 (122-131; 146-157)</li> <li>• Locate and skim Washington University Authorship Policy</li> </ul>   |
| <b>Week 12<br/>11-19</b> | What are the important issues in  | <ul style="list-style-type: none"> <li>• Cambon-Thompson (2004): "The social and ethical issues of post-genomic biobanks"</li> </ul>  |

|                                |  |   |
|--------------------------------|--|---|
|                                | genetic research and biological samples?   | <ul style="list-style-type: none"> <li>Allen et al (2010) "Human Tissue Ownership and use in research: What laboratorians and researchers should know."</li> </ul>  |
| <b>Week 13</b><br><b>11-26</b> | How can community involvement improve the ethics and scientific value of research? | <ul style="list-style-type: none"> <li>Holzer et al (2014): "Why We Need Community Engagement in Medical Research"</li> <li>Dickert &amp; Sugarman (2005). "Ethical Goals of Community Consultation in Research."</li> </ul>  |
| <b>Week 14</b><br><b>12-3</b>  | What do you do when you think you observe research wrongdoing?                     | <ul style="list-style-type: none"> <li>S&amp;R Ch.2 (40-46)</li> <li>Responding to Research Wrongdoing: A User-Friendly Guide <a href="http://www.ethicsresearch.com/images/RRW_7-17-10.pdf">http://www.ethicsresearch.com/images/RRW_7-17-10.pdf</a></li> </ul>                    |
| <b>Week 15</b><br><b>12-10</b> | How do you choose a good mentor and be a good mentee?                              | <ul style="list-style-type: none"> <li>S&amp;R Ch.4 (85-90; 96-99)</li> <li>Ch. 12: Making Collaborations Work <a href="http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch12.pdf">http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch12.pdf</a></li> </ul> |

## Assessment/Grading

### Summary of Course Assignment Point Values:

|                          |             |
|--------------------------|-------------|
| Bi-Weekly Journals       | 15%         |
| Attendance/Participation | 15%         |
| In-Class Activities      | 45%         |
| Quizzes                  | 15%         |
| Weekend Reads Project    | <u>10%</u>  |
|                          | <b>100%</b> |

**Grading Scale:** This course utilizes the standard CRTC grading scale. The grade value for each letter grade is as follows:

| Grades/sub-grades                                | 4-point scale |
|--|---------------|
| A+ (98% to 100%)                                 | 4.00          |
| A (93% to 97%)                                   | 4.00          |
| A- (90% to 92%)                                  | 3.7           |
| B+ (88% to 89%)                                  | 3.3           |
| <b>B (83% to 87%) – minimum for Core courses</b> | <b>3.00</b>   |
| B- (80% to 82%)                                  | 2.7           |
| C+ (77% to 79%)                                  | 2.3           |
| <b>C (73% to 77%) – minimum for Electives</b>    | <b>2.00</b>   |
| C- (70% to 72%)                                  | 1.7           |

**Penalties for Late Work:**

Missed in-class Activities can be made-up without penalty and are due at the start of the next class (4pm Monday). Journals less than 24 hours late will receive partial credit. Assignments turned in more than 24 hours late and missed quizzes receive NO credit.

**Feedback and Grading Timeline:**

We will endeavor to grade assignments as promptly as possible. In general, journals and quizzes will be graded and turned around within 24-48 hours. In class activities will generally be graded within one week, although this may take longer in some cases. Late assignments will not be subject to these grading turnaround times and will be graded before the end of the semester.

**Technical Support**

If you have any technical problems accessing [Blackboard](#) please e-mail [crtc@email.wustl.edu](mailto:crtc@email.wustl.edu). Note, this mailbox is not monitored in the evening or on weekends. If you need immediate help after hours please put a service request into <https://wusm.service-now.com>.

**CTSA Core Competencies for Master’s Degree Candidates**

The following Clinical and Translational Science Award (CTSA) competencies are met by this course.

**Core Thematic Areas****RESPONSIBLE CONDUCT OF RESEARCH COMPETENCIES****Clinical Research Ethics Competencies**

- Summarize the history of research abuses and the rationale for creating codes, regulations, and systems for protecting participants in clinical research that requires community input.
- Critique a clinical or translational research proposal for risks to human subjects.
- Explain the special issues that arise in research with vulnerable participants and the need for additional safeguards.
- Determine the need for a risk-benefit ratio that is in balance with the outcomes in clinical and translational research.
- Describe the elements of voluntary informed consent, including increasing knowledge about research, avoiding undue influence or coercion, and assuring the decision-making capacity of participants.
- Assure the need for privacy protection throughout all phases of a study.
- Assure the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
- Adhere to IRB application procedures.
- Explain how the structural arrangement of science and the research industry may influence the behavior of scientists and the production of scientific knowledge.

**Responsible Conduct of Research Competencies**

- Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research.
- Adhere to the procedures to report unprofessional behavior by colleagues who engage in misconduct in research.
- Implement procedures for the identification, prevention, and management of financial, intellectual, and employment conflicts of interests.

- Apply the rules and professional standards that govern the data collection, sharing, and protection throughout all phases of clinical and translational research.
- Apply elements of voluntary informed consent, of fostering understanding of information about clinical research, and for avoiding undue influence or coercion, and taking into consideration the decision-making capacity of participants.
- Explain the need for privacy protection and best practices for protecting privacy throughout all phases of a study.
- Explain the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
- Explain the function of the IRB.

## Course Policies

### Drop Dates:

If the occasion should arise that you want or need to drop this class, please see me first. You can drop for any reason during the course of the semester, however you may only receive a partial or no tuition reimbursement depending upon how far into the semester you drop the course. See the [Academic Calendar](#) for your program for specific dates and reimbursement policies. Note, late withdrawals will also appear on your transcript as a withdrawal.

### CRTC Academic Policy Guidelines:

Guidelines regarding CRTC course registration and enrollment, grades, tuition obligation, and academic leave are consolidated in the [CRTC Academic Policy Guidelines](#). Please take a moment to review this document.

### CRTC Guidelines for Academic and Non-Academic Transgressions:

By registering for this course you have agreed to the terms of the [CRTC Guidelines for Academic and Non-Academic Transgressions](#). If you have not already reviewed this policy, please be sure to before beginning any CRTC related coursework.

### Academic Integrity/Plagiarism:

- Academic dishonesty is a serious offense that may lead to probation, suspension, or dismissal from the University. One form of academic dishonesty is plagiarism – the use of an author's ideas, statements, or approaches without crediting the source. Academic dishonesty also includes such acts as cheating by copying information from another student. **Plagiarism and cheating are not acceptable.**
- Academic dishonesty will be reported to the Office of the Registrar for possible action. The coursemaster will make an academic judgment about the student's grade on that work and in that course. The CRTC process regarding academic dishonesty is described in the [CRTC Guidelines for Academic and Non-Academic Transgressions](#)

### Writing Assistance:

For additional help on your writing, consult the expert staff of [The Writing Center](#) in Olin Library (first floor). It can be enormously helpful to ask someone outside a course to read your essays and to provide feedback on strength of argument, clarity, organization, etc.

### Disability Resources:

Washington University is committed to providing accommodations and/or services to students with documented disabilities. Washington University's [Cornerstone: Center for Advanced Learning Disability Resources](#) is the University's official resource for students with disabilities and students with suspected disabilities. DR assists students with disabilities by providing guidance and accommodations to ensure equal access to our campus, both physically and academically. To learn more about its services, initiate the process of formal documentation

and/or to arrange for accommodations, please contact [Disability Resources](#) at the start of the course.

**Mental Health Resources:**

Mental Health Services' professional staff members work with students to resolve personal and interpersonal difficulties, many of which can affect the academic experience. These include conflicts with or worry about friends or family, concerns about eating or drinking patterns, and feelings of anxiety and depression. See: <http://shs.wustl.edu/MentalHealth>.

**Reporting Policies:**

Please also [review the CRTC website for policies](#) regarding sexual assault reporting and reporting concerns about bias, prejudice or discrimination.