

Ethical and Regulatory Issues in Clinical Research

Fall 2016

FLTC

Course Director: Stephanie Solomon Cargill solomon2@slu.edu

Teaching Assistant: Tim Rubbelke rubbelts@slu.edu

Office Hours: Monday 2-4

Course Description

This course prepares researchers to critically evaluate ethical and regulatory issues in clinical and translational research and make ethical decisions based upon them. The principal goals of this course are to prepare clinical and translational researchers to identify ethical issues in clinical research and the situational factors that give rise to them, to identify ethics and 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. By the end of the course, participants will:

- Understand the regulatory framework that governs human subjects research and the distinction between compliance and ethics
- Be able to identify major ethical concerns in the conduct of clinical research, including situational factors that may give rise to ethical concerns
- Be able to apply an ethical problem-solving model in clinical research

Grading

Grade Composition

Weekly Journal entries	30%
Attendance/Participation	15%
In-class Activities	40%
Quizzes	15%

Grading Scale

A+ (98%-100%)

A (93%-97%)

A- (90%-92%)

B+ (88% -89%)

B (83%-87%)

B- (80%-82%)

C+ (77%-79%)

C (73%-77%)

C- (70%-72%)

B GPA required for graduation

Textbook

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

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:

Home 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 turn-in: holds a folder where one member of your group will submit your In-class Activity sheet at the end of each class.

Journals: holds a link to all the journals for the class.

My Grades: a running account of your grades for the class.

Tools: other tools, like email and other functions, for Blackboard.

Journals

Option 1: Each student will choose **ONE** of the journal prompts for each class day (given on Blackboard) and write a 1-2 page, double-spaced written response to it. This Option will ask you to reflect on your personal experience with the topic of the week. The thoughts articulated in the response paper will contribute to the class discussion, which will touch on these topics.

Option 2: If you have not had personal experience with the topic of the week, you may choose one bulleted event from that week's "Weekend Reads" and follow the link and read it. Then write a 1.5 - 2 page, double-spaced written summary and response to it. NOTE: YOU CAN DO NO MORE THAN 3 OF THESE!!!

*Note: There are a couple of journals that also ask for a URL of a policy. This is REQUIRED in addition to whichever type of journal entry you choose.

- Submission: These should be submitted under "Journals" on Blackboard, or in the day's folder under the journal icon by 12am (midnight) the night before the class. Please copy and paste your response into the Journal box provided, DO NOT ATTACH AS A FILE.
- Partial credit: Incomplete assignments or assignments less than 24 hours late will receive partial credit. Assignments turned in more than 24 hours late receive NO credit.
- # of Required Journals: You may skip TWO of the journals without losing credit. This can be on the week you have a presentation, or when you miss a class, or any other time. Any missed reflection papers after two will cause you to lose points. If you do not miss two reflection papers, any extra will count for extra credit.

In-Class 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).
- If you miss class, you may do the Activity worksheet on your own and submit the write-up to Blackboard (“Make-up Activity turn-in” tab) for credit before the beginning of the class the next week.
- 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.

Participation and Attendance:

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.

You may miss 2 classes (for any reason) without penalty, after that it will affect your participation grade.

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 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.*

**Note: This does not make up for the impact these absences will make on your participation grade. You also cannot make up the quizzes.*

Quizzes:

At the **beginning** of each class day, I will administer a short True/False quiz over the readings due for that day. There are no makeups for the quizzes, but the points of two quizzes will count for extra credit (which could offset some lower quiz grades or those that you have missed.)

Personal Safety Escorts

The Protective Services Department provides escorts for employees and medical students by vehicle. Walking escorts are also available. An officer will transport in a vehicle or walk with the requesting party to campus garages or parking lots and from one building to another to insure their personal safety. Campus personnel should take advantage of the campus shuttle system for routine rides to their campus destinations. Vehicle escorts off-campus will only be conducted at the discretion of the on-duty Protective Services Supervisor. Response time for escorts will vary according to the number of Protective Services personnel on duty and the demand for services. The demand for escorts increases during winter months when darkness comes early and/or the weather is inclement. To request a personal safety escort, dial **314 362-4357**.

Disability policy

Washington University is committed to providing accommodations and/or services to students with documented disabilities. Students who are seeking support for a disability or a suspected disability should contact Disability Resources at 935-4153. Disability Resources is responsible for approving all disability-related accommodations for WU students, and students are responsible for providing faculty members with formal documentation of their approved accommodations at least two weeks prior to using those accommodations. I will accept Disability Resources VISA forms by email and personal delivery. If you have already been approved for accommodations, I request that you provide me with a copy of your VISA within the first two weeks of the semester.

Date	Topic	Readings
Class 1 8-29	Introduction to Research Ethics	S&R Ch.1 (1-9; 17-26) PR Wolpe “Reasons Scientists Avoid Thinking about Ethics”—Wolpe <i>Weekend Reads</i> http://retractionwatch.com/category/weekend-reads/
9-5	Labor Day	No Class
Class 2 9-12	Research Misconduct and Questionable Practices	S&R Ch. 2 (28-40; 46-48) Locate and skim Washington University Research Integrity Policy Weekend Reads
Class 3 9-19	Data Issues I: Analysis and Interpretation Speaker: Leslie McIntosh	Resnik, DB. “Statistics, Ethics, and Research: An Agenda for Education and Reform” Weekend Reads
Class 4 9-26	Data Issues II: Owning and sharing data Speaker: Jennifer Richards	S&R Ch. 8 (74-78; 100-117; 183-188) Locate and skim Washington University Intellectual Property Policy Weekend Reads
Class 5 10-3	Mentoring and Collaboration Speakers: Mentoring Panel	S&R Ch.4 (85-90; 96-99) Ch. 12: Making Collaborations Work http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch12.pdf Weekend Reads
Class 6 10-10	Data Issues III: Data Management and Information Security Speaker: Kevin Hardcastle Chief Information Security Officer WUSTL	Ch.8: Data Management and Laboratory Notebooks” <i>Making the Right Moves: A Practical Guide to Scientific Management</i> , Burroughs Wellcome Fund at http://www.hhmi.org/resources/labmanagement/downloads/moves2_ch8.pdf Wilson and Schreier et al. “Research Records and the Resolution of Misconduct Allegations at Research Universities” Weekend Reads
Class 7	Authorship and Peer Review	S&R Ch. 6-7 (122-131; 146-157)

10-17		Locate and skim Washington University Authorship Policy Weekend Reads
Class 8 10-24	Human Subjects Protections I: Speaker: Martha Jones HRPO	S&R Ch. 11 (236-263) The Belmont Report Weekend Reads
Class 9 10-31	Human Subjects Protections II: Voluntariness Informed Consent	S&R Ch. 11 (263-265) Hornig and Grady “Misunderstanding in Clinical Research” Applebaum et al. “Voluntariness of Consent to Research” Weekend Reads
Class 10 11-7	Human Subjects Protections III: Vulnerability and Special Populations	S&R Ch.11 (268-277) Levine et al. “The Limitations of Vulnerability” Weekend Reads
Class 11 11-14 (Cargill not there)	Conflicts of Interest and Commitment Speaker: Alan Fellers COI Manager	S&R Ch. 9 (194-205) WUSTL School of Medicine COI Policy at http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx Weekend Reads
Class 12 11-21	Genetic Research and Biological Samples	Cambon-Thompson (2004): “The social and ethical issues of post-genomic biobanks” Allen et al (2010) “Human Tissue Ownership and use in research: What laboratorians and researchers should know.” Weekend Reads
Class 13 11-28	Scientists as Responsible members of Society	S&R Ch.12 (283-297) Weekend Reads
Class 14 12-5	Research with communities	Holzer et al (2014): “Why We Need Community Engagement in Medical Research” Dickert & Sugarman (2005). “Ethical Goals of Community Consultation in Research.” Weekend Reads
Class 15 12-12	Response to Misconduct and Wrongdoing	S&R Ch.2 (40-46) Responding to Research Wrongdoing: A User-Friendly Guide http://www.ethicsresearch.com/images/RRW_7-17-10.pdf