Responsible Conduct of Scientific Research
BMS 670/EHT 675
Course Syllabus
Fall 2009
Wednesdays, 3:30-4:30 p.m.
Center for Medical Science 1st Floor Conference Room

INSTRUCTORS

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OFFICE HOURS:

By Appointment.

COURSE DESCRIPTION:

The course is designed to meeting current federal regulations, which require that all institutions receiving NIH training grants provide training in the responsible conduct of research. The purpose of this course is to engage students in reading, considering, and discussing the responsible conduct of scientific research.

COURSE PREREQUISITES:

None

COURSE FORMAT:

Course topics will be covered by a combination of one or more of the following elements: lectures, assigned readings in the course text ("Introduction to the Responsible Conduct of Research"), additional recommended readings provided by the instructors, assigned case studies, and discussion in class. The course will be structured around weekly 1hour seminar sessions. The first half of the session will be devoted to a discussion of the assigned readings and the ethical issues which they raise. The second half of the session will be devoted to discussing and applying those issues to the assigned case for the session.

COURSE REQUIREMENTS:

Attendance and participation in classroom discussion is mandatory and will provide the basis for credit. Grades are assigned on a "Satisfactory/Unsatisfactory" basis.

To receive credit for the course, each student will be expected to:

1) Lead at least one classroom discussion; and

2) Actively participate in all classroom discussions.

Although students are expected to attend all classes, we understand that emergencies can sometimes arise. Students who miss a class will be asked to write a short paper outlining a controversy or discussing an issue relevant to the responsible conduct of scientific research. The topic of the paper will be assigned by one of the course instructors. The length of the paper will increase exponentially for each class missed, for the first missed class, students will write a 2-page paper; for the second class, a 4-page paper; for the third class, an 8-page paper, etc. Students who fail to read the assigned materials and who attend class unprepared to fully participate also will be required to write a paper.

ONLINE TEXT: ORI Introduction to Responsible Conduct of Research
Nicholas H. Steneck Revised 2007

http://www.ori.hhs.gov/documents/rcrintro.pdf

Additional readings will be assigned by the instructors. All students are expected to review the assigned reading and cases prior to class. Students also are encouraged to independently research and review other cases and papers related to the weekly discussion topics.

SOME RECOMMENDED ON-LINE RESOURSES:

American Journal of Bioethics/ Bioethics Net:	http://bioethics.net/
Belmont Report:	http://ohsr.od.nih.gov/guidelines/belmont.html
Journal of Medical Ethics Online:	http://jme.bmjjournals.com/
Natl. Bioethics Advisory Committee:	http://georgetown.edu/research/nrcbl/nbac/
Office of Research Integrity:	http://ori.dhhs.gov/

TENTATIVE SCHEDULE:

NOTE: The course schedule or organization may be changed as necessary to better achieve the course objectives.

9/2		**RCR Course Objectives**	
	Topics	**Steneck Readings**	**Student Leader**
9/9	Research Misconduct	pp 1-29	
9/16	Data Management Practices	pp 86-101	
9/23	Mentoring and Trainee Responsibilities	pp 102-115	
9/30	Collaborative Research	pp 116-127	
10/7	Authorship and Publication	pp 132-145	
10/14	Peer Review	pp 146-157	
10/21	Conflicts of Interest	pp 66-81	
10/28	The Welfare of Laboratory Animals	pp 50-65	
11/4	The Protection of Human Subjects I	pp 32-49	
11/11	The Protection of Human Subjects II	pp 32--49	
11/18	Cross-Cultural Research	Assigned Readings	
12/2	Genetic Testing and Research	Assigned Readings	

ADDITIONAL READINGS:

9/2 Introduction to Course; Ethics and Decision-making

- What is ethics?
- Ethics and Morality
- Value of Ethics
- Ethical Relativism
- SUNY Albany Academic Honesty Guidelines

9/9 Research Misconduct

- Fixing Fraud
- BioTech Fraud
- NYSDOH APPM 633.4
- Misconduct Case 1
- Misconduct Case 2

9/16 Data Management Practices

- David Baltimore/Imanishi-Kari Case
- Patents_Technology Transfer
- Patents_Students
- Jessica Banks Case Study

9/23 Mentoring and Trainee Responsibilities

- Lelieveldt H. (2004) What (Not) to Expect From Your Supervisor
- Yaner_Graduate Student Mentoring
- Bob Bailey Case Study

9/30 Collaborative Research

- Wadsworth Center Materials Transfer Agreement Form
- Wadsworth Center Sample Collaboration Agreement Form
- Benowitz S. (2002) When Scientists Don't Share: Is Secrecy a Necessary Evil?

10/7 Authorship and Publication

- Nature Cell Biology: Reproducing Data
- Ghost Writers
- Charlie West Case Study
- Diane Archer Case Study

10/14 Peer Review

- Chemical and Engineering News Article on Peer Review 2/11/08

- Stem Cell Paper Retraction
- Students asked to review manuscript

10/21 Conflicts of Interest

- COI Reading 1
- COI Reading 2
- Jesse Gelsinger Case
- Levinsky NG. (2002) Nonfinancial Conflicts of Interest in Research.

10/28 The Welfare of Laboratory Animals

- Moral Status of Animals- British Broadcasting Corporation
- HUSU Statement on Animals in Biomedical Research

11/4 The Protection of Human Subjects I

- Belmont Report
- 45CFR46, the Common Rule
- Declaration of Helsinki Revisions
- Dead Son's Sperm Case

11/11 The Protection of Human Subjects II

- Informed Consent Documents
- McGuire Dunn
- Tuskegee Syphilis Study
- Milgram Experiment
- Stanford Prison Experiment

11/18 Cross-Cultural Research

- Wendler D, Emanuel EJ, and RK Lie. (2004) The Standard of Care Debate: Can Research in Developing Countries Be Both Ethical and Responsive to Those Countries' Health Needs?
- Trovan and Meningitis case study
- Ellen- Maternal viral transmission study case study

12/2 Genetic Testing and Research

- Arthur Caplan- "Peter Pan" Treatment 2007
- Arthur Caplan- Rebates for human eggs 2007
- Meslin EM, and KA Quaid. (2004) Ethical Issues in the Collection, Storage, and Research Use of Human Biological Materials
- New York State Civil Rights Law 79, Appendix L