

PROFESSIONAL and ETHICAL ISSUES IN BIOMEDICAL RESEARCH
Pharmacology 751
Autumn Quarter, 2010

Contents: Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues.

Prerequisites: graduate standing

Objectives: After completing this course the student will:

- have an understanding of the professional and ethical issues in biomedical research;
- have developed a rational approach for dealing with such issues;
- be familiar with the professional and University resources for addressing ethical issues; and
- be able to apply a reasoned approach when faced with an ethical dilemma.

Credits: Successful completion of this class will be rewarded with 2 graduate credits.

Meeting time/place: One two-hour class/week on Tuesdays from 4:00-6:00 pm.

Location: 1167 Graves Hall

Class Structure:

The course is discussion-based, with a small lecture component. Class participation is essential. Students are required to use Carmen to access course materials at <https://carmen.osu.edu>. The website will have supplementary reading material, sample cases, and a brief problem, questionnaire or scenario that will appear as a quiz (responses linked with names) or as a survey (names of respondents known, but responses not linked with individual names). The quiz or survey will be available for 5 days before the Tuesday class (Wed by 6pm – Sun at 11pm for all but the first class). Prior to each class, students are to read the materials and respond to the quiz if assigned.

Each class will include:

- an introduction by the faculty
- faculty-led discussion of the quiz results if applicable
- discussion of practice cases

Email Policy: The course faculty may communicate additional class information to students through the university email system and will use the email addresses assigned by the university (typically lastname.x@osu.edu) and provided by the registrar on the official class roster. **Students are responsible for checking their university email or for being certain that their university email is forwarded to their ISP.** "I didn't get the email" will not be an acceptable excuse.

Grading: The course is graded Satisfactory/Unsatisfactory.

To achieve a grade of "Satisfactory", students must accumulate 210 of 240 possible points.

Points are distributed as follows:

- 100 points for attendance (10 points/class; possible grades are 0 or 10)
- 90 points for on-line quizzes and surveys (10 points/quiz or survey; possible grades are 0 or 10)
- 50 points for class participation, which will be assigned by the faculty based on contributions to class discussion.

Faculty:	Prof. Rich H. Fertel 5073 Graves Hall 333 West Tenth Avenue	phone: 292-1587 e-mail: fertel.1@osu.edu
	Prof. Alan S. Litsky S-2035 Davis Research Center 480 West Ninth Avenue	phone: 293-4827 e-mail: litsky.1@osu.edu
	Prof. Lynne E. Olson 301 Goss Labs 1925 Coffey Road	phone: 292-9717 e-mail: olson.3@osu.edu

PROFESSIONAL and ETHICAL ISSUES IN BIOMEDICAL RESEARCH

Veterinary Biosciences 751

1 Graduate Credit Hour

First Term Summer Quarter, 2007

8-10am Fridays, 322 Goss Labs

Content: Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues.

Text: *Science and Ethics* by Bernard Rollin, supplemented by additional readings. I have purchased sufficient copies of the book for the class, which should arrive next week. You may borrow a copy (please don't mark in it) or purchase a copy at cost.

Prerequisites: graduate standing in a graduate program within the College of Veterinary Medicine or permission of the instructor

Objectives: After completing this course the student will:

- have an understanding of some the professional and ethical issues in biomedical research;
- have developed a rational approach for dealing with such issues;
- be familiar with some professional and University resources for addressing ethical and professional issues; and
- be able to apply a reasoned approach when faced with an ethical or professional dilemma.

Class Structure:

The course is discussion-based; therefore class participation is essential. Students are required to use Carmen (<http://www.carmen.osu.edu>) to access supplemental course materials and to respond to weekly assignments known as "Questions of the Week". Prior to each class, students are to read the materials and respond to the questions. There will be a "practice" Question of the Week that will be due before the first class; i.e. this one won't count towards the course requirements, but will give you experience using the quiz/survey function so that you are prepared for when they do count.

Grading: The course is graded Pass/Fail

To achieve a grade of "Pass", students must attend classes, participate in the discussions, and submit answers to the "Questions of the Week" beginning week 2. Students may miss two hours of class and two Questions of the Week without penalty or explanation. Missing more than two hours of class requires that the absence be deemed excusable by the course coordinator in order to receive a passing grade. Examples of excusable absences would include illness (self or child), a death in the family, attending a national meeting etc. Please plan your laboratory work accordingly.

Email Policy: The course coordinator may communicate additional class information to students through the university email system and will use the email addresses assigned by the university (typically lastname.x@osu.edu) and provided by the registrar on the official class roster. **Students are responsible for checking their university email or for being certain that their university email is forwarded to their ISP.** "I didn't get the email" will not be an acceptable excuse.

Faculty: Lynne E. Olson, PhD
Professor of Veterinary Biosciences
e-mail: olson.3@osu.edu
phone: 292-9717
350 Veterinary Medicine Academic Bldg.
1900 Coffey Road

PROFESSIONAL and ETHICAL ISSUES IN BIOMEDICAL RESEARCH
Pharmacology/Biomedical Engineering 751
Autumn Quarter, 2005

Contents: Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues.

Prerequisites: graduate standing

Objectives: After completing this course the student will:

- have an understanding of the professional and ethical issues in biomedical research;
- have developed a rational approach for dealing with such issues;
- be familiar with the professional and University resources for addressing ethical issues; and
- be able to apply a reasoned approach when faced with an ethical dilemma.

Credits: Successful completion of this class will be rewarded with 2 graduate credits.

Meeting time/place: One two-hour class/week on Tuesdays from 4:00-6:00 pm.

Location: 1167 Graves Hall

Class Structure:

The course is discussion-based, with a small lecture component. Class participation is essential. Students are required to use WebCT to access course materials at <https://enigma.optometry.ohio-state.edu/>. The website will have supplementary reading material, sample cases, and a brief problem, questionnaire or scenario that will appear as a quiz (responses linked with names) or as a survey (names of respondents known, but responses not linked with individual names). The quiz or survey will be available for 5 days before the Tuesday class (Wed by 6pm – Sun at 11pm). Prior to each class, students are to read the materials (if any) and respond to the quiz.

Each class will include:

- a brief introductory lecture by the faculty
- faculty-led discussion of the quiz results if applicable
- student-led discussion of practice cases (may be assigned to defend various view-points)
- student-led discussion of real cases (see below)

The class meeting during finals week will consist of student-led discussions of student-prepared scenarios. Each student is to compose a scenario, modeled after the cases discussed in class. The case must include a title and discussion questions and is to be submitted in electronic format by November 22 (email address for submission to be provided). Case summaries will be made available on-line and the class will vote on which cases to discuss on the final day of class. This will be your opportunity to explore specific issues in more detail, or to ask questions in a "case-based" fashion.

Discussion of real cases:

We have generated a list of cases of misconduct or other behaviors that have raised issues in the scientific community. Each student will select a case and each case will be selected by more than one student, creating a group. Group members will work together and be graded (**by faculty and by students**) as a group. Groups are expected to come to class prepared to lead a discussion regarding:

- the issues involved
- how the case was resolved
- consequences for parties involved in the case (if available)
- strategies that could be devised to minimize the chances of a repeat of the incident.

Groups will have 15-20 minutes for their presentation and **discussion**. Powerpoint presentations are encouraged, but are not required. Any presentation materials should be made available to the faculty in electronic format so they can be posted on the course WebCT site. The handout for the case can be used to track down additional materials as necessary.

Note: Real cases make difficult teaching material because they usually involve many issues and can be quite complex. However, we believe that it will be helpful for students to see how these cases play out in public.

Email Policy: The course faculty may communicate additional class information to students through the university email system and will use the email addresses assigned by the university (typically lastname.x@osu.edu) and provided by the registrar on the official class roster. **Students are responsible for checking their university email or for being certain that their university email is forwarded to their ISP.** "I didn't get the email" will not be an acceptable excuse.

PROFESSIONAL and ETHICAL ISSUES IN BIOMEDICAL RESEARCH

Neurosciences Graduate Program Seminar 797 Winter Quarter, 2004

Contents: Introduction to professional and ethical issues confronting biomedical research and researchers and approaches to dealing with such issues.

Prerequisites: graduate standing in the Neurosciences Graduate Program or permission of the instructor

Objectives: After completing this course the student will:

- have an understanding of some the professional and ethical issues in biomedical research;
- have developed a rational approach for dealing with such issues;
- be familiar with some professional and University resources for addressing ethical and professional issues; and
- be able to apply a reasoned approach when faced with an ethical or professional dilemma.

Credits: Successful completion of this class will be rewarded with 1 graduate credit.

Meeting time/place: One one-hour class/week on Wednesdays from 2:30 – 3:30 pm.

Location: 4078 Graves Hall (Neuroscience Conference Room)

Class Structure:

The course is discussion-based, with a small lecture component. Class participation is essential. Students are required to use WebCT to access course materials at <https://enigma.optometry.ohio-state.edu/>. The website will have introductory reading material, sample cases, and a brief problem, questionnaire or scenario that will appear as a quiz available through the "Question of the Week" icon. Each quiz will be available for 5 days before the Wednesday class, becoming available at 6pm on Thursday and closing at midnight on Monday. Prior to each class, students are to read the materials and respond to the quiz. There is no quiz for the first class, although there will be assigned reading – watch your mailbox.

Each class will include:

- a brief introductory lecture by the faculty
- faculty-facilitated discussion of the web cases, quiz results, and assigned readings

Grading: The course is graded Pass/Fail

February 25 Ethical issues involving human subjects research
Dr. Jeff Kuret

March 3 Disagreement, dispute, managing conflicts, whistle-blowing
Dr. Tony Brown and Dr. Firdaus Dhabhar

March 10 Stem cell research
Dr. Tom Boyd

**Vision Science 796: Ethics in Biomedical Research
Autumn 2010**

Instructor: Karla Zadnik, OD PhD

Course objectives:

- The student should finish the course with a general understanding of the issues surrounding the ethical conduct of science.
- The student should understand what constitutes scientific authorship.
- The student should be able to draft a protocol for research on human subjects.
- The student should have gained an ability to think about scientific conduct issues in an ethical decision-making way.

Required book: *The Immortal Life of Henrietta Lacks* by Rebecca Skloot

Date	Time	Lectures	Readings (to be distributed; subject to change at preceding class)
September 29	Wednesday 530-7pm 635 Fry	Human subjects concerns: historical perspectives	No reading
October 6	Wednesday Second floor Prior Health Sciences Library	Patient confidentiality; human subjects concerns	Gunsalus <i>Science</i> editorial; <i>Bad Blood</i> chapters; Hornblum's chapter from <i>Acres of Skin</i>
October 20	Wednesday 530-7pm Second floor Prior Health Sciences Library	Institutional Review Boards	OSU IRB materials 8/12/07 <i>Dispatch</i> article <i>NY Times</i> article <i>Wall Street Journal</i> article on Guatemala; 2009 <i>Time</i> article on HIV vaccine
October 27	Wednesday 530-7pm Second floor Prior Health Sciences Library	Scientific misconduct	OSU policy and procedures concerning research misconduct; Bird and Housman chapter; Bailar chapter; both from Elliott and Stern <i>Research Ethics</i>
November 3	Wednesday 530-7pm Second floor Prior Health Sciences Library	Race and ethnicity in research	Beecher article; <i>NY Times</i> article on 2008 Nobel Prize; <i>Science</i> articles on AIDS trials; <i>USA Today</i> AIDS vaccine
November 8	Monday 6-730pm Second floor Prior Health Sciences Library	Ethics in clinical research, eg, equipoise	Declaration of Helsinki; NIH policies on inclusion of women, minorities, and children
December 1	Wednesday 530-830pm Second floor Prior Health Sciences Library	Issues of authorship/conflict of interest ; issues of peer review	Jones article; McKneally article; Laskin editorial; Liesegang et al., article; <i>Annals of Internal Medicine</i> Vancouver requirements

Assignments and Examinations

Participation in discussions	All quarter	50% of grade
Ethical case study	Due November 8	20% of grade
Ethical case study paper	Due December 8 (final)	30% of grade

Office hours: By appointment (292-6603; zadnik.4@osu.edu; 580-7267 [cell phone])

NGSP/BME Research Ethics
RESPONSIBLE CODUCT IN NEUROSCIENCE RESEARCH
Neuroscience Graduate Studies Program
The Ohio State University

Questions to be Addressed & Cases to be Analyzed

Basic readings:

- Macrina, Francis L. *Scientific Integrity*, Third edition, ASM Press, 2005.
Murphy, Timothy F. *Case Studies in Biomedical Research Ethics*, The MIT Press, 2004.
Steneck, Nicholas H. *ORI Introduction to the Responsible Conduct of Research*, 2004.

Topic #1 Science, Research and Research Misconduct

Questions:

- 1) What's the crucial difference between "noise reduction" and data falsification?
- 2) What prompts researchers to commit fraud in scientific research? (Possible answers – competition for grades/honors/grants, the huge size of scientific enterprise, easy manipulation of digital images, etc.)
- 3) What are the short-term and long-term consequences of research misconduct?
- 4) What steps might be taken to prevent or reduce research misconduct?

Cases:

- Mark Houser's data falsification (research in primate cognition and behavior)
www.youtube.com/watch?v=S9R2P7fo7Bk
<http://news.sciencemag.org/scienceinsider/2010/08/harvard-dean-confirms-misconduct.html>
<http://harvardmagazine.com/breaking-news/harvard-dean-details-hauser-scientific-misconduct>
- Duplicating image data by a graduate student in the Neuroscience Program, UIUC
<http://ori.hhs.gov/misconduct/cases/Venters.shtml>
- The Herrmann-Brach Affair, 1997, Germany (manipulation of digital images)
www.nature.com/nm/wilma/v3n11.878588926.html
www.sciencemag.org/cgi/reprint/296/5574/1778b.pdf
www.sciencemag.org/cgi/content/full/277/5328/894
- Photo manipulation
An article in NY Times www.nytimes.com/2006/01/24/science/24frau.html?_r=2
Examples of inappropriate manipulation
(Presentation by Emma Hill, PhD, Executive Editor at JCB)
<https://nic.med.harvard.edu/Emma%20Hill.pdf>
- The Aftermath of Scientific Fraud *Cell*, 124 (5):873-875

Topic #2 Conflict of Interest

Questions:

- 1) Today, many researchers have financial interests in corporations that sponsor biomedical research. In which ways might these interests influence their decisions when conducting studies?
- 2) Conflicts of interest arise when researchers are in the position of making decisions that benefit them, but have negative consequences for their institutions or subjects. Is disclosure of financial interests always enough to protect against the worst effects of conflicts of interest?

Cases:

- Conflict scandal of Neuropsychopharmacology's chief, Charles Nemeroff
<http://www.the-scientist.com/news/home/24445/>
http://www.cjr.org/the_observatory/reprimanded_psychiatrist_bad_a.php

Topic #3 Mentoring

Questions:

- 1) What should you discuss and clarify with your mentor during your initial meeting, or before beginning work on a project? [Possible answers: short-term and long-term goals, what the mentor expects from the trainee, timelines for research, the border between private and professional matters, data access and data ownership, authorship, etc.]
- 2) What does a trainee expect from the mentor?
- 3) To whom should you turn when a serious mentor-trainee trouble arises?

Reference:

- "Mentoring Tool Kit" Brigham and Women's Hospital (with several links)
www.brighamandwomens.org/CFDD/MentoringToolkit/MentoringRelationship.aspx

Topic #4 Authorship and Publication

Questions:

- 1) Clarify who should be listed as first author, a coauthor or a senior author.
- 2) Is it appropriate to acknowledge a person (say, a leading expert in that field who did not actively participate in the project in question) as an author simply to please that person, to help you get promoted, or to avoid retaliation from him/her? Specify other cases of improper authorship, and clarify what does and does not qualify toward authorship.
- 3) In cases discussed in 2), how might a postdoctoral fellow or a junior faculty member respond to one's claim to being an author?

Cases:

- Authorship disputes

Strange, *Am J Physiol Cell Physiol* 295, 2008: C567-C575.

<http://ajpcell.physiology.org/cgi/content/full/295/3/C567>

Case analysis by a PI, an ethicist, a journal editor and a university ombudsperson

http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.1470170286102423077#sidebar

- Guest authorship supported by drug companies

Neurology Today 8 (14), 17 July 2008: 37-8.

http://journals.lww.com/neurotodayonline/Fulltext/2008/07170/Neurology_Journals_How_They_Hope_to_Discourage.16.aspx

Topic #5 Peer Review

Questions:

- 1) Who should *not* serve as a peer reviewer? [Conflict of interest, etc.]
- 2) When a peer reviewer unintentionally identifies the author, or when he/she finds in the submitted paper novel findings that could overturn his or her previously published data, or findings that could be used to benefit his or her own research, what are the proper ways of handling it?
- 2) Direct contact between the reviewer and the authors during the review process is usually forbidden. Why do you think this is so? What are the possible (direct and indirect) consequences of this breach of confidentiality?

Cases and references:

- A survey of researchers concerning their perceptions about ethical problems with journal peer review. Resnik DB et al. *Sci Eng Ethics*, September 2008, 14(3): 305-10.
www.ncbi.nlm.nih.gov/pmc/articles/PMC2642979/

- Nature's peer review debate

(List of complaints, scenarios from real cases, and editor's/reviewer's perspectives)

www.nature.com/nature/peerreview/debate/nature05006.html

www.nature.com/nature/peerreview/debate/index.html

Topic #6 Data Management and Ownership

Questions:

- 1) What are the proper ways of recording and storing data? Articulate how hard-copy/electronic evidence should be recorded and stored.
- 2) What do you need to know about appropriate methods to produce reliable data?

Cases:

- Data destruction scandal in Sweden
(Research on deficits in attention, motor control and perception)
<http://www.bmj.com/content/329/7457/72.1/reply>
- Voodoo Correlation in fMRI studies, or “the Salmon Study”
(Data collection and analysis)
http://www.pashler.com/Articles/Vul_etal_2008inpress.pdf
<http://prefrontal.org/blog/2009/09/the-story-behind-the-atlantic-salmon/>

Topic #7 Collaboration

Questions:

- 1) What considerations should researchers take into account when participating in multi-institutional clinical trials? Can they publish their findings, or should all the collected data be centralized?
- 2) What are the possible concerns of conducting collaborative projects carried out in different countries? Which country’s rules should be used, and what steps should be taken when researchers start and end a collaboration?

Cases and references:

- The Imanishi-Kari (or the Baltimore) Case
Professor Baltimore’s own analysis
www.issues.org/19.4/updated/baltimore.html
- ORI’s recommendations on good collaboration
http://ori.dhhs.gov/education/science_not_golden.shtml

Topic #8 Use of Human Subjects

Questions:

- 1) Why is informed consent so important today? What are the long-term consequences of not obtaining informed consent from potential research subjects?
- 2) What should potential subjects know about the proposed research and their protection?
- 3) Consider the cases in which risk outweighs benefit in neuroscience research involving human subjects.

Cases and References:

- Geron’s first ESC clinical trial for spinal cord injury
www.shepherd.org/news/releases/2010/10/shepherd-center-patient-treated-in-geron-clinical

- ProTECT III Clinical Trials Ethical Concerns
www.examiner.com/healthy-living-in-national/breakthrough-traumatic-brain-injury-treatment-part-3-protect-iii-clinical-trials-ethical-concerns
- Ethical Issues in Consenting Vulnerable Patients for Neuroscience Research
Labuzetta et al. *Journal of Psychopharmacology*, published online on January 21, 2010
<http://jop.sagepub.com/content/early/2010/01/21/0269881109349838.abstract>
- Deception of Subjects in Neuroscience
The Journal of Neuroscience 28(19), May 7, 2008:4841-4843
<http://www.jneurosci.org/cgi/reprint/28/19/4841.pdf>
- Emerging Ethical Issues in Neuroscience
Martha J. Farah, *Nature Neuroscience* 5(11), 2002: 1123-1129.

Topic #9 Animal Experiments

Questions:

- 1) **Where do you draw the line between permissible and impermissible animal experiments?**

Cases:

- Primate study at UCLA attacked by animal activists
http://www.sfn.org/index.aspx?pagename=guidelinespolicies_carstatement
- Pro-test for science at UCLA
<http://www.ucla-pro-test.org>
www.youtube.com/user/speakingofresearch#p/a/u/1/5RALTi42h0k
- OSU's reply to recent attack against its Spinal Cord Injury Program
<http://researchnews.osu.edu/archive/spinalreply.htm>
<http://researchnews.osu.edu/archive/olawok.htm>