G504 - INTRODUCTION TO RESEARCH ETHICS

Section: Course Director: Kimberly A. Quaid, Ph.D.
Time: Tuesday 3-4:40 p.m.
Place: Room 112 in the Nursing School Building
Office Phone: 278-4039 (Bioethics)
Email: @iupui.
Office hours: By appointment call 278-4039 (Bioethics)
Cross-listed as: MHHS M504 3065

Background: Beginning in 1990, the National Institutes of Health (NIH) required all pre-doctoral and postdoctoral trainees supported by training grants (T-32 grants) to receive formal training in the responsible conduct of research. This course was developed and offered for the first time in the fall of 1996 in order to meet the federal requirements for these trainees. Since that time, a number of schools and departments at IUPUI have chosen to require their graduate students to take this course. In December of 2000, the Office of Research Integrity (ORI) announced a new federal policy that all research staff on NIH-supported grants would be required to document formal training in research ethics. The original deadline was October 2003 for all research staff to have received a program of instruction. On February 5, 2001, the Bush Administration suspended the implementation policy. Implementation is now occurring on a piecemeal basis, (e.g. the current requirement for all key personnel on projects involving research with human subjects is to document training in human subjects research). However, there is a high likelihood that the policy will be implemented at some point in the future.

The course covers historical and contemporary issues related to scientific integrity and the responsible conduct of research including policies and procedures related to scientific misconduct, authorship and peer review, conflicts of interest, the use of humans and animals in biomedical research, international research and ethical issues related to genetic technology.

Purpose: One definition of the word “ethical” is “conforming to accepted standards, especially professional standards, of conduct.” The purpose of this class is not to inculcate virtue, nor to determine whether or not you are ethical; rather, the purpose is to inform you about the rules and the accepted standards of behavior and to help you develop skills for dealing with hard problems on your own. This is important because all too often there are no hard and fast rules for determining what is the proper thing to do. Standards of conduct may vary from community to community, or even from discipline to discipline. While students often find this fact frustrating, it also means that one must learn to think through these issues for oneself in order to develop a plan of action that is defensible to oneself in the event that one may have to explain it to others.

About the Course Director: I organized the course in 1995 and have taught in and directed the course since that time. I was the Executive Secretary for the Chair of the IUPUI Committee on Ethics in Research from 1995-1998 and was Chair of the Committee from 1998-2002. I am a psychologist by training and am currently a tenured Professor in the Department of Medical and Molecular Genetics as well as a Faculty Investigator of the IU Center for Bioethics established
in 2001. I am the Co-Director of the Masters Program in Genetic Counseling and direct the Predictive Testing Program which offers predictive genetic testing for individuals at risk for late onset autosomal dominant genetic diseases for which genes have been found including Huntington disease, early onset Alzheimer disease and Gerstmann-Straussler-Scheinker disease.

Degrees:
B.A. in Psychology, Brown University, Providence, RI
M.A. and Ph.D. in Psychology and Public Health, The Johns Hopkins University, Baltimore, MD

Course Goals: The goals are that at the end of this course, students will be able to:
1. Demonstrate the skills needed to solve problems involving relevant topic areas of the responsible conduct of research.
2. Clearly articulate both verbally and in writing ethical and legally acceptable solutions to problems that arise in the conduct of science.
3. Propose and critically analyze solutions to problems in the context of relevant written codes and unwritten conventions.
4. Develop an interest in and a positive attitude toward lifelong learning in matters of scientific integrity and the responsible conduct of their chosen profession.

Course Objective: The primary objective of this course is to provide graduate students, postdoctoral students, and faculty with skills and resources valuable for survival. The primary goals of this course are:
1. To refine and define expected standards of conduct.
2. To increase your confidence in dealing with difficult issues.
3. To meet current NIH requirements for formal training in research ethics.

Cheating and Plagiarism: Students are instructed to make themselves aware of University regulations concerning plagiarism, the maintenance of academic honesty and the definitions of unacceptable behavior and cheating. Academic misconduct of any sort will not be tolerated and will be dealt with as outlined in the IU/IUPUI Code of Student Rights, Responsibilities, and Conduct, which can be viewed at: //www.iupui.edu/code/

Examples of misconduct include but are not limited to:
1. Cheating
   A student must not use or attempt to use unauthorized assistance, materials, information, or study aids in any academic exercise
2. Fabrication
   A student must not falsify or invent any information or data in an academic exercise including, but not limited to, records or reports, laboratory results, and citations to the sources of information.
3. Plagiarism
   A student must not adopt or reproduce ideas, words, or statements of another person
without appropriate acknowledgment. A student must give credit to the originality of others and acknowledge an indebtedness whenever he or she does any of the following:

a. Quotes another person's actual words, either oral or written
b. Paraphrases another person's words, either oral or written
c. Uses another person's idea, opinion, or theory; or
d. Borrows facts, statistics, or other illustrative material, unless the information is common knowledge.

4. Interference
   a. A student must not steal, change, destroy, or impede another student's work.
   b. A student must not give or offer a bribe, promise favors, or make threats with the intention of affecting a grade or the evaluation of academic performance.

Potential consequences for academic misconduct:
If the instructor has information that one of his/her students committed an act of academic misconduct, the faculty member will hold an informal conference with the student. The conference will be prompt and private. If the faculty member concludes that the student is responsible for the misconduct, then the faculty member will impose an appropriate academic sanction (i.e., lower or failing grade on the assignment, assessing a lower or failing grade for the course).

Disability Accommodations: Students needing accommodations because of a disability will need to register with Adaptive Educational Services (AES) and complete the appropriate forms issued by AES before accommodations will be given. The AES office is located in Taylor Hall, UC 100. You can also reach the office by calling 274-3241.

Visit ://aes.iupui.edu/ for more information.

Texts:

Readings in addition to those in the Macrina text will be available through Oncourse under the Resources tab.

Grading:
This course may be taken either for a grade or Pass/Fail. If you wish to take the course Pass/Fail, you will need to register for this option with the registrar when you sign up for the course or during the first few weeks in class. The deadline for choosing the Pass/Fail option is September 6, 2015 at 5:00. If you do not register for this option, you will receive a grade.

In order to meet the needs of the various constituents on campus, this course can be taken for variable credit ranging from 2-3 credits. The expectations for each of these credit options are explained below. Attendance will be taken.

1. Two Credits
   Students who are taking this class for two credits are expected to attend and to
participate actively in all sessions. In addition there will be a paper, a take home mid-term and
take-home final. For those of you who wish to take the course for a grade, the grading for the
course is as follows:

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<th>Component</th>
<th>Percentage</th>
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<tr>
<td>Attendance/Class Participation</td>
<td>10%</td>
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<tr>
<td>Written Assignments</td>
<td>30%</td>
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<tr>
<td>Midterm</td>
<td>30%</td>
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<tr>
<td>Final Examination</td>
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2. Three Credits

Students who are taking this class for three credits are expected to attend and to
participate actively in all sessions. In addition to the written assignment, there will be a take
home mid-term, a take home final examination and a 10-12 page paper. Paper topics must be
approved by me by mid-semester. For those of you who wish to take the course for a grade, the
grading for the course is as follows:

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<tbody>
<tr>
<td>Attendance/Class Participation</td>
<td>10%</td>
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<tr>
<td>First Written Assignment</td>
<td>20%</td>
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<tr>
<td>Final Paper</td>
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<tr>
<td>Mid-term</td>
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<tr>
<td>Final Examination</td>
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Case Analysis: One way to learn to think through these issues is through case analysis.
Occasionally, we will be discussing various cases in class. Most will be short cases from your
book. For some days, depending on time, the last part of the class will consist of a discussion of
cases related to the topic of the day. You may be asked to break into groups to discuss the cases
amongst yourselves and then present your conclusions to the class in an organized manner.
When and if we break into groups, I suggest that each group choose one presenter to present the
case to the rest of the class and one recorder to take notes of the discussion.

Each case will be evaluated on the basis of the following criteria:
1. Identification of issues and points of conflict presented in the case.
2. Identification of interested parties
3. Identification of possible actions and consequences
4. Identification of obligations of interested parties
5. Conclusion and rationale: In other words, you must come to a conclusion regarding
what is the proper thing to do and justify your conclusion. This justification should refer
to specific moral principles (Dr. Schwartz’s lecture should be helpful), should be
logical, and should flow from your conclusion.

Written Assignments: All written assignments must be typed and must be handed in as a paper
copy on the day of class that the assignment is due. If there is a problem handing in a paper on
time, I must be informed of this fact prior to the due date for the paper. I know that you are all
busy and I try my best to be flexible. If, for some reason, you cannot hand in an assignment on
time, one letter grade will be subtracted for each day that the assignment is late. For the first
written assignment you can choose between I or II as described below.

**I. Topic-Oriented Project Due 10/22/13.**

Analysis of ethical issues

For this paper, I would like you to present and analyze an ethical issue in an area of scientific activity that is of particular interest to you in your own work. Examples might include ethical issues in public health, research with cognitively impaired subjects, research with children, research with human biological materials, genetic research on autopsy specimens, research with animals, disclosure of information obtained through research etc. The focus should be on the issues of professional ethics for scientists, researchers or health care professionals. Papers should be 5-7 pages in length excluding any references.

**II. Case Analysis Due 10/22/2013**

For this assignment, I would like you to write and analyze a scenario that poses a problem in one of the topics in research ethics covered in this class. Scenarios should be similar in length and format to those presented in your textbook at the end of each chapter, but should be your own work and, preferably, reflect some of your own experience. The scenarios should be suitable for discussion in class and if they are based in fact, should contain no identifying information. Your analysis can follow that presented in the Bebeau monograph or you may wish to ask questions that arise from your scenario and then answer the questions. Papers should be 5-7 pages in length excluding any references.

**III. Midterm Exam**

The midterm will be handed out October 1, 2013 and will be a take-home open book midterm to be handed in at the beginning of class on October 8, 2013. It will cover the first half of the class.

**IV. Final Exam**

The final exam will be a take-home open book final that is handed out on the last day of class which is December 3, 2013. You should complete the final on your own. That is to say that the final is not a group effort. A word to the wise: It is not a good thing to plagiarize answers to a final exam for a class in research ethics. In fact, you would all be advised to give the citation for your answers on the final. The final is due before noon on Tuesday December 10, 2013. Finals should be typed and handed in to me at my office, IB130, Room 159 or put in my mailbox in the Department of Medical and Molecular Genetics.
V. Final Paper

For those taking the class for three credits, a final paper is expected. You may look through the text for a particular topic in research ethics that interests you and may be especially relevant to your particular specialty or you may analyze a case that has been in the media. Unfortunately there is no dearth of examples. Possibilities might include the Jesse Gelsinger case, the South Korean stem cell debacle, genetic testing of children for late onset disorders, or the recent troubles at IU Bloomington. The paper should be 10-12 pages in length excluding references.

Please discuss the paper topic you have chosen with me prior to embarking on writing the paper. The paper is due any time before the last day of class which is December 3, 2013.

VI. Grading

Points will be added and the grade will be calculated based on the following percentages:

- A+ 100%
- A  93-99%
- A- 90-92%
- B+ 88-89%
- B  83-87%
- B- 80-82%
- C+ 78-79%
- C  73-77%
- C- 70-72%
- D+ 68-69%
- D  63-67%
- D- 60-62%
- F  <=59%

Week 1: 8/20/13 - General Orientation to Course

Speaker: Kimberly A. Quaid, Ph.D.
Professor, Department of Medical and Molecular Genetics
Faculty Investigator, Indiana University Center for Bioethics

Also, if you want to understand why anyone really cares about this stuff, I suggest the following: Go to: www.healtoronto.com/gallodocs.

Readings:

Read the Executive Summary. Robert Gallo is the scientist who claimed to have discovered the AIDS virus. As you might imagine, this was a really big deal in the science world. Gallo was accused of stealing the virus from a group of French scientists. Believe me, it is fascinating reading.

Walter Stewart and Ned Feder are the Click and Clack of research integrity. Drs. Stewart and Feder were NIH employees who took it as their sacred mission to ferret out research misconduct. In the process, they made many enemies and they were eventually ordered to cease these activities by NIH.
Week 2:  8/27/13 –
Speaker:  Peter H. Schwartz, M.D., Ph.D.
Associate Professor, Department of Philosophy
Faculty Investigator, Indiana University Center for Bioethics

Readings:
2.  The Belmont Report (Please include Link to the Belmont Report here)

Week 3:  9/3/2013– History of Science and Misconduct
Speaker:  William Schneider, Ph.D.
Professor, Department of History

Readings:

Week 4:  9/10/13– Scientific Misconduct: Current Definitions, Policies and Procedures -
Speaker:  Kimberly A. Quaid, Ph.D.
Professor, Department of Medical and Molecular Genetics
Faculty Investigator, Indiana University Center for Bioethics

Readings:

Week 5:  9/17/13 – Data Management and Authorship
Speaker:  Janice S. Blum, Ph.D.
Chancellor’s Professor, Microbiology and Immunology
Readings:

Week 6: 9/24/13 – Authorship, Collaboration, Publication and Reviewing Practices
Speaker: Kimberly A. Quaid, Ph.D.
Professor, Department of Medical and Molecular Genetics
Faculty Investigator, Indiana University Center for Bioethics

Readings:
1. Macrina FL Chapter 4: Authorship and Peer Review. In Scientific Integrity pages 61-90.

Week 7: 10/1/13 – Animal Use in Research
Speaker: Debra L. Hickman, DVM, MS, DACLAM
Director, Laboratory Animal Resource Center
Associate Research Professor, LARC
Adjunct Associate Research Professor, Dept. of Cellular and Integrative Physiology

Readings:

MIDTERM TO BE HANDED OUT DUE 10/8/2013

Week 8: 10/08/13 – Research with Cognitively Impaired Subjects
Speaker: Mary Guerriero Austrom, Ph.D.
Wesley P. Martin Professor of Alzheimer Disease Education
Department of Psychiatry
Director, Education Core
Alzheimer Disease Center

Readings:

**MIDTERM DUE**

**Week 9: October 15, 2013 FALL BREAK - NO CLASS**

**Week 10: 10/22/13 – Science, Industry and Conflict of Interest**

**Speakers:** Sherry Oswalt-Smith
IUPUI Conflict of Interest/Export Controls Manager
Angela Reese
IUPUI Conflict of Interest/Export Controls Specialist
Office of Research Administration

**Readings:**
1. Bradley SG Chapter 7: Managing Conflicting Interests in *Scientific Integrity* pages 159-186.

**First Paper Due TODAY!!!!!!!!!!**

**Week 11: 10/29/13- Ethical Issues in Research with Human Biological Materials**

**Speaker:** Kimberly A. Quaid, Ph.D.
Professor, Department of Medical and Molecular Genetics
Faculty Investigator, Indiana University Center for Bioethics

**Readings:**

**Week 12: 11/5/13 – Research with Children and Adolescents**

**Speaker:** Mary A. Ott, M.D.
Assistant Professor of Pediatrics  
Section of Adolescent Medicine  
Department of Pediatrics

Readings:

Cases for Discussion: 1. Adolescent Men and STI

Week 13: 11/12/13 – History of Research with Human Subjects  
Speaker: William Schneider, Ph.D.  
Professor, Department of History

Readings:

Week 14: 11/19/13 — International Research Ethics  
Speaker: Eric Meslin, Ph.D.  
Director, Indiana University Center for Bioethics  
Professor of Medicine, Medical and Molecular Genetics, and Philosophy  
Associate Dean for Bioethics

10
Readings: To Be Determined.

Week 15: 11/26/13 Compliance Considerations for Human Subjects Research: Overview of Regulations and IRBs
Speaker: Edye Taylor, JD, MA, CIP
Compliance Project Manager
IU Clinical Research Compliance Office

Readings:
4. Office of Human Research Protection http://www.hhs.gov/ohrp/ Familiarize yourself with this website

Week 16: 12/03/13

HAND OUT FINAL EXAMINATION DUE DECEMBER 10, 2013
FINAL PAPERS DUE

On-Line Resources on Research Ethics

://www.indiana.edu/~poynter/tre-onln.html#
://www.research.umn.edu/ethics/
://www.onlineethics.