



**Mel and Enid Zuckerman College of Public Health
University of Arizona**

Syllabus

EPID/CPH 651

**Bioethics, Regulations and Repercussions in Clinical Research
Fall Semester 2008**

Time:

Thursday afternoon, 3:30-5:30 p.m.

Location:

Drachman Hall, Room A127

Course Director:

Rebecca Dahl, RN, PhD
Director, Human Subjects Protection Program
1235 N. Mountain
P.O. Box 245137
(520) 626-5925
rdahl@email.arizona.edu

Office Hours:

By appointment

Course Description:

This course will present principals in bioethics and the application of those principles in clinical research. The course content will include; the history of research ethics, implications for performance of research with human subjects, responsible conduct and good clinical practice, ethics of genetic research, conduct of international research and basis information about the role of the investigator in research with vertebrate animals.

Course Prerequisites:

Permission of instructor

Course Learning Objectives:

At the end of the course, participants should be able to:

- ❑ Identify ethical, legal and social implications of research with human participants.
- ❑ Use the website for obtaining relevant information on regulations involving human subjects.
- ❑ Demonstrate problem-solving ability from information obtained during the course to research conducted with human subjects.
- ❑ Apply course information in the design, development, conduct and evaluation of research with human subjects.
- ❑ Apply theoretical approaches to current issues surrounding research with human subjects.
- ❑ Demonstrate basic knowledge regarding research with vertebrate animals and the interaction between animal and human subjects research.

Course Materials:

Course Text: *Ethics and regulation of clinical research*. Second edition. Robert J. Levine. New Haven and London: Yale University Press, 1988.

Recommended readings: on reserve at *E-Reserves*

Course Note: will be provided the day of the lecture.

Course Requirements:

Requirements include preparation of case study assignments and written take-home final examination. The take-home final exam will be distributed in class on December 4th and is due on December 11th at 12:00 p.m. Deliver it to Rebecca Dahl, Human Subjects Protection Program, 1235 N. Mountain, P.O. Box 245137. It may also be sent by electronic mail to rdahl@email.arizona.edu.

Grading Policies:

Oral/written case study assignments: 30% (if written paper and presentation notes are not turned in within one week of the case study presentation, the grade will be lowered by one full grade) Class participation: 30%; Final Exam: 40%. Final grades are based on the following point scale:

- A = 90–100%
- B = 80-89%
- C = 70-79%
- D = 60-69%
- E < 60%

Class Attendance/Participation:

Weekly class attendance and participation in discussion required. All holidays or special events observed by organized religions will be honored for those students who show affiliation with that particular religion.

Course Schedule:

Dates	Class Content	Cases
Readings for Class (<i>to be read prior to class</i>)	Introduction to the Course Course Requirements: <ul style="list-style-type: none">• Weekly preparation• Weekly reading• Take home exam	Case Studies – to be presented following each regular lecture unless otherwise indicated
August 28 th - (Week 1) Reading: Levine, Chapter 1 Emmanuel, E.H., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? <u>Journal of the American Medical Association, 283</u> , 2701-2711. U.S. Public Health Service (1973). <u>Final report of the Tuskegee syphilis study ad hoc advisory panel</u> . Washington, DC: Author	Lecture: Historical Perspectives Discussion: Historical accounts of research	Case Study: Walter Reed – Yellow Fever Experiment
September 4 th – (Week 2) Reading: Levine, Chapter 7 Annas, G.J. (2002). Medical privacy and medical research – judging the new federal regulations. <u>New England Journal of Medicine, 346</u> (3), 216-220. Melton, G. B. (1990). Brief research report: Certificate of confidentiality under the	Lecture: Privacy, Confidentiality, & HIPAA Discussion: HIPAA – privacy regulations	Case Study: Oregon Health and Sciences Center – Privacy and High School Athletes

<p>Public Health Service Act: Strong protection but not enough. <u>Violence and Victims</u>, 5(1), 67-70.</p>		
<p>September 11th – (Week 3)</p> <p>Reading: Groeger, J. & Barnes, M. (2003). Conflict of interest in human subject research. <u>Critical Care Medicine</u>, 31(3), 137-142.</p> <p>Wechsler, J. (May, 2003). Subject protection is goal of draft guidance on conflicts of interest. <u>Applied Clinical Trials</u>, 26-28.</p> <p>Morin, K., Rakatansky, H. Riddick, F., Morse, L., O'Bannon, J., Goldrich, M., Ray, P., Weiss, M., Sade, R., & Spillman, M. (2002). Managing conflicts of interest in the conduct of clinical trials. <u>The Journal of the American Medical Association</u>, 287(1), 78-84.</p>	<p>Lecture: Financial Conflict of Interest</p> <p>Guest Lecture</p>	<p>Case Study: Jesse Gelsinger - Gene Transfer</p>
<p>September 18th – (Week 4)</p> <p>Reading: http://www.ahsc.arizona.edu/uac/notes/classes/LAWS00/Lr02.html</p> <p>http://www.ahsc.arizona.edu/uac/notes/classes/IACUC01/IACUCrole.html</p> <p>Wilson-Saunders, S. Animal rights: A bioethical approach to our relationship with animals. 1-15.</p>	<p>Lecture: Research and Vertebrate Animals</p> <p>Guest Speaker</p>	<p>Guest lecture will occur as scheduled</p>
<p>September 25th – (Week 5)</p> <p>Reading:</p>	<p>Lecture: Protecting Individuals Categorized as Vulnerable</p>	<p>Case Study: Willowbrook - Hepatitis Research</p>

<p>Levine, Chapters 10 and 13</p> <p>Jonsen, A. (2006) Nontherapeutic research with children: The Ramsey versus McCormick debate. <u>The Journal of Pediatrics</u>, 149(1), 12-14.</p> <p>Ross, L. (2006). Phase I research and the meaning of direct benefit. <u>The Journal of Pediatrics</u>, 149(1), 20-24.</p> <p>Reading: Levine, Chapter 11</p> <p>Cherniack, E. (2001). Informed consent for medical research by the elderly. <u>Experimental Aging Research</u>, 28, 183-198.</p> <p>Wendler, D. (2005). Protecting Subjects who cannot give consent. <u>Hastings Center Report</u>, 35(5), 37-43.</p>	<p>Discussion: Children in special situations</p> <p>Research involving adults with diminished capacity to consent</p>	<p>Case Study: Jewish Chronic Disease Hospital</p>
<p>October 2nd – (Week 6)</p> <p>Reading: Levine, Chapter 3</p>	<p>Lecture: Recognizing Risk, Maximizing Benefit</p> <p>Discussion: Investigator perception of risk</p>	<p>Case Study: University of Rochester and Hoiyan Wan</p>
<p>October 9th – (Week 7)</p> <p>Reading: Levine, Chapter 14</p> <p>Steinbrook, R. (2002). Improving protection for research subjects. <u>New England Journal of Medicine</u>, 346(18), 1425-1430.</p>	<p>Lecture: Institutional Review Boards</p> <p>Discussion: Overview of the process</p>	<p>Case Study: John Hopkins - IRB and Hexamethonium Research</p>

<p>Slater, E.E. (2002). IRB reform. <u>New England Journal of Medicine</u>, 346(18), 1402-1404.</p>		
<p>October 16th – (Week 8)</p> <p>Reading: FDA Audit Manual (Handout)</p>	<p>Lecture: The FDA Audit and Findings of Noncompliance</p> <p>Discussion: The requirement to report</p>	<p>Case Study: Oklahoma - Melanoma</p>
<p>October 23rd – (Week 9)</p> <p>Reading: Clayton, E. (2003). Ethical, legal, and social implications of genomic medicine. <u>New England Journal of Medicine</u>, 349(6), 562-569.</p> <p>Dettweiler, U., & Simon, P. (2001). Points to consider for ethics committees in human gene therapy trials. <u>Bioethics</u>, 15(5/6), 491-500.</p>	<p>Lecture: Role of Specimens and Genetics in Research</p> <p>Discussion: Rights of the subject</p>	<p>Case Study: Mo – Cell Line</p>
<p>October 30th (Week 10)</p> <p>Reading: Levine, Chapter 9</p> <p>Boman, J. & Jevne, R. (2000). Pearls, pith, and provocation: Ethical evaluation in qualitative research. <u>Qualitative Health Research</u>, 10(4), 547-554.</p> <p>Clarke, S. (1999). Justifying deception in social science research. <u>Journal of Applied Philosophy</u>, 16(2), 151-166.</p> <p>Oakes, J.M. (2002). Risks and wrongs in social science research.</p>	<p>Lecture: Ethics and Social Science Research</p> <p>Discussion: Deception in research</p>	<p>Case Study: Laud Humphreys – Tearoom Study</p>

<u>Evaluation Review, 26(5), 443-479.</u>		
November 6 th – (Week 11) Reading: Levine, Chapter 2	Lecture: Research and Human Subjects Discussion: Translating principals into practice	Case Study: Current Case Studies
November 13 th – (Week 12) Reading: Dresser, R. (2001). Defining misconduct: Will we know it when we see it? <u>Hastings Center Report, 31(3), 31-32.</u> Neal, J.M., & Rathmell, J.P. (2006). Scientific Misconduct. <u>Regional Anesthesia and Pain Medicine, 31(4), 294-295.</u> Pascal, C.B. (2006). Complainant Issues in research misconduct: The office of research integrity experience. <u>Experimental Biology and Medicine, 231, 2164-1270.</u>	Lecture: Research Misconduct Discussion: Faculty misconduct	Case Study: Robert Fiddes, M.D. and Fraud
November 20 th – (Week 13) Reading: Levine, Chapter 5	Lecture: Informed Consent Discussion: Waiving of informed consent	Case Study: Havasupai – Use of Specimens
November 27 th – (Week 14) No Class - Thanksgiving		
December 4 th – (Week 15) Reading: Jansen, L.A. (2005). A closer look at the bad deal trial: Beyond clinical equipoise. <u>Hastings Center Report, 35(5), 29-36.</u>	Lecture: Ethics and Clinical Trial Design Discussion: Research and treatment	Case Study: Propulsid – Infant Death

<p>Silverman, H., Miller, M.A., & Franklin, G. (2004). Control group selection in critical care randomized controlled trials evaluating interventional strategies: An ethical assessment. <u>Critical Care Medicine</u>, 32(3), 852-857.</p>		
<p>December 11th</p>	<p>Final Exam Due</p>	

Communications:

You are responsible for reading emails sent to your UA account from your professor and the announcements that are placed on the course web site. Information about readings, news events, your grades, assignments and other course related topics may be communicated to you with these electronic methods. The official policy can be found at: <http://www.registrar.arizona.edu/emailpolicy.htm>

Policy on academic integrity:

Students are expected to abide by the University of Arizona Code of Academic Integrity found at <http://w3.arizona.edu/~studpubs/policies/cacaint.htm>.

Classroom Behavior:

(Statement of expected behavior and respectful exchange of ideas)
 Students are expected to be familiar with the UA Policy on Disruptive Behavior in an Instructional Setting found at <http://web.arizona.edu/~policy/disruptive.pdf> and the Policy on Threatening Behavior by Students found at <http://web.arizona.edu/~policy/threatening.pdf>

Grievance Policy:

Should a student feel he or she has been treated unfairly, there are a number of resources available. With few exceptions, students should first attempt to resolve difficulties informally by bringing those concerns directly to the person responsible for the action, or with the student's graduate advisor, Assistant Dean for Student and Alumni Affairs, department head, or the immediate supervisor of the person responsible for the action. If the problem cannot be resolved informally, the student may file a formal grievance using the [Graduate College Grievance Policy](http://grad.arizona.edu/catalog/policies/academic-policies/grievance-policy) found at <http://grad.arizona.edu/catalog/policies/academic-policies/grievance-policy>

Disability Accommodation:

If you anticipate issues related to the format or requirements of this course, please meet with me. I would like us to discuss ways to ensure your full participation in the course. If you determine that formal, disability-related accommodations are necessary, it is very important that you be registered with Disability Resources (621-3268; drc.arizona.edu) and notify me of your eligibility for reasonable accommodations. We can then plan how best to coordinate your accommodations. The official policy can be found at: <http://catalog.arizona.edu/2008%2D09/policies/disability.htm>

Academic Integrity: All UA students are responsible for upholding the University of Arizona Code of Academic Integrity, available through the office of the Dean of Students and online: The official policy found at: <http://dos.web.arizona.edu/uapolicies/scc5308abcd.html> and <http://dos.web.arizona.edu/uapolicies/cai1.html>.

Grade Appeal Policy:

<http://catalog.arizona.edu/2008%2D09/policies/gradappeal.htm>

Syllabus Changes:

Information contained in the course syllabus, other than the grade and absence policies, may be subject to change with reasonable advance notice, as deemed appropriate.

Plagiarism: What counts as plagiarism?

- Copying and pasting information from a web site or another source, and then revising it so that it sounds like your original idea.
- Doing an assignment/essay/take home test with a friend and then handing in separate assignments that contain the same ideas, language, phrases, etc.
- Quoting a passage without quotation marks or citations, so that it looks like your own.
- Paraphrasing a passage without citing it, so that it looks like your own.
- Hiring another person to do your work for you, or purchasing a paper through any of the on- or off-line sources.