

HAMLIN UNIVERSITY SCHOOL OF LAW

Bioethics & Law

Spring 2013

Professor Thaddeus Pope

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Time: Sundays, 9:20 to 11:30 a.m.

Place: Law Room 105

Midterm Exam: 48-hour “take home” anytime between February 24 and March 2

Final Exam: 72-hour “take home” anytime during the exam period

I. Course Description

Developments in biotechnology and the life sciences have thrown into question existing policy approaches and instruments dealing with a vast array of topics in healthcare. Bioethics focuses on these unsettled questions at the margin. It is a very broad field, covering issues such as: the definition of death, end-of-life decisions, reproduction, and privacy. This law school offers separate courses on Genetics, Medical Decisions at the End of Life, Assisted Reproductive Technologies, and Public Health. Accordingly, this course will focus on areas of bioethics not already covered in other courses.

In this course, we will focus on three issues: (1) human subjects research, (2) the allocation of human organs, and (3) healthcare rationing. The problems tackled in this course are interesting and current. The course will provide you with the opportunity to observe the legal system’s response to novel and important issues of great public interest. You not only will learn some substantive law but also will gain a greater appreciation for the operation of legal process, as you see how the system attempts to come to grips with novel and complex issues.

II. Course Objectives

Upon completion of the course, students will have:

- A. A basic systematic understanding of the legal principles and rules governing:
 - 1. The federal regulation of human subject research
 - 2. The allocation of transplantable human organs
 - 3. The rationing of healthcare resources
- B. Improved skills and greater experience reading, interpreting, and applying administrative regulations
- C. Competence articulating cogent arguments using core principles of bioethics
- D. Further honed legal analysis and writing abilities, through:
 - 1. Exposure to and critique of legal arguments in judicial opinions, legislative reports, and scholarly writing
 - 2. Participation in classroom discussion and group-based exercises
 - 3. Completion of and feedback on weekly problems
 - 4. Completion of and feedback on a written midterm examination
 - 5. Completion of and feedback on a written final examination
- E. Integration of material learned in other classes, especially administrative law, constitutional law, and torts

III. Required Materials

- A. There is no casebook for this course. All course materials will be distributed through the course TWEN site. I recommend that you download these documents in PDF instead of opening and reading them in HTML. Alternatively, by using citations of the sources on TWEN, you can obtain almost all course materials directly through Westlaw or Lexis, should you want to use their dedicated printers. However, using such printing resources probably will not work for the small minority of course materials that are comprised of medical journals, reports, and PACER documents.
- B. While we will use a fair number of traditional appellate court opinions, a substantial portion of the course materials will be comprised of: statutes, regulations, government reports, and academic law and policy articles.

- C. Due to the rapid and current changes in this area, other materials may be added or substituted.

IV. **Class Schedule**

- A. The class will meet on Sundays from 9:20 to 11:30 a.m. in Law Room 105.
- B. No class: The class will meet thirteen times. But the class will **not** meet in-person on the following four Sundays: January 27 due to a conference conflict; February 17 due to a university holiday; March 10 due to implementation of the program-wide distance learning format; and March 31 due to Spring Break. The first class meets on January 13. The last class meets on April 21.
- C. Online Class: Two class sessions will be offered in an asynchronous online format: January 27 and March 10. This means that you will be able to “attend” these two sessions from wherever you have Internet access.
- D. Review Class: Depending on class interest, I am happy to schedule an extra “review” class during the weeks before the final exam. Please email your questions to me at least 24 hours before such session to better enable me to answer them. I am also happy to meet, at any time during the semester, both with individual students in my office, and with small groups. For example, last year, several students found it useful to review essays that they wrote on extra practice problems.

V. **What to Do First -- in January**

- A. Register for the TWEN site with the email address that you use most regularly.
- B. If you have not used TWEN before, review the student user guide.
- C. Read the initial class assignments posted on the TWEN site.
- D. Calendar key course dates into your planning and calendaring systems.
- E. Review the instructions for my Spring 2012 and Fall 2012 final exams (available at www.thaddeuspope.com).

VI. **Attendance, Preparation, and Participation**

- A. Attendance: Under American Bar Association rules, 80% attendance is required to allow you to write the final exam. Attendance will be taken by passing class lists for signature at the start of each class session.

- B. Class Preparation: I employ only a moderate amount of lecture but lots of case method and problem method questions and problems. Consequently, students must come to class prepared to discuss the material assigned. All assigned cases should be read and briefed. It is useful to analyze each case using the following headings: (i) essential substantive facts, (ii) procedural posture, (iii) issues, (iv) legal principles, (v) reasoning, and (vi) holding. You do not need to know the correct answer (if there is one), but know the reading material and make a reasonable effort to think about the issues raised.
- C. Preparation Time: It is impossible to say exactly how much time you will need for class preparation, since each person's needs are different. But it is likely that you will need around **six hours** of preparation for each class. This includes: reading the materials, briefing the cases, consolidating prior notes, and taking the weekly quiz.
- D. Warning about Class Preparation: Brief the cases **yourself**. Do not make use of commercially prepared outlines before writing your own brief. As Professor DeWolf (at Gonzaga Law) explains, "they are like narcotics. Initially they make you feel good (by taking away your anxiety), but precisely for that reason they have a corrosive effect upon your learning. It is as though you were taking violin lessons, and instead of playing the scales you were assigned by your teacher, you bought a tape of Itzak Perlman playing those scales."
- E. Class Participation: **All** students are expected to participate in class discussions. Sometimes this will be through "clickers" like PollAnywhere. Other times, it will be by "cold calling." If illness or emergency prevents you from being fully prepared, please notify me **before** class. As explained in Section X below, 10% of your course grade is based on class participation.
- F. Meandering Discussion: I want to leave discussion sufficiently free so that you discover key points on your own and feel ownership in lessons learned. Still, I must exert control over class discussion to ensure that you are exposed to key points and to ensure that you are not confused by a discussion that runs too long or too tangentially. It is inappropriate and unfair to hold scores of students hostage to the too-peculiar (even if brilliant) line of inquiry of just one or two students. If we did not get to them, I am happy to explore your questions outside class in any of the ways described in section XIII below.
- G. Laptops: I will use an instant-poll tool (probably PollAnywhere) in which the entire class "votes" on the answers to orally-posed problems through a browser-supported template. Accordingly, laptops are welcome. If you do not bring a laptop, I expect that you can "vote" either through a neighbor's laptop (after refreshing the browser) or through your cell phone. After clicking-in, students will discuss their answers in small groups and then re-vote. Only then will we review the problems.

- H. TWEN Participation: Students are encouraged to participate not only in class but also through the TWEN discussion boards. Start a new thread or comment on one already in progress. The best posts: (i) are full of insight and analysis (critical thinking), (ii) reference the course materials, and (iii) are clearly written (organization & style).
- I. Volunteering: I will frequently ask a question that stumps the person whom I have called on. I will give that person time to think about the question, and see if they can come up with an answer. It will sometimes happen that you have an answer, and instinctively raise your hand to volunteer. I may or may not call on you at that moment. I would prefer your attempt to answer than mine, but best of all is to continue dialogue with the student who was initially called on. Nonetheless, to move things along I may let the volunteer help. Please be sensitive to the fact that the student who is called on often suffers from stage fright, and the most obvious things slip from their mind.
- J. Ask Questions: I will begin each class by asking for both administrative and substantive questions. If you want to know what pages we will cover, please ask. If you are having trouble grasping a particular doctrine, please ask. Alternatively, send an email or start a discussion thread on TWEN.
- K. Show & Tell: The topics in this class are constantly in the news and in the plot lines of movies and broadcast shows. If you notice a story that illustrates or discusses a class topic, please send me an email or start a discussion thread on TWEN. It is both fun and rewarding to work through legal problems in the context of a visually compelling, dramatic clip.
- L. Outlining: The traditional method of exam preparation for law students involves making an outline of all course material. After every unit of material (*e.g.* human subjects research), but at least every two weeks, you should review and consolidate your case notes, class notes, and other material into an outline, flowchart, or other document. Furthermore, you should aim to edit and revise this growing document every time you add to it, both to improve the organization and to clarify the content. In short, the more **actively** you engage the materials, the better your grasp and retention will be.

VII. Classroom Etiquette

- A. The classroom environment must be conducive to learning for all students. Distractions made possible by advances in technology may undermine that goal.
- B. Audial: During class, in addition to the usual courtesies, kindly disable and refrain from using cell phones, pagers, and any other communication device other than your laptop computer. And please mute your laptop.

- C. Visual: Please refrain from displaying wallpaper, screen savers, or other material on your laptop computer that you can reasonably expect to be offensive or distracting to other students.
- D. End Time: I will be diligent about starting the class precisely at 9:20 and ending it precisely at 11:30. In return, please do not begin to pack-up early while others are still trying to be engaged in the class discourse.

VIII. Grading

- A. Weekly Quizzes (20%) – see section IX
- B. Class Participation (5%) – see section X
- C. Midterm Exam (25%) – see section XII
- D. Final Exam (50%) – see section XIII
- E. To make my calculations more objective and transparent, I convert all the above percentages into points. There are a total of 300 points for the course. The final exam is worth 150 points. The Midterm exam is worth 75 points. The weekly quizzes are worth a total of 60 points. Class participation is worth 15 points. Grading methods are more fully explained in the next four sections.

IX. Required Weekly Quizzes

- A. Rationale: I will assign weekly quizzes for three reasons. First, while I will provide informal, oral feedback during class discussions, I do not want the first **formal** feedback that you receive to be your graded midterm or final exam. Second, I want you to approach the material **actively**. Third, because later topics in this course build on and interrelate to earlier ones, I want to provide some external motivation to stay current.
- B. Format: Some quizzes will be comprised of three multiple choice questions. Others will entail drafting a roughly 250-word essay. These (along with the midterm) constitute “formative assessment,” while the final exam constitutes “summative assessment.”
- C. Due Date: You will complete the quizzes before class on the course TWEN site. I will announce and post the quizzes on most Sundays. They will be due before class the following Sunday. I will review the quiz in Sunday’s class or post a feedback memo. The immediately upcoming assignments (readings, quizzes) will always be posted on the TWEN home page.

- D. Coverage: These weekly quizzes are primarily meant to test basic understanding of legal principles covered at about the time of the quiz. They are simpler than questions on the midterm and final exams that require more analysis.
- E. Grading: I will grade the quizzes. The ten quizzes, in the cumulative, comprise 20% of your total course grade (60 of 300 points). Each quiz is worth 2% of your total course grade (6 of 300 points).
- F. TWEN: Many students have found it useful to approach the multiple choice question quizzes in this manner: (i) open and print the quiz, (ii) answer the questions “offline,” and then (iii) log-in and submit their answers. The short essay quizzes should be submitted as Word or PDF files in TWEN’s “Assignment Drop Box,” rather than by using the “Quiz” protocol. If you ever have a technical problem, just email me your quiz answers.

X. Class Participation

- A. Class participation comprises 5% of your course grade, 15 of the 300 total course points.
- B. The typical student who regularly meaningfully participates will earn all 15 points. Those who are unprepared or frequently absent will earn either half or none of these points.

XI. Midterm Exam

- A. Date: The midterm exam is a self-scheduled “take home” that you can download and complete during any 48-hour period anytime between 4:00 p.m. on Sunday, February 24 and 11:00 p.m. on Saturday, March 2. Specific instructions for downloading the exam and uploading your answers will be distributed by February 22 and will be reviewed in-class on February 24.
- B. Weight: The midterm exam comprises 25% of your course grade, 75 of the 300 total course points.
- C. Length: You will have a generous 48-hour period in which to outline, write, proofread, and polish your midterm exam. But you hardly need to use all this time. The exam is designed to be completed within just two hours.
- D. Grades: The only letter grade for this course is the final course “letter” grade based on the total 300 points. Nevertheless, to enable you to gauge your relative performance, I will assign letter grades to the midterm exams. While the numeric scores compute into the “course” grade (75 of 300 points), midterm letter grades are informational only.

- E. Everything else about the midterm exam is the same as the final exam.

XII. Final Exam

- A. Date: The final exam is a take-home that you may download and complete during any 72-hours within the exam period.
- B. Weight: The final exam comprises 50% of your course grade, 150 of the 300 total course points.
- C. Format and Length: The final examination will be comprised of three roughly equal parts. This three-part structure has been proven to maximize an exam's reliability and validity.
1. The first part will include multiple choice questions (roughly 25 questions).
 2. The second part will include short or "directed" essay questions (roughly two questions) focused on one or two specific issues.
 3. The third part will include a long essay problem. The essays are essentially hypothetical factual circumstances in which you will be expected to: (i) identify the legal issues, (ii) analyze the problems by applying the correct legal principles to the facts, and (iii) argue for a reasonable conclusion.
- D. Coverage: The exam will test those concepts and issues either covered in assigned readings or explored during class lectures and discussions. The exam will roughly reflect the relative time and emphasis devoted to topics in the course. For example, malpractice will be tested more heavily than licensure.
- E. Open Book: On the exam, you will be allowed to use any written or printed materials that you choose. But no consultation or discussion with any other person is permitted.
- F. Warning about Open Book: Having your notes and materials will **not** relieve you of the need to already know the material. Indeed, it is very probable that if you do not study for this exam **exactly** as you would for a closed-book exam, then you will do very poorly and perhaps not pass.
- G. Grading: All exams will receive a raw score from zero to 150. The raw score is meaningful only relative to the raw score of the other students in the class. The raw score will be added to the midterm and quiz scores. That total will then be converted to a scaled score, based on the class curve. For example, if the highest raw score in the class were 240/300, then that student would receive an A. The final grades will comport with Law School's grading policies.

- H. Grading Criteria: I have posted six years of my *Health Law* midterm and final exams and exam feedback memos to twww.thaddeuspope.com. These exams (especially before 2007) had a different coverage than we will have in this course. Indeed, the coverage in none of these prior classes will be identical to yours. Your exams will be **based only** on what we cover in this class. Still, by working through these old exams, you can get a good sense of the criteria that I employ in grading. In short, I look for:
1. An ability to muster relevant evidence and authority to make arguments both cogently and clearly
 2. An understanding of substantive legal doctrine
 3. An appreciation for broader policy concerns that influence how legal doctrine applies to novel situations
- I. Exam Feedback: Several weeks after the exam, I will post on the TWEN site: (i) a copy of the exam, (ii) a blank scoring sheet and explanatory memo, and (iii) model answers.
- J. Grade Finality: All grades are final. While sometimes seemingly unfair in application, pursuant to school rules, there will be no negotiations regarding revisions, except to correct any mathematical or clerical errors in computing the final score.
- K. Exam Review: I will be happy to go over the exam with anyone who schedules an appointment to review the exam. On request, I will scan and email you a copy of **your** exam answers. If – after reviewing these against the exam, the feedback memo, model answers, and your notes – you have questions about your exam, please email those to me in advance of our meeting so that I can be sufficiently prepared to ensure a productive and efficient meeting.

XIII. Office Hours

I look forward to talking to you outside class. There are several means of doing this:

- A. After class: I will remain in the classroom after each class for all trailing questions, until or unless we are kicked out by another class.
- B. Office: I can typically be found in my office before and after class. If this is not a convenient time, just let me know in class or by email and we can make an appointment with each other. You are welcome to drop in my office anytime, but it is best to confirm a specific time in advance. If you have a specific question, I recommend that you send me the question via email ahead of time. In this way, I can think about your question and offer my best assistance.

- C. Email: Feel free to e-mail me anytime at tpope01@hamline.edu. In urgent circumstances cc thadmpope@aol.com and thaddeus.pope@gmail.com. I will try to promptly answer any question as soon as possible.
- D. TWEN: Whether you want to elaborate on or clarify the required materials or class discussions, you can start a discussion thread on the TWEN site. You are encouraged to provide constructive comments within each other's threads.
- E. Lunch or Coffee: I have found that grabbing a quick lunch or coffee/tea is a good way to get to know each other. If you and one or two other students want to share a bite/coffee/tea, please let me know.

XIV. TWEN Site

The TWEN site will include the following materials:

- A. All required reading for the course (*e.g.* cases, statutes, regulations, articles)
- B. PowerPoint slides for each class, posted before each class
- C. Links to MP3 recordings of selected classes and periodic summaries
- D. Links to periodic video summaries of selected topics
- E. Weekly Quizzes (see section IX, *supra*)
- F. Optional supplementary and background reading
- G. Materials concerning health law writing and career opportunities

Warning!! Do not permit the availability of these materials to deter you from preparing and participating in class. I provide these materials to supplement and enhance classroom learning, not to substitute for it. It is important to remember that knowledge acquisition is only one small part of law school education. I plan to do little lecturing during classes. Lectures may seem to provide more value – more content, more certainty. It may seem like you are “learning” more. But this would be poor preparation for the practice of law where there is little certainty. Furthermore, nonattendance is not an option given University and ABA attendance requirements, and the grading policy described above.

XV. Study Aids and Reference Materials

Despite the prevalence of health law courses in U.S. law schools, there are, as yet, few student-oriented ancillary materials. But there are numerous clear and lucid law review articles and background reports. I will provide copies of, or links to, the more useful of these materials on a topic-by-topic basis. And you have direct free access to most of these through HeinOnline, Westlaw, Lexis, and other databases.

There are also some good reference books. You really **do not** need to use any of these sources. I list them here only should you want to consult them to get more depth or breadth on certain issues.

A. **Study Aids for Law Students**

1. CARL COLEMAN, JERRY MENIKOFF, JESSE GOLDNER & NANCY DUBLER, THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS (Lexis/Nexis 2005).
2. BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLTZFUS JOST & ROBERT L. SCHWARTZ, HEALTH LAW (2d ed. West Hornbook series 2000) (adapted from the 3-volume practitioner series).
3. MARK A. HALL, IRA MARK ELLMAN & DANIEL S. STROUSE, HEALTH CARE LAW AND ETHICS IN A NUTSHELL (3d ed. West 2011).
4. SANDRA H. JOHNSON & ROBERT L. SCHWARTZ, BIOETHICS AND LAW IN A NUTSHELL (West 2009).
5. ROBERT D. MILLER, PROBLEMS IN HEALTH CARE LAW (9th ed. Jones & Bartlett 2006).

B. **Study Aids for Non-Lawyers**

1. TONIA D. AIKEN, LEGAL AND ETHICAL ISSUES IN HEALTH OCCUPATIONS (Elsevier 2008).
2. GEORGE J. ANNAS, THE RIGHTS OF PATIENTS: THE AUTHORITATIVE ACLU GUIDE TO THE RIGHTS OF PATIENTS (3d ed. NYU 2004).
3. CAROLYN BUPPERT, NURSE PRACTITIONER'S BUSINESS PRACTICE AND LEGAL GUIDE (4th ed. Jones & Bartlett 2011).
4. BONNIE FREMGEN, MEDICAL LAW AND ETHICS (4th ed. Prentice Hall 2011).
5. CARL HORN, LAW FOR PHYSICIANS: AN OVERVIEW OF MEDICAL LEGAL ISSUES (AMA 2000).
6. JANICE L. KAZMIER, HEALTH CARE LAW (Cengage Learning 2008).
7. MARCIA A. LEWIS & CARL D. TAMPARO, MEDICAL LAW, ETHICS, AND BIOETHICS (6th ed. F.A. Davis 2007).
8. GEORGE D. POZGAR & NINA SANTUCCI, LEGAL ASPECTS OF HEALTH CARE ADMINISTRATION (11th ed. Jones & Bartlett 2012).
9. RONALD W. SCOTT, PROMOTING LEGAL AND ETHICAL AWARENESS: A PRIMER FOR HEALTH PROFESSIONALS AND PATIENTS (Elsevier 2008).

C. General Reference Materials

This is, of course, a highly select list. I have not included CLE or practitioner-oriented materials.

1. AMERICAN COLLEGE OF LEGAL MEDICINE TEXTBOOK COMMITTEE, LEGAL MEDICINE (Mosby 7th ed. 2007).
2. AMERICAN HEALTH LAWYERS ASSOCIATION, FUNDAMENTALS OF HEALTH LAW (West 5th ed. 2011), Westlaw: AHLA-PAPERS.
3. AMERICAN HEALTH LAWYERS ASSOCIATION, HEALTH LAW PRACTICE GUIDE (West CBC 3-vol. looseleaf), Westlaw: HTHLPG.
4. ALISON BARNES ET AL., HEALTH CARE LAW DESK REFERENCE (ALI-ABA 2001).
5. SCOTT BECKER, HEALTH CARE LAW: A PRACTICAL GUIDE (Lexis 1-vol. looseleaf), on LEXIS.
6. BNA HEALTH LAW AND BUSINESS LIBRARY, WEB PORTFOLIOS LIBRARY (BNA Online) (also available in print or CD-ROM).
7. DEAN M. HARRIS, CONTEMPORARY ISSUES IN HEALTHCARE LAW AND ETHICS (Health Admin. Press 2003).
8. PAUL C. LASKY ED., HOSPITAL LAW MANUAL (Aspen 5-vol. looseleaf).
9. BRYAN A. LIANG, HEALTH LAW & POLICY: A SURVIVAL GUIDE TO MEDICOLEGAL ISSUES FOR PRACTITIONERS (Butterworth Heinemann 2000).
10. MICHAEL G. MACDONALD ED., TREATISE ON HEALTH CARE LAW (Matthew Bender 5-vol. looseleaf), on LEXIS.

XVI. Course Reading Outline

The outline below is intended to give you a sense of the course coverage. It is **not** a reading schedule. Given the interactive nature of the law school classroom, it is difficult to predict, much less promise, exactly what material we will be covering on a specific future date. Closely (but not exactly) following its sequence, I will give the specific assignment for the following week during the prior week.

The current assignment will always be posted on the TWEN home page. Old assignments will be collected as a TWEN “document” under the “Admin” tab. All the following materials are available from the TWEN site. Alternatively, most of them can

be also obtained from Westlaw and Lexis, if you would find printing from their dedicated printers more convenient. I will probably assign additional material to reinforce and link legal concepts presented below.

1. Human Subjects Research

a. History of Experimental Abuses – Part I

- i. *Opening Statement*, Trial of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949).
- ii. *Judgment*, Trial of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949) (including the “Nuremberg Code”).
- iii. Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 Yale J. Int’l L. 401 (1997).

b. History of Experimental Abuses – Part II

- i. Henry Beecher, *Ethics and Clinical Research*, 274 New Eng. J. Med. 1354 (1966).
- ii. Presidential Commission for the Study of Bioethical Issues, *A Study Guide to “Ethically Impossible” STD Research in Guatemala from 1946 to 1948* (Nov. 2012).
- iii. *About the USPHS Syphilis Study*, http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx
- iv. Jack Geiger, *An Experiment with Lives* (Review of *Bad Blood*), N.Y. Times, June 21, 1981.

c. Federal Regulation of Research with Human Subjects

DHHS human subject protection regulations were first issued in 1974. They are even now still under consideration for revision. *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, 76 Fed. Reg. 44,512 (July 26, 2011). Also, while we will not cover them, note that the FDA has separate regulations governing research involving drugs, devices, and biological products. 21 C.F.R. parts 50 & 56.

- i. *Belmont Report* (1978)
- ii. World Medical Association, *Declaration of Helsinki* (1975)
- iii. 45 C.F.R. part 46, subpart A, 45 C.F.R. §§ 46.101-124
- iv. Complete the NIH online training course. It is available at <http://phrp.nihtraining.com/users/login.php>. Training time averages 1-2 hours. It is self-paced and may be interrupted and resumed. Submit a hard copy of the certificate issued by the NIH at the end of the course.

v. Optional Videos

1. An overview of the regulations is provided in OHRP, *When Pls Come a 'Knockin': Everything Investigators Want to Know* (40-minute video)
<http://www.youtube.com/watch?v=FLoHNTuifGQ&list=SP5965CB14C2506914&index=1>
2. The informed consent requirements are covered in OHRP, *General Informed Consent Requirements* (19-minute video),
<http://www.youtube.com/watch?v=URo4x4pv68A&list=SP5965CB14C2506914&index=10>

d. Institutional Review Boards (IRBs)

- i. 45 C.F.R. part 46, subpart E, 45 C.F.R. §§ 46.501-.505
- ii. Simulated IRB protocols and meeting
- iii. Optional Videos
 1. Some of the key IRB membership requirements are covered in OHRP, *IRB Membership* (16-minute video),
<http://www.youtube.com/watch?v=GHtIbdLkSwU&list=SP5965CB14C2506914&index=5>
 2. Some of the key IRB record-keeping requirements are covered in OHRP, *IRB Records – Part I* (6-minute video),
<http://www.youtube.com/watch?v=j7FCLfiJ1Ms&list=SP5965CB14C2506914&index=8>; OHRP, *IRB Records – Part II* (14-minute video), http://www.youtube.com/watch?v=_AcXU-EGvIg&list=SP5965CB14C2506914&index=7

e. Challenges of the IRB System

- i. Cases
 1. *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001).
 2. Robert Steinbrook, *Protecting Research Subjects – The Crisis at Johns Hopkins*, 346 New Eng. J. Med. 716 (2002).
- ii. Articles
 1. *Testimony of Ezekiel J. Emanuel before the President's Council on Bioethics*, Sept. 12, 2002.
 2. Hazel Glenn Beh, *The Role of IRBs in Protecting Human Subjects: Are We Ready to Fix a Broken System?* 26 L. & Psychol. Rev. 1 (2002).
 3. Jesse Goldner, *Dealing with Conflicts of Interest: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J. Law, Med. & Ethics 379-404 (2000).

f. Protecting Vulnerable Subjects

- i. 45 C.F.R. part 46, subparts B, C, and D
- ii. *Report of the Advisory Committee on Human Radiation Experiments*, 276 JAMA 403 (1996).
- iii. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc).

2. Allocating Human Organs

a. Background on Organ Transplantation

- i. Albert R. Jonsen, *The Ethics of Organ Transplantation: A Brief History*, 14 Virtual Mentor 264-268 (2012).
- ii. Institute of Medicine, *Organ Donation: Opportunities for Action* 15-62 (2006).
- iii. UNOS, *Talking About Transplantation: What Every Patient Needs to Know* 4-8 (2012).

b. Get Involved

- i. Review the LifeSource *Volunteer Training Manual*. LifeSource, headquartered in St. Paul, is the non-profit organization dedicated to saving lives through organ and tissue donation in Minnesota, North Dakota, South Dakota and western Wisconsin.
- ii. Minnesotans can document their decision to be an organ and tissue donor by registering online at www.DonateLifeMN.org

c. Federal Standards for Organ Distribution

- i. National Organ Transplant Act (NOTA) and related provisions, 42 U.S.C. §§ 273-274i-4.
- ii. Organ Procurement and Transplantation Network (OPTN), 42 C.F.R. part 121, 42 C.F.R. §§ 121.1-13.
- iii. OPTN/UNOS Ethics Committee, *Ethical Principles to be Considered in the Allocation of Human Organs* (June 22, 2010).

d. Controversial Issues in Organ Allocation

- i. Daniel Brudney, *Are Alcoholics Less Deserving of Liver Transplants?* 37(1) Hastings Center Report 41-47 (2007).
- ii. John Harris, *The Survival Lottery*, 50 Philosophy 81-87 (1975).

**** NOTE:** The following section of the syllabus is still under construction **

3. Rationing Healthcare

a. Need for Rationing: Medical Spending: What We Pay and What We Get

- i. Peter Singer, *Why We Must Ration*, N.Y. Times Mag. (July 15, 2009).
- ii. Nat Hentoff, *Health Care Rationing Obama Believes In*, CATO Commentary (June 9, 2010).
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