

The Dark Side of Medicine

Section: LPS 140, Summer 2015 Day/Time: Classroom: Office hours:
Instructor: B. Holman Office: SST 740 e-mail: bholman@uci.edu

Description: This course will explore the tension between obtaining reliable knowledge and ethical practice. We do so by examining a number of cases where those involved in medical research were seen in retrospect to have made horrendous ethical judgments. After examining each case, we will look at the practices that arose to prevent such abuses in the future. The first case study examines Nazi medical doctors' horrifying use of human subjects in medical experiments and the Nuremberg Code of medical ethics. Next, we look at racial prejudice, the Tuskegee syphilis study, and the Belmont Report. We will next examine the Thalidomide disaster, the resultant legislation that established the modern FDA, and the codification of the randomized clinical trial (RCT). After seeing the justification for the phased experiment, we will spend considerable time exploring a number of ethical problems that arise in RCTs by examining the AIDS crisis, homophobia, Gay activist groups, and the development of AZT. Within this context we will explore: when research (rather than treatment) is ethically permissible; whether it is ethical to use placebos; the recruitment of participants from vulnerable populations; and the role of diversity in RCTs. Finally, we will examine the rise of "Big Pharma" and the large private industry to run such trials. We will examine how the various roles of drug development have been professionalized and examine how various actors in medical research manage (or fail to manage) conflicts of interest. We will close by asking whether modern research is on the verge of another horrifying wake-up call.

Requirements:

1. Readings

Instead of everyone reading all the readings, each week everyone will read a common core and then take special responsibility for one of the three remaining readings. This effectively reduces each student's reading load by half! Consider for example the reading assignment for class 7 below. The "(C)" means that the material is "common core" material and will be read/watched by everyone. The common core material introduces arguments pertaining to the salient ethical issues in the case we examining that week. In this case the reading is a number of short papers on whether and when placebos are ethical. In addition, students will also be responsible for reading one additional primary reading each week. Students in group (a) read: a selection on clinical trials, students in group (b) read the section on patient empowerment, and group (c) reads about how AIDS activist impacted the knowledge generating process. For various reasons (see below), **readings must be read before the class that covers them.**

7	The Politics of Treatment	(C) The Ethics of Placebo Control (<i>ERACR</i> p. 127- 143) Impure Science: Clinical Trials (p.181-207) Impure Science: Patient Empowerment(p.208-235) Impure Science: Activism and Knowledge(p.236-264)
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2. Participation (Bonus)

Active and informed participation: Students are expected to come to class prepared and ready to engage in an informed discussion of the material. Students are expected to actively participate in classroom discussions. Participation includes asking questions, raising objections, offering defenses, commenting on the significance of a point, clarifying an argument or a claim, and drawing out the connections between an issue from our current discussion and issues raised in our other readings. Substantial contributions can raise your grade.

3. Class Wiki (70% of final grade)

Creating the Wiki: Weeks 2-4	25%
<u>Creating the Wiki: Weeks 5-10</u>	<u>45% (30% page owner, 15% page associate)</u>
Total Class Wiki	70%

Over the duration of the course the class will collectively create a wiki on the material covered in class. The end product will be a collective account of what we have covered in the course (i.e. a study guide for the final!).

Each student will be assigned to one of three groups for each class session. These groups will change twice over the course of the quarter and will be randomly assigned. Responsibilities are slightly different for classes 2-4 than for 5-10.

A. Creating the wiki: Weeks 2-4 (25% of final grade)

During the first few classes (weeks 2-4) students will create a summary of the articles as a group. A summary contains 3 sections. The first identifies the central philosophical question(s) addressed by the piece, the second (and main portion) summarizes the relevant portion of the text, the third briefly relates the case back to the questions for the week.

Summaries should be roughly 400-600 words, though some summaries will naturally exceed this boundary on one end or the other. Consider this a helpful guideline as opposed to a requirement. Other guidelines can be found in the “Writing Good Summaries” document on the class website. The purpose of these summaries is to learn to take real case examples and bring them to bear on philosophical arguments (i.e. these are not research papers). Accordingly, students **should not** use outside resources. Evidence of outside research will be considered cause to reduce a grade, or in extreme cases be considered a violation of academic integrity and can warrant further action (see: Academic Integrity Policy below).

Summaries must be finalized by **11:59pm the night before the lecture** to give classmates from other groups the opportunity to read the summary. Work can be distributed within your group in any manner the group can agree to. Grades will be assigned to the group. In extreme circumstances where a group member fails to abide by their agreed contribution, students can petition for separate grades by sending me an

email. Group members should take other steps to avoid such situations (email the student, etc.) and such petitions should be seen as a last resort.

B. Creating the wiki: weeks 5-10 (Total: 45% of the final grade)

Each student will choose one article and will then “own” the relevant wiki page for that article. The sign-up sheet will be available through eee starting ENTER DATE (Week 1). Students must have chosen a article by ENTER DATE ONE WEEK LATER. Students will also be “associated” with 5 other articles (one per class, except the class that you are an owner of). As can be seen in the schedule of readings, there are two sets: (a), (b), and (c) is the first set; (i), (ii), (iii) is the second. There are three groups in each set. Students will be in the group that the article that they own is in and they will be randomly assigned to a group in the other set.

For example, if a student signs up to be the owner of:

Class 6: (b) Impure Science: Consolidation and Refinement (p. 132-155)

They will also be associates for the two other (b) articles:

Class 5: (b) Impure Science: Conceptualizing AIDS (p. 27-52)

Class 7: (b) Impure Science: Patient Empowerment(p.208-235)

The student will also be randomly assigned into group (i), (ii) or (iii) for classes 8-10. Groups will be assigned on Aug 15th.

i. Contribution #1: Page Owner (30% of final grade)

Initial summary (20% of final grade) Post a summary of the article roughly **three days in advance** of the class that covers the article. Specifically, if the class is on a Tues, the article should be posted by 11:59 pm Saturday and if the class is on a Thurs, the article should be posted by 11:59 pm Monday

Moderating and finalizing (10% of final grade) The owner is expected to be the class expert on the article. Between the time the summary is posted and the class when it is covered, the owner will answer questions raised in discussion posts, moderate discussions from other students, and attempt to address interpretive questions (i.e. figure out what an author means when it is unclear or when there is dispute between students). Within a day **after class**, the owner is responsible for finalizing the wiki page and incorporating into it any insight gained from class lecture and discussion. Lastly, the owner should expect to answer questions about the article as students prepare for the final exam.

ii. Contribution #2: Page Associate (15% of final grade)

For each class, students are associated with a one of three readings. Students are expected to acquire a solid understanding of that article and to ensure that quality of the corresponding wiki page. Ways to fulfill this responsibility are much the same as class participation and include: participating in discussion threads (asking questions, raising objections, offering defenses, commenting on the significance of a point, clarifying an argument or a claim, and drawing out the connections between an issue from the current discussion and issues raised in our other readings). In addition, if you think that the

owner has misinterpreted or neglected a particular section or that their writing is unclear you can leave a comment suggesting a change (be specific) or asking for clarification.

3. Final exam (30% of final grade):

Includes short answer and essay questions. The short answer responses will involve summarizing the main argument of a paper read for class (i.e. exactly what each wiki page is intended to be). The essay questions will ask you to summarize one of the main positions explored in the class, explain objections to that position, and explain whether you think the objections are successful (i.e. justify your own position). The exam covers the entire term's required material, as well as any additional material covered in lectures, but with greater emphasis on the latter part of the term. A list of possible essay questions will be distributed one week before the final.

Class policies:

Academic Integrity: Plagiarism, cheating, etc. will not be tolerated and the University policy on Academic Honesty will be followed strictly. Students who have any questions or uncertainty whatsoever about this policy are responsible for meeting individually with the instructor to discuss the policy. Anyone found violating this policy will receive an F for the course and will be reported to the appropriate University officials. I am extremely firm on this matter.

Late assignments: Because your fellow classmates depend on your contributions late assignments **will not be accepted**. In severe circumstances (i.e. hospitalization, death of a family member etc.) accommodations can be made given the student can provide supporting documentation.

Disabilities: It is the student's responsibility to notify the instructor in advance of the need for accommodation of a University verified disability. I will gladly provide the required accommodations.

Preferred names and gender pronouns: I would like to make every effort to create a safe space. If you have a preferred name or gender pronoun that is not reflected in the roster, please let me know.

Students should also refer to the University General Catalog about standard policies and procedures

Materials:

The primary reading for this class will be

- 1: *Ethical and Regulatory Aspects of Clinical Research* by E. J. Emanuel, et. al.
- 2: *Bad Blood: The Scandalous Story of the Tuskegee Experiment- When Government Doctors Played God and Science Went Mad.* By James Jones.
- 3: *Impure Science: AIDS Activism and The Politics of Knowledge*, by Steven Epstein
- 4: *White Coat Black Hat: Adventures on the Dark Side of Medicine*, by Carl Elliott

Schedule of Readings and notation:

(C) indicates common core material that everyone should read.

The (1), (2), (3); (a), (b), (c); and (i), (ii), (iii); indicate which groups that will be associated with that reading for the purposes of creating the wiki,

Meeting	Topic	Readings
1 (//)	Intro to the course/ Nazi Medical Doctors	(C) Ethical and regulatory guidance for research with humans (<i>ERACR</i> p. 25- 28) (C) The Nuremberg Code & The Helsinki Declaration (<i>ERACR</i> p. 28-32) (1) Proctor, “Nazi Doctors, Racial Medicine, and Human Experimentation (2) Pross, “Nazi Doctors, German Medicine, and Historical Truth” (3) Taylor, “Opening Statement of the Prosecution, December 9, 1946”
2 (//)	Tuskegee Part 1 Informed Consent	(C) Informed Consent in Human Research (<i>ERACR</i> p. 189-197) (C) Freedman, “A Moral Theory of Informed Consent (<i>ERACR</i> p. 203-207) (1) <i>Bad Blood: Racism and Medicine</i> (p. 1-29) (2) <i>Bad Blood: Syphilis</i> (p. 29-60) (3) <i>Bad Blood: Disease Control in Macon County</i> (p. 61-90)
3 (//)	Tuskegee, Part 2 The Therapeutic Misconception	(C) The Belmont Report (<i>ERACR</i> p. 33- 39) (C) Applebaum, et. al. “False Hopes and Best Data: Consent to Research and the Therapeutic Misconception (<i>ERACR</i> p. 216- 220) (C) Hauchhauser, “Therapeutic Misconception and Recruiting Double Speak in the Informed Consent Process.” (<i>ERACR</i> p. 220-224) (1) <i>Bad Blood: Recruiting Patients</i> (p.91-132) (2) <i>Bad Blood: Autopsy of a Tragedy</i> (p.133-171) (3) <i>Bad Blood: The Aftermath</i> (p.172-205)
4 (//)	Thalidomide, the FDA, and the Phased Experiment	(C) The Ethics of Clinical Trial Design (<i>ERACR</i> p. 95-102) (C) Hellman & Hellman, “Of Mice but not Men, Problems of the Randomized Clinical Trial” (<i>ERACR</i> p. 113-116) (C) Lipsett, The Ethics of Phase 1 Trial (<i>ERACR</i> p. 144- 146) (1) Carpenter, <i>Reputation and Power: Image and Power</i> (228-256) (2) Carpenter, <i>Rep. and Power: The Battle over Reform</i> (256-280) (3) Carpenter, <i>Rep. and Power: Conceptual Power</i> (280-298)

5 (//)	Background on AIDS	(C) Freedman, "Equipoise and the Ethics of Clinical Research" (<i>ERACR</i> p. 117- 120) (C) "RCTs- Lessons from ECMO" (<i>ERACR</i> p. 121-126) (a) <i>Impure Science: Controversy and Credibility in AIDS Research</i> (p. 1-26) (b) <i>Impure Science: Conceptualizing AIDS</i> (p. 27-52) (c) <i>Impure Science: Lifestyle vs. Virus</i> (p. 53-78)
6 (//)	"The Gay Disease": The Politics of Causation	(a) <i>Impure Science: The Construction of Scientific Proof</i> (p. 79-132) (b) <i>Impure Science: Consolidation and Refinement</i> (p. 132-155) (c) <i>Impure Science: Closing the Controversy</i> (p. 156-180)
7 (//)	The Politics of Treatment	(C) The Ethics of Placebo Control (<i>ERACR</i> p. 127- 143) (a) <i>Impure Science: Clinical Trials</i> (p.181-207) (b) <i>Impure Science: Patient Empowerment</i> (p.208-235) (c) <i>Impure Science: Activism and Knowledge</i> (p.236-264)
8 (//)	The Politics of Participation	(C) Dresser, "Wanted, Single White Male for Medical Research" (<i>ERACR</i> p. 166- 170) (C) Weijer and Crouch, "Why Should We Include Women and Minorities in RCTs?" (<i>ERACR</i> p. 171- 174) <i>Impure Science</i> Surrogate Markers(p.265-295) <i>Impure Science</i> Living with Uncertainty (p.296-324) <i>Impure Science: The Transformation of AIDS Research</i> (p.325-354)
9 (//)	Guinea Pigs, Ghosts, and Detain Men	(C) Scientific Misconduct (<i>ERACR</i> p. 385-418) <i>White Coat: Paid participants</i> (p. 1-24) <i>White Coat: Paid authors</i> (p. 25-50) <i>White Coat: Paid sales reps</i> (p. 51-75)
10 (//)	The Thought Leaders, The Flacks, The Ethicists	(C) Challenges to the Institutional Review Board System (<i>ERACR</i> p. 419-444) <i>White Coat: Paid Experts</i> (p. 76-109) <i>White Coat: Paid Public Relations</i> (p. 110-139) <i>White Coat: Paid Ethicists</i> (p. 139-171)
Final exam		