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2019

### Biomedical Ethics and Responsible Conduct of Research

Katherine Mendis

*CUNY School of Medicine*

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**MASTER'S IN  
TRANSLATIONAL  
MEDICINE** THE CITY COLLEGE  
OF NEW YORK

**MEDS I8100: BIOMEDICAL ETHICS AND RESPONSIBLE CONDUCT OF RESEARCH  
FALL 2019 SEMESTER (1 credit)**

*Katherine Mendis, Course Director (kmendis@med.cuny.edu)*

*Office hours: by appointment via e-mail*

*Office location: Harris Hall 303E*

This course will meet on selected Tuesdays from 10:00 am - noon in Harris 012.

***Description:***

This course is an introduction to the moral challenges that arise in the design and execution of biomedical research and the development of medical interventions. A historical review segues into detailed examination of key ethical concepts and principles, as well as topics of particular concern. At the culmination of the semester, students apply their knowledge of research ethics to an ethical analysis of their MTM BioDesign projects.

***Course Goals:***

1. To introduce students to the ethical issues that arise in biomedical research; the philosophical methods, concepts and principles that are employed to analyze them, and how the field has been shaped by changes in society and developments in biomedical science.
2. To develop students' critical thinking, writing, and oral communication skills.
3. To introduce a philosophical framework for researchers to analyze, discuss, and resolve moral dilemmas that arise in their work.

***Course Components and Objectives:***

This course will be conducted in a seminar format. Students will be assessed through in-class presentations and a final seminar paper. Upon completion of this course students will be expected to:

- Demonstrate a basic understanding of current issues in research ethics, the philosophical methods of evaluating them, and their social and scientific implications.
- Identify and analyze ethical issues relevant to the process of developing a medical intervention and bringing it to market.
- Critically assess moral arguments orally and in writing.
- Articulate and defend positions on moral issues orally and in writing.

**Course Requirements:**

| Item                           | Date                     | % of Course Grade |
|--------------------------------|--------------------------|-------------------|
| Mini-Paper                     | August 27                | 5%                |
| Reading Presentation           | September 3 – October 29 | 25%               |
| Final Paper Proposal           | November 1               | 10%               |
| Final Paper                    | November 16              | 25%               |
| BioDesign Project Presentation | December 3 or 10 or 17   | 25%               |
| Attendance/Participation       | Ongoing                  | 10%               |



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### **Grading Scale:**

Grades of A, A-, B+, B, B-, C or F will be assigned based on the overall score from all graded materials listed above.

### **Course Policies:**

**Professionalism:** Attendance is required. Students are responsible for notifying the instructor as soon as possible if they will be absent from any class session. More than one unapproved absence will result in no participation credit (which is 10% of the overall course grade).

Students will not be permitted to submit late work or reschedule a presentation without prior approval from the Course Director or written documentation of an emergency (e.g. doctor's note, mechanic's receipt).

**Honor Code/Plagiarism Policy:** This course recognizes and endorses the CUNY Policy on Academic Integrity. Course faculty share your commitment to creating an environment that fosters professionalism in our educational community.

To help you in understanding what plagiarism is and how to avoid it, please read the guide provided by the CUNY's offices of the provost and student affairs: [https://www.gc.cuny.edu/CUNY\\_GC/media/CUNY-Graduate-Center/PDF/Publications/AvoidingPlagiarism.pdf?ext=.pdf](https://www.gc.cuny.edu/CUNY_GC/media/CUNY-Graduate-Center/PDF/Publications/AvoidingPlagiarism.pdf?ext=.pdf)

If the instructor is made aware of cheating or plagiarism in any form either by a specific individual or at the class level, the matter will be referred to the Office of the Academic Integrity Official; **the student(s) will receive a failing grade for the assignment and possibly for the course.** Please consult CUNY's policy on academic integrity for further information: <http://web.cuny.edu/academics/info-central/policies/academic-integrity.pdf>.

**Policy on Accommodations for Students with Disabilities:** The AccessAbility Center/Student Disability Services ensures equal access and full participation to all of City College's programs, services, and activities by coordinating and implementing appropriate accommodations. If you are a student with a disability who requires accommodations and services, please visit the office in NAC 1/218, or contact AAC/SDS via email ([disabilityservices@ccny.cuny.edu](mailto:disabilityservices@ccny.cuny.edu)), or phone (212-650-5913 or TTY/TTD 212-650-8441).

Qualified students with disabilities will be provided reasonable academic accommodations if determined eligible by the AAC. Prior to granting disability accommodations in this course, the instructor must receive written verification of a student's eligibility from the AAC. It is the student's responsibility to initiate contact with the AAC and to follow the established procedures for having the accommodation notice sent to the instructor.



**COURSE SCHEDULE WITH READINGS**

**\*\*There is no textbook assigned for this course. All readings will be posted on Blackboard.\*\***

| Session | Date | Topic   | Preparation  |
|---------|------|---|--|
| 1       | 8/27 | Introduction to Course/<br>Troubling Cases in the<br>History of Medical<br>Research | <ul style="list-style-type: none"> <li>• <b>Group 1:</b> Spettel S, White MD Mark Donald. The Portrayal of J. Marion Sims' Controversial Surgical Legacy. <i>J Urol.</i> June 2011;185: 2424-2427.</li> <li>• <b>Group 1:</b> Berger R Nazi Science—The Dachau Hypothermia Experiments. <i>N Engl J Med.</i> 1990; 322(20): 1435-1440.</li> <li>• <b>Group 2:</b> Brandt A. Racism and Research: The Case of the Tuskegee Syphilis Study. <i>Hastings Cent Rep.</i> 1978; 8(6): 21-29.</li> <li>• <b>Group 2:</b> Reverby S. 'Normal Exposure' and Inoculation: Syphilis: A PHS 'Tuskegee' Doctor in Guatemala, 1946-48. <i>J Policy Hist.</i> 2011; (23(01): 6-28.</li> <li>• <b>Group 3:</b> NIH: Exploring Bioethics. <i>Willowbrook Hepatitis Experiments.</i> Education Development Center: National Institutes of Health; 2009.</li> <li>• <b>Group 3:</b> Lerner B. Sins of Omission—Cancer Research without Informed Consent. <i>N Engl J Med.</i> 2004; 351(7): 628-630.</li> </ul> |
| 2       | 9/3  | What is at stake in<br>Research Ethics?   | <ul style="list-style-type: none"> <li>• Jonas H. Philosophical Reflections on Experimenting with Human Subjects. <i>Daedalus</i> 1969; (98)2: 219-247.</li> <li>□ Rhodes R. Rethinking Research Ethics. <i>Am J Bioeth.</i> 2005; 5(1):7-28.</li> </ul>   |
| 3       | 9/10 | Clinical Needs and<br>Social Values   | <p>Presentation Due</p> <ul style="list-style-type: none"> <li>□ Kermit P. Enhancement technology and outcomes: what professionals and researchers can learn from those skeptical about cochlear implants. <i>Health Care Anal.</i> 2012; 20(4):367-384.</li> <li>□ Dreger, A, Feder E, Tamar-Mattis A. Prenatal Dexamethasone for Congenital Adrenal Hyperplasia: An Ethics Canary in the Modern Medical Mine. <i>J Bioeth Inq.</i> 2012; 9(3): 277-294.</li> </ul>   |
| 4       | 9/17 | Responsible Conduct of<br>Research  | <p>Presentation Due</p> <ul style="list-style-type: none"> <li>□ Shamoo AE, Resnik DB. Chapter 3: Data Acquisition and Management. In: <i>Responsible Conduct of Research.</i> New York, NY: Oxford University Press; 2009: 39-67.</li> <li>□ Chapter 7: Publication and Peer Review. 110-139.</li> <li>□ Chapter 8: Misconduct. 140-166.</li> <li>□ Chapter 10: Conflicts of Interest and Scientific Objectivity. 189-214.</li> </ul>   |
| 5       | 9/24 | Research on Human<br>Subjects: General<br>Concerns                                  | <p>Presentation Due</p> <ul style="list-style-type: none"> <li>□ Freedman B. Equipoise and the Ethics of Clinical Research. <i>N Engl J Med.</i> 1987; 317: 141-145.</li> <li>□ Temple R, Ellenberg S. Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments: Part 1B Ethical Issues. <i>Ann Intern Med.</i> 2000 Sep 19;133(6):455-63.</li> </ul>   |



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|   |                                    |                                 |   |
|---|------------------------------------|---------------------------------|---|
|   |                                    |                                 | <ul style="list-style-type: none"> <li><input type="checkbox"/> Wendler D, Grady C. What Should Research Participants Understand to Understand They Are Participating in Research? <i>Bioethics</i> 2008; 22(4): 203-208.</li> <li><input type="checkbox"/> Appelbaum P et al. False Hopes and Best Data: Consent to Research and the Therapeutic Misconception. <i>Hastings Cent Rep.</i> 1987; 17(2): 20-24.</li> </ul>   |
| 6 | 10/15                              | Research on Vulnerable Subjects | <p>Presentation Due</p> <ul style="list-style-type: none"> <li>• Kant I. Duties Toward Animals. In Infield L (trans.) <i>Lectures on Ethics</i> New York, NY: Harper and Row; 1790:239-41.</li> <li>• Singer P. All Animals are Equal. In <i>Philosophic Exchange</i> 1974. Brockport, NY: Center for Philosophic Exchange 1974:103-16.</li> <li><input type="checkbox"/> Kopelman L. Children as Research Subjects: A Dilemma. <i>Eth Health Care.</i> 2003; 2-7.</li> <li><input type="checkbox"/> Strong C. How Should Risks and Benefits Be Balanced in Research Involving Pregnant Women and Fetuses? <i>IRB.</i> 2011 Nov-Dec; 33(6): 1-5.</li> <li><input type="checkbox"/> Charland L. Cynthia's Dilemma: Consenting to Heroin Prescription. <i>Am J Bioeth.</i>2002; 2(2): 37-47.</li> </ul>                                     |
| 7 | 10/29                              | Justice and Biomedical Research | <p>Presentation Due</p> <ul style="list-style-type: none"> <li>• Buchanan A. Justice: A Philosophical Review 1981 in <i>Justice in Health Care.</i> USA: OUP; 2009.</li> <li><input type="checkbox"/> Hawkins J, Emanuel E. Clarifying Confusions about Coercion. <i>Hastings Cent Rep.</i> Sept 2005; 35(5):16-19.</li> <li><input type="checkbox"/> Angell M, The ethics of clinical research in the Third World. <i>N Engl J Med.</i> 1997; 337: 847-849</li> <li><input type="checkbox"/> Lackey D, Clinical Trials in Developing Countries: A Review of the Moral Issues. <i>Mt Sinai J Med.</i> 2001;68(1): 4-12.</li> <li><input type="checkbox"/> Emanuel E, et al. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. 2004 <i>J Infect Dis.</i> March 2004;189: 930-7.</li> </ul> |
|   | 11/1                               | Due Date                        | Final Paper Proposal Due via Blackboard   |
|   | 11/16                              | Online Due Date                 | Final Papers Due via Blackboard   |
| 8 | 12/3<br>OR<br>12/10<br>OR<br>12/17 | Final Presentations             | Final Presentations In-Class  |