

**RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY**  
**New Brunswick, NJ**

**Foundations of Medical Ethics & Policy**

10:652:201

**FALL 2019**

- Instructor:** Dr. Francis Barchi  
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[francis.barchi@rutgers.edu](mailto:francis.barchi@rutgers.edu)
- Office hours:** By appointment only
- Course Schedule:** Mondays and Wednesdays, 1:10pm – 2:30pm
- Location:** Academic Building, Rm. AB1150
- Course Credits:** Three (3)
- Rutgers Canvas:** Access: <https://tlt.rutgers.edu/canvas>. Log in using Rutgers NetID and password.  
[Students who are new to Canvas may wish to refer to the on-line tutorial found at <https://tlt.rutgers.edu/getting-started-canvas-students> ]

### **I. Course Overview**

This course introduces students to the conceptual foundations of medical ethics, emphasizing how particular moral traditions and theories have influenced the development of policies and practices in health care and health research over time and in different setting around the world. The course combines lectures with small-group casework to encourage students to ‘think-through’ the moral and often practical challenges that arise in the practice of medicine, and health research.

### **II. Learning Objectives**

Upon successful completion of this course, students will be able to:

1. Identify the philosophical approaches that provide the foundations for modern clinical, research, and public health ethics
2. Illustrate how different values and belief systems influence health care and health-related research and how different stakeholders perceive these activities.
3. Trace the development of the ethics regulatory environment that guides modern-day research and the historical cases of research abuse that have shaped it.
4. Identify ethical issues in research protocol design and practical ways in which they may be resolved.
5. Apply ethical principles and regulatory requirements to case examples situated in clinical and research settings.
6. Apply critical reasoning skills to assess stakeholder interests, risks and benefits, and choose and defend a course of action.
7. Recognize ethical dilemmas and address them using enhanced communication skills and a commitment to ethical health practice and research.

### III. Course Structure

This course will meet bi-weekly on Mondays and Wednesdays from 1:10pm – 2:30pm during the Fall 2019 semester. The course will use a combination of lectures, discussions, and analyses of cases studies.

### IV. Course Text:

Beauchamp, T. L., & Childress, J. F. (2012). *Principles of biomedical ethics* (7<sup>th</sup> Ed.) New York: Oxford University Press. ISBN-10: 0199924589

**V. Journal articles and case analyses:** Journal articles and case analyses that are assigned will be uploaded onto the Canvas site.

### VI. Course Topics and Schedule:

Students should read the assigned readings in advance of the class date under which they appear. Consider them 'preparation' for class discussion.

Assignments are due on the dates listed for each assignment. **Assignments will not be accepted after the due date and time unless prior approval for a late submission has been given by Dr. Barchi.**

### Course Units

#### Unit 1

#### **Ethics, morality and their place in the biomedical sciences**

Moral norms and the common morality

A moral framework for health care and research

Key concepts: prima facie obligations, moral dilemmas, & the moral agent

#### **Readings:**

Beauchamp & Childress, Chapters 1 & 2 pages 1 – 55

#### Unit 2

#### **Personhood and moral status; the problem of moral status**

What makes us 'persons'? What makes us deserving of moral status? What allows us to exclude 'others' and how are they defined?

Theories about personhood: Being 'human' (biological and psychological properties); cognitive capacity; moral agency; sentience; special relationships

The debate on the moral status of animals and its place in medical ethics and health policy

Use of theories over time to justify denial of moral status to certain groups of beings in healthcare settings

#### **Readings:**

Beauchamp & Childress, Chap 3 pp. 62-94

Armstrong, S. J. & Botzler, R. G. (eds.) (2008). *The Animal Ethics Reader* (2<sup>nd</sup> Ed.), New York: Routledge. Part I: Theories of Animal Ethics, pp. 15 – 59.

#### Unit 3

#### **Conceptual foundations of medical ethics**

- Utilitarian theories
- Deontological theories
- Virtue ethics

- Feminist ethics and the ethics of care
- Communitarianism
- Ubuntu and African philosophical traditions

Strengths and weaknesses of moral theories as guides to decision-making and practice in healthcare and research

Putting ethical theories to work

**Readings:**

Beauchamp & Childress: Chap. 9, pp. 351-384

**Unit 4**

**Health and human rights**

Rights theories

The 'right to health' and its implications for health care policy and practice

The culture debate: The role of culture, cultural relativism or cultural imperialism in health care policy and practice

**Readings:**

Office of the United Nations High Commission for Human Rights, Fact Sheet 30: The United Nations Human Rights Treaty System, pp. 1-21

UN Office of the High Commission on Human Rights. A human rights-based approach to health. 4 pp

Mann, J. (1997). Medicine and public health ethics & human rights. *Hastings Center Report*, 27:3, 6-13.

Macklin, R. (1999). Philosophers and anthropologists debate. In R. Macklin (1999). *Against relativism: Cultural diversity and the search for ethical universals in medicine*, Chap. 2. New York & Oxford: Oxford University Press.

Christakis, N. A. (1992). Ethics are local: engaging cross-cultural variations in the ethics for clinical research. *Social Science & Medicine*, 35(9), 1079-1091.

Paasche-Orlow, M. (2004). The ethics of cultural competence. *Academic Medicine*, 79(4), 347-350.

**Unit 5**

**Moral principles: Respect for autonomy**

Autonomy in biomedical and biobehavioral settings

Children and health decision-making

Respect for personhood and the public good

Implications of autonomy for public health law, policy, and practice

**Readings:**

Beauchamp & Childress: Chap. 4, pp 101-141

Videos:

**The Child Act** (2017). Access through Rutgers Kanopy.

**Unit 6**      **Moral principles: Nonmaleficence and beneficence**  
 Nonmaleficence and beneficence in biomedical and biobehavioral settings  
 Implications of nonmaleficence and beneficence for public health law, policy, and practice

**Readings:**

Beauchamp & Childress, Chapters 5 & 6, pp. 150-241

**Unit 7**      **Moral principles: Justice**  
 Theories of justice and resource allocation  
 Justice in biomedical and biobehavioral settings  
 Implications of justice for public health law, policy, and practice  
 Vulnerability in health care and health research  
 Applying ethical principles to address vulnerability  
 Putting theories to work: Priority setting in public health

**Readings:**

Beauchamp & Childress, Chap. 7, 249-293.

Presidential Commission for the Study of Bioethical Issues (2014). *Vulnerable populations: Background*. Washington, DC: Author. Pp. 1-31 [Learning module]

Kipnis, K. (2003). Seven vulnerabilities in the pediatric research subject. *Theoretical Medicine*, 24: 107-120. [This is a bit impenetrable. Read for the general points. Don't fret the details.]

Macklin, R. (2003). Bioethics, vulnerability, and protection. *Bioethics*, 17, 472-486

Persad, G., Wertheimer, A., & Emanuel, E. J. (2009). Principles for allocation of scarce medical interventions. *The Lancet*, 373(9661), 423-431.

Williams, A. (1992). Cost-effectiveness analysis: is it ethical? *Journal of Medical Ethics*, 18(1), 7-11.

**Unit 8**      **Clinical care, research, and the changing roles of physician and patient**  
 In the eye of the beholder: The medical gaze and the patient experience

**Readings:**

Armstrong, D. (1984). The patient's view. *Social Science & Medicine*, 18(9), 737-744.

Cassell, E. J. (1976). Illness and disease. *Hastings Center Report*, 6(2), 27-37.

Selected readings from: Foucault, M. (1963). *The birth of the clinic: An archaeology of medical perception*. New York: Random House [April 1994 Vintage Books Edition]

Brody, H., & Miller, F. G. (2003). The clinician-investigator: unavoidable but manageable tension. *Kennedy Institute of Ethics Journal*, 13(4), 329-346. [Read for the BIG ideas. Do not fret the detail.]

Jansen, L. A. (2008). Doctor vs. scientist? *Hastings Center Report*, 38(2), 3-3.

Merritt, M. (2005). Moral conflict in clinical trials. *Ethics*, 115(2), 306-330. [Read for the BIG ideas. Do not fret the detail.]

## Unit 9

### Research ethics and the origins of modern day human subjects protections

Paradigm cases in medical research in the United States

Paradigm cases in social science research in the United States

When experiments travel: Ethical issues in international research

Paradigm cases in international research

Research in humanitarian disasters

#### Readings:

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *Ethical principles and guidelines for research involving human subjects* [The Belmont Report].

The Nuremberg Code (1948).

Beecher, H. K. (1966). Ethics and clinical research. *New England Journal of Medicine*, 274:24, 367-372.

Brandt, A.M. (1978). Racism and research: The case of the Tuskegee Syphilis Study, *The Hastings Center Report*, 8:6, 21-29.

Brody, B. A. (2002). Ethical issues in clinical trials in developing countries. *Statistics in Medicine*, 21, 2853-2858. doi: 10.1002/sim.1289

Council for International Organizations of Medical Sciences (CIOMS) (2016). *International guidelines for health-related research involving humans*.

NOTE: This is the best source of explanations about the Declaration of Helsinki, and was written expressly to provide guidance on research conducted in developing countries. It's useful to read in its entirety, but you are only required to read the Opening statements (in boldface) for each of the twenty-three (23) guidelines.

Emanuel, E. J., Wendler, D., Grady, C. (2000). What makes clinical research ethical? *JAMA*, 283(20), 2701-2711.

Emmanuel, E. J., Wendler, D., Killon, J. & Grady, C. (2004). What makes clinical research in developing countries ethical? The benchmarks of ethical research. *The Journal of Infectious Diseases*, 189, 930-937.

Final Report of the President's Advisory Committee on Human Radiation Experiment: Executive Summary, pp. 1-9.

Ford, N., Mills, E. J. Zachariah, R., & Upshur, R. (2009). Ethics of conducting research in conflict settings. *Conflict and Health*, 3(7). doi:10.1186/1752-1505-3-7

Hornblum, A. M. (1997). They were cheap and available: prisoners as research subjects in twentieth century America. *BMJ*, 315(7120), 1437-1441.

Jacobsen, K., & Landau, L. B. (2003). The dual imperative in refugee research: Some methodological and ethical considerations in social science research on forced migration. *Disasters*, 27, 185-206. doi:10.1111/1467-7717.00228.

Reverby, S. M. (2011). “Normal exposure” and inoculation syphilis: A PHS “Tuskegee” doctor in Guatemala, 1946-1948. *Journal of Political History*, 23, 6-28.

LANDMARK CASE: The Trovan Study

- Stephens, J. (2000, December 17). Where profits and lives hang in balance: Finding an abundance of subjects and lack of oversight abroad, big drug companies test offshore to speed products to market. *The Washington Post*. Retrieved from Lexis Nexis database.
- Stephens, J. (2001, January 16). Doctors say drug trial’s approval was backdated. *The Washington Post*. Retrieved from Lexis Nexis database.
- Stephens, J. (2009, April 4). Pfizer reaches settlement in Nigerian drug-trial case. *The Washington Post*. Retrieved from Lexis Nexis database

Leaning, J. (2001). Ethics of research in refugee populations. *Lancet*, 357, 1432-1433.

Lurie, P. & Wolfe, S. (1997) Unethical trials of interventions to reduce perinatal transmission of the HIV virus in developing countries. *New England Journal of Medicine*, 337:12, 853-856.

Mastroianni, A. C., & Kahn, J. P. (2002). Risk and responsibility: Ethics, Grimes v Kennedy Krieger, and public health research involving children. *American Journal of Public Health*, 92(7), 1073-1076.

Sieber, J. (1977-8). [Case study]. Laud Humphreys and the Tearoom Sex Study. pp. 1-2

Varmus, H. & Satcher, D. (1997) Ethical complexities of conducting research in developing countries. *New England Journal of Medicine*, 337:14, 1003-1005.

Wendler, D., Emanuel, E.J., & Lie, R. K. (2004) The standard of care debate: Can research in developing countries be both ethical and responsive to those countries’ health needs? *American Journal of Public Health*, 94:6, 923-928.

Willowbrook Experiments, NIH Science Education Program [Sakai] pp. 1-4

World Medical Association (1964, rev. 2013). *Declaration of Helsinki: Ethical principles for medical research involving human subjects*.

**Videos:**

1962: The Stanley Milgram Obedience Study, [https://youtu.be/ek4pWJ0\\_XNo](https://youtu.be/ek4pWJ0_XNo) (44:26 minutes)

1970s: The Stanford Prison Experiments, [https://youtu.be/L\\_LKzEqIPto](https://youtu.be/L_LKzEqIPto) (29:00 minutes)

“The Constant Gardener” (2005) or “Miss Evers Boys” (1997) [Rutgers Library, Kanopy]

**Unit 10**

**Group Project: Ethical Research Design-a-Thon**

See 2018 version of the Design-a-thon as a sample, pages 10-11.

**VII. Summary of Assignment and Assessment Due Dates**

Due dates to be assigned	Assignment # 1: Case analysis: <i>The community health nurse and the HIV patient</i> .
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Due dates to be assigned	Assignment # 2: Case analysis: <i>Planning with limited resources for a severe influenza pandemic</i>
Due dates to be assigned	Mid-term exam Closed book, no internet, must use black or blue ink.
Due dates to be assigned	Assignment #3: Case analysis: <i>"It's over, Debbie"</i> .
Friday, October 28, 10:00pm	Assignment #4: CITI Training Certificate of Completion
Due dates to be assigned	Assignment #5: Case Analysis: The Belmont Report and the US Public Health Service Tuskegee Syphilis Study
Due dates to be assigned	Assignment #6: Commentary on ethical issues in "The Constant Gardener"
Due dates to be assigned	Assignment #7: Case analysis: TBD
Wednesday, December 12	IN CLASS: Part 1: End of semester assessment
Sunday, December 16	By 11:59 Final written case analysis due on Canvas by 11:59pm

### VIII. Information regarding Assignments and Assessments

- 1. Human Subjects Training Certification:** As part of this course, all students will be required to complete the CITI training in Human Subjects Research.

Instructions for accessing and completing the CITI training Human Subjects Research:

Log into the CITI website (<https://www.citiprogram.org/> )

Register with CITI (See Instructions: Initial Registration for New Learners)

Affiliate with "Rutgers-The State University of New Jersey (All Campuses)"

Successfully Complete All of Your CITI Training Modules

Save an electronic copy of your Completion Report for future IRB Submissions

To print your CITI Certificate (Completion Report):

Log into the CITI website

Go to Main Menu

Click "Print Report" in the Completion Report Column

Copies of each student's Rutgers CITI training certificate in Human Subjects Research must be posted to Canvas **no later than Friday, October 28, at 10:00pm.**

- 2. Case writing:** Case studies in ethical issues in biomedicine form the backbone of this course. All students will be asked to read and contribute actively to discussions about cases as part of each class. Students will be asked to prepare written case analyses of six such cases; completed case analyses are to be completed and uploaded to Canvas in advance of the class session in which they will be discussed. Late posting of assignments will **only** be accepted with PRIOR approval from the instructor. **PLEASE NOTE: The case for which you receive the lowest score will be removed from the gradebook.**
- 3. End of semester assessment:** The end of semester assessment will involve two activities. These activities are intended to 1) assess student familiarity with the key moral theories, principles, and key regulatory documents that guide the practice of medicine and medical research and 2) assess their ability to identify ethical issues and apply moral theories, ethical principles, and key ethics regulatory guidance to address them.

In-class multiple-choice and short-answer test      Wednesday, December 11, 1:10pm – 2:30pm  
[Closed book, no Internet]

Take home case analysis      Due Monday, December 16 @ 11:59pm  
[Open book/Internet, as needed]

**Grading Rubric:**

Participation:	20%
CITI certification	5%
Mid-term	20%
Case analyses	20%
End of year assessment (2 parts)	35%

**Assessment and Grading:** A, B+, B, C+, C, D, and F

[NOTE: While students are encouraged to understand the strengths and weaknesses of their assessments and case analyses, grades are NOT negotiable. Make-up work or extra credit are not available options for improving one's grade, although the instructor is more than happy to work with students to improve their understanding of course concepts and their future performance.]

**IX. Course Policies and Expectations****Attendance**

Students are expected to attend all class sessions. Please make every effort to arrive on time as class will begin promptly. Arriving late to class is strongly discouraged. Repeat offenders will, at the discretion of the instructor, be marked as 'absent'. Unexcused absences WILL result in a reduction of your grade for class participation. Observance of religious holidays listed in the University calendar is recognized as an excused absence, but please let me know in advance if you will miss class for this reason.

- **Excused absences** include those unavoidable absences due to observance of religious holidays listed in the University Calendar, illness, family emergencies, or academic opportunities, cleared in advance with the instructor, that conflict with class attendance. Please report absences, preferably in advance, through the university's self-reporting absence system, accessed at <https://sims.rutgers.edu/ssra/>. **Please note: Reporting your absence in advance does not "excuse" you, unless you have received permission from the instructor.**
- **Longer periods of absence.** If you anticipate missing more than one week of classes for serious illness, confidential, or sensitive personal reasons, you should also consult with a New Brunswick Dean of Students who will help to verify your extended absences from classes.
- **Absences due to illnesses.** If your absence is due to illness, visit University Health Services for information about campus health services, including information about: how to make an appointment, self-care advice for colds/flu, mental health and counseling options, and how to access the "After Hours Nurse Line" for medical advice. **In order for an absence due to illness to count as an excused absent, you will need to furnish the instructor with a note from the medical center or a health provider.**

**In class-conduct:**

Please note that due to the discussion format on which much of this course is based, students are expected to attend every class and to be on time. Attendance will be noted and students who are repeat offenders on attendance and/or timeliness will be marked down accordingly on their participation grade.

Computers and IPADs may be used for note-taking, but may not be used for purposes unrelated to this course. Phones may not be used at any time, nor may they be held in student hands, or placed on the table surfaces during class hours.



This course and its classroom are to be treated as safe environments in which students are free to hold and express a wide variety of opinions. All students are asked to be respectful of others' rights to their views and sensitive to their feelings. Ethics discourse is grounded in one's ability to draw on moral theories, principles, and regulatory frameworks, not solely on the strength of one's convictions; students should endeavor to support their views using the course materials provided as well as other references materials found in the scholarly literature.

**Academic Integrity Policy**

This course adheres to the university's Academic Integrity Policy and infractions are taken seriously. All students are required to review this policy, which has been posted to the Sakai site under 'Resources/Administration'.

**Disability Accommodation**

Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student with a disability must contact the appropriate disability services office at the campus where you are officially enrolled, participate in an intake interview, and provide documentation: <https://ods.rutgers.edu/students/documentation-guidelines>. If the documentation supports your request for reasonable accommodation, your campus's disability services office will provide you with a Letter of Accommodations. Please share this letter with me and discuss the accommodations you need as early in the course as possible. To begin this process, please complete the Registration form on the ODS web site at: <https://ods.rutgers.edu/students/registration-form>.

**Course Evaluation**

This course will be evaluated by online surveys as administered by the Rutgers Center for Teaching Advancement and Assessment Research (10:652:301).

## ETHICAL CONSIDERATIONS IN DESIGNING AND IMPLEMENTING RESEARCH IN LOW-RESOURCE INTERNATIONAL SETTINGS

### ETHICAL RESEARCH DESIGN-A-THON

Country X has asked your US university to help address the alarming rate of HIV among its adolescent population ages 13-24 years. While the country has met with considerable success in reducing the prevalence of HIV in its population overall due to improvements in its ability to reduce rates of mother-to-child transmission and promote HIV risk reduction behaviors among adults, the rate of new infections among young people has not decreased significantly over the past decade. Public health officials in the Ministry of Health believe that high-risk behaviors among adolescents is not well understood and that inadequate attention is being paid to social norms that may shape the extent to which adolescents engage in protective or high-risk behaviors.

To respond to this request, the university has assembled three separate teams- one that concerns itself with the scientific aspects of the project, one that will be responsible for designing follow-on intervention strategies, and one team that is tasked with ensuring that the study is designed in such a way that it meets the highest ethical standards for research. The scientific team has decided to conduct in-depth interviews with young people in Country X. You plan on collecting data from 90 adolescent males and females ages 13-24 in each of the Country's 20 districts for a total sample of 1800 subjects. The study is being funded by the Gates Foundation, which has indicated it will commit future resources to an implementation phase if the study succeeds in identifying targets of opportunity for meaningful intervention.

**Your team is the ethics squad. You've convened an 'ethical research design-a-thon' to establish the basic framework under which the study should be designed and implemented. In other words, how should the investigators set up this study so that it meets the highest ethical standards?**

Your reference 'toolkit' includes the following:

- The Belmont Report
- The Common Rule
- The Declaration of Helsinki
- (CIOMS, 2016) *The International Ethical Guidelines for Health-related Research Involving Humans*
- Emanuel, E., Wendler, D., Killen, J., & Grady, C. (2004). What makes clinical research in developing countries ethical? The benchmarks of ethical research. *The Journal of Infectious Diseases*, 189, 930-937.

Your final report should be in the form of a 'list' of major ethical 'topics'. Under each topic, your team will need to identify 1) potential areas of concern, 2) potential strategies for alleviating/minimizing those concerns and 3) language in one or more of the reference tools (with specific location within reference document) that supports your team's recommendations. Your final recommendations will be due in class on Monday, November 19<sup>th</sup>.

### BACKGROUND

#### Country

- 60% of the population lives in and around the capital city, where most of the country's health infrastructure is located.
- Democratic
- Low corruption

- High literacy rate, particularly among youth
- 10% of each class from the national university are able to secure employment after graduation
- High unemployment among youth ages 15-30
- 40% of the population lives in rural environments, where there one in five people live on less than \$1.25 (PPP) per day
- Common sources of livelihood in rural areas: subsistence farming
- Although English is the ‘official’ language of the country, most citizens speak a ‘local language’ and there are an addition 18 sub-languages spoken within the population, particularly among tribal groups in the more remote areas of the country.

### **Health System**

- Each of the 20 districts have a district hospital but capacity is uneven, with more remote districts having little more than a facility staffed by nurses and community health workers.
- Uneven system of health care delivery, with majority of services concentrated in urban areas
- Limited distribution of antiretroviral therapies that is dependent upon international/pharmaceutical donor relationships.
- Mental health services extremely thin.
- Country has a network of health clinics throughout the 20 districts to provide voluntary counseling and testing for HIV and to dispense anti-retroviral medications.

### **Social Norms**

- Community-level decisions are made by a council of village leaders, who are typically male. Researchers typically request permission from these councils prior to embarking on a study in a particular village/community.
- Homosexuality is illegal. LGBTQ community is ‘underground’ and its members highly stigmatized.
- Pre-marital sex is ostensibly ‘forbidden’ although rates of children born out of wedlock are high.
- HIV is highly stigmatized.
- Gender-based violence is widespread with women and girls experiencing high rates of sexual, psychological, economic, and physical violence within intimate relationships, families, and social structures.
- Women are largely marginalized as decision-makers.
- High rates of early marriage/sexual debut for girls, with many being married at a very young age to much older men.
- Girl children remain at home under the guardianship of their parents or older male relatives until they marry.
- Boy children may leave their natal home at the age of 16 and are treated as independent adults at age 18, regardless of family status or employment.
- High education is available free from the government to all students who pass qualifying exams at the end of their high school years.
- The government provides tuition, housing and a living allowance to all university students but disparities remain between those students who come from remote, poor regions, and those students who live in or near the capital city.
- It has been reported that young women from poverty will enter into relationships with older, well-to-do men (sugar-daddies) while at university in order to be able to enjoy a lifestyle comparable to their more well-to-do peers.