700.665.11 Introduction to Ethics of U.S. and International Human Subject Research
Johns Hopkins Berman Institute of Bioethics
Summer Institute
2 Credits

June 3-7, 2019
1:00 - 4:20 pm

Course Syllabus

Course Faculty:
Joseph Ali, JD
Johns Hopkins Berman Institute of Bioethics and Johns Hopkins
Bloomberg School of Public Health
Deering Hall 208
jali@jhu.edu

Teaching Assistant:
Diana Mendoza-Cervantes, MBE - Senior Research Program Coordinator
Johns Hopkins Berman Institute of Bioethics
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Guest Lecturers:
Juli Bollinger, BS MS - Genetic Research Analyst, Johns Hopkins Berman Institute of Bioethics

Edward Fuchs, MBA PAC - Associate Director of the Drug Development Unit in the Division of Clinical Pharmacology, Johns Hopkins School of Medicine

Nancy E. Kass, ScD - Vice Provost for Graduate and Professional Education, Johns Hopkins University; Phoebe R. Berman Professor of Bioethics and Public Health, Berman Institute of Bioethics

Caitlin Kennedy, PhD - Associate Professor and Program Director, Social and Behavioral Interventions, Department of International Health, Johns Hopkins Bloomberg School of Public Health

Joan B. Cobb Pettit, JD MA - Executive Director, JHSPH Institutional Review Board Office

Sheree Schwartz, PhD MPH - Assistant Scientist, Department of Epidemiology, Johns Hopkins School of Public Health
Course Description
This course provides an introduction to the ethics of human subject research and allows participants to apply what they learn to case examples from the U.S. and international settings. Presents ethical principles and a framework for analysis. Reviews key U.S. and international regulations that guide the ethical conduct of research. Through lectures and moderated discussions, addresses a variety of issues including: informed consent for research participation; ethical aspects of study design; just selection of research subjects and duties of justice when working in resource poor settings; and the role and function of institutional review boards/ethics review committees. Uses case discussions to explore research in both domestic and international settings.

Learning Objectives
Upon successfully completing this course, students will be able to:
1. Explain core research ethics constructs and requirements
2. Apply ethics principles and a framework to research ethics case scenarios
3. Reason through ethical issues that arise in the conduct of human subject research, both in the U.S. and globally

Methods of Assessment
Student who are taking this course for credit will be assessed as follows:
20% class participation
30% quizzes
   - Completion of question prompts included in the three assigned cases; submitted via email (jali@jhu.edu) prior to class on the day that each case will be discussed
50% analytic paper
   - Due no later than 11:59pm on June 17th via email (jali@jhu.edu). Assignment to be distributed June 7th

Readings
All participants are expected to read course material before each day’s session. Additional readings on particular topics are available on request. In addition, all students are expected to read case materials distributed before class sessions in which case studies will be discussed. All readings are available on CoursePlus (https://courseplus.jhu.edu).

Core Readings:


References:
## Course Overview

### June 3 - Monday - Day One

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Description</th>
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<tbody>
<tr>
<td>1:00-1:30</td>
<td>Lecture 1 (Ali)</td>
<td>Introduction to Participants and Course</td>
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<tr>
<td>1:30-2:15</td>
<td>Lecture 2 (Ali)</td>
<td>Introduction to Research Ethics Principles, Regs &amp; Guidelines</td>
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<td>2:15-3:00</td>
<td>Lecture 3 (Ali)</td>
<td>Framework for Ethical Analysis</td>
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<td>3:00-3:20</td>
<td>Break</td>
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<tr>
<td>3:20-4:20</td>
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<td>Case A: Research in Epidemics</td>
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### June 4 – Tuesday - Day Two

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<tbody>
<tr>
<td>1:00-1:45</td>
<td>Lecture 4 (Ali)</td>
<td>Informed Consent</td>
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<tr>
<td>1:45-2:20</td>
<td>Lecture 5 (Kass)</td>
<td>Justice/Vulnerable Populations</td>
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<td>2:20-3:00</td>
<td>Lecture 6 (Kass)</td>
<td>Study Design</td>
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<td>3:00-3:20</td>
<td>Break</td>
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<tr>
<td>3:20-4:20</td>
<td>Discussion Session (Pettit)</td>
<td>Research Ethics Committees</td>
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### June 5 – Wednesday - Day Three

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<th>Time</th>
<th>Activity</th>
<th>Description</th>
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<tbody>
<tr>
<td>1:00-2:00</td>
<td>Lecture 7 (Kennedy)</td>
<td>Social and Behavioral Research: Focus on Qualitative Research</td>
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<tr>
<td>2:00-3:00</td>
<td>Lecture 8 (Schwartz)</td>
<td>Human Rights and Research Ethics</td>
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<td>3:00-3:20</td>
<td>Break</td>
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<td>3:20-4:20</td>
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<td>Case B: Evaluating a Disability Rehabilitation Program</td>
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### June 6 – Thursday - Day Four

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<tbody>
<tr>
<td>1:00-1:30</td>
<td>Lecture 9 (Ali)</td>
<td>Ancillary Care</td>
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<tr>
<td>1:30-3:00</td>
<td>Lecture 10 (Fuchs)</td>
<td>Ethics &amp; Trials with Healthy Volunteers</td>
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<td>3:00-3:20</td>
<td>Break</td>
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<td>3:20-4:20</td>
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<td>Case C: Research Inducements</td>
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### June 7 – Friday - Day Five

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<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1:00-1:30</td>
<td>Lecture 11 (Ali)</td>
<td>Privacy and Confidentiality</td>
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<td>1:30-2:30</td>
<td>Lecture 12 (Bollinger)</td>
<td>Genetics and Biobanking</td>
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<td>2:30-2:50</td>
<td>Break</td>
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<tr>
<td>2:50-3:50</td>
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<td>Debate: Broad vs specific consent for future use of identifiable health information and/or specimens</td>
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<td>3:50-4:20</td>
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<td>Wrap-up</td>
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Course Readings

Day One – June 3

Topics: Introduction to Research Ethics Principles, Regs & Guidelines; Framework for Ethical Analysis

Required:


Framework for analyzing a case

Supplemental:


Day Two – June 4

**Topics:** Informed Consent; Justice/Vulnerable Populations; Study Design; Research Ethics Committees

**Required:**


Varmus H and Satcher D. (1997). Ethical complexities of conducting research in developing countries. NEJM, 337(14): 1003-1005. (Study design)

Benatar SB. 2002. Reflections and Recommendations on Research Ethics in Developing Countries. Social Science and Medicine 54:1131-1141. (Research Ethics Committees)

**Supplemental:**


Molyneux CS, Wassenaar DR, Peshu N, Marsh K. 2005. 'Even if they ask you to Stand by a Tree All Day, You Will Have to do it (Laughter) ': Community
Voices and the Notion and Practice of Informed Consent For Biomedical Research In Developing Countries. Social Science and Medicine 61:443-454.

Day Three – June 5

Topics: Ethics & Qualitative Research; Human Rights & Research Ethics

Required:


Supplemental:

**Day Four – June 6**

**Topics:** Ancillary Care; Ethics & Trials with Healthy Volunteers

**Required:**


**Supplemental:**


Topics: Privacy & Confidentiality; Genetics & Biobanking

Required:


Broad Consent provisions found at 45 C.F.R. 46.116(d) and related regulatory language cross-referenced in the broad consent section https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116


Supplemental:
