Instructor:
Beth E. Rivin, MD, MPH
Phone: (206) 616-3674
Email: brivin@uw.edu
Office Location: William H. Gates Hall Room 446
Office Hours: By appointment

Summary of Course
This course will explore the legal requirements and ethical principles governing responsible conduct of international research, with a focus on research in low- and middle-income countries. The course compares and contrasts law and ethical standards in wealthy countries, resource-poor settings and ethnically distinct communities and considers how necessary adjustments can and should be made to improve research capacity while simultaneously protecting the human rights of individuals and populations, especially vulnerable groups. The class will review case studies to discuss informed consent, standards of care, post-trial access to research products and other issues involving ethical conduct of research in different countries, healthcare systems and research environments.

Course Objectives
By the end of the course, students will be able to:
1. Describe the history of medical research and case studies of violations of research ethics in low- and middle-income countries and wealthy countries.
2. Compare and contrast established western principles of research ethics, international ethics guidelines and alternative research ethics frameworks.
3. Critically analyze current international ethical models and the implementation of those models in research.
4. Define current issues and problems facing researchers and research participants in global health research today.
5. Describe the development of research ethics review and the challenges that are faced in resource-poor country contexts today.

Required Texts
The required text is Ethical Issues in International Biomedical Research, A Casebook, edited by James V. Lavery, Christine Grady, Elizabeth R. Wahl and Ezekiel J. Emanuel. Hereinafter in the syllabus, the textbook will be referred to as “Casebook.” The other required book is The Immortal Life of Henrietta Lacks by Rebecca Skloot. Other reading materials for the course will be available on the course website.

Course Grade
Your course grade will be based on the following course assignments:
1. Class participation, excluding case study discussions (10%)
2. Leading discussion of case studies (10%).

3. Mid-term Assignment (5 pages, 20%), due by noon on Monday, October 28, 2013 via its Assignments link on CANVAS

4. Presentation of Final Paper Topic (25%).

5. Final Paper (~10 pages): Research and critique of international research or a topic related to international research ethics. Students will find (e.g., through PubMed search or NIH search) a published study that fits within the international context in this class, or they may discuss a current research project or prior research experience. Students may also decide to research a specific topic of interest related to international research ethics (35%), due by noon on Friday, December 13, 2013 via its Assignments link on CANVAS

With respect to class participation, the expectation for each class will be that the student arrives prepared and ready to engage in discussion, having previously briefed the assigned readings and discussion questions.

There is no final exam.

Disability-related Needs

To request academic accommodations due to a disability, please contact Disability Resources for Students (DRS), 448 Schmitz, (206) 543-8924 (V), (206) 543-8925 (TTY). If you have a letter from DRS, please present the letter to me so we can discuss the accommodations you might need in this class.

The following syllabus is tentative and subject to change.

Course Syllabus and Schedule

Students are required to read The Immortal Life of Henrietta Lacks before the mid-term. Questions on the mid-term will refer to the book.

September 23, 2013
I. Introduction: Research in an International Context
Class Objectives:
A. Describe context of health in low-resource settings and its implications for ethical research;
B. Discuss challenges of conducting cross-cultural clinical trials;
C. Identify barriers in cross-cultural research;
D. Introduce ethical guidelines.
Readings:
September 25, 2013
II. History of Research Ethics – An International Construct

Class Objectives:
A. Examine the history of medical research and ethics;
B. Review the development of the Nuremberg Code;
C. Analyze America’s history of clinical research.

Readings:
- Belmont Report (10 pages)
- Declaration of Helsinki (5 pages) (skim)

September 30, 2013
III. U.S. Regulation of International Research

Guest Lecturer: Linda Coleman

Class Objectives:
A. Review the Fed Code and its role in protecting international human subjects research
B. Provide current examples of challenges facing researchers conducting research internationally
C. Discuss IRB composition and procedures for compliance with federal regulations in order to protect human subjects

Readings:

October 2, 2013
IV. Controversies in International Clinical Research

Class Objectives:
A. Review international guidelines for research
   1. Protections afforded to research participants, in general, and special populations, in particular
   2. Fair benefits of research
   3. Institutional review of research
B. Explore leading controversies

Readings:
- Declaration of Helsinki (5 pages) (read)
October 7, 2013
V. Respect for Persons and Individual Autonomy
Class Objectives:
A. Examine autonomy, the definition and its history
B. Compare the Western concept of autonomy and consent to Non-Western views
C. Discuss informed consent in international research
Readings:
Casebook, Case 17, pages 281-294.

October 9, 2013
VI. Using Electronic Databases for Multidisciplinary Research
Guest Lecturer: Reference Librarian, Gallagher Law Library

October 14, 2013
VII. Informed Consent Continued
Class Objectives:
A. Examine elements of consent in international research
   1. Capacity to Consent
   2. Full Disclosure of material information
   3. Understanding of information
   4. Voluntary decision making
B. Contrast adherence to law/guidelines for ethical standards and protection of vulnerable populations
C. Discuss community vs. individual consent
Readings:
Casebook Case 16, page 263-280.

October 16, 2013
VIII. Informed Consent with Community Partnership
Class Objectives:
A. Review current knowledge about investigator perspectives on informed consent
B. Discuss mechanism of informed consent that focuses on collaboration and partnership of community
Readings:
Casebook, Case 2, pages 43-63.
October 21, 2013
IX. Fair Selection of Subjects and Communities in Research

Class Objectives:
A. Examine subject & community selection in international research
B. Discuss methods to improve fairness and prevent exploitation of vulnerable populations
C. Review the role of investigators and tools they have in preventing exploitation
D. Explore the important function of local IRBs in fair selection of subjects & communities

Readings:

Casebook, Case 10, pages 171-183.

October 23, 2013
X. Respect for Enrolled Subjects and Communities in Research

Class Objectives:
A. Review investigator’s duty to provide protection of enrolled subjects and communities in research
B. Examine international guidelines for epidemiological studies
C. Discuss ethical and safety considerations for research involving violence against women

Readings:
CIOMS International Ethical Review of Epidemiological Studies, 2009
(SKIM) WHO, Department of Gender and Women’s Health, Putting women first: ethical and safety recommendations for research on domestic violence against women, Geneva: WHO; 2001 Available at: http://www.who.int/gender/documents/violence/who_fch_gwh_01.1/en/

Casebook, case 21, pages 347-359.

October 28, 2013
XI. Standard of Care and Obligations for Medical Treatment During Trial

Class Objectives:
A. Discuss what is meant by standard of care in a clinical research trial
B. Explore the controversies around standard of care: global and local standards
C. Compare different perspectives about obligations for ancillary care

Readings:

Risk-Benefit Analysis
XII. October 30, 2013
Guest Lecturer: Linda Coleman
Class Objectives:
A. Review the concept of risk in international research
B. Define and discuss the risk benefit analysis
C. Apply the risk benefit analysis to cases
Readings:
Casebook, Case 12, pages 203-216

November 4, 2013
XIII. Affordable Drugs: The documentary film, "Dying for Drugs"
Class Objectives:
A. Analyze the role of the pharmaceutical industry in providing affordable and accessible drugs
B. Examine the ethical implications and practical impacts of differential pharmaceutical pricing
C. Evaluate the ethical aspects of patented vs. generic drugs
Readings:
Ruth Macklin, Double Standards in Medical Research in Developing Countries, Chapter 6, “Making Drugs Affordable”, 2004, Pages 163-191. (28 pages)

November 6, 2013
XIV. Justice Overview and Post-Trial Access
Class Objectives:
A. Discuss justice in research with a focus on distributive justice and fair benefits
B. Review international guidelines on post-trial access
C. Examine the controversies about fair benefits of research
Readings:

November 11, 2013
No Class – Veterans Day

November 13, 2013
XV. Community Participatory Research (CPR)
Guest Lecturer
Class Objectives:
A. Review history of the methodology
B. Describe goals and partnership between community and researcher
C. Examine Phases/steps in developing CPR
D. Discuss examples of successful CPR
Readings:

November 18, 2013
XVI. Exploitation in Research
Class Objectives:
A. Discuss the different definitions and perspectives on international research exploitation
B. Explore the impact of different perspectives on ethical review and policy involving international research
Readings:
Ruth Macklin, Double Standards in Medical Research in Developing Countries, Chapter 4, “Avoiding Exploitation”, 2004, pages TBD
Jennifer S. Hawkins and Ezekiel J. Emanuel, Exploitation and Developing Countries, The Ethics of Clinical Research, Chapter 7, pages 206-245
Casebook, Case 6 pages 105-115

November 20, 2013
XVII. Global Health Ethics
Class Objectives:
A. Define the foundational principles of global health ethics
B. Explore the development of a global ethical framework based on international human rights
C. Review ethical standards for global health research publication
Readings:
Carla Angelski, Conrad V Fernandez, Charles Weijer and Jun Gao, The publication of ethically uncertain research: attitudes and practices of journal editors, BMC Medical Ethics 2012, 13:4

November 25, 2013
XVIII. Capacity Building
Class Objectives:
A. Describe capacity building and its components
B. Review different types of capacity building in research ethics
C. Discuss the role of collaborative partnerships between research sponsor and host communities
Readings:

**November 27, 2013 cancelled-Thanksgiving**

**December 3, 2012**
**XIX. Presentation of Final Papers**

**December 5, 2012**
**XX. Presentation of Final Papers**
Course evaluations