COURSE OBJECTIVE:

The purpose of this course is to acquaint students with an introduction to ethical theory and principles of bioethics, for students to become familiar with ethics requirements when conducting research with human subjects and with animals in the U.S. and/or developing countries, and for students to become more sensitive to the moral considerations inherent to public health research. Through lectures and small group case discussion, the following topics will be covered: ethical theory and principles, informed consent in research; Institutional Review Boards; the just selection of research participants; cultural relativism; ethical issues in vaccine research; ethics and human rights; appropriate use of placebos; what is owed to research participants and communities after research is completed; the use of animals in research; and scientific and academic integrity. For small group case discussions and for assignments, students will have the choice of working through research examples either from the U.S. or a developing country setting. Student evaluation is based on classroom participation and small group case discussion, a consent assignment, a quiz about human subjects regulations, and a final paper or project. This course satisfies the NIH's and the School's requirement for training in the responsible conduct of research.

REQUIRED READINGS:

The majority of course readings can be found in the following text:


The reader is available for purchase through the Johns Hopkins Matthews Bookstore. There will also be 1 or 2 copies of the reader on reserve in the Lilienfeld library.

All other course readings will be available through E-Reserves. The website to access the course readings is: http://eres.welch.jhmi.edu/coursepage.asp?cid=45. The password for the site is: 306665sph.

COURSE REQUIREMENTS and ASSIGNMENTS:
1. **Participation:** You are required to attend class, keep up with the reading, and participate in class. If you miss class, it is your responsibility to go to the course website (described below) to get any handouts that were distributed that day. Those who make exceptional contributions during class and small group discussions will receive an 3-5 extra credit points in grading.

1. **In-class exercises:** There are three in-class exercises during the term. These include serving on a "mock IRB" and analyzing cases. These sessions will occur on February 3, February 17, and March 9. In-class exercises will be ungraded, and you may work with other students on these exercises. If you must miss one of these sessions, you are required to write a short (1/2 to 1 page) analysis of that case to hand in. This must be handed in within one week of returning to class.

2. **Completion of CHR training module on research ethics:** Before the end of the term, you need to go to the CHR website and complete the 45 minute training module on human subjects research. This will allow you to submit NIH grants and fulfill one piece of the school’s requirement to have studies approved by the CHR. The website is [http://www.jhsph.edu/chr/training_module.html](http://www.jhsph.edu/chr/training_module.html). We are able to monitor on the CHR website who has already completed the module. This is pass/fail but required. NOTE: In past years, some students have said that it is useful to do this early in the term, at least before the mid-term.

4. **Consent assignment:** You will be provided with a choice of two research projects (one from the U.S.; one international). You must write a consent form for one of these studies. More extensive instructions will be distributed with the assignment. This assignment will be graded, and it must be done on your own; that is, you should not work with other students on this assignment. We will also post a sample consent form on our class website to help those of you who have not drafted consent forms previously. TAs will also provide guidance on writing consent forms, according to the JHSPH template, during office hours.

The consent form assignment will be distributed in class on Tuesday, January 27th, and is due on **Thursday, February 5.** One point will be deducted for every day the assignment is late, if no prior arrangements were made.

5. **In-class mid-term:** There will be an in-class mid term (30-40 minutes) on Tuesday, February 17. The mid-term will focus on material covered to date, including the U.S. regulations and on IRBs. This will occur at the beginning of class on **Tuesday, February 17.** Anyone who anticipates missing class that day should see one of the instructors or TAs as soon as possible.

1. **Final case study assignment:** A final case study assignment is due in class on the last day of the class, **Thursday, March 11.** Any conflicts with this date must be discussed in advance with the instructors. We will distribute 4 case studies. You need to pick two of these. You must write about 4-5 pages on each case, double spaced, 12 point font. You must use references from the course in your
analyses. More description of this assignment will be provided when the cases are distributed in class.

In lieu of final case study assignment, students may write an original paper on any topic related to research ethics of interest. However, this must be approved by the instructors in advance, ideally 2 weeks before the term and in no circumstances less than 1 week before the end of the term. NOTE: This is a great option for people with a strong interest in exploring a particular topic, but students who have chosen this option in the past have found it more challenging than doing the case analyses.

GRADING POLICY:

Your final grade for this class is based on the total number of points you accumulate out of a possible total of 100 points.

1. The consent assignment is worth 20 points;
2. The mid term is worth 35 points;
3. The case analysis is worth 45 points.
4. Extra credit: You will receive 3-5 extra credit points for outstanding participation and attendance.

Late assignments: One point will be deducted for every day an assignment is late, if no prior arrangements were made.

COMMUNICATION WITH COURSE INSTRUCTORS:

Dr. Kass can be reached by email at nkass@jhsph.edu or by phone at 955-0310. Dr. Kass is in HH 344.

Dr. Andrea Ruff can be reached by email at aruff@jhsph.edu or by phone at 955-1633. Dr. Ruff's office is Hygiene W5501.

Amy Medley can be reached by email at amedley@jhsph.edu. Amy will hold office hours from 12-1 on Tuesdays in E 5031.

Neal Dickert can be reached by email at ndickert@jhsph.edu. Neal will hold office hours Thursdays after class, 3-4 PM in HH 349.

Please address e-mail inquiries concerning the class to all of the above, when possible, so that the first available person can answer your questions.

Claire Snyder will serve as a part-time TA for the purposes of leading small group discussions and grading. Claire can be reached by email at csnyder@jhsph.edu

COURSE WEBSITE
A web supplement site has been developed for this course. The web site includes the syllabus, course description, and links to other sites of interest. The site will be updated after every class to include hand-outs and assignments, as relevant. Please go to the web site to get the hand outs if you ever miss class. To access the web site:

1. go to: https://apps1.jhsph.edu/courses/index.cfm
1.2 click: Research Ethics and Integrity under Department of Health Policy and Management
1.3 Password is: stu306665
1. **TUESDAY, JANUARY 20:** Introduction to course; Introduction to Ethical Theory and Principles of Bioethics: Dr. Nancy Kass

2. **THURSDAY, JANUARY 22:** History of research ethics and ethical codes/regulations governing research with human participants: Dr. Nancy Kass
   
   
   

References:

   
   
   
   D. **Reader #9 (pp. 56-80)**- Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO) (2002). International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva: CIOMS.
   

3. **TUESDAY, JANUARY 27:** Informed Consent: Dr. Nancy Kass. Guest Lecturer: Dr. Keith West

   → Consent assignment distributed in class


4. THURSDAY, JANUARY 29: Institutional Review Boards (IRBs)


C. JHU Committee On Human Research Checklist for Reviewers (to be distributed in class)

D. Reader #8 (pp. 39-55)- Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Code of Federal Regulations, Title 45, Part 46 “Protection of Human Subjects.”

5. TUESDAY, FEBRUARY 3: Case Study #1: Kennedy-Krieger Lead abatement study in East Baltimore (Small groups)


6. THURSDAY, FEBRUARY 5: The Tuskegee Syphilis Study (VIDEO shown in class): Dr. Vanessa Gamble, Department of Health Policy and Management and Morgan-Hopkins Center for Health Disparities Solutions

→ Consent assignment due in class


7. **TUESDAY, FEBRUARY 10**: Research with Animals: Dr. Hilary Bok, Department of Philosophy, Johns Hopkins University

A. Reading to be announced.

B. U.S. Department of Health and Human Services, Public Health Services. *Instructions for PHS 398, Sections pertaining to research on animals*.

8. **THURSDAY, FEBRUARY 12**: Ethical issues in epidemiologic and health services research.


9. **TUESDAY, FEBRUARY 17**: In-class quiz and Mock IRB session (small groups)

→ In-class quiz during first 30-35 minutes of class.

The remainder of class will be a mock-IRB session in small groups.

10. **THURSDAY, FEBRUARY 19**: Privacy and Confidentiality in research: Dr. Michael Sweat, Department of International Health, BSPH.


11. **TUESDAY, FEBRUARY, 24**: Research Ethics and Human Rights: Dr. Chris Beyrer, Departments of Epidemiology and International Health, BSPH


12. **THURSDAY, FEBRUARY 26:** Clinical research issues: Phase 1 research with healthy volunteers, Dr. Charles Flexner, Department of Medicine, Johns Hopkins School of Medicine.


13. **TUESDAY, MARCH 2:** Placebo-Controlled Studies in Asthmatic Children: Dr. Benjamin Wilfond, NIH Department of Clinical Bioethics, National Human Genome Research Institute


**Recommended:**


14. **THURSDAY, MARCH 4:** Ethics and Study Design: Dr. Steven Goodman, Departments of Oncology, Epidemiology, and Biostatistics, Johns Hopkins School of Medicine and BSHP


15. **TUESDAY, MARCH 9: Case study #3: UNAIDS Vaccine Trial (small groups)**

A. UNAIDS, Draft Scenario of Hypothetical HIV Vaccine Study Proposal

16. **THURSDAY, MARCH 11: Professional integrity, authorship, and conflict of interest: Dr. Andrea Ruff**

→ Final paper/project due in class