I. Course Description

This course addresses ethical issues related to public health research. This term we will examine such topics as guidelines for ethical conduct of research; the Tuskegee Syphilis Study; ethical practices in transnational research; ethics of funding health research; clinical trials and the role of the FDA in protecting patients and research participants from unapproved biologics; and ethical frameworks concerning community engagement in health research. During our exploration of these topics we will draw upon codes and guidelines for ethical conduct of health research as well as scholarship from bioethics, public health, and social studies of health research. At the end of the course you will be familiar with key readings, ethical frameworks, contemporary debates in public health research ethics, and various topics falling within the scope of research ethics.

II. Course Prerequisites

None.
III. Course Goals, Objectives & Competencies

Through course readings, podcasts and videos, discussion board posts, and writing assignments you will learn to identify and analyze ethical issues related to public health research. You will develop skills in ethical analysis and develop a better understanding of public health research ethics. The course will help you use evidence, reasoning, and argumentation when addressing complex moral issues related to public health research. You will develop the following competencies in this course:

1) You will read, understand, analyze, and learn how to apply key ethical codes, regulations, and frameworks related to public health research and policy. In particular, you will become competent in interpreting and applying the Nuremberg Code, Belmont Report, Declaration of Helsinki, and Code of Federal Regulations, Part 46, Protection of Human Subjects.

2) You will develop competency in understanding, interpreting, and grasping the historical significance of the Tuskegee Syphilis Study and the involvement of physicians and researchers from the U.S. Public Health Service. In particular, you will become competent in reviewing relevant literature related to the Tuskegee Syphilis Study and understanding how disclosure of this research ethics scandal resulted in the emergence of institutional review boards, federal regulations governing human subjects research, and other protections for participants in human subjects research.

3) You will become competent in application of federal regulations and ethical frameworks to the conduct of cross-cultural health research taking place in settings outside the United States. In particular, you will become competent in understanding challenges of “translating” such research ethics concepts as “randomization,” “blinding,” and “informed consent” in settings where these concepts are not widely known and understood.

4) You will be introduced to an ongoing moral controversy related to a clinical study conducted at the University of Minnesota. You will be asked to identify various ethical and legal issues raised by this case study.

5) You will become competent in understanding the role that regulatory agencies such as the FDA and clinical trial design plays in protecting research participants, promoting public health, and shielding citizens from fraud, adverse events, and other forms of harm.

6) You will become competent in analyzing how to develop ethical community participation in public health research. In particular, you will become competent in use and application of such concepts as “community engaged research,” “participatory research,” and “community consent” to research.

7) You will become competent in critical ethical analysis of priority-setting in public health research and how research agendas are promoted and funded.

8) Finally, you will develop general familiarity and competency with use of ethical concepts and frameworks in public health research and policy.

IV. Course Topics and Readings

The course is organized into seven lessons. Each lesson includes assigned readings and related course material (such as PowerPoint presentations). You should read all assigned texts and familiarize yourself with accompanying videos and podcasts. Please note that assigned readings are available as PDF files on the course website. You do not need to purchase a textbook for this course. Information about assignments follows the list of topics and readings.
Schedule of Topics and Readings

Lesson 1: March 24-March 28
Introduction to Research Ethics

Readings


Lesson 2: March 31-April 4
The U.S. Public Health Service and the Tuskegee Syphilis Study
Watch: The Deadly Deception, by Denisce DiAnni, PBS/WGBH NOVA documentary video, 1993. Available at: http://www.youtube.com/watch?v=vmVTmhYa52A

Readings


Lesson 3: April 7-April 11
Ethical Challenges in Conducting Cross-Cultural Health Research

Readings


Lesson 4: April 14-April 18
Dan Markingson, the University of Minnesota, & Governance of Human Subjects Research

Readings


Lesson 5: April 21-April 25

Access to Unproven Stem Cell Interventions & the FDA: Translational Research & Ethics of Public Health Policy

Watch webcast: CBS 60 Minutes - Stem Cell Snake Oil:
Part 2: [http://www.youtube.com/watch?v=njSMTfPRz9g&feature=relmfu](http://www.youtube.com/watch?v=njSMTfPRz9g&feature=relmfu)
Extra: Warning about Stem Cell Fraud: [http://www.youtube.com/watch?v=Rb2NBlmL1es](http://www.youtube.com/watch?v=Rb2NBlmL1es)

Readings


Lesson 6: April 28-May 2

Ethical Dimensions of Community Participation in Health Research

Readings


Lesson 7: May 5-May 9

Ethics of Research Funding and Global Public Health Philanthropy: Examining The Bill & Melinda Gates Foundation


Readings


Course Assignments

Week One: March 24-March 28
Read all assigned articles and contribute at least one post to the Week 1 forum. Contribute to forum by 5pm Friday, March 28.

Week Two: March 31-April 4
Read all assigned articles and contribute at least one post to the Week 2 forum. Contribute to forum by 5pm Friday, April 4.

Week Three: April 7-April 11
Read all assigned articles, contribute at least one post to the Week 3 forum, and submit your first writing assignment.

Writing assignment: Local understandings of health, illness, healing, and research sometimes differ from the explanatory models of public health researchers. Likewise, regional understandings of moral conduct can conflict with the moral norms and legal standards governing international health research. Drawing upon this week’s assigned readings, answer the following questions. 1) What ethical issues did Vincanne Adams and her colleagues have to address during their research and what is your assessment of how the research team responded to these challenges? 2) Is it possible to "translate" across cultural fault lines such concepts as “informed consent” and “placebo” or are misunderstandings and ethical conflicts inevitable? 3) What general lessons can public health researchers extract from the writings of Dr. Adams and her colleagues? Prepare a 1250 word writing assignment (no less than 1200 words and no more than 1300 words) and submit your ethical analysis to the assignment drop box. Deadline: Must submit writing assignment by 5pm Friday, April 11. Value: 45% of final grade.

Week Four: April 14-April 18
Read all assigned articles and contribute at least one post to the Week 4 forum. Contribute to forum by 5pm Friday, April 18.

Week Five: April 21-April 25
Read all assigned articles and contribute at least one post to the Week 5 forum. Contribute to forum by 5pm Friday, April 25.

Week Six: April 28-May 2
Read all assigned articles, contribute at least one post to the Week 6 forum, and submit your final writing assignment.

Writing assignment: Drawing upon this week’s assigned readings, examine ethical issues associated with community engagement in global public health research. What are some ethical and scientific benefits associated with local community engagement in research initiatives? Are there any risks or disadvantages involved in promoting community engagement in public health research? Drawing upon this week’s readings, identify key issues that public health researchers must consider when trying to promote community engagement in health research. Submit your 1250 word writing assignment (no less than 1200 words and no more than 1300 words) to the assignment drop box. Deadline: Must submit writing assignment by 5pm Friday, May 2. Value: 45% of final grade.

Week Seven: May 5-May 9
Read all assigned articles and contribute at least one post to the Week 7 forum. Contribute to forum by 5pm Friday, May 9.
Contributing Posts to the Weekly Discussion Boards

Since we do not meet in a formal classroom setting, contributing to the weekly discussion boards is the primary way for you to interact with your classmates, respond to assigned reading material, and grapple with the topics covered in this course. I am not assigning questions for you to address in your posts. Rather, you have considerable discretion in deciding how you want to contribute to discussion board exchanges. You are welcome to: 1) respond to one or more of the assigned readings; 2) address key ethical issues covered by assigned articles; 3) pose a relevant question to your classmates; 4) provide an in-depth response to a classmate’s post; 5) challenge assumptions or claims in assigned reading material; 6) draw connections between various themes covered in the course; 7) contribute in a manner that I have not identified but which promotes debate and reflection among your classmates. Initial posts should be at least 4-5 sentences and make an informed, meaningful contribution to online discussion. Subsequent posts can be extended or brief depending upon whether you want to develop an idea or simply acknowledge a point made by a classmate. Adding your informed contributions to the discussion board is the online equivalent of attending class and participating in classroom debate. You are expected to contribute posts each week. **Posts to discussion boards are worth a total of 10% of your final grade for the course.** You will receive full points (10%) if you make meaningful, informed contributions to the discussion boards. Failure to submit posts as well as submitting posts that are not relevant to assigned readings and topics will reduce the grade you receive for your posts.

Guidelines for Preparing Writing Assignments:

Writing assignments should:

- Be well-constructed and reasoned in a thoughtful, considered manner. You should not simply take a “position” about how particular ethical issues should be addressed. Rather, you should provide reasons, arguments, and evidence in support of your claims.
- Focus on key values, competing arguments, and how to address conflicting moral considerations
- Acknowledge and address moral complexity
- Proceed beyond questions and concerns and develop ethical analyses that provide insight into how public health practitioners should address particular topics
- Focus upon ethical issues and avoid simply providing an overview of the subject matter and readings. Do not merely repeat arguments made in assigned course material. Rather, use this material to develop your own ethical analysis of assigned topics.

V. Grading Policy:

Your final grade for the course will be based upon how well you complete your two writing assignments and whether you make meaningful contributions to the weekly discussion boards. You are not permitted to do “bonus” work to make up missed assignments or improve your grade. In addition, you are not allowed to revise or redo assignments. All work must be submitted by specified deadlines. Late work will not be accepted unless you have in advance arranged an extension with the instructor.

**Grades:**

- A 93-100%
- A- 90-92%
- B+ 87-89%
- B 83-86%
- B- 80-82%
- C+ 77-79%
- C 73-76%
- C- 70-72%
- D 60-69%
- F <60%
**Incomplete Grade**

An incomplete grade is permitted only in cases of exceptional circumstances and following consultation with the instructor. In such cases an “I” grade will require a specific written agreement between the instructor and the student specifying the time and manner in which the student will complete the course requirements. Extension for completion of the work will not exceed one year.

**University of Minnesota Uniform Grading and Transcript Policy**

A link to the policy can be found at onestop.umn.edu.

**Grade Option Change** (if applicable)

Students in Master of Public Health programs in the School of Public Health MUST take this course for a letter grade and receive at least a B- in order to receive credit towards the MPH degree. Please contact Program Major Coordinator for more information. If applicable, students may change grading options during the initial registration period. Grade option changes can be found at: onestop.umn.edu.

**VI. Course Withdrawal**

School of Public Health students may withdraw from a course through the second week of the semester without permission. No “W” will appear on the transcript. After the second week, students are required to do the following:

- The student must contact and notify their advisor and course instructor informing them of the decision to withdraw from the course;
- The student must send an email to the SPH Student Services Center (SSC) at sph-ssc@umn.edu. The email must provide the student name, ID#, course number, section number, semester, and year with instructions to withdraw the student from the course, and acknowledgement that the instructor and advisor have been contacted.
- The advisor and instructor must email the SSC acknowledging the student is canceling the course. All parties must be notified of the student’s intent.
- The SSC will complete the process by withdrawing the student from the course after receiving all emails (student, advisor, and instructor). A “W” will be placed on the student transcript.
- After discussion with their advisor and notification to the instructor, students may withdraw up until the eighth week of the semester. There is no appeal process.

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Student Services Center at sph-ssc@umn.edu for further information.

**VII. Student Conduct, Scholastic Dishonesty and Sexual Harassment Policies**

Students are responsible for knowing the University of Minnesota, Board of Regents' policy on Student Conduct and Sexual Harassment found at www.umn.edu/regents/polindex.html.

Students are responsible for knowing the university policy on student conduct and scholastic dishonesty: http://www1.umn.edu/regents/policies/academic/StudentConductCode.pdf.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the Office of Student Academic Integrity (OSAI, www.osai.umn.edu). Scholastic dishonesty, as defined by University of Minnesota policy, will result in a grade of “F” or “N” for the entire course. The University’s Student Conduct Code defines scholastic dishonesty as “plagiarizing; cheating on assignments or examinations;
engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis.”

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: http://writing.umn.edu/tww/plagiarism/.

Students must properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to http://tutorial.lib.umn.edu/ and click on “Citing Sources”. Original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable. Consult the instructor if you have questions concerning originality of work and appropriate use of citations.

VIII. Disability Statement
It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite 180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).