

**Credits:** 1  
**Course duration:** November 1-December 13, 2010  
**Meeting Time:** Internet-delivered course  
**Meeting Place:** Internet-delivered course  
**Instructor:** Leigh Turner, PhD  
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## **I. Course Description**

This course addresses ethical issues related to public health research. This term we will pay particular attention to such topics as ethical issues related to global public health research, community engagement in health research, translation of moral norms and scientific practices in particular cultural contexts, ethics of funding public health initiatives, research partnerships and research capacity building, and public health ethics and globalization of clinical trials. To explore these topics we will draw upon scholarship from bioethics, public health, and the social sciences. At the end of the course you will be familiar with key readings, ethical frameworks, and current debates in public health research ethics.

## **II. Course Prerequisites**

None.

## **III. Course Goals and Objectives**

Through course readings, podcasts, webcasts, 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.

#### IV. Course Topics and Readings

The course is organized into seven lessons. Each lesson includes assigned readings and related course material. You should read all assigned articles and familiarize yourself with accompanying videos and podcasts. Information about assignments follows the list of topics and readings.

##### Schedule of Topics and Readings

##### Lesson 1: November 1-November 5

##### Public Health Research Ethics: Clinical Trials and Moral Controversies

Watch webcast: Solomon (Solly) Benatar. Clinical Trials: Ethical Issues in High-Burden Countries. Available at: [http://www.kaisernetwork.org/health\\_cast/hcast\\_index.cfm?display=detail&hc=1951](http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1951) Click the “Video” link to watch Benatar’s lecture. Click the play button twice if you have difficulty viewing the video.

##### Readings

- Lurie, Peter, and Wolfe, Sidney. 1997. Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries. *New England Journal of Medicine* 337: 853-856.
- Varmus, Harold, and Satcher, David. 1997. Ethical Complexities of Conducting Research in Developing Countries. *New England Journal of Medicine* 337: 1003-1005.
- Shapiro, H., Meslin, E. 2001. Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries. *New England Journal of Medicine* 345: 139-142.
- Bhutta, Zulfiqar. 2004. Standards of care in research. *British Medical Journal* 329: 1114-1115.
- Emanuel, Ezekial, Wendler, David, Killen, Jack, and Grady, Christine. 2004. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *Journal of Infectious Diseases* 189: 930-937.

##### Lesson 2: November 8-November 12

##### Health Research in Cross-Cultural Perspective: Translating Moral Norms and Scientific Practices

Watch webcast: Vincanne Adams. The Challenge of Cross-Cultural Clinical Research in Tibetan Medicine. (The recording begins with the title “Tibetan Medicine: Integration in Research and in the Clinic.”) <http://www.youtube.com/watch?v=pMsxsoAyDps>

##### Readings

- Adams, V, Miller, S, Craig, S, Samen, A, Nyima, Sonam, Droyoung, Lhakpen, and Varner M. 2005. The challenge of cross-cultural clinical trials research: case report from the Tibetan Autonomous Region, People’s Republic of China. *Medical Anthropology Quarterly* 19: 267-289.
- Adams, V. Miller, S., Craig, S, Sonam, Nyima, Droyoung, Le, P, Varner, M. 2007. Informed Consent in Cross-cultural Perspective: Clinical Research in the Tibetan Autonomous Region, PRC. *Culture, Medicine, and Psychiatry* 31: 445-472.

### **Lesson 3: November 15-November 19**

#### **Local Understandings of Health Research and Health Researchers: Putting Research in Historical and Social Context**

Listen to podcast: Melissa Graboyes. “Facts in the Fantastic and Truth in the Tall Tales: East African Understandings of Medical Research, 1950-present.” Podcast is available at: <http://128.197.26.34/africa/resources/rodney/index2.html>. Graboyes’ podcast is in the top left box.

#### Readings

- Geissler, P, and Pool, R. 2006. Popular concerns about medical research projects in sub-Saharan Africa—a critical voice in debates about medical research ethics. *Tropical Medicine and International Health* 11: 975-982.
- Geissler, P. Wenzel. 2005. ‘Kachinja are Coming!’ Encounters Around Medical Research Work in a Kenyan Village. *Africa* 75: 173-202.
- Kingori, P, Muchimba, M, Sikateyo, B, Amadi, B, Kelly, P. 2010. ‘Rumours and clinical trials: a retrospective examination of a paediatric malnutrition study in Zambia, southern Africa. *BMC Public Health* 10: 556.
- Graboyes, M. 2010. Fines, Orders, Fear...and Consent? Medical Research in East Africa, C. 1950s. *Developing World Bioethics* 10, 1: 34-41.

### **Lesson 4: November 22-November 26**

#### **Community Engagement in Global Health Research**

Watch webcast: Faiza Rab and Nusura Thaitawat. “Community Participation in Health Research: Perspectives of Developing Countries” and “Ethics of Community Engagement: Experience From Prime-Boost HIV Vaccine Phase III Trial, Thailand”. Available at Centre for Global eHealth Innovation, UHN: <http://epresence.ehealthinnovation.org/epresence/1/watch/241.aspx>

#### Readings

- Page-Shafer, K., Saphonn, V., Sun, L, Vun, M, Cooper, D, Kaldor, J. 2005. HIV prevention research in a resource-limited setting: the experience of planning a trial in Cambodia. *The Lancet* 366: 1499-503.
- Newman, P. 2006. Towards a science of community engagement. *The Lancet* 367: 302.
- Lavery, J, Tinadana, P, Scott, T, Harrington, L, Ramsey, J, Ytuarte-Nunez, C, James, A. 2010. Towards a framework for community engagement in global health research. *Trends in Parasitology* 26: 279-283.
- Tindana, P, Singh, J, Tracy, S, Upshur, R, Daar, A, Singer, P, Frohlich, J, Lavery, J. 2007. Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. *PLoS Medicine* 4, 9: e273.

### **Lesson 5: November 29-December 3**

#### **Research Partnerships and Research Capacity Support**

Watch webcast: Eva Harris. 2006. Infectious Disease Research in Latin America: A Platform for Scientific Capacity Building and Social Mobilization. Go to this website and click “Watch webcast”: [http://webcast.berkeley.edu/event\\_details.php?webcastid=19243](http://webcast.berkeley.edu/event_details.php?webcastid=19243). If you want to learn more about Harris’ work you can watch this interview with her: <http://www.uctv.tv/search-details.asp?showID=7778>.

## Readings

- Harris, Eva and Tanner, Marcel. 2000. Health technology transfer. *British Medical Journal* 321: 817-820.
- Costello, Anthony and Zumla, Alimuddin. 2000. Moving to research partnerships in developing countries. 2000. *British Medical Journal* 321: 827-829.
- Edejer, Tessa Tan-Torres. 1999. North-South research partnerships: the ethics of carrying out research in developing countries. *British Medical Journal* 319: 438-441.
- Sitthi-amorn, C. and Somrongthong, R. 2000. Strengthening health research capacity in developing countries: a critical element for achieving health equity. *British Medical Journal* 321: 813-817.

### **Lesson 6: December 6-December 10**

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

Watch video: Bill Moyers Special Edition. “Health, Wealth and Bill Gates” at: <http://www.pbs.org/now/science/gates.html#>. If you are unable to watch the video you can find a transcript of the interview at: [http://www.pbs.org/now/transcript/transcript\\_gates.html](http://www.pbs.org/now/transcript/transcript_gates.html)

## Readings

- Specter, Michael. 2005. What Money Can Buy. *The New Yorker*. October 24: 56-71. Available at: <http://www.michaelspecter.com/pdf/gates.pdf>
- Birn, Anne-Emanuelle. 2005. Gates’s grandest challenge: transcending technology as public health ideology. *The Lancet* 366: 514-519.
- Brown, Hannah. 2007. Great Expectations. *British Medical Journal* 334: 874-876.
- McCoy, D, Kembhavi, G, Luintel, A. 2009. The Bill & Melinda Gates Foundation’s grant-making programme for global health. *The Lancet* 373: 1645-1653.

### **Lesson 7: December 13**

#### **Globalization of Clinical Trials: Research Ethics and Public Health**

Watch video: Testing Grounds: Our medicine at what cost? St. Petersburg Times. 2008. Webcast available at: <http://www.tampabay.com/specials/2008/reports/india/>. Click “CONTINUE” to start video. Listen to: Controversy over Outsourcing Drug Clinical Trials to India. NPR. All Things Considered. August 13, 2004. Podcast available at: <http://www.npr.org/templates/story/story.php?storyId=3850929>

## Readings

- Glickman, Seth, McHutchison, John, Peterson, Eric, Cairns, Charles, Harrington, Robert, Califf, Robert, and Schulman, Kevin. 2009. Ethical and Scientific Implications of the Globalization of Clinical Research. *New England Journal of Medicine* 360: 816-823.

- Nundy, Samiran, and Gulhati, Chandra. 2005. A New Colonialism?—Conducting Clinical Trials in India. *New England Journal of Medicine* 352; 16: 1633-1636.
- Kahn, Jennifer. 2006. A Nation of Guinea Pigs. *Wired* 14: 3. Available at: [http://www.wired.com/wired/archive/14.03/indiadrug\\_pr.html](http://www.wired.com/wired/archive/14.03/indiadrug_pr.html)
- Hundley, Kris. 2008. Drugs are expensive. Life is cheap. *St. Petersburg Times*. December 11. Available at: <http://www.tampabay.com/news/business/article934677.ece>

## Course Assignments

### **Week One: November 1-November 5**

Read all assigned articles and contribute at least one post to the Week 1 discussion board.

### **Week Two: November 8-November 12**

Read all assigned articles, contribute at least one post to the Week 2 discussion board, and submit your first mini-essay.

Mini-essay: 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 and legal norms governing international health research. Drawing upon this week’s assigned readings, identify ethical challenges related to cross-cultural health research. What ethical conflicts can emerge in cross-cultural research? How should health researchers address such conflicts? Is it possible to "translate" across cultural boundaries such concepts as “informed consent” and “placebo” or are misunderstandings and ethical conflicts inevitable? How should public health researchers try to resolve ethical issues generated by cross-cultural research? Prepare a 1000 word commentary and submit your ethical analysis to the assignment drop box. **Deadline: Must submit commentary before 5pm Friday, November 12. Value: 30% of final grade.**

### **Week Three: November 15-November 19**

Read all assigned articles and contribute at least one post to the Week 3 discussion board.

### **Week Four: November 22-November 26**

Read all assigned articles, contribute at least one post to the Week 4 discussion board, and submit your second mini-essay.

Mini-essay: 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 risks involved in promoting community engagement in public health research? What ethical issues need to be considered when researchers plan to engage communities in research projects? Submit your 1000 word commentary to the assignment drop box. **Deadline: Must submit commentary before 5pm Friday, November 26. Value: 35% of final grade.**

### **Week Five: November 29-December 3**

Read all assigned articles and contribute at least one post to the Week 5 discussion board.

### **Week Six: December 6-December 10**

Read all assigned articles, contribute at least one post to the Week 6 discussion board, and submit your final mini-essay.

Mini-essay: Write a 1000 word commentary addressing ethical issues related to research funding and global public health philanthropy. This week’s readings examine The Bill & Melinda Gates Foundation

and its “Grand Challenges” in Global Health. Why does Anne-Emanuelle Birn criticize the “Grand Challenges” framework of the foundation? What alternative model of global public health funding and public health research does she support? How do the articles by Brown and McCoy, Kembhavi, and Luintel contribute to critical analysis of the activities of the Gates Foundation? Were you to have an opportunity to shape global public health research what research agenda or framework would you propose to public health researchers? Please submit your commentary to the assignment drop box.

**Deadline: Must submit commentary before 5pm Friday, December 10. Value: 35% of final grade.**

### **Week Seven: December 13-December 15**

Read all assigned articles. Final exams begin December 16. With final exams commencing this week (not in this course but in other classes), you are welcome to contribute to the Week 7 discussion board but posts are not required. Again, you are welcome to interact with your classmates but contributing posts this week is optional.

### **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 main 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. While your posts will not be graded, you will be deducted 5 points for every week (out of the first six weeks) that you do not contribute to the discussion boards. Put in more constructive terms, contributing to the discussion boards is your main way to interact with classmates and contribute to online discussion. Adding your informed, considered thoughts to the discussion board is the online equivalent of attending class and participating in classroom debate.

### **Guidelines for Preparing Mini-essays:**

Mini-essays 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 simply 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 your attendance, active participation in class, and how well you complete your assignments. You will not be allowed to do “bonus” work to make up missed assignments or improve your grade. In addition, you will not be 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](http://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](http://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](mailto: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](http://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](mailto: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](http://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](http://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).