

University of Southern California  
Department of Preventive Medicine  
Master of Public Health Program

**PM 568: Ethical Issues in International Health Research: Promotion & Intervention**

**Faculty:**

Donna Spruijt-Metz Ph.D. <a href="mailto:dmetz@usc.edu">dmetz@usc.edu</a> 626 457-6631 Office Hours: By appointment Office: HSA 4101	Lourdes Baezconde-Garbanati Ph.D <a href="mailto:baezcond@hsc.usc.edu">baezcond@hsc.usc.edu</a> 626-457-6606 Office Hours: By appointment Office: HSA 4231	Guest speakers: Paula Healani Palmer Ph.D., Jennifer Unger, Ph.D., David Conti, Ph.D. Gary Swan, Ph.D.
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**Day and Time:** Tuesdays, 9:00 am – 12:30 pm

**Classroom:** Alhambra Health Sciences Campus, Room 7059

**Course Description**

Sixty billion (\$60 billion) U.S. dollars are currently spent in health research and development around the world. The World Health Organization, the United Nations, the World Bank and other key players in developing countries often help to frame the politics and ethics of global health for the developing world. In an interactive learning environment this course will explore ethical principles in the distribution of health resources, the conduct of global public health research and the implementation of public health initiatives and practices across different nations, cultures and religions, as well as differences in the concepts of right and wrong. Utilizing multiple formats including case studies, class discussions, interactions with key international ethicists, and role play, the course will shed light on ethical dilemmas that impact biomedical and psychosocial Human Subjects research. More specific areas to be explored include the role of national and international Institutional Review Boards, research integrity, the ethics of health as a political entitlement, state obligation, or a commercial commodity, the right to health, the ethical challenges of institutionalizing world wide western concepts of informed consent procedures and confidentiality while at the same time seeking to advance scientific discovery and promote universal public health justice for the poor and disadvantaged. Utilizing a framework for the elimination of health disparities world wide, we will also explore the ethical foundations of past and current scientific practices and the personal and professional ethical issues that public health practitioners and researchers may encounter today in their work on global health.

**Learning Objectives**

At the completion of the course students will be able to:

- 1) Articulate the important ethical issues of biomedical research, particularly health promotion and disease prevention research and intervention, involving human subjects
- 2) Discuss the major ethical issues involved International biomedical research, particularly health promotion and disease prevention research and intervention, done with Human Subjects.
- 3) Outline the ramifications of confidentiality, informed consent, the concept of justice, and other important ethical concepts (Beauchamp and Childress 1994) in human subjects research and public health

interventions

- 4) Describe the Institutional Review process, and be able to accomplish submissions of research and intervention projects to Institutional Review Boards.
- 5) Follow and discuss the mounting ethical issues to which the constantly changing landscape of genetics research gives rise, both in the US and in other countries and cultures.
- 6) Appreciate the role culture and religion play in the development of a sense of right and wrong and views on ethics.

**Course prerequisites:**

Completion of PM 501 (Foundations in Health Education Behavior) or permission of instructor.

**Required course readings:**

In lieu of a textbook, a course reader, will be available from the HSC bookstore.

**Course Requirements and Evaluation**

**1. Required Reading**

You are responsible for all of the listed reading. If you miss a class, you are responsible for all of the reading for the session you missed as well as all of the reading for the following session. Students are expected to complete the weekly readings BEFORE class.

**2. Homework: due at the beginning of each class**

**Homework # 1 Reflections:**

At the beginning of each **Tuesday class** you will be required to turn in a **one page\*** (double spaced, typed) commentary/reflection on the required reading for that week. For instance, at the beginning of week 2, you will be required to turn in commentary/reflections on Chapter 1, 2 and 33 of the **Book**. Articles from the **Book** and **Reader** are part of the assignment; address them in your reflections. We are **not** looking for an outline or summary of the reading materials! I am looking for 1) a synthesis of the week's reading, 2) a well-founded critique, 3) relevance of the readings (or lack thereof) to your own work/life experience and 4) how this knowledge might impact how you plan to conduct research in the future. Our purpose here is twofold. One is to get some reflection going on the reading materials and the subject matter. The second is to use your reflections and commentaries to enrich and direct the class discussions. Please turn in your first reflection in a folder, so that I can keep your reflections carefully filed for you. They will be returned at the end of the semester.

*\*reflections may be longer, but not shorter. Longer papers tend to become summaries rather than reflections, which is **not** the assignment.*

**3. Class participation**

This course involves extensive discussion and analysis of the readings and any materials brought to class by the instructor or students. Emphasis is on critical reading, analysis and synthesis of the material. Prior reading of assigned materials is essential. We are looking for a scholarly, critical approach. We are expecting you to connect and relate the knowledge that you acquire to your prior knowledge base and to your past experiences. Active participation in the class includes sharing your knowledge and experience in class and serious work on in-class brief collaborative group projects. These will sometimes involve written products to be turned in.

Presentation of the final paper in class as well as presentation of work in progress is included in class participation.

***This is an interactive classroom environment.*** You are encouraged to participate in the development of the class. Your input can influence the form that I choose, the topics we cover and the criteria that I use for grading.

4. **Final Paper/Presentation** Students will be asked to complete a literature review-type paper or a qualitative/interview based paper on a topic in Health Promotion Ethics. Final projects are individual, not group projects. **Topics must be approved by Dr. Spruijt-Metz.** Students will present their papers BRIEFLY in class during the last 1-2 weeks of class.

Criteria for the final paper:

Approximately 20 type-written pages double-spaced

At least 12 peer-review journal references

Formatted in APA style

Your paper will take the form either of 1) a literature review or 2) a qualitative, study based on interview data. Make sure to speak to the instructor early in the semester if you choose to pursue the interview option.

Make sure in your paper to include clear descriptions of:

- ◆ Main topic
- ◆ Definition of main constructs
- ◆ Sketch the 'big picture'
- ◆ Main issues, hypotheses, questions or goals
- ◆ Discussion of methods of available research papers or literature reviews (including subjects, measures, possible confounders, operationalizations, validity, search strategies) - you might want to speak generally or single out a few of the main papers mentioned)
- ◆ Which conclusions were drawn? (If the paper is exploratory, which hypotheses were generated?) Which questions are raised?
- ◆ Do the research results or health outcomes justify the conclusions?
- ◆ Implications (for descriptive or exploratory research, possible implications)
- ◆ Limitations of this particular paper/research design/etc.
- ◆ Critique, ethical strengths and weaknesses of (the premises of) research/interventions/treatments.
- ◆ Provide a framework for the elimination of health disparities to your paper as appropriate
- ◆ Compare and contrast ethical dilemmas addressed in your paper within a global health perspective OR among Eastern and Western cultures OR among different religions or cultural groups

**Grading Criteria:**

FINAL PAPER (45 points)

PRESENTATION (20 points)

HOMEWORK (25 points)

IN-CLASS PARTICIPATION (10 points)

**Grading Scale:**

A = 93-100 points

A- = 90-92 points

B+ = 87-89 points

B = 83-86 points  
B- = 80-82 points  
C+ = 77-79 points  
C = 73-76 points  
C- = 70-72 points  
D+ = 67-69 points  
D = 63-66 points  
D- = 60-63 points  
F = 59 or fewer points

### **Students with Disabilities**

Any student requesting academic accommodations based on a disability is required to register with Disability Services and Programs (DSP) each semester. A letter of verification for approved accommodations can be obtained from DSP. Please be certain the letter is delivered to me as early in the semester as possible. DSP is located in on the University Park campus in STU 301 and is open 8:30 a.m. – 5:00 p.m., Monday through Friday. The phone number is (213) 740-0776.

### **Electronic Course Management**

TOTALe (also known as BlackBoard) is the online learning portal through which many USC professors provide electronic copies of their course materials, including syllabuses, readings, and handouts. Students may obtain access TOTALe at [learn.usc.edu](http://learn.usc.edu) and use their USC computer user name and password to access the "MyUSC" portal page. All courses that students are enrolled in that are using TOTALe will appear on the page as a link. Simply follow the link to access online course materials and grades.

### **Course Policy and Procedures**

1. Students are expected to attend classes regularly.
2. All students are expected to read *SCampus* regarding plagiarism and its possible consequences.
3. Assignments are due no later than 4:00pm on the date listed on the course handout. It is assumed that students not submitting papers on schedule have had more time to complete them.
4. Any personal or family emergency or health problem will be considered as an exception to the above policy. Illness should be documented
5. Personal emergencies or serious health problems are the only reasons for granting an incomplete in the course. An incomplete (IN) will only be assigned if there is work not completed because of a documented illness or some other emergency occurring after the 12th week of the semester. Arrangements for an IN or IN removal must be initiated by the student, agreed to in advance by the instructor, and reported on an official "Incomplete (IN) completion form."

## WEEK-BY-WEEK COURSE OUTLINE

Instructor: Baezconde-Garbanati

### **Week 1) Introduction to Ethics and ethical issues in Health Promotion and Disease Prevention**

1. Understanding the international public health playing field
  - i. Who are the players
  - ii. Framing the politics and ethics of global health
2. Health disparities – a global model to reach parity in health
3. Health as a norm
4. The concept of personal control and responsibility
5. Characteristics of information on health: which behaviors are healthy? Do we know what we are doing?
6. The issue of voluntariness

#### **Readings:**

1. Spruijt-Metz, Donna (1999). Ethical issues in adolescent health education. IN: *Adolescence, Affect and Health* (Chapter 2). London: Psychology Press.
2. Code of Ethics for the Health Education Profession. Society for Public Health Education, 1976-2003. (Accessed January 5, 2004, at <http://www.sophe.org/about/ethics.html>.)
3. MacQueen KM, Buehler JW. Ethics, practice, and research in public health. *American Journal of Public Health*. 94(6):928-31, 2004 Jun.

Instructor: Spruijt-Metz

### **Week 2) Overview of different schools of medical ethics:**

1. Normative,
2. Descriptive,
3. Metaethics
4. The distribution of health resources
5. The conduct of global public health research
6. Conducting research with children and other vulnerable populations

#### **Readings:**

1. Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 4th ed. New York: Oxford University Press; 1994. Chapters 1 (p 1-23), 3-6 (p.57-227)

Instructor: Spruijt-Metz

### **Week 3) The “Georgetown Mantra” – 4 principles of Medical Ethics**

1. Respect for autonomy
2. Benevolence
3. Nonmalficence
4. Justice
  - i. Rawls concept of justice and responsibility: Health Disparities and the ethics of research in minority or underserved populations
    1. What are the issues related to health promotion research as it is controversial and/or unavailable to all populations?

**Readings:**

1. Rawls J. A theory of justice. Cambridge: Mass., Belknap Press of Harvard University Press; 1971. , Chapters 1-2 (3-86)
2. Kass NE. Public health ethics: from foundations and frameworks to justice and global public health. *Journal of Law, Medicine & Ethics*. 32(2):232-42, 190, 2004.

Instructor: Spruijt-Metz

**Week 4) What is confidentiality?**

1. What are the current practices?
2. In order to protect confidentiality, conduct culturally competent research and uphold ethical standards, what practices may need to change, which practices can remain uniform?
3. What are the consequences of inconsistencies across cultural and geographical boundaries for the research findings?
4. Personal and professional ethical issues that public health practitioners and researchers face today

**Readings:**

1. Hall DL, Ames RT. Anticipating China: thinking through the narratives of Chinese and Western culture. Albany: State University of New York Press; 1995, Introduction xiii-xx1, Chapter 2 (pages 111-175).
2. Howard DE. Lothen-Kline C. Boekeloo BO. Using the case-study methodology to teach ethics to public health students. *Health Promotion Practice*. 5(2):151-9, 2004 Apr
3. Brosco JP. History and ethics in public health research. *Professional Ethics*. 11(3):45-64, 2003  
Brandenburg T. Guillory J. Melnick A. Thomas JC. Williams C. The public in public health ethics: the Public Health Society responds. *American Journal of Public Health*. 94(1):7; author reply 7-8, 2004 Jan

Guest Speaker: Fumi Stark

**Week 5) Everything you ever wanted to know (but were afraid to ask) about Institutional Review Boards**

1. Writing an IRB application
2. Informed consent
3. Who is on the IRB and how did they get there?
4. What are the various types of review (exempt, expedited, full board, etc.)
5. What criteria does the IRB use to evaluate studies?
6. What activities qualify as research and who qualifies as a research subject?
7. Consent issues for various types of research subjects (children, adolescents, emancipated minors, adults, adults who aren't competent to provide consent, secondary subjects, etc.)
8. Working with multiple IRBs across campuses, institutions, and nations--which IRB has jurisdiction?
9. International issues

**Readings:**

1. Quinn SC. Ethics in public health research: protecting human subjects: the role of community advisory boards. *American Journal of Public Health*. 94(6):918-22, 2004 Jun.

2. Dominguez RA, Feaster DJ, Twiggs LB, Altman NH. Searching for an efficient institutional review board review model: Interrelationship of trainee-investigators, funding, and initial approval. *Journal of Laboratory & Clinical Medicine* 2005;145(2):65-71.
3. Green LA, Fryer GE, Jr., Froom P, Culpepper L, Froom J. Opportunities, challenges, and lessons of international research in practice-based research networks: the case of an international study of acute otitis media. *Annals of Family Medicine* 2004;2(5):429-33.
4. Bosk CL, De Vries RG. Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research. *Annals of the American Academy of Political & Social Science* 2004;595:249-63.
5. Shah S, Whittle A, Wilfond B, Gensler G, Wendler D. How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research? *JAMA: Journal of the American Medical Association* 2004;291(4):476-82.

Instructor: Baezconde-Garbanati

**Week 6) Major issues in ethics of biomedical research**

1. How to educate the public to understand our findings and educate scientists to present them honestly and clearly.
2. How to explain uncertainty to the public.
3. Stories that address traditional as well as new ideas of right and wrong. What are the gray areas and how discuss them – how can we talk to one another about them?
4. How do people (doctors, researchers, patients, subjects, politicians and policy makers, the general public) deal with uncertainty?
5. Ethical dilemmas in the implementation of global public health initiatives across different countries

**Readings:**

1. Excerpts from Hans Christian Anderson, Sun Tzu, Hassidic Tales, Vedic Hero Literature, Buddhist literature and Islamic fairy tales.
2. Tversky A, Kahneman D. Judgment under uncertainty: Heuristics and biases. In. Cambridge, MA, US: MIT Press; 2002. Chapter 1
3. Bernheim RG. Public health ethics: the voices of practitioners. *Journal of Law, Medicine & Ethics*. 31(4 Suppl):104-9, 2003
4. Mastroianni AC, Kahn JP. Risk and responsibility: ethics, Grimes v Kennedy Krieger, and public health research involving children. *American Journal of Public Health*. 92(7):1073-6, 2002 Jul

Guest Speakers: Duncan Thomas & Barbara Koenig

**Week 7) Ethics and genetic research (1)**

1. Genetics: The new frontier for ethics and law
2. What does it mean to have a gene for a disease?
3. What are the ethical, moral and legal ramifications of collecting family genetic data?
4. The right to know, right not to know.
5. Cohort effect of how people feel about genetics? Genetic determinism part of the older generation?
6. An overview of funded proposals from the center of excellence

Guest Speaker: Conti

**Week 8) Ethics and genetic research (2)**

1. How do you write about something that is an advance in science and give an adequate representation of the uncertainty of your findings.
2. How do people conceptualize of new things (like genetics) according to their ideas of good and bad? For instance, stem cell research was lumped into the abortion debate, something they know, and then decisions are based on generalizations that may (or may not) be appropriate.

**Readings:**

1. Morris J, Gwinn M, Clyne M, Khoury MJ. Public knowledge regarding the role of genetic susceptibility to environmentally induced health conditions. *Community Genetics* 2003;6(1):22-8.
2. Shields AE, Fortun M, Hammonds EM, et al. The Use of Race Variables in Genetic Studies of Complex Traits and the Goal of Reducing Health Disparities: A Transdisciplinary Perspective. *American Psychologist* 2005;60(1):77-103.
3. Thomas JC, Sage M, Dillenberg J, Guillory VJ. A code of ethics for public health. [Editorial] *American Journal of Public Health*. 92(7):1057-9, 2002 Jul

Instructor: Spruijt-Metz & Guest Speaker: Conti

**Week 9) Field Trip**

1. Students can chose from
  - i. Observing a meeting of the Institutional Review Board
  - ii. Visiting a genetic research laboratory where Dr. Conti will point out all the physically tangible areas where ethical issues come into play – where things can go wrong and the role of the IRB.
  - iii. At this time, students should complete HIPPA and NIH Human subjects training if they have not already done so

**No Readings this week.**

Instructor: Spruijt-Metz

**Week 10) Religion, Health and Medical Ethics 1**

1. Why isn't this the same as culture?
2. The Abrahamic Traditions

**Readings:**

1. Koenig, Harold G. et al (2001). *Handbook of Religion and Health*. New York: Oxford University Press. Introduction, part 1 of Chapter 1 (p. 3-24)
2. Excerpts from Torah, Koran and Christian Bible

Instructor: Spruijt-Metz

**Week 11) Religion, Health and Medical Ethics 2**



1. Eastern Traditions including Hindi, Islam, Confucius, and Dao

**Readings:**

1. Campbell, Courtney S. (1998). Religion and the Body in Medical Research. Kennedy Institute of Ethics Journal - Volume 8, Number 3, September, pp. 275-305
2. Excerpts from Vedic texts, Lao Tzu, Zen masters, Confucius

Guest Speaker: Gary Swan

**Week 12) The International genetics society and other international, cross-cultural case studies**

1. Ethical issues discussed by the International Genetics Society
2. The right to health
3. Are ethical principles comparable across international boundaries? Are they implemented equally?
4. Ethical challenges of institutionalizing world wide, western concepts of informed consent, confidentiality, etc.
5. Broadening the discussion to case studies on non-genetic research in other countries and cultures:
  - i. the ethics of testing AIDS drugs in Africa, where they are totally desperate for AIDS drugs of any kind;
  - ii. clinical trials that are being "outsourced" throughout Asia because they're cheaper there;
  - iii. people from the U.S. going to Europe to get treatments that they can't get in the U.S.,
  - iv. Hispanic cultural norms about the father making the decisions for the family, not telling someone they have cancer, etc

**Readings:**

1. Turner, Leigh (2001). Medical Ethics in a Multicultural Society. Journal of the Royal Society of Medicine, 94, 592-594.
2. Seto, Belinda History of Medical Ethics and Perspectives on Disparities in Minority Recruitment and Involvement in Health Research. American Journal of the Medical Sciences. 322(5):246-250, November 2001.

Instructor: Spruijt-Metz

**Week 13) Culture and Ethics – an International perspective**

1. How do notions of right and wrong develop? Reading one another's hero stories
2. Should ethical standards of research be universal or should they differ based on local beliefs and customs?
3. To what extent should local customs, traditions, and norms change researchers' practices with regard to procedures for gaining consent and/or data collection? For example, as in research conducted in China, what does informed consent that we obtain mean? Are we respecting autonomy?
4. How is confidentiality protected here and in China?

**Readings:**

1. Qiu RZ. Conflict of interests in research ethics: a Chinese perspective. *Journal of Clinical Ethics* 2004;15(1):48-50.
2. Cyranoski D. Are China's bioethics under control? *Nature* 2003;424(6946):239.
3. Lynoe N, Sandlund M, Jacobsson L, Nordberg G, Jin T. Informed consent in China: quality of information provided to participants in a research project. *Scandinavian Journal of Public Health* 2004;32(6):472-5.

Instructor: Baezconde-Garbanati

**Week 14) Culture and Ethics – Methods and procedures in International research**

1. What types of benefits/incentives must be offered to a relatively disadvantaged population and what types of inducements may be excessive?
2. When teachers or governments urge subjects to participate, are we obtaining informed consent without coercion as stipulated in the Declaration of Helsinki?
3. In what ways does our research incorporate approaches that respect values and beliefs of the various cultures within which we work?
4. Research integrity
  - i. The ethics of health as a political entitlement, state obligation or commercial commodity

**Readings:**

1. World Medical Association. Declaration of Helsinki. Helsinki, Finland; 1964, 2002.
2. Readings will be taken from current events, late breaking new articles and issues in medical ethics and international health-related research. Additionally, the International Genetics Society website resources will be used extensively throughout the class.

Instructors: Spruijt-Metz & Baezconde-Garbanati

**Week 15) Presentation of Final Projects**

Finals Week

**Week 16) Final Papers Due**