

Master of Public Health Program

Public Health Ethics

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Course Code: PUBH 5505.01

Credit hours: 1

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Introduction

This interactive course is divided into three main parts: 1) public health ethics; 2) research ethics, including responsible conduct of research; and 3) global health ethics. Obviously, these overlap in the important ways, which will inform our discussion. The course includes face-to-face and small group discussion, guided readings and the completion of online training modules required for IRB and NIH purposes. Students will learn to apply these concepts to research and public health practice through a case-based approach, which analyzes the relationships between ethics, policy and culture. Students will also assess their own research environment to analyze where principles of research ethics are being applied.

Goals:

Students will become familiar with key principles of public health and global health ethics and basic concepts and processes related to research ethics and responsible research conduct.

Course Learning Objectives

Upon successfully completing this class, students will be able to:

1. Identify key ethical and legal guidelines governing public and global health practice, research, collaborative research, and industry-sponsored research.
2. Explain the critical importance of evidence in advancing public health knowledge
3. Understand the theoretical basis for ethical and political controversies in public and global health policy and practice.
4. Understand the broader scopes of the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and sociocultural impacts of scientific research.
5. Understand responsible acquisition of research data and laboratory tools, and their related ownership, sharing and management issues.
6. Describe guidelines for the protection of special populations in research.
7. Define informed consent and the components necessary for a valid consent.

8. Recognize the roles and responsibilities of federal agencies and Institutional Review Boards regarding research. Demonstrate the ability to use the respective guidelines to ensure safe laboratory procedures when conducting research with human participants and/or live vertebrate animals
9. Identify guidelines for responsible authorship, publication and peer review.
10. Understand the mentor/mentee responsibilities and relationships in a research environment.
11. Recognize scientific misconduct and understand appropriate procedures to respond.
12. Identify personal, professional, and financial conflicts of interest and strategies for dealing with conflicts.
13. Define additional challenges posed by conducting research outside the United States
14. Recognize how some of those challenges identify issues in local research.

Course Competencies

The content and methods of this course contribute to students' development of the following competencies for the Master of Public Health program:

1. Discuss the means by which structural bias, social inequities and racism undermine health and create challenges to achieving health equity at organizational, community and societal levels (CEPH CC6)
2. Apply awareness of cultural values and practices to the design or implementation of public health policies or programs (CEPH CC8)
3. Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence (CEPH CC12)
4. Advocate for political, social or economic policies and programs that will improve health in diverse populations (CEPH CC14)
5. Describe the importance of cultural competence in communicating public health content (CEPH CC20)
6. Communicate audience-appropriate public health content, both in writing and through oral presentation (CEPH CC19)
7. Understand the ethical foundation for research regulations and their principles as applied to human subjects research, including autonomy, beneficence, and justice (VU Epi. CC5)

Teaching Methods

Format: The course format includes formal face-to-face lecture and small group sessions, tailored to provide a solid foundation for each student's career preparation. Face-to-face sessions are augmented with online interactive sessions.

Deliverables Include:

1. Development of a written public health dilemma case from professional experience that focuses on the ethical and cultural challenges raised. You should also address any systemic challenges to equity and how you would work with other stakeholders (~3 double space pages)
2. The certificate printed out at the completion of the NIH tutorial
3. Completed IRB tutorial examination. Successful completion of the IRB examination will allow the student to serve as an investigator for IRB protocols at Vanderbilt.
4. The certificate for completion of the WHO course

Completion of the NIH course and the IRB course will fulfill the HHS requirement for training in human subjects research required on grant submissions, so students should save copies of both certificates. Interpretation of group discussions will allow students to apply the ethical components learned from the formal and informal training to their own specific areas of research.

ALL MATERIALS MUST BE SUBMITTED ELECTRONICALLY IN THE APPROPRIATE SUBMISSIONS FOLDER IN BRIGHTSPACE UNDER ASSIGNMENTS AND ACTIVITIES. I WILL NOT ACCEPT PAPER SUBMISSIONS.

Competency	Assessment Opportunity
Discuss the means by which structural bias, social inequities and racism undermine health and create challenges to achieving health equity at organizational, community and societal levels (CEPH CC6)	These competencies will be assessed through a written assignment that will address a public health issue that they have identified, placing it in historical, ethical, and legal context.
Apply awareness of cultural values and practices to the design or implementation of public health policies or programs (CEPH CC8)	
Discuss multiple dimensions of the policy-making process, including the roles of ethics and evidence (CEPH CC12)	
Advocate for political, social or economic policies and programs that will improve health in diverse populations (CEPH CC14)	
Describe the importance of cultural competence in communicating public health content (CEPH CC20)	
Communicate audience-appropriate public health content, both in writing and through oral presentation (CEPH CC19)	
Understand the ethical foundation for research regulations and their principles as applied to human subjects research, including autonomy, beneficence, and justice (VU Epi. CC5)	CITI program

Student Assessment

Students will describe the importance of ethical and cultural values and practices by developing a case about a public health dilemma from their professional experience. They will also address cultural issues and practices raised in working with other stakeholders in public health and highlight cultural competence in communicating public health content.

Students will demonstrate their understanding of the ethical foundation for research regulations and their principles as applied to human subjects research, including autonomy, beneficence, and justice through successful completion of both the *NIH Protecting Human Participants Protection* course along with CITI training modules. These issues should also be addressed, if appropriate, in their case studies. They will also complete the WHO course due to importance of the globalization of public health.

Evaluation and Grading

Course grades will be determined based on the following School of Medicine Grading Scale (see VUSM Course Catalog, pg. 56):

A+ = 4.0

B+ = 3.3

C+ = 2.3

A = 4.0

B = 3.0

C = 2.0

A - = 3.7

B - = 2.7

C - = 1.7 (no earned hours/quality hours and quality points only)

F= No Credit	
Completion of Modules	30%
Class Participation	30%
Public Health Dilemma Case	40%

Schedule (Face to face sessions mandatory due to the participation component of the course):
2600 Village at Vanderbilt, 1:00-3:00 pm

Course evaluations: The MPH program is dedicated to providing a high quality curricular experience. Students are required to complete course evaluations for quality enhancement purposes. No grades will be released until all evaluations have been completed.

Academic Integrity

All students are required to adhere to the Vanderbilt University Honor Code in preparation and submission of assignments and exams. Students can acquaint themselves with the Honor System through the Vanderbilt University Student Handbook (http://www.vanderbilt.edu/student_handbook/chapter2.html) and the School of Medicine Student Handbook (<https://medschool.vanderbilt.edu/student-affairs/student-handbook>). Graduate and professional students may also obtain information from the office of the dean of their respective school or college.

Any incident involving plagiarism will result in failure of the course.

Absences

The Master of Public Health Program's policy on student absences:

- 1 credit hour courses: For courses that meet 4-6 times during a semester, attendance is required in every class (unless specific arrangements have been made in advance of enrolling in the course). Course instructor may determine if additional absences will be allowed.

Students with Disabilities

Accommodations for students with disabilities will be arranged with appropriate documentation from the Center for Opportunity Development. Students with learning disabilities may be approved for alternative test arrangements through the Psychological and Testing Center.

Laptops and Cell Phones

Laptops may be used for course purposes only such as taking notes, identifying supplemental information pertinent to a discussion or for accessing class readings. Cellphones should be turned off during the entire class session, unless the course director indicates otherwise. As adult learners, it is expected that students will refrain from using electronic devices for non-course-related activities.

Course Sessions and Readings

The following is a *preliminary* list of the topic modules and readings. An updated list of required and optional readings for each session will be provided and posted on the BrightSpace website.

Text/Materials

1. Online NIH and IRB trainings (described below)
2. Selected Readings

More in depth resources – *optional* readings are listed for each session; they are not required

The sources below are more general. They are not required but are good places to start for further study

Public health ethics

- Drue H. Barrett, Leonard W. Ortmann, Angus Dawson, Carla Saenz, Andreas Reis, Gail Bolan, Public Health Ethics: Cases Spanning the Globe free e-book, <https://link.springer.com/book/10.1007/978-3-319-23847-0> -- I have assigned several chapters as well.
- The American Public Health Association's Principles of the Ethical Practice of Public Health (2002) can be found here -- https://www.apha.org/~media/files/pdf/membergroups/ethics_brochure.ashx --- but it is currently being revised
- CIOMS Guide to Active Vaccine Safety Surveillance (2017) <https://cioms.ch/shop/product/cioms-guide-to-active-vaccine-safety-surveillance/>

Research ethics

- National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Science, Engineering, Medicine, and Public Policy; Committee on Responsible Science, Fostering Integrity in Research (2017) <https://www.nap.edu/catalog/21896/fostering-integrity-in-research>
- Public Health Research, in Public Health Ethics: Spanning the Globe, <https://link.springer.com/chapter/10.1007/978-3-319-23847-09> , is particularly helpful.

Global health ethics

- CIOMS, International Ethical Guidelines for Health-Related Research Involving Humans (2016) <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>
- CIOMS, International Ethical Guidelines for Epidemiological Studies (2009) https://cioms.ch/wp-content/uploads/2017/01/International_Ethical_Guidelines_LR.pdf

Session 1:

Description: Introduction to Public Health Ethics

Required Readings and work to be done before class:

- **The most important thing for you to do before this class is to identify an issue that is particularly intriguing and/or something that you particularly want to learn in this class – you will be asked to discuss this in small groups**
- Complete modules 1 and 4 of the public health ethics training through the North Carolina Institute for Public Health. Go to <http://nciph.sph.unc.edu/tws/>. Create an account. Login and look for the training tab. Choose public health ethics. Complete modules 1 and 4.
- **NOTE THAT YOU HAVE TO INTERVIEW PEOPLE BEFORE SESSION 4 (see assignment below) SO YOU SHOULD START**

Optional resources for this class:

- Read Public Health Ethics: Global Cases, Practice, and Context, starting at Section 1.3, https://link.springer.com/chapter/10.1007/978-3-319-23847-0_1, and Essential Cases in the Development of Public Health Ethics, in Public Health Ethics: Spanning the Globe. https://link.springer.com/chapter/10.1007/978-3-319-23847-0_2
- 2017 List Reportable Diseases
- Disclosures of PHI that can be made without authorization

Session 2:

Description: Public Health Ethics cases

Required Actions and Readings prior to class:

- Think about a public health ethics issue you may have encountered
- Read these two chapters
 - Obesity prevention, Public Health Ethics: Global Cases, Practice, and Context https://link.springer.com/chapter/10.1007/978-3-319-23847-0_5#Sec11
 - Stigmatization cases, Public Health Ethics: Global Cases, Practice, and Context https://link.springer.com/chapter/10.1007/978-3-319-23847-0_5#Sec15

Optional issues for this class:

- Reading materials on the Disneyland measles outbreak and the decision to eliminate religious exemption in California to be placed on BrightSpace -- 4 articles
- Health disparities, Public Health Ethics: Global Cases, Practice, and Context https://link.springer.com/chapter/10.1007/978-3-319-23847-0_3#Sec17

Session 3:

Description: Research Ethics

The Common Rule and HIPAA – we will summarize these quickly in class and focus on the changes in the new Common Rule. Topics of particular note are when consent is required, return of research results, and the impact of new advisory guidance on broad consent from the Secretary’s Advisory Committee on Human Research Protections. <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html> will also discuss autonomy, beneficence, and justice and some of the critique of the ways those principles have been implemented

Complete the following internet resources before you come to class:

1. NIH tutorial
Go to <http://phrp.nihtraining.com/users/login.php> . Login to the Protecting Human Participants Protection course. Complete the tutorial and print out the certificate at the end of the tutorial. Keep in your files for reference with grant submissions. Please submit a copy to the OHRP folder in the submissions folder before the beginning of class.
2. IRB tutorial

Go to <https://www.citiprogram.org/>. Click on the “CITI Training” tab on the left side of the screen. New Users must register. You will be completing Modules 1-3 in the CITI training program. After completing Modules 1-3, submit the course completion certificate located on the VU Institutional Page within the CITI program. File a copy of the certification, which must be completed prior to your participating as an investigator on any human subjects studies. Please submit a copy of your certificate to the CITI folder of Brightspace

Optional readings:

Faden RR, Kass NE, Goodman SN, Pronovost P, Tunis S, Beauchamp TL, An ethics framework for a learning health care system: a departure from traditional research ethics and clinical ethics, *Hastings Cent Rep.* 2013 Jan-Feb;Spec No:S16-27, attached – this article critiques principlism and includes the primary author of the Belmont report

The following chapter is helpful, but not required. Public Health Research, in *Public Health Ethics: Spanning the Globe*, https://link.springer.com/chapter/10.1007/978-3-319-23847-0_9

Session 4:

Description: Research Ethics – Responsible Conduct

Preparation prior to class:

1. Review materials

a. On Being A Scientist: A Guide to Responsible Conduct in Research National Academy of Sciences on-line text (you can access for free online)

(Go to http://www.nap.edu/catalog.php?record_id=12192 Scroll down and complete the readings for each section).

- Research misconduct
- Conflict of interest
- Authorship and team science -- JAMA

2. Treasure hunt – drawing from experience

a. Perform a structured interview (in person, not by email) with at least 3 senior faculty (associate professor or higher – ideally one of these will be your mentor) that addresses the following issues:

- How do you decide on authorship (who is an author and order) for a project?
- What is the best way to approach the topic with colleagues?
- Can you give me an example of when this went well?
- When it didn't go well?
- What did you wish you knew about authorship when you were at my stage of your career?

b. Bring your notes to class prepared to share the collective wisdom

Come to class prepared to discuss these concepts (consider including these words/issues in your case and discussion):

1. Authorship/data management

- a. Credit and responsibility
- b. Who should be an author?
- c. Transparency

- Within a team
 - Beyond a team
2. Data management
 - a. Data integrity and quality
 - b. Data ownership
 - Data sharing
 3. Research misconduct

Session 5:

Description: Global Health Ethics – the focus in this class will be on the relevance of cultural differences in global public health and research ethics

Prior to class complete Global Health Training Centre, Research Ethics Online Training –

<https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/> designed by World Health Organization, and place certificate in the assignment folder

Optional Readings:

- WHO Global Health Ethics: Key Issues (2015) --
<http://www.who.int/ethics/publications/global-health-ethics/en/>
- Collaborative partnerships/informed consent in context
Ethical Challenges in Short-Term Global Health Training
<http://ethicsandglobalhealth.org/> Developing Cultural Understanding, Understanding Informed Consent for Research

Session 6:

Description: Global Health Ethics – clinical trials in emergency settings/ benefit sharing/ ancillary care

Optional Readings:

- Declaration of Helsinki, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> Please focus on the ways that ethical issues differ between the US and international context
- Ethical Challenges in Short-Term Global Health Training
<http://ethicsandglobalhealth.org/Ensuring> Sustainable and Appropriate Benefits, Addressing “Ancillary Benefits”

Session 7:

Description: Wrapping It Up