

**EPID 7700: Ethical issues in public health and health care decision-making
Spring 2018**

COURSE INFORMATION

COURSE NUMBER:	EPID7700
Room:	101 Miller Hall
TOOLS:	Bring your laptop plus paper and pen to class every meeting!
SCHEDULE:	Saturdays, 9 to noon, 101 Miller Hall Health Sciences Camps (Prince Avenue) Parking available in front of Miller Hall, Free on the weekends

This course is taught by:

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Office hours:

110 Miller Hall by appointment or via Skype by appointment. *Note: I welcome face-to-face meetings and will make every effort to find a time that works for you. You will find it easiest to meet if you schedule an appointment in advance.* **Email:** tonimile@uga.edu

One important part of graduate education is self-guided learning. This is a graduate-level course. I expect students to approach their studies with the following attitude:

1. I am here because I want to be.
2. The knowledge I gain from this course will be used in my future professional life.
3. Since the facts will change overtime, it is important to learn strategies to upgrade my knowledge.

These are the core papers for our group to help us develop a common perspective:

Core papers for the ethics component of this seminar

1. Scott, C. (2014). *Why law pervades medicine: An Essay on Ethics in Health Care*. Notre Dame Journal of Law, Ethics & Public Policy. Volume 14, Issue 1, Article 9. <http://scholarship.law.nd.edu/ndjlepp>
2. Pittenger, DJ. (2001) *Hypothesis testing as a moral choice*. Ethics & Behavior 11:2, 151 – 162. ISSN:1050 – 8422
3. Raha, S. (2011) *A critique of statistical hypothesis testing in clinical research*. J Ayurveda & Integrative Medicine DOI: 10.4103/0975-9476.85548
4. Smith D, Miles TP (2013) *The application of Belmont Report Principles to Policy Development*. J Gerontological Nursing 39(12):16-21. <https://doi.org/10.3928/000989134-20131028-07>
5. Peng Y. (2016) *The morality and ethics governing CRISPR-Cas9 patents in China*. Nature biotechnology 34(6):616.

Core papers for the disease component of this seminar

6. To review your basic epidemiology: Epidemiology 4th or 5th Edition by Leon Gordis, ISBN: 97814557377338 or the text of your choice.
7. Wang H., Laura D-L, Lofgren KT, Rajaratnam J K, Marcus J R, Levin-Rector A, Levitz CE, Lopez A D, Murray C JL. (2012) Age-specific and sex-specific mortality in 187 countries, 1970–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 380: 2071–94. [International chronic disease]
8. Global action plan for the prevention and control of non-communicable diseases 2013 – 2020 World Health Organization 2013. [International chronic disease]
9. Health, United States, 2013. Special Feature on Prescription Drugs, National Center for Health Statistics Hyattsville, MD. 2014. [Example of complications associated with chronic disease treatment]
10. Feldbaum H, Lee K, Michaud J. Global health and foreign policy. Epidemiologic Reviews Vol. 32, 2010 DOI: 10.1093/epirev/mxq006 [International chronic disease]
11. Clouston SAP et al 2013. *The Dynamic Relationship Between Physical Function and Cognition in Longitudinal Aging Cohorts*. Epidemiologic Reviews DOI: 10.1093/epirev/mxs004 [Chronic disease and the life course]
12. Temel S. et al 2013 *Evidence-Based Pre-conceptional Lifestyle Interventions*. DOI: 10.1093/epirev/mxt003 [Chronic disease and the life course]
13. Velentgas P, Dreyer NA, Nourjah P, Smith SR, Torchia MM, eds. *Developing a protocol for observational comparative effectiveness research: a user's guide*. AHRQ Publications No. 12(13)-EHC099. Rockville, MD: Agency for Healthcare Research and Quality; January 2013, www.effectivehealthcare.ahrq.gov/Methods-OCER.cfm [Cross cutting concept paper]

My area of research and interests webpages plus recent publications:

Epi Department: https://www.publichealth.uga.edu/epibio/about/directory/biostatistics/toni_miles

Google Scholar Page: <https://scholar.google.com/citations?user=LjtAlygAAAAJ&hl=en>

COURSE OBJECTIVES:

Upon completion of this course, the student should gain confidence with application chronic disease concepts, ethics concepts, and interdisciplinary team research.

Epidemiologic methods are an evolving science. I want you to develop the habit of self-directed learning. The following is a list of good resources for your use. Have questions or need information? Consult the following resources:

- Use the CDC Principles of Epidemiology site to review Epidemiology fundamentals. Here's the link to the site: <http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson3/section2.html>
- Georgia's Online Analytical Statistical Information system OASIS (<http://oasis.state.ga.us/oasis/>)
- Centers for Disease Control and Prevention: Wonder (<http://wonder.cdc.gov/>)
- Health U.S. (<http://www.cdc.gov/nchs/hus.htm>)
- Fundamentals of statistics, Statsoft <http://www.statsoft.com/Textbook>
- Morbidity and Mortality Weekly Report (MMWR) <http://www.cdc.gov/mmwr/index.html>
- United States Census, <http://www.census.gov/>
- World Health Organization <http://www.who.int/en/>
- Pan American Health Organization, <http://www.paho.org/hq/>
- Institute for Health Metrics, U of Washington, <HTTP://VIZHUB.HEALTHDATA.ORG/GBD-COMPARE/>
- The WWW Virtual Library of Medicine and Health: Epidemiology. <http://www.epibiostat.ucsf.edu/epidem/epidem.html>. Note: This webpage is maintained by the University of California, San Francisco. If you have a question about U.S. and International Public Health Agencies, start here.

These sources reflect state (OASIS), national (CDC, MMWR, Census), and international (PAHO, WHO, Global Burden of Disease) data sources. The fundamentals of epidemiology can also be studied using the Virtual Library of Medicine and Health plus the Institute for Health Metrics at the University of Washington.

METHODOLOGY:

Classes meets for 3 hour blocks. During each session, the first part will focus on the introduction of new concepts. In the second part, you will engage in activities to illustrate the use of the new ideas. You will work in groups throughout the semester to gain experience

GENERAL INFORMATION:

Grades are based on performance of the following tasks:

Attendance	20%
In-class discussions	35%
Interdisciplinary team work (assigned topic) and issue briefs	25%
Completion of all Online Human Subjects Protection Training	20%

Notice: There are no examinations. The world does not work that way. We will not either. This makes showing up for class the most important part of the learning here.

Student Classroom Conduct:

This course thrives on classroom discussion. I expect respect of others' opinions and beliefs. While I encourage a lively conversation, I will not tolerate disrespect. The requirement for respectful conversation also extends to any online discussions.

Students are encouraged to bring electronic devices to access the internet for class-related questions. This is particularly important for the group work. However, if I see unrelated web-based activities during class, you will receive a grade of zero for the session.

Attendance:

Students are expected to attend and be on time for all classes unless otherwise arranged. It is particularly important that you attend each session. If you know in advance that you will have a schedule conflict, please provide written notice at the beginning of the semester. Illness and other emergencies are handled on a case-by-case basis.

In order to maximize the benefit from this course it is important to not simply show up, but to be ready to actively participate in the course. Part of your grade will be based on attendance *and* participation.

Other recommendations for success:

If you are not a native English speaker it is in your best interest to practice language outside of the typical work day – both written and spoken. Having coffee with colleagues is a good way to practice.

If you are a native English speaker but you want / need to improve your understanding of other languages, meeting outside of the classroom with your fellow students is a great way to learn or improve. UGA has graduate students from across the globe. Reach and make a friend!

COLLEGE POLICIES AND SERVICES:

Academic Honesty: Cheating, Plagiarism, and Collusion

As with all your courses, academic integrity is expected and required of each student. **No exceptions.** Every student must agree to abide by UGA's academic honesty policy and procedures known as *A Culture of Honesty*, which can be found at: http://www.uga.edu/honesty/ahpd/culture_honesty.htm

Students with Disabilities

If you have a documented disability, I will work with you to develop appropriate accommodations for your disability. First, contact the Disability Services, Office of Disability Services 114 Clark Howell Hall (706) 542-8719, <http://www.dissvcs.uga.edu> first. Next, we will meet to discuss your specific needs. In this course, we are committed to an all-inclusive process. However, your first responsibility as a student is to make your needs known.

ASSESSMENTS

1. All members must complete all modules of online CITI training (Due January 31, 2018).
2. Monthly assignments of written issue briefs with critique and feedback from class mates.
3. Interim drafts of products from your group.

PRODUCTS

Four analyses of the ethics associated with chronic disease and related clinical trials written by all members of the class. One analysis is due each month.

January – Duration of trials

February – Selection of outcomes

March – Participant selection issues

April – Topic of student choice

Writing an Issue Brief: (750 to 1000 words total)

Issue:

State the issue in 2 to 3 sentences

Summary / Recommendation:

State your summary or recommended action in 2 or 3 sentences. What are we missing? How do we respond to this issue? What do we know? Factors related to this issue.

Measurement and data:

Are there relevant statistics that define the problem? How were they ascertained? Do we need additional data? Be very specific with the data recommendation.

End with 3 to 5 cited sources for further reading.

Grading Rubric Issue Brief

Objective / Criteria	Needs Improvement	Meets expectations	Exceptional
Ease of readability (Ease 45 to 55 on the Fleisher Scale)	0	5	10
Grade level 10 to 12 years.			
Formulation of your primary idea.			
Use of data and other sources to support your summary			
Discussion of ethics framework			
10 to 20 bonus points for short discussion of policy or public health laws relevant to the issue. These include items such as payment policy for prevention related activity; laws governing action; etc.			

EXAMPLES OF ISSUE BRIEFS FROM PRIOR CLASSES

#1 Issue/Question:

The 'Right to Try' bill introduces the right to use unapproved drugs by patients diagnosed with a serious illness. This bill will allow seriously ill patients to bypass the Food and Drug Administration (FDA) to get access to unapproved drugs. Should seriously ill patients bypass the FDA to get access to unapproved drugs?

Recommendation:

House Representative David Scott and Senators John Isakson and David Perdue should vote against this bill and instead provide provisions to the current Expanded Access policy.

Background:

Every year, over one million people die from a terminal illness. For many years, these terminally ill people struggle to find a cure or to get accepted into a promising clinical trial. The right to try bill gives terminally ill patients the right to seek drug treatments that remain in clinical trials. This could be drugs that passed phase one of the Food and Drug Administration's (FDA) approval process, but they have not been fully approved by the FDA. The right to try bill is primarily for patients who are very sick and have exhausted all possible treatment options. These patients are usually too sick to even qualify for clinical trials.

Allowing access to drugs before approval could put patients in harm's way as patients receiving the drugs are often too vulnerable. There is a current process that the FDA uses that allows terminally ill patients without other options to access drugs outside of clinical trials. The Expanded Access policy requires patients to apply for access to the drugs to receive approval from the FDA. When approval is received, the safety of the drug is explained along with the side effects. The right to try bill seeks to remove the FDA from this process to make it quicker and easier for patients who do not have much time left.

The mission of the FDA is to protect the public health by ensuring the safety, efficacy, and security of human drugs. If you remove the FDA from this process, you are removing the protection and regulation needed to make sure drugs do no harm to patients. Over the years, the Expanded Access policy has provided patients with the drugs needed by request of the physician and the patient. Since the issue with the current policy is that it takes too long, modifications can be made to expedite the process for those who are terminally ill. This will keep the FDA involved because they are needed to provide oversight to ensure that the drugs are administered correctly and that patients are aware of the side effects. Although to those who are dying this may not matter, they are still considered a vulnerable population that needs to be protected regardless. To ensure that drug companies and doctors do not take advantage of one of our most vulnerable populations, the safeguard of the FDA is much needed.

A better plan for terminally ill patients will be to make changes to the Expanded Access policy that requires an expedited approval process by the FDA. Patients will have the right to make their own choices, they can receive their drugs in an expedited manner, but they will also be correctly informed of the potential side effects and outcomes. Patients should have the right to choose drugs that are not approved yet but they must be informed of their potential risks and benefits. This will make sure that patients can receive the drugs that they want but they will have protection from the FDA to ensure they are aware of the consequences.

Sources:

https://www.washingtonpost.com/news/to-your-health/wp/2018/03/18/former-fda-commissioners-say-right-to-try-bills-could-endanger-vulnerable-patients/?utm_term=.4b7c697c8ee3

<https://www.congress.gov/bill/115th-congress/house-bill/878/text>

<https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html>

#2 **Title:** Ethical pitfalls in the “scientific method”.

Issue: Several ethical pitfalls relating to the Belmont principles exist in the four steps of the scientific method.

Recommendation:

Persons championing the scientific method should take a step back and make deliberate efforts to incorporate ethical principles at each of the four steps of the scientific method.

Researchers should put ethics first, before science as they observe and describe phenomena, formulate hypotheses, during prediction, and in the performance of experimental tests.

Background:

The scientific method is the process by which scientists, collectively and over time, endeavor to construct an accurate (that is, reliable, consistent and non-arbitrary) representation of the world [3].

The scientific method has four steps: (i) observation and description of a phenomenon or group of phenomena; (ii) formulation of a hypothesis to explain the phenomena; (iii) use of the hypothesis to predict the existence of other phenomena, or to predict quantitatively the results of new observations; and (iv) performance of experimental tests of the predictions by several independent experimenters and properly performed experiments [3].

There are ethical pitfalls relating to the Belmont principles (i.e., respect for persons, beneficence and justice) that exist at each of the four steps of the scientific method. The observation step could run afoul of all three principles by not respecting privacy, by not benefiting the participants, and collecting the observational data using a process that is not just.

Formulation of a hypothesis to explain the phenomena: The notion of hypothesis testing itself (i.e. the theory) is challenged on the grounds that a hypothesis is an unclear distinction, and assigning a probability on an unclear distinction is an exercise that does not lead to clarity of action. Hypotheses are about causal models in our head and can never pass the clarity test [2]. As such, the theory of hypothesis formulation and its consequence i.e. hypothesis testing could violate the principle of respect for persons due to its ambiguity. It is not clear and therefore participants involved in the study are denied the right to receive clear information concerning the study objectives.

Use of the hypothesis to predict the existence of other phenomena, or to predict quantitatively the results of new observations: Errors in statistical inference undermine the principle of beneficence. Good conclusions and predictions arrived at due to errors in sampling and study design are worthless. Establishing criteria for rejecting or failing to reject a null hypothesis requires a careful consideration of the costs of Type I and Type II errors relative to the benefits of correct decisions [1].

Performance of experimental tests of the predictions by several independent experimenters and properly performed experiments: All the three principles are at stake, for this step. Respect for persons could be undermined where participants don't consent to experimentation, where their privacy is not respected or where the study takes advantage of persons with diminished autonomy such as prisoners by performing experiments on them. More so, it could violate the principle of beneficence by performing experiments that don't benefit the study participants and harming study participants for example testing a new drug in a clinical trial. The drug could harm study participants. Violation of the “justice” principle could occur if the benefits and risks of the study are not fairly distributed among study participants. An example is where persons in the placebo arm of the study don't receive treatment at the end of the study where the treatment proves beneficial at interim analyses.

References

1. http://www.tandfonline.com/doi/abs/10.1207/S15327019EB1102_3
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3193681/>
3. http://teacher.nsrj.rochester.edu/phy_labs/AppendixE/AppendixE.html

#3 Title: Population stigma due to disease associated genes.

Issue: Genetic testing associates harmful genes with certain communities. This may result in discrimination of such populations.

Recommendation: Legislate Laws and policies to protect communities from discrimination based on their genes.

Background

There is an increase in the volume of genetic data associated with particular populations across the globe. Whereas there are efforts to prevent discrimination and ensure confidentiality and privacy at an individual level, not much has been done at community level (Barrett 2006).

There are many pieces of proposed legislation in the United States Congress to protect citizens from genetic discrimination. These proposals have been promoted by ethicists on the principle of confidentiality and privacy. There is no doubt that this approach is succeeding (Nass & Levit, L. A. Gostin 2009). Despite these advances in reducing stigma at an individual level, discrimination of communities based on genetic testing results remains untouched. For instance, there are cancer mutations which are more prevalent in African populations posing a risk for stigma (Maitra & H.Hruban 2008). In such a scenario, this information is necessary for public health planning yet exposing the community to discrimination.

To explain this effect, consider the HIV mandatory testing policy in Zambia due to an increased incidence of HIV. Legalized mandatory HIV testing is ethics dilemma to communities (Ministry of Health Zambia 2013). There is a risk of increase in community level stigma with this mandatory testing. Although compulsory testing is necessary to reduce incidence, there will be information implicating sections of society.

In addition, there is evidence that individuals from outbreak prone communities suffer stigma even when they do not pose a risk (Nass & Levit, L. A. Gostin 2009). It is therefore crucial that we recognize this gap and support or institute policies that safeguard communities from such stigma.

As a recommendation, public health schools are encouraged to think about this challenge and design courses that are responsive to this challenge. As it is at an individual level, it would be wise not to disclose genetic abnormalities concerning particular communities in public but rather deal confidentially with such populations to craft appropriate responses. Lastly, all these suggestions could be crafted in a law to protect society from community discrimination.

References

- Barrett, G., 2006. National survey of British public's views on use of identifiable medical data by the National Cancer Registry. *Bmj*, 332(7549), pp.1068–1072. Available at: <http://www.bmj.com/cgi/doi/10.1136/bmj.38805.473738.7C>.
- Maitra, A. & H.Hruban, R., 2008. Pancreatic Cancer. *Cancer Research*, (3), pp.1–30.
- Ministry of Health Zambia, 2013. Zambia Consolidated Guidelines for Treatment and Prevention of HIV Infection. , (December), pp.1–57.
- Nass, S.J. & Levit, L. A. Gostin, O.L., 2009. *The value, importance, and oversight of health research*, Available at: <http://www.ncbi.nlm.nih.gov/books/NBK9571/> accessed 01/08/2016.