Term Information

Effective Term	Spring 2015
Previous Value	*Autumn 2014*

Course Change Information

What change is being proposed? (If more than one, what changes are being proposed?)

GE: Cultures and Ideas course

What is the rationale for the proposed change(s)?

See attached

What are the programmatic implications of the proposed change(s)?

(e.g. program requirements to be added or removed, changes to be made in available resources, effect on other programs that use the course)?

See attached

Is approval of the requrest contingent upon the approval of other course or curricular program request? No

Is this a request to withdraw the course? No

General Information

Course Bulletin Listing/Subject Area	Biomedical Sciences Grad Prog
Fiscal Unit/Academic Org	School of Biomedical Sciences - D2506
College/Academic Group	The College of Medicine
Level/Career	Undergraduate
Course Number/Catalog	2010
Course Title	Ethics of Biomedical Science Research
Transcript Abbreviation	Ethics Bio Sci Res
Course Description	Provides a foundation in traditional ethics, a consideration of the subcategories of bioethics, neuroethics, and eugenics and instructs students in how to apply ethics to contemporary issues in research and technology. This course also satisfies the basic components of Responsible Conduct of Research (RCR) education.
Semester Credit Hours/Units	Fixed: 3

Offering Information

Length Of Course	14 Week
Flexibly Scheduled Course	Never
Does any section of this course have a distance education component?	No
Grading Basis	Letter Grade
Repeatable	No
Course Components	Lecture
Grade Roster Component	Lecture
Credit Available by Exam	No
Admission Condition Course	No
Off Campus	Never
Campus of Offering	Columbus

Prerequisites and Exclusions

Prerequisites/Corequisites

Exclusions

Cross-Listings

Cross-Listings

Subject/CIP Code

Subject/CIP Code	51.3201
Subsidy Level	Baccalaureate Course
Intended Rank	Freshman, Sophomore, Junior, Senior

Requirement/Elective Designation

Required for this unit's degrees, majors, and/or minors
General Education course:
Culture and Ideas
The course is an elective (for this or other units) or is a service course for other units

Previous Value

Required for this unit's degrees, majors, and/or minors
The course is an elective (for this or other units) or is a service course for other units

Course Details

Course goals or learning objectives/outcomes

- Upon completion of the course, the student will:
  explain traditional approaches to ethical issues and basic moral concepts, and apply their understanding to constructively critique biomedical case studies,
- discuss contemporary issues in biomedical science with sufficient knowledge of their historical and scientific background, and
- analyze established policies and codes for research.

Content Topic List

- Birth of Bioethics and Human Subject Research
- Research on Genes, Cells, Embryos and Animals
- Scientific Integrity

Attachments

- Syllabus_BSGP2010.docx

  (Syllabus. Owner: Lahmers,Amy Kathryn)

- ProposedGE_BSGP2010_Assessment.docx

  (GEC Course Assessment Plan. Owner: Lahmers,Amy Kathryn)

- ProposedGE_BSGP2010_1014 REV.docx: Revised 11/24/2014

  (GEC Course Assessment Plan. Owner: Lahmers,Amy Kathryn)

- Syllabus_BSGP2010_1014 REV.docx: Revised 11/24/2014

  (Syllabus. Owner: Lahmers,Amy Kathryn)

Comments

- submitting revisions requested (see 2 new attachments included) *(by Lahmers,Amy Kathryn on 11/24/2014 08:37 AM)*
- See 10-14-14 e-mail to A. Lahmers. *(by Vankeerbergen,Bernadette Chantal on 10/14/2014 09:15 AM)*

Workflow Information

Status	User(s)	Date/Time	Step
Submitted	Lahmers,Amy Kathryn	07/03/2014 08:38 AM	Submitted for Approval
Approved	Lahmers,Amy Kathryn	07/07/2014 11:43 AM	Unit Approval
Approved	Clinchot,Daniel Michael	07/07/2014 12:08 PM	College Approval
Revision Requested	Vankeerbergen,Bernadette Chantal	10/14/2014 09:15 AM	ASCCAO Approval
Submitted	Lahmers,Amy Kathryn	11/24/2014 08:38 AM	Submitted for Approval
Approved	Lahmers,Amy Kathryn	11/24/2014 08:39 AM	Unit Approval
Approved	Clinchot,Daniel Michael	11/24/2014 08:51 AM	College Approval
Pending Approval	Nolen,Dawn Vankeerbergen,Bernadette Chantal Hanlin,Deborah Kay Jenkins,Mary Ellen Bigler Hogle,Danielle Nicole	11/24/2014 08:51 AM	ASCCAO Approval

The Ohio State University
College of Medicine
Center for Bioethics and Medical Humanities

Autumn quarter 2015

Course Number: BSGP2010
Credit Hours: 3 Units

Title: **Ethics of Biomedical Science Research**

Instructor: Name Mariko Nakano-Okuno, Ph.D
Title Assistant Professor - Practice, General Internal Medicine
Address 065 Meiling Hall
370 W 9th Avenue Columbus, OH 43210-1238
Phone 614-747-3334
e-mail nakano.9@osu.edu
Office Hours By appointment

Class Day/Time: TBD

Class Location: TBD

Texts: **E. Emanuel et al., *The Oxford Textbook of Clinical Research Ethics*, 2011**
Francis L. Macrina, *Scientific Integrity*, 2005
Additional readings are assigned in class or available on reserve. See agenda (shown below) for details.

Course Overview:

Ethics should play a prominent role in the execution of scientific and medical research and in the design of policies and regulations to guide such research. The broad intent of this course is to highlight the importance of ethics in research and to explore how and why bioethics is relevant to personal decision-making, policy formation, public regulation, and the law. This course will a) provide a foundation in traditional ethics, a consideration of the subcategories of bioethics, neuroethics, and eugenics and b) instruct students in how to apply ethics to contemporary issues in research and technology. **This course also satisfies the basic components of Responsible Conduct of Research (RCR) education.**

Course Objectives:

Upon completion of the course, the student will:

1) explain traditional approaches to ethical issues and basic moral concepts, and apply their understanding to constructively critique biomedical case studies,
2) discuss contemporary issues in biomedical science with sufficient knowledge of their historical and scientific background, and
3) analyze established policies and codes for research.

GE 'Culture and Ideas' Goals and ELO:

Goals: Students evaluate significant cultural phenomena and ideas in order to develop capacities for aesthetic and historical response and judgment; and interpretation and evaluation.

Expected Learning Outcomes (ELO) :
***ELO1*:** Students analyze and interpret major forms of human thought, culture, and expression.
***ELO2*:** Students evaluate how ideas influence the character of human beliefs, the perception of reality, and the norms which guide human behavior.

How BSGP2010 helps students achieve these ELOs: The broad intent of BSGP2010 is to highlight the importance of ethics in biomedical science research, and to let students critically analyze recent ethical issues and debates in stem cell research, neuroscience, genetics and other lines of biomedical science research as well as issues in responsible conduct of research.
There are three kinds of topics covered by BSGP 2010:

Topic group 1. Historical and regulatory backgrounds of biomedical research ethics. (See "Topic Schedule," Topic #2-4, History and Politics of Biomedical Research and Human Experimentation; Topic #5, Eugenics Movement in the early 20C; and Topic #6-7, ethical debates over Psychosurgery in the mid 20C and how it affected current bioethics policies.)

Topic group 2: Basic moral concepts used in discussions of biomedical research ethics. (Three traditional approaches – consequentialist, deontological and contractarian approaches – are discussed in Topic 1; two of the major basic bioethical concepts, informed consent and respect for persons, are discussed in Topic 2-4 and 8; and other basic concepts, such as beneficence, justice and privacy, are mainly discussed in Topic 9, 10 and 11, respectively.)

Topic group 3: Contemporary issues and debates in biomedical research ethics. (Topics 5, 6-7, 12-25, which deal with issues in stem cell research, neuroscience, reproductive technologies, genetics and genomics, biological patents, conflict of interest cases, and commercialized clinical trials and scientific misconduct cases.)

By going through Group 1 and 2 topics, students will be prompted to analyze and interpret major forms of human thought, culture, and expression, which will meet ELO1. By discussing Group 3 topics, students will be asked to evaluate how ideas they discussed in Group 1&2 topics influence their beliefs, perception of reality, and the norms they would propose to guide their behavior in conducting biomedical science research, which will meet ELO2.

Course Requirements: No Prerequisites**.**

Course Grading:

Final grades for the course will be determined as follows:

20%	Attendance	80 points
20%	Written Analysis	80 points
20%	Midterm Exam	80 points
40%	Final Exam (Cumulative)	160 points
		TOTAL = 400 points

Your overall mastery (scaled 0 to 100) is your total score divided by four.

Final Grading Scale

The grading will use the official marks of the University (Rule 3335-7-21) to include: A, A-, B+, B, B-, C+, C, C-, D+, D, E, EN, I, and W.

100-93	A	79-76	C+
92-90	A-	75-73	C
89-86	B+	72-70	C-
85-83	B	69-66	D+
82-80	B-	65-63	D
		62-0	E

Statement of Student Rights:

Students with disabilities that have been certified by the Office for Disability Services will be appropriately accommodated and should inform the instructor as soon as possible of their needs. The Office for Disability Services is located in 150 Pomerene Hall, 1760 Neil Avenue; telephone 292-3307, TDD 292-0901; http://www.ods.ohio-state.edu/.

Academic Misconduct:

It is the responsibility of the Committee on Academic Misconduct to investigate or establishprocedures for the investigation of all reported cases of student academic misconduct. The term “academic misconduct” includes all forms of student academic misconduct wherever committed; illustrated by, but not limited to, cases of plagiarism and dishonest practices in connection with examinations. Instructors shall report all instances of alleged academic misconduct to the committee (Faculty Rule 3335-5-487). For additional information, see the Code of Student Conduct http://studentlife.osu.edu/csc/.”

Agenda:

Assignments

Attendance–***Please remember that attendance is crucial for your grade.*** Students whose attendance rate is 70% or lower will automatically drop the course. For your absence to be counted as an excused absence, a written justification with proof (a dated doctor's note, an ER receipt, a Jury Summons, etc.) should be submitted *before or immediately after* the date you will be or were absent.

Written Analysis – Students are required to submit two essays during the semester. Due dates are shown below:

1st essay Friday, Week 3, 11:00 pm
2nd essay Friday, Week 8, 11:00pm

Each essay should be **over 1000 words** in length. One essay per student should be submitted. All essays should be submitted electronically on the "discussion board" section of the course website (Carmen) by the due date. *Late submission may receive minus 4 points.* Evaluation will be based on whether the written analysis shows 1) sufficient scientific and regulatory knowledge of the issue, 2) knowledge of the controversy and its background, and 3) examination of different perspectives and careful reflection in developing the student's own opinion.

For more details about the assigned topics, please refer to the file "Discussion topics/Written assignment" posted on the course website (Carmen).

Exams – Mid-term and final exams will cover material from lectures, required readings, and discussion sections. **Makeup exams will not be given.** In case you have an illness or emergency and are unable to take an exam, you are responsible for contacting your TA before the examination. A written verification regarding the illness or emergency must be provided. If you feel that a mistake has been made in grading your exam, submit your exam and a typed justification to your TA by 5pm on Friday of the week following the exam.

The mid-term exam consists of 30 multiple-choice questions (2 point each) and 4 long-answer questions (5 points each). The total score is 80 points. Those questions will cover traditional approaches to ethical issues, the history of bioethics, past and present scientific policies and famous ethical guidelines
The final exam will consist of 50 multiple-choice questions (2 point each), 5 short-answer questions (6 points each) and 6 long-answer questions (5 points each). The total score is 160 points.
Two weeks before each exam, files entitled "the instruction on how to prepare for the exam" and "sample questions" will be provided on the course website. Please read them very carefully.

Topic Schedule

1. Introduction: Biomedical Research and Ethics

- The scope of "biomedical research" that this course will deal with
- Definition of "ethics," subcategories of ethics (meta-ethics, normative and applied) and how ethics can deal with the issues in biomedical research
- Three methods of normative ethics: Consequentialist, Deontological, and Contractarian approaches

Additional readings:
Henry Sidgwick, *The Methods of Ethics,* 1874
R. M. Hare, *Moral Thinking*, 1982

Sessions 2 through 12 – Birth of Bioethics and Human Subject Research

2. History and Politics of Biomedical Research and Human Experimentation I

- Hippocratic Tradition
- Evolution of quantitative methods: vital statistics, epidemiology theory 17-19C
- Development of clinical trial methodology, placebo and randomization
- Ethics of self-experimentation: development of anesthesia, vaccination, and others
- Experiments on unconsenting humans, 18C-: variolation, vaccination and immunization
- Rudimentary requirements for informed consent / safety monitoring
  - US Yellow Fever Commission in Cuba, 1900
  - Prussian Ministry's Directive on Human Experimentation, 1900
  - Rockfeller Institute's Syphilis Experiment Scandal, 1911-12
  - Sulfanilamide Scandal, 1937

Hippocratic Oath
Thomas Percival, *Medical Ethics*, 1803
Henry Rose Carter, *Yellow Fever: An Epidemiological and Historical Study of Its Place of Origin*, 1931

3 & 4. History and Politics of Biomedical Research and Human Experimentation II

- The Nazi Germany experiments and the Nuremberg Code
- Japan's Unit 731 experiments and the US military experiments during WWII
- The Declaration of Helsinki
- Postwar human experiments:
  - Human radiation experiments
  - Guatemala Syphilis Experiments
  - Thalidomide tragedy and Kefauver-Harris amendment
  - Jewish Chronic Disease Hospical Case
  - The Milgram Experiments
  - Willowbrook Hepatitis Study
  - Tuskegee Syphilis Study
- The National Research Act, the Belmont Report and the Belmont Principles, 1974 and 1979
- Presidential Commission on Moral Science: Protecting Participants in Human Subjects Research, 2011

Paul M. McNeill, A History of Unethical Experimentation on Human Subjects in his *The Ethics and Politics of Human Experimentation*, Cambridge University Press, 1993, Ch.1
Henry K. Beecher, "Ethics and Clinical Research," *The New England Journal of Medicine*, 274, 1966: 1354-1360.
Presidential Commission, "Ethically Impossible: STD Research in Guatemala from '46-'48, 2011.

5. Eugenics and its contemporary implications

- History, from Francis Galton to eugenic movements in the late 19C – early 20C
  Compulsory sterilization policy in the US
  The Buck v. Bell Decision, 1927
  Nazi eugenics in Germany
- Eugenic implications of contemporary biomedical sciences & technologies
  IQ hereditary debates
  "Soft eugenics" public health policy in Singapore
  Genetics and reproductive technologies

Francis Galton, Eugenics: Its Definition, Scope, and Aims, *The American Journal of Sociology,* Vol.10, No.1 (July 1904), pp.1-6.

6 & 7. Neuroethics: Neuroimaging and Neuromodulation

- Emerging field of neuroethics
- Clinical/non clinical uses of brain imaging
- Neuroimaging for criminals
- Psychopharmacology
- Neuromodulation for movement disorders, psychiatric disorders and others
- Lessons from past lobotomy practices in 1930s-1970s

Walter Freeman, Ethics of Psychosurgery, *The New England Journal of Medicine*, Vol.249, No.20 (Nov. 12, 1953), pp.798-801.

8. Respect for Persons and Informed Consent

- "Respect for Persons" versus "Respect for Autonomy"
- Two streams of informed consent: Research IC and Therapeutic IC
- Informed consent in Phase I Clinical Trials
- Informed consent in double-blind placebo-controlled clinical trials
- "Presumed consent" in cohort studies: the Icelandic healthcare database project
- "Broad consent" for research using stored tissue samples

The Declaration of Lisbon
R. R. Faden, T. L. Beauchamp et al., A History and Theory of Informed Consent, 1986.
E. J. Emanuel and F. G. Miller, "The Ethics of Placebo-Controlled Trials -- A Middle Ground," ***NEJM*** **345, 2001: 915-919.**
Who Owns Our Genes?**, Nordic Council of Ministers, Copenhagen 2000**

9. Beneficence and Non-Maleficence: Risk-Benefit Analysis

- Defining and quantifying benefits and risks
- Classifying risks and benefits to research subjects
- Classifying risks and benefits to the society
- When can we justify research risks?
- Clinical equipoise
- The Harvard ECMO Trial

E.J. Emanuel, D. Wendler and C. Grady, "What Makes Clinical Research Ethical?" ***JAMA*** **283, 2000:2701-11.**
B. Freedman, "Equipoise and the ethics of clinical research," ***NEJM*** **317, 1987: 141-5.**

R. Truog, "Informed Consent and Research Design in Critical Care Medicine," Crit Care 1999, **3**:R29–R33.

10. Justice: Fair Protection and Fair Access

- Defining Justice
- Lessons from Tuskegee, Willowbrook and Human Radiation Experiments
- Including minorities in research: The 1985 Report by the Task Force on Black and Minority Health
- Inclusion of women and children: The NIH Revitalization Act, 1993; NIH's 1998 policy

A. R. Jensen, ***The Birth of Bioethics*****, 1998.**
Henry Sidgwick, ***The Methods of Ethics*****, 1907.**
John Rawls, ***A Theory of Justice*****, 1999.**
The UCSF survey on inclusion of minorities in prostate Cancer clinical trials, 2012.

11. Privacy and Confidentiality

- Cases of privacy breach in clinical research
- Physician-patient privilege
- *Whalen v. Roe*
- *Tarasoff v. Board of Regents 1974*
- *Commonwealth v. Kobrin*
- Subpoenas, Certificates of Confidentiality/Confidentiality Assurances
- HIPAA Privacy Rule
- Difficulties surrounding the de-identification of Personal Health Information
- The role of Privacy Board

Essential Issues for Leaders: Emerging Challenges in Health Care**, Joint Commission Resources, 2001.**
HIPAA Privacy Rule

12. Ethics of International Research

- Ethical issues in international HIV/AIDS research
- Lessons from Tuskegee and Guatemala Studies
- Distributive justice

- Global access to effective and affordable drugs and treatment
- Ethical issues of outsourcing clinical trials to developing countries

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects
Adriana Petryna, "When Experiments Travel: Clinical Trials and the Global Search for Human Subjects," 2009.

13. Midterm Exam

Sessions 14 through 20 – Research on Genes, Cells, Embryos and Animals

14 & 15. Experiments on Animals

- Historical development of Animal Protection Movements
  - Martin's Act and Martial Hall's five principles, mid 19C (UK)
  - The 3Rs, proposed in 1959
  - "Dogs in Concentration Camps" in *Life* Magazine
  - The Guide, 1963-
  - Animal Welfare Act, 1966
  - ARI's campaign against cat experiment at American Museum of Natural History, Draize test & LD50 test, trauma research on baboons in 1970s-80s
  - PHS Policy on Humane Care and Use of Laboratory Animals, 1986-
- The role of IACUC
- Types of arguments against animal experiments

David Gegrazia, The Ethics of Animal Research: What Are the Prospects for Agreement?
Baruch A. Brody, Defending Animal Research: An International Perspective
In Beauchamp and Walters, eds. *Contemporary Issues in Bioethics*, 6th ed, Wadsworth, 2003, pp.418-426, 426-436.
The Guide
Animal Welfare Act
PHS Policy on Humane Care and Use of Laboratory Animals
CIOMS International Guiding Principles for Biomedical Research Involving Animals, 1985
NAS Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research

16. Stem Cell Research I: Human Embryonic Stem Cell Research

- Kinds of stem cells and the unique characteristics of human embryonic stem cells
- Applications of stem cell research, regenerative medicine, and SCNT
- President GW Bush's remarks on August 9, 2001
- Bush's case for embryo adoption
- Dickey-Wicker Amendment
- President Obama's executive order, March 9, 2009
- Pros and Cons

Peter Singer, The Moral Status of the Embryo In Gregory E. Pence, ed. *Classic Works in Medical Ethics*, McGraw-Hill, 1998.

17. Stem Cell Research II: Court Battle and the Advent of iPS Cells

- Dr. Theresa Deisher's Stem Cell Crusade
- *Sherley v. Sebelius*
- Promise of iPS Cells
- Argument for continuous use of hES cells

Sherley v. Sebelius
I Hyun et al. "New Advances in iPS Cell Research Do Not Obviate the Need for Human Embryonic Stem Cells," *Cell Stem Cell* 1 (Oct. 2007):367-8.

18. Stem Cell Research III: iPS-Based Clinical Research and Human-to-Animal Chimeras

- Therapeutic misconception in cell therapy clinical trials
- RIKEN's pilot study on iPSC-derived retinal cell transplant
- Dr. Nakauchi on creating iPSC-derived human organs in pigs
- Creating human mini-organs in a petri dish
- Human-to-animal chimeras for organ transplant purposes
- Ethics of creating human brains or neurons in nonhuman animals

Karpowicz, P., Cohen, C.B., and van der Kooy, D. *Kennedy Inst. Ethics J.* 15 (2005), 107–134.
Matthew H. Haber & Bryan Benham, *The American Journal of Bioethics*, 12 (2012):9, 17-25,

19. Whole Genome Sequencing and Genomic Privacy

- Review of HIPAA Privacy Rule
- Clinical and nonclinical uses of whole genome sequencing
- Concerns about the identifiability of de-identified personal information via the use of the DNA database and publicly available databases
- Ethical issues of incidental findings

The HIPAA Privacy Rule, 2000, 2002.
Presidential Commission, *Privacy and Progress in Whole Genome Sequencing*, 2012.
Presidential Commission, *Incidental Findings: Anticipate and Communicate,* 2013.

20. Economic Aspects of Research: Patenting Life

- Governmental Funding versus Industrial R&D
- The Bayh-Dole Act of 1980
- The Federal Technology Act of 1986
- Patent system, patenting life forms, natural products and genes
  Brief history of intellectual property, 1200s-
- *Diamond v. Chakrabarty,* 1980

- Patents on Harvard oncomouse and human ES cells
- Myriad Gene Patent Litigation

The Bayh-Dole Act, 1980
The Federal Technology Act, 1986
Diamond v Chacrabarty, 1980
Association for Molecular Pathology v. Myriad Genetics, 2013

Sessions 21 through 25 – Scientific Integrity

21 & 22. Scientific Misconduct and the Accountability of Scientists

- Misconduct and fraud in science and scientific publishing
  Fabrication, falsification and plagiarism, and the "honest error" clause
- Classical misconduct cases: Alsabti, Spector, Pearce, Herrmann/Brach, Poelman, Baltimore/Imanishi-Kari Affairs
- The Schön scandal
- The South Korean stem cell scandal
- Japan's STAP cell scandal
- The role of the Office of Research Integrity.
- Psychological, environmental and social factors to tempt some scientists to commit scientific fraud
- Data managment
- Peer review: its fairness

Martinson, BC et al, "Scientists behaving badly," Nature, 435(9), June 2005:737-738.
"Misconduct finding at Bell Labs shakes physics community," Nature 419, Oct. 2002: 419-421.
Federal Research Misconduct Policy, 2000
PHS Policies on Research Misconduct: Final Rule, 2005.

23. Conflict of Interest

- Three kinds of conflict: commitment, conscience and interest
- Financial, academic, tangible and intangible conflict of interest
- Examples of COI in biomedical research
- Senator Grassley's effort to detect COIs in biotech fields
- Jesse Gelsinger's case
- Ways to handle COI

Paul Gelsinger and Adil E. Shamoo, *Hastings Center Report* 28, no.2 (2008): 25-27
***Objectivity in Research,* 1995**
42 CFR Part 50, Subpart F, revised 2011

24. Paying Research Subjects

- Ethics of offering financial compensation or incentives for health research participants
- Pros and cons and their theoretical assumptions
- Comparison with the case for compensating organ donors

C Grady, J Clin Invest. Jul 1, 2005; 115(7): 1681–1687.
M L Russel et al, Journal of Medical Ethics 2000;26:126–130.
E Ripley et al, J. Clinical Research Best Practices 4 (3), 2008.
R Korobkin, "No Compensation" or "Pro Compensation": Moore v. Regents and Default Rules for Human Tissue Donations, Journal of Health Law, 40(1), 2007: 1-27.

25. Data Ownership and Authorship

- The meaning of authorship in biomedical sciences
- Who qualifies for (first, last and middle) authorship
- Gift / Guest /Honorary authorship
- Ghost authorship
- Responsibilities of authors
- Collaboration and communication

  Review of South Korean Stem Cell Scandal, the Schön scandal and Baltimore/Imanishi-Kari cases.

ICMJE, The Uniform Requirements for Manuscripts Submitted to Biomedical Journals, updated 2008.
PC Gøtzsche et al., "Ghose authorship in induscry-initiated randomized trials," PLoS Med 4(1), 2007: e19.
A Marušić, L Bošnjak and A Jerončić, "A Systematic Review of Research on the Meaning, Ethics and Practices of Authorship across Scholarly Disciplines," PLoS One 6(9), 2011: e23477.

Final Exam

Further Readings (Optional)

1. Basic Texts on Bioethics

Pence, Gregory E. ed. 2007. *Classic Cases in Medical Ethics*, McGraw-Hill.

Pence, Gregory E. ed. 1998. *Classic Works in Medical Ethics*, McGraw-Hill.

Kuhse, Helga and Singer, Peter eds. 1998. *A Companion to Bioethics*, Blackwell.

Burley, Justine and Harris, John eds. 2004. *A Companion to Genethics*, Blackwell.

Faden, Ruth R., Beauchamp, Tom L. et al., 1986. *A History and Theory of Informed Consent*, Oxford U.P.

Beauchamp, Tom L. and Childress, James F. 2001. *Principles of Biomedical Ethics*, 5th ed., Oxford University Press.

2. Basic Texts on Ethics and Ethical Theories

Rachels, James. 2006. *The Elements of Moral Philosophy*, 5th ed., McGraw-Hill.

Hare, R. M. 1981. *Moral Thinking: Its Levels, Methods and Points*, Oxford University Press.
----------, 1952. *The Language of Morals*, Oxford University Press.

Hobbes, Thomas, 1651, *Leviathan*, Ch.13.

Kant, Immanuel, 1784. *Idea For A Universal History With A Cosmopolitan Purpose*.
----------, 1785. *Groundwork of the Metaphysics of Morals*.
----------, 1797. *The Metaphysics of Morals*, Part II.

Bentham, Jeremy, 1823. *An Introduction to the Principles of Morals and Legislation*, Ch.1.

Mill, J. S. 1863. *Utilitarianism*, Ch.2.

Sidgwick, Henry. 1907. *The Methods of Ethics*, 7th ed.

Rawls, John. 1971, 1999. *A Theory of Justice*, Harvard University Press.

Anscombe, G.E.M. 1958. 'Modern Moral Philosophy', *Philosophy*, 33: 1-19.

3. Particular Topics in Biomedical Ethics

Welsome, Eileen, 2000. *The Plutonium Files: America's Secret Medical Experiments in the Cold War*, Delta.

Emanuel, E. J. and Miller, F. G. 2001. "The Ethics of Placebo-Controlled Trials -- A Middle Ground," *New England Journal of Medicine* 345, no. 12 (Sep. 20, 2001): 915-919.

Kevles, Daniel. 1985. *In the Name of Eugenics*, Knopf.

Hare, R. M. 1993. "Embryo Experimentation: Public Policy in a Pluralist Society," in his *Essays on Bioethics*, 1993, ch.8.

Ruse, Michael and Pynes, Christopher A (eds.). 2003. *The Stem Cell Controversy: Debating the Issues*, Prometheus Books.

Illes, Judy (ed.). 2005. *Neuroethics: Defining the Issues in Theory, Practice and Policy*, Oxford University Press.

Ackerman, Sandra J. 2006. *Hard Science, Hard Choices: Facts, Ethics, and Policies Guiding Brain Science Today* (Dana Foundation Series on Neuroethics), Dana Press.

Buchanan, Allen, Brock, Dan W., Daniels, Norman and Wikler, Daniel. 2001. *From Chance to Choice: Genetics and Justice,* Cambridge University Press.

Evans, John H. 2002. *Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate,* University of Chicago Press.

Glover, Jonathan. 2006. *Choosing Children: Genes, Disability, and Design* (Uehiro Series in Practical Ethics), Oxford University Press.

Sandel, Michael J. 2004. "The Case Against Perfection." *The Atlantic Monthly,* April, pp 51-62.

Gegrazia, D. "E The Ethics of Animal Research: What Are the Prospects for Agreement?" and Brody, Baruch A. "E Defending Animal Research: An International Perspective," in Beauchamp and Walters, eds. *Contemporary Issues in Bioethics*, 6th ed, Wadsworth, 2003, pp.418-426, 426-436.

Loue, Sana and Pike, Earl C (eds.). 2007. *Case Studies in Ethics and HIV Research*, Springer.

Macrina, Francis L. 2005. *Scientific Integrity: Text and Cases in Responsible Conduct of Research*, 3rd ed., ASM Press.

Thompson, Dennis F. 2004. *Restoring Responsibility: Ethics in Government, Business, and Healthcare*, Cambridge University Press.

Couzin, Jennifer and Michael Schirber, "Fraud Upends Oral Cancer Field Casting Doubt on Prevention Trial," *Science*, 27 January, 2006.

Erwin, Edward. 1994. *Ethical Issues in Scientific Research: An Anthology*, Routledge.

Huxley, Aldous. 1998. *A Brave New World*.

Ishiguro, Kazuo. 2005. *Never Let Me Go*, Knopf.

The Presidential Commission for the Study of Bioethical Issues. www.bioethics.gov

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

CENTER FOR BIOETHICS AND MEDICAL HUMANITIES

GE CREDIT PROPOSAL FOR BSGP 2010

Category: Cultures and Ideas

Goals: Students evaluate significant cultural phenomena and ideas in order to develop capacities for aesthetic and historical response and judgment; and interpretation and evaluation.

Expected Learning Outcomes (ELO):
ELO1: Students analyze and interpret major forms of human thought, culture, and expression.
ELO2: Students evaluate how ideas influence the character of human beliefs, the perception of reality, and the norms which guide human behavior.

GE Rationale for BSGP 2010 Meeting Expected Learning Outcomes:

A. How do the course objectives address the GE category expected learning outcomes?

The broad intent of the proposed course, BSGP2010 – Ethics of Biomedical Science Research, is to highlight the importance of ethics in biomedical science research, and to let students critically analyze recent ethical issues and debates in stem cell research, neuroscience, genetics and other lines of biomedical science research as well as issues in responsible conduct of research. The Course Objectives of BSGP 2010 read as follows (emphasis added):

Upon completion of the course, the student will:
1) explain *traditional approaches to ethical issues and basic moral concepts*, and *apply* their understanding to constructively critique biomedical case studies,
2) discuss contemporary issues in biomedical science *with sufficient knowledge of their historical and scientific background*, and
3) *analyze* established policies and codes for research.

Objectives 1)-2) mean that the course will let students learn, interpret and analyze the major forms of human thought in the context of biomedical research ethics, which will meet Expected Learning Outcomes One (**ELO1**). Objectives 1)-3) also clearly indicate that, by discussing contemporary issues in biomedical research *with ample knowledge of their historical, scientific and regulatory backgrounds as well as basic moral concepts*, students will be required to evaluate how traditional and basic moral concepts and historical ideas influence i) human beliefs about the ethicality of biomedical science and technology, ii) human

perception of reality about the recent issues in biomedical research, and iii) the norms about scientific integrity. Thus the course objectives also meet Expected Learning Outcomes Two (**ELO2**).

B. How do the readings assigned address the GE category expected learning outcomes?

The two core textbooks for BSGP 2010 are:
Emanuel E. et al., *The Oxford Textbook of Clinical Research Ethics*, 2011.
Francis L. Macrina ed., *Scientific Integrity*, 2005.

The Oxford Textbook of Clinical Research Ethics covers a wide range of contemporary issues in biomedical research, including human subject research, clinical trials, the use of biological samples, genetic screening and research on vulnerable population. It also contains detailed descriptions of relevant regulations and their historical background (including discussions of unethical biomedical research conducted before, during and after WWII). Francis Macrina's *Scientific Integrity* supplements *The Oxford Textbook* by covering some important areas that the latter does not cover, namely, the responsible conduct of research and the use of animals in biomedical experimentation. Chapter 2 of *Scientific Integrity* also covers major traditional approaches to the issues in biomedical ethics (utilitarianism, deontology, the case study approach and moral reasoning in the conduct of science). As such, the combination of the two textbooks covers i) traditional approaches to ethical issues in biomedical research, including basic moral concepts and culturally defined regulations --- in other words, "major forms of human thought, culture and expression" -- as well as ii) contemporary cases/case scenarios in which human beliefs, the perception of reality, and the norms about biomedical research are significantly influenced by traditional or more radical ideas. Besides these two core textbooks, additional readings are assigned, including Francis Galton's eugenic ideas in the early 20C and Dr. Walter Freeman's defense of prefrontal lobotomy in the mid 20C. These additional readings will make students further consider how ideas formed in a certain culture in a certain historical trend could influence one's ethical judgment and how we could rationally avoid such influences. Thus, these assigned readings address both of the GE category expected learning outcomes, **ELO1** and **ELO2**.

C. How do the topics address the GE category expected learning outcomes?

There are three kinds of topics covered by BSGP 2010:

Topic group 1. Historical and regulatory backgrounds of biomedical research ethics.

(See Topic schedule #2-4, History and Politics of Biomedical Research and Human Experimentation, which cover Hippocratic tradition, emergence of informed consent policies, the Declaration of Helsinki and the Belmont Report, all of which are key ethical guidelines historically formed; Topic #5 discusses Eugenics Movement in the early 20C and debates over it; and Topic #6-7 deals with ethical debates over Psychosurgery in the mid 20C and how it affected current bioethics policies.)

Topic group 2: Basic moral concepts used in discussions of biomedical research ethics.

(Three traditional approaches – consequentialist, deontological and contractarian approaches – are discussed in Topic 1; two of the major basic bioethical concepts, informed consent and respect for persons, are discussed in Topic 2-4 and 8; and other basic concepts, such as beneficence, justice and privacy, are mainly discussed in Topic 9, 10 and 11, respectively. See "Topic Schedule" in syllabus for details.)

Topic group 3: Contemporary issues and debates in biomedical research ethics.

(Topics 5, 6-7, 12-25, which deal with issues in stem cell research, neuroscience, reproductive technologies, genetics and genomics, biological patents, conflict of interest cases, and commercialized clinical trials and scientific misconduct cases.)

By going through Group 1 and 2 topics, students will be prompted to analyze and interpret major forms of human thought, culture, and expression, which will meet ELO1. By discussing Group 3 topics, students will be asked to evaluate how ideas they discussed in Group 1&2 topics influence their beliefs, perception of reality, and the norms they would propose to guide their behavior in conducting biomedical science research, which will meet ELO2.

D. How do the written assignments address the GE category expected learning outcomes?

The proposed course requires two written assignments (>1000 words), in which students are asked to analyze existing ethics policies and regulations (Mid-term paper) and one of the contemporary bioethical debates (Term paper) by interpreting and applying some of the basic moral concepts they have learned in class. The discussion questions will be presented as follows:

Written assignment #1: Critical examination of past and present ethical guidelines and regulations on biomedical research.

1) Consider the driving force that made us shape ethical guidelines for biomedical research. What were the drafters' original intentions to create the Nuremberg Code, the WMA Declaration of Helsinki, or the Belmont Report? What are the essential messages of these guidelines?
2) Consider the shortcomings of these major codes of ethics or other regulations developed in the past. Why were some of them ineffective, and how have we improved them?
3) Consider current guidelines and regulations in the US and worldwide. What are their essences? Are they consistent, reasonable, and practicable? If you think these guidelines and regulations are still ineffective, how can we improve on them?

Written assignment #2: What constitutes ethical research?
On what specific conditions can biomedical research be conducted ethically --- or at least not unethically?

Discuss this question by referring to at least ***one*** of the following topics (Group 1) while applying your analyses of at least ***two*** of the following concepts (Group 2):

Group 1 Topics: Stem Cell Research/ Regenerative Medicine/ Animal testing/ human-to-animal chimeras/Neuroimaging / Neuromodulation/Research on human embryos/ Reproductive technologies/Jesse Gelsinger's case/ Clinical trials in developing countries/ Patenting life.

Group 2 Concepts: respect for persons/autonomy/risk-benefit ratio/justice/moral status/animal welfare/ human dignity/scientific integrity.

The course syllabus clarifies that evaluation will be based on whether the written analysis shows 1) sufficient scientific and regulatory knowledge of the issue, 2) knowledge of the controversy and its background, and 3) examination of different perspectives and careful reflection in developing the student's own opinion. The format and the evaluation criteria of Written Assignments #1 and 2 will guide students to analyze and interpret basic moral concepts and traditional bioethical principles and to evaluate how those moral concepts, principles and traditional ideas influence their evaluation and judgment about ethical issues in biomedical science research, which will meet both **ELO1** and **ELO2**.

E. How does the course aim to sharpen students' response, judgment, and evaluation skills?

The Midterm and Final Exam will test students' knowledge and understanding of the historical, regulatory and scientific backgrounds of biomedical research ethics, and thereby help students to acquire accuracy in interpreting and applying traditional ideas and approaches to ethical issues in biomedical science research. In-class discussion and written analyses of recent ethical issues in biomedical research will train students to interpret, critically analyze and apply such cultural and traditional human ideas to evaluate important issues in biomedical research, while letting them reconsider their own attitudes towards life and the meaning of advancement in biomedical sciences and technologies. Thus the course format, the variety of topics, written assignments and exams will all contribute to sharpen student's response, judgment and evaluation skills in the field of biomedical ethics.

GE Assessment Plan:

The effectiveness of the course in achieving the GE expected learning outcomes over time (rather than individual student grades) will be assessed in the following ways:

A. Description of the specific methods the faculty will use to demonstrate that the aggregate of his/her students are achieving the goals and expected learning outcomes of this GE category.

As a direct measure for GE assessment, the course instructor will ask students to complete the following pre-course survey every semester, and compare its results with the results of Midterm and Final Exams and Written Assignment #1 and 2 of the same group of students. Pre-course survey will be provided in the "Survey" section of the "Activities" area of Carmen's course website. Exams will be paper tests, and Final Exam will be cumulative. A specific sample of written assignment #1 and 2 is provided in the above (see Section D of the GE Rationale).

Pre-course survey

This is a simple survey to check students' average pre-course understanding of the basic concepts of biomedical ethics. Your answers to these questions will not be scored and *never* affect your grades, so please be honest in competing this survey. You can also omit responding to any questions that make you feel uncomfortable.

1. Please describe what you know about the notion of **informed consent** in the context of biomedical research. (0-250 words)

2. Please describe what you know about the concept of **scientific integrity**. (0-250 words)

The instructor will use this survey to measure students' academic progress throughout the course and to improve upon the course contents. Your cooperation is greatly appreciated.

Sample embedded questions in Exams (short answer questions, 4 points each):

1. What are the three basic ethical principles for biomedical and behavioral research involving human subjects presented in the Belmont Report? And what does each of the principles require us to do?

2. Explain the "3R" Principles of Animal Research. What do the 3R's stand for and what does each "R" require us to do?

3. Describe three major types of research misconduct, referring to the ORI definitions.

Sample question 1 corresponds to pre-survey question 1.
Sample questions 2 and 3 correspond to pre-survey question 2.

When comparing pre-survey results with the results of Exams, the following points will be checked to see how students made progress to achieve the goals and expected learning outcomes, including ELO1 and ELO2:

☐ Whether students demonstrate accurate understanding of *historical and regulatory background* of ethics in biomedical research. (Measured by the number of correct answers to questions)

☐ How detailed and profound the students' understanding of traditional ethical principles and basic moral concepts used in ethical issues and debates over biomedical research is. (Measured by the accuracy and comprehensiveness in students' answers)

When comparing pre-survey results with Written Assignment #1 and 2, the following points will be evaluated to see if students' overall achievement satisfies ELO1, ELO2 and the overall goals of the Culture and Ideas category:

☐ Whether students demonstrate, in Written Assignment #1, sufficient analyses and interpretation of ethical reasoning behind the formation of traditional ethical guidelines for biomedical research, such as the Nuremberg Code, the WMA Declaration of Helsinki and the Belmont Report.

☐ Whether students demonstrate accurate understanding of *historical and regulatory background* of the ethical issue that they have chosen to discuss in Written Assignment #2.

☐ How detailed and profound the students' interpretations of traditional ethical principles and basic moral concepts are.

☐ How logically and critically students apply their analyses of traditional ethical principles and basic moral concepts to the discussion of recent issues in biomedical science research.

Also, to supplement the direct measure described above, the proposed course may utilize student comment sections in Student Evaluation of Instructions (SEI) as an indirect measure when those comments clearly reflect the students' self-evaluations of what they have learnt through this course as regards to ELO1 (Analysis and interpretation of major forms of human thought, culture, and expression) and ELO2 (Evaluation of how ideas influence the character of human beliefs, the perception of reality, and the norms which guide human behavior).

B. Explanation of the level of student achievement expected.

The faculty would define "success" in terms of student achievement of learning outcomes as more than 70% of enrolled students answering each of the embedded questions correctly *AND* average score of 65/80 for Written Assignment #2.

C. Description of follow-up/feedback process.

The faculty will use the collected student achievement data to improve the instructional style (which may lead to the increase or decrease in time spent for in-class discussion, lecture, Q&A sessions or office hours), to revise course content, or to change the frequency of exams and written assignments (which may lead to more in-class quizzes and short essays). After the second offering of the course, the faculty will submit an initial report summarizing the GE assessment results following the format of sections I and II of the "Assessment Report Requirements" in Appendix 6.