DUQUESNE UNIVERSITY

CENTER FOR HEALTHCARE ETHICS

McANULTY COLLEGE AND GRADUATE SCHOOL OF LIBERAL ARTS

COURSE HCE-654: RESEARCH ETHICS

Fall 2017 (version March 2017)

College: McAnulty College and Graduate School of Liberal Arts
Syllabus: HCE-654, **RESEARCH ETHICS**, Fall 2017
Course: Tuesday 3:05-5:45 pm., Fisher Hall TBD
Office hours: Appointment, Fisher Hall 300;

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Course instructor: Henk ten Have, M.D., Ph.D.
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OUTLINE

The course will make students familiar with the recent issues and debates in research ethics. It will start with the history of the debate on ethics and research (focusing on exemplary cases). It will analyze the various ethical dimensions of different types of research in the field of healthcare, in particular informed consent, risk-benefit assessment, ethical review, and research with special populations. It then offers the opportunity to study in more detail specific topics as international research, research with children, animal research, clinical data sharing, and pre-approval access.

COURSE DESCRIPTION

The course will introduce students to ethical issues related to healthcare research. It will focus on the historical and ethical analysis of these issues. Starting from a historical analysis of major events in the development of medical research, the ethical dimensions of different types of research in healthcare will be studied. The focus will then be directed on several areas that are currently debated: international research, research with children, animal research, clinical data sharing (as an outcome of the movement towards global commons, discussed in the course on Global Bioethics), and pre-approval access to investigational drugs (previously known as 'compassionate use'; currently know in the U.S. as the 'right to try' legislation movement).

COURSE OBJECTIVES

The course aims to prepare students for the writing of the Dissertation Proposal. In particular it will focus on the development of research competencies. Upon completion of this course students should master the following competencies, as should be demonstrated both in specific research projects and presentations, and in the final course essay:

a. Historical analysis of the present-day debate on research ethics, explaining why and how current research ethics has developed, as well as what ethical concerns have emerged and how these have been addressed and regulated;

b. Systematic examination of fundamental ethical issues in relation to research, understanding and explaining how the contemporary debate is informed by fundamental interpretations of basic notions as informed consent, risk-benefit assessment and ethical review;
c. Critical analysis of specific ethical debates and concerns regarding either international research, or research with children, or animal research, or clinical data sharing, or pre-approval access to investigational drugs.

LEARNING OUTCOMES

After completion of the course students should be able to:

a. identify the historical developments that have led to current research ethics
b. explain the fundamental ethical notions that inform the contemporary debate about research in healthcare
c. analyze critically current debates and concerns in one specific area of research ethics.

In the context of the General HCE Program Learning Outcomes several of these Learning Outcomes pertain to HCE-656.

d. Fundamental Knowledge.
Students can understand and analyze HCE theory and methods as well as major applied topics in research ethics.
e. Multi-disciplinary Study.
Students can critically relate HCE with multi-disciplinary fields in health care, specifically in connection to the historical background and the ethical analysis of fundamental notions.
f. Scholarship
Students can research and write scholarly essays, teach and communicate effectively, and present academic papers that:
    - present cogent arguments(s),
    - engage scholarly literature, and
    - demonstrate critical thinking and analysis.

COURSE STRUCTURE

The course is organized in three Research Projects
Research project 1 is focused on course objective 1. The study will study and researching the historical background and development of research ethics. The student is requested to study a specific case in depth and make an oral presentation in class.
Research project 2 is focused on all course objectives, integrating historical and ethical analysis of a selected specific area of research ethics. The student should study and research thee relevant literature, write a 7 page research paper (wth 20 note references), and present this in class.
Research paper 3 is the course essay. The student submits the outline of the course essay in Week 4 and will receive feedback of the Instructor. The paper will be extensively discussed in class during Week 12-15. It will integrate the three research competencies.

COURSE ESSAY

The course research essay will require students to substantively apply the Course Research Competencies to a particular issue (theoretical or practical). Requirements:

1. Start to reflect on the thesis of your research essay from the beginning of the course.
2. Thesis and 1-page outline with basic bibliography to be submitted in week 4 (12 September 2017) (email to tenhaveh@duq.edu).
3. You will receive feedback before and in Week 5.
4. Each student will present the research essay (max. 30 minutes) during the final weeks of the course and submit a copy of the essay by December 8.
5. The essay length should be **25 pages**, double-spacing, font 12.
6. Students must adopt the format of the *Chicago Manual of Style*, as required by the College for dissertation submissions.
7. Select a research thesis that is the core of your essay, and is presented in the Introduction and reflected in the title of the essay. For example:
    i. "Why is the notion of informed consent useful in international medical research", or
    ii. 'Are waivers of informed consent ethically justified in the context of public health research?"
8. Present a brief Introduction (presenting the thesis) and Conclusion (summarizing how the thesis has been answered).
9. Notes to the references made in the essay.
    i. Use end notes (as opposed to foot notes at the bottom of the page).
    ii. Do not use notes for narrative explanations – they belong in the main text.
    iii. There should be approximately 100 end notes in the essay.
    iv. Check *Chicago Manual Style* for correct presentation of notes.
10. Bibliography. List all the references in alphabetical order. Only list items actually referred to in the essay. Check *Chicago Manual Style* for correct presentation of the literature references.
11. Divisions and subdivisions. Use major divisions and subdivisions, evenly distributed throughout the essay, to lay out the sequence of concepts.
12. Use of online references. Online references must be accurately identified with complete web address etc, including the date of access.

COURSE SCHEDULE

WEEK 1 **Overview of the course**
22 August **Introduction into research ethics**

Research project #1

Objective: Historical analysis of the present-day debate on research ethics, explaining why and how current research ethics has developed, as well as what ethical concerns have emerged and how these have been addressed and regulated;

Research project 1 and oral presentation:
Address three questions:

- What are the significant aspects of the case?
- Why and how has the case had an impact on the developments of research ethics?
- Can a case like this happen again in today's healthcare research? Explain why of why not

Prepare an oral presentation of 15 minutes (plus 15 minutes discussion; powerpoints may be used)

Readings:

- David J. Rothman: *Strangers at the bedside. A history of how law and bioethics transformed medical decision making*. Basic Books, New York, 1991; 2003.
- Ezekiel J Emanuel et al. (eds.): *The Oxford Textbook of Clinical Research Ethics*. Oxford University Press, Oxford/New York, 2008; Chapters 1-10 (pp. 9-120).

WEEK 2 **Why and how has current research ethics develop**
29 August **Background, history and cases**
Case 1: Yellow fever
Case 2: Nazi experiments
Case 3: Japanese experiments
Case 4: Streptomycin
Case 5: Polio vaccin
Case 6: Jewish Chronis Disease Hospital

WEEK 3 Case 7: Willowbrook
5 September Case 8: Tuskegee
Case 9: HIV research
Case 10: Gelsinger case
Case 11: Henri Beeacher
Case 12: Ethics commission

Research project #2

Objective: Systematic examination of fundamental ethical issues in relation to research, understanding and explaining how the contemporary debate is informed by fundamental interpretations of basic notions as informed consent, risk-benefit assessment and ethical review;

Research paper 2

- select a specific area of research ethics (International research; research with children; animal research; clinical data sharing; pre-approval access to investigational drugs)
- study the requested readings for you selected area;
- write an analysis in a paper of max. 7 pages (excl references and bibliography; 20 note references).
- in this analysis answer the following question: what are the three most important ethical issues in your selected area? Explain:
  a. why are they important
  b. how are they usually addressed
  c. how can they be solved or eliminated
- submit the research paper ultimately Friday before class

Readings:

- Paul Oliver: *The student's guide to research ethics*. McGraw Hill/Open University Press, Maidenhead, UK, 2010 (2nd edition).
- Ezekiel J Emanuel et al. (eds.): *The Oxford Textbook of Clinical Research Ethics*. Oxford University Press, Oxford/New York, 2008 (Chapters 11-15; pp. 123-167; Chapters 20-23; pp. 201-241; Chapters 24-25; pp. 245-272; Chapters 47-48; pp. 503-526; Chapters 55-59; pp. 591-660.

WEEK 4	**What makes research ethical?**
12 September	**Informed consent** **Ethics review committee** Submit draft outline of course essay
WEEK 5	**What makes research ethical?**
19 September	**Research integrity**
WEEK 6	**International Research**
26 Sep	Paper presentations and evaluation Readings: • Ruth Macklin: *Ethics and global health. Research, policy and practice*. Oxford University Press, New York, 2011.

- Ruth Macklin: *Double standards in medical research in developing countries.* Cambridge University Press, Cambridge UK, 2004.
- Adriana Petryna: *When experiments travel. Clinical trials and the global search for human subjects.* Princeton University Press, Princeton and Oxford, 2009.

WEEK 7 **Research with children**
3 October Paper presentations and evaluation

Readings:

- Jonathon Sargeant and Deborah Harcourt: *Doing ethical research with children*. McGraw Hill/Open University Press, Maidenhead UK, 2012.
- Priscilla Alderson and Virginia Morrow: *The ethics of research with children and young people. A practical handbook.* SAGE, Los Angeles, 1995, 2011 (2nd edition).
- Lainie Friedman Ross: *Children in medical research. Access versus protection*. New York: Oxford University Press, 2006.

WEEK 8 **Animal research**
10 October Paper presentations and evaluation

Readings:

- Jeremy Garrett (ed): *The ethics of animal research. Exploring the controversy*. MIT Press, Cambridge MA, 2012
- Vaughan Monamy: *Animal experimentation. A guide to the issues*. Cambridge, UK: Cambridge University Press, 2009 (2nd edition).
- Nuffield Council on Bioethics: *The ethics of research involving animals*. London, 2005 (http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20research%20involving%20animals%20-%20full%20report.pdf)
- Susan Gilbert, Gregory Kaebnick and Thomas Murray (eds): *Animal Research Ethics. Evolving view and practices*. A Hastings Center Special Report, November-December 2012; 42 (6): S1-40.

WEEK 9 **Clinical data sharing**
17 October Paper presentations and evaluation

Readings:

- Institute of Medicine: *Sharing clinical trial data: Maximizing benefits, minimizing risk*. The National Academies Press,

Washington DC, January 2015 (http://www.nap.edu/openbook.php?record_id=18998).

- Committee on Strategies for Responsible Sharing of Clinical Trial Data: *Discussion Framework for Clinical Trial Data Sharing: Guiding principles, elements, and activities*. National Academies Press, Washington DC, February 2015.
- Louise Corti, Veerle Van den Eynden, Libby Bishop and Matthew Woollard: *Managing and sharing research data. A guide to good practice*. SAGE Publication, London, 2014.
- Borgerson K: Redundant, secretive, and isolated: when are clinical trials scientifically valid? *Kennedy Institute of Ethics Journal* 2014; 24(4): 385-411.
- Rosenblatt M, Jain SH and Cahill M: Sharing of clinical trial data: Benefits, risks, and uniform principles. *Annals of Internal Medicine* 2015; 162(4): 306-7.
- Drazen JM: Sharing individual patient data from clinical trials. *New England Journal of Medicine* 2015; 372(3): 201-2.
- Knoppers BM, Harris JR, Budin-Ljøsne I and Dove ES: A human rights approach to an international code of conduct for genomic and clinical data sharing. *Human Genetics* 2014; 133(7): 895-903.

WEEK 10 **Pre-approval access to investigational drugs**
24 October Paper presentations and evaluation

Readings:

- Lisa Forman and Jillian Clare Kohler (eds.): *Access to medicines as a human right; Implications for pharmaceutical industry responsibility*. University of Toronto Press: Toronto/Buffalo/London, 2012.
- Jonathan J. Darrow, Ameet Sarpatwari, Jerry Avorn and Aaron S. Kesselheim: Practical, legal, and ethical issues in expanded access to investigational drugs. *New England Journal of Medicine* 2015; 372(2): 279-286.
- Okie, S: Access before approval – a right to take experimental drugs? *New England Journal of Medicine* 2006; 355: 437-440.
- Marks, GS: Expanded access rules pose quandary for drug developers. *Nature Biotechnology* 2009; 27: 871-2.
- Falit BP and CP Gross: Access to experimental drugs for terminally ill patients. *JAMA* 2008; 300: 2793-5.
- Leonard EW: Right to experimental treatment: FDA new drug approval, constitutional rights, and the public's health. *Journal of Law, Medicine and Ethics* 2009; 37: 269-279.
- *Guidance for industry: expanded access to investigational drugs for treatment use*. Rockvillee (MD), Food and Drug Administration, 2013

(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf).

- European Medicines Agency: *Guideline on compassionate use of medicinal products*, 2007 (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004075.pdf)
- Mussa Rahbari and Nuh N.Rahbari: Compassionate use of medicinal products in Europe: current status and perspectives. *Bulletin of the World Health Organization* 2011; 89; 163-163. doi: 10.2471/BLT.10.085712 (http://www.who.int/bulletin/volumes/89/3/10-085712/en/)

WEEK 11 **CITI Training Program**
31 October Each student will do this online training course. All key personnel engaged in human subject research must complete the program prior to IRB approval of a new or continuing review application. See: www.duq.edu/research/research-conduct/human-subjects---irb.
Make sure you register and create an account. We are going through the course Health Care Ethics committee. If successfully completed, you will receive a certificate.

Research project #3

WEEK 12 **Global Research Challenges: Pandemics**
7 November Kelly Lecture Eric Meslin

WEEK 13 **Global Research Challenges: Disasters**
14 November Kelly Lecture Ruth Macklin

21 November: Thanksgiving; no class

WEEK 14 **Discussing and reviewing course essays**
28 November: Reporting course essay

WEEK 15
5 December: **Discussing and reviewing course essays**
Reporting course essay

8 December: Deadline submission course essay

HCE HANDBOOK. The Center for Healthcare ethics has developed a *Handbook* of Policies, Procedures, and Guidelines to guide students in all curriculum related matters. The *Handbook* is available on the website of the Center.

COURSE GRADE. There will be no examinations. The course grade will be assigned based on the quality of the course Research Essay and the two Research Projects. The grade will be a combination of 15% for each of the Research Projects (50% for class presentations on project readings and 50% for the written project) and 70% for the final essay. No midterm grades will be assigned. End of term grades will be assigned adopting grading policy in the McAnulty College and Graduate School of Liberal Arts, as follows:

A	4.0	distinguished scholarly work
A-	3.7	
B+	3.3	
B	3.0	normal progress towards degree
B-	2.7	
C+	2.3	
C	2.0	warning; student subject to departmental action
F	0.0	

ACADEMIC INTEGRITY. This syllabus incorporates the "Expectations of Academic Integrity." Cheating and plagiarism cannot be tolerated. All relevant policies of the McAnulty College and Graduate School of Liberal Arts apply.

REASONABLE ACCOMMODATIONS.
Students with documented disabilities are entitled to reasonable accommodations if needed. If you need accommodations, please contact the Office of Freshman Development and Special Student Services in 309 Duquesne Union (412-396-6657) as soon as possible. Accommodations cannot always be granted retrospectively.