DUQUESNE UNIVERSITY
CENTER FOR HEALTHCARE ETHICS
McANULTY COLLEGE AND GRADUATE SCHOOL OF LIBERAL ARTS

COURSE HCE-654: RESEARCH ETHICS

Fall 2013 (version 27 April 2013)
College: McAnulty College and Graduate School of Liberal Arts
Syllabus: HCE-654, RESEARCH ETHICS, Fall 2013
Course: Tuesday 3:05-5:45 pm., Fisher Hall TBD
Office hours: Appointment, Fisher Hall 300;
              Tel. (412) 396-4504
              Email: tenhaveh@duq.edu
Course instructor: Henk ten Have, M.D., Ph.D.
                 Director and Professor, Center for Healthcare Ethics
                 Duquesne University, 600 Forbes Avenue, Pittsburgh

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, and research integrity.

COURSE OBJECTIVES

a) Course description. The course will make students familiar with 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, and research integrity.

b) Research competencies. Upon completion of the course students should master the following competencies, as should be demonstrated both in specific research projects and presentations, and in the research 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 research integrity.

c) **General HCE Program Learning Outcomes.** Several of these Learning Outcomes pertain to HCE-656.

   a. **Fundamental Knowledge.**
   Students can understand and analyze HCE theory and methods as well as major applied topics in research ethics.

   b. **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.

   c. **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 PROCEDURES.**

a) **Course components**
   The Fall semester will be divided into five components:

   i. **Introduction of the course:** 27 August. The program as well as main contents of the course will be clarified

   ii. Research Project #1, week 1-3; prepare teaching presentation for Seminar #2, Sept. 17

   iii. Research Project #2 (10 pages), week 4-7; due Friday October 11 for Seminar #3, October 15

   iv. Research Project #3 (10 pages), week 8-11; due Friday Nov. 8 for Seminar #4, Nov. 12

      2. Option to submit mid-term essay. For students who want to be assisted in their progress, a draft of the essay can be submitted for feedback; by Friday Oct. 11.

b) **Research projects**

   1. **Reading Requirements.** Each Research Project will require students to critically engage the equivalent of 2 or 3 books to (a) master the relevant knowledge and (b) engage in critical reading and writing.

   2. **Research competencies.** The research competencies in the course are
identified by the three Research Projects: (a) historical analysis, (b) systematic examination of fundamental ethical issues, and (c) ethical analysis of a specialized area of concern. Each Research Project will demonstrate that the student has mastered the specific competency.

3. **Relation of Projects with Essay.** The three Research Projects may be integrated into the Research Essay but not in a manner of cut-and-paste from one to the other. The Research Essay typically demonstrates that the student can apply and integrate all three research competencies in relation to a specific topic or issue in research ethics.

4. **Projects:**
   i. **Research competency of historical analysis:**
      
      **Project:** Teaching a case
      
      
      2. Make teams of 2 students selecting each 1 case. Each team selects a different case.
      
      3. Analyze the case and prepare a teaching presentation, addressing 3 questions:
         a. What are the significant aspects of the case?
         b. Why and how has the case had an impact on the development of research ethics?
         c. Can a case like this one happen again in today’s healthcare research? Explain why or why not.
      
      4. Teach the case as a team in a mini-lesson of max. 10 minutes.
      
      **Format:** each team teaches the case in max. 10 minutes. Powerpoints or overheads may be used.

      **Required Readings:**
      - 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).

   ii. **Research competency of systematic examination of fundamental ethical issues:**
      
      **10 Page Project:**
      
      What makes research ethical, and how can the ethical quality of research be strengthened in today’s society and culture?
iii. Research competency of ethical analysis of specialized areas of concern:

10 Page Project:
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?

Format: 10 pages (double spaced; font 12) plus approximately 30 references/end notes

Required Readings:
1. Select 1 area of special concern:
   a. International research
   b. Research with children
   c. Animal research
   d. Research integrity

2. Select the requested readings for your selected area (see at the last pages of this Syllabus). Each area requires you to read 3 new books that are outstanding in this area. There is no requirement to read the books for the specialized areas that you have not selected. Relevant information regarding your selected area can also be found in the general books used earlier in the course.

   c) Research Seminars. There will be four seminars introducing each of the three research competencies.

   1. Week 1. Seminar #1 to introduce Research Project #1
      i. Introduction to the area of research ethics
      ii. Discussion of research essay requirements
      iii. Research Essay thesis and 1-page outline with basic bibliography
to be submitted by end of week 3

2. **Week 5.** Seminar #2 to introduce Research Project #2
   i. Discussion of progress on research essays
   ii. Teaching presentations (10 minutes max) of completed Research Project #1

3. **Week 9.** Seminar #3 to introduce Research Project #3
   i. Discussion of progress on research essays
   ii. Discussion of completed Research Project #2

4. **Week 14.** Seminar #4 to discuss the Research Essay
   i. Discussion of completed Research Project #3
   ii. Brief presentations (8 min) of the research essays

d) **Research 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 by the end of week 3 (Sept 13) (email to tenhaveh@duq.edu).
3. You will receive feedback before and in Seminar #2.
4. Progress will be reported in the subsequent Seminars.
5. Each student will briefly present the research essay (max. 8 minutes) during the final Seminar and submit a copy of the essay by date assigned.
6. The essay length should be **30 pages**, double-spacing, font 12.
7. Students must adopt the format of the *Chicago Manual of Style*, as required by the College for dissertation submissions.
8. 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?’
9. Present a brief Introduction (presenting the thesis) and Conclusion (summarizing how the thesis has been answered).
10. 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.
11. 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.
12. Divisions and subdivisions. Use major divisions and subdivisions, evenly distributed throughout the essay, to lay out the sequence of concepts.
13. Use of online references. Online references must be accurately identified with complete web address etc, including the date of access.

**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 three research projects. The grade will be a combination of 10% for each of the three research projects 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:

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<th>Grade</th>
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<td>B+</td>
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<tr>
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<td>normal progress towards degree</td>
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<tr>
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<td>C</td>
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<td>warning; student subject to departmental action</td>
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**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.
COURSE READINGS

HCE 654, Research Ethics, 2013 Fall

Required reading: Books

1. General texts for all students (all 5 books need to be read by all students):


2. Specialised texts depending on the area of practical application (following your choice of one area); here you only have to study the literature in your area of choice (for each area 3 books need to be read depending on your selected area).

   a. International research


b. Research with children


c. Animal research


(http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20research%20involving%20animals%20-%20full%20report.pdf)


d. Research integrity

Tony Mayer and Nicholas Steneck (eds.): *Promoting research integrity in a global environment*. World Scientific Publishers C., Singapore, 2012


Research competency #1: Historical analysis


- Chapters 1-10 (pp. 9-120).

Research competency #2: Systematic examination of fundamental ethical issues in relation to research


- 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)

- Chapter 10 (pp. 106-116)
- Chapter 20 (pp. 239-250)
- Chapter 25 (pp. 306-325)

Research competency #3: Ethical analysis of specialized areas of concern

International research


- Chapter 16 (pp.168-173)
- Chapter 63 (pp.697-708)
- Chapters 64-67 (pp.711-744)

- Chapter 26 (pp.326-341)
- Chapter 27 (pp.342-355)

Research with children


- Chapter 42 (pp.446-460)
- Chapter 49 (pp.527-538)
- Chapter 60 (pp.661-669)

- Chapter 22 (pp.261-277)

Animal research


(http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20research%20involving%20animals%20full%20report.pdf)

**Research integrity**

Tony Mayer and Nicholas Steneck (eds.): *Promoting research integrity in a global environment*. World Scientific Publishers C., Singapore, 2012


- Chapters 68-73 (pp.747-804)

- Chapter 26 (pp. 326-341)

**COURSE SCHEDULE**

**Tuesday August 27. Seminar #1**  
**Research competency #1: Historical analysis**  
**Project #1**  
September 3, and10, Research Project #1  
Submit Essay Thesis, 1-page outline, basic bibliography, by Fri. October 1

**Tuesday September 17. Seminar #2**  
**Research competency #2: Systematic examination of fundamental ethical issues**  
**Project #2**  
September 24, October 2 and 8, Research Project #2  
Submit Project #2 by Fri. October 11  
Optional: submit mid-term draft Research Essay, by Fri. October 11.
Tuesday October 15. Seminar #3

Research competency #3: Ethical analysis of specialized areas of concern
Project #3
October 23 and 29, November 5, Research Project #3
Submit Project 3# by Fri. November 8.

Tuesday November 12. Seminar #4
Research essay
Submit Research Essay by Tuesday, December 10