Outline
The course will familiarize students with the recent issues and debates in research ethics. It will start with an introduction in empirical research in bioethics. This empirical basis will serve as an example from which research ethics will be explored. The course 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 details subjects as international research, research with children, animal research, ethics review committees, and research integrity.

Course Objectives

a) Course Description
This course trains students in the basics of empirical research in bioethics and provides knowledge and skills to ethically assess healthcare research projects. Given the importance of qualitative research in healthcare ethics, there is a particular focus on qualitative research. Students learn to propose, design, and assess qualitative research projects and they gain hands-on experience with interviewing and qualitative data analysis. Through reading, class discussions, and direct practice, students learn to ethically assess healthcare research projects.

b) Competencies
Upon completion of the course students should master the following competencies, as should be demonstrated throughout the research projects and presentations, class participation and in the research essay:

a. The ability to critically reflect upon the relationships between normative bioethics and empirical research, including the capacity to propose empirical research projects that could meaningfully contribute to normative argument development

b. The capability to critically assess the ethical aspects of research in healthcare

c. The capacity of argument development in specific topics in research ethics

c) General HCE Program Learning Outcomes
The following HCE Program Learning Outcomes pertain to this course.
Fundamental Knowledge. Students can understand and analyze issues in research ethics.

Multi-disciplinary Study. Students can critically relate religious research ethics with multi-disciplinary fields in health care as a diverse and global enterprise, in particular empirical research, but, also, medicine, philosophy, and science.

Scholarship. Students can research and write scholarly essays, teach and communicate effectively, and present academic papers that present cogent argument(s), engage scholarly literature, and demonstrate critical thinking and analysis in the field of research ethics.

Ethical Leadership. Students can function as experts in research ethics and provide guidance on ethical aspects of health research, particularly in IRBs.

Course Procedures

a) Research Projects and Required Readings

a.1) General Procedure

For this course, the students have to complete three written assignments: two research projects, and one research essay (25 pages plus endnotes and bibliography). Students will prepare and submit these assignments as per the schedule below.

i. Research Project #1, due Wednesday, October 16
ii. Research Project #2, due Wednesday, November 6
iii. Research Essay, due Wednesday, December 11
   • Submit Essay thesis, a 500 words abstract, outline, and basic bibliography, by Friday, October 25.
   • 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 Wednesday, November 20.
   • Final version is due Wednesday, December 11.

Research protocols and interviews will be discussed and analyzed in class on November 5. At the end of the course, the students will also prepare an interactive 20-minute presentation of their research essay, which they will present in the three final class sessions.

Reading Requirements. In order to be able to complete the assignments, students will need to read the course literature and master the relevant knowledge. The mini essay of research assignment #2 requires the students to integrate the course literature of part 2.

Literature integration. Students should include approximately 25 notes in the mini essay referring to the texts assigned for the project. Endnotes and bibliography as well as title page and table of content do not count towards the prescribed number of pages.

Research competencies. The research competencies in the course are identified by the three course parts: critical reflection upon the relationships between normative bioethics and empirical research (part 1), critical assessment of the ethical aspects of research in health care (part 2), and argument
development in specific topics in research ethics (part 3). Each Research Project will demonstrate that the student has mastered the specific competency.

Relation of Projects with Essay. The mini essay 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 has mastered a specific research competency. While the research papers are focused on one specific competency, the course essay must demonstrate all three competencies. The course essay furthermore is based on a self-selected thesis different for each student, while the topics of the research papers are given and similar for all students.

a.2) Research Project #1: Interview and Research Protocol
This research project consists of two parts. The first part is a semi-structured interview of an adult. In the interview, the interviewer tries to find out why (or why not) the interviewee would want to participate in medical research and under which conditions. Interviews should last at least twenty minutes, be recorded and transcribed. For this interview, students use the interview guide that will be developed in class.

The second part of this research project consists of developing a research protocol for an empirical study that attempts to find out why (or why not) people would want to participate in medical research and under which conditions. To develop this research protocol, students rely on the protocol summary form of Duquesne University Institutional Review Board.

a.4) Research Project #2: Informed consent form and mini essay
This project, too, consists of two parts. In the first part, students develop a consent form for the study that they described in their research protocol (Research Project #1). To develop this research protocol, students use the draft consent form of Duquesne University Institutional Review Board.

For the second part, students write a seven-page essay in which they critically evaluate the extent to which research subjects may be put at risk in medical research from a normative ethical perspective.

b) Course Schedule

Week 1: Tue Aug 27. Introduction to the course requirements, procedures and theme

Part 1 Empirical Methods for Bioethics

Required readings. The journal articles will be available through Blackboard.

Week 2: Tue Sept 3. The relationship between empirical data and bioethics

Readings:


Week 3: Tue Sept 10. Interviews

Readings:

**Week 4: Tue Sept 17, Content analysis**

Readings:


**Week 5: Tue Sept 24, Survey research**

Readings:


**Part 2 Research Ethics**

**Week 6: Tue Oct 1, Research integrity and searching for an ethical framework for biomedical research**

Readings:


**Week 7: Tue Oct 8, Historical background of research ethics and trust as the foundation for research with human subjects**

Readings:


Week 8: Tue Oct 15. Informed consent, Privacy and Confidentiality

Readings:


Week 9: Tue Oct 22. Vulnerable subjects

Readings:


Week 10: Tue Oct 29. Benefits and Responsiveness to Host Countries, Standard of care

Readings:


Week 11: Tue Nov 5. Discussion research protocols and group work interview analysis

Part 3 Special Topics in Research Ethics

Week 12: Tue Nov 12. Student presentations

Week 13: Tue Nov 19. Student presentations

Tue Nov 26. Thanksgiving break, no class

Week 14: Tue Dec 3. Student presentations
c) Research Essay

The research essay will require students to substantively apply the Research Competencies of this course to a particular topic in health research. For the essay, students choose an issue or topic in research ethics (international research, research with children, animal research, ethics review committees, research integrity). They develop a creative, critical argument regarding that issue or topic. Before the conclusion, students add one additional section entitled ‘Suggestions for future research.’ In that section they briefly present a proposal for an empirical study that, if ever completed, could further sustain the ethical argument that was developed in the research essay. Students in the Catholic program need to clarify throughout their essay how a Christian anthropology informs the presented analysis. For them, the empirical project that is proposed in the section ‘Suggestions for future research’ needs to pay attention to Roman Catholic views.

Requirements:

1. Start to reflect on the thesis of your course essay from the beginning of the course.
2. Thesis, a 500 words abstract, outline, and basic bibliography to be submitted by Friday, October 25.
3. Students will receive general feedback in class and individual feedback through Blackboard.
4. Submit a copy of the essay by date assigned.
5. The course essay length should be at least 25 pages, double-spacing; the main body of text; title page, table of content, endnotes and bibliography do not count towards the 25 pages.
6. Students must adopt the format of the Chicago Manual of Style, as required by the College for dissertation submissions.
7. Students can quote from publications in any language, but need to provide an English translation.
8. Select an Essay Title that reflects a research thesis.
9. Make a Title page and a separate Table of Content.
10. Present a brief Introduction and Conclusion.
11. Notes to the references made in the essay.
   a. Use end notes (as opposed to foot notes at the bottom of the page).
   b. Do not use notes for narrative explanations – they belong in the main text.
   c. There should be approximately 100 end notes in the essay.
12. Bibliography. List all the references in alphabetical order. Only list items actually referred to in the essay.
13. Divisions and subdivisions. Use major divisions (headings) and subdivisions (subheadings), evenly distributed throughout the essay, to lay out the sequence of concepts and arguments.
14. Use of online references. Online references must be accurately identified with complete web address etc., including the date of access. Students are requested to critically deal with content from the internet.

HCE Handbook. The Center for Healthcare ethics has developed a Handbook of Policies, Procedures, and Guidelines to guide students in all curriculum related matters.

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 10% for each of the two research projects, 10% for class presentations, 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.