IOWA SCHOLARS IN CLINICAL INVESTIGATION
AND
THE UNIVERSITY OF IOWA COLLEGE OF PUBLIC HEALTH

CLINICAL RESEARCH ETHICS
(EPID:6950:0001)

SYLLABUS, SPRING 2015

Course Website: http://icon.uiowa.edu/
(EPID:6950:0001 Spr15 Clinical Research Ethics)

Course meets Wednesdays, 10:30am-12:20pm
ICTS Conference Room (C44-A GH)

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1. PURPOSE OF COURSE

*Clinical Research Ethics* is a 2-semester hour course with a 3-credit option (see Course Requirements below). The course introduces students to some of the key ethical, legal, and policy issues that investigators encounter as they conduct clinical research. In this course we take for granted that clinical research ethics matters to investigators, and we do so because clinical research is at heart a *moral* undertaking due both to its subjects (human beings) and its goals (human health). This means that in clinical research, science and ethics are inseparable. We also recognize that clinical research is a *public* undertaking and therefore requires a vocabulary to articulate ethical justifications for research decisions so that their moral basis can be transparent to study subjects, Institutional Review Boards, and society. This course introduces you to topics, values, and policies you need to understand in order to design and conduct clinical research that is ethically sound.

2. OVERALL OBJECTIVES

1. Appreciate the inseparable relationship between science and ethics in clinical research.
2. Recognize common ethical challenges in clinical research.
3. Recognize the ethical aspects of the design and conduct of clinical research that require explicit assessment and justification.
4. Understand key regulations that govern clinical research.
5. Understand the ethical values that guide the regulation of clinical research.
6. Apply principles of clinical research ethics to student’s own clinical research interests.

3. FORMAT

The course will meet once each week, on **Wednesdays 10:30am-12:20pm in the ICTS Conference Room (C44-A GH)**. We will use a seminar format in which students will actively participate in group discussions. Attendance at all class sessions is required.

4. REQUIRED READINGS

The required readings for each week are posted as URL links or PDF files on the ICON course website ([http://icon.uiowa.edu/](http://icon.uiowa.edu/)). If for some reason a URL link does not function properly, you can access articles through Hardin Library as follows:

1. **Access**: [http://infolink.lib.uiowa.edu/sfx_local/a-z/default?perform=search](http://infolink.lib.uiowa.edu/sfx_local/a-z/default?perform=search)
2. **Search** the name of the journal
3. **Click** on the InfoLink button for the journal
4. In one of the provided spaces under the bolded category “Full text”, enter the article’s year, volume, issue (if available), and start page.
5. You may need to navigate further within the Journal’s website to locate the table of contents of the relevant issue.
5. COURSE REQUIREMENTS

5.1. Attendance and Participation (30 grading points): Consistent class attendance and participation in class discussions is critical to getting the most out of this course. Schedule conflicts with routine clinical or other duties should be resolved through discussion with your supervisors prior to enrollment in this course. Unavoidable, expected absences from class should be preceded by an email or other communication to the CRE course director and coordinator explaining the reason for the absence. In-class participation through active and respectful dialogue and interaction is key.

Gaps in Attendance and Participation (GAP) Notices: GAP notices will be emailed on an as-needed basis to students whose attendance and/or participation is cause for concern. If students continue to lag after receiving these notices, deductions will be made from their Attendance and Participation grading points.

Make-Up Work is Required in Cases of Approved Absences: If an absence is determined to be necessary, the student will write a one-page, single-spaced reflection on each of the assigned readings for the session that was missed.

5.2. Weekly Topic Questions (35 grading points): Each week, students must write at least one substantial and thoughtful discussion question on the week’s seminar topic. Pose a question that builds on the readings, but that is not answered in the readings. Upload your questions to the ICON course website or email them to Laura Shinkunas by 6PM the night before the Wednesday class session. Instructors will be provided with a copy of all student questions to integrate into the class sessions.

5.3. Personal Ethics Assessment (PEA) (35 grading points): Students must write a PEA, which is a description and assessment of a personal experience or observation that raises a research ethics or research conduct/integrity issue of some kind. You should describe why you think this is an issue from an ethical perspective, and how you think a similar situation in the future could be avoided or better managed.

Your PEA must be typed, double-spaced, and about 2 pages in length (long enough to describe and assess the issue you are addressing). After you have completed your PEA, please upload it into the Dropbox of the ICON course website. You need to upload the PEA by 8AM Mon March 23. Authors of PEAs will be invited to offer up their PEAs for discussion during class. The goal of these discussions is to allow the group to reflect constructively on the different cases. Names will be taken off the PEAs before circulation to class participants, but it is possible, particularly in a small class, for the authors of the PEAs to become known through the dynamics of discussion. Class participants will be asked to respect the privacy of all PEA authors.

3-Credit Hour Option: In addition to the above, students enrolled for 3-credit hours must:

5.4. Final Paper (30 grading points): Students enrolled for 3 credit hours will write a final research ethics paper that is double-spaced and 6-8 pages in length. The paper can be focused on a topic of the student’s choice, but needs to be reflective of the research ethics issues covered in the course. See top of page 14 of this Syllabus for further details on the final paper.
6. Grading

<table>
<thead>
<tr>
<th>Requirements</th>
<th>2 Credit hours</th>
<th>3 Credit hours</th>
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<tbody>
<tr>
<td>Class Attendance</td>
<td>15 points</td>
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<td>Class Participation</td>
<td>15 points</td>
<td>15 points</td>
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<tr>
<td>Weekly Topic Questions</td>
<td>35 points</td>
<td>35 points</td>
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<tr>
<td>Personal Ethics Assessment (PEA)</td>
<td>35 points</td>
<td>35 points</td>
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<tr>
<td>Final Paper (6-8 pages)</td>
<td>Not required</td>
<td>30 points</td>
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Point totals: 100 points 130 points

Final grades will be determined by converting total number of points to percentages, then determining a symbol grade using the following ranges: 90-100% (A), 80-89% (B), 70-79% (C), 60-69% (D), less than 60% (fail).
7. COURSE SCHEDULE

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<th>Topics and Readings</th>
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<td>Week 1:</td>
<td>Course Overview and Introduction to Research Ethics (Simon)</td>
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<tr>
<td>Jan 21</td>
<td>Learning Objectives</td>
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<tr>
<td></td>
<td>Through this week’s readings and class discussion, we will aim to identify and understand:</td>
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<tr>
<td></td>
<td>▪ The inherent ethical and moral tensions in scientific experimentation involving human participants.</td>
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<td>▪ The historical context for current ethical considerations, law and guidance.</td>
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<td></td>
<td>▪ The key place of the Belmont principles and Nuremberg Code in protecting human research participants.</td>
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<td>Required Readings (on ICON)</td>
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<td></td>
<td>Recommended Readings/Resources</td>
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<tr>
<td>Week 2:</td>
<td>What Is Research? What is Ethical Research? (Simon)</td>
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<tr>
<td>Jan 28</td>
<td>Learning Objectives</td>
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<td></td>
<td>Through this week’s readings and class discussion, we will aim to identify and understand:</td>
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<td></td>
<td>▪ The different benchmarks for determining whether a clinical trial is ethical.</td>
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<td>▪ The (nuanced) differences between clinical research and practice.</td>
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</table>
Required Readings (on ICON)


Recommended Readings


Week 3: *Philosophical Foundations (Lauris Kaldjian)*

Feb 4

Learning Objectives

Through this week’s readings and class discussion, we will aim to identify and understand:

- The relevance of philosophy to human subjects research and research protections.
- The concept of moral reasoning.
- The different ethical theories that can help organize thinking about research ethics.

Required Readings (on ICON)


Recommended Readings


Week 4: *Integrity and Good Practice in Research, Part I (Richard Hichwa)*

Feb 11

Learning Objectives

Through this week’s readings and class discussion, we will aim to identify and understand:

- Values and guidelines for professional self-regulation in research.
- Government and institutional regulations and policies for research integrity.
- Research misconduct definitions and policies.
- Good data management practices.
Week 5:  
**Integrity and Good Practice in Research, Part II (Richard Hichwa)**  
*Feb 18*

**Learning Objectives**
Through this week’s readings and class discussion, we will aim to identify and understand:
- Mentor and trainee responsibilities.
- Integrity in collaborative research.
- Authorship roles and responsibilities.
- Integrity in peer review.

**Required Readings (on ICON)**
- Peer review case study

**Recommended Readings/Resources**
- The Office of Research Integrity’s web site ([http://ori.hhs.gov/](http://ori.hhs.gov/))

Week 6:  
**Informed Consent, Part I (Simon)**  
*Feb 25*

**Learning Objectives**
Through this week’s readings and class discussion, we will aim to identify and understand:
- The ethical and moral principles underlying informed consent.
- The components of informed consent (disclosure, voluntariness, understanding).
- Common criticisms and alleged problems with respect to informed consent.

**Required Readings (on ICON)**
Recommended Readings

**Week 7:**

*Informed Consent, Part II (Simon)*

Learning Objectives
Through this week’s readings and class discussion, we will aim to identify and understand:
- Informed consent as a learning process.
- Informed consent as a communication process.
- What you can do to be a better informed consent agent and ambassador.

Required Readings (on ICON)

Recommended Readings

**Week 8:**

*Institutional Review Boards (Michele Countryman and Leona Ryan)*

Learning Objectives
Through this week’s readings and class discussion, we will aim to identify and understand:
- What an institutional review board (IRB) is and does.
- How IRBs fit into the wider system of research governance.
- How investigators interface with IRBs.

Required Readings (on ICON)

Recommended Readings

Mar 16-20  UI Spring Break

Mar 23  *Personal Ethics Assessments are due -- please upload to ICON by 8am*

Week 9:  March 25  
**CLASS DISCUSSION -- Personal Ethics Assessments**

**Learning Objectives**
Through this week’s class discussion, we will aim to identify and understand:
- Typical student concerns surrounding ethics of research
- The ethical principles underlying these concerns
- Possible solutions to commonplace ethical issues in research

Week 10:  Apr 1  
**Privacy & Confidentiality (Kelly O’Berry)**

**Learning Objectives**
Through this week’s readings and class discussion, we will aim to identify and understand:
- Why privacy and confidentiality are important in research ethics.
- The difference between privacy and confidentiality.
- Relevant human subjects regulations concerning privacy and confidentiality.

**Required Readings (on ICON)**

**Recommended Readings**
Week 11: **Ethics of Genetic and Genomic Research (Simon)**

**Apr 8**

**Learning Objectives**

Through this week’s readings and class discussion, we will aim to identify and understand:

- Key ethical, legal, and social issues surrounding genetic and genomic research.
- Informed consent challenges surrounding biobanking.
- Policy needs for new genetic and genomic research.

**Required Readings (on ICON)**


**Recommended Readings**


Week 12: **Vulnerable Populations & Special Circumstances (David Moser)**

**Apr 15**

**Learning Objectives**

Through this week’s readings and class discussion, we will aim to identify and understand:

- Which populations are considered vulnerable.
- Research allowances with prison populations.
- The need for contextual awareness and cultural sensitivity.

**Required Readings (on ICON)**


**Recommended Readings**

**Week 13: Research Ethics in Developing Countries (Simon)**

**Learning Objectives**
Through this week’s readings and class discussion, we will aim to identify and understand:
- Vulnerable populations in international research.
- The “double-standards” argument and counter-argument.
- What international researchers can do to enhance subject protection.

**Required Readings (on ICON)**

**Recommended Readings**

**Week 14: Conflicts of Interest (Lauris Kaldjian)**

**Learning Objectives**
Through this week’s readings and class discussion, we will aim to identify and understand:
- Key definitions of conflict of interest (COI).
- Typical research situations involving COI.
- Regulations and strategies for avoiding COI.
Required Readings (on ICON)

Recommended Readings

Week 15: Ethical Research with Children (Simon)

May 6

Learning Objectives
Through this week’s discussion, we will aim to identify and understand:
- Research ethics issues specific to pediatric populations.
- How to assess these issues in a principled and empirical way.

Required Readings (on ICON)
- Lantos, J. D. Learning the right lessons from the SUPPORT trial controversy. Arch Dis Child Fetal Neonatal Ed, 99(1), F4-5.
- Consent document from the SUPPORT trial (please read the document and come to class prepared to discuss its strengths and shortcomings)

Recommended Readings
8. Requirements for Final Paper

For students enrolled in the 3-credit hour option, a paper is required that addresses a specific ethical issue or issues relevant to the course and the student’s research interests. Students will have the option of selecting from a number of topics that the instructor will provide, or of choosing a topic aligned with their own research interests. The paper should demonstrate critical thinking, balance of perspective, and excellent knowledge of the selected topic. Supporting references are a must. The paper must be double-spaced, dated, and with pages numbered throughout. **Font size: 12.** Cite references throughout narrative and include reference details at the end of the text. Use any recognized referencing format you like (such as APA, New England Journal of Medicine, Social Science and Medicine, or other, but use it consistently. Remember to clearly and consistently cite your sources for information and identify quotes as such. This should occur in the text as well as in a reference list at the end of the paper. See Icon for additional guidelines on writing this paper.

9. Communication with the Course Instructors and Course Coordinator

Please feel free to contact the course instructors or course coordinator as needed by email. You should expect to receive replies by email within 24-48 hours. As needed, office meetings can be arranged to discuss questions in person.

10. Departmental Administrative Contact Information

If needed, the Departmental Executive Officer in the College of Public Health relevant to this course is Prof. James Torner, Chair, Department of Epidemiology (Office: C21P-1 GH, Phone: 384-5001).

11. Availability of Modifications for Students with Disabilities

The Course Director would like to hear from anyone who has a disability which may require seating modifications or testing accommodations or accommodations of other class requirements, so that appropriate arrangements may be made. Please contact the Course Director by email.

12. Procedures for Student Complaints

It is the policy of The University of Iowa that each student shall be guaranteed certain rights and freedoms. A list of these rights and the procedures for complaints against faculty can be found at: [http://www.uiowa.edu/~vpss/policies/i/d.shtml#main][Instructors]

13. Collegiate Policy on Plagiarism

Plagiarism is the unacknowledged use of another’s ideas expressed in either the author’s original words or in a manner similar to the original form. It is the student’s responsibility to seek clarification of any situation in which he/she is uncertain whether plagiarism is/has been involved. Policies governing plagiarism can be found at [http://www.grad.uiowa.edu/Pubs/ManualRulesReqs.asp](http://www.grad.uiowa.edu/Pubs/ManualRulesReqs.asp)