Research Ethics and Integrity in Social and Behavioral Science Research
16:910:657

Social Work Doctoral Annex, Seminar Room 1st Fl.
Wednesdays, 9:00 – 11:40 AM

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Office hours: By appointment only

I. Course Overview
This course is designed to provide a broad overview of research ethics and scientific integrity, with particular attention to how an ethics framework and ethics regulations influence the design and conduct of social and behavioral science research in US and international settings. Using a combination of reading assignments, lectures, case-based analyses and topical discussions, the course is designed for graduate students who are undertaking or preparing to undertake research in the social or behavioral sciences.

II. Learning Objectives
Upon successful completion of this course, students will be able to:

1. Identify the philosophical approaches that guide the modern day research environment.
2. Identify values and belief systems that shape how social and behavioral science research involving individuals, vulnerable populations, and communities is conducted.
3. Understand the regulatory environment that guides modern-day research for the social scientist and the historical cases of research abuse that have shaped it.
4. Identify ethical issues in research protocol design and practical ways in which they may be resolved.
5. Apply ethical principles and regulatory requirements to their own current and future research program.
III. Course Structure

This course will meet weekly on Wednesdays for one two and one-half hour session during the Spring Semester. The course will use a combination of lectures, discussions, and analyses of cases studies.

1. Course Texts:


In addition the following materials will be available on Sakai:
A. Ethics and regulatory guidance documents, including:
   • American Psychiatric Association’s Task Force on Research Ethics (2006). Ethical principles and practices for research involving human participants with mental illness. Psychiatric Services, 57, 552-557.
   • American Psychological Association (2012). Guidelines for ethical conduct in the care and use of nonhuman animals in research.
   • American Sociological Association (1999). American Sociological Association code of ethics and policies and procedures of the ASA Committee on Professional Ethics.
   • Council for International Organizations of Medical Sciences (CIOMS) (2002). International guidelines for biomedical research involving human subjects.
   • HUGO Council (March 21, 1996). Human Genome Organisation - Statement on the principled conduct of genetics research.


An additional resource that may be of interest is available online at: http://www.hhs.gov/ohrp/humansubjects/anprmchangetable.html

• US Department of Health and Human Services. Regulatory changes in ANPRM: Comparison of existing rules with some of the changes being considered. (re. proposed changes to Federal regulations regarding use of human subjects in research).

B. Journal articles and case analyses as assigned.

Successful completion of ORSP Human Subjects Certification Test: All Rutgers faculty, staff, graduate students, and undergraduate students who serve as principal investigators on human subjects protocols or key personnel (all individuals who are responsible for the design and/or conduct of the study) are required to participate in this Human Subjects Certification Program. All students enrolled in this course must have submitted a copy of their certification letter to the instructor no later than 9:00am Wednesday, February 6th.

If you have not previously completed this program, you can access the test at the following website: http://orsp.rutgers.edu/Humans/hscp.php. This website will provide you background on the Certification Program, and the following will take you to the learning and exam-materials associated with Certification. To go to the Human Subjects Certification program on Sakai, click https://sakai.rutgers.edu/sitelogin.jsp?site=600c1140-3890-4274-00ca-dd17d37107ba

2. Course Assignments
   a. Weekly case analyses: Students will be given eight (8) short cases over the course of the semester to review. Each case will be accompanied by a question/series of questions to be answered briefly in 2-3 pages. Work is to be posted to the instructor using Dropbox on the Course Sakai site not later than 5:00pm the evening before the class in which the case will be discussed. For grading purposes, each case will be valued at a maximum of 5 points. The top six scores will be tallied for the purposes of calculating a final grade.

   b. Informed consent exercise: Students will be given a choice of two research studies- one domestic and one international for which they will draft an informed consent document. For grading purposes, this exercise will be valued at a maximum of 10 points.
c. **Participation in Mock—IRB/Protocol design activities April 24 and May 1** (Not graded, but students who are unable to attend an exercise will be required to submit a 4-6 page analysis of the case that was discussed in the missed session.)

d. **Final project:** Students will prepare 4-5 page case analyses for four cases provided by the instructor. Case analyses should reference texts and guidance documents covered during the semester. All citations and references should be presented in accordance with the Publication manual of the American Psychological Association, 6th edition.

e. **Alternate final project:** Doctoral students who have dissertation ideas in mind (populations, topic, possible research questions, methodologies, etc.) and would like to work on the components of their intended research that will be the focus of future IRB review may, with permission of the instructor as well as their dissertation advisor, elect to work on the development of a model (or actual) IRB submission as an alternate to the final project described in item ‘d’ above.

For grading purposes, final projects will be valued at a maximum of 40 points.

3. **Course Topics**
   a. Conceptual foundations— theoretical and moral frameworks
   b. Historical foundations of the modern-day research environment
   c. Respect for persons in the context of social and behavioral research
   d. Beneficence and the welfare of research participants
   e. Justice and vulnerable populations
   f. The US regulatory framework and the Institutional Review Board
   g. Special issues in international research
   h. Ethical issues in animal research
   i. Honesty in research
      i. Error, bias, and conflict of interest
      ii. Authorship and publication
      iii. Openness and intellectual property
      iv. Whistleblowing, mentorship, harassment
   j. Scientific responsibility
   k. Research in the practice setting

4. **Grading rubric**

   Participation: 20%
   Case assignments (Best 6 of 8) 30%
   Informed Consent Exercise 10%
   Final Project 40%

**ACADEMIC INTEGRITY**

All work submitted in a graduate course must be your own. It is unethical and a violation of the University’s Academic Integrity Policy to present the ideas or words of another without clearly and fully identifying the source. Inadequate citations will be construed as an attempt to
misrepresent the cited material as your own. Use the APA citation style which is described in the Publication manual of the American Psychological Association, 6th edition.

Plagiarism is the representation of the words or ideas of another as one’s own in any academic exercise. To avoid plagiarism, every direct quotation must be identified by quotation marks or by appropriate indentation and must be properly cited in the text or footnote. Acknowledgement is required when material from another source is stored in print, electronic, or other medium and is paraphrased or summarized in whole or in part in one’s own words. To acknowledge a paraphrase properly, one might state: “to paraphrase Plato’s comment…” and conclude with a footnote identifying the exact reference. A footnote acknowledging only a directly quoted statement does not suffice to notify the reader of any preceding or succeeding paraphrased material. Information which is common knowledge, such as names of leaders of prominent nations, basic scientific laws, etc., need not be footnoted; however, all facts or information obtained in reading or research that are not common knowledge among students in the course must be acknowledged. In addition to materials specifically cited in the text, only materials that contribute to one’s general understanding of the subject may be acknowledged in the bibliography. Plagiarism can, in some cases, be a subtle issue. Any question about what constitutes plagiarism should be discussed with the faculty member.

Plagiarism as described in the University’s Academic Integrity Policy is as follows: “Plagiarism: Plagiarism is the use of another person’s words, ideas, or results without giving that person appropriate credit. To avoid plagiarism, every direct quotation must be identified by quotation marks or appropriate indentation and both direct quotation and paraphrasing must be cited properly according to the accepted format for the particular discipline or as required by the instructor in a course. Some common examples of plagiarism are:

- Copying word for word (i.e. quoting directly) from an oral, printed, or electronic source without proper attribution.
- Paraphrasing without proper attribution, i.e., presenting in one’s own words another person’s written words or ideas as if they were one’s own.
- Submitting a purchased or downloaded term paper or other materials to satisfy a course requirement.
- Incorporating into one’s work graphs, drawings, photographs, diagrams, tables, spreadsheets, computer programs, or other nontextual material from other sources without proper attribution”.

Plagiarism along with any and all other violations of academic integrity by graduate and professional students will normally be penalized more severely than violations by undergraduate students. Since all violations of academic integrity by a graduate or professional student are potentially separable under the Academic Integrity Policy, faculty members should not adjudicate alleged academic integrity violations by graduate and professional students, but should refer such allegations to the appropriate Academic Integrity Facilitator (AIF) or to the Office of Student Conduct. The AIF that you should contact is Antoinette Y. Farmer, 848.932.5358. The student shall be notified in writing, by email or hand delivery, of the alleged violation and of the fact that the matter has been referred to the AIF for adjudication. This notification shall be done within 10 days of identifying the alleged violation. Once the student has been notified of the allegation, the student may not drop the course or withdraw from the
school until the adjudication process is complete. A TZ or incomplete grade shall be assigned until the case is resolved. For more information regarding the Rutgers Academic Integrity Policies and Procedures, see: http://academicintegrity.rutgers.edu/academic-integrity-at-rutgers. It has been recommended by the Office of Student Conduct that the honor pledge below be written on all examinations and major course assignments.

DISABILITY ACCOMMODATION

Please Note: Any student who believes that s/he may need an accommodation in this class due to a disability should contact the University Office of Disability Services, Lucy Stone Hall, Livingston Campus 54 Joyce Kilmer Avenue, Suite A145, Piscataway, NJ 08854-8045, email address: dsoffice@rci.rutgers, Phone: (848) 445-6800, fax: (732) 445-3388, for a letter of accommodation. (Undergraduate New Brunswick students should contact the Coordinator for Students with Disabilities for their College.) Students who are taken courses in Camden should contact Mr. Tim S. Pure, Assistant Director/Disability Services Coordinator, Rutgers-Camden Learning Center, Armitage, Hall, Room 231, 311 N. 5th Street, Camden, NJ 08102, email address: tpure@camden.rutgers.edu. Students who are taken courses in Newark should contact Ms. Genevieve Sumski, Disability Services Coordinator, Robeson Campus Center-Newark, 350 ML King, Jr. Boulevard, Newark, NJ 07102-1898. Any student, who has already received a letter of accommodation, should contact the instructor privately to discuss implementation of his/her accommodations immediately. Failure to discuss implementation of accommodations with the instructor promptly may result in denial of your accommodations.
### Topics, Readings, and Assignments

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<tr>
<th>Wednesday, January 23</th>
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<tbody>
<tr>
<td><strong>TOPICS:</strong></td>
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<tr>
<td>• Introductions</td>
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<td>• Review of course goals and construction of syllabus</td>
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<td>• Schedule/reschedule</td>
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<td>• The significance of research ethics for social and behavioral science</td>
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<td>• Where do morals, ethics, and rules ‘sit’ in the research environment</td>
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<td>• Overview of Guidance and Regulatory Documents</td>
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<th>Wednesday, January 30</th>
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<tr>
<td><strong>TOPICS:</strong> Conceptual and Historical Foundations of Contemporary Research Ethics</td>
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<td>• Consequentialist approaches</td>
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<td>• Deontological approaches</td>
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<td>• Virtue ethics</td>
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<td>• Ethics of care</td>
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<td>• Landmark Cases:</td>
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<tr>
<td>• An Ethical Reasoning Model</td>
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<tr>
<td><strong>READINGS:</strong></td>
</tr>
<tr>
<td>• Israel &amp; Hay, Chaps. 1 &amp; 2, (pp. 1–22) &amp; Chap. 9 (pp. 129-143)</td>
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<tr>
<td>• Macrina, Chapter 2 (pp. 19-39)</td>
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<tr>
<td><strong>ASSIGNMENTS:</strong> Case analysis #1. Confidentiality and Risk of Harm to Others.</td>
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<th>Wednesday, February 6</th>
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<tr>
<td><strong>TOPICS:</strong> US guidance on human subjects research</td>
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<tr>
<td><strong>LANDMARK CASE:</strong> The Tuskegee Syphilis Study</td>
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<td><strong>READINGS:</strong></td>
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<tr>
<td>• Israel &amp; Hay, Chap. 3, (pp. 23 – 39)</td>
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<tr>
<td>• Macrina, Chap. 5 (pp. 91-126)</td>
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<td>• The Belmont Report</td>
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<td>• US CFR 45 §46 Human Subjects</td>
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<tr>
<td>• University of Pennsylvania Reviewer Checklists:</td>
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<tr>
<td>o Pregnant women, fetuses, neonates, and fetal material (Subpart B)</td>
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<td>o Prisoners (Subpart C)</td>
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Children (Subpart D)

ASSIGNMENTS: Case Analysis #2. Must be posted to Dropbox by 5:00pm Tuesday, Feb.5.

Wednesday, February 13

TOPICS: International guidance on human subjects research

LANDMARK CASE: Clinical Trials of AZT to Prevent Mother-to-Infant Transmission of HIV in Developing Nations


READINGS:
- World Medical Association (2008). Declaration of Helsinki

ASSIGNMENTS:
Case Analysis #3: Must be posted to Dropbox by 5:00pm Tuesday, February 12.
Note: Informed Consent exercise due February 27th will be distributed in class.

Wednesday, February 20

TOPICS: Respect for persons

- Principle of autonomy
- Informed consent
- Voluntariness
- Privacy and confidentiality
- Incorporating respect for persons into research design

READINGS:
- Israel & Hay, Chaps. 5 and 6 (pp. 60 – 94)


**Wednesday, February 27**

**TOPICS: Beneficence and Justice**
- Conceptual foundations
- Beneficence and justice as constructs in the research environment
- Variability in how regulatory environments weight these concepts in ethics review
- Incorporating beneficence and justice into research design

**READINGS:**
- Israel & Hay, Chap. 7, pp. 95 – 113)

**ASSIGNMENTS:** Informed Consent Exercise.

**Wednesday, March 6**

**TOPICS: Research involving vulnerable populations**
- Definitions
- Vulnerability in the research environment
- Intrinsic factors
- Extrinsic factors

**READINGS:**


**ASSIGNMENTS:** Case Analysis #4.

**Wednesday, March 20  UNIVERSITY HOLIDAY**

**Wednesday, March 27**

**TOPICS:**

- Ethical issues in community- and population-based research
- Ethical challenges in conducting research in the practice setting

**READINGS:**


**ASSIGNMENTS:** Case Analysis #6.

**Tuesday, April 2  6:00 – 8:30pm**

**TOPICS:** Ethical issues in designing and conducting research in international settings

**LANDMARK CASE:** UPHS Syphilis Study in Guatemala


**READINGS:**

- Macrina, Chap. 8 (pp. 187-210)


**ASSIGNMENTS:**

**Wednesday, April 3**

**TOPICS: Publication, Authorship and Peer Review**

**READINGS:**
- Macrina, Chaps. 3, 4, and 9 (pp. 39-90, 211-246)

**LANDMARK CASES:**

**Catekin**

**Betty Dong**

**David Kern**

**Nancy Olivieri**

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<thead>
<tr>
<th>Wednesday, April 10</th>
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<tr>
<td>TOPICS: Misconduct and Conflicts of Interest</td>
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<td>READINGS:</td>
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<tr>
<td>• Macrina, Chaps. 1 &amp; 7 (pp. 1-18 &amp; 159-1860)</td>
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<th>Wednesday, April 17</th>
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<tr>
<td>TOPICS:</td>
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<td>I. Ethical issues around use of animals in research</td>
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<td>II. Introduction to Institutional Review Boards (IRBs)</td>
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<td>• Origins and history of IRBs</td>
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<td>• Roles and Responsibilities of IRBs</td>
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<td>• IRBs in International Settings</td>
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<tr>
<td>READINGS:</td>
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<tr>
<td>• Macrina, Chap. 6 (pp. 127-157)</td>
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<tr>
<td>• Please visit and familiarize yourself with the Rutgers Office of Research and Sponsored Programs IRB site found at <a href="http://orsp.rutgers.edu/index.php?q=content/institutional-review-board-irb">http://orsp.rutgers.edu/index.php?q=content/institutional-review-board-irb</a></td>
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<tr>
<td>• Israel &amp; Hay, Chap. 4 (pp. 40 – 59)</td>
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<td>ASSIGNMENTS: Case Analysis #7.</td>
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<th>Wednesday, April 24</th>
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<tr>
<td>TOPICS: Mock IRB/PROTOCOL DESIGN EXERCISE. Case to be distributed by April 17.</td>
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<td>READINGS RELATED TO EXERCISE: To be assigned.</td>
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<td>READINGS:</td>
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<tr>
<th>Wednesday, May 1 FINAL CLASS</th>
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<tr>
<td>TOPICS: Mock IRB/PROTOCOL DESIGN EXERCISE: Case to be distributed April 24</td>
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<td>READINGS RELATED TO EXERCISE: To be assigned.</td>
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