

**UNIVERSITY OF WISCONSIN-MILWAUKEE  
HELEN BADER SCHOOL OF SOCIAL WELFARE,**

**SW 991  
Proseminar in Research Ethics**

Semester/Year: Fall 2007  
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**Course Description**

This 1-credit skills proseminar is designed to familiarize students with key principles for conducting research responsibly, with integrity, and with assurance of ethical conduct for human participants. It also seeks to develop skills necessary to successfully complete the human subjects/institutional review board process. The course utilizes self-paced, web-based training opportunities in conjunction with critical analysis of readings, research examples/situations, and experiential learning opportunities (i.e., observation of IRB review meetings, developing components of an IRB proposal). This course is appropriate for social work doctoral students as well as for graduate students in other professions and disciplines.

**Prerequisites**

Students enrolled in this course must have graduate standing or signed permission of the instructor.

**Specific Course Goals and Objectives**

The goals of the social work doctoral program include preparing students to make contributions to the profession as researchers, scholars, and educators. Individuals in these roles require a strong working knowledge and skill base related to the ethical conduct of research. Toward this end, the objectives of this course are to enable students to demonstrate the following:

1. Awareness of issues surrounding the responsible conduct of research and specific threats to research integrity;
2. Ability to successfully complete the on-line NIH tutorial on ethical conduct of research, as evidenced by a certificate of completion (this is more in-depth than the current UWM IRB tutorial);
3. Ability to critically analyze ethical issues that might arise in all phases of conducting research with human participants (recruitment, retention, data collection, data storage, reporting results, etc.), including research with women, minority populations, children and other protected populations;
4. Ability to write effective proposals for IRB review for projects fitting various categories (i.e., exempt, minimal risk, research with protected populations, and risk/deception studies);
5. Observation of real-world IRB procedures during committee review of proposals.

**Texts/Required Reading Sources**

- Required chapters and articles are accessible through electronic reserve via D2L or as web-based, on-line resources.
- National Academy of Sciences (1995). On being a scientist: Responsible conduct in research. This resource is available on line at: <http://www.nap.edu/readingroom/books/obas/>
- The Office of Research Integrity (ORI), 2005 document: Introduction to the responsible conduct of research (Nicholas H. Steneck) available at <http://ori.dhhs.gov/documents/rcrintro.pdf>. Sections required.
- Required on-line tutorial on human subjects research is accessible at: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. This on-line tutorial requires about 2 hours to complete and is designed for those involved in conducting clinical trials research with human subjects. ***Be sure that you print your completion certificate at the end!!!***
- Required on-line tutorial on informed consent is accessible at: [http://www.research.umn.edu/consent/menu\\_soc.html](http://www.research.umn.edu/consent/menu_soc.html).
- This website contains NIH information for researchers concerning HIPAA Privacy Rules. Excerpts will be assigned reading for this course.  
[http://privacyruleandresearch.nih.gov/pr\\_02.asp](http://privacyruleandresearch.nih.gov/pr_02.asp)  
Or, as PDF file, [http://privacyruleandresearch.nih.gov/pdf/HIPAA\\_Booklet\\_4-14-2003.pdf](http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf)
- This is the UWM website for IRB proposal construction and submission which will be the foundation for assigned protocol development.  
<http://www.uwm.edu/Dept/EHSRM/IRB/Guide/index.html>

### **Learning Environment and Resources**

Many of the course materials are accessible to registered students through D2L at <http://www.uwm.edu/UWM/Student/elearning.html>. All students enrolled in social work courses have access to the computer lab located on the 10<sup>th</sup> floor of Enderis Hall and at other locations throughout campus. For specific locations/hours see <https://www3.uwm.edu/IMT/services/campus/ccls/>.

Campus policy information regarding participation by students with disabilities, accommodations for religious observances, academic conduct/misconduct, incomplete grading policies, complaint procedures, grade appeal procedures, sexual harassment and safety policies, final exam date requirements, and other standing policies/procedures is available on-line at: <http://www.uwm.edu/Dept/SecU/SyllabusLinks.pdf>.

### **Assignments/Grading**

Student grades in this course are based on the following criteria (full details attached):

Successful completion of the NIH tutorial with certificate: 15%

Critiques of two case examples: 20%

Critical review of IRB session attended: 15%

IRB proposals constructed (one “exempt”=20%, one “minimal risk”=30%): 50%

Late assignments will be graded downward for every 24 hours past due (i.e., letter grade equivalents will be in 1/3 increments, such that an “A” becomes “A-,” “B+” becomes “B,” etc.). Students submitting allowed group/team projects will share the same grade; the instructor will not attempt to distinguish relative contributions. University policies regarding the course grade of “Incomplete” will be followed.

## **Class Schedule/Outline**

(each session meets 110 minutes, once per week for 8 weeks)

### **Week 1: Introduction, Overview of Responsible Conduct In Research**

*Research Protocol Integrity*

*Data Integrity*

*Potential Conflicts of Interest in Research*

*Reporting Research Results*

*Publication Integrity*

*Defining Misconduct in Research*

*Responding to Misconduct*

#### **Required Readings:**

- National Academy of Sciences (1995). *On Being a Scientist* (available online at [www.nap.edu/readingroom/books/obas](http://www.nap.edu/readingroom/books/obas) or for purchase on line \$7);
- European Science Foundation (2000) *Policy Briefing: Good Scientific Practice in Research and Scholarship* (electronic reserve)

#### **Assignments Due:** Student Information Sheets;

Before week 7, complete the on-line NIH tutorial with certificate;

Before week 8, attend an IRB full board review meeting (call IRB office to ask for invitation as an observer); meeting schedule is on line at

<http://www.uwm.edu/Dept/EHSRM/IRB>; If schedule does not work out, another institution's IRB may be substituted by consultation with instructor.

### **Week 2: Responsible Conduct of Research (continued)**

#### **Required Readings:**

- ORI Introduction to the Responsible Conduct of Research (2005), section III, chapter 6: Conducting research: Data Management Practices, Data ownership, data collection, data protection, sharing, future considerations (pp. 83-102)
- ORI Introduction to the Responsible Conduct of Research (2005), section III, chapter 7: Mentor and Trainee Responsibilities: Basic responsibilities, research environment, supervision and review, transition to independent researcher (pp. 103-116)
- ORI Introduction to the Responsible Conduct of Research (2005), section III, chapter 8: Collaborative Research: Roles and relationships, management, different research settings (pp. 117-128)
- ORI Introduction to the Responsible Conduct of Research (2005), section IV, chapter 9: Reporting and reviewing research: Authorship and Publication (pp. 129-146).
- ORI Introduction to the Responsible Conduct of Research (2005), section IV, chapter 10: Peer review (pp. 147-158).
- Federal Policy on Research Misconduct (2000) online at:  
<http://onlineethics.org/fedresmis.html>

**Assignments Due:** Critique of one case study presented in "On Being a Scientist"

### **Week 3: Overview of Issues in Research Involving Human Participants and Special Populations**

*History of IRB process/principles*

*What constitutes "research"?*

*What constitutes research with "human subjects"?*

*Levels of risk/IRB review*

*HIPAA Privacy in Research*

*Federally mandated populations: inclusion of women, minorities, children*

*Recruiting diverse samples and research integrity*

**Required Readings:**

- The following website is the updated NIH policy on inclusion of women and minorities in clinical research:  
[http://grants2.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants2.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)
- The following federal regulations for the protection of human subjects excerpts from [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm): Subpart A 46.101 & 46.102,
- The following website contains the Belmont Report which should be read in its entirety:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- The following address issues in recruitment of minority populations. You are expected to read three of them:
  - Shavers, V. L., Lynch, C. F., & Burmeister, L. F. (2002). Racial differences in factors that influence the willingness to participate in medical research studies. *Annals of Epidemiology*, 12(4), 248-256.
  - Sage, G. P. (1994). Drug prevention research with Native-American populations: Some considerations. In A. Cázares & L. A. Beatty (Eds.), *Scientific methods for prevention intervention research* (pp. 235-248). Rockville, MD: National Institute on Drug Abuse (Research Monograph No. 139).
  - Brown, B. A., Long, H. L., Gould, H., Weitz, T., & Milliken, N. A conceptual model for the recruitment of diverse women into research studies. *Journal of Women's Health & Gender-Based Medicine*, 9(6), 625-632. (July-August)
  - Castro, F. G., Harmon, M. P., Coe, K., & Tafoya-Barraza, H. M. (1994). Drug prevention research with Hispanic populations: Theoretical and methodological issues and a generic structural model. In A. Cázares & L. A. Beatty (Eds.), *Scientific methods for prevention intervention research* (pp. 203-234). Rockville, MD: National Institute on Drug Abuse (Research Monograph No. 139).
  - Clay, C., Ellis, M. A., Amodeo, M., Fassler, I., & Griffin, M. L. (2003). Recruiting a community sample of African American subjects: The nuts and bolts of a successful effort. *Families in Society-The Journal of Contemporary Human Services*, 84(3), 396-404.

**Assignments Due:** Critique of one case study presented in class.

**Week 4: Consent Process**

*Consent versus Assent*

*Elements of Consent*

*Consenting Procedures*

**Required Readings:**

- The following federal regulations for the protection of human subjects excerpts from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>: Subpart A 46.116 & 46.117

- The following website contains a reader for the general population informing study participants of what they should know before deciding to enroll in a mental health clinic trial: <http://www.nimh.nih.gov/publicat/clinres.cfm>

## **Week 5: Research with Protected Populations: Minors, Fetuses, Pregnant Women**

*Consent Issues*

*Law, policies, and politics*

### **Required Readings:**

- The following federal regulations for the protection of human subjects excerpts from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>: Subpart B 46.201 & 46.202, 46.204 through 46.207; also Subpart D 46.401 through 46.409

**Assignments Due:** “Exempt” IRB protocol due.

## **Week 6: Research with Protected Populations: Those Who Are Incarcerated, Cognitively Impaired, or Mentally Ill**

*Determining Capacity for Consent*

*Screening In & Out of Studies*

### **Required Readings:**

- The following federal regulations for the protection of human subjects excerpts from <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>: Subpart C 46.301 through 46.306
- Janofsky, J. S., McCarthy, R. J., & Folstein, M. F. (1992). The Hopkins Competency Assessment Test: A brief method for evaluating patients' capacity to give informed consent. *Hospital and Community Psychiatry, 43*, 132-133.
- Saks, E. R., Dunn, L. B., Marshall, B. J., Nayak, G. V., Golshan, S., & Jeste, D. V. (2002). The California Scale of Appreciation: A new instrument to measure the appreciation component of capacity to consent to research. *American Journal of Geriatric Psychiatry, 10*, 166-174.
- Zayas, L. H., Cabassa, L. J., & Perez, M. C. (2005). Capacity-to-consent in psychiatric research: Development and preliminary testing of a screening tool. *Research on Social Work Practice, 15*, 545-556.
- Kim, S.Y.H., & Karlawish, J.H.T. (2003) Ethics and politics of research involving subjects with impaired decision-making abilities. *Neurology, 62*, 1645-1646.
- Stocking, C. B., Hougham, G.W., Baron, A.R., & Sachs, G.A. (2003) Are the rules for research with subjects with dementia changing? Views from the field. *Neurology, 61*, 1649-1651.
- Buckles, V.D., Powlishta, K.K., Palmer, J.L., Coats, M., Hosto, T., Buckley, A., & Morris, J.C. (2003) Understanding informed consent by demented individuals. *Neurology, 61*, 1662-1666.

## **Week 7: Additional Issues and Team work on minimal risk protocol**

*Internet Research*

*International Research*

### **Required Readings:**

- Scott, C.K., & White, W. L. (2005) Ethical issues in the conduct of longitudinal studies of addiction treatment. *Journal of Substance Abuse Treatment*, 28(2, *supp. 1*), S91-S101.
- Ethical decision-making and Internet research (2002) AoIR (on reserve)
- Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule (on reserve)
- Kass, N.E., Maman, S., & Atkinson, J. (2005) Motivations, understanding and voluntariness in international randomized trials. *IRB: Ethics & Human Research*, 27(6), 1-8. (on reserve)

**Assignments Due:** NIH Tutorial Certificate due

**Week 8: Discuss IRB meeting attended, wrap up, etc**

**Assignments Due:** UWM IRB session critique; “Minimal Risk” protocol due.

Additional Reading Resources:

Childress, J. F. & Meslin, E. M. (2005). *Belmont revisited: Ethical principles for research with human subjects*. Washington, DC: Georgetown University Press.

Steneck, N. H. (2004). *ORI introduction to the responsible conduct of research*. Rockville, MD: U.S. Dept. of Health and Human Services, Office of Research Integrity.

Trimble, J. E. & Fisher, C. B. (2006). *The handbook of ethical research with ethnocultural populations and communities*. Thousand Oaks, CA: Sage Publications.

Kodish, E. (2005). *Ethics and research with children: A case-based approach*. New York: Oxford University Press.

Leadbeater, B. J. R. (2006). *Ethical issues in community-based research with children and youth*. Toronto: University of Toronto Press.

Buchanan, E. A. (2004). *Readings in virtual research ethics: Issues and controversies*. Hershey, PA: Information Science Publications.

Waring, D. W. R. & Lemmens, T. (2006). *Law and ethics in biomedical research: Regulation, conflict of interest, and liability*. Toronto: University of Toronto Press.

Murphy, T. F. (2004). *Case studies in biomedical research ethics*. Cambridge, MA: MIT Press.

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DOCTORAL PROGRAM IN SOCIAL WORK**

**SW 991 : Proseminar in Research Ethics**

**Assignment 1: Case Study Critique from “On Being a Scientist”**

Due date: in class, week 2

**Learning Objectives:** The purpose of this assignment is for students to critically analyze a research ethics dilemma related to the responsible conduct of research and conducting research with integrity.

**Specific Details:** This analysis should be single-spaced, 1 ½-2 pages. Students may elect to work in pairs or alone on this assignment—partners will be assigned equal grades, as the instructor will not attempt to determine relative contributions to the product.

**Step One.** Select one of the following case studies presented in “On Being a Scientist”:

- The Selection of Data (Deborah & Kathleen)
- The Sharing of Research Materials (Ed)
- Credit Where Credit is Due (Ben)
- Who Should Get Credit for the Discovery of Pulsars? (Jocelyn Bell)
- A Career in the Balance (Francine)

**Step Two.** Present a critical analysis of the case that includes the following:

- Your perspectives in response to the probes listed in the case example, integrating the discussion issues/questions listed in the appendix. Your analysis should include multiple sides of the issue(s).
- What should happen next and why do you think so?

**Grading:** This assignment is worth 10% of the course grade; it represents one of two case example critiques that total 20% of the course grade together. The grading scheme is based on the following criteria:

- 8 pts. – completeness and adequacy of analysis
  - 2 pts – quality of presentation of your points, arguments, and analyses
- (10 Total possible points)

Letter grade equivalents: 10=A, 9=A-, 8=B+, 7=B, 6=B-, 5=C+, 4=C, 3=C-, 2=D, 1/0=E

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**Assignment 2: Case Study Critique from Current Case**

Due date: in class, week 3

**Learning Objectives:** The purpose of this assignment is for students to critically analyze a current case related to the responsible conduct of research and conducting research with integrity.

**Specific Details:** This analysis should be single-spaced, 1 ½-2 pages. Students may elect to work in pairs or alone on this assignment—partners will be assigned equal grades, as the instructor will not attempt to determine relative contributions to the product.

**Step One.** Select one of the case studies presented by the instructor

**Step Two.** Present a critical analysis of the case that includes the following:

- Identify what you think are the top 2-3 issues in the case.
- Provide your perspectives about these issues in relation to the case. Your analysis should include multiple sides of the issues.
- Why do you think the problem(s) might have happened?
- What should individuals and institutions do to make sure this does not happen?

**Grading:** This assignment is worth 10% of the course grade; it represents one of two case example critiques that total 20% of the course grade together. The grading scheme is based on the following criteria:

8 pts. – completeness and adequacy of analysis

2 pts – quality of presentation of your points, arguments, and analyses

(10 Total possible points)

Letter grade equivalents: 10=A, 9=A-, 8=B+, 7=B, 6=B-, 5=C+, 4=C, 3=C-, 2=D, 1/0=E

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**SW 991 : Proseminar in Research Ethics**

**Due:** Week 8

**Assignment 3:** Critical Review of IRB Session

**Learning Objectives:** The purpose of this assignment is to experience a live IRB review session (in a non-threatening context—having your own work reviewed can alter your perceptions drastically!!!), and to think critically about what you observed.

**Specific Details:** Schedule with the IRB administrator an opportunity to observe one IRB review meeting. Plan way ahead—these meetings may only happen once per month!

While you are in the meeting, remember that you are an invited guest observer. You are not a participant. Be respectful and courteous toward the IRB committee members, IRB staff, and IRB applicants whose proposals are being reviewed. This includes making sure that you do not discuss what you observed outside of the class/assignment, and that in all situations your discussions and written notes/assignment should use pseudonyms and mask the identities of the persons involved. This even means avoiding discussing the specific topic that was reviewed and the department that the scientists come from.

**Critique Elements:**

1. Think about the IRB meeting from the perspective of the IRB committee member. What about the meeting and review process is compelling and attractive to a busy faculty or community board member and that might encourage them to volunteer for this role? What about the meeting is unattractive and might discourage people from volunteering for this role? Would you be likely to volunteer for this type of role? Why/why not?
2. Think about the IRB meeting from the perspective of the scientists applying for approval to involve human subjects in their research. What kinds of issues came up in response to their protocols? What kinds of solutions were offered? What level of understanding of IRB issues did you think the scientists exhibited? What about the meeting was encouraging/discouraging to the scientists?
3. Think about the IRB meeting from the perspective of potential study participants. What would you be glad versus disturbed to know took place in the review process? How well do you think the scientists were able to protect participants' interests in their proposals (e.g., what grade would you give them)? How well do you think the IRB board members were able to protect participants' interests in response to the proposals?

Your finished analysis should be 3-4 pages in length (single spaced, typed). You may work in pairs to write the analysis, but you both must attend the same meeting.

**Grading:** This assignment is worth 15% of the course grade. The grading scheme is based on the following criteria:

8 pts. – completeness and adequacy of analysis (good job of addressing points above)

2 pts – quality of presentation of your points, arguments, and analyses

(10 Total possible points)

Letter grade equivalents: 10=A, 9=A-, 8=B+, 7=B, 6=B-, 5=C+, 4=C, 3=C-, 2=D, 1/0=E

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**SW 991 : Proseminar in Research Ethics**

**Due:** Week 5

**Assignment 4:** Exempt Protocol

**Learning Objectives:** To have the experience of preparing an exempt protocol for human subjects research, following the UWM IRB guidelines for submission. This exposes you to the experience of making the many choices and decisions involved in developing such a protocol and to having to present it in such a way that an interdisciplinary board could reasonably review it.

**Specific Details:** Using the UWM IRB website guidelines, develop an exempt protocol with all of its constituent elements. You may make up the study or use a study that you find in the literature.

You may work in pairs to write the proposal.

**Grading:** This assignment is worth 20% of the course grade. The grading scheme is based on the following criteria:

2 pts—contains all necessary elements per the guidelines

2 pts—all aspects fit the “exempt” criteria

6 pts—presentation appropriate for review board audience and would “pass” with board approval with no more than 1 condition. (Loss of ½ point for each additional condition that would be imposed)

(10 Total possible points)

Letter grade equivalents: 10=A, 9=A-, 8=B+, 7=B, 6=B-, 5=C+, 4=C, 3=C-, 2=D, 1/0=E

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**Due:** Week 8

**Assignment 5:** Minimal Risk Protocol

**Learning Objectives:** To have the experience of preparing a minimal risk protocol for human subjects research with a protected population, following the UWM IRB guidelines for submission. This exposes you to the experience of making the many choices and decisions involved in developing such a protocol and to having to present it in such a way that an interdisciplinary board could reasonably review it.

**Specific Details:** Using the UWM IRB website guidelines, develop a minimal risk protocol with all of its constituent elements. You may make up the study or use a study that you find in the literature, but you should include at least one “protected” population.

You may work in pairs to write the proposal.

**Grading:** This assignment is worth 30% of the course grade. The grading scheme is based on the following criteria:

- 2 pts—contains all necessary elements per the guidelines
- 1 pts—proposal fits the “minimal risk” criteria
- 2 pts—special/protected population issues addressed appropriately
- 5 pts—presentation appropriate for review board audience and would “pass” with board approval with no more than 1 condition. (Loss of ½ point for each additional condition that would be imposed)

(10 Total possible points)

Letter grade equivalents: 10=A, 9=A-, 8=B+, 7=B, 6=B-, 5=C+, 4=C, 3=C-, 2=D, 1/0=E

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**SW 991 : Proseminar in Research Ethics**

**Due:** Week 7

**Assignment 6:** NIH Research Ethics Tutorial Certificate Earned

**Learning Objectives:** To demonstrate familiarity with sufficient aspects of the tutorial content to be able to earn the certificate.

**Specific Details:** Complete the on-line tutorial on human subjects research which is accessible at: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. This on-line tutorial requires about 2 hours to complete and is designed for those involved in conducting clinical trials research with human subjects.

***Be sure that you print your completion certificate at the end!!!***

**Grading:** This assignment is pass/fail. With the certificate, you pass, without the certificate, you fail. The certificate is worth 15% of the course grade.