Methods in Clinical Research
NUR 930 – Section 001
3 Credits
Spring 2017, Wednesdays 9:00a.m.-12:00p.m.

Catalog Course Description: Advanced research designs, measurement and data collection strategies. Draws on a broad range of behavioral and health disciplines relevant to nursing. Logic of statistical models used in the evaluation of research designs and measures.

Additional Course Description: This course will focus on a broad range of research designs and analytic issues related to the study of health status and health outcomes in individuals and populations. The discussion will center on the relative merits of choosing experimental/quasi-experimental or observational/survey designs, retrospective vs. prospective designs, and cross-sectional vs. longitudinal designs. A major theme in this discussion is how the quality of the evidence that is sought (descriptive statements, causal statements, statements that can be generalized to larger target populations) is influenced by the particular study designs chosen. Detailed analyses of published research (both well- and ill-designed) will shed light on the relationship between research design and quality of obtained evidence. A second theme involves the trade-offs between institutional constraints and human subject protection as well as practical and financial constraints that may require compromises in the design of a clinical research study. In line with this focus on the feasibility of research in clinical settings, problems in research implementation and quality of evidence are stressed, including issues such as: safeguarding the rights of human subjects, the trade-offs between the demands of sampling theory versus practical subject recruitment and retention, data management and quality assurance, data analysis issues in the face of ‘incomplete’ clinical data sets, etc. A third emphasis is on students’ development of a first study design.

Course Objectives: At the completion of this course the student will be able to:
1. Compare and contrast research designs to answer clinical research questions.
2. Evaluate clinical research methods and instruments.
3. Demonstrate skill in the design and evaluation of interventional and observational clinical research studies.

Professional Standards & Guidelines: The curriculum is guided by the following documents:

Faculty:

Jiying Ling, PhD, RN, Assistant Professor
Office: Bott Building for Nursing Education and Research, Office C-241
Phone: 517-353-8591 (Office)
Email: jiying.ling@hc.msu.edu
Office Hours: Wednesday 1:00-3:00 PM and by appointment; e-mail is the preferred contact with the instructor: messages will usually be answered within a few hours, but always within 48 hours.

Course website: The course content can be accessed through the Desire2Learn course management system (https://d2l.msu.edu). You can log into this site using your MSUNetID name and password.

Please contact me by phone as soon as possible if you need particular accommodations due to a disability so that we can make suitable arrangements.

Instruction:

a. Methodology: Seminar discussion (major emphasis!), student weekly discussions, some lectures, manuscript review practices, and proposal writing.

b. Writing Requirements: The College of Nursing requires that students refer to a style manual when writing required papers and bibliographies. The reference format adopted by the College of Nursing is the publication manual of the American Psychological Association (most recent edition).

c. Required Texts:


Course Evaluation:

a. Learning Assessments and Grading:

   ❖ In-Class Discussion (10%): Each week, students will be assigned to individual class discussion. The discussion involves taking the lead of analyzing one of the assigned research articles, addressing: 1) the appropriateness of the study design in light of the stated study purposes, the study implementation in the areas of 2) recruitment/sampling, 3) measurement/data collection, 4) data analysis, and 5) interpretation and discussion.

   ❖ Manuscript Review 1 and 2 (15% X 2 = 30%): Each student is required to critically review and analyze two submitted research papers over the course semester following journal review guidelines. Each review will be no longer than 3-pages (double space). Remember that a review should elaborate on both positive and negative aspects of the research paper. Journal reviewer’s comments, point-by-point responses to reviewers’ comments, and final published paper will be provided to students as feedback. Students are required to carefully review the provided documents to learn how to become a journal reviewer and respond to reviewers’ comments.

   ❖ Research Proposal (50%): At the beginning of the class, each student will select his/her area of research interest with the help of the instructor and major professor. Students are required to explore one research topic using one research design. Students are required to submit a research proposal (7 single-spaced pages) following the NRSA format (http://grants.nih.gov/grants/guide/pa-files/PA-16-309.html) including the following sections: 1) Specific aims (1 page); 2) Background and Significance (1-2 pages); and 3) Methods on overall research design, sampling method, participant recruitment method, data collection, and data analysis (4-5 pages).
Student Presentation (10%): Each student will have 20 minutes to present his/her research proposal with 10 minutes for questions and comments. Students can choose any presentation style and mode to make the presentation effective and interesting.

b. Course Grading Scale: The standard College of Nursing grading scale will be utilized.

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<th>%</th>
<th>GRADE</th>
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<tr>
<td>94 – 100</td>
<td>4.0</td>
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<td>87 – 93</td>
<td>3.5</td>
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<td>80 – 86</td>
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<td>(Minimum passing grade)</td>
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<td>75 – 79</td>
<td>2.5</td>
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<td>70 – 74</td>
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<td>60 – 64</td>
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<td>Below 60</td>
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Please note: Final Course Grades will not be rounded.

c. Examinations and Academic Dishonesty

Lectures, quizzes and examinations must remain the property of the College of Nursing and must not be copied or saved in any form for use with others. A quiz or exam should never be printed. Any of these activities indicate academic dishonesty. According to University policy, consequences for academic dishonesty may include failure of the course, expulsion from the major, or expulsion from the university. You are advised to complete and submit your own work. Exams are NOT group projects and must not be shared with other students in any way.

Professionalism:

All graduate students at Michigan State University should be fully familiar with the Graduate Student Rights and Responsibilities Articles (published by the Graduate School; available at http://splife.studentlife.msu.edu), University guidelines for ethical research - published by the University Committee on Research Involving Human Subjects [UCRIHS]; available at http://hrpp.msu.edu), and MSU Guidelines for Integrity in Research and Creative Activities, https://grad.msu.edu/researchintegrity).

The Graduate Student Rights and Responsibilities (GSRR) Articles address professional standards for graduate students as follows: “Each department/school and college shall communicate to graduate students, at the time of their enrollment in a degree program or course in the unit, any specific codes of professional and academic standards covering the conduct expected of them.” (Article 2.4.7). “The graduate student shares with the faculty the responsibility for maintaining the integrity of scholarship, grades, and professional standards” (Article 2.3.8).

In addition to meeting academic standards included in the Academic Progression Guidelines, students and faculty in the PhD Nursing Programs have shared responsibility for adherence to the professional standards presented in the CON Doctoral Student Handbook.

Professional expectations are rooted in the maintenance of high quality working relationships with faculty, peers, research participants, staff, and all others with whom the graduate student interacts. Aspects of high quality working relationships that are addressed in the GSSR as shared faculty-student responsibilities include: mutual respect, understanding, and dedication to the education process (2.1.2); maintenance of a collegial atmosphere (2.3.7); and mutual trust and civility (2.3.1.2).
University & College Policies:

The College of Nursing expects that students will demonstrate professional behavior in all situations. Specific expectations for clinical and other professional venues can be found in the appropriate handbook. You are responsible for reviewing and acting in accordance with the policies and procedures found in the following sources, including the following topics: Professionalism, Academic Integrity, Accommodations for Students with Disabilities, Disruptive Behavior, Attendance, Compliance, and Progression.

- CON MSN Student Handbook: [http://nursing.msu.edu/MSN%20Programs/Handbooks/default.htm](http://nursing.msu.edu/MSN%20Programs/Handbooks/default.htm)
- MSU Spartan Life Online: [http://www.vps.msu.edu/SpLife](http://www.vps.msu.edu/SpLife)
- Information for MSU Students: [http://www.msu.edu/current/index.html](http://www.msu.edu/current/index.html)
- Academic Programs: [http://www.reg.msu.edu/AcademicPrograms](http://www.reg.msu.edu/AcademicPrograms)
- Code of Teaching Responsibility and Student Assessments and Final Grades: [http://www.reg.msu.edu/AcademicPrograms/Print.asp?Section=514](http://www.reg.msu.edu/AcademicPrograms/Print.asp?Section=514)
- Integrity of Scholarship and Grades: [http://www.reg.msu.edu/AcademicPrograms/Print.asp?Section=534](http://www.reg.msu.edu/AcademicPrograms/Print.asp?Section=534)

University Policies:

**Academic integrity:** Article 2.3.3 of the Academic Freedom Report states that "The student shares with the faculty the responsibility for maintaining the integrity of scholarship, grades, and professional standards." In addition, the College adheres to the policies on academic honesty as specified in General Student Regulations 1.0, Protection of Scholarship and Grades; the all-University Policy on Integrity of Scholarship and Grades; and Ordinance 17.00, Examinations (See Spartan Life: Student Handbook and Resource Guide [http://splife.studentlife.msu.edu/](http://splife.studentlife.msu.edu/)) and/or the MSU Web site: [www.msu.edu](http://www.msu.edu). Therefore, unless authorized by your instructor, you are expected to complete all course assignments, including homework, lab work, quizzes, tests and exams, without assistance from any source. You are expected to develop original work for this course; therefore, you may not submit course work you completed for another course to satisfy the requirements for this course. Also, you are not authorized to use the [www.allmsu.com](http://www.allmsu.com) Web site to complete any course work. Students who violate MSU rules may receive a penalty grade, including--but not limited to--a failing grade on the assignment or in the course. Contact your instructor if you are unsure about the appropriateness of your course work. (See also [https://www.msu.edu/unit/ombud/academic-integrity/index.html#regulations](https://www.msu.edu/unit/ombud/academic-integrity/index.html#regulations))

**Accommodations for students with disabilities:** Students with disabilities should contact the Resource Center for Persons with Disabilities to establish reasonable accommodations. For an appointment with a disability specialist, call 353-9642 (voice), 355-1293 (TTY), or visit [MyProfile.rcpd.msu.edu](http://www.rcpd.msu.edu).

**Attendance:** Students whose names do not appear on the official class list for this course may not attend this class. Students who fail to attend the first four class sessions or class by the fifth day of the semester, whichever occurs first, may be dropped from the course. See the Ombudsman's web site for a discussion of student observance of major religious holidays, student-athlete participation in athletic competition, student participation in university-approved field trips, medical excuses and a dean's drop for students who fail to attend class sessions at the beginning of the semester.

**College of Nursing Policies:** Professional Development Guidelines found in CON Student Handbooks at CON website [http://nursing.msu.edu/MSN%20Programs/Handbooks/default.htm](http://nursing.msu.edu/MSN%20Programs/Handbooks/default.htm). Students are responsible for the information found in the CON (BSN, MSN, DNP, or PhD - choose one) Student Handbook.
# Course Calendar

<table>
<thead>
<tr>
<th>Class</th>
<th>Date</th>
<th>Topic</th>
<th>Reading</th>
<th>Assignment</th>
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<tbody>
<tr>
<td>1</td>
<td>1/11</td>
<td><strong>Introduction:</strong></td>
<td>Texts:</td>
<td>Introduce yourself in class:</td>
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<tr>
<td></td>
<td>8:30-</td>
<td>• What is “research”?</td>
<td>Polit &amp; Beck: Chapter 1-3</td>
<td>Where have you been?</td>
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<tr>
<td></td>
<td>11:30am</td>
<td>• Quantitative and qualitative research</td>
<td>NINR 2016 strategic plan: Advancing science, improving lives:</td>
<td>What have you been doing?</td>
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<td>• Evidence-based nursing</td>
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<td>Who is your assigned mentor?</td>
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<td>• Translational research</td>
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<td>What is your research interest?</td>
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<td></td>
<td>• Steps in qualitative and quantitative research</td>
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<td>What are your research experiences?</td>
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<td>2</td>
<td>1/12</td>
<td><strong>Conceptualizing and Planning A Study:</strong></td>
<td>Texts:</td>
<td>In-class discussion</td>
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<td>9-12pm</td>
<td>• Research problems</td>
<td>Polit &amp; Beck: Chapter 4-6</td>
<td>Proposal research topic: each student will briefly present research topic to the class</td>
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<td>• Specific aims</td>
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<td>• Hypotheses</td>
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<td>• Systematic literature review</td>
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<td>• Meta-analysis</td>
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| 3 | 1/18 | **Rigor in Research:**  
  • Validity and validity threats  
  • Internal validity  
  • Construct validity  
  • External validity  
  • Trustworthiness and integrity in qualitative research  
  • Strategies to enhance quality in qualitative inquiry  | **Texts:**  
  Polit & Beck: Chapter 10, 25, 29  
  SCC: Chapter 2-3  
  **Papers:**  
|---|---|---|---|---|
| 4 | 1/25 | **Qualitative Research Methods:**  
  • Ethnography  
  • Phenomenology  
  • Grounded theory  
  • Case studies  
  • Narrative analyses | **Texts:**  
  Polit & Beck: Chapter 21, 24  
  **Papers:**  
| 5 | 2/01 | **Pilot and Feasibility Study:**  
  • Pilot studies | **Texts:** None  | In-class discussion |
| 6 | 2/08 | **Sampling:**  
 1. Sampling in quantitative research  
   - Convenience sampling  
   - Quota sampling  
   - Consecutive sampling  
   - Purposive sampling  
   - Simple random sampling  
   - Stratified random sampling  
   - Multistage cluster sampling  
   - Systematic sampling  
 2. Sampling in qualitative research | **Papers:**  
Polt & Beck: Chapter 12, 22  
**In-class discussion**  
**Manuscript Review 1**  
(manuscript provided on 2/01)  
(Due 2/14, 5:00PM)
<table>
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<tr>
<th>Date</th>
<th>Topic</th>
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| 7 2/15 | **Data Collection:**
- Structured self-report instruments
- Structured observation
- Biophysiologic measures
- Measurement reliability and validity
- Developing and testing self-reported scales
- Different types of qualitative interviews

**Texts:**
Polit & Beck: Chapter 13, 14, 15, 23

**Papers:**

| 8 2/22 | **Experimental Design:**
- Pretest-posttest control group design
- Alternative-treatments design with pretest
- Multiple treatments and controls with pretest
- Factorial designs
- Longitudinal designs
- Crossover designs

**Texts:**
Polit & Beck: Chapter 9 - P.183-197
S C C: Chapter 8

**Papers:**
3. Mdege, N. D., Brabyn, S., Hewitt, C., Richardson, R., & Torgerson, D. J. (2014). The 2× 2 cluster randomized controlled factorial trial design is mainly used for efficiency and to explore intervention interactions: a systematic review. *Journal of Clinical Epidemiology, 67*(10),

**In-class discussion**

**Proposal background/significance:**
each student will briefly present research significance to the class.

### Quasi-Experimental Design I

- Lack a control group
- Lack pretest observations on the outcome
- With both control groups and pretest

**Texts:**
*Polit & Beck: Chapter 9 - P.197-203*
*S C C: Chapter 4*

**Papers:**
1. TREND statement:

### Quasi-Experimental Design II

- Interrupted time-series designs

**Texts:**
*S C C: Chapters 6*

**Papers:**
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Observational Research I:</th>
<th>Texts:</th>
<th>Papers:</th>
<th>In-class discussion</th>
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<td></td>
<td></td>
<td>Ecological study</td>
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3. Ensenauer, R., Chmitorz, A., Riedel, C., Fenske, N., | In-class discussion |
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<tr>
<th>Date</th>
<th>Texts/Papers</th>
<th>Notes</th>
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| 13/4/05 | **Mixed Methods Research:**  
  - Definition  
  - Mixed methods design  
  - Using mixed methods to design interventions  
  - Using mixed methods to pilot test an intervention  
  **Texts:** Polit & Beck: Chapter 26-28  
| 14/4/12 | **Emerging Research Methods:**  
  - Sequential, Multiple Assignment, Randomized Trial (SMART): [https://methodology.psu.edu/ra/adap-inter](https://methodology.psu.edu/ra/adap-inter)  
  - The Multiphase Optimization Strategy (MOST): [https://methodology.psu.edu/ra/most](https://methodology.psu.edu/ra/most)  
  **Texts:** None  

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<tr>
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<tr>
<td>15</td>
<td>4/19</td>
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<td>16</td>
<td>4/26</td>
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<tr>
<td>17</td>
<td>5/03</td>
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