Methods in Clinical Research
NUR 930 – Section 001
Room C288 Life Sciences
Tuesdays 9:10a.m. 12:00p.m.
3 Credits
Summer 2016

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.

Standards Documents: The curriculum is guided by the following documents:


Course Faculty:

Manfred Stommel, Ph.D., Professor  
Office: Bott Building for Nursing Education and Research, Office C-350  
Phone: 517-355-5123 (office)  
Email: stommel@msu.edu  
Office Hours: Tuesday 12:00-1:00 p.m. 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.

Instruction:

a. **Methodology:** Seminar discussion (major emphasis!), student weekly presentations, some lecture.

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:**


All required materials can be obtained from Spartan Bookstore located in the basement of Fee hall on campus ([http://www.msu.edu/dig/msumap/fee.html](http://www.msu.edu/dig/msumap/fee.html)); on the web at [http://www.spartanbook.com](http://www.spartanbook.com); by phone at 517.353.9560; by fax at 517.353.9827; by email at ccasec@msu.edu.

d. **Required Readings:**

case-control study of its effect on hospital-acquired influenza among patients. BMC Infectious Disease, 12, 30.


**Course website:** This is an on-line course that 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.

D2L Help Line
1.800.500.1554 (24 hrs, 7 days/week) or 1.517.355.2345 (24 hrs, 7 days/week). [www.D2L.msu.edu](http://www.D2L.msu.edu).

Always check with the D2L Help Line first!

**Frequently Called Telephone Numbers**

Simulation Lab, Life Sciences; 355-5765 (with answering machine)
Media Lab (Andy Greger) Life Sciences, 353-9020
College of Nursing Student Support Services A117 Life Sciences 353-4827.

**Course Evaluation:**

a. **Learning Assessments and Grading:**

- Tests (40%) – These in-class exams will cover all course content including the assigned readings. (Information on the in-class exams will be provided two weeks in advance.)
- Analysis of published research studies (30%):
  - Each week, students will be assigned to individual class presentations.
  - The presentations involve taking the lead in analyzing one of the assigned research articles, addressing: (1) the appropriateness of the study design in light of the stated study goals, the study implementation in the areas of (2) recruitment/sampling, (3) measurement/data collection, (4) data analysis, and (5) interpretation.
- A research proposal covering five segments with the following content (30%):
  - Statement of a research problem, containing research question(s), hypotheses, rationale and brief background discussion (maximum of 3 pages); particular emphasis is placed on clear identification of outcome variables and predictor/independent variables (5%).
  - Discussion of a chosen research design (maximum 3 pages), containing a clear description of a specific design and a rationale for its choice (10%).
  - Outline of a sampling and recruitment plan (maximum 2 pages), including both theoretical and practical rationales for particular sampling methods chosen (5%).
Statement of a Study Implementation Plan (3 pages maximum) containing a list of all resources necessary for the implementation of the study, a tentative budget, and specific timelines (5%).

Preparation of a UCRIHS human-subjects-approval application for the study (5%).

All research proposal segments will be presented and discussed in the seminar, after which the student will submit a modified/improved version for final evaluation.

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

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<td>60 – 64</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.

d. Research Proposal Outline: The following contains a brief outline of all the major segments in a research proposal. It should be used as a guideline in the preparation of the proposal segments for the seminar.

- Introduction: topic area and focus of the proposal plus literature review: a short summary of the substantive background issues and (if applicable) the methodological issues involved in past research.
- Rationale for your research problem: what problem does it address/solve, what research agenda does it advance, who would be interested in the knowledge generated by your study? etc.
- Theoretical Modeling: a conceptual or theoretical model, presented verbally or graphically, that specifies the relationships among MAIN concepts (and variables representing the concepts) that are part of the proposed research study.
- A full statement of the research problem, research questions and (if applicable) research hypotheses; the research question(s) should be clearly related to an explicit statement about the aims and purposes of the proposed study; questions or hypotheses include a clear formulation of the logical status of the variables involved, i.e., in the framework of the proposed study, do
the variables simply identify foci of observations/data collection (as in some descriptive studies) or do they function as dependent, intervening, independent or confounding variables within the theoretical model?

- (The following section is optional and may not apply:) Short description of past research efforts: past research projects and publications that led to the current application; preparatory work in measurement or sampling; past access to relevant target populations, etc.
- Measurement of key variables: a precise description of the outcomes measures chosen that represent the key concepts in the proposed research (including the measurement properties of chosen scales, data collection techniques, handling of known measurement problems, such as recall bias, etc.)
- Research design: a detailed description of the research design with a rationale for the chosen design:
  - Is the design cross-sectional or longitudinal, how many observations on the study participants, etc.
  - Prospective or retrospective,
  - Experimental, quasi-experimental or non-experimental,
  - Relies on primary data or secondary data collection.
- Study Sample:
  - A detailed description of the target population,
  - Recruitment plan and sampling procedures,
  - Determination of initial sample size in light of likely subject attrition over the course of the study and required statistical power,
  - For intervention studies: a detailed description of subject assignment procedures, including randomization procedures,
  - A description of procedures to minimize subject attrition.
- Study Implementation:
  - A description of all major task categories involved in the implementation of the research project, including the suggested personnel for the various tasks, traveling, resource needs, etc.
  - Time table: a plan that specifies all major anticipated study phases and their likely duration.
- Data Analysis: an outline of an analysis plan that details suggested approaches to data analysis, statistical models employed, interpretative methods, software implementations to be used.
- A description of procedures to safeguard the rights of human subjects.

**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://www.vps.msu.edu/SpLife/gradrights.htm](http://www.vps.msu.edu/SpLife/gradrights.htm)); University guidelines for ethical research - published by the University Committee on Research Involving Human Subjects [UCRIHS]; available at [http://www.msu.edu/user/ucrihs/](http://www.msu.edu/user/ucrihs/); The MSU Guidelines for Integrity in Research and Creative Activities, [http://grad.msu.edu/all/ris04activities.pdf](http://grad.msu.edu/all/ris04activities.pdf) and specific principles for informal conflict management, in the Graduate Student Resource Guide (published by the Graduate School; available at [http://grad.msu.edu/conflict.htm](http://grad.msu.edu/conflict.htm)).

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.

- MSU Spartan Life Online: http://www.vps.msu.edu/Splife
- Information for MSU Students: http://www.msu.edu/current/index.html
- Academic Programs: 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
- Integrity of Scholarship and Grades: 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/ and/or the MSU Web site: 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 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

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

**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.
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| 1 | 5/17 | **Course introduction:**  
  - What is “science”?  
  - Components of a research design  
  - Extracting design components from published research studies  
  - Asking Researchable Questions  
  - Theoretical vs. practical choices | Texts:  
  - Shadish et al.: Chapter 1;  
  - Hulley et al., Chapters 1-2;  
  - Stommel & Wills, Chapter 2; |
| 2 | 5/24 | **Experimental vs. non-experimental sciences: where does nursing research fit?**  
  - Human action versus human behavior  
  - Causal explanations vs. motivational explanations  
  - Criteria for causal inference  
  - Internal and External Validity  
  - Causal inference from intervention and observational studies  
  - Generalizability of research studies | Texts:  
  - Shadish et al.: Chapter 1-2;  
  - Stommel & Wills, Chapter 3  
  
  Papers:  
  - Susser, 1991;  
  - Wikipedia:“Placebo”;  
  - Howick et al., 2013. |
| 3 | 5/31 | **Causal inference in experimental studies I:**  
  - Designs with separate control groups  
  - Factorial designs  
  - The logic of randomization  
  - Matching and randomization  
  - Threats to validity | Texts:  
  - Hulley et al., Chapters 10;  
  - Shadish et al.: Chapters 2, 8, pp. 246-266;  
  - Stommel & Wills, Chapter 4  
  
  Studies to be analyzed in class:  
  - Johannson et al., 2014;  
  - McQueen et al., 2013;  
  - Nolte et al., 2012;  
  - Teri et al., 2011 |
| 4 | 6/7 | **Causal inference in experimental studies II:**  
  - Repeated measures and repeated treatment designs  
  - Cross-over designs  
  
  Discussion of Student Research Problems | Texts:  
  - Hulley et al., Chapters 10;  
  - Shadish et al.: Chapter 8, pp. 266-269;  
  - Chapter 9;  
  - Stommel & Wills: Chapter 5  
  
  Studies to be analyzed in class:  
  - Bean et al., 2012;  
  - Chen et al., 2013;  
  - Cheng et al., 2014; |
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<tr>
<td>5</td>
<td>6/14</td>
<td>Causal inference in experimental studies III:</td>
<td>Texts: Hulley et al., Chapters 11, pp. 167-169; Shadish et al.: Chapter 8, pp.269-278; Chapters 9, 10; Papers: Craig et al. 2008; Guyatt et al., 2011; Nelson et al., 2012; Schulz et al. , 2010; (CONSORT) White et al., 2011</td>
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<td>6</td>
<td>6/21</td>
<td>Characteristics of quasi-experimental designs:</td>
<td>Texts: Shadish et al.: Chapters 4, 5, 6; Stommel &amp; Wills, 6-7; TREND Guidelines Studies to be analyzed in class: Ericson, 2012; Des Jarlais et al., 2004; (TREND) Forbes et al., 2006; Kirkland et al., 2012; Torre &amp; Daley, 2013</td>
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<td>7</td>
<td>6/28</td>
<td>Quantitative observational studies I:</td>
<td>Texts: Stommel &amp;Wills: Chapters 8-9; Hulley et al., Chapter 7 Studies to be analyzed in class: Baer et al., 2011; Engels et al., 2011; Messmer et al., 2013.</td>
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<td>8</td>
<td>7/5</td>
<td>MID-TERM EXAM (1 hour)</td>
<td>Covers material through 6/21 Texts: Hulley et al., Chapter 8; Stommel &amp;Wills: Chapters 10-11; Studies to be analyzed in class: Benet et al., 2012; Engels et al., 2011; Messmer et al., 2013;</td>
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<td>10</td>
<td>7/12</td>
<td>Quantitative observational studies III:</td>
<td>Texts and Papers: Hulley et al., Chapter 13; S&amp;W: Chapters 12, 18; STROBE Guidelines for reporting observational studies. Studies to be analyzed in class: Flegal et al., 2007; Stommel et Schoenborn, 2010; Stommel et al., 2004;</td>
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| 11   | 7/19 | Measurement and Instrument Development Studies:  
- Reliability and validity in measurement  
- Sensitivity, specificity, PPV, NPV  
- Instrument development studies  
- Mixed methodology studies | Texts:  
Hulley et al., Chapters 3, 5-6, 13;  
Shadish et al.: Chapters 2;  
Stommel & Wills, 13-15  
Studies to be analyzed in class:  
Brener et al., 2003;  
Stommel & Schoenborn, 2009;  
Stommel & Osier, 2014 |
| 12   | 7/26 | Key concepts in sampling  
- Units of analysis and definitions of populations  
- Samples and Populations  
- Types of Sampling: Convenience, systematic, Simple random, stratified random, Cluster sampling  
- Statistical Inference based on probability sampling: clusters, strata, weighting algorithms,  
- Statistical inference versus induction: types of generalizations  
- Sampling for Clinical Intervention Studies  
- Recruitment and retention of subjects | Texts:  
Hulley et al., Chapters 3, 5-6;  
Shadish et al.: Chapters 11-12;  
Stommel & Wills, Chapter 19-21  
Studies to be analyzed in class:  
Flegal et al., 2007;  
Vermes & Stommel, 2014 |
| 13   | 8/2  | Study Implementation:  
- Pilot testing  
- Developing study procedures, interviewer training  
- Quality control in research studies: Intervention fidelity, blinding, self-selection bias  
- Practical Sampling Issues  
- Preparation for data analysis: formatting, coding & cleaning data, handling missing data | Texts and papers:  
Hulley et al.: Chapter 14-17;  
Shadish et al.: Chapters 9, 10;  
Neumark et al., 2001; |
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<td>14</td>
<td>8/9</td>
<td><strong>FINAL EXAM (1 hour)</strong></td>
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<td>• Consent forms</td>
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<td>• High risk/institutionalized subjects</td>
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<td>• Using existing databases for recruitment purposes</td>
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<td>• Data management &amp; the rights of human subjects</td>
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<td>• Scientific integrity and the research process</td>
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<td>Research using existing data</td>
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<td>Principles of writing:</td>
<td>CONSORT standards TREND standards PCORI methodology standards</td>
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<td>• A journal article</td>
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<td>15</td>
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<td><strong>PRESENTATION AND DISCUSSION OF STUDENT RESEARCH PROPOSALS</strong></td>
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