

**College of Nursing  
Michigan State University**

**NUR 930: Methods in Clinical Research  
Course Syllabus  
Spring, 2004  
Wednesday, 9-11:50  
B109A Life Science Building**

**Faculty:**

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## **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 will be used to 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 on the one hand and research design demands on the other, since clinical research occurs in institutional settings that offer researchers limited control in shaping the evidence. In line with this focus on the feasibility of research in clinical settings, the relationship between practical aspects of research implementation and quality of evidence is 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.

## **Course Objectives:**

At the conclusion of the course, the student will be able to:

1. Analyze the strengths and limitations of research designs used most frequently in health care research.
2. Compare major methods of probability/non-probability sampling and techniques to calculate adequate sample size.
3. Identify data analysis strategies appropriate to specific research designs.
4. Critique research designs and data analytic strategies in published research studies.
5. Understand theoretical and practical issues related to the protection of the rights of human subjects in research.
6. Formulate strategies for research implementation including the development of study timelines, subject recruitment and retention, data management plans and methods to assure data quality.
7. Develop a research proposal.

## **Required Textbooks:**

Hulley, B., Cummings, S., Browner, W., Grady, D., Hearst, N. & Newman, T.B. *Designing Clinical Research*. Philadelphia, PA: Lippincott, Williams & Wilkins, 2001. (H et al.)

Shadish, W.R., Cook, T.D. & Campbell, D.T. *Experimental and Quasi-Experimental Designs for generalized causal Inference*. Boston, MA: Houghton Mifflin Company; 2002. (SC&C)

Stommel, M. & Wills, C. *Clinical Research: Concepts and Principles for Advanced Practice Nurses*. Philadelphia, PA: Lippincott, Williams & Wilkins; 2004. (S&W)

## Required Readings:

- Aiken, L.H., Clarke, S.P., Sloan, D.M., Sochalski, J & Silber J.H. (2002). Hospital nurse staffing and patient mortality, nurse burnout and job dissatisfaction. *Journal of the American Medical Association*, 288, 22, 16, 1987-93.
- Armstrong-Stassen, M., Cameron, S.J., Mantler, J. & Horsburgh, M.E. (2001). The impact of hospital amalgamation on the job attitudes of nurses. *Canadian Journal of Administrative Sciences*, 18, 3, 149-62.
- Beck, C.T. (1993). Teetering on the edge: A substantive theory of postpartum depression. *Nursing Research*, 42, 1, 42-8.
- Beck, C.T. (1997). Developing a research program using qualitative and quantitative research approaches. *Nursing Outlook*, 45, 6, 265-9.
- Beck, C.T. & Gable, R.K. (2000). Postpartum depression screening scale: development and psychometric testing. *Nursing Research*, 49, 5, 272-83.
- Beck, C.T. & Gable, R.K. (2001). Comparative analysis of performance of the postpartum depression screening scale with two other depression instruments. *Nursing Research*, 50, 4, 242-49.
- Becker, H.S. (1958). Problems of inference and proof in participant observation. *American Sociological Review*, 23, 6, 652-60.
- Casey, B.M., McIntire, D.D., & Leveno, K.J. (2001). The continuing value of the Apgar score for the assessment of newborn infants. *The New England Journal of Medicine*, 344, 7, 467-71.
- Clark, M.E., Lipe, A.W., & Bilbrey, M. (1998). Use of music to decrease aggressive behaviors in people with dementia. *Gerontological Nursing*, 24(7), 10-17.
- DeFloor, T. & Grypdonck, M.H.F. (2000). Do pressure relief cushions really relieve pressure? *Western Journal of Nursing Research*, 22, 3, 335-50.
- Duncan, K. & Pozehl, B. (1999). Effects of performance feedback on patient pain outcomes. *Clinical Nursing Research*, 9(4), 379-97.
- Fay, B. & Moon, J.D. (1998). What would an adequate philosophy of social science look like? Pp. 171-189 in: Klemke, E.D., Hollinger, R. & Rudge, D.W. (eds.). *Introductory Readings in the Philosophy of Science*. Amherst, NY: Prometheus Books.
- Fogg, L. & Gross D. (2000). Threats to validity in randomized clinical trials. *Research in Nursing & Health*, 23, 79-87.
- Foster-Fitzpatrick, L., Ortiz, A., Sibilano, H., Marcantonio, R., & Braun, L.T. (1999). The effects of crossed leg on blood pressure measurement. *Nursing Research*, 48, 105-108.
- Gremse, D.A., Greer, A.S., Vacic, J. & DiPalma, J.A. (2003). Abdominal pain associated with lactose ingestion in children with lactose intolerance. *Clinical Pediatrics*, 42, 4, 341-5.
- Gross D. & Fogg, L. (2001). Clinical trials in the 21<sup>st</sup> century: The case for participant-centered research. *Research in Nursing & Health*, 24, 530-9.
- Hutchinson, S.A. (2001). The development of qualitative research: Taking stock. *Qualitative Health Research*, 11, 505-521.
- Jakicic, J.M., Marcus, B.H., Gallagher, B.I., Napolitano, M. & Lang, W. (2003). Effect of exercise duration and intensity on weightloss in overweight, sedentary women: a randomized clinical trial. *Journal of the American Medical Association*, 290, 10, 1323-30.
- Lantz, P.M., Stencil, D., Lippert, M.T., Beversdorf, S., Jaros, L. and Remington, P.L. (1995). Breast and cervical cancer screening in a low-income managed care sample: The efficacy of physician letters and phone calls. *American Journal of Public Health*, 85, 6, 834-6.

- Lee, I-M, Rexrode, K.M., Cook, N.R., Manson, J.E., & Buring, J.E. (2001). Physical activity and coronary heart disease in women: Is "no pain, no gain" passe? *Journal of the American Medical Association*, 285, 11, 1447-54.
- Lusk, S.L., Ronis, D.L., Kazanis, A.S., Eakin, B.L., Hong, O., Raymond, D.M. (2003). Effectiveness of a tailored intervention to increase factory workers' use of hearing protection. *Nursing Research*, 52, 5, 289-95.
- Machlup, F. (1998). Are the social sciences really inferior? Pp. 135-153 in: Klemke, E.D., Hollinger, R. & Rudge, D.W. (eds.). *Introductory Readings in the Philosophy of Science*. Amherst, NY: Prometheus Books.
- McKenzie, I. & Wurr, C. (2000). Early suicide following discharge from a psychiatric hospital. *Suicide & Life - Threatening Behavior*, 31, 3, 358-363.
- Metheny, M.A. & Stewart, B.J. (2002). Testing feeding tube placement during continuous tube feedings. *Applied Nursing Research*, 15, 4, 254-8.
- Miles, M.S., Holditch-Davis, D., Eron, J., Black, B.P., Pedersen, C. & Harris, D.A. (2003). An HIV self-care symptom management intervention for African American mothers. *Nursing Research*, 52, 6, 350-60.
- Mundinger, M.O., Kane, R.L., Lenz, E.R., Totten, A.M., Tsai, W-Y., Cleary, P.D., Friedewald, W.T., Siu, A.L. & Shelanski, M.L. (2000). Primary care outcomes in patients treated by nurse practitioners or physicians: A randomized trial. *Journal of the American Medical Association*, 283, 1, 59-68.
- Oman, R.F. & Oman, K.K. (2003). A case-control study of psycho-social and aerobic exercise factors in women with symptoms of depression. (2003). *The Journal of Psychology*, 137, 1, 338-50.
- Pallikkathyayil, L., Crighton, F., & Aaronson, L.S. (1998). Balancing ethical quandaries with scientific rigor: Part 1. *Western Journal of Nursing Research*, 20, 388-393.
- Pallikkathyayil, L., Crighton, F., & Aaronson, L.S. (1998). Balancing ethical quandaries with scientific rigor: Part 2. *Western Journal of Nursing Research*, 20, 501-507.
- Sandelowski, M. (2000a). Whatever happened to qualitative description? *Research in Nursing & Health*, 23, 334-340.
- Sandelowski, M. (2000b). Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Research in Nursing & Health*, 23, 246-255.
- Sandelowski, M. (2001). Real qualitative researchers do not count: The use of numbers in qualitative research. *Research in Nursing & Health*, 24, 230-240.
- Sidani, S., Epstein, D.R., and Moritz, P. (2003). An alternative paradigm for clinical nursing research: an exemplar. *Research in Nursing & Health*, 64, 3, 244-55.
- Stommel, M., Given, C.W., & Given, B.A. (1998). Racial differences in the division of labor among primary and secondary caregivers. *Research on Aging*, 20, 1, 242-257.
- Stommel, M., Given, B.A. & Given, C.W. (2002). Depression and functional status as predictors of death among cancer patients. *Cancer*, 94, 10, 2719-27.
- Stommel, M. & Wills, C. (2004). Testing the effectiveness of nursing interventions: Clinical trials are still useful (and sometimes indispensable). Submitted to: *Research in Nursing & Health*.
- Susser, M. (1991). What is a cause and how do we know one? A grammar for pragmatic epidemiology. *American Journal of Epidemiology*, 133, 7, 635-48.
- Tsubono, Y., Nishino, Y., Komatsu, S., Hsieh, C-C., Kanemura, S., Tsuji, I., Nakatsuka, H., Fukao, A., Satoh, H. & Hisamichi, S. (2001). Green tea and the risk of gastric cancer in Japan. *The New England Journal of Medicine*, 344, 9, 632-6.

Wassem, R. & Dudley, W. (2003). Symptom management and adjustment of patients with multiple sclerosis: A 4-year longitudinal intervention study. *Clinical Nursing Research*, 12, 1, 102-117.

### **Recommended Readings:**

- Brink, P.J. and Wood, M.J. *Advanced Design in Nursing Research*. Thousand Oaks, CA: Sage Publications, Inc.
- Brink, P.J. & Wood, M.J. *Basic Steps in Planning Nursing Research: From Question to Proposal*. (5<sup>th</sup> ed.). Boston, MA: Jones and Bartlett Publishers; 2001.
- Converse, J.M. & Presser, S. *Survey Questions: Handcrafting the Standardized Questionnaire*. Newbury park, CA: Sage Publications; QASS 63; 1986.
- Ellis, M.V. (1999). Repeated measures designs. *The Counseling Psychologist*, 27(4), 552-78.
- Fowler, F.J., *Survey Research Methods (3<sup>rd</sup> Edition)*. Thousand Oaks, CA: Sage Publications, 2001. (F)
- Kane, R., *Understanding Health Outcomes*. Gaithersburg, Md: Aspen Press, 1997
- Henry, G. T. *Practical Sampling*. Newbury park, CA: Sage Publications; 1990.
- Lavrakas, P.J. *Telephone Survey Methods: Sampling, Selection and Supervision*. Thousand Oaks, CA: Sage Publications, 1993
- Lipsey, M.W. and Wilson, D.B. *Practical Metanalysis*. Thousand Oaks, CA: Sage Publications, 2000
- MacMahon B. and Trichopoulos, D. *Epidemiology: Principles & Methods*. (2<sup>nd</sup> ed.). Boston, MA: Little, Brown and Company; 1996
- Mangione, T.W. *Mail Surveys: Improving the Quality*. Thousand Oaks, CA: Sage Publications, 1995
- Mulay, M. *A Step by Step Guide to Clinical Trials*. Boston, MA: Jones and Bartlett, 2001
- Miles, M.B. and Huberman, A.M. *Qualitative data analysis: an expanded sourcebook*. Thousand Oaks, CA: Sage Publications, 1994.
- Munhill, P.L. *Nursing Research: A Qualitative Perspective*. Boston, MA: Jones and Bartlett Publishers, Inc., 2001
- Polit, D.F., & Beck, C.T. (2004). *Nursing research: Principles and methods (7th ed.)*. Philadelphia: Lippincott.
- Tashakkori, A., and Teddlie, C., *Mixed Methodology: Combining Qualitative and Quantitative Approaches*. Thousand Oaks, CA: Sage Publications, 1998.

**Instructional method:**

some lecture, seminar discussion (major emphasis!), student presentations.

**Methods of evaluation:**

1. Tests (60 %) – These in-class exams will cover lecture material and assigned readings. (See separate hand-out for detailed information on the mid-term and final exams.)
2. Five written, separate segments of a research proposal with the following content:
  - a. 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 (10%).
  - b. Discussion of a chosen research design (maximum 2 pages), containing a clear description of a specific design and a rationale for its choice (10%).
  - c. Outline of a sampling and recruitment plan (maximum 2 pages), including both theoretical and practical rationales for particular sampling methods chosen (10%).
  - d. Statement of a Study Implementation Plan (4 pages maximum) containing a list of all resources necessary for the implementation of the study, a tentative budget, and specific timelines (10%).
  - e. Preparation of a UCRIHS human subjects approval application form for the study (10%).

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.

## 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 specify the 'level' (B&W) of the question(s); 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:
  - 1) is the design cross-sectional or longitudinal, how many observations on the study participants, etc.
  - 2) prospective or retrospective,
  - 3) experimental, quasi-experimental or non-experimental,
  - 4) relies on primary data or secondary data collection.
- Study Sample:
  - 1) a detailed description of the target population,
  - 2) recruitment plan and sampling procedures,
  - 3) determination of initial sample size in light of likely subject attrition over the course of the study and required statistical power,
  - 4) for intervention studies: a detailed description of subject assignment procedures, including randomization procedures,
  - 5) a description of procedures to minimize subject attrition.
- Study Implementation:
  - 1) 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.

- 2) 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.

## Course Calendar:

Week	Date	Topic	Reading/Assignment/Activity
1	1/14	<u>Course introduction:</u> <ul style="list-style-type: none"> <li>• What is “science”?</li> <li>• Components of a research design</li> <li>• Extracting design components from published research studies</li> <li>• Asking Researchable Questions</li> <li>• Theoretical vs. practical choices</li> </ul>	<u>Texts:</u> SC&C: Chapter 1; S&W: Chapter 2; H et al., Chapters 1-2.
2	1/21	<u>Are nursing researchers social or natural scientists?</u> <ul style="list-style-type: none"> <li>• Causal inference</li> <li>• Motivational understanding</li> <li>• Human action versus human behavior</li> <li>• Criteria for “correct” causal inference</li> <li>• Criteria for “correct” interpretation of human understandings</li> <li>• Induction versus deduction</li> <li>• Internal and External Validity</li> </ul>	<u>Texts:</u> SC&C: Chapter 1; S&W: Chapters 2, 3, 12;  <u>Papers:</u> Fay & Moon (1998); Hutchinson (2001); Machlup (1998); Sandelowski (2001); Susser (1991);
3	1/28	<u>Causal inference in experimental studies I:</u> <ul style="list-style-type: none"> <li>• Designs with separate control groups</li> <li>• The logic of randomization</li> <li>• Threats to validity</li> </ul>	<u>Texts:</u> H et al., Chapters 10; SC&C: Chapters 2, 8, pp. 246-266; S&W: Chapters 3-4; <u>Studies to be analyzed in class:</u> Jakicic et al., 2003; Lantz et al., 1995; Lusk et al., 2003; Munding et al., 2000;
4	2/4	<u>Causal inference in experimental studies II:</u> <ul style="list-style-type: none"> <li>• Repeated measures and repeated treatment designs</li> <li>• Cross-over designs</li> </ul> <u>Discussion of Student Research Problems</u>	<u>Texts:</u> H et al., Chapters 10; S&W: Chapters 3-4; SC&C: Chapter 8, pp. 266-269; <u>Studies to be analyzed in class:</u> Clark et al., 1998; Gremse et al., 2003; Miles et al., 2003;

<b>Week</b>	<b>Date</b>	<b>Topic</b>	<b>Reading/Assignment/Activity</b>
5	2/11	<u>Causal inference in experimental studies III:</u> <ul style="list-style-type: none"> <li>• Practical Problems in Intervention Studies and Clinical Trials</li> <li>• Strategies to improve validity of intervention studies</li> <li>• Ethics of intervention studies</li> </ul>	<u>Texts:</u> H et al., Chapters 11, pp. 167-169; S,C & C: pp.269-278; Chapters 9, 10; S&W: Chapters 5 <u>Papers:</u> Fogg & Gross, 2000; Gross & Fogg, 2001; Sidani et al., 2003; Stommel & Wills, 2004;
6	2/18	<u>Characteristics of quasi-experimental designs:</u> <ul style="list-style-type: none"> <li>• Non-equivalent control group designs</li> <li>• Interrupted time-series designs</li> <li>• Causal Inference without random assignment</li> </ul>	<u>Texts:</u> S&W: Chapters 6-7; SC&C: Chapters 4, 5, 6; <u>Studies to be analyzed in class:</u> Duncan & Pozehl, 2000; Foster-Fitzpatrick et al. 1999; Metheny & Stewart, 2002;
7	2/25	<u>Quantitative observational studies I:</u> <ul style="list-style-type: none"> <li>• Cohort studies</li> <li>• Selection Criteria</li> <li>• Retrospective and prospective design</li> <li>• Attrition problems</li> </ul> <u>Discussion of Student Research Designs</u>	<u>Texts:</u> S&W: Chapters 8-9; H et al., Chapter 7; <u>Studies to be analyzed in class:</u> Casey et al., 2001; Lee et al., 2001; Tsubono et al., 2001; Stommel et al., 2002;
8	3/3	<b>MIDTERM EXAM</b>	Covers material through 2/20
	3/8-3/12	<b>SPRING BREAK</b>	
9	3/17	<u>Quantitative observational studies II:</u> <ul style="list-style-type: none"> <li>• Case Control studies</li> <li>• Selection Criteria</li> <li>• Retrospective and prospective design</li> <li>• Recall bias</li> </ul>	<u>Texts:</u> H et al., Chapter 8; S&W: Chapters 10-11; <u>Studies to be analyzed in class:</u> McKenzie & Wurr, 2000; Oman & Oman, 2003; Stommel et al., 1998;
10	3/24	<u>Quantitative observational studies III:</u> <ul style="list-style-type: none"> <li>• Survey designs: cross-sectional, longitudinal, panel studies</li> </ul> <u>Exploratory designs:</u> <ul style="list-style-type: none"> <li>• Instrument development studies</li> <li>• Mixed methodology studies</li> </ul>	<u>Texts and Papers:</u> H et al., Chapter 13; S&W: Chapters 12, 18; Sandelowski (2000b); Sandelowski (2001); <u>Studies to be analyzed in class:</u> Armstrong-Stassen et al., 2001; Beck (1993); Beck (1997); Beck & Gable (2000); Beck & Gable (2001);

Week	Date	Topic	Reading/Assignment/Activity
11	3/31	<p><u>Key concepts in sampling</u></p> <ul style="list-style-type: none"> <li>• Units of analysis and definitions of populations</li> <li>• Samples and Populations</li> <li>• Types of Sampling</li> <li>• Statistical Inference based on probability sampling</li> <li>• Statistical inference versus induction: types of generalizations</li> <li>• Meta-analysis</li> <li>• Practical Sampling Issues</li> <li>• Recruitment and retention of subjects</li> </ul>	<p><u>Texts:</u>  H et al., Chapters: 3, 5-6, 13;  SC&amp;C: Chapters 11-13;  S&amp;W: Chapters 19-21; pp. 273-275;</p>
12	4/7	<p><u>Study Implementation:</u></p> <ul style="list-style-type: none"> <li>• Pilot testing</li> <li>• Developing study procedures, interviewer training and supervision</li> <li>• Quality control in research studies</li> <li>• Preparations for data management and analysis: formatting, coding and cleaning data, dealing with missing data</li> </ul> <p><u>Safeguarding the rights of human subjects in research:</u></p> <ul style="list-style-type: none"> <li>• High risk subjects</li> <li>• Approaching human subjects</li> <li>• Using existing data bases on human subjects for recruitment purposes</li> <li>• Data management issues related to safeguarding the rights of human subjects in research</li> <li>• Use of secondary data and the rights of human subjects</li> <li>• Scientific integrity and the research process</li> </ul>	<p><u>Texts and papers:</u>  H et al.: Chapter 14 – 17;  SC&amp;C: Chapters 9, 10;  S&amp;W: Chapter 23, 24;  Pallikkathyayil et al, 1998 (Part 1&amp;2);</p> <p>Midwest Nursing Research Society Guidelines for Scientific Integrity;  American Psychological Association Guidelines for Ethical Conduct;  Michigan State University Committee on Research Involving Human Subjects, website:  <a href="http://www.apa.org/ethics/code.html">http://www.apa.org/ethics/code.html</a>  MSU Procedures on Allegations Involving Misconduct in Research and Creative Activities, website:  <a href="http://www.msu.edu/dig/miscon/">http://www.msu.edu/dig/miscon/</a></p>

Week	Date	Topic	Reading/Assignment/Activity
13	4/14	<u>Data analysis strategies: Overview of data analysis options and examples for interpretation I:</u> <ul style="list-style-type: none"> <li>• Analysis of experimental vs. non-experimental data</li> <li>• Cross-sectional vs. longitudinal data (including panel studies and time series data)</li> <li>• Data with continuous outcome measures</li> <li>• Data with categorical outcome measures</li> </ul>	<u>Texts:</u> H et al.: Chapter 17; SC&C: Chapters 9, 10; S&W: Chapter 23;  TBA: Special Assignments
14	4/21	<u>Data analysis strategies: Overview of data analysis options and examples for interpretation I:</u> <ul style="list-style-type: none"> <li>• Time to event/survival data</li> <li>• Data with matched study samples</li> <li>• Data with complex sampling designs</li> <li>• Measurement models</li> </ul> <u>Principles of writing:</u> <ul style="list-style-type: none"> <li>• A proposal</li> <li>• A journal article</li> </ul> <u>Discussion of Student Sampling and Study Implementation Plans</u>	<u>Texts:</u> H et al., Chapter 19; S&W, Chapter 26;
15	4/28	FINAL EXAM	Covers material through 4/10
16	5/3	FINALS WEEK	