Methods in Clinical Research

NUR 930 Credits 3
Wednesday, 1:50-4:40
500A West Fee Hall
Spring, 2010

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.

Course Objectives:

At the conclusion of the 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.

Prerequisites: None

Co-Requisites: None

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


Faculty:
Debra Schutte, PhD, RN
Associate Professor
424A West Fee Hall
(517) 43-4310
debra.schutte@hc.msu.edu

Required Texts


Methods in Clinical Research  
NUR 930 Credits 3  
Wednesday, 1:50-4:40  
500A West Fee Hall  
Spring, 2010  
Additional Course Content

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 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, and data analysis issues in the face of ‘incomplete’ clinical data sets.

Additional Course Objectives:

At the conclusion of the course, the student will be able to:
4. Analyze the strengths and limitations of research designs used most frequently in health care research.
5. Compare major methods of probability/non-probability sampling and techniques to calculate adequate sample size.
6. Critique research designs and data analytic strategies in published research studies.
7. Discuss theoretical and practical issues related to the protection of the rights of human subjects in research.
8. Formulate strategies for research implementation including the development of study timelines, subject recruitment and retention, data management plans and methods to assure data quality.
9. Develop a research proposal.
Course Requirements & Grading Summary

35%  **Methods Section Drafts and Mini Presentations (105 points)**
Specific Aims/Significance (15 points)
Conceptual Framework (15 points)
Research Design (15 points)
Sample & Setting (15 points)
Instruments (15 points)
Procedures-recruitment and data collection (15 points)
Data Management and Analysis (15 points)

32%  **Research Methods Formal Class Presentation (95 points)**

33%  **Research Methods Paper (100 points)**

Your final course grade is based upon the total points earned during the semester, according to the following criteria

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<thead>
<tr>
<th>Points</th>
<th>%</th>
<th>GRADE</th>
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<tbody>
<tr>
<td>270-300</td>
<td>90 – 100</td>
<td>4.0</td>
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<tr>
<td>255-269</td>
<td>85-89</td>
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<td>240-254</td>
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<td></td>
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<td>(Minimum passing grade)</td>
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<td>225-239</td>
<td>75-79</td>
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<tr>
<td>210-224</td>
<td>70-74</td>
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<tr>
<td>195-209</td>
<td>65-69</td>
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<tr>
<td>180-194</td>
<td>60 – 64</td>
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<td>&lt;180</td>
<td>Below 60</td>
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<td>Week</td>
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<tr>
<td>1</td>
<td>1-13-10</td>
<td>Science and Production of Knowledge</td>
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<td>(On-line)</td>
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<td>2</td>
<td>1-20-10</td>
<td>Course Overview/Syllabus Overview of Research Methods Elements of a Research Proposal</td>
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<td>3</td>
<td>1-27-10</td>
<td>Problem, Purpose, and Specific Aims</td>
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<td>4</td>
<td>2-3-10</td>
<td>Conceptual Framework</td>
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<td>5</td>
<td>2-10-10</td>
<td>Research Design 1: Overview and Non-Experimental Designs</td>
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<td>6</td>
<td>2-17-10</td>
<td>Research Design 2: Experimental Designs</td>
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<td>7</td>
<td>2-24-10</td>
<td>Research Design 3: Quasi-Experimental Designs</td>
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<td>8</td>
<td>3-3-10</td>
<td>Research Design 4: Mixed Methods and Other Designs</td>
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<td>9</td>
<td>3-10-10</td>
<td>Spring Break</td>
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<tr>
<td>10</td>
<td>3-17-10</td>
<td>Sample and Setting</td>
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<td>11</td>
<td>3-24-10</td>
<td>Instrumentation</td>
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<td>12</td>
<td>3-31-10</td>
<td>Data Collection</td>
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<td>Week</td>
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<td>13</td>
<td>4-7-10</td>
<td>Data Management and Analysis</td>
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<td>14</td>
<td>4-14-10</td>
<td>Other Considerations (Potential problems/alternative plans; Limitations; Human Subjects)</td>
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<td>15</td>
<td>4-21-10</td>
<td>Seminar topic: TBD Paper and Presentation Workshop</td>
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<td>16</td>
<td>4-28-10</td>
<td>Final Presentations Course Evaluation</td>
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* Additional readings from primary sources will also be assigned most weeks.
Specific Assignment Information

Methods Section Drafts and Mini Presentations

The major end-product of our course is the development of the methods section of a research proposal that ideally will form the foundation for your dissertation research, NRSA proposal or other grant application activities. The Methods Section Drafts and corresponding Mini Presentations are designed to assist you to incrementally develop your research proposal. The following elements of the research proposal will be drafted and presented during the semester according to the following schedule:

1) Specific Aims/Significance pages: 1/20/10
2) Conceptual Framework pages: 2/3/10
3) Research Design paragraph: 3/3/10
4) Sample & Settings sections: 3/17/10
5) Instruments section: 3/24/10
6) Recruitment and Data collection procedures: 3/31/10
7) Data Management and Data Analyses sections: 4/7/10

On the due date, students are expected to hand in the draft written section of each methods topic. In addition, students will present their plans for that particular methods topic in class, building a PowerPoint presentation that will form the basis of their Research Methods Formal Class Presentation. The Mini Presentations will provide the forum for our in-class discussion and workshop. In addition, you will receive instructor feedback on the written section to assist you in building your final Research Methods Paper. More detailed descriptions of the specific methods sections will be provided in class throughout the semester.

Methods Section drafts and corresponding Mini Presentations (15 points X 7) are worth 35% of the course grade, or 105 points.

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Research Methods Formal Class Presentation

Due 04/28/10 in class.

Students will share their final research methods plan in class as a 30 minute presentation (20 minute presentation; 10 minute questions & answers) supported by PowerPoint slides and appropriate handouts. The formal presentation should include the same elements as the Research Methods Paper. The student’s major professors and the Director of the Doctoral Program may be invited to class to provide additional opportunity for critique and discussion.

The Research Methods Formal Class Presentation is worth 33% of the course grade, or 95 points.
Due 04/28/10 in class.

The Research Methods Paper is your opportunity to formulate and describe a research plan to address your emerging research questions. The final Research Methods Paper should include the following elements:

1. Specific Aims, 1 page. (10 pts).
2. Significance and Impact of Research, 1 page (10 points)
3. Conceptual Framework for proposed research, 2 pages (10 pts).
4. Methods Section, 7-10 pages (60 points):
   a. Design
   b. Sample and Setting
   c. Instrumentation
   d. Procedures (Recruitment and Data Collection)
   e. Data Management and Data Analysis
   f. Limitations
5. References (10pts).

The Research Methods Paper will be evaluated for both content and mechanics; see General Assignment Information for formatting guidelines.

The Research Methods Paper is worth 33% of the course grade, or 100 points.

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General Assignment Information

Written Assignments: All written assignments should be completed in Microsoft Word using the following guidelines: Arial 11-point font, 1 inch margins, and single-spaced. These guidelines are consistent with NIH grant application requirements. All written assignments and presentations should be completed using APA format (6th edition).

Additional guidelines about writing quality: All assignments will be evaluated for both quality of content and quality of presentation/mechanics, including appropriate citation of sources. Don’t forget to use spell-check, proofread, and revise! The best strategy to assess the quality of the content of your writing is to use a multi-step writing process. Outline, draft, verify that the organization is evident, verify that you actually did what the assignment requires, have a peer review and critique, incorporate suggestions, and revise!

Deadlines: Deadlines are important to help you plan your work and to allow adequate time to receive instructor feedback. Exceptions can be made for exceptional circumstances, if the request is handled proactively and in a professional manner. Without prior approval, late assignments will lose 10% of the points per week late (prorated daily). Assignments will not be accepted more than one week following the deadline.
Other Relevant 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 Student handbook  [http://nursing.msu.edu/handbooks.asp](http://nursing.msu.edu/handbooks.asp)
- Information for Current Students—including Rights, Responsibilities and Regulations for Students [http://www.msu.edu/current/index.html](http://www.msu.edu/current/index.html)
- Academic Programs [http://www.reg.msu.edu/UCC/AcademicPrograms.asp](http://www.reg.msu.edu/UCC/AcademicPrograms.asp)