Guidelines for Master’s Paper Case Study Options

(Approved MEC April 2012)

**Does a Case Study require IRB or HIPPA approval?**

A case study may be a report of treatment (including innovative treatment, e.g., surgery), and, as such, does not meet the Common Rule definition of research (a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge).

**If any of the following is present, the activity is considered research rather than a case study (and would require IRB approval) if:**

- There is a plan to perform the treatment on some individuals but not on others.
- Investigational drug(s) or device(s) are involved (off-label use of an approved drug or device for the sake of an individual patient does not constitute research).
- There is a clear intent before treating the patient to use systematically collected data that would not ordinarily be collected in the course of clinical practice in reporting and publishing the case study.
- There is intent to manipulate medications (even approved ones) to determine maximum effectiveness, or to test if they work consistently well.
- Extra tests are conducted for the sake of reportability.
- There is a protocol/study plan.
- Records or data sheets are maintained separate from clinical records (particularly with identifiers).
- The primary purpose is to answer a research question, not to provide care.
- There is a possibility that the treatment might yield a case series if it is effective in others (e.g., testing a hypothesis).

Case studies may be published; the published report must be descriptive, not analytical.

Case studies that contain no PHI (i.e., health information paired with identifiers) do not need to be reviewed by the IRB or the HIPAA Privacy Board. Neither HIPAA Authorization nor a waiver of HIPAA authorization is required. Case studies that contain identifiers will be reviewed by the Privacy Board, which will determine the need for authorization. (Topic 30.23 [Office of Human Research Ethics](#))
Guidelines for Case Study Option 1

Clinically Focused Case Study

*Purpose:* In clinical practice, the case study is a critically, thoughtfully and thoroughly described account of a patient and/or family’s experience with diagnosis and treatment recommendations presented within an evidence-based context.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>
| I. Introduction | - Introduce the issues being highlighted or addressed by the case  
- Identify the rationale for why this case is important to nursing  
- Describe the background of the case, including the nature, scope, and significance of the underlying illness |
| II. Review of the Literature | - Summarize the current literature related to the clinical problem.  
- Compare and contrast the recent currently accepted treatments, guidelines, or protocols, and/or solutions to the clinical issue |
| III. Physical, Pathophysiological, Pharmacological or Psychological Basis of Diagnosis, Treatment or Intervention | - Describe the theoretical framework and/or scientific bases that provide the rationale for the diagnosis, treatment or intervention. |
| IV. Case Details for a Clinical Case | Using the professional literature and/or conceptual/theoretical framework:  
- Describe, in considerable detail, the nature of the case: chief or initial complaint; initial physical and/or psychosocial assessment and key findings; possible treatments; actual treatments the patient received; complicating factors (i.e. those features of the case that compromised, obstructed or impeded treatment; resource advantages or limitations (financial or insurance) or other resource issues that influenced care; patient status at follow-up. |
| V. Analysis & Discussion for Clinical Case | - Identify problems with the current treatment guidelines with regard to this particular case  
- Present treatment or other implications of the case. This will include key points that are illustrated in the case and helpful for clinicians to know.  
- Present “lessons learned” in caring for this patient (or addressing this systems problem). |
| VI. Expected Outcomes | - Describe the specific and measurable expected outcomes of your proposed management.  
- Quantify your expectations and support your expectations with evidence from published peer-reviewed scientific literature. |
| VII. Conclusions | - Briefly describe your conclusions. Conclusions should flow directly from what has been previously been presented. Conclusions are typically a synthesis or concise summary. |
| VIII. References | - Complete list in APA format |
| VII. Appendices (as applicable) | - Consent Form, if applicable  
- Tables and Figures  
- Charts and Diagrams  
- IRB approval, if applicable |

[http://www.sagepub.com/journalsProdManSub.nav?prodId=Journal201493](http://www.sagepub.com/journalsProdManSub.nav?prodId=Journal201493)
Guidelines for Case Study Option 2  
Health Care Systems Focus

Purpose: Case studies provide nurses in clinical and non-clinical roles with examples of possible solutions to challenging problems in clinical practice or systems of health care delivery. In health care systems these case study concepts are applied to an organization’s experience with a systems problem.

| I. Introduction | - Introduce issue, concern or system problem being highlighted  
|                 | - Identify the rationale for why this case is important to nursing  
|                 | - Describe the background of the case, including the nature, scope, and significance of the underlying systems problem or challenge |
| II. Review of the Literature | - Summarize the current literature related to the identified problem.  
|                       | - Compare and contrast the recent currently accepted treatments, guidelines, or protocols, and/or solutions to the clinical issue or systems problem. |
| III. Systems Basis for Solution | - Describe the theoretical framework and/or scientific bases that provide the foundational structure of the issue and/or solution. |
| IV. Methods | - Describe the methods used to investigate the problem.  
|             | - Describe data collection procedures.  
|             | - Identify and describe at least two competing or alternative evidence-informed approaches or solutions for addressing the systems problem.  
|             | - Develop and describe a simple framework for critiquing the approaches or solutions. This may include the use of 3 to 5 criteria for evaluating the approaches, such as cost, feasibility and effectiveness. |
| V. Analysis & Outcomes of Health Care Systems Case | - Critique the proposed approaches or solutions to the health care systems problem using your evaluation criteria and available published peer-reviewed research literature.  
|             | - Select a strategy for addressing the problem based on your assessment. Defend your selection.  
|             | - Identify the potential barriers to success of implementing your solution. |
| VI. Expected Outcomes | - Describe the specific and measurable expected outcomes of your proposed solution(s).  
|                  | - Quantify your expectations and support your expectations with evidence from published peer-reviewed scientific literature. |
| VII. Conclusions | - Briefly describe your conclusions. Conclusions should flow directly from what has been previously been presented. Conclusions are typically a synthesis or concise summary. |
| VIII. References | - Complete list in current APA format or other format as agreed upon by the committee |

[http://www.sagepub.com/journalsProdManSub.nav?prodlId=Journal201493](http://www.sagepub.com/journalsProdManSub.nav?prodlId=Journal201493)