SOUTHEAST MISSOURI STATE UNIVERSITY

DEPARTMENT OF NURSING

MASTER OF SCIENCE IN NURSING

THESIS GUIDELINES

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1998-99
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CHAPTER I

INTRODUCTION

A thesis, derived from the investigation of a nursing problem pertinent to families in rural settings, may be selected as the capstone experience required for graduation from the MSN Program. The nursing faculty believe that the thesis experience prepares the student with the skills to identify researchable problems and design and implement research studies. This investigation can emerge from the student's own identification of a problem or the replication of a previous research study.

The following thesis guidelines are intended to direct graduate nursing students completing the thesis capstone option. Students are encouraged to consult these guidelines as they progress through various stages of thesis development. Although these guidelines minimize the possibility for misunderstanding or uncertainty concerning preparation and submission of the thesis, they are not designed to answer all questions.

The guidelines supplement information in the current Graduate Bulletin, but for matters not addressed in either source, the student must consult the most current APA Publication Manual especially on specific matters of style or format. Before the final revision, the student should resolve any questions with the Thesis Chairperson and, if necessary, with the Department of Nursing’s (DON) Director of Graduate Studies and/or the Dean of the School of Graduate Studies. Those persons not meeting the final deadline will be automatically deleted from the graduation list. EACH CANDIDATE, NOT THE FACULTY ADVISOR OR THESIS CHAIRPERSON, IS RESPONSIBLE FOR MEETING GRADUATE SCHOOL REQUIREMENTS AND DEADLINES. Deadlines are published each semester at the School of Graduate Studies website http://www.semo.edu/gradschool/deadlines.htm.

The formal guidelines were developed by the graduate nursing faculty during the Spring Semester, 1998. Faculty members holding graduate status and the Dean of the School of Graduate Studies participated in the preparation by reviewing and approving the guidelines. The guidelines were revised by the DON Director of Graduate Studies in Summer 2011 to reflect changes in University, Graduate School, and MSN program policies and procedures related to the thesis process. Students may access a copy of the Thesis Guidelines from the DON’s homepage: http://www.semo.edu/nursing/.

Placement in the Graduate Program

The core course NS-620/Advanced Nursing Research Methods and Designs provides content on the critical analysis of nursing research and the process of scientific inquiry. Emphasis is on problem identification, design methodology, and analysis. Course activities are designed to facilitate the investigation of issues in advanced nursing practice with families in rural settings.

NS-694/Thesis is the course in which students complete their thesis. STUDENTS SHOULD BE CERTIFIED FOR CANDIDACY AND HAVE SUCCESSFULLY DEFENDED THEIR THESIS PROPOSAL BEFORE REGISTERING FOR THESIS CREDIT HOURS. THE UNIVERSITY REQUIRES AN INITIAL ENROLLMENT IN THESIS (NS-694) OF 3 CREDIT HOURS. Credit for the thesis work will be assigned to the semester in which the student has successfully defended the thesis by completing the Oral
Examination (GR-699). Students should be enrolled for thesis credit during the semester in which they plan to defend their thesis and graduate. **IF FOR ANY REASON THESIS HOURS HAVE BEEN COMPLETED PRIOR TO THE SEMESTER OF GRADUATION, A FEE EQUIVALENT TO 1 CREDIT HOUR WILL BE CHARGED IF THE STUDENT IS NOT ENROLLED IN ANY OTHER COURSEWORK.**

Pre- or co-requisites to enrolling in NS-694/Thesis are:

1. Candidacy (prerequisite);
2. NS-600/Theoretical Foundations of Nursing Practice (prerequisite);
3. NS-620/Advanced Nursing Research Methods & Designs (prerequisite);
4. NS-638/Primary Care I Family Health or NS643 Advanced Nursing Roles Nurse Educator (co-requisite);
5. Successful defense of thesis proposal (prerequisite); and
6. Receipt of completed "Topic Approval Sheet for Thesis or Creative Project" from the Dean of the School of Graduate Studies (see Appendix A).

**Thesis Topics**

The following points should be considered during the process of selecting a thesis topic. They are:

1. Relevance to advanced nursing practice in rural areas and expectation of contribution to existing knowledge in the specific area selected.

2. Individual interest of the graduate student.

3. Depth and breadth of the topic should reflect graduate level yet be able to be completed within a reasonable length of time.

Faculty will assist in determining that the thesis topic and the planned approach are realistic and conform to the resources likely to be available to the student.
The following checklist provides an overview of the activities involved in completion of the thesis. Students are encouraged to periodically refer to this checklist:

1. Prepare written PROBLEM STATEMENT.

2. Submit written PROBLEM STATEMENT to the prospective Thesis Chairperson ask for advice regarding Thesis Committee Members and obtain signatures of Thesis Chairperson on the "Topic Approval Sheet for Thesis or Creative Project" (obtained from the Office of Graduate Studies website).

3. Submit written PROBLEM STATEMENT to prospective Second Thesis Committee Member and obtain signature on the "Topic Approval Sheet for Thesis or Creative Project."

4. Submit "Topic Approval Sheet for Thesis or Creative Project" and PROBLEM STATEMENT to the Dean of the School of Graduate Studies for topic approval and appointment of Third Thesis Committee Member. You may request a specific faculty member as the third committee member if that individual holds graduate faculty status and is not nursing faculty. This request should be made in memo format and submitted via email to the Dean of the School of Graduate Studies. It is advantageous to seek support from the prospective third committee member prior to submitting the appointment request.

5. Complete CHAPTERS I, II, and III of thesis (proposal format). The detail of CHAPTER II (Review of the Literature) may vary prior to defense.


7. Consult with Thesis Chairperson regarding changes in proposal after Thesis Committee meeting.

8. At the time the proposal is approved, obtain signatures of appointed Third Committee Member and DON Chairperson on the "Topic Approval Sheet for Thesis or Creative Project" and submit to the Dean of the School of Graduate Studies.

9. Read the "student friendly" version of the Policy for Research Involving Human Subjects (see Appendix B). This activity can be accomplished while the Committee Members are preparing for the thesis proposal defense.

10. Prepare "Summary of Research Involving Human Subjects" for College of Health and Human Services Committee on Research Involving Human Subjects (see Appendix C). This preparation can be conducted while the Committee Members are preparing for the thesis proposal defense.

11. If the proposed research is to be conducted in another institution, see page 23 for additional information.

12. Submit seven copies of the "Summary of Research Involving Human Subjects", consent form, and appropriate other relevant forms (i.e., instruments) and the original copy of the "Application for the Conduct of a Project Involving Human Subjects" (see Appendix D) to the Chair of the College Committee on Research Involving Human Subjects. Expect at least
a two - four week review process. Submissions should be planned so as to occur at least two weeks prior to the end of semester (prior to finals week). Holidays during the semester and semester breaks should also be considered. Submissions are to be made by the first or the fifteenth of each month.

13. Consult with Thesis Chairperson regarding the outcome of the review for protection of human rights.

14. If revisions in the proposal are required, ask the Thesis Chairperson to review the revisions, then submit the revised proposal to the Chairperson of the College Committee on Research Involving Human Subjects.

15. Upon receipt of Approval from the Dean of College of Health and Human Services to conduct research involving human subjects (see Appendix E), may begin data collection.

16. Register for Thesis Hours as appropriate after successful defense of thesis proposal.

17. Schedule (time and room) Thesis Committee meetings in consultation with Thesis Chairperson by contacting the DON Administrative Assistant.

18. At the direction of the Thesis Committee, schedule Oral Examination (time and room).

19. **SUBMIT COMPLETED COPY OF THESIS TO THESIS COMMITTEE MEMBERS AT LEAST TWO WEEKS PRIOR TO SCHEDULED ORAL EXAMINATION.**


21. At the time of the Oral Examination, obtain Thesis Committee Members signatures on the "Acceptance Sheet for Graduate Thesis" (see Appendix F). This sheet is to be held by the Thesis Chairperson until the thesis corrections are made and approved.

22. Correct thesis according to Chairperson's directions.

23. Obtain DON Chairperson’s signature on “Acceptance Sheet for Graduate Thesis”.

24. Submit the original copy of the approved thesis and the “Acceptance Sheet for Graduate Thesis” to the School of Graduate Studies.

**Role of the Student**

The student should assume personal responsibility for meeting the requirements and deadlines outlined by the Department of Nursing (DON) and the School of Graduate Studies and for developing the thesis under the guidance of the Thesis Committee.

The calendar of deadlines is available each semester on the School of Graduate Studies website at [http://www.semo.edu/gradschool/news/index.htm](http://www.semo.edu/gradschool/news/index.htm). These regulations and deadlines must be adhered to in writing the thesis. It is the student's responsibility to obtain current copies of the indicated materials.

The following schedule is recommended to provide the student with an organized approach to the Oral Examination (thesis defense) and will provide the best time for adequate
review by the Thesis Committee. However, the student must be expected to provide faculty with a copy of the thesis for review at least TWO WEEKS prior to expecting feedback from said faculty at any time during the thesis experience.

<table>
<thead>
<tr>
<th>Weeks Before Expected Date of Graduation</th>
<th>Final Semester Prior to Graduation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-enrollment or during enrollment at beginning of semester</td>
<td>Beginning of semester enroll in GR-699/ Master's Oral Examination and complete Intent to Graduate Form (see Appendix G).</td>
</tr>
<tr>
<td>12</td>
<td>Distribution of thesis draft to Thesis Chairperson.</td>
</tr>
<tr>
<td>10</td>
<td>Approval of thesis by Thesis Chairperson.</td>
</tr>
<tr>
<td>7</td>
<td>Oral Examination (thesis defense).</td>
</tr>
<tr>
<td>5</td>
<td>Approval of thesis (corrections and format) by Thesis Chairperson and Department Chairperson.</td>
</tr>
<tr>
<td>4</td>
<td>Original final copy of thesis and acceptance sheet of thesis to the School of Graduate Studies (see Appendix F).</td>
</tr>
</tbody>
</table>

Graduation dates are published on the Registrar’s website at http://www.semo.edu/registrar/academic_calendar.htm.

**Role of the Thesis Chairperson**

The Thesis Chairperson must hold a DON faculty appointment and graduate faculty status and have experience as a thesis chairperson or committee member (see Appendix P). **WHEN REQUESTING THAT A GRADUATE NURSING FACULTY MEMBER SERVE AS CHAIRPERSON, STUDENTS SHOULD SUBMIT A WRITTEN PROBLEM STATEMENT FOR THE PROSPECTIVE CHAIRPERSON TO REVIEW PRIOR TO ACCEPTING THE THESIS CHAIRPERSON ROLE.** Prior to approaching graduate nursing faculty members about their willingness to serve as the Second Thesis Committee Member, the advice and counsel of the Thesis Chairperson should be sought.

1. Serve as the Chairperson of the Thesis Committee, providing assistance and direction to the student so that a scholarly thesis results.

2. Sign the "Topic Approval Sheet for Thesis or Creative Project" (see Appendix A) indicating agreement to serve as Thesis Chairperson for a given student. **The**
decision to serve as Thesis Chairperson should be based upon prior review and interest in the student's identified research problem.

3. Assist the student in identifying the Second Thesis Committee Member.

4. With the student, discuss the thesis proposal, its scope, needed resources, and anticipated schedule of activities.

5. Meet with the student to periodically review written work for thesis proposal and provide feedback on its appropriateness and general quality.

6. Assist the student in identifying the appropriate approval process to conduct the research and to obtain the necessary consents.

7. When the thesis proposal is developed, assist the student to establish date, schedule room, and notify other Thesis Committee Members for approval of thesis proposal. **THESES COMMITTEE MEMBERS SHOULD RECEIVE A COMPLETE COPY OF THE THESIS PROPOSAL, INCLUDING FIRST THREE CHAPTERS OF THESIS (CHAPTER II REVIEW OF THE LITERATURE MAY VARY IN DETAIL), REFERENCE LIST, CONSENTS, AND INSTRUMENTS, AT LEAST TWO WEEKS PRIOR TO THE COMMITTEE MEETING.**

8. Review with the student the recommendations of the Committee to achieve thesis proposal approval.

9. Approve the prepared protocol (see Appendix C) for submission to the College of Health and Human Services Committee on Research Involving Human Subjects and/or the University Committee on Research Involving Human Subjects to receive approval to conduct the research.

10. Review with the student the recommendations from either committee regarding protection of human subjects.

11. Meet with the student and other Thesis Committee Members to discuss problems and progress as necessary.

12. Collaborate with student and other Thesis Committee Members in periodic reviews of written work and provide feedback on appropriateness and general quality of the work.

13. Assist the student to establish date of Oral Examination, to schedule room for Examination, and to notify other Thesis Committee Members.

14. Prior to the Oral Examination, review the completed thesis work and identify thesis-specific questions to be directed to the candidate.

15. Chair the Oral Examination. With other members of the Committee, conduct the examination and assess the candidate's achievement of the objectives of the program.

16. Counsel the student regarding the Oral Examination outcomes and any needed changes in the thesis.
17. **WHEN THESIS IS RE-SUBMITTED BY THE STUDENT, CHECK TO SEE THAT ALL NECESSARY CHANGES HAVE BEEN MADE AND APPROVE THESIS AS COMPLETED INCLUDING FORMAT AND CONSTRUCTION ASPECTS.** Committee Members may be asked to review these revisions.

18. File a grade for the thesis and inform the School of Graduate Studies that the Oral Examination has been successfully completed.
Role of Thesis Committee Member

The role of Thesis Committee Member may differ depending on the needs of the student and the Thesis Committee load of the faculty member. Research interests of nursing faculty with designation as having graduate faculty status and Thesis Chairperson status are available in Appendix P. The usual functions of Thesis Committee Members are as follow:

1. Review and critique the thesis as requested by the Thesis Chairperson and/or student.

2. Attend all meetings of the total Thesis Committee.

3. Serve as a resource person for particular aspects of the thesis as requested by the student (e.g., clinical content/expertise or design/methodology).

The Third Thesis Committee Member is appointed by the Dean of the School of Graduate Studies and may be better able to read and critique the thesis work with greater objectivity and impartiality than someone who is more actively involved the process. The Third (appointed) Committee Member and the DON Chairperson should withhold their signatures on the "Topic Approval Sheet for Thesis or Creative Project" (see Appendix A) until all members of the committee have met with the student and have agreed on the thesis proposal.

Thesis Committee

Prior to enrolling for NS-694/Thesis, the student's Thesis Committee must be approved by the Dean of the School of Graduate Studies. All members of the student's Thesis Committee must hold graduate faculty status at Southeast Missouri State University and be approved as Thesis Committee members by the Dean of the School of Graduate Studies. A Thesis Committee consists of a Thesis Chairperson and at least two other members. **STUDENTS MAY NOT ENROLL FOR THEESIS HOURS UNTIL SUCH TIME THAT THE THESIS COMMITTEE HAS BEEN APPROVED AND ALL PREREQUISITES HAVE BEEN MET.**

When the Thesis Chairperson and the Second Thesis Committee Member have agreed to serve, their signatures should be submitted to the Dean of the School of Graduate Studies, on the, "Topic Approval Sheet for Thesis or Creative Project" (see Appendix A). The Dean of the School of Graduate Studies will then appoint the Third Thesis Committee Member. The student and Thesis Chairperson will be notified of the name of the Third Thesis Committee Member by the Dean of the School of Graduate Studies (see Appendix H). The student will keep the "Topic Approval Sheet for Thesis or Creative Project" until successful defense of the thesis proposal. Upon successful defense of the thesis proposal, the Third Thesis Committee Member will sign the "Topic Approval Sheet for Thesis or Creative Project." The student will then seek the signature of the DON Chairperson and return the completed form to the School of Graduate Studies.

During the thesis process, students should schedule periodic conferences with the Thesis Chairperson to discuss progress on the thesis. **These conferences should be held at least monthly.**
Thesis Committee Meetings

The number and frequency of Thesis Committee meetings depends on the rate at which the student progresses. Some Thesis Chairpersons prefer to meet individually with the student for the period of time during the development of initial drafts. Other Thesis Chairpersons prefer to involve committee members in more meetings. The student and Thesis Chairperson should discuss the preferred method of Thesis Committee functioning.

The minimum number of Thesis Committee meetings with the Third Thesis Committee Member should be at least two. The first meeting should be after the first three chapters are written and the proposal is ready for review by the College Committee on Research Involving Human Subjects (thesis proposal defense). The second meeting should be at the time of the Oral Examination of the thesis. Conference rooms in Crisp Hall (CH-213, CH-331, and CH-208) are available upon request for committee meetings and Oral Examinations. Committee members should have any thesis materials at least two weeks prior to any meeting. Meetings during finals week of any semester are discouraged.
CHAPTER II

THESIS PROPOSAL DIRECTIVES

The thesis proposal is the formal document reviewed by the Thesis Committee for approval of the thesis requirement. The thesis proposal should acquaint the reader with the main elements of the research process up to the actual collection and analysis of data. In essence, the thesis proposal represents the first three chapters of the thesis. However, depending on the guidance of the Thesis Chairperson and the type of research being conducted (i.e. qualitative), CHAPTER II (Review of the Literature) may vary in depth and breadth at the time of the proposal defense.

Proposal and Thesis Formats

Although the nursing department specifies the most current edition of the *APA Publication Manual* as the manual of style for theses generated by graduate nursing students, the instructions in this guide supersede all manuals and EVERY STUDENT must follow these guidelines. Under no circumstances should the thesis follow a variety of manuals, and the student must be sure to use the current edition of the *APA Publication Manual*. No thesis manual, however, can answer all questions that arise. The student's Thesis Chairperson and Committee can answer most questions, but the student may consult the DON Director of Graduate Studies and/or the Dean for the School of Graduate Studies at any stage in the writing of the thesis.

The thesis should be written in a clear and concise style. Particular attention should be given to such matters as diction, grammar, punctuation, and consistency of style. As is commonly done, the thesis proposal is written in future tense, and the actual thesis, itself, is written in past tense.

The student is instructed to follow information found in these guidelines and then information in the current edition of the *APA Publication Manual*. Conflicting information should be resolved with the Thesis Chairperson.

The following preparatory information applies to all theses from the Department of Nursing, College of Health & Human Services, Southeast Missouri State University:

1. The completed thesis must include in the following order at least: a title page, acceptance sheet, abstract, table of contents, acknowledgement (optional), body of the thesis, references, and appendix.

2. The following headings are appropriate:

   CHAPTER III
   Instruments

   Jalowiec Coping Scale
   Validity.
   Concurrent validity.
3. **ALL MARGINS (TOP, BOTTOM, RIGHT AND LEFT) SHALL BE 1 AND 1/2 INCHES FROM THE PAPER EDGE.**

4. Introductory pages such as the Table of Contents are numbered with lower-case Roman numerals at the bottom and center of each page 1 and 1/2 inches from the bottom edge.

The Title Page and Acceptance Page are counted as the first two pages although numbers do not appear on them. The first page showing a number will be the page following the Acceptance Page which will be numbered as page iii.

Numbering with Arabic numerals begins with CHAPTER I, the first page of which is page 1. These numbers are placed in the upper right corner of each page, 1 and 1/2 inches from the top and 1 and 1/2 inches from the right edge except on the first page of each chapter, which is to be numbered at the bottom center, 1 and 1/2 inches from the bottom edge and is separated from the text by at least one double space.

5. Double spacing shall be used throughout the thesis except for footnotes, spacing at end of sections, long blocked quotations, long tables, and the References section.

**TRIPLE SPACING SHALL BE USED AT THE END OF EACH SECTION BEFORE THE TITLE OF THE NEXT SECTION AND BETWEEN THE TITLE OF EACH CHAPTER AND THE TEXT.**

Long blocked quotations, long tables, and reference citations shall be single spaced.

There should be double spacing between citations in the References section but single spacing of the actual citations.

6. The black font must be (10 or 12 pitch) and used consistently throughout the thesis. Script type and other irregular typefaces and colors are unacceptable. **COURIER OR TIMES NEW ROMAN FONTS ARE PREFERRED.**

7. Should the student choose not to do the typing of the manuscript, the student is still responsible for the form, accuracy, and completeness of the thesis. **A TYPIST IS NOT AN EDITOR, STATISTICIAN, OR EXPERT ON APA REQUIREMENTS.** The student must proofread the thesis and correct any errors before submitting the paper to the School of Graduate Studies.
Quantitative Proposal Format

Consider the following section headings except for TITLE PAGE as appropriate level headings in wording and format for the quantitative thesis proposal. **EACH CHAPTER WILL BEGIN WITH AN INTRODUCTORY PARAGRAPH THAT IS NOT TITLED AND END WITH A SUMMARY SECTION THAT IS TITLED.**

**TITLE PAGE**

**CHAPTER I**
**INTRODUCTION**

Problem Statement
Purpose of the Study
Justification for the Study
Theoretical/Conceptual Framework (CHOOSE ONE)
Assumptions
Research Questions/Hypotheses/Objectives (CHOOSE ONE)
Definition of Terms
Delimitations
Summary

**CHAPTER II**
**REVIEW OF THE LITERATURE**

To include review of the theoretical and empirical (research) literature with chapter subheadings reflective of study variables to be determined under the guidance of the Thesis Chairperson. Depth and breadth of this chapter may vary from thesis to thesis at the time of the proposal defense.

**CHAPTER III**
**METHODS**

Population and Sample
Setting
Protection of Human Subjects
Instruments
Data Collection Procedure
Statistical Methods
Limitations
Summary

**REFERENCES**

**APPENDIX**
Qualitative Proposal Format

Consider the following section headings except for TITLE PAGE as appropriate level headings in wording and format for the qualitative thesis proposal. **THE ACTUAL FORMAT OF THE THESIS WILL DEPEND UPON THE QUALITATIVE METHOD USED IN THE RESEARCH DESIGN. THEREFORE, THESE BROAD CHAPTER SUBHEADINGS MAY OR MAY NOT APPLY IN EVERY INSTANCE.** The Thesis Chairperson will provide the definitive guidelines trying to keep as close to the same wording as possible for consistency in the thesis product. **EACH CHAPTER WILL BEGIN WITH AN INTRODUCTORY PARAGRAPH THAT IS NOT TITLED AND END WITH A SUMMARY SECTION THAT IS TITLED.**

**TITLE PAGE**

**CHAPTER I**
**INTRODUCTION**

Statement of the Phenomenon of Interest  
Purpose of the Study  
Type of Study  
Justification for the Study  
Philosophical/Theoretical/Conceptual Framework (**CHOOSE ONE**)  
Research Questions/Objectives (**CHOOSE ONE**)  
Definition of Terms (**IF APPROPRIATE**)  
Delimitations (**IF APPROPRIATE**)  
Summary

**CHAPTER II**
**REVIEW OF THE LITERATURE**

To include review of the theoretical and empirical (research) literature with chapter subheadings reflective of study variables to be determined under the guidance of the Thesis Chairperson. At the time of the proposal defense, the depth and breadth of the Review of the Literature will be determined by the chosen qualitative research method. It is understood by nature of qualitative research methodology that the Review of the Literature may be very short at the time of the proposal defense and will be expanded with the completion of **CHAPTERS IV AND V**.

**CHAPTER III**
**METHODS**

Participant Selection  
Setting  
Protection of Human Participants  
Role of the Researcher  
Data Collection Methods  
Data Generation  
Summary
Proposal Submission, Review and Approval

The outline for the Thesis Proposal (essentially CHAPTERS I and III with some development of CHAPTER II) should be written in future tense, because the study is being proposed for future investigation. Introductory comments set the stage. A few paragraphs will be needed to lay the groundwork with the last paragraph logically leading into the problem statement or the phenomenon of interest.

The problem statement or phenomenon of interest establishes the specific focus of the study. The problem statement may be expressed in the interrogative or declarative form. The purpose of the study states the specific aim or goal of the study. The type of study in the qualitative proposal gives the type of qualitative method to be used and its appropriateness to provide data relative to the phenomenon of interest. Justification for the study provides a logical documented argument to convince the reader that the proposed study is worthwhile to advanced practice nursing in rural settings.

The philosophical/theoretical/conceptual framework includes the specific formulation by a given author about the phenomenon to be investigated. Thus, only one of the three terms will be appropriate for the heading. Selection of the term is determined from the use of either a philosophy, conceptual framework, or theory to guide the research. Assumptions are factual or problematic assertions that are untestable, "universal truths", situationally relevant, or flow from the philosophical/theoretical/conceptual framework.

Hypotheses, research questions, or objectives predict the outcome of the study. Selection depends on the study design. Conceptual and operational definitions are used for all measurable variables and relevant terms found in the hypotheses, objectives, or research questions. Delimitations delineate the scope of the study.

In CHAPTER II, the review of the literature incorporates theoretical and empirical literature with relevance for the proposed study. In qualitative proposals, the content, depth, and breadth of the literature review will be determined by the chosen design under the guidance of the Thesis Chairperson.

CHAPTER III begins with a brief discussion of the design based upon acceptable criteria as well as the stated variables or phenomenon to be investigated. The setting includes a description of the physical conditions consistently present during the application of treatment/measurement/collection of the data. Measures used to gain entry to the setting are appropriate to qualitative studies. The population from which the subjects/participants are recruited is identified, and the criteria for sample selection and the sampling technique or protocol are included. The data collection procedures, as well as any instruments, interview protocols, etc., are specifically delineated. Measures to protect human subjects are given. The Researcher’s Role in data collection is thoroughly described in qualitative studies. The type of proposed data analysis is included with the level of significance for quantitative designs. Each choice of a statistical technique is defended as appropriate to specific research questions/ objectives/ hypotheses and to description of the sample. The procedure for generating data from qualitative sources is provided in detail.
The review and approval of the thesis proposal are under direction of the Thesis Committee. At the time of the thesis proposal defense, the Third Thesis Committee Member signs the "Topic Approval Sheet for Thesis or Creative Project." The student then obtains the signature of the DON Chairperson and returns the form to the School of Graduate Studies. Additional review and approval of the thesis project will be conducted by the University/College of Health and Human Services Committees on Research Involving Human Subjects. Finally, any review board of a hospital, school, health agency, or other setting where the student plans to conduct research may give written approval for the conduct of the research within its institution.
Consects

Before composing the subject statement of informed consent, the student should review examples in Appendix I. To comply with federal regulations for informed consent, certain exact phrases or sections may be required as part of subject consent. These requirements are updated periodically by the University Committee on Research Involving Human Subjects. Therefore, students should closely attend to the information in these guidelines.

The basic elements of informed consent should always be addressed and are to assure subjects:

1. A fair explanation of the procedures to be followed, including identification of those which are experimental. The purpose of the study as well as what the subject will be expected to do within the guidelines of the study.

2. That the identified benefits outweigh the identified risks.

3. A description of the attendant discomforts and/or risks.

4. A description of the benefits to be expected.

5. A disclosure of appropriate alternative procedures.

6. An offer to answer any questions concerning the procedures.

7. A statement that the subject participation is voluntary, and the subject is free to withdraw consent and to discontinue participation in the study at any time without repercussions.

8. A statement that the rights and welfare of any subject will be protected.

9. The name of the principal investigator, and a telephone number where the principal investigator can be contacted (give the DON's number or a work number, not your home number) and the approximate number of subjects to be studied.

10. The statement "If you have any questions about your rights as a research subject please feel free to contact the chairperson of the College of Health and Human Services Committee on Research Involving Human Subjects: (insert the current chairperson's name and office phone number here).

Copies of the subject consent form, any agency consent form, the approval of the Committee on Research Involving Human Subjects, any other review committee approvals, the consent to replicate a study or permission from appropriate sources to use copyrighted materials (i.e., instruments, figures, models, etc.) should be placed in the Appendixes of the proposal and thesis.

Extensive use of materials by other authors requires written permission from the owner(s) of the copyright. A statement must appear in the work that permission for use has been granted with the permission form placed in the Appendix. The source must appear in full on the first page of the quoted material together with any specific "credit line" requested by the copyright holder. Use of an entire table, figure, or other illustration as well as quotes of prose over 300 to 500 words is considered extensive. Other works requiring written
permission include poems, musical lyrics, stories, computer programs, questionnaires, and other published instruments for data collection.

University/College of Health and Human Services
Committees on Research Involving Human Subjects

The University Committee Chairperson assures the Thesis Committee and Graduate School that any study involving human subjects meets the criteria expressed in the University guidelines for research involving human subjects. For nursing students, the approval to proceed with data collection usually comes from the Dean of the College of Health and Human Services when the approval process is completed. Data collection prior to receipt of written permission from the Dean is unethical and may result in censure.

Approval for protection of human subjects occurs AFTER approval of the thesis proposal by the Thesis Committee and before data collection can begin. The student submits to the Chairperson of the College Committee on Research Involving Human Subjects, seven copies of the "Summary of Research Involving Human Subjects" (see Appendix C), and the original copy of the "Application for the Conduct of a Project Involving Human Subjects" (see Appendix D) with appropriate signatures, the subject consent form, any instruments for data collection, and any other relevant attachments. The Chairperson will distribute the materials to the Committee Members for review as required by the nature of the research’s involvement of human subjects; Committee members will review the materials before meeting to make a decision. At that point, the student will be contacted for any changes or revisions that need to be made. After two copies of any revisions are received by the Chairperson of the Committee, the materials will be forwarded to the College Dean for approval. The student will be contacted by the Dean, stating that the research project has been approved. At that point, the student is free to collect data.

NO MATERIALS WILL BE ACCEPTED FOR PROTECTION OF HUMAN SUBJECTS REVIEW AFTER TWO WEEKS BEFORE THE END OF THE REGULAR SEMESTER (NOT INCLUDING FINALS WEEK). Any materials received after that timeline will be reviewed the following semester. Until further notice, the Chairperson of the College of Health and Human Services Committee on Research Involving Human Subjects is Dr. Marcia Brown Haims, Department of Communication Disorders, (573) 651-2188.
Conducting Research in Other Institutions

If the proposed research is to be conducted in any institution other than Southeast Missouri State University, the proposal may need to be reviewed through that institution's review mechanism **AFTER** being reviewed by the University.

Southeast Health and St. Francis Medical Center have standing research review committees. Approval to conduct research at any institution or agency should be obtained from the nursing department of that institution. Guidelines for obtaining approval to conduct research at the hospitals in the city are outlined below. STUDENTS MUST HAVE THEIR PROPOSALS APPROVED BY THE UNIVERSITY BEFORE THEY SEEK APPROVAL TO CONDUCT THEIR RESEARCH AT ANY INSTITUTION OR AGENCY.

Southeast Health

See Appendix J for "Research Guidelines for Southeast Health."

St. Francis Medical Center

See Appendix K for “Research Guidelines for St. Francis Medical Center.”
CHAPTER III

THESIS DIRECTIVES

The thesis is the mechanism for reporting the result(s) of student research activities. The thesis is, for all practical purposes, an elaboration of the thesis proposal with the addition of two chapters for reporting the results of the research activities and interpretation of the results as discussion, conclusions, and nursing implications. **THE THESIS IS WRITTEN IN PAST TENSE AS THE RESEARCH HAS BEEN ACCOMPLISHED IN THE PAST AND IS NOW COMPLETED.**

Quantitative Thesis Chapter Outline

- TITLE PAGE (see Appendix L)
- ACCEPTANCE PAGE (see Appendix F)
- ABSTRACT
- TABLE OF CONTENTS
- LIST OF TABLES
- LIST OF FIGURES
- ACKNOWLEDGMENTS

CHAPTER I

INTRODUCTION

Problem Statement
Purpose of the Study
Justification for the Study
Theoretical/Conceptual Framework (CHOOSE ONE)
Assumptions
Research Questions/Hypotheses/Objectives (CHOOSE ONE)
Definition of Terms
Delimitations
Summary

CHAPTER II

REVIEW OF THE LITERATURE

To include review of the theoretical and empirical literature with chapter subheadings reflective of study variables to be determined under guidance of the Thesis Chairperson
Summary
CHAPTER III
METHODS

Population and Sample
Setting
Protection of Human Subjects
Instruments
Data Collection Procedure
Summary

CHAPTER IV
ANALYSIS OF DATA

Description of the Sample
Findings
Limitations of the Study
Summary

CHAPTER V
DISCUSSION AND CONCLUSIONS

Discussion of Findings
Conclusions
Implications for Nursing
Recommendations for Further Study
Summary

REFERENCES

APPENDIX

Comments on Each Chapter

CHAPTER I
INTRODUCTION

Provide a brief background to the study or the “state of the art” of the topic for the study. This introduction should lead into and set the stage for the problem statement. The introduction should provide a description of the larger context in which the problem is found. Narrow the big picture to the specific study at hand demonstrating the relationship between the big picture and the current study. Draw attention to the topic’s applicability to advanced nursing practice in rural settings.

The problem statement may be made in the declarative or interrogative format. It should delineate the problem to which the research will be addressing. This is the first subheading in CHAPTER I. Consider the problem’s researchability, feasibility, and significance.

The purpose of the study will include the specific research variables, the population to be studied, and the setting for the study. By nature of the verb used to describe the reason for conducting the study, the study design will be determined.
The justification for the study should express the significance or need for this study to nursing; especially advanced nursing practice with families in rural settings. The justification is a tight inductive or deductive argument to support conducting the research. It will be based upon theoretical and empirical support from the literature and could be considered a shortened version of the review of the literature.

The Theoretical/Conceptual Framework will describe the nursing or other theory chosen to guide the research process. The framework should be described in detail with appropriate schematic support. The ultimate objective of this section is to show how the research variables relate to the chosen Theoretical/Conceptual Framework.

Indicate the assumptions that form the base for the study. Consider universal assumptions, assumptions that flow from the theoretical/conceptual framework, and assumptions inherent in the type of proposed research methodology.

Identify and describe each of the major variables (concepts) in the study and how they relate to each other. List the hypotheses, research questions, or objectives.

All research variables and major relevant terms found in the research questions, hypothesis, or objectives are to be conceptually defined from the literature or even a dictionary/encyclopedia. Operational definitions will be the methods of measurement for the research variables.

Delimitations give the boundaries of the study and consider what is not part of the research study. Rationale are given for the selected delimitations. (e.g., One delimitation could be a rural setting; although the phenomenon to be studied could also be studied in an urban setting. The scope of the study will be delimited to only the rural environment. Therefore, the phenomenon as it exists in the urban environment is beyond the scope of the study. Study findings are not to be generalized to the urban environment. A rationale to support this delimitation might be the inadequate research base relating to the phenomenon as it exists in the rural environment while being sufficiently or widely researched in the urban setting.) Many delimitations can lead to the narrowing of the research focus to the point of limiting generalization of the findings. Certain specific delimitations could also affect the findings’ generalizability and could become limitations of the study.

Each chapter of the thesis should conclude with a summary of relevant issues and discussions included within that particular chapter.

CHAPTER II
REVIEW OF THE LITERATURE

In reviewing the literature, the challenge is to bring the reader up-to-date on the specific area of study. If possible place the problem in the context of nursing practice in relationship to current and past work. There is an assumption here that the student is more knowledgeable in this area because of reading and working in the area even though the reader may also have substantial knowledge of the topic. Describe the status of current research in the topical field.

An in-depth review of the literature since 2000 is expected. Seminal works prior to 2000 may be included to show development of the knowledge base regarding the research topic.
Write the review with some attention given to the reader. Include introductory paragraphs that direct the reader's attention to the major concepts. Create some organizing framework for the literature that is under review. It is often helpful to follow the same organizational patterns as was used when writing the conceptual framework. Summarize the reviewed studies in relation to each concept and assist the reader to come to a conclusion about the variable as it pertains to the study.

The literature review should cover the problem while building a case for the study. Make a case that the study is of importance. Keep in mind that the reader is primarily concerned with the current study and will want to understand the state of knowledge about that topic. Build a case for the current study by a critique of relevant studies including those which may oppose the study's general hypothesis. Critique all aspects of these studies, i.e. sample size or selection, setting, overall design, statistical analysis, and limitations.

The summary of this chapter should be a point-by-point development of a justification for the study’s existence. Importance to advanced nursing practice with families in rural settings should be emphasized.

CHAPTER III
METHODS

Organize this chapter in a way that is appropriate to the study. Provide the reader with all the information about the study that should allow the reader to replicate the study.

The chapter may begin with a reference to CHAPTER I by restating the research question(s). The design of the study must be explained, whether basic or applied research, a quantitative or qualitative research method, experimental or nonexperimental research design, and the specific design. Rationale for the appropriateness of the design should be provided. If an experimental design was used, specify the dependent and independent variables. A level of significance should be stated at this time.

Identify the accessible population from which the sample was selected as well as the target population to which the findings will be generalized. Identify the characteristics used for subject selection (sampling criteria) and, if appropriate, those characteristics which disqualified a potential subject from the study. Identify the type of sampling procedure used and the method of selection used to obtain an unbiased sample whether probability or nonprobability and the specific sampling design. Describe the procedure followed to obtain the sample. How were potential subjects recruited? If the study involved control and experimental groups, describe the procedure for assigning subjects to each group. The size of the sample should be indicated with rationale for size either from the literature or based upon the results of a power analysis. If a power analysis was conducted, then the alpha, degree of power, and effect size should be described.

Describe the setting for the study in such a way that indicates why the setting is an appropriate one for the topic, the subjects, and the chosen design. Include any details in the description that would be necessary for replicating the study especially during treatment or measurement of the response. In some cases it may be appropriate to discuss the overall setting of the study (i.e., the county, the state, the hospital,) as well as the actual, specific setting for the data collection (i.e., subject’s home, hospital room).

Protection of Human Subjects will include information regarding approval of the study by appropriate university committees and any other groups designated for that purpose.
PLEASE NOTE PRIOR TO DATA COLLECTION; APPROVAL TO CONDUCT THE STUDY WILL BE OBTAINED FROM THE COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS, COLLEGE OF HEALTH AND HUMAN SERVICES, SOUTHEAST MISSOURI STATE UNIVERSITY. In some cases, especially if subjects are children, the University Committee on Research Involving Human Subjects will approve the study for protection of human subjects. All approvals will be placed in the thesis appendix. In addition, any subject statement of informed consent will be described by discussion of the major components underlying the capacity for making an informed consent to participate in any research. Specifically, risk and benefits to the subject for participation, the voluntary nature of participation, and the voluntary opportunity to withdraw from participation at any time should be emphasized. Issues regarding privacy and confidentiality of the collected data should be addressed in detail.

Another section of CHAPTER III must include all of the instruments used in the study, including a demographic instrument. State how EACH instrument was constructed, what variables were being measured, etc. If the instrument was borrowed from another study, include reliability and validity data. If the instrument was locally constructed, include why the instrument was created, who created it, pilot-tested it, etc. Include how reliability and validity were examined. The central issue in this sub-section is three-fold: what does the instrument purport to measure (a validity concern); can the data gathered by the use of the instrument be trusted (a reliability concern); and what sources of error were present during the administration or collection of the data. Further description of the instrument should include the level of data generated by the use of the instrument, maximum and minimum scores on the instrument if appropriate, length of time to complete the instrument, what a higher or lower score means, and number of items and type of format. Demographic data are to be described with rationale for selection and level of generated data.

Next outline the protocol or procedures to be used during data collection. Provide the reader sufficient detail to understand what you have done so that replication of the study is possible. A step-by-step description of how the treatment was applied and the response measured. It is the activation of the design chosen for the study and must be congruent with it. The timeframe of this section should be from the recruitment of the subject until the data have been collected.

CHAPTER IV
ANALYSIS OF DATA

Focus the results on clarity. A description of the characteristics of the sample would be included here considering the demographic data. Analysis of the data will be by appropriate measures of central tendency and dispersion. The research variables will also be included in the sample description with appropriate measures of central tendency and dispersion. The sample description should end with a paragraph describing the characteristics of a typical subject.

Perhaps the significance of the results can best be viewed by examining each question, hypothesis, or objective one at a time. Write the findings section so that the reader is aware of the significance or non-significance of specific results. Stick to the results, “just the facts.”

Research objectives, questions, or hypotheses should be answered in the same order as originally presented. Tables can be used to summarize data so that it is not necessary to
repeat all of the information in the text. The treatment of the data is enumerated along with the statistical analysis. Each choice of a statistical technique is supported.

Limitations should address factors to the degree that they can be recognized that diminish the generalizability and/or conclusions of the study. Threats to the study’s internal and external validity should be considered.

CHAPTER V
DISCUSSION AND CONCLUSIONS

For purposes of organization under discussion of findings, address findings related to each research question. In the final chapter, answer the research question(s) posed in the first chapter. Was anything of significance (statistical and/or clinical) discovered from the study? Relate the results to the big picture outlined in the introduction. It is also possible to outline those areas that were found wanting in the study or in which the findings confirm or refute findings from other related studies. How do the results extend or clarify existing knowledge? At this point the investigator is allowed a certain degree of creativity and posing of opinion based upon having conducted the study.

If the sample size was really too small, it is appropriate to state this fact when drawing suggestions and conclusions from the data. (e.g. State: “Based upon the findings and limitations of the study, the following conclusions are cautiously made.”) Conclusions should be derived from the findings related to each research question. Significant findings especially should be addressed. Conclusions are usually stated in the present tense.

Recommendations for further study should reflect noted limitations in the study and other populations or settings to expand the generalizability of the study’s findings. Proposing to move from descriptive research to more experimental designs would also be appropriate in the recommendation for further study.

What is the significance or implications of the results for nursing theory/practice/administration/education? Specifically, what is the significance of the results for advanced nursing practice with families in rural settings? This section is very important and should be thoughtfully developed and supported by the investigator.

The summary in this last chapter should be very similar to an abstract for the study.
Qualitative Thesis Chapter Outline

TITLE PAGE
ACCEPTANCE PAGE
ABSTRACT
TABLE OF CONTENTS
LIST OF TABLES
LIST OF FIGURES
ACKNOWLEDGMENTS

CHAPTER I
INTRODUCTION

Statement of the Phenomenon of Interest
Purpose of the Study
Type of Study
Justification for the Study
Philosophical/Theoretical/Conceptual Framework (CHOOSE ONE)
Assumptions
Research Questions/Objectives (CHOOSE ONE)
Definition of Terms (IF APPROPRIATE)
Delimitations (IF APPROPRIATE)
Summary

CHAPTER II
REVIEW OF THE LITERATURE

To include review of the theoretical and empirical literature with chapter subheadings reflective of phenomenon of interest to be determined under the guidance of the Thesis Committee.
This chapter content will also be determined by the chosen qualitative research method.
Summary

CHAPTER III
METHODS

Participant Selection
Setting
Protection of Human Participants
Role of the Researcher
Data Collection Methods
Data Generation
Summary
CHAPTER IV
ANALYSIS OF DATA

Description of the Participants
Empirical Grounding of the Study
  Findings
  Confirmation\Criticism
  Limitations
  Summary

CHAPTER V
DISCUSSION AND CONCLUSIONS

Discussion of Findings
Conclusions
Implications for Nursing
Recommendations for Further Study
Summary

REFERENCES

APPENDIX
CHAPTER I
INTRODUCTION

What is the larger context in which the phenomenon is found? Who has interest in this domain of inquiry? Narrow the big picture to the specific study at hand demonstrating the relationship between the big picture and the current study.

What is known about the phenomenon? What has not been answered by present research and practice? This section will be the first section of CHAPTER I.

Depending on the phenomenon of interest, a problem may or may not be identified. However, the purpose of the study sets the direction of the study, the type of study, and the analysis to be used to generate the study’s findings.

The type of study should be described in detail with support for its relevancy to the phenomenon of interest and purpose of the study.

The justification for the study should express the significance or need for this study to nursing/nurses, especially nurses providing care to families in rural settings. How will the research add to the body of nursing knowledge? The justification is a tight inductive or deductive argument to support conducting the research. It will be based upon theoretical and empirical support from the literature and could be considered a shortened version of the review of the literature.

The Philosophical/Theoretical/Conceptual Framework will describe the nursing or other theory chosen to guide the research process. The framework should be described in detail with appropriate schematic support. The ultimate objective of this section is to show how the research variables relate to the chosen Theoretical/Conceptual Framework. In grounded theory research, when the focus is the development of theory, this section will not be necessary.

Certain assumptions inherent in nursing may guide the investigator's thinking in regard to the phenomenon under study. These assumptions need to be identified and be congruent with the method of inquiry or type of study. Assumptions differ from method to method, and the student should seek assistance from the Thesis Chairperson as needed.

List the research objectives or questions. In most qualitative research, objectives will be appropriate. Conceptual definitions may be scant prior to data collection and become more refined as CHAPTERS IV AND V are developed. Delimitations by the nature of qualitative research will be scant. See comments regarding quantitative delimitations on page 26.

Each chapter of the thesis should conclude with a summary of relevant issues and discussions included within that chapter.

CHAPTER II
REVIEW OF THE LITERATURE

Reviewing the literature in a qualitative study is based on the type of study chosen. Some methods require the investigator to suspend any prior theoretical commitments or at
least state and put aside assumptions about the phenomenon of interest. However, such "bracketing" does not mean that the investigator is ignorant about the relevant literature surrounding the phenomenon. The literature review's depth and breadth prior to data collection and analysis will be determined under the guidance of the Thesis Committee and by the type of study and design.

In most cases, the review will be just enough to provide justification for the study and place it in context. Grounded theory may require no review of the literature until examination of the findings in analysis of the data. However, ethnographic and historical research may require in-depth and early development of a literature review.

Regardless of the depth and breadth of the literature review prior to data collection and analysis, the Review of the Literature will be expanded during the development of CHAPTER IV and especially CHAPTER V. Thus, the completed thesis will show an adequate and scholarly review of the literature pertaining to the phenomenon under study.

CHAPTER III
METHODS

Organize this chapter in a way that is appropriate to the study. Provide the reader with all the information about the study that would allow the reader to replicate the study.

The design of the study must be explained, e.g. grounded theory, phenomenology, ethnography, etc. Rationale for the appropriateness of the design should be provided.

Prior to participant selection, decide upon a term to be used for the subjects (e.g., participants, informants, or respondents). Any of the terms may be chosen, just be consistent in the use of the selected term. Identify the characteristics used for participant selection (sampling criteria). How were potential participants recruited? Each study's sample is based on the number and type of participants in order to gather as much information as possible about the phenomenon of interest. Purposive selection (nonprobability sampling) of participants is attempted in order to increase the range of data exposure. Ex post facto discussion of the size of the sample would be based upon the number of participants needed to reflect data saturation or redundancy.

Describe the setting for the study in such a way that indicates why the setting is an appropriate one for the chosen design. Include any details in the description that would be necessary for replicating the study especially during data collection.

Protection of Human Participants will include information regarding approval of the study by appropriate university committees and any other groups designated for that purpose. PLEASE NOTE PRIOR TO DATA COLLECTION; APPROVAL TO CONDUCT THE STUDY WILL BE OBTAINED FROM THE COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS, COLLEGE OF HEALTH AND HUMAN SERVICES, SOUTHEAST MISSOURI STATE UNIVERSITY. In some cases, especially if subjects are children, the University Committee on Research Involving Human Subjects will approve the study for protection of human subjects. All approvals will be placed in the thesis appendix. In addition, any subject statement of informed consent will be described by discussion of the major components underlying the capacity for making an informed consent to participate in any research. Specifically, risk and benefits to the subject for participation, the voluntary nature of participation, and the voluntary opportunity to
withdraw from participation at any time should be emphasized.Issues regarding privacy and confidentiality of collected data should be addressed in detail.

It is important to describe the researcher’s role when gaining entry to sites for data collection, in the selection of the sample, and in the consideration of ethical constraints. Any possible investigator-related threats to the credibility of the data should be addressed and minimized. Rigor in the research process should be maintained through open mindness, detailed adherence to the selected philosophical perspective, thorough data collection, and consideration of all data.

Next outline the protocol or procedures to be used during data collection. Any demographic data collection method should be described in the same detail as in quantitative research (see pages 28-29). The goal of the data collection is not to make generalizations about the larger population. Data collection may continue parallel to participant selection until no new information is found or until saturation of the data occurs. The method of data collection should be described in detail so that replication of the study would be possible. It is the activation of the design chosen for the study and must be congruent with it. It is important to identify who collected the data, how the data were collected, what elements constituted the data, and the length of time for data collection.

Generation of the data should provide a documented method(s) of data analysis. The steps to be taken in the analysis process should be detailed so that replication of the study would be possible.

CHAPTER IV
ANALYSIS OF DATA

Focus the results on clarity. A description of the characteristics of the participants would be included here. The section would end with a paragraph describing the typical participant.

The role of the investigator is crucial to data collection and analysis in qualitative research. The role of the investigator may be that of 1) collecting, analyzing, and interpreting or 2) immersing, observing, comparing, conceptualizing, and validating.

Methods of data analysis will depend on the study design. Tables can be used to summarize data so that it is not necessary to repeat all of the information in the text. Rigor of the research will be based on the logic of the emerging theory and the clarity with which it sheds light on the phenomenon.

Basic qualitative research i.e. content analysis, phenomenology, etc. It is important to show the inductive process leading from the raw data (narrative-text) through codification (codes), categorization (categories), and thematic development (themes). Linkages between codes, categories, and themes should be clear. It is at this point that the intuition and creativity of the researcher is implemented; with support of the participants’ own words.

Confirmation/criticism of the data relates to the reliability and validity of the findings and should be analyzed using the concept of trustworthiness or truthfulness of the generated data (LoBiondo-Wood & Haber, 2010). Methods to establish credibility, auditability, transferability, and dependability, as well as usefulness and fittingness of the data should be described in detail to confirm the date.
Credibility refers to whether the research participants recognize the description of the experience as their own. Were the data reviewed by the participants (all or a smaller group) as to its credibility? This participant review may be informal during data collection or formally at the end of data collection. Evidence of prolonged engagement and persistent observation in data collection for in-depth understanding, to test for misinformation and to build trust and rapport with participants are essential to credibility for the data’s scope and depth. Credibility can also be enhanced by triangulation, the use of multiple referents to draw conclusions about what is the truth. Triangulation can include multiple data sources, the investigators, themselves, and methods of data collection. Lastly, credibility of the data can be supported by the researcher’s credibility as estimated by the researcher’s training, qualifications, and experience and especially any personal connections between the researcher and the topic, community, or participants under study.

Auditability refers to the ability of another researcher to follow the thinking, decision making, and methods used by the original researcher. Was the research process documented? An example of decision making may be presented in table form or the process may be reviewed by experts to validate such groupings and linkages or codes, categories, themes, clusters, etc. An audit inquiry by an external expert would include the collected data and supporting documents. Auditability leads to confirmability of the data’s objectivity and neutrality such that two separate individuals could reach agreement of the meaning of the data.

Fittingness refers to how well the research findings fit outside the study situation. Would the results be meaningful to individuals not involved in the research? Other research studies that may have found similar perceptions or meanings for others who have experienced the phenomenon would support fittingness of the data.

The transferability of the data supports its fittingness or applicability to other contents. The richness of the data description in the research report is important to this concept.

Dependability refers to stability of data over time and conditions. Very similar to the reliability of quantitative studies, dependability can be established by the process of stepwise replication where two separate teams of two or more researchers approach the data collection and analysis processes separately but with continuous communication.

Limitations should address factors to the degree that they can be recognized to diminish the trustworthiness of the data and, therefore, the conclusions of the study.

The text in this section can be directly attributed to:


CHAPTER V
DISCUSSION AND CONCLUSIONS

In the final chapter, state how the research objectives/questions posed in CHAPTER I were met or answered. Relate the results to the big picture outlined in the introduction. It is also possible to outline those areas that were found wanting in the study, or in which the findings confirm or refute findings from other related studies. How do the results extend or clarify existing knowledge?

At this point, the investigator is allowed a certain degree of creativity and intuition in discussing the richness of the qualitative data in describing the phenomenon.

Conclusions should be derived from the findings at their broadest development theme versus code. Conclusions are usually stated in the present tense.

What is the significance of the results for nursing (theory, practice, administration, education)? Specifically, what is the significance of the results for the practice of advanced nursing practice with families in rural settings? Recommendations for further study should reflect extension of information about the phenomenon under study.

Thesis Style

When using the latest edition of the APA Publication Manual, as a guide for the preparation of the thesis, please note that:

1. The APA Publication Manual refers to the typing of a manuscript to be submitted for publication and thus is not relevant to the typing of a thesis. NO RUNNING HEADS ARE USED IN THESIS DEVELOPMENT.

2. The works of others are to be credited when used in the thesis, chapter authors as well as editors. Should you have any questions about proper citation of material, please consult your Thesis Chairperson AFTER reviewing the latest edition of the APA Publication Manual.

3. Figures and their titles are prepared differently than tables and their titles. Figures and tables are presented within the text rather than in an appendix using the double line spacing format of the text.
Example of Figure

The answer to the proposed questions may be found in Figure 1. It is not surprising that the concepts are inter-related.

![Diagram of General Systems Theory's interaction of constructs]

*Figure 1. General Systems Theory’s interaction of constructs*

Example of Table

As noted in the data presented in Table 1, several conclusions can be made.

<table>
<thead>
<tr>
<th>Level of Sexual Intercourse</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>156</td>
<td>54.4</td>
</tr>
<tr>
<td>Once</td>
<td>31</td>
<td>12.4</td>
</tr>
<tr>
<td>Seldom (once every 2-3 months)</td>
<td>22</td>
<td>8.8</td>
</tr>
<tr>
<td>Occasionally (once a month)</td>
<td>19</td>
<td>7.6</td>
</tr>
<tr>
<td>Often (2-3 times a month)</td>
<td>19</td>
<td>7.6</td>
</tr>
<tr>
<td>Frequently (once a week)</td>
<td>17</td>
<td>6.8</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>2.4</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>250</td>
<td>100</td>
</tr>
</tbody>
</table>
Title Page

The date on the Title Page (see Appendix L) indicates the month and year the degree is conferred, irregardless of when the work was completed. This page is counted as Page One but the number does not appear on the page. Typing of the title page should result in an exact line by line replication of the example in Appendix L including the placement of the lines on the page.

Acceptance Page

The date on the Acceptance Page is the date of the Oral Examination. This page is counted as Page Two, but the number does not appear on the page. The Acceptance Page, with respect to typeface, paper, etc., must be the same as the remainder of the thesis, and must be signed in black ink by all Committee Members. The number of lines for signatures must be identical to the number of Thesis Committee Members. Typing of the Acceptance Page should result in an exact line by line replication of the example in Appendix F including the placement of the lines on the page.

Acknowledgments Page

Acknowledgment should be given to any agency or institution that financially supported the student's research or education program. Such acknowledgment would include traineeships and research grants not “pay-back” loans or financial aid. Examples of appropriate ways to acknowledge receipt of traineeship monies are as follows:

1. "This research was supported in part by funds made available through the Professional Nurse Traineeship Program Grant No. 5 All NU 00269-12 awarded by the Division of Nursing, BHPR - HPSA, United States Department of Health and Human Services."

2. "This research was supported, in part, by funds made available through Manpower Research and Demonstration Funds Grant NO. 1 T24 MH 18163-01 awarded by the National Institute of Mental Health."

3. “This research was supported in part, by funds awarded through the Margaret Woods Allen Award from the Lambda Theta Chapter of Sigma Theta Tau, International Honor Society of Nursing.”

Students should consult the DON Director of Graduate Studies for the appropriate traineeship grant number for the year in which funding was received.
Thesis Abstract

The thesis abstract should be a brief (no more than 2 double-spaced typed pages) overview of the study with sufficient detail for the reader to decide whether the contents are of interest. The abstract should be placed in front of the thesis. The abstract should include a brief statement or description of the:

1. Introduction to the problem/phenomenon of interest or purpose of the study.

2. Research aim/objective, question, or hypothesis.

3. Methodology including:
   a. study design
   b. subjects/participants
   c. data collection methods and procedure
   d. findings
   e. conclusions and implications

The abstract should be submitted with the thesis to Thesis Committee members at least two weeks before the scheduled Oral Examination date. The same rules for margins and spacing as for the thesis apply for the abstract. Center the complete title at the top of the first page. If the title runs to more than one line, the second and subsequent lines are single spaced and are shorter than the top line (inverted pyramid form). Use the date of the month and year of graduation, not the month and year the thesis is completed. Remember that the abstract must be equivalent to the thesis in meeting the standards for scholarship and presentation of materials.
Illustrations

All charts, graphs, figures, tables, questionnaires, maps, and other illustrations used in the thesis should be designed to comply with the margin rules of 1 and 1/2 inches for each margin. Photocopying may be used if reduction in size is necessary to comply with margins.

The tables and figures should be labeled and numbered in accordance with APA format style. **It is preferable that any hand drawn figures be illustrated in black ink.** Photographs may be printed on photographic paper or dry mounted on the required bond paper. The presentation of information broadside on the page should meet margin specifications. The use of folded pages is discouraged.

Plagiarism

Plagiarism is defined as the appropriation, theft, purchase or obtaining by any means another's work and the unacknowledged submission or incorporation of that work as one's own that is offered for credit. Plagiarism is characterized by failure to acknowledge the source of the work and includes the use of ideas and words which belong to others. It also includes the unacknowledged use of created products such as audio and videotapes, graphs, charts, tables, artwork, and photographs. Documentation should be prepared in accordance with the *APA Publication Manual*.

Each acknowledgment should contain complete and accurate information on the cited source. Inaccurate information in citations while not falling within the definition of plagiarism constitutes questionable writing methods and is negatively sanctioned in grading. When in doubt, ask a faculty member for clarification.

The reference list should include all those sources cited in the body of the paper. Should a student be accused of committing plagiarism, the process outlined in the Academic Dishonesty Policy will be followed (see DON, *MSN Graduate Student Handbook*).
CHAPTER IV

ORAL EXAMINATION GUIDELINES

The final stage of the thesis process is the Oral Examination using the thesis as a basis for scholarly interaction between the student and faculty. The major purpose of the examination is for the Master of Science in Nursing candidate to: justify and support the conceptual framework/study design, review of the literature, methods, findings, and interpretations of the thesis research; and relate the findings and interpretations to core aspects of the program of study.

Conduct of Oral Examination (Thesis Defense)

The student and Thesis Committee should schedule the Oral Examination one month before graduation. The student with the Chairperson's assistance should arrange a room for the examination and notify Committee Members of the arrangements. The student should submit a cleanup to date copy of the thesis to each Committee Member at least two weeks before the examination.

The Oral Examination must be scheduled by deadlines posted in each semester on the School of Graduate Studies website.

The Thesis Committee Members are responsible for conducting the Oral Examination. The candidate may invite other person(s) to attend if desired. However, only the Committee Members will pose questions of the candidate.

Preparation for the Oral Examination

The student is expected to know the research well. Even though the candidate has spent an enormous amount of time on all phases of the thesis, it is a good idea to read the entire thesis just prior to the defense. It may be helpful to anticipate what questions could be asked, formulate answers to these questions, and perhaps verbalize the responses.

It is important to remember that the time from the proposal stage to the time the thesis is defended may be several months to a year. Much could be written in this time period that is not incorporated into the thesis, but the candidate could be expected to respond to questions about current works. Therefore, the candidate should keep abreast of current work related to the research topic.
Materials Permitted in the Oral Examination

The candidate is expected to bring a copy of the thesis to the Oral Examination. In addition to the manuscript, the candidate may bring note cards. However, the student is discouraged from bringing so much material that it can be distracting and/or become disorganized.

The candidate will be asked to prepare an oral presentation. This presentation will include the use of materials in a PowerPoint format. The Chairperson, in collaboration with the candidate, plans this part of the defense. The student will be asked to summarize the research efforts and conclusions.

Questions to Expect

The nature of the research dictates the kinds of questions asked. Because diligent work has been required to prepare the paper, it is assumed that the candidate can answer questions related to the substance of the paper.

The Thesis Committee Chairperson serves as Chairperson for the Oral Examination and may begin the examination by asking one or more introductory questions. Examples of introductory questions are provided. However, specific questions must be answered in the defense related to the program objectives.

1. "How did you become interested in this research topic?"
2. "Would you briefly summarize your research?"
3. "What are the major accomplishments of your research?"
4. "What did you learn from this research experience?"
5. "How do you intend to use your research findings?"
6. "What additional questions do you now have as a result of your study?"
7. "What contribution have you made to new knowledge?"
8. "If you could repeat this research what would you do differently?"

It is the responsibility of the candidate to discuss the opening of the Oral Examination with the Chairperson prior to the defense. Once the introductory question is answered by the candidate, members of the committee may begin asking questions.
Answering the Questions

The major role of the candidate in the Oral Examination is to answer searching questions regarding the research. A candidate may not know the answer to all questions. If the answer is not known or cannot be answered by the research, the candidate could respond with: "I don't know" or "This question cannot be answered from my research." However, if the response is the latter, the candidate may formulate an answer on the basis of the literature or opinion. The candidate should, however, make the frame of reference clear.

The candidate should formulate sharp, concise, and accurate answers. The questions should be answered first, followed by an elaboration if appropriate. After an answer, the candidate may ask, "Does that answer your question?" or "Would you like me to elaborate?"

Expect to be asked questions that are not crystal clear. If you do not completely understand, ask that the question be restated or rephrased. Be sure you know the question before you formulate an answer! You may rephrase the question thusly, "Are you asking...?"

Candidates are expected to keep their poise; to defend and not be defensive; to be scholarly and not opinionated. However, when asked for an opinion, give it; do not be afraid to express yourself!

When the Oral Examination is Completed

When the questioning is completed, the candidate is asked to "say a few words," or "Would you like to make any further comments?" This time may be used to thank the committee; to share what you may have learned in the defense. Other comments may be appropriate but do not exaggerate or belabor the point.

The candidate will be asked to leave the room when the Committee Members are deliberating about the quality of the defense. The Committee decides whether the examination is acceptable or unacceptable. The candidate is asked to return to the room, and the decision of the Committee is announced to the student.

Some changes in the original manuscript are usually required. It is usually left to the discretion of the Thesis Chairperson to see that these changes are incorporated into the thesis. The Chairperson will keep the acceptance sheet until satisfied that all corrections are made. After the Committee is adjourned, the candidate meets with the Chairperson to discuss the specifics of the changes.
Criteria for Evaluating the Thesis Experience

Criteria for evaluating the Oral Examination is found in Appendix M. Criteria for evaluating the written Thesis is found in Appendix N. Criteria for evaluating the thesis process is found in Appendix O.

Grade for the Thesis Experience

Credit is given for the thesis experience. The Thesis Chairperson submits the grade giving credit for the thesis experience to the Registrar.

Final Copy

A final copy of the thesis is to be submitted to the Dean of the School of Graduate Studies by the deadline stated for the semester in which the student plans to graduate. It is the responsibility of the student and the Thesis Committee to ensure that each thesis in all respects maintains the highest standards of research style, content, and format. In no case will a thesis be accepted in the School of Graduate Studies until it has been approved and signed by the Thesis Committee Members and the Chairperson of the Department of Nursing. For purposes of appearance and reproduction all signatures MUST BE IN BLACK INK.

The final copy of the thesis must be printed on bond paper of at least 20 pound weight with 25-50% rag content. The original is expected to be “perfect.” Only a high quality clean copy will be accepted; therefore, the student must exercise care in the selection of commercial duplicating services. The student should refuse to accept work that does not meet the standards of these guidelines.

The University requires the original copy of each thesis. The two bound copies of the thesis required by the University and the one bound copy required by the Department of Nursing must be processed for binding through the School of Graduate Studies. The student may order additional bound copies for personal use at the time of submission of the thesis. It is customary to have a bound copy made for the Thesis Chairperson. Students are responsible for completing the binding and copy order in the School of Graduate Studies and for all costs incurred. All requests for printing and binding are made through the School of Graduate Studies. Delivery of bound copies to the School of Graduate Studies takes about two months.
APPENDIX
Appendix A
Topic Approval Sheet for Thesis or Creative Project
Southeast Missouri State University

TOPIC APPROVAL SHEET FOR THESIS OR CREATIVE PROJECT

My signature herewith is to effect that I agree to serve as chair for the thesis committee or creative project for the student named below.

This form is to be accompanied by a brief and tentative description of the proposed thesis or creative project including the problem and the research method.

This form may be signed by the second member as an indication of tentative approval of the concept. The appointed committee member and chairperson should withhold their signatures until all members of the committee have met with the candidate and have agreed on the proposal. The chair of the committee and student should make arrangements for the proposal meeting as soon as the third member has been appointed by the Dean of Graduate Studies & Research.

COMMITTEE MEMBERS

1. _______________________________ (Signature, Committee Chair) (mm/dd/yy)

2. _______________________________ (Signature, Second Committee Chair) (mm/dd/yy)

3. _______________________________ (Signature, Third Committee Chair) (mm/dd/yy)
   (To be appointed by the Dean of Graduate Studies & Research)

   _______________________________ (Signature, Department Chairperson) (mm/dd/yy)

   [ ] THESIS [ ] CREATIVE PROJECT (Check one)

Title: ________________________________________________________________

________________________________________________________________________

Student’s Name: ___________________________ E-mail Address: ___________________________

Current Address: ____________________________________________________________

________________________________________________________________________

1
Major Area:   

(______________________________)   

_____________________________   ____________________________  
(Student's Signature)   (mm/dd/yy)  

Graduate Office Approval:  

(______________________________)   ____________________________  
(Dean of Graduate Studies & Research)   (mm/dd/yy)
Appendix B
Operational Policy for Research Involving Human Subjects
University Faculty Handbook
Operational Policy for Research Involving Human Subjects

Southeast Missouri State University recognizes its role in society to further human knowledge, to advance the sum of such knowledge through teaching and research, and to protect the rights and welfare of human subjects involved in research. Similarly, the University acknowledges the rights of the faculty, staff and administrators to utilize appropriate educational methods and research techniques in their classes, in instructionally-related activities and in Student Services programming and activities.

Human subjects are involved in many areas of research in which there is potential risk to the individual, such as experimental research utilizing drugs, vaccines, and radioactive materials. Less obvious are classroom or Student Services programming-related research activities in which risks to human subjects may be significant.

The Committee on Research Involving Human Subjects is best qualified to ensure that human subjects will receive adequate protective measures, that faculty, staff and administrative privileges to pursue the advancement of knowledge are guaranteed, and that restrictive policies which might discourage research, innovative teaching and programming are eliminated. This committee is the official review body for the University and functions as the Institutional Review Board as set forth in federal legislation. Its function is to conduct initial and continuing review of those research proposals which use human subjects and to determine that such proposals are in accordance with existing federal regulations. The committee operates under and reports directly to the Office of the Provost.

Members of the committee shall possess varying backgrounds so that their review of research proposals will assure that the rights and welfare of human subjects are adequately safeguarded. The committee must be sufficiently qualified through the expertise and diversity of its membership to ensure respect for its advice and counsel. When necessary, the committee will solicit opinions from individuals having recognized expertise in a specific area. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
Decisions concerning human subjects in research are not made unilaterally by the committee. Through a deliberative process, it is the responsibility of the department chairperson, the College Review Committee (CRC), the college dean of the research investigator conducting the study, and the University Committee to ensure that the rights of human subjects are protected. For projects originating from Student Services personnel, the Student Services Review Committee (SSRC) will act as the CRC, and the Dean of Students will assume the review functions delegated to the college dean in this document.

Definitions of Terms

As used in this document, research is defined as a trial or special observation, usually made under conditions determined by the investigator, which aims to test a hypothesis or to discover some unknown principle, effect, or relationship. Activities which use experiments, tests, and observations designed to elicit non-public information are types of research. Research does not include the conducting of classroom experiments or demonstrations or programming done for an educational purpose. Routine course and program development including evaluation of the effectiveness of such development and the assessment of established courses or programs is not research as defined and does not require review. (See next section for details of requirements for or exemptions from review.)

Determining the degree of risk in research involves making a series of judgments because certain risks are inherent in life itself. For certain types of research projects (especially medical), the risk is quite obvious. Somewhat different are those research procedures in which the subjects perform strenuous physical exertion or undergo varying degrees of public embarrassment and humiliation. These experiences may constitute a psychological threat to the subject, thereby posing another type of risk.

In reviewing research proposals involving human subjects, the reviewing body will place the research activity into one of two categories:

**Category 1** - those research activities in which the subjects involved have no more than the risks associated with their customary everyday activities or risks associated with the performance of routine physical or psychological examinations or tests by qualified individuals.

**Category 2** - those research activities in which the risk to subjects is greater than that encountered when performing customary activities under ordinary conditions.

As used in this document, human subjects are part of the investigator-subject relationship in a research activity which has the discovery of new knowledge as its primary objective. Of course, there are several types of human subjects, including adults, minors, residents of institutions, etc. Donors of organs, tissues, etc., are also considered to be subjects.
As used in this document, the definition of human subjects excludes the normal professional-client relationship which has the welfare of the client as the sole objective. Examples of such relationships are those in which the client is receiving aid or services consistent with accepted and established practice (e.g., physician and patient).

**Procedure for the Review of Research Proposals Involving Human Subjects**

During the preparation of the research proposal, the research investigator has the responsibility to seek advice from the department chairperson, college dean, Dean of Students and/or Human Subjects Committee Chairperson regarding potential implications for the rights of human subjects. If human subjects are not involved, the investigator may proceed with the study without consulting the committee.

Any research activity conducted by the faculty, staff, or students involving human subjects will be reviewed by the college dean or Dean of Students, by the CRC or SSRC, by the University Committee, or by both the CRC or SSRC and the University Committee. However, some proposals are exempt from full review.

These include

1. Secondary use of existing data documents and pathological or diagnostic specimens if the subjects are not identifiable.
2. Use of publicly available data, regardless of whether the subjects are identifiable.
3. Non-intervening observations of public behavior. The exemption includes research involving observations of public behavior of children where the investigator(s) does not participate in the activities being observed.
4. Interviews and surveys of adults (with exceptions noted below). Interview, survey, and observation of public behavior procedures are not exempt and must be reviewed when

   1. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,

   AND

   2. The subject's responses, if they became known outside the research, could reasonably place the subject at risk, or expose the subject to criminal or civil liability, or be damaging to the subject's financial standing or employability,

   OR

   3. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol,
OR

4. The subjects are minor children. All research using interview and survey procedures that include children as the subjects must be reviewed.

(For educational/classroom study exemption, see Definition of Terms, Research)

Projects involving human subjects but considered exempt from full review by the investigator may be initially submitted to the college dean or Dean of Students and the chairperson of the College or Student Services Review Committee who will act for the College or Student Services Committee. The material submitted will include a brief outline of the project including survey instruments, interview protocols and/or methods to protect the identity of subjects when secondary data etc., are used and the rationale for considering the project exempt from full review. If the college dean or Dean of Students and the chairperson of the College or Student Services Review Committee concur that the project is exempt, the Dean or Dean of Students will inform the investigator, and she/he may proceed with the study. At that time, the investigator will submit a copy to the University Committee Chairperson for retrospective review. If either the college dean or Dean of Students or the chairperson of the College or Student Services Review Committee thinks the project is not exempt, the project must be subjected to the normal review process. In the event that the college dean, Dean of Students and/or chairperson of the College or Student Services Committee are among the proposers, the project must be submitted to the entire College or Student Services Committee and to the University Chairperson for retrospective review.

If the project is not exempt from full review, the proposal normally must be submitted to the College or Student Services Review Committee. If funds external to the University are sought and the granting agency requires approval at the University Committee level, the investigator may submit the research proposal directly to the University Committee for review.

The following materials and information will be submitted by the proposer for research requiring full review:

A brief outline of the project; if applicable, survey instruments, interview protocols, and a description of methods to protect the identity of subjects when secondary data are used; a description of what risks to subjects can be reasonably expected; methods for obtaining informed consent; and methods for ensuring the subjects' rights of privacy and confidentiality of data.

If a designation of Category 1 is expected, the proposer may submit rationale to support risks no greater than customary everyday activities or risks associated with routine physical or psychological examinations and indicate the level of qualifications of investigators to undertake the study. If a designation of Category 2 is expected, the proposer should submit an explanation describing the need for the level of risk, what is being done to minimize risk, and qualifications of the investigators to carry out the research.
Investigators are encouraged to include only information pertinent to the safety of human subjects.

The CRC or SSRC will determine whether the human subjects to be studied in the investigation are in Category 1 or in Category 2 and will verify that procedures for human subject protection will meet University and federal guidelines. The decision of the CRC or SSRC, together with the research proposal, is then sent to the College Dean or Dean of Students. When the dean or Dean of Students agrees with the CRC or SSRC that the research involving human subjects is in Category 1 and that the guidelines for protection of human subjects have been met, the College Dean or Dean of Students will inform the investigator that she/he may proceed with the study, and the College Dean or Dean of Students will send to the University Committee a copy of the researcher's proposal together with a report of action taken by the CRC or SSRC and the College Dean or Dean of Students' statement of approval. In these instances, the University Committee has the responsibility for a retrospective review. All proposals subject to retrospective review by the University Committee will be examined for appropriate safeguarding of human subjects. If adequate safeguarding is not evident, the University Committee Chair will notify the appropriate Dean or Dean of Students and CRC or SSRC Chair, and the research will cease until agreement among all parties is reached.

When the College Dean or Dean of Students agrees with the CRC or SSRC that the research involving human subjects is in Category 2 or when the College Dean or Dean of Students and the CRC or SSRC do not agree on the category, the dean or Dean of Students will inform the investigator that the proposal must be submitted to the University Committee for review. When the category is in question or for proposals submitted directly to the University Committee, the University Committee will decide whether the research is Category 1 or Category 2. Following review of the proposal, recommendations of the committee are sent to the Provost. (See section "Responsibilities of the Committee: Notification of Committee Action" for details.)

**Responsibilities of the Principal Investigator**

The following statements are presented as guidelines for research projects involving human subjects. The investigator should consult these guides when planning the research project. The committee also will utilize these statements during its evaluation of research proposals submitted by faculty, staff, and students of the University.

The investigator must be qualified in the field in which the research is conducted. If during the research the investigator finds herself/himself in areas beyond her/his level of competency, appropriate consultation must be obtained.
Informed Consent

Research involving human subjects normally is not permitted without the voluntary consent of the human subject or the consent of her/his authorized representative if the subject lacks the capacity to consent. The investigator should provide the subject with all appropriate information, whether positive or negative, which is likely to influence the subject’s decision to participate. No coercion, explicit or implicit, may be used to obtain or maintain cooperation. To assure that the subject’s decision is truly free, the investigator must exercise particular care in certain circumstances. Examples include relationships involving a measure of control over the potential subject, e.g., teacher/student employer/employee, and in institutions such as prisons and hospitals.

Certain research studies utilize subjects (e.g., minors, the mentally retarded etc.) that require special consideration. Competent adults must give their own informed consent. If the research involves incompetent adults, it is the investigator’s responsibility to make certain that consent for participation is obtained from authorized representatives in accordance with applicable statutes and regulations.

Assent must be obtained from competent children. "Children" are individuals below the legal age of consent. Age, maturity, and psychological state are to be considered when determining competency of the child/children. Assent means a child’s affirmative agreement to participate in research. Failure to object should not be construed as consent. Informed consent must also be obtained from one of the child’s parents or guardians. For research which involves greater than minimal risk and no prospect of direct benefit to the child, both parents must give their permission unless one parent is deceased, unknown incompetent, or not reasonably available, or when one parent has legal custody of the child. This requirement may be waived for research designed for conditions for a subject population for which parental or guardian consent is not a reasonable requirement to protect the subjects (e.g., abused or neglected children).

When the research involves minimal risk to the subject (Category 1), there is no single method required to assure that the subject consents to participation. Whether the subject’s consent is obtained orally or is implicit in voluntary participation in a well-advertised activity or is secured via a written document, it must be "informed consent." The term "informed consent" implies that the individual has exercised free power of choice without the presence or excessive inducement or any element of deceit, fraud, duress, force, or other form of restraint or coercion. While not mandatory, written documentation is strongly recommended.

A dilemma arises in some research because fully informing the subjects would invalidate the experiment. If it is necessary to withhold information from the subject, the investigator must carefully inform the reviewers of what information will be withheld and must clearly justify the withholding of information.
Nondisclosure of information to subjects must not be used simply to assure their participation in the research.

Investigators whose proposed research activity is in Category 2 are obligated to obtain legally effective informed consent. The basic elements of information necessary to such consent include:

1. A fair explanation of the procedures to be followed and their purposes, including identification of any procedures which are experimental;
2. A description of any attendant discomforts and risks reasonably to be expected;
3. A description of any benefits reasonably to be expected;
4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
5. An offer to answer any inquiries concerning the procedure;
6. An instruction that the individual is free to withdraw his or her consent and to discontinue participation in the project or activity at any time without prejudice to the subject;
7. An explanation of appropriate complaint procedures.

A written document is preferred for obtaining the consent of subjects involved in research activity in Category 2. If consent is obtained orally, the investigator must provide some documentation of consent for the records.

However consent is obtained, the method used must be described and justified in the material sent to the committee for review. Such materials might include, for example, a summary of oral explanations to be given to the participants when obtaining their informed consent. Also to be submitted to the committee is an explanation of how the investigator plans to monitor the risks and safeguard the subject during the course of the investigation.

Note 1: The method of obtaining consent must not include any exculpatory language through which the subject waives, or appears to waive, any of her/his legal rights, including any release of the University or its agents from liability or negligence. Obtaining a signed consent form is not a release. Rather, it is simply an evidence of disclosure to the subject of essential information necessary to obtain informed consent.

Note 2: Special procedures are required for obtaining and documenting informed consent of subjects placed at risk in activities supported by many external sources of funds.

**Treatment of Human Subjects**

It is incumbent upon the investigator to make sure that all human subjects are treated with respect and dignity, not just by the principal investigator, but by the research associates as well. The principal investigator should make it clear to
the subjects that they are free to discontinue their participation in the research at any time without prejudice to the subject.

In those research projects that have potential risk to the subject, the investigator must make every effort to minimize the risks or discomfort related to the subject's participation. For example, if the research activity exposes the subject to considerable physical risk, the investigator must consider whether the subject's response should be monitored by a physician during the testing.

The investigator whose research plans place subjects at risk has the responsibility for justifying that risk. Such a justification will indicate that a thorough search of the literature has been made to ascertain that either the experiment has already been performed with animal subjects or good reasons exist for not utilizing animal subjects; that similar research has not already provided an adequate answer to the research question; and that the design of the study is adequate to yield worthwhile data on the topic under investigation.

The investigator is responsible for the research procedure during the investigation and must be sensitive to individual differences which may predispose certain individuals to experience harmful psychological or physical consequences by participating in the study. Realizing this, the researcher must exercise care to exclude such individuals from the research sample. Should unanticipated harmful effects develop during the research, the investigator shall take immediate steps to correct the situation. For those studies having the potential to produce undesirable effects which may be manifested later, the investigator's responsibility is to plan appropriate follow-up procedures.

The responsibilities of the investigator include scheduling a debriefing session with the subjects following the conclusion of the research. The methodological procedures associated with the study may have caused certain subjects to experience anxiety, embarrassment, and loss of self-esteem. The experimenter should determine whether the subjects have suffered such effects. If they have, the investigator must take positive steps to counteract the effects the study produced. Debriefing procedures to be used must also be described to reviewers. The reviewers must then decide whether the subject's rights and welfare are adequately protected.

The investigator should make every effort to see that the subjects are rewarded or recognized for their participation. Such benefits could be material (money or gifts), educational (added information or knowledge), some other self-enhancing gains (e.g., improved health and well-being), or the award of a certificate of participation. Any payment intended for the subjects should not be so large as to constitute an excessive inducement to participate. The investigator's description of the research submitted to the committee shall include plans to reward or recognize the subjects.
Confidentiality of Data

It is the investigator's responsibility to protect the rights of subjects against invasions of their privacy. The investigator must exercise care in obtaining and handling sensitive material and has ethical obligations to treat in confidence all private or personal information related to the subjects. The investigator should explain to those subjects providing information of a private or personal nature how such information will be used. Whenever feasible, such information from subjects should be obtained anonymously. If this is not possible, the data should be coded and the code separated from the data and kept in a secure place. Finally, the investigator should make certain such data are destroyed when the research is concluded.

The investigator must specify in the description of the project submitted to the committee for review her/his plans to ensure the confidentiality of the data and anonymity of the subjects. The following points can serve as a checklist to ensure that adequate protection will be provided:

1. The instruments for procuring data should be carefully constructed to ensure that only personal information absolutely essential to the study is acquired.
2. Personal information checklists which permit identification of the subject should be stored in files accessible only to authorized personnel.
3. Data containing personal information should be changed into coded form as soon as feasible. This means removal of the name and any other information which would reveal the subject's identity.
4. Adequate procedures for the disposal of data must be included in the research plans.
5. The identity of subjects must not be released without their express permission.

Certain research studies utilize data involving identifiable subjects that were collected previously for a different purpose. In such instance, the investigator must (a) re-evaluate the risk to the subjects, (b) determine whether the new use is within the scope of the original consent, and (c) provide for the anonymity of subjects in the intended study.

Complaint Procedures

It is also the responsibility of the principal investigator to advise all subjects, either in writing or orally, of their right to file a complaint with the University Committee. Each subject shall be given the name, address, and telephone number of the appropriate person to contact to register a complaint regarding her/his participation in the research. The participant or her/his legal representative should direct the complaint to the chairperson of the committee with a copy to the Provost/Provost's representative.
The University Committee has the responsibility for investigating all complaints. After its investigation, the committee will report its findings to the Provost. Normally, these findings will indicate one of the following: (a) that the complaint is invalid, (b) that the complaint is valid and that the principal investigator must submit an amended statement of procedure for consideration by the committee, (c) that the complaint is valid and that committee approval of the research project is withdrawn. In all cases, the Provost notifies both the principal investigator and the complainant (if identified) of the findings of the investigation and of the action to be taken.

Academic Affairs Revised 4/93
Appendix C
Summary of Research Involving Human Subjects
SUMMARY OF RESEARCH INVOLVING HUMAN SUBJECTS

Project Title__________________________________________________________

______________________________________________________________________

Investigator(s)________________________________________________________

Thesis committee chair (if investigator is a graduate student)

______________________________________________________________________

Department Chair______________________________________________________

1. Briefly describe the project's overall purpose and primary objectives:

2. Briefly describe the subject population to be used {specifically noting if any of them are minors, residents of institutions (for example, prisons or mental hospitals), mentally or physically handicapped or donors of organs/tissues}. Also describe the procedures of identifying/recruiting subjects, any compensation paid to the subjects, procedures to be used in the treatment of subjects or the method of obtaining data from the subjects:

3. Briefly describe the procedures that will be used to assure subject confidentiality: specifically state whether or not the subjects will be identifiable from raw and/or processed data; state how data will be protected from unauthorized personnel (e.g., stored in locked filing cabinets, etc.); whether or not the data will be destroyed upon completion of the project; whether or not publications of the project (theses, papers, articles, video tapes, etc.) will allow identification of individual subjects:
4. Describe the potential risks to the subjects that may result from their participation in the project:

5. Describe the potential benefits to subjects or society that may result from the project:

6. Please attach informed consent form, and copies of all test forms, questionnaires, list of instruments and/or materials to be utilized in the project. Also please attach any additional human subjects committee approvals from other institutions where research will be conducted.
Appendix D
Application for the Conduct of a Project Involving Human Subjects
SOUTHEAST MISSOURI STATE UNIVERSITY
COLLEGE OF HEALTH AND HUMAN SERVICES

Application for the Conduct of a Project Involving Human Subjects

SUBMITTED TO: College Committee on Research Involving Human Subjects

PROJECT TITLE:

DEPARTMENT:

In making this application, I certify that I have read and understand the guidelines and procedures developed by the University for the protection of human subjects as outlined in the Faculty Handbook posted on Southeast Missouri State University’s homepage. I fully intend to comply with the letter and spirit of the University policy.

Principal Investigator Date

Principal Investigator Date

This proposal has been reviewed and approved by the Chair of the Department.

Approved:

Chair of the Department Date

This proposal has been reviewed and approved by the College Committee on Research Involving Human Subjects. It has been determined to be a project in Category I _____ or Category II _____.

Approved:

Chair of the College Committee on Research Involving Human Subjects Date

This proposal has been reviewed and approved by the Dean of the College. It has been determined to be a project in Category I _____ or Category II _____.

Approved:

Dean, College of Health & Human Services Date
Appendix E
Sample Letter of Approval of Research for Protection of Human Subjects
MEMORANDUM

TO: Department of Nursing

STUDY: The Influence of Age, Gender, and Perceived Health Status on Health-Promotion Behaviors Among Rural Veterans

FROM: Paul Keys, Dean
College of Health and Human Services

DATE: February 6, 1996

SUBJECT: Authorization to Proceed with Study After Human Subjects Review

This memorandum is your official authorization to proceed with the study named above after a human subject review by the College Review Committee (CRC).

The CRC and I agree that this is a category 1 project, meaning that subjects have no more than ordinary risk by involvement in the study.

I appreciate your effort in this scholarly work.

CRC Chairperson
Department Chairperson
University Committee
Appendix F
Acceptance Sheet for Graduate Thesis
ACCEPTANCE SHEET FOR GRADUATE THESIS
SOUTHEAST MISSOURI STATE UNIVERSITY
DEPARTMENT OF NURSING

Title:

Student’s Name:

Major Area: Master of Science in Nursing

Committee Members

1. ____________________________________________
   (Committee Chairperson) (Date)

2. ____________________________________________
   (Committee Member) (Date)

3. ____________________________________________
   (Committee Member) (Date)

Approval________________________________________
   (Department Chairperson) (Date)

Approval________________________________________
   (Dean of Graduate Studies) (Date)
Appendix G
Graduation Intent Form & Cap and Gown Order Form
GRADUATION INTENT FORM
Southeast Missouri State University
MASTERS AND SPECIALIST
DEGREE COMPLETION INSTRUCTIONS

• **ENROLL** for the semester in which you plan to graduate **BEFORE** you apply for graduation. **YOU MUST ENROLL IN ONE OF THE FOLLOWING:** GR698-COMPREHENSIVE EXAM, GR699-ORAL EXAM, OR GR799-SPECIALIST ORAL EXAM. If your enrollment only consist of one of the exams listed above you will pay a one-hour fee. If you are enrolled in other course work you will not be charged an additional fee for the exam.

• **SUBMIT COMPLETED GRADUATION INTENT FORM** to the Graduate Office, MH 106, by the first week of classes of the semester in which you intend to complete your degree.

• **CAP AND GOWN ORDER** must be completed and turned in with the *Graduation Intent Form* in order to participate in the graduation ceremonies. If one is not received a cap and gown will not be available. You pay $35.00 graduation fee regardless of whether you participate or not.

• **$35 GRADUATION FEE** payable at Bursar’s Office after the charge is added to your account. Please make arrangements to pay all debts prior to the end of the semester.

• **LATE APPLICATIONS** will not be reviewed in time to add course work to meet requirements.

• **SUMMER GRADUATION:** because there is no summer graduate commencement exercises, candidates completing summer course work may be eligible to participate in the spring ceremony or the following fall ceremony. If you plan to walk in the spring commencement you will need to submit the *Graduation Intent Form* at the beginning of the spring semester.

• **ADDRESS INFORMATION** you provide on the Graduation Intent Form is used to contact you. A **CHANGE IN ADDRESS THAT IS NOT REPORTED** could cause a delay in the dated graduation information.

• To graduate with **ACADEMIC DISTINCTION** you must have a 3.9 or better g.p.a. in your program ending the prior semester.

• **GRADUATE SCHOOL DEADLINES DATES** for completing your degree are listed in the **SCHEDULE OF CLASSES** each semester on the ‘GRADUATE SCHOOL INSTRUCTIONS’ page of the schedule. Please refer to this page in the publication.

**IT IS YOUR RESPONSIBILITY TO SEE THAT EVERYTHING IS IN ORDER FOR YOUR GRADUATION.**

PLEASE KEEP TOP SHEET FOR YOUR INFORMATION.
GRADUATION INTENT FORM
SCHOOL OF GRADUATE STUDIES

Graduation semester: ____________________

**SUMMER GRADUATES ONLY. Commencement Participation In: ____________________

Spring ____ (graduation intent form must be turned in by February 1st) and must have advisors approval and signature: Advisor ____________________  Advisor’s Signature ____________________

Fall ____  None ____

Name to appear on Diploma: ____________________

SS#: _______ - _______ - _______
Male ____ Female ____

*Are you a citizen of another country? Y ____ N ____
If you are a U.S. citizen, check one: White ____ American Indian/Alaskan Native __________ African-American ____ Hispanic ____ Asian/Pacific

Address to which Diploma should be mailed:

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Local Address:
(if different than above) Street City

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Telephone# Home (____) ______ - _______  Work (____) ______ - _______

E-mail address: ____________________

Are you a Graduate Assistant: Y ____ N ____

Have you been Advanced to Candidacy: Y ____ N ____

Are you a member of Phi Kappa Phi Y ____ N ____

Degree: (circle one)  MA  MS  MBA  MME  MNS  MPA  MSN  SPECIALIST

Major Area: ____________________

Name of Graduate Advisor / Specialist Committee Chairperson: ____________________

If completing a thesis, please list name of Committee Chairperson: ____________________

Thesis title: ____________________
List the course/s and final examinations in which you will be enrolled in this graduating semester to complete your degree requirements. If you **make any changes in this schedule**, contact the Graduate Office.

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Indicate below if you will be taking the comprehensive examination or the oral examination.

GR698 Comprehensive Exam [ ]  GR699 Oral Exam [ ]  GR799 Specialist Oral Exam [ ]

This form is NOT an enrollment form.
Cap and Gown Order Form

Last Name: __________________________________________

First Name: __________________________________________

Middle Initial: ____________________________

Gender (check one):  [ ] Male  [ ] Female

Cap Size: _____________

Weight: _____________

Height With Shoes: _____ Feet _____ Inches

Degree Earned: __________________________________________

Name of School Placing Order: Southeast Missouri State University

Address of School (City & State): Cape Girardeau, MO

The Cap and Gown Order Form MUST be submitted together with the Graduation Intent Form.
Appendix H
Sample Letter of Appointment of Third Thesis Committee Member
June 29, 2011

Dear

Ken Heischmidt, College of Business, has agreed to serve as the third member of your thesis committee. It would now be appropriate to schedule a meeting of your entire committee to discuss your proposal in detail and finalize your plans.

Enclosed is your Topic Approval Form. As soon as your proposal has been accepted and the third committee member has signed, return the top copy to my office.

Sincerely,

Sheila R. Caskey
Dean of Graduate Studies
and Extended Learning

SRC/ga

cc: E. Jackson
Appendix I
Sample Consent Forms
SAMPLE INFORMED CONSENT FORM

Title of Project:

Investigator:

Department:

Phone number:

The purpose of this project is:  (BRIEFLY describe the purpose of the project)

I understand that, as part of this project, I will:  (describe what will be expected of the subject)

I understand that the risks associated with this procedure include:  (describe any potential risks to the subject)

I understand that my participation is voluntary; I may refuse to participate and/or discontinue my participation at any time without penalty or prejudice.  I understand that my participation or lack thereof will in no way affect my ______________ (e.g., grade in this course, treatment in this facility, etc.).

I understand that all information collected in this project will be held confidential; (please BRIEFLY describe the procedures being taken to ensure confidentiality).

I understand that by agreeing to participate in this project and signing this form, I have not waived any of my legal rights.

I understand that any questions or concerns I have will be addressed by the above named investigator.  If I have further questions, I may contact the chairperson of the Human Subjects' Committee, Dr. Marcia Brown-Haims at 573-651-2188.

Signature_____________________________________________

Date__________________________________________________
STATEMENT OF INFORMED CONSENT (EXAMPLE)

Project Title: Hospice: Attitudes and Perceptions of Rural Men
Investigator: Elaine Jackson, PhD, RN
               Graduate Nursing Student
Department: Nursing
Southeast Missouri State University
Phone Number: 573-651-2871

I understand that the purpose of this research project is to (put actual purpose statement here and possibly sampling inclusion criteria so that potential subject knows how they were selected).

I understand that as part of this research project, I agree to (if interviewed and audio or video taped need to say so here or indicate what will be required of subject and how long it will take)

I understand that my participation is voluntary; I may refuse to participate and/or discontinue my participation at any time without penalty or prejudice.

I understand that all information collected in this study will be held confidential. My name will not appear on any of the research instruments. My identity will not be revealed while the study is being conducted or when the study is reported. All data will be reported as grouped data. (Who will have access to the raw data?)

I understand that there are no foreseeable risks for participating in the study. While I will not personally benefit from the study, study findings may assist those who work with (specify) to better serve individuals most in need of care.

I understand that by agreeing to participate in this study and signing this form, I have not waived any of my legal rights.

I understand that any questions or concerns I have regarding my participation in the project will be addressed by the above named investigator. Should I have any questions about the rights of research subjects, I may contact Dr. Marcia Haims, Chairperson of the Committee on Research Involving Human Subjects, College of Health and Human Services, Southeast Missouri State University (573-651-2188).

___________________________ Subject’s Signature                Date

I have explained the study to the above subject and have sought the subject’s understanding for informed consent.

____________________________ Investigator’s Signature         Date

7/11
Appendix J
Research Guidelines for Southeast Health
Southeast Missouri Hospital Nursing Research Council
Application to Conduct a Research Project

Title of research proposal:

Principal investigator:

Position and unit in the hospital:

Mailing address:

Telephone number:

E-mail address:

Southeast Missouri Hospital sponsor:

Other organizations involved with this project and indicate if IRB approval has been granted by
the organization (ie. university, medical facilities, pharmaceutical companies):

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<tr>
<th>Principal Investigator’ Signature</th>
<th>Date Submitted</th>
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<th>Unit Manager or Department Head</th>
<th>Date Approved</th>
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Recommendations: _____ No _____ Yes (attached)

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<tr>
<th>Nursing Research Council Chairperson</th>
<th>Date Approved</th>
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Eligible as Exempt from IRC Review: _____ No _____ Yes: 45CFR46.101(b) Category _____

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<th>Institutional Review Committee Representative (if applicable)</th>
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Southeast Missouri Hospital
Nursing Research Council
Application to Conduct a Research Project

Members of the Nursing Research Council appreciate your interest in conducting research at Southeast Missouri Hospital. All research projects must be approved by the Southeast Missouri Hospital Nursing Research Council and/or the Institutional Review Committee prior to beginning the project. This packet contains required forms and information on the process to obtain approval to conduct research. Please contact the chair or members of the Nursing Research Council if you would like assistance writing a research proposal or completing the application. The purposes of the Nursing Research Council are to:

1. Promote quality nursing research to be conducted by nurses at Southeast Missouri Hospital.
2. Identify areas suitable for investigation and nursing research.
3. Review proposed research studies.
4. Facilitate application to conduct research to the Institutional Review Committee at Southeast Missouri Hospital.
5. Facilitate nursing research conducted by nurses.
6. Monitor the progress of ongoing research studies in the organization.
7. Support and implement procedures to protect the rights of human subjects.
8. Support the integration of research findings into the delivery of nursing care and nursing administration.

Instructions for Application

1. Submit a brief research proposal for the Nursing Research Council by responding to the requested information on the Guideline for a Research Proposal.
2. Complete and submit the Institutional Review Committee Application. The IRC chair or representative has the authority to classify the study eligible as exempt from IRC review [45 CFR 46.101(b)] or eligible for an expedited review [45 CFR 46.110].
3. Contact the unit Managers or Department Heads of the hospital where staff or patients would be involved with the study during the recruitment, intervention, and/or data collection. Obtain the Managers’ or Department Heads’ signature on the application or submit a written statement by them confirming approval of the study.
4. Provide a copy of the full research proposal if applicable.
5. Provide any pertinent information or other forms related to the study.
6. Provide a copy of the proposed Informed Consent Form.
7. Submit a certificate documenting the successful completion of a course on human subject protection. The National Institutes of Health has developed a computer-based training module, which can be accessed through links in the NIH web site. http://cme.nci.nih.gov/ retrieved 6/11/04 or http://cme/cancer/gov/c01
8. Submit a statement describing how findings from the study will be disseminated.
   A. How will findings be used in clinical practice?
   B. Describe method to be used to communicate outcomes of the study (publication in peer reviewed journal, poster presentation at conference, presentation to Nursing Research Council and/or unit).
   C. The principal investigator is expected to make a copy of the completed research available to Southeast Missouri Hospital to be bound and placed in the library.
Guideline for a Research Proposal

Title of research proposal:
Principal investigator:
Position and unit in the hospital:
Mailing address:
Telephone number:
E-mail address:
Southeast Missouri Hospital sponsor:
Other organizations involved with this project and indicate if IRB approval has been granted by
the organization (ie. university, medical facilities, pharmaceutical companies):

I. Introduction
   A. Purpose and research question(s)
   B. Describe the relevance of the study to nursing
   C. Theoretical framework (optional)

II. Methodology
   A. Design of the study
   B. Subjects
      1. Description of participants
      2. Inclusion and exclusion criteria
      3. Expected number
      4. Recruitment method
   C. Intervention (if applicable)
      1. What is the intervention
      2. How and who will implement the intervention
      3. When and where will the intervention be implemented
   D. Data collection
      1. What data will be collected
      2. Who will collect the data
      3. How will data be collected and stored
      4. When will data be collected
      5. Where will be data be collected
      6. Description of tools and/or assessment technique and data recording methods
   E. Potential involvement of hospital staff
      1. Identify the unit(s) on which the research will be conducted
      2. Time involvement
      3. Unit resources required and budgetary implications for the unit (ie. supplies, equipment, physical facilities)
      4. Impact on current policies
      5. Duration of research team presence on the unit
      6. Nature of involvement of research team within the unit
   F. Human subjects protection
      1. Confidentiality: how it will be maintained
      2. Risk/benefits to participants
      3. Voluntary participation and able to withdrawal without consequences.
   G. Data analysis: is analysis method and/or statistical tests appropriate for the data collected, and is it appropriate for the research questions
Guideline for Informed Consent

No research involving human beings can be conducted without obtaining the legally effective informed consent of the participants or the participants’ authorized representatives. Consent should be obtained without coercion or undue influence. The consent form should be signed by the participant or legally authorized representative. If the consent form is presented orally to the participant, a witness to the oral presentation should sign the consent form. An IRB may waive some of the required elements or may waive the requirement to obtain informed consent if the research involves no more than minimal risk to the participants or if the research could not be carried out without the waiver. IRB must document why the requirements are waived. Participants should receive a copy of the consent form. No statement can waive the participant’s legal rights or releases the investigator or institution from liability for negligence. (See 45 CFR 46.116 and 46.117 for specific information.)

The purpose of the consent process is to provide people sufficient information so they can decide whether to participate in the research. They should clearly understand what they can expect to happen and what they would be expected to do while participating in the study. The informed consent document is a summary of the research study and participants’ rights. The informed consent document should be signed before participants are involved in the research. However, the consent process continues throughout the research project as the researcher addresses the participants’ concerns and confirms that the participants understand the purpose and steps of the study. Only in this way can researchers ensure that the rights of the participants are protected and that the process of informed consent is maintained.

Short sentences and simple language, written at the eighth grade or lower reading level, should be used on consent documents. Medical, technical, or legal jargon should not be used. Consent forms should be written in the second person, using active voice and personal pronouns to reflect a conversation between the researcher and participant. Using large fonts, subheadings, and boarders make the document easier to read. Graphics, including simple outlines, flow charts, diagrams, study schemas, and calendars can be used to improve clarity (National Cancer Institute, 2004).

General requirements for informed consent (45 CFR 46.116) and explanation (NCI, 2004):

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

   The purpose should be placed in context of standard care. Participants should be able to understand what is going to happen to them in the study and distinguish what is standard care from what is investigational care. They should understand what additional standard care, that otherwise would not be given, is provided because they are in the study. The protocol regimens should be clearly listed. Explain how it will be determined which regimen the participant will receive if there is more than one study group.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

   Physical risks of participation should be described. Nonphysical risks should be included when they could affect the patient’s decision about participation such as time commitments, travel considerations, financial implications, and psychological effects. The risks should be compared to the risks of common
standard therapeutic alternatives and to the option of no treatment. The risks associated with standard treatment that would be delivered regardless of participation in the study should not be included in the consent document. Information about the risks of standard medical procedures should continue to be provided in separate informed documents as part of usual medical care.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
   Statements regarding potential benefits should be based on available data. No investigational approach should be identified as the only chance for cure or contrasted with standard approaches that offer no chance of cure. When relevant, the consent form should state that the investigational therapy may be no better than or may even be inferior to standard therapy or have no therapeutic effect.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
   List the alternatives to participation in the research such as the standard therapy treatment.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
   The confidentiality section of the informed consent document should state that although measures will be taken to protect the privacy and security of personally-identifiable data, absolute confidentiality cannot be guaranteed. The consent document should list the organizations that will have access to personally-identifiable information, and describe the purposes that the information will be disclosed. The document should state that personally-identifiable information may be disclosed as required by law.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and who to contact in the event of a research-related injury to the subject.

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

The following is a template of an informed consent form. This can be adapted by replacing the blank lines, suggestions, and examples with specific information as appropriate for your study. Statements in this template that are not appropriate to your study can be deleted as long as the required elements listed above are addressed. (NCI, 2004)

**Title of the Study**

This is a research study, which will include people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your health care team, friends, and family. If you have any questions, you can ask the researcher for more explanation.

You are being asked to take part in this study because you (list the inclusion criteria). About _____ people will take part in this study.

**Purpose**

The purpose of this research is (explain in 1 or 2 sentences).

**What will happen if you take part in this study?**
(For randomized studies) You will be placed into one of the study groups described below. Neither you nor the researcher can choose the group you will be in. A computer program will place you in one of the study groups, and you will have an equal chance of being placed in either (any) group.

You will take part in the following procedures:
(If you are in Group 1) These (exams, tests, or procedures) are part of regular care and may be done even if you do not join the study: (List tests and procedures in bulleted format. Explain what will happen. Include the frequency, time involved, and where it will take place for each procedure.)

(If you are in Group 2) These (procedures) will be done (or done more often) because you are in this study: (List tests and procedures in bulleted format. Explain what will happen. Make it clear which interventions depart from routine care. Include the frequency, time involved, and where it will take place for each procedure.)

You will be asked to (do what) for (length of time or indicate time frame and requirements for follow-up). (If long-term follow-up) We would like to keep track of your (condition) by calling you on the telephone once a year.

(A simplified calendar or chart of the study plan may be inserted. Provide an explanation of the chart.) Another way to find out what will happen to you during the study is to read the chart below.

**Can you stop being in the study?**

You can decide to stop the study at any time. Tell the researcher if you are thinking about stopping. (She/he) can tell you how to stop safely and discuss what follow-up care could be most helpful to you.

The researcher may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.
What side effects or risks can you expect from being in the study?

There are no known risks for taking part in this study.

Or (Physical and nonphysical risks and side effects should include such things as the inability to work. Whenever possible, describe side effects by how they make a patient feel, for example, “Loss or red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath.”)

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don’t know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the (drug or intervention). You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the (procedures, drugs, interventions, or devices) include those which are: (list in bullet form under each) Likely, Less Likely, Rare but serious

(Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. OR To the best of your knowledge, you are not pregnant or breast feeding. If you do become pregnant while taking part in this study, you should notify the researcher. This information will help the researcher provide the best care for you and your unborn child. Add statement about birth control, pregnancy test, or sterility if appropriate.)

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope (procedures, drugs, interventions, devices) will be more useful compared to the usual treatment, there is no proof of this yet.

Information from this study will help (doctors) learn more about (procedures, drugs, interventions, devices). This information could help future (patients, etc).

What other choices do you have if you do not take part in this study?

Your other choices may include:
- Getting treatment or care without being in a study
- Taking part in another study
- Getting no treatment
- (List alternative specific procedures or treatments)

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at your medical records for research, quality, assurance, and data analysis include: (list relevant organizations like study sponsors, university advisors, IRB, etc.)
What are the costs of taking part in this study?
(If applicable, inform the participant of any tests or procedures for which there is no charge.)
(If there will be a charge, clearly explain what charges will be billed.) You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your (disease) in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment.
Or: The (study sponsor) is supplying (drug) at no cost to you. However, you or your health plan may need to pay for costs of the supplies and personnel who give you the (drug).
Or: There are not costs for taking part in this study.

You will not be paid for taking part in this study.

What happens if you become injured because you took part in this study?
It is important that you tell the researcher if you feel that you have been injured because of taking part in this study. You may contact ___________ , the researcher, at ___________ and/or a Southeast Missouri Hospital representative at ___________ regarding questions about the research or to report a research related injury.

The researcher(s) and/or representatives of Southeast Missouri Hospital will provide immediate medical treatment if you are injured because you took part in this research project. You and/or your health plan will be charged for this medical care. The researcher(s) and/or Southeast Missouri Hospital will not pay for medical treatment if you are injured because you took part in this study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

What are your rights if you take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your (medical care, employment, etc.).

Who can answer your questions about the study?
You can talk to the researcher about any questions or concerns you have about this study. Contact the researcher, (name), at (phone number) or (email address).

For questions about your rights while taking part in this study, call (name), a member of the Southeast Missouri Hospital Institutional Review Board (a group of people who review the research to protect your rights) at (number).(We should probably list Mr. Dan Berry and/or Dr. Twila Brown here)
Signature
I have been given a copy of this informed consent form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

________________________  ________________________
Participant’s signature     Date

________________________  ________________________
Parent or legal guardian’s signature on participant’s behalf if less than 18 years old.

________________________  ________________________
Investigator’s signature  Witness’s signature if information was presented orally

References:


Categories of Research that may be Eligible for an Expedited Review by the IRC (45 CFR 46.110)

Institutional Review Committee chair or representative has the authority to classify the study eligible for an expedited review. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or experienced IRB members.

A. Research activities that may be reviewed through the expedited review:
   1. Present no more than minimal risk to human subjects (probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations [45 CFR 46.102(i)])
   2. Involve only procedures listed in one or more of the following 9 categories
      1. Clinical studies of drugs and medical devices only when condition these conditions are met.
         a. Research on drugs for which an investigational new drug application is not required (21 CFR Part 312)
         b. Research on medical devices for which an investigational device exemption application is not required (21 CFR Part 812), or the device is approved for marketing.
      2. Collection of blood samples by finger stick, heel stick, or venipuncture:
         a. From healthy, nonpregnant adults who weigh at least 110 pounds. The amounts may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
         b. From other adults and children considering the age, weight, health of the subjects, collection procedure, amount of blood to be collected, and frequency of collection. The amount may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not be more frequent than 2 times per week.
      3. Prospective collection of biological specimens by noninvasive means. Some examples are: hair/nail clippings, deciduous teeth, excreta, sweat, saliva, sputum, placenta at delivery, amniotic fluid when membranes rupture, dental plaque, mucosal and skin cells by swabbing.
      4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwave. Some examples are: physical sensors applied to the body that do not involve input of significant amounts of energy into the subject, testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, ultrasound, Doppler blood flow, echocardiography, body composition assessment, and strength testing.
      5. Research involving documents, records, or specimens collected for nonresearch purposes. Some research in this category may be exempt from Department of Health and Human Services (DHHS) regulations.
      6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including perception, cognition, motivation, identity, language, communication, cultural beliefs, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt from DHHS regulations.

8. Continuing review of research previously approved by the IRB where:
   a. Research is permanently closed to the enrollment of new subjects, all subjects have completed research-related interventions, and research remains active only for long-term follow-up of subjects.
   b. No subjects have been enrolled and no additional risks are identified.
   c. The remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

B. The categories in this list apply regardless of the age of the subjects, except as noted.

C. Expedited review may not be used where identification of subjects and/or their responses would place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation unless protections will be implemented so that risks to invasion of privacy are not greater than minimal.

D. Expedited review may not be used for classified research involving human subjects.

E. The standard requirement for informed consent applies to expedited review studies.

F. Categories 1 through 7 pertain to both initial and continuing IRB review.

References:


Categories of Research that may be Exempt from IRC Review (45 CFR 46.101(b))

Institutional Review Committee representative has the authority to classify the study as exempt from IRC review when human subjects are only involved in one or more of the following six categories. **

1. Research conducted in educational settings, involving normal educational practices such as instructional strategies.
2. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior
   Unless
   a. Subjects can be identified directly or through identifies linked to the subjects.  
   b. Disclosure of the subjects' responses could place the subjects at risk of criminal or civil liability or damage the subjects’ financial standing, employability, or reputation.
3. Research involving educational tests, survey procedures, interview procedures, or observation of public behavior if the subjects are public officials or absolute confidentiality is federally mandated.
4. Research involving existing data, documents, records, or specimens that are
   a. Publicly available or
   b. When the subjects cannot be identified directly or through identifiers linked to the subjects.
5. Demonstration projects concerning public benefit or service programs.
6. Taste and quality evaluation of foods without additives exceeding regulated levels.

**Exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

1“Identifiers linked to the subject” means identifiers such as names, Social Security numbers, medical record numbers, and code numbers that permit data to be linked to subjects or to associated medical, financial, or employment information.

2“Existing data” is a term that applies to retrospective studies involving already collected data where data must be “on the shelf” when the protocol is initiated. Secondary data analysis using existing data to address new research questions is exempt if participants cannot be identified.
A status of “No Human Subjects” applies when data are given to a researcher by others after being permanently and completely de-linked from the identity of living subjects.

3“Publicly available sources” refers to public sources of data such as telephone books and public records. This does not automatically apply to data obtained from organizations that make data sets broadly accessible to researchers at a reasonable cost.
Appendix K
Research Guidelines for St. Francis Medical Center
The purpose of the Research and Clinical Investigation Committee is to provide direction and to facilitate inquiry into valid and reliable research studies. It also provides a process for the incorporation of research studies into clinical practice.

PURPOSE:

The multi-disciplinary Research and Clinical Investigation Committee is an integral component of the organizational structure. The committee's primary goals are to foster a practice environment that is more research based; and to enhance quality improvement of patient care through utilizing the research process. The committee’s secondary goal is to encourage and support ongoing research projects.

FUNCTION:

1. Responsibilities of the committee are:
   a. To coordinate investigation in designated practice areas
   b. To offer consultation on research design
   c. To facilitate grant approvals
   d. To supervise the application of research into clinical practice
   e. To review and approve nursing and other non-medical research

2. Responsibilities of the chairperson are:
   a. Setting meeting date and notifying committee members
   b. Facilitating the routing of research articles and abstracts
   c. Working with the chairperson of the Policy/Procedure Committee to incorporate research data into clinical procedures
   d. Working in collaborating with the Nursing Practice Committee Chairperson to assure that the standards of practice are based on valid research results
   e. Approving minutes
   f. Communicating activities to the Collaborative Practice Council
   g. Serving as liaison to other departments and committees
   h. Interacting with the Institutional Review Board
   i. Collaborating with the university utilizing their research expertise
   j. Preparing and submitting an annual report of committee activities

3. Responsibilities of the members are:
   a. Attending meetings
   b. Acting as liaison to clinical practice areas
   c. Reviewing current research
   d. Assisting others in research project development
   e. Participating in educational presentations
   f. Actively supporting the purpose and goals of the committee
   g. Serving as sub-committee chairperson when appropriate
MEMBERSHIP:

The membership will consist of Clinical Nurse II, III, and IV levels, nurses in expanded practice roles, nurse managers, respiratory therapist, rehabilitation professional and social worker. The membership is not restricted and is open to any individuals interested in research. Regular attendance is required in order to remain on the committee membership roster. To facilitate business, small working groups and sub-committees will be formed as appropriate.

MEETINGS:

This committee will hold meetings once/year or more frequently if necessary. It is intended that the majority of work be completed by smaller working groups.

SECRETARIAL SUPPORT:

Secretarial support will be provided by the secretary who normally performs the clerical duties for the individual who is chairperson of the committee. This person must be skilled in the use of the word processor.

/jcl

Revised: 1/21/92, 12/92, 02/96, 02/99

Blood and Body Fluid OSHA Category III

RESCLINV.COM

END OF POLICY

RESEARCH AND CLINICAL INVESTIGATION COMMITTEE
SUBMISSION PROCEDURE FOR RESEARCH PROPOSALS TO BE PERFORMED WITHIN OR UNDER THE AUSPICES OF SAINT FRANCIS MEDICAL CENTER

One purpose of the Research and Clinical Investigation Committee of Saint Francis Medical Center is to advise potential researchers on the preparation of research proposals. When the proposal is formulated and the research design is constructed, the Research and Clinical Investigation Committee has the responsibility to review submitted proposals, collaborate with the principle researcher, recommend alterations in the proposal or design, and approve the implementation of the project.

The Research and Clinical Investigation Committee takes seriously its responsibility to assure that valid, reliable and ethical research is done under the auspices of Saint Francis Medical Center. At the same time, we wish to make the application process informal and painless.

Patient satisfaction surveys, QA/I projects, or procedure testing done by the Nursing Practice Committee are not required to submit to this process. The Research and Clinical Investigation Committee is available to advise and support such endeavors as requested. Research projects that are to be submitted for review by the Research and Clinical Investigation Committee prior to implementation include the following:

- part of an academic requirement
- originating outside Saint Francis Medical Center
- originating within Saint Francis Medical Center, directed at the community (non-patients)

The principle researcher provides the following information to the chair of the Research and Clinical Investigation Committee or a designee. This submission may be as few as 5-6 pages but should not exceed ten.

- completed cover page (form is provided by the committee)
- five copies of the following –
- proposal/abstract to include
  - background information
  - research questions/hypotheses
  - brief literature review
  - description of research design/methodology
  - bibliography/reference list (to be written using APA format)
  - consent form when appropriate
  - investigation tool
- IRB approval letter (if applicable)

The committee chair or a designee will assemble a subcommittee of 3-4 members. This subcommittee will consist of appropriate clinical or administrative experts specific to the proposal as indicated. The submitted proposal will be distributed as soon as possible for the members’ review. Within ten (10) working days of receipt, the proposal will be reviewed by the subcommittee. It may facilitate the review if the principle investigator is available to clarify details and answer questions during or immediately
following the meeting. At that time, the principle investigator will be notified of either approval or recommendations for alterations in the proposal. Once approved, the project may be implemented immediately. If changes are recommended, the investigator will also be informed of an expected process for a second review. This second review may be a documentation with the subcommittee chair that recommended changes have been implemented or a meeting of the subcommittee.

Guidelines – Each submission will be reviewed on its own merit as valid and reliable research. The subcommittee will also review each proposal in light of the philosophy and mission of Saint Francis Medical Center. The subcommittee will be mindful of research that is part of an academic requirement. These have been approved by the Institutional Review Board of the academic program; any recommended changes must be congruent with that IRB. If a compromise cannot be achieved, the investigator may need to consider not including Saint Francis Medical Center as a research site.

The principle investigator will provide the Research and Clinical Investigation Committee with an analysis of data at the completion of the study. The Research and Clinical Investigation Committee also expects feedback on the support and assistance of Saint Francis Medical Center and its staff to the individual research process.

In the event that a published article arises from the project, Saint Francis Medical Center expects acknowledgment of support and assistance provided during the research within the published article.

Upon approval of a research proposal, the Committee chair will send a copy of the approval letter to the Vice President, Patient Care Services. Additional copies will be sent to the Director of the involved department or the Patient Care Directors.

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110306
RESEARCH AND CLINICAL INVESTIGATION COMMITTEE
APPLICATION TO PERFORM RESEARCH

Date _________________________

Researcher’s Name ____________________________________________________________

Address ______________________________________________________________________

Phone Numbers: home __________________; cell __________________; work _____________

Is this project meeting academic requirements?  No _________ Yes ________

If yes, specify: __________________________________________________________________

What SFMC staff/employees will be involved with this research? __________________________

Discuss time frames, expectations, pre-research training, etc., which will involve SFMC staff:
_________________________________________________________________________________

What plans do you have to present this study? __________________________________________
_________________________________________________________________________________

How is this project being funded? ___________________________________________________
_________________________________________________________________________________

Who will be responsible for the day-to-day monitoring of data collection, effects on patients, family
and staff, and ongoing research problems?
_________________________________________________________________________________

SFMC Research and Clinical Investigation Committee requires the Department Director, Manager, or
Supervisor of the area(s) where research will be conducted to approve the feasibility for the proposal.
Please have the signature(s) of the above.

Signature of Department Director, Manager, or Supervisor ____________________________ Date

Application Received by ________________________
(Chairperson or Designee) ______________________ Date

/cdl
Saint Francis Medical Center Policy and Procedures

<table>
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<tr>
<th>Section: ADMINISTRATIVE</th>
<th>Originating Department: ADMINISTRATION</th>
<th>Effective Date: 01/01/1993</th>
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<tbody>
<tr>
<td>Title: INSTITUTIONAL REVIEW BOARD</td>
<td>Executive Approval: Steven C. Bjelich</td>
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Policy:

A. The Institutional Review Board (IRB) is a board designated by the Medical Center to review, approve the initiation of, and to conduct continuing review of bio-medical research involving human subjects in accordance with the Food and Drug Administration (FDA) regulations and the Ethical and Religious Directive for Catholic Health Care Services. The IRB has the authority to approve, require modification in (to secure approval) or disapprove the research.

B. The membership of the IRB shall consist of at least five (5) members, including the Chairperson, with varying backgrounds sufficiently qualified through experience and expertise with the professional competence necessary to review the specific research activities. The diversity of the membership shall give consideration to such issues as community attitudes, to promote respect for its advice, and counsel in safeguarding the rights and welfare of human subjects. Membership shall include persons with the following knowledge and background:

1. The membership shall be nondiscriminatory, considering qualified persons of both sexes, not consisting entirely of men or entirely of women.

2. There shall be at least one member whose primary concerns are in the scientific area and at least one member in a non-scientific area.

3. There shall be at least one member who is not otherwise affiliated with the Medical Center or part of the immediate family of a person affiliated with the Medical Center.

4. There shall be at least one member who also serves on the Medical Center’s Ethics Committee.

5. No member who has a conflicting interest shall participate in the initial or continuing review of any research except to provide requested information.

6. The IRB may invite individuals with competencies in special areas to assist in the review, without voting privileges.

7. The Chairperson and the members of the IRB are appointed by the President/CEO of the Medical Center in consultation with the President of the Medical Staff. Each term will be for three (3) years. A member may be reappointed with no limit of the number of terms served.

8. Included in the IRB membership are the Vice President of Patient Care as a voting member and the President/CEO of the Medical Center as a non-voting member. At least one IRB member serves as the IRB’s linkage to the Medical Center’s Board of Directors.

C. The purpose of the IRB review is to assure the following:

1. Risks to the subject are minimized.
a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
b. Whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes.

2. Risks to subject are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. The IRB must decide if the proposed investigation poses a significant risk or a non-significant risk to patients.

A significant risk (SR) study involves an investigational device or study that presents a potential for serious risks to the health, safety, and welfare of a subject and that is:

a. an implant;
b. for use in supporting or sustaining human life;
c. substantially important in diagnosing, curing, mitigating, or treating disease in preventing impairment of human health.

A non-significant risk (NSR) device is an investigational device that does not meet the definition for a significant risk study.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purpose of the research and the setting in which the research will be conducted.

4. Potential subjects are provided with adequate information to participate or refuse to participate in the proposed research. "Adequate information" includes at least an explanation of the following:
   a. The purpose of the research and expected duration of the subject's participation;
   b. A description of expected benefits, potential discomforts, and risks; alternative services that might prove advantageous to the individual;
   c. A full explanation of the procedures to be followed.

Subjects are informed that refusing to participate or discontinuing participation at any time will not compromise their access to care, treatment, and services not related to the research.

5. Informed consent will be sought from each prospective subject or the subjects legally authorized representative and will be documented in accordance with, and to the extent required by FDA's informed consent regulations. Consent forms should include the following:
   a. Name and address of the person who provided the information and the date the form was signed;
   b. Explanation of the participant's right to privacy, confidentiality, and safety.

All information given to subjects should be in the subject's medical record or research file along with consent forms.

6. Where appropriate, the research plan makes adequate provisions for monitoring data collected to ensure the safety of subjects.

7. The IRB will require, where appropriate, adequate provisions for monitoring the data collected to ensure the safety of the subjects and adequate provisions to protect their privacy and maintain confidentiality in compliance with current HIPPA and other relevant regulations.

8. Appropriate additional safeguards have been included in the study to protect the rights and welfare of subjects who are members of a particular vulnerable group.
a. The IRB is subject to the FDA’s IRB’s regulations when the use of the FDA regulated products is reviewed and approved.

b. Minimum standards to assure human subject protection are required if the FDA is to accept the data from investigational studies not conducted under an investigational new drug or an investigational device exemption.

c. When the IRB has questions regarding the determination whether an investigational new drug application (IND) is required for the study of a drug or a device (IDE), for clinical investigations involving a drug, the IRB can contact the Document Management and Reporting Branch, Center for Drug Evaluation and Research (CDER), 301-443-4320; for a biological product, the Division of Biological Investigational New Drugs, Office of Biological Research and Review, Center for Biological Evaluation and Research (CBER), 301-443-4864; and for a medical device, the Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), 301-493-8162. If the IRB is unsure about whether a test article is a “drug” or a “device”, the IRB may contact the Office of Health Affairs, 301-443-1382.

9. Assure that the researcher understands that if a research-related injury (that is, physical, psychological, social, financial, or otherwise) occurs, the principle investigator should attempt to address any harmful consequences the subject may have experienced as a result of research procedures.

10. The research is consistent with the Ethical and Religious Directives for Catholic Health Care Services

II. PROCEDURAL RESPONSIBILITIES/FUNCTIONS OF THE IRB AND THE INVESTIGATOR

A. The IRB will utilize the following procedure for:

1. Conducting its initial and continuing review of research study and/or protocol and for reporting its findings and actions to the investigator and the Medical Center.

2. Determining required frequency of continuing review of projects.

3. Ensuring prompt reporting to the IRB of changes in research activity.

4. Ensuring that changes in approved research may not be initiated without IRB review and approval.

B. Procedure for submitting a research study or protocol for IRB review and approval.

1. The investigator must submit a written, signed request for the IRB’s consideration, including the following information:

a. Professional qualifications to do the research study or protocol. If new or unique clinical training is required, separate privileging would be required by the Credentials Committee.

b. Study protocol which addresses the purpose, sponsor, subject criteria, justification, study design, description of procedures, results of previous related research, management of adverse reactions, informed consent procedures, provisions for selection of subjects and monitoring procedures.

c. Protocol and protocol updates must be received by the IRB coordinator prior to a meeting being scheduled.

d. Investigators must report to the IRB any adverse reactions or other unanticipated problems.

e. Investigator will provide IRB with a fully completed/signed protocol and informed consent.

f. Any proposed changes in protocol previously approved by the IRB will be promptly reported to the IRB.
C. IRB members will be notified of the time and place of scheduled meetings.

1. The agenda and materials to be reviewed will be distributed to the members prior to the meeting.

2. Upon written request of the Chairperson of the IRB, the investigator may be invited to the IRB meeting to give additional information or justification for the protocol.

3. When approving research, the following criteria will be followed:
   
a. Risks to subjects are minimized if:
      1. procedures are consistent with sound research design and do not unnecessarily expose the subject to risk; and
      2. Whenever appropriate, using procedures already being performed on the subjects for diagnostic and treatment purposes.
   
b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result, considering only those risks and benefits that may result from the research or protocol.

4. Selection of subjects is equitable and the IRB should consider the purposes of the research and the setting in which the research will be conducted.

5. Following the IRB’s decision regarding approval of a protocol or study, the IRB will notify the investigator in writing of the decision. If the IRB decides, the request shall include in its written notification a statement of reasons for decision, and give the investigator an opportunity to respond in person or in writing.

6. The IRB will stipulate the frequency of ongoing reviews or progress reports of the research protocol.

D. Meeting and recording responsibilities of the IRB:

1. The IRB shall meet to review, approve, or disapprove a research study, protocol, or consent.

2. The IRB shall conduct continuing review of the research at intervals appropriate to the degree of risk, but not less than once per year.

3. A majority of the IRB must be present at a convened meeting to transact business, including at least one member whose concerns are primarily in non-scientific areas. For approval, disapproval, or rejection of a study, a simple majority of members present is required.

4. IRB shall maintain adequate documentation of all research proposals reviewed (including scientific evaluations, consent documents, progress reports, and reports of injuries to subjects).

5. Minutes of IRB meetings shall show attendance, actions taken, the vote, reasons for requiring changes or in disapproving a research and a summary of the discussion and resolutions. The IRB shall notify investigators and the Medical Center of its decisions in writing. Minutes of the IRB meetings are forwarded to the Medical Staff Executive Committee on which all Medical Staff department chairpersons serve for informational purposes.

6. IRB shall maintain records of continuing review activities, including an ongoing log of research approved or disapproved.
7. Copies of all correspondence shall be maintained.

8. List of IRB members identified by name, earned degrees, representative capacity, indicators of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contribution, shall be maintained.

9. The records required by this regulation shall be maintained for at least three years after completion of research and the records shall be accessible for inspections and copying by authorized representatives of FDA.

III. EMERGENCY USE

A. Emergency use of an investigational drug/procedure without full IRB approval may be granted only in the following instances:

1. The patient has a life-threatening condition in which no standard, acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

2. An Investigational New Drug (IND) is necessary. The manufacturer must be contacted to determine if the drug or biologic can be made available for us in this one (1) patient under the company’s IND. If the company elects not to name the physician as an investigator, the physician can contact the FDA directly for an IND.

3. The emergency must be reported to the IRB within five (5) working days.

4. Any subsequent use of the investigational product at the Medical Center is subject to IRB review.

5. Informed consent must be obtained from the subject, or the subject’s legally authorized representative, unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

   a. That the subject is confronted by a life-threatening situation necessitating the use of the test article.
   b. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
   c. Time is not sufficient to obtain consent from the subject’s legal representative.
   d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject.

B. Use of a test article in an investigation designed to be conducted under emergency conditions (e.g., emergency from research) usually does not qualify for the emergency use exemption.

C. Sufficient background information on the drug/procedure exists for the Medical Center to utilize.

D. The full IRB will review the emergency use of a drug/procedure and the protocol at a special called meeting to be arranged as soon as possible after granting emergency approval.

IV. EXPEDITED REVIEW

An expedited review process may be followed if it is the type of category of research established and published in the Federal Register, and if the research involves no more than minimal risk, or to review minor changes in previously approved research during the period of which approval is authorized.
A. Review must be carried out by two (2) or more experienced reviewers designated by the Chairperson from among members of the IRB.

B. Reviewers may exercise all the authorities of the IRB, except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited reviewed procedure.

C. Reviewers may recommend that the project be reviewed by the full IRB with a recommendation to disapprove.

D. The full IRB will be informed, in writing, of all proposals approved under expedited review.

E. The FDA, or the Medical Center, may terminate the use of expedited review, if necessary, to protect subjects.

V. SUSPENSION OR TERMINATION OF RESEARCH APPROVAL

A. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects.

B. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, and shall be reported promptly to the investigator, the Medical Center Administration, and to the FDA.

References: Department of Health and Human Services
Food and Drug Administration Institutional Review
Code of Federal Regulations - Parts 1 to 99 - Revised 04/01/96
Food and Drug Administration Information Sheets - Revised 10/95

*To ensure that research is conducted ethically in order to assure that the rights and welfare of subjects are protected, the FDA has regulations which govern human subject protection aspects of research on products regulated by the agency.

Originating Department: Administration
Effective Date: January, 1993
Reviewed Dates: 08/96, 07/97, 10/98, 06/04, 04/07, 03/08, 05/08, 04/09
Revised: 04/05, 07/05, 08/06, 06/07

Approved: _______________________________
Steven C. Bjelich, FACHE-D
President & CEO

Distribution: All Areas
Blood & Body Fluid: OSHA Category III

Approval:

Approved by Administration on January, 1993.
Approved by Institutional Review Board on January, 1993
Approved by Medical Staff Executive Committee on January, 1993.
Approved by Board of Directors on January, 1993.

Reviewed and reapproved by Institutional Review Board on July 18, 1997

/clw
IRB SUBMISSION GUIDELINES

To maintain the efficient functionality of the Institutional Review Board, we ask that you please submit the following items prior to our setting a meeting date and time.

1. A letter, addressed to Dr. Wm. D. Stahr, Chairman, and sent to the attention of Connie Friedrich at Saint Francis, introducing the study and requesting that a meeting date and time be set for the IRB to review the study for possible approval;

2. A one- to two-page summary of the study;

3. Complete and submitted a fully executed and signed copy of the IRB Application form;

4. A copy of the proposed consent form (separate from the full text);

5. A copy of the full study protocol; and

6. Your contact information including phone numbers and address.

When we have received and reviewed this information, we will place the study/project on the agenda of the next scheduled IRB meeting (meetings are held on a quarterly basis, normally in March, June, September and December). Please recognize that the IRB study protocol(s) must be sent to each member approximately ten days in advance, to allow them time to review the study and prepare for the meeting. Your cooperation and patience in this process would be most appreciated.

Respectfully,

Connie Friedrich

Connie Friedrich
Medical Staff Coordinator
(573) 331-5130 or (573) 331-5137
APPLICATION FOR APPROVAL OF HUMAN SUBJECT RESEARCH (IRB)

Date of Submission

IRB reviewers must have sufficient information about the study to make a determination about whether the research is approvable. Primary reviewers receive the full protocol that is submitted but the remainder of the committee uses the following summary when making a decision about approvability. Incomplete forms will not be accepted and returned for completion.

Advance Research Title:

<table>
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<tr>
<th>Principal Investigator Information:</th>
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<tr>
<td>Name:</td>
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<td>Address:</td>
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<td>Phone number:</td>
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<td>Fax number:</td>
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<tr>
<td>E-mail address:</td>
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<tr>
<td>Name of Department Chair:</td>
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<td>Co-Investigators:</td>
</tr>
</tbody>
</table>

Person & Address to which correspondence should be mailed:

Coordinator Information (Please list the person that the IRB can contact with questions):

| Name:                             |
| Address:                          |
| Phone number:                     |
| Fax number:                       |
| E-mail address:                   |

LEVEL OF RISK/TYPE OF REVIEW REQUESTED

Indicate the level of risk:  [ ] Minimal  [ ] Greater than Minimal

Indicate the type of review requested:  [ ] Full Board  [ ] Expedite

STUDY INFORMATION

Proposed Start Date

Proposed Closure Date

Number of participants to be enrolled.

Is the number of anticipated subjects adequate for valid statistical analysis?  [ ] Yes  [ ] No

How long will each participant be followed after the intervention has taken place?

Indicate the duration of study participation per participant.

Indicate the duration of the entire study.

Is there any gender and/or racial/ethnic exclusions? (If yes, please explain on attached paper)  [ ] Yes  [ ] No

Is there a conflict of interest between the principal investigator or any co-investigator or research coordinator involved in this study? (If yes please attach a detailed explanation)  [ ] Yes  [ ] No

Will the study utilize Saint Francis Medical Center staff (If yes, approval must be obtained from staff managers in writing)  [ ] Yes  [ ] No
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<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>Does this research involve an investigational drug or biologic?</td>
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<tr>
<td>Does this research involve an approved drug or biologic being used for an unapproved indication</td>
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<td>Does this research involve a significant risk device that is not approved by the FDA</td>
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<td>Does this research involve data relating to an identifiable third party (e.g. Family members) that will not be consented?</td>
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<td>Does this research include minors (ages 0-17)</td>
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<td>Does this research involve pregnant participants?</td>
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<td>Does this research involve HIV testing for research purposes?</td>
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<td>Does this research involve collection or use of any type of tissue or data to be used for any form of molecular (genetic) research?</td>
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<td>Does this research involve the use of audiotapes, videotapes or photographs?</td>
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<td>Is the research industry sponsored?</td>
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<td>Does this study require a modified consent process?</td>
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<td>When will the consent take place?</td>
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<td>Where will the consent take place?</td>
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<td>Who will be responsible for obtaining initial and ongoing consent?</td>
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<td>Will this research target the cognitively impaired?</td>
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<td>Will any part of the research be conducted outside the United States?</td>
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<td>Does this research involve collection of data/tissue for future research?</td>
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<tr>
<td>Will the research participant receive exposure to ionizing radiation from radiation therapy, diagnostic radiology imaging studies, standard nuclear medicine studies or other administration of radioactive drugs that would not occur except for the subject's participation in research protocol?</td>
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<td>Does this study involve the use of a placebo?</td>
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<td>Do you or any investigator participating in the study have, or anticipate having, any income from or financial interest in: the sponsor of the protocol, the supporting organization, or the company that owns/licenses the technology being studied?</td>
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<td>Does this research involve interviews or questionnaires? (If yes, attach questionnaire to submission packet.)</td>
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<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
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<td>Will this research uncover an incriminating data (i.e. drug testing, sensitive questionnaires, etc)?</td>
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<td>Does this research involve prisoners?</td>
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<tr>
<td>Is this an ancillary protocol or compassionate use protocol that related to a &quot;master protocol&quot; that has already been submitted to the IRB?</td>
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<tr>
<td>To your knowledge, has this protocol been reviewed by the Saint Francis Medical Center IRB or disapproved by any IRB? (If yes, please attach details)</td>
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<tr>
<td>Does the principal investigator or any co-investigator or research coordinator involved in this study (or in aggregate with his/her spouse, dependents or members of his/her household) have a personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?</td>
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<tr>
<td>Does the principal investigator or any co-investigator or research coordinator involved in this study possess an equity interest in the entity that either sponsors this research or owns the technology being evaluated that exceeds 5% ownership interest or a current value of $25,000?</td>
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<tr>
<td>Does the principal investigator or any co-investigator or research coordinator involved in this study receive salary, royalty, or other payments from the entity that either sponsors this research or owns the technology being evaluated that is expected to exceed $10,000 per year?</td>
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<tr>
<td>Does the principal investigator or any co-investigator or research coordinator involved in this study have an agreement with the University or an external entity that would entitle sharing current or future commercial proceeds related to the technology being evaluated (e.g., royalties through a license agreement)?</td>
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<tr>
<td>Does the principal investigator or any co-investigator or research coordinator involved in this study have a financial relationship with a start-up company (which is being monitored by the Entrepreneurial Oversight Committee) that has an option or license to utilize the technology being evaluated?</td>
<td></td>
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<tr>
<td>Will the patient need to have testing, services, procedures, samples obtained, or hands-on care at Saint Francis Medical Center? (If no, skip the rest of this section.)</td>
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<tr>
<td>Will the patient or their insurance be billed for these services?</td>
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<tr>
<td>Will the industry sponsor be billed or provide reimbursement for services provided?</td>
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<tr>
<td>Have appropriate arrangements been made to bill the procedures to the industry sponsor?</td>
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<tr>
<td>If you answered no to both previous questions who will be responsible for financial reimbursement to the Medical Center?</td>
<td></td>
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<tr>
<td>Will approval of the study prohibit Saint Francis Medical Center from billing a patient, their insurance, or receiving compensation for services rendered in order to comply with the protocol and consent form?</td>
<td></td>
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</tr>
<tr>
<td>If you answered yes to any of the above four questions you must obtain approval from the Director and Vice President over the area</td>
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</tbody>
</table>
My signature affirms that a) I have been made aware of the financial circumstances involved if this study is approved and the need to possibly alter billing practices b) I will make the necessary arrangements to assure that the proper billing method is used to minimize any inconveniences to the patient and to adhere to the consent form.

Director ____________________________________________________________________________ Vice President ____________________________________________________________________________

What is the purpose/rationale of this study?

________________________________________________________________________________________

What are your objectives for the study?

________________________________________________________________________________________

What is your Rationale/Justification for the study?

________________________________________________________________________________________

Describe the subject’s participation; explain what will be expected of the participants.

________________________________________________________________________________________

Please list all potential risks.
Likely: ________________________________________________________________________________
Less Likely: _____________________________________________________________________________
Rare: _________________________________________________________________________________

Is death a reasonable risk of the study? [ ] Yes  [ ] No

How will risks be minimized?

________________________________________________________________________________________

What arrangements for medical treatment, if needed, have been made?

________________________________________________________________________________________
What resources are needed to conduct this research in a manner that protects participants?

Will these resources be available to you for this study? [ ] Yes  [ ] No
What are the potential benefits for subjects?

How will the results of this research benefit society?

How do the above stated benefits outweigh the risks inherent in the research?

Will patients be financially compensated for participation? [ ] Yes  [ ] No  Amount: ______
List the inclusion criteria. Do NOT reference the protocol.

List the exclusion criteria. Do NOT reference the protocol.

List all recruitment techniques that will be used. Attach copies of any advertisements.
List the efforts that will be taken to ensure patient confidentiality.

List all data sources (i.e. medical records, test results, questionnaires, billing records)

List all people who will have access to the data.

List all identifiers that will be collected (i.e. names, phone numbers, health plan information, biometrics, or any unique identifying number, characteristic or code, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher)

List steps that have been taken to ensure data security for storage and transmission (i.e. secure network, password protection, encryption, locked cabinet, locked office)

The Office for Human Research and Protection recommends researchers to be educated in research. Describe what education/training you have received regarding research.

Does the study involve vulnerable subjects? If so, describe the special protections that have been implemented.
CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES

By signing below I agree/certify that:

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.

2. I have adequate resources and facilities to carry out the proposed research.

3. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
   - I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
   - I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.

4. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements; and (f) the current IRB approval status of the research study.

5. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.

6. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.

7. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).
   - I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.

8. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.

9. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.

10. I will submit an annual report using the sample template provided to me by the IRB. I understand in order for the committee to review my request to participate as the primary investigator I am required to attend the meeting in which my study being reviewed. If I am unable to attend I agree to send a co-investigator or other person familiar with the study in my place to represent me.
11. I will submit all documents to the IRB at least ten days before the next scheduled meeting.

12. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.

13. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.

14. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.

15. I will ensure that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved.

Principal Investigator Name (printed/typed)  Principal Investigator signature  Date

Please submit your packet to Julie Poston or Connie Friedrich in Medical Affairs with all required forms, cover sheet, letter requesting IRB approval addressed to Clyde Neminger, Summary of the study protocol, full protocol, consent form, recruitment documents, and any other pertinent documents. The IRB committee will consider your study request at the next scheduled meeting. Meetings are held quarterly on the second Thursday of March, June, September, and December. All requests must be submitted at least two weeks prior to the meeting date for consideration at the next meeting. For a list of meeting dates or if you have any questions please call 573-331-5130.
Appendix L
Sample Title Page
A DISCRIMINATIVE STUDY OF METHODS OF THE QUANTITATIVE
DETERMINATION OF FLOURINE

A Thesis
Presented to
the Faculty of the Graduate School
Southeast Missouri State University
Department of Nursing

In Partial Fulfillment
of the Requirements for the Degree
Master of Science in Nursing

by
Nancy Jennings White

May, 2011
Appendix M
Criteria for Evaluation of Oral Examination
FACULTY EVALUATION OF STUDENT'S ORAL PRESENTATION OF RESEARCH

Please circle the letter next to each question that most closely matches your response based upon a scale of: A=Outstanding; B=Above Average; C=Average; D=Below Average; E=Not Performed. Leave blank if not applicable.

**Presentation Style:**

A B C D E 1. Maintained eye contact without excessive reading of notes
A B C D E 2. Presented within the time frame (20 min.).
A B C D E 3. Presented ideas in a rational/logical format.
A B C D E 4. Exhibited appropriate and enthusiastic affect (not monotone & not over emotional).
A B C D E 5. Asked faculty to clarify questions as needed.
A B C D E 6. Used appropriate language (avoided excessive fillers, e.g. uhs, ums, or ands).
A B C D E 7. Responded to faculty questions and concerns in an appropriate manner.
A B C D E 8. Creatively used instructional technology to enhance presentation of the research findings.

**Demonstration of Scholarship:**

A B C D E 9. Presented findings based on data versus non-supported opinion.
A B C D E 10. Discussed research project and findings from a broad variety of perspectives.
A B C D E 11. Supported research study with a comprehensive literature review.
A B C D E 12. Clearly described the conceptual framework that guided the study.
A B C D E 13. Clearly described the study design (including sample, setting, and instruments).
A B C D E 14. Clearly summarized findings from the research study.
A B C D E 15. Used correct research terminology and appropriate documentation.
A B C D E 16. Discussed how the findings of the study could influence nursing practice, education, administration, further research, health policy development, and/or legal/ethical practice issues.
A B C D E 17. Overall performance of candidate’s oral defense.
Appendix N
Criteria for Evaluation of Written Thesis
### FACULTY AND STUDENT EVALUATION
**OF WRITTEN QUANTITATIVE RESEARCH STUDY**

Please circle the letter next to each question that most closely matches your response based upon a scale of: A=Outstanding; B=Above Average; C=Average; D=Below Average; E=Not Performed. Leave blank if not applicable.

<table>
<thead>
<tr>
<th>Question</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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<tbody>
<tr>
<td>1. The title clearly and concisely described the research problem, research variables and population.</td>
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<tr>
<td>2. The purpose of the study was clearly described.</td>
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<td>3. The identified conceptual/theoretical framework guided the study’s research methods (schema/model enhanced understanding of framework)</td>
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<td>4. The research question(s), hypothesis(es), or objective(s), accurately and concisely stated.</td>
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<td>5. The review of the literature was comprehensive and relevant to the problem.</td>
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<td>6. The design of the study was clearly described.</td>
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<td>7. The sample and sample selection was clearly identified.</td>
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<td>8. Instrument(s) clearly described including reliability and validity.</td>
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<td>9. Human subject review and recommendations were followed.</td>
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<td>10. Data collection methods (where, when, and how) were clearly described for replication of the study.</td>
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<td>11. Appropriate data analysis procedure(s) was used.</td>
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<td>12. Presentation of findings was objective rather than subjective, speculative, or over generalized.</td>
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<td>13. Implications of research findings identified for nursing practice, education, and administration as appropriate to show the significance of the research to nursing.</td>
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<td>14. Conclusions were supported by the data and clearly stated.</td>
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<td>15. Writing style was clear, concise, and organized using correct grammar, spelling, and punctuation.</td>
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FACULTY AND STUDENT EVALUATION
OF WRITTEN QUALITATIVE RESEARCH STUDY

Please circle the letter next to each question that most closely matches your response based upon a scale of: A=Outstanding; B=Above Average; C=Average; D=Below Average; E=Not Performed. Leave blank if not applicable.

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<tr>
<td>A</td>
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<td>D</td>
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<tr>
<td>1. The title clearly and concisely described the phenomenon being studied.</td>
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<td>2. The purpose of the study was clearly described.</td>
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<td>3. Justification for using a qualitative approach was appropriately discussed.</td>
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<td>4. The research question(s) guiding the study were accurately and concisely stated.</td>
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<td>5. The review of the literature clearly related study findings to existing literature and supported identified implications for future research.</td>
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<tr>
<td>6. The design of the study was clearly described.</td>
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<td>7. The sample and sample selection was clearly identified.</td>
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<td>8. Qualitative approaches to validity were appropriately discussed.</td>
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<td>9. Human subject review and recommendations were followed.</td>
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<tr>
<td>10. Data collection methods (where, when, and how) were clearly described for replication of the study.</td>
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<tr>
<td>11. Appropriate data analysis procedure(s) was used and adequately explained.</td>
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<tr>
<td>12. Presentation of findings was objective rather than subjective, speculative, or over generalized.</td>
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<tr>
<td>13. Conclusions regarding implications for further research and nursing practice were supported by the data and clearly stated.</td>
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<tr>
<td>14. Writing style was clear, concise, and organized using correct grammar, spelling, and punctuation.</td>
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Appendix O
Criteria for Evaluation of Thesis Process
RESEARCH PROJECT CHAIRPERSON AND GRADUATE STUDENT
EVALUATION OF THE RESEARCH PROJECT PROCESS

Please use a scan sheet to respond to the following questions based upon a scale of:
A=Outstanding; B=Above Average; C=Average; D=Below Average; E=Not Performed.
Leave blank if not applicable.

A B C D E 1. Met with Project Chairperson in a consistently independent and regular manner.

A B C D E 2. Promptly followed guidance of Chair and Committee Members on modifications to proposal and final manuscript.

A B C D E 3. Defended rationales for research endeavor without becoming defensive.

A B C D E 4. Demonstrated involvement in data analysis.

A B C D E 5. Demonstrated preparedness for meetings, having read the literature prior to making decisions regarding research endeavor.

A B C D E 6. Able to effectively debate the various alternatives to design selection relative to the research topic and problem.

A B C D E 7. Kept Committee Members informed on progress of research endeavor and used their expertise appropriately.

A B C D E 8. Maintained a scholarly, inquisitive, and positive attitude during the research project process.
<table>
<thead>
<tr>
<th>Faculty Specialty</th>
<th>Research Expertise</th>
<th>Interest</th>
<th>Methodology Expertise</th>
<th>Research Option Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kathryn Farwell, PhD, CARN-AP</td>
<td>Chemical dependency&lt;br&gt;Chemically dependent nurses, recovery, social support, locus of control, history of female alcoholism</td>
<td>Addictions research</td>
<td>Qualitative&lt;br&gt;Quantitative (Triangulation)&lt;br&gt;Historical</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Psychiatric–Mental Health Nursing</td>
<td>Role development in student nurses&lt;br&gt;Critical thinking of nursing students</td>
<td>Critical thinking</td>
<td>Quasi Experimental Quantitative</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Gloria Green, PhD, RN</td>
<td>Medical – Surgical Nursing</td>
<td>Thinking skills&lt;br&gt;Emergency/Critical care Pediatrics</td>
<td>Quantitative Descriptive</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Kathy Ham, EdD, RN</td>
<td>Medical-Surgical and Child Nursing</td>
<td>Moral &amp; Cognitive development&lt;br&gt;Ethical decision making</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
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<tr>
<td>Linda Heitman, PhD, RNC</td>
<td>Medical – Surgical Nursing</td>
<td>Genetic and behavioral cardiac risk factors&lt;br&gt;Renal transplantation</td>
<td>College nursing&lt;br&gt;Organ transplantation&lt;br&gt;Health care ethics&lt;br&gt;Medical – Surgical nursing issues</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Elaine Jackson, PhD, RN</td>
<td>Maternal – Parent/Child Nursing</td>
<td>Adolescent contraceptive use&lt;br&gt;Adolescent pregnancy/parenting</td>
<td>Child abuse / neglect&lt;br&gt;School nursing&lt;br&gt;Women’s health care needs in rural settings&lt;br&gt;Sexual health issues&lt;br&gt;MCH nursing issues</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Brenda Johnson, PhD, RN</td>
<td>Gerontological Nursing</td>
<td>Dementia&lt;br&gt;Personhood</td>
<td>Exploratory&lt;br&gt;Descriptive&lt;br&gt;Phenomenological methods</td>
<td>Chair – Yes&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Bobbi Palmer, MSN, APRN, BC-FNP</td>
<td>Family Nurse Practitioner</td>
<td>Pain management</td>
<td>Pain assessment&lt;br&gt;Physical assessment</td>
<td>Chair – No&lt;br&gt;Committee - Yes</td>
</tr>
<tr>
<td>Desma Reno, MSN, RN</td>
<td>Gerontological Nursing</td>
<td>Chronic illness with elderly&lt;br&gt;Restraint reduction</td>
<td>Chronic illness issues&lt;br&gt;Caregiver issues&lt;br&gt;Issues in elder care&lt;br&gt;Client advocacy</td>
<td>Survey&lt;br&gt;Non-experimental designs</td>
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<tr>
<td>Name</td>
<td>Role</td>
<td>Research Areas/Topics</td>
<td>Research Methods</td>
<td>Chair</td>
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<tr>
<td>Julie Sappington, PhD, RN</td>
<td>Community Health &amp; Child Nursing</td>
<td>Family’s role in teen driving safety, older adults and exercise CAM, stress management, older adults and sexuality, teaching strategies, learning styles</td>
<td>Qualitative-interpretive phenomenology</td>
<td>Chair - Yes</td>
</tr>
<tr>
<td>Ann Sprengel, EdD, RN</td>
<td>Medical – Surgical Nursing</td>
<td>Predicting student attrition rates Teaching strategies (gaming, stimulation) Learning styles</td>
<td>Medical-Surgical nursing Teaching Gender issues</td>
<td>Quantitative</td>
</tr>
<tr>
<td>Janet Weber, EdD, RN</td>
<td>Medical – Surgical Nursing</td>
<td>Nursing diagnosis Interactive Teaching/Learning methods Learning styles Online curriculum development Nursing assessment</td>
<td>Nursing management Holistic assessment Nursing diagnoses: hopelessness, spiritual distress, altered nutrition Interactive learning environments</td>
<td>Quasi Experimental Qualitative</td>
</tr>
<tr>
<td>Terri Woods, EdD, RN</td>
<td>Community Health</td>
<td>Curriculum and Instruction Ethical issues in home health / community Hospice Physical assessment</td>
<td>Quantitative Descriptive Survey</td>
<td>Chair – Yes</td>
</tr>
<tr>
<td>Madonna Weiss, MSN, APRN, BC-FNP</td>
<td>Family Nurse Practitioner</td>
<td>Peripheral Vascular Disease Physical assessment Management of Chronic illnesses Geriatrics</td>
<td>Qualitative</td>
<td>Chair – No</td>
</tr>
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