PENROSE-ST. FRANCIS HEALTH SERVICES

INTERDISCIPLINARY PRACTICES

SUBJECT: **Nursing** **Research Studies**

PREVIOUS DATES: 7/02, 8/09 EFFECTIVE DATE: 2/11

RECOMMENDED BY: Interdisciplinary Practice Committee

ADMINISTRATION APPROVAL: Jeff Oram-Smith, MD, CMO Katherine D McCord, RN, CNO

GUIDELINES FOR CARE:

Research studies conducted by Penrose St. Francis nursing associates and/or students is conducted in a safe, efficient, and prescribed manner that protects the safety of the participant and is consistent with all federal, state, and local regulations.  Conducting nursing research is one way PSFHS nurses contribute to the profession of nursing. Basing practice on the current evidence available and contributing to this body of evidence are key behaviors exhibited by professional nurses. Nursing Research at PSFHS is guided by the Nursing EBP/Research Council.  All research proposals must undergo scientific review by the EBP/Research Council and Institutional Review Board.

PRACTICES:

1. The investigator will be responsible for obtaining permission from unit manager and director to do the study.
2. Researcher will contact the current Chairperson of the Evidence Based Practice/Research Council (EBP). The chairperson will discuss the proposal with the researcher and assign a mentor, who will assist her/him throughout the research process. If the researcher is associated with a university, please submit a copy of the university IRB approval along with the proposal.
3. When the researcher’s proposal is complete (see Appendix I), the application should be submitted to the EBP Chairperson for review and approval.
   1. Researcher will electronically send written proposal to the Chairperson of the EBP Council including required attachments.
   2. The Chairperson will forward proposal to at least two EBP Council members. The selected EBP Council members will act for the EBP Council.
   3. EBP Council members will review the proposal and recommend approval or revisions.
   4. The Chairperson will either
      1. Forward proposal and recommendations for approval to the Chief Nursing Officer (CNO) or,
      2. Forward the proposal to the EBP Council for further review and discussion or,
      3. Return the proposal to the researcher with recommendations for revisions. The researcher will make revisions and resubmit or withdraw request.
   5. The CNO will determine final approval based on review of proposal and EBP Council recommendations. If the CNO requests further discussion, the proposal will be placed on the EBP Council agenda for expanded review.
4. Following the approval of the EBP Council and Chief Nursing Officer, the researcher will submit to the IRB. Submission to the IRB requires the researcher (s) provide proof of completion of education on protecting human research participants. National Institutes of Health provides an online course, "[Protecting Human Research Participants (PHRP)](http://phrp.nihtraining.com)." This web-based tutorial is intended for use by those involved in the design and conduct of research involving human participants and available at <http://phrp.nihtraining.com/users/login.php>.
5. Following the approval of the EBP Council, CNO *,* and the IRB *but* prior to data collection, the researcher will meet with the clinical manager of the unit(s)/director involved in the research study
6. As part of the approval for conducting the study, the researcher agrees to:
   1. Provide quarterly updates of progress of the research study to the EBP Council
   2. Present the results of the research to the EBP Council and Nursing Leadership Council
   3. Submit a copy of the study’s final report (including an abstract) within six months of the study’s completion, and if publication is anticipated, name of journal. Once published, submit article to the EBP.
   4. Agree that the research facility and the research participants shall not be identified by name in the study or any publication. The IRB will provide a preferred statement for describing the research setting.
7. If a chart review will be required, a separate “student/researcher” Clinical Information System code must be requested.
   1. To obtain a researcher’s code, the PSF sponsor must first obtain IRB approval for research study.
   2. The investigator shall notify Director Health Information Management (HIM) of research proposal, provide copy of IRB approval and facilitate a meeting between researcher and Director HIM.
   3. The Director of HIM will coordinate access to records.

REFERENCES:

Penrose St. Francis Health Services, Institutional Review Board (IRB) Policy l-07-f. (2008). Polit, D., & Beck, C. (2008). *Nursing research: Generating and assessing evidence for nursing practice.* Philadelphia: Lippincott Williams & Wilkins.

**Appendix I**

**The research proposal must contain the following information as applicable (from IDPC I-07-f Institutional Review Board):**

Proposal Elements

1. Investigator Information
   1. Name, address, phone, email and credentials
   2. If PSFHS associate, state unit and name of manager.
   3. If student, list name of approved school and faculty sponsor name and contact information. State academic major.
   4. If faculty, list name of approved school.
2. Sponsor of Study. The sponsor of the study, or if student, name of school/program student attends. Study will only be permitted by schools that have an educational affiliation agreement with PSFHS, or PSFHS associate. Sponsor may be an EBP Council member, Clinical Manager, Faculty.
3. Title of Study and Dates of Study
4. Introduction including topic area and significance (presents background information on the work and establishes the frameworks of your future research). Explain why this area is important to the general area under study. State location of study.
5. Statement of the Problem and Research Question
6. Literature Review (describes possible connection to the past research on the same problem). The literature review should establish the need for the research and indicates the researcher is knowledgeable about the area. Identifies unanswered questions and places your study in perspective. Summarize what is currently known. Make key points clearly and succinctly.
7. Research Design/Methodology. A description of how you would go about collecting data and test the questions you are examining. For example, what type of methods may be used:
   * Case studies (n = 1>5)
   * Questionnaires (n>30)
   * Interviews
   * Mathematical modelling
   * Computer simulation
   * Statistical analysis of industrial or economic data

The methods need to be described in detail to show the connection to research question and where you are going to get the actual data. Describe the data collection in detail, such that somebody else could conduct this part while replicating your part.

Identify variables you propose to control (minimize confounding variables) and how you propose to control them (sampling, statistics)

Sampling method and rationale for choice. Describe the sample you would test and explain why you have chosen this sample. Include age, and language background and socio-economic information, if relevant to the design. Are there any participants you would exclude? Why, why not? (Inclusion/Exclusion Criteria). Describe how you will recruit your subjects. Delineate how the privacy and safety of subjects will be protected. State the sample size.

Explain instrumentation to be used in the study, including surveys, scales, interview protocols, observation grids.

Data Collection plan. Specify what data will be collected, by whom and any criteria for inclusion of date. List any training needed for data collection. Include general timelines. Explanation of how the data collected will be monitored to ensure the safety of subjects and provisions for managing adverse reactions. Documentation of how the confidentiality of data will be maintained.

Data Analysis plan which may include statistical tests/measures--e.g., mean, frequency, correlation, paired t-test—or other method, e.g., inductive analysis.

Subject safety should describe any risks involved to the subject. See IDP I-07-f for items to include in the consent.

8. Significance and Conclusion. Discuss, in general, how your proposed research would lead to a significant improvement over the original studies, and how it would benefit the field. Address limitations of study. (In other words, why should someone care? If you were applying for money to do this, why would someone fund you? If you wanted to publish your results, why would they be interested?)

9. References. Include all references in APA style.

Attachments, if applicable.

* + - Informed Consent forms
    - CV or Resume (required)
    - Instruments to be used including validity and reliability data and references
    - Interview protocols
    - Cover letters or flyers to recruit participants

Following approval from the EBP Council and CNO, submission to the IRB will also require:

* Statement of approval/support from the CNO
* If student or faculty, university IRB approval
* NIH Training Certificate

Last review facilitated by Rochelle Salmore, RN, Clinical Manager Wound Clinic, Transport, Chair of Evidence Based Practice Council