

Robert Packer Hospital
POLICY & PROCEDURE

SECTION: Administrative	SUBJECT: Nursing Research	DEPT. Nursing
EFFECTIVE: 3-5-2008		POLICY # RPH-A-605 -1022
SUPERSEDES: 1-8-2008		PAGE # Page 1 of 4
DISTRIBUTION: Nursing		

Policy: Research involving nurses in roles as investigators, subjects, care givers or data collectors must be reviewed by the GHS Institutional Review Board (IRB) and the Nursing Research Council (NRC). Prior to submission to the GHS Research Council, all research proposals must undergo scientific review by the NRC.

Procedure:

The NRC conducts the departmental scientific review for nurse investigators or for studies where the subjects are RPH nurses. It is the objective of the NRC to assist nurse investigators with the research approval process.

Nurse researchers must be either an employee of RPH or a contracted student from an accredited School of Nursing. Other person wishing to conduct nursing research must meet the following eligibility requirements:

1. Posses a current nursing license in the Commonwealth of Pennsylvania
2. Provide proof of current BLS certification*
3. Documentation of a PPD administered and read within the past 12 months*
4. Documentation of a negative five panel drug screen consistent with Guthrie policy.
5. Documentation of Personal Health Insurance*
6. Copy of Immunization Records to include:
 - A. Two dates for Measles, Mumps, Rubella immunization or Rubella/Rubeola Titer.
 - B. Positive History of Chicken Pox or Varicella Titer.
 - C. Documentation of Hepatitis B Immunization.
 - D. Documentation of Tetanus within 10 Years.
7. Complete GHS Corporate Compliance training and the Fire & Safety Competency
8. Complete other competencies, as appropriate to the practice setting
9. Human Subjects Training, as stated on the Guthrie IRB Website

** only required for nurse researchers entering the patient care area*

All researchers (employee and nonemployee) must provide proof of appropriate insurance.

All expenses associated with meeting these requirements are the sole responsibility of the nonemployed Nurse Researcher. After all these requirements are met, the outside nurse researcher must obtain an identification badge from Human Resources. All nurse researchers will be paired with a NRC Liaison, as appointed by the NRC, for guidance and support in meeting these requirements. All nurse researchers must understand that it is their responsibility to protect all protected health information of all study participants. Study information must be kept in a locked or password protected location.

I. Departmental Scientific Review

- A. Investigators are required to contact the Department of Nursing Education & Research (DNER) during the stages of proposal development. A copy of the guidelines for the review process will be provided and time frames for accomplishing the review within investigator deadlines will be established.
- B. Investigator must present five copies of their research proposal, utilizing the format below, five copies of the RPH Nursing Research Cover Sheet and five copies of the entire research protocol to DNER. The research proposal shall contain:
1. Abstract
 2. Background information sufficient to establish the significance of studying this problem (do not submit the entire literature review)
 3. Description of the problem, study objectives and hypothesis
 4. Description of research plan: sample selection, instruments, procedures
 5. Projected plan for analysis and interpretation of data, as well as a description of how all personal health information will be protected.
 6. Consent forms where applicable and a description describing how consent will be obtained
 7. Data collection instruments, questionnaires and cover letters where appropriate
 8. Estimate of number of patients/staff to be involved
 9. Plan for involved RPH staff training and education
 10. Estimate of time per subject and total staff nurse time involved (to include training time)
 11. A letter of support from the Director/Manager of the departments involved
 12. Time frame for conducting of study
 13. Potential implications for study for nursing practice
 14. Plan for communicating final report
- C. If a proposal is being submitted by a student, a letter from the faculty member who is the primary advisor on the project must accompany the proposal submission. The letter must identify how the faculty member can be reached by letter, telephone and email and must contain the faculty member's endorsement of the project.
- D. The proposal will be reviewed within 30 days of submission to DNER, by a subcommittee of the NRC. The subcommittee will consist of at least
1. Two master's prepared nurses
 2. Two NRC members. Priority will be given to council members whose units are involved in the study, if applicable
 3. Nursing Research Consultant, if available

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- E. Approval of research proposals will be dependent of the following:
1. The problem is relevant and timely
 2. The research design is appropriate and logical
 3. The rights and safety of patients and staff have been adequately safeguarded
 4. There is potential benefit to patients, staff or the nursing profession
 5. The study will not interfere with or compromise existing nursing care
 6. The study is feasible in terms of staff time, space and/or materials required
 7. There is a plan to share the study results with the nursing staff and the nursing leadership team
- F. The outcomes for the review of scientific merit will result in one of the following actions:
1. Full approval
 2. Approval pending review of revisions
 3. Disapproval

One of the master's prepared nurses from the subcommittee will assist the investigator in addressing any revisions as a result of the review. The changes must be resubmitted to the subcommittee within 30 days. The subcommittee will review the revisions before granting approval.

The cover sheet will be signed by the subcommittee members and the investigator may then apply to the IRB.

II. Human Subjects Review

- A. The next step to conduct nursing research at RPH is to obtain IRB approval. The investigator should contact the IRB Administrator to be placed on the IRB schedule and complete the appropriate forms required by the IRB. In some limited circumstances, a proposed research project may:
- i. not meet the definition of "human subjects" research (as defined by Department of Health and Human Services regulations) or "clinical investigation" (as defined by Food and Drug Administration regulations) and thus would not be subject to IRB oversight; or
 - ii. be exempt from IRB oversight.
- Only the Chair of the IRB is authorized to make these determinations.
- B. Data collection may begin when the investigator submits the letter of approval from the IRB to the DNER office. A study start date and reporting schedule will be determined at this time.
- C. The letter of approval, along with a copy of the study protocol should be then submitted to the director/manager of any units on which the study will take place.

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III. Ongoing Study Status Reporting

- A. It is the responsibility of the researcher to keep the NRC apprised of the status of the study every six months (from the study start date) utilizing the Study Report Form. This form shall be submitted to DNER two weeks before the due date.
- B. Upon study completion (or termination), the researcher will complete the Exit Report Form and appear before the NRC with an Exit Presentation. This presentation shall include:
 - 1. Study outcomes
 - 2. Implications for nursing practice
 - 3. Implication for future nursing research
 - 4. Publication plans

Key Contact: Clinical Nurse Educator, Facilitator Nurse Research Council