

## Kennedy Krieger Institute

### Policy and Procedure for Research Involving Nursing Resources

*April 2011*

#### **Policy:**

Human research projects conducted within the Kennedy Krieger Institute (KKI) that require the use of nursing time and effort must be reviewed and approved by Nursing Administration. This policy is intended for the conduct of research and is not intended for clinical performance improvement activity. Approval must be obtained **in writing** before initiating a protocol that involves nursing staff. The policy and forms are available at <http://intranet.kki.org/research/forms.html> or from Nursing Administration. This signed approval form does not have to be submitted to the Johns Hopkins Medicine Institutional Review Board (JHMIRB) as part of the IRB application.

#### **Objective:**

To provide guidelines for research studies involving nursing resources. Nursing administration will assess and determine if and how nurses' participation may impact the delivery of safe and appropriate care. This assessment will include a dialogue with the PI and any involved managers, staff, or other appropriate disciplines.

#### **Procedure:**

**Form:** Source: Nursing Administration

1.1 Applicant completes the **KKI Research Involving Nursing Resources Form** (Attachment A).

1.2 Applicant completes the appropriate Johns Hopkins Medicine Institutional Review Board forms as directed by the IRB guidelines.

1.3 Applicant submits the completed **KKI Research Involving Nursing Resources Form** to the KKI Director of Nursing Research and attaches the research protocol (eFormA or sponsor protocol). Please provide the JHMIRB application RPN number on the space on the form.

1.4 The Director of Nursing Research will review the form and protocol, and sign off on the protocol or notify the applicant of issues that require resolution before approval. Once the protocol is complete, the Director of Nursing Research will forward it to the Nurse Executive for approval and signature.

1.5 The Nurse Executive will review the form with the nurse manager(s). The Nurse Executive will either approve the requested services or forward issues and concerns to the Director of Nursing Research.

1.6 The Director of Nursing Research will notify the applicant and the KKI Office of Research Compliance when all signatures are obtained.

1.7 The applicant may initiate the project after approval from the KKI Department of Nursing, KKI Office of Research Compliance, and the Johns Hopkins Medicine Institutional Review Board. A copy of JHMIRB study approval must be forwarded to the KKI Director of Nursing Research before study initiation.

1.8 A copy of the signed **KKI Research Involving Nursing Resources** approval form and research protocol will be kept in a research binder on each participating nursing unit. Nursing data collection activities should be explicated in detail (i.e. blood draw- tube type and amount of blood) and included in unit research binder.

Attachment A  
Kennedy Krieger Institute  
Department of Nursing

**Research Involving Nursing Resources  
Approval Form**

Please review the KKI Research Involving Nursing Resources Approval Procedure prior to completing this form. Send completed application to Elaine Stashinko, PhD, RN, Director of Nursing Research, Kennedy Krieger Institute, 801 N. Broadway, Room 582; Baltimore, MD 21205 or email to [stashinko@kennedykrieger.org](mailto:stashinko@kennedykrieger.org).

A complete application includes:

1. Request for Approval of Research Involving Nursing Resources
2. Research Proposal

PROJECT NAME: \_\_\_\_\_  
\_\_\_\_\_

PRINCIPAL INVESTIGATOR: \_\_\_\_\_

KKI INVESTIGATOR (If different than above):

Institution/ Department:

Telephone: Work: \_\_\_\_\_ Pager \_\_\_\_\_

Email: \_\_\_\_\_

OTHER INVESTIGATORS (name and title):

JHMIRB Application Number: \_\_\_\_\_

JHMIRB approval date: \_\_\_\_\_

Written Consent Required: Y N

**Check one category**

- Nurses are the target sample**
- Nurses will collect data or conduct a study procedure (e.g. data collection, assessment or blood draw)**

**CLINICAL RESOURCES REQUIRED**

1. Describe the activities for which nursing staff will be responsible (Check all that apply):

Vital signs   Blood draw   Blood processing (i.e. Centrifuge, shipping)   Specimen Collection   Survey Administration

Other \_\_\_\_\_

2. Type and number of nurses sought \_\_\_\_\_

3.

Time Required of Each Nurse			
	Study Orientation	Per Subject Contact	Overall Participation (hours per week)
As Study Participant			
As Data Collector			
Other			

4. Type and number of patients/ research participants sought \_\_\_\_\_

5. Clinical areas or units to be involved \_\_\_\_\_

6. Time of day when data will be collected [day, evening, or night shift].

7. Data collection period [anticipated start and end dates].

From: \_\_\_\_\_ To: \_\_\_\_\_

8. Is there any equipment involved in this protocol?    No    Yes. If yes, what type of equipment?

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9. Space Requirements

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**FEEDBACK AND COMPENSATION**

1. If nursing service involvement is essential for completion of the study, indicate plans for acknowledging contributions of nursing service in subsequent publications:  
\_\_\_\_\_ Credit to unit for service  
\_\_\_\_\_ Footnote naming nurse contributors  
\_\_\_\_\_ Opportunity to participate in writing papers, if desired  
\_\_\_\_\_ Other (specify): \_\_\_\_\_
  
2. Plans for feedback of study results (check all that apply):  
\_\_\_\_\_ Discuss findings at nursing staff meetings on request  
\_\_\_\_\_ Send abstract of completed study to unit(s)  
\_\_\_\_\_ Other plan (specify): \_\_\_\_\_
  
3. How will participating nurses be compensated for their participation?  
\_\_\_\_\_ OP/IP Care costs budgeted in grant  
\_\_\_\_\_ Percent effort allocation  
\_\_\_\_\_ Part of nursing practice - paid from unit budget  
\_\_\_\_\_ Other
  
4. Upon study completion, submit a summary of the results to the KKI Director of Nursing Research.

I certify that the above information is correct:

\_\_\_\_\_  
(Principal Investigator) (Date)

**APPROVAL SIGNATURES**

\_\_\_\_\_  
(Nurse Manager) (Date)

\_\_\_\_\_  
(Director of Nursing Research) (Date)

\_\_\_\_\_  
(Senior Vice President, Nursing and Patient Services/ Nurse Executive) (Date)

**COMMENTS FROM THE REVIEWERS:**