Approval of Research Involving Nursing or Nursing Resources

Instructions: This form is to be completed for any research requiring the use of Johns Hopkins Health System (JHHS) Department of Nursing resources or if JHHS nursing staff will be recruited as study participants. Please complete Sections I-IV, obtain signatures for Section V, and upload the completed form **with required Department of Nursing signatures** into the eIRB application Section 11-8.

Approval checklist (in order of completion):

☐ Study team member completes Sections I-IV

☐ Completed form **and** eForm A/study protocol sent to:

- Nurse Scientist (JHHS)
    - Departmental Director of Nursing/Designee approval obtained ☐
        - Please note if the study is conducted in more than one Department, the signature of each Department Director is needed.
    - Senior Director Hospital Capacity Management and Emergency Nursing (JHBMC) ☐
    - CNO/Designee (HCGH, Sibley Memorial, Suburban) ☐
- Director of Nursing Practice, Education, and Research (JHHS)

☐ Signed, completed form returned to Principal Investigator and/or other study contacts

☐ Form uploaded into eIRB

For questions, please contact:

- Heather Watson, Ph.D., RN, Nurse Scientist, hwatson7@jhmi.edu or 410-614-8139 (JHHS)
- TaJuanda Carter, Administrative Coordinator, tcarte68@jhmi.edu or 410-955-1342 (JHHS)
- Cynthia Walters, DNP, RN, NE-BC, Senior Director Hospital Capacity Management and Emergency Nursing, cwalter2@jhmi.edu or 410-550-0183 (JHBMC)

Section I
STUDY INFORMATION

1. Study Title: _____
   _____
2. Principal Investigator: _____
3. Address: _____
4. Telephone Work: _____ Email: _____
5. Additional Study Contact(s): _____
6. Study length (anticipated start and end dates) From: _____ To: _____
7. **Site(s) where JHHS nursing staff will be involved:**

☐ The Johns Hopkins Hospital (JHH) ☐ Johns Hopkins Bayview Medical Center (JHBMC)
☐ Howard County General Hospital (HCGH) ☐ Sibley Memorial Hospital
☐ Suburban Hospital ☐ All Children's Hospital

For Students Only
Advisor's Name: _____ Number: _____
Advisor's Institution: _____
Degree Pursued: _____

Section II
NURSING AND CLINICAL RESOURCES REQUIRED

1. Type(s) of activities that nursing staff will be responsible for within research study protocol:

☐ Study participants ☐ Specimen collection* ☐ Data collection
☐ Documentation ☐ Study form completion ☐ Study recruitment
☐ Data analysis
☐ Other _____

*Be sure to note if the study unit uses nurses or phlebotomy for blood draws

Describe what nurse's will do specifically to support the study, e.g. draw blood three times during the study per subject.

2. Time required of **<u>each</u>** nurse e.g. 10 minutes to hang a mini bag medication, twice per day = 20 minutes per nurse, per participant (see examples on page 4):

	For Orientation	During Study
Study participants		
Data/sample collection		
Other		

a. Will there be any equipment involved in this protocol? ☐ YES ☐ NO

b. Please describe how the study team will orient the nurses to the protocol, including how nurses can contact the study team, where to find completed consents for participants, education on any specialized equipment needed for specimens or medication, etc. (present at staff meetings, discuss with nurse manager, study binder available)

3. Type(s) and number of nurses sought: _____

4. Department where research will occur (ex. Surgery, Medicine, Oncology) _____

5. Clinical area(s) or unit(s) to be involved: _____

6. Type(s) and number of patients sought: _____

7. Time(s) of day when nursing resources will be required:

☐ Day Shift (7a – 3p)
☐ Evening Shift (3p – 11p)
☐ Night Shift (11p – 7a)
☐ AM Shift (7a – 7p)
☐ PM Shift (7p – 7a)

Section III
FEEDBACK AND COMPENSATION

1. Plan(s) for acknowledging contribution of nursing staff in subsequent publications:
   - ☐ Credit to unit for service
   - ☐ Acknowledgement naming nurse contributors
   - ☐ Opportunity to participate in writing papers
   - ☐ Other _____

2. Plan(s) for feedback of study results:
   - ☐ Discuss findings at nursing staff meetings on request
   - ☐ Send abstract of completed study to unit(s)
   - ☐ Other _____

3. Compensation for participation:
   - ☐ Grant or stipend to unit
   - ☐ Direct payment or gift
   - ☐ No payment or compensation will be provided
   - ☐ Other _____

Upon study completion, please provide to the Departmental Director of Nursing or CNO/Designee:

- **Notification of study closure or ending of required nursing resources**
- **Written summary of the study findings**
- **Summary of nursing resources required (ex. total number of nursing hours needed)**
- **Description of feedback and compensation provided to nursing staff**

This summary will be sent on or about (date): _____

Examples for quantifying nurses' time (this is not all-inclusive):

1. Administering medications-10 minutes minimum
2. Monitoring vital signs-5-10 minutes
3. Drawing blood-10-15 minutes
4. Obtaining urine/stool/sputum samples-10 minutes
5. Hanging blood products-1 hour minimum
6. Filling out study forms (nurses cannot obtain consent unless part of the study team) 10 minutes

*If any protocol requires multiple interventions e.g. drawing blood and monitoring vital signs, please combine the amounts when accounting for the time required by each nurse.

Utilizing nursing resources should be considered within the context of the nurses' existing workload. If the required tasks amount to increased burden on the nurses' typical workflow, the study team might consider employing a study nurse to carry out the protocol requirements. Proper education, orientation, and support for the nurses ensures adherence to the protocol and reduces the risk of protocol events.

Questions to consider:

1. Have you approached the unit you intend to have study participants on to ensure feasibility?
2. Have you considered having a clinical nurse as part of your study team to act as a full-member, consultant, champion, or liaison?
3. Does your study team have a collaborative relationship with the staff on the unit/units where the study will occur?

Section IV
PERMISSION FOR RELEASE OF PROPOSAL & REQUIRED SIGNATURES

May copies of this proposal be provided to nurses or students who are learning the research process?

☐ YES ☐ NO

I certify that the above information is correct:

Principal Investigator Date

Signature of Advisor, if student Date

Section V
NURSING ADMINISTRATIVE APPROVAL

☐ **The Johns Hopkins Hospital and Johns Hopkins Health System**

Departmental Director of Nursing Date

Nurse Scientist Date

Director of Nursing, Practice, Education and Research Date

☐ **Johns Hopkins Bayview Medical Center**

Departmental Director of Nursing Date

Senior Director Hospital Capacity Management and Emergency Nursing Date

☐ **Howard County General Hospital** ☐ **Sibley Memorial Hospital** ☐ **Suburban Hospital**

CNO/Designee Date

CNO/Designee Date

CNO/Designee Date

☐ **All Children's Hospital**

CNO/Designee Date