**Approval of Research Involving JHSCS Resources**

Instructions: This form is to be completed for any research requiring the use of Johns Hopkins Surgery Centers Series (JHSCS) resources or if JHSCS staff will be recruited as study participants. Please complete Sections I-IV, obtain signatures for Section V, and upload the completed form **with required signatures** into the eIRB application Section 10.

For questions while completing the form, please contact: JHSCSResearch@jh.edu

\*\*\*This form is not required for research which only involves record review\*\*\*.

**Approval checklist (in order of completion)**: Study team member completes Sections I-IV

Completed form **and** eForm/study protocol, consent and all patient-facing materials sent to:

* JHSCSResearch@jh.edu

Signed, completed form returned to Principal Investigator and/or other study contacts Form uploaded into eIRB

# Section I

## STUDY INFORMATION

1. Study Title:
2. Principal Investigator:
3. Telephone Work: Email:
4. Additional Study Contact(s) include name and email:
5. Study length (anticipated start and end dates)

|  |  |
| --- | --- |
| From: | To: |

1. **Site(s) where JHSCS staff will be involved:**

Green Spring Station PIII ASC

 Lutherville ASC

 Fertility Center ASC

Howard County ASC

Bethesda ASC

White Marsh ASC

Knoll North ASC

Other:

**For Students Only**

Advisor’s Name:

Number:

Advisor's Institution:

Degree Pursued:

# Section II

## STAFF AND CLINICAL RESOURCES REQUIRED

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

|  |  |  |
| --- | --- | --- |
| Study participants | Specimen collection\* | Data collection |
| Clinical 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 JHSCS staff/nurse’s will do specifically to support the study, e.g. draw blood three times during the study per subject.

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

|  |  |  |
| --- | --- | --- |
|  | Pre Study Activities  | During Study |
|  |  |  |
| JHSCS Nurses doing Data/sample collection |  |  |
| Other |  |  |

1. Will there be any new equipment and or supplies involved in this protocol?
2. Will any standard of care equipment be modified in this protocol?
3. Please describe how the study team will orient the JHSCS staff to the protocol, including how staff/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 administrator, study binder available)
4. Type(s) and number of JHSCS staff sought:
5. Type(s) and number of patients sought:

# Section III

# JHSCS STAFF AS RESEARCH PARTICIPANTS

# Will any JHSCS staff be enrolled as research participants?

# If so, how many JHSCS staff do you anticipate enrolling in your research?

# Who will be responsible for recruiting/consenting JHSCS employees? Please note it may not be someone who supervises the employees.

1. Time required of **each** JHSCS Staff as research participants:

|  |  |  |
| --- | --- | --- |
| Study Activity Type (e.g. interviews) | Time Required for Specific Study A | Total Time |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Section IV

## FEEDBACK AND COMPENSATION

1. Plan(s) for acknowledging contribution of staff in subsequent publications: Credit to ASC/JHSCS for service

Acknowledgement naming staff/nurse contributors Opportunity to participate in writing papers

Other

1. Plan(s) for feedback of study results:

Discuss findings at staff meetings on request Send abstract of completed study to unit(s)

Other

1. Compensation for participation:

Grant or stipend to unit Direct payment or gift

No payment or compensation will be provided

Other

**Upon study completion, please send the following to JHSCSResearch@ju.edu**

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

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

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

Questions to consider:

1. Have you approached the ASC 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 at the ASC where the study will occur?
4. How many non-JHSCS staff members will be on site and what are their roles in the study?
5. Will any non-JHSCS staff members need to be present in the room during the intra-operative phase of care?
6. Will this study add additional time to the Prep RNs preoperative patient preparation time?
7. Will this study add additional procedure time?
8. Will this study extend throughput/add additional PACU recovery time?
9. Is there a specific post op evaluation/observation time required? (for example: Patient must be observed post operatively for two hours to monitor for any potential side effects)

# Section IV

## PERMISSION FOR RELEASE OF PROPOSAL & REQUIRED SIGNATURES

May copies of this proposal be provided to staff/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

## ADMINISTRATIVE APPROVAL

JHSCS Senior Director of Nursing Date

JHSCS Vice President, Operations Date