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| The purpose of TGH Unit Operation Review of Proposed Study Worksheet is to assist study teams, TGH Units, TGH Departments, TGH nursing administration/leadership and the TGH Office of Clinical Research (OCR) in supporting the unit awareness of research conduct and determining the impact of a proposed study on the Unit’s resources. ***The TGH Unit Operation Review of Proposed Study Worksheet will be referred to as “Worksheet” throughout the document*****INSTRUCTIONS FOR STUDY TEAM SUBMITTER:****STEP 1:** Identify the (up to three) most-impacted TGH Units or Departments (referred to as “Units” throughout the document) that will be impacted by the research study. **Complete one worksheet for each identified Unit.****STEP 2:** Complete **Section 1**: Study Information **STEP 3:** Complete **Section 2**: List the TGH Hospital Unit that will be impacted by the study and/or care of the patient and the Unit manager **STEP 4:** Complete **one** of the following two sections:* **Section 3: No Unit Support Needed.** No nursing or ancillary support is required. All research procedures do not impact department operations or nursing care and is being done by the research staff (e.g. informed consent) and/or the procedures are standard of care (SOC). This Worksheet is being completed solely to make the Unit staff aware of the proposed research activities to be conducted on the Unit.
* **Section 4: Unit Support Needed.** TGH nursing or ancillary support is required or the Unit’s resources will be used.

**STEP 5:** Meet or have a phone conference with the identified Unit Nurse Manager and additional unit representatives as needed (e.g. Unit Nurse Educator; Department Manager) to review the study specifics. Obtain signatures (Section 5) from the Unit Nurse Manager (if only Section 3 is completed, i.e. if no unit support or resource is needed) or from the Unit Nurse Manager *and* the Department Manager (if Section 4 is completed, i.e. unit support and resources are needed). The following documents must be provided at this meeting for inclusion in the review:1. Protocol
2. Unit Operational Review of Proposed Study Worksheet
3. Investigator Brochure, if applicable
4. Instructions for Use, if applicable
5. TGH Drug Research Information Sheet (for all drug studies)
6. TGH Device Research Information Sheet (for all device studies)

**STEP 6:** Send the signed worksheet and the draft of the Nursing Administration Support Letter to research@TGH.org. |

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| **Section 1: Study Information** |
| Full Study Title: |  |
| Short Study Title:  |  |
| Study Protocol Number: |  |
| Projected Enrollment: |  |
| PI Name: |  |
| Study Coordinator:  |  |
| Submitter’s Name:  |  |
| Submitter’s Email:  |  |
| Study Summary: |  |

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| Section 2: Impacted TGH Unit  |
| Unit Name: |  |
| Unit Nurse Manager: |  |
| Unit Director: |  |

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| Section 3: No Unit Support Needed [ ]  N/A  |
| Research team, complete this section if: * + No nursing or ancillary support is required
	+ No unit resources are needed
	+ Research procedures conducted by research staff (such as informed consent) will not impact unit operations
	+ All procedures are standard of care
 |
| Provide a summary of the researchprocedures that will be conducted bythe research staff at TGH (e.g. informed consent): |  |
| Provide a summary of the research procedures that are performed by the unit nurses or unit staff outlined as standard of care in the protocol or indicate N/A:  |  |

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| Section 4: Unit Support Needed [ ]  N/A |
| Research team, complete this section if: * + Nursing or ancillary support is required
	+ Unit resources are needed
	+ Research procedures conducted by research staff (such as informed consent) will impact unit operations
	+ Deviations from standard of care procedures are requested.
 |
| **Item:** | **Explanation of Research Activity** **or N/A** | **PERFORMED BY** **RESEARCH STAFF** **1. Specify role (e.g. PI, CRC)****2. Enter N/A if not applicable** | **PERFORMED BY TGH STAFF****1. Enter TGH staff role (e.g. nurse, phlebotomist)****2. Enter time needed in 0.25hr increments****3. Enter N/A if not applicable** |
| Recruitment |  |  |  |
| Informed Consent (Enrollment) |  |  | N/A. Informed consent must always be done by research staff. |
| Drug Administration |  |  |  |
| Special procedures |  |  |  |
| Vital signs/physical exams |  |  |  |
| Blood draws |  |  |  |
| Questionnaires/surveys |  |  |  |
|  Special monitoring |  |  |  |
| Other: |  |  |  |
| Other: |  |  |  |
| Other: |  |  |  |
|  Are any of the Unit’s supplies, equipment, or resources being requested to support this study? | [ ]  YES [ ]  NOIf so, please clarify: |
| Describe the education plan for the affected hospital units: |  |
|  Is a unit representative needed to attend the Site Initiation Visit (SIV)? | [ ]  YES [ ]  NOIf so, who will attend?Date of site initiation visit (if known):  |
| Additional Comments: |

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| Section 5: Unit Determination |
| This section is to be completed by the Unit Nurse Manager or Unit Department Manager after working with the research study team to determine the feasibility of facilitating this study on the unit based on the impact on the unit’s operations.* If the study is deemed feasible, check “Yes, feasible” and sign/date the form. The Unit Director’s approval is needed if Section 4 is completed.
* If the study is deemed NOT feasible, check “No, not feasible”; enter the reason in the comment section; and sign/date the form.
 |
| [ ]  Yes, feasible[ ]  No, not feasible |
| **Comments** |
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| --- | --- | --- | --- |
| Role: | Name (Print): | Signature: | Date: |
| Study Staff Representative |  |  |  |
| Unit Nurse Manager |  |  |  |
| Department Manager or Unit Director |  |  |  |
| Other Applicable Manager |  |  |  |