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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/department awareness of research conduct and determining the impact of a proposed study on the Unit’s/Department’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 -TGH units/departments (referred to as “Units” throughout the document) that will be impacted by the research study. It is best to complete one worksheet for each identified unit/department. However, units that are similarly impacted may be placed on the same sheet.  **STEP 2:** Complete **Section 1**: Study Information.  **STEP 3:** Complete **Section 2**: List the TGH units/departments that will be impacted by the study and/or care of the patient and the Unit manager. Add additional rows to the table as applicable.  **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:** Submit to the Program Coordinator- Feasibility. The Program Coordinator will route for signatures and organize unit review discussions as needed.. |

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

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

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| Section 3: No Unit/Department Support Needed  N/A | |
| Research team, complete this section if:   * + No nursing or ancillary support is required   + No Unit/Department 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 research  procedures that will be conducted by  the 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/Department 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  NO  If 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  NO  If so, who will attend?  Date of site initiation visit (if known): | | |
| Additional Comments: | | | |

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| Section 5: Unit/Department Determination |
| This section is to be completed by the Unit Nurse Manager or Department Manager after working with the research study team to determine the feasibility of facilitating this study on the unit/department based on the impact on the Unit’s/Department’s operations.   * If the study is deemed feasible, check “Yes, feasible” and sign/date the form. The Unit/Department 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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| **Section 6: Signatures** | | | |
| Role: | Name (Print): | Signature: | Date: |
| Study Staff Representative |  |  |  |
| Unit Nurse Manager |  |  |  |
| Department Manager or Unit Director |  |  |  |
| Other Applicable Manager |  |  |  |
| Nursing Administration |  |  |  |