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| The purpose of this document is to assist study teams, TGH Units, TGH Departments, TGH nursing leadership and the TGH Office of Clinical Research (OCR) in supporting the unit awareness of research conduct and determining the feasibility of bedside nursing support and/or other ancillary support. Study teams, please complete the following tasks:***TGH Unit Awareness & Support Worksheet will be referred to as “Worksheet” throughout the document*****INSTRUCTIONS FOR STUDY TEAM SUBMITTER:****STEP 1:** Identify all TGH Units (or Departments – referred to as “Units” throughout the document) that will be impacted by the research study* Identify the top three (3) Units where majority of research procedures will be performed
* **Complete one worksheet for each of the top three (3) identified Units**

**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:** **Unit Awareness:** No nursing or ancillary support is required. All research procedures that do not impact department operations or nursing care conducted by the research staff (e.g. informed consent) and/or the procedures are routine care
* **Section 4: Unit Support:** TGH bedside nursing support or ancillary support is required

**STEP 5:** Meet or have a phone conference with the identified Unit Manager and additional unit representative, as needed (e.g. Unit Nurse Educator; Department Manager), to review the study specifics. Complete **Section 5**: Meeting Information**STEP 6:** Finalize the worksheet* Ensure each worksheet is completed in its entirety (**Sections 1-5**)
* Route the completed worksheet to the Unit Manager and provide the following instructions to the Unit Manager:
	+ Complete **Section 6**
	+ Sign/Date the worksheet
	+ Obtain Unit Director/Vice President (VP) approval if **Section 4** is completed
	+ Return a PDF of the signed/dated worksheet to the study team
* If the study is deemed “feasible” by the Unit Manager, sign and date the worksheet, as indicated. Proceed to **STEP 7**
* If the study is deemed “not feasible” by the Unit Manager, the process stops

**STEP 7**: After receiving all completed worksheet(s) from Unit Manager(s), send the document package for review:* Complete the TGH Unit Awareness & Support letter
* Submit the following to Mary Kutash, Advanced Nurse Specialist Research mkutash@tgh.org , for review:
	+ Signed worksheet(s),
	+ Word version of the TGH Unit Awareness & Support letter
	+ Protocol
	+ Drug Research Information Sheet, if applicable
	+ Device Procedure Research Information sheet, if applicable
* Place the following in the email subject line:
	+ PI NAME\_Short Study Title (as per protocol)\_TGH Unit Awareness & Support submission

**STEP 8:** Upon receipt of theTGH Unit Awareness & Support letter: * Submit TGH Unit Awareness & Support Worksheet(s) and TGH Unit Awareness & 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 #s: |  |
| PI Name: |  |
| Study Coordinator:  |  |
| Submitter’s Name and contact information | Name:Email: |

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| Section 2: TGH Hospital Unit that will be impacted by the study and/or care of the patient: |
| Unit Name: |  |
| Unit Manager: |  |

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| Section 3: Unit Awareness [ ]  N/A  |
| * Criteria:
	+ No nursing or ancillary support is required
	+ All research procedures that do not impact nursing care or Unit operations conducted by the research staff (e.g. informed consent) and/or the procedures are routine care
* Instructions:
	+ Complete items 1 & 2 below
 |
| 1. Provide a summary of the research procedures conducted by the Research staff at TGH (e.g. informed consent):
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| 1. Provide a summary of the research procedures that are performed by the unit nurses or staff outlined as routine care in the protocol or indicate N/A:
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| Section 4: Unit Support [ ]  N/A |
| * Criteria:
	+ TGH bedside nursing support is required; and / or
	+ TGH ancillary support is required (e.g. EKG; lab, procedures)
* Instructions:
	+ Determine nursing support/ancillary support versus research staff task for each line item
	+ Describe nursing and/or ancillary support and/or unit supplies required for the study for each line item
	+ Summarize contributions and expectations of both the unit and research team in the Comments column or enter N/A if not applicable to the study
	+ Identify which study tasks will be performed by the research staff in the Performed by Research Staff column
	+ Identify the amount of additional time for research activities, in increments of 0.25 hours, that will be required from bedside nurses/ancillary support for each applicable line item and capture the information in the SUPPORT column
 |
| **Item:** | **Comments or N/A** | **Performed by Research Staff Y/N or N/A (specify research staff role (e.g. PI; CRC))** | **SUPPORT: Y- (enter time) or N or N/A Additional Bedside Nursing Time/Ancillary Support Required per Patient (increments of 0.25)** |
| * Informed Consent
 |  |  |  |
| * Investigational Product (IP) Administration
 |  |  |  |
| * Special procedures
 |  |  |  |
| * Vital signs/Assessments
 |  |  |  |
| * Blood draws
 |  |  |  |
| * Supplies
 |  |  |  |
| * Special monitoring
 |  |  |  |
| * Other:
 |  |  |  |
| List possible side effects of the IP: |  |  |  |
| Describe the education plan for the effected hospital units: |  |  |  |
| What unit representative will attend the Site Initiation Visit (SIV)? |  |  |  |
| Will order sets be provided as part of the study? [ ]  YES [ ]  NO* Describe:
 |  |  |  |
| Will a Research Information Sheet be provided as part of the study? [ ]  YES [ ]  NO* If no add a comment
* If yes, include with the submission package
 |  |  |  |

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| Section 5: Meeting Information |
| Meeting/Phone Conference Details: | Date:Location: |
| Research Representatives: |  |
| Unit Manager: |  |
| Additional Unit Representatives (Name, Title) e.g. Unit Nurse Educator: |  |

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| Section 6: Unit Determination |
| * Section completed by the Unit Manager
* Instructions for the Unit Manager:
	+ If additional information is required, work with the study team and/or ancillary department until you have obtained all information needed to determine feasibility of the study
	+ If the study is deemed feasible, check “Yes, feasible”; sign/date the form. Obtain Unit Director/VP approval if Section 4 is completed. Return a PDF of the document to the submitter
	+ If the study is deemed not feasible, check “No, not feasible”; enter the reason in the comment section; sign/date the form and return a PDF copy of the document to the submitter, Mary Kutash (mkutash@tgh.org) and research@tgh.org
 |
| [ ]  Yes, feasible[ ]  No, not feasible |
| **Comments** |
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Study Team Representative:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PRINT NAME

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature/Date

|  |  |  |  |
| --- | --- | --- | --- |
| Role: | Name (Print): | Signature: | Date: |
| Unit Manager |  |  |  |
| Department Manager, if applicable |  |  |  |
| Unit Director/VP Approval, if applicable |  |  |  |