**Notes:**

* **This document is currently set to track changes, your text will be red. Please keep this mode turned on and submit this form as a Word document to** [**research@tgh.org**](mailto:research@tgh.org)**. Please do not save it as a PDF.**

|  |  |
| --- | --- |
| **GENERAL INFORMATION** | |
| **Full Study Title:** | Enter Study Title. |
| **Study Protocol Number:** | Enter PROTOCOL ID or USF IRB Study ID. |
| **Study Type:** | Please select a study type from the list  If Prospective, define intervention type: Choose an item.  If other, specify: Click or tap here to enter text. |
| **IRB of Record:** | Select IRB from the list or enter name |
| **IRB #:** | Enter IRB # or make a selection |
| [**NCT #**](http://www.clinicaltrials.gov/)**:** | Enter NCT# or make a selection |
| **Short Study Description:**  (1-2 sentences summarizing the purpose of the study) | Enter Short Study Description. |
| **PI Information** | |
| Principal Investigator (PI) Name: | Enter PI Name |
| Affiliation and Department: | Enter PI Employer and Department or Service Line. |
| Mailing Address: | Enter PI work address |
| Email: | Enter PI email. |
| Cell Phone: | Enter PI Phone Number. |
| Credentialed at TGH? | Choose an item. |
| **Submitter or Primary Contact** | |
| Name: | Enter Submitter or Primary Contact Name. |
| Cell Phone or Telephone: | Enter Submitter or Primary Contact Phone Number. |
| Email: | Enter Submitter or Primary Contact Email Address |
| **Regulatory Contact (if different from Submitter or Primary Contact)** | |
| Name: | Enter Regulatory Contact Name. |
| Cell Phone or Telephone: | Enter Regulatory Contact Phone Number |
| Email: | Enter Regulatory Contact email address. |

| **SECTION A. STUDY INTAKE** |
| --- |

|  |  |  |
| --- | --- | --- |
| **Funding:** | Please select a funding source from the list  If other, specify: Click or tap here to enter text. | |
| **Sponsor Name:** | Enter Sponsor Name.  Not applicable | |
| **Contracted Research Organization (CRO):** | Enter CRO Name.  Not applicable | |
| **Checklist for study submission:** | **Submit the following documents for all study types:** | |
| Research Study Proposal Form (this form) (Required) | Attached to email submission |
| Study Protocol (Required) | Choose an item. |
| Data collection forms/EDC Manual/eCRF pages | Choose an item. |
| PI CV (signed and dated within last 3 years) | Choose an item. |
| Informed consent form (Required, unless the study has or is expected to have a waiver of informed consent) | Choose an item. |
| Draft Budget, (Required, if the study is funded) | Choose an item. |
| Draft Contract or Data Use Agreement (Required, if applicable) | Choose an item. |
| **Additional documents required if study involves FDA monitored investigational drug or device** | |
| Investigator Brochure or Instructions for Use | Choose an item. |
| FDA [IND](https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application) or [IDE](https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide) approval letter | Choose an item. |
| CMS National Coverage Determination for [CED](https://www.cms.gov/medicare/coverage/coverage-with-evidence-development), [CAS](https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-CAS-Investigational-Studies), or [IDE](https://www.cms.gov/medicare/coverage/ide) studies and billing/coding guidelines. | Choose an item. |
| **Additional documents required as applicable** | |
| Pharmacy manual, if TGH Investigational Drug Services (IDS) are requested | Choose an item. |
| Lab manual, if the study requires TGH support for specimen processing | Choose an item. |
| Imaging manual, if image transfers are required or if study imaging modalities differ from standard of care operating procedures | Choose an item. |
| **CONTINUE TO SECTION B ONLY IF THIS IS HUMAN SUBJECTS RESEARCH**  **(i.e. not retrospective chart review)** | | |

| **SECTION B. FEASIBILITY REVIEW** |
| --- |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Number of planned subjects:** | Enter the # of patient to be enrolled at your site. | | | | |
| **Number of months expected to be open to enrollment** | Click or tap here to enter text. | | | | |
| **Study Phase:** | Select a Study Phase | | | | |
| **Does the study involve stem cells or gene therapy/transfer?** | Choose an item.  If yes, provide a description: Click or tap here to enter text. | | | | |
| **Is the study cancer-relevant?** | Choose an item. | | | | |
| **Does the study involve banking biospecimens?** | Choose an item. | | | | |
| **Do any of the investigators have a financial interest related to this research or research sponsor?** | Choose an item.  If yes, please have the PI fill out the disclosure form by clicking [here](https://tgh.cqs.symplr.com/Portal/CreateForm/450082).  (Conflict of Interest (COI) Examples include equity, ownership, speakers’ bureau, consulting, travel, and education.) | | | | |
| **Does the study involve USF or TGH-owned intellectual property (IP) that needs to be protected? (This question does not relate to Sponsor’s IP)** | Choose an item. | | | | |
| **Does this study have one or more sub-studies?** | Choose an item.  If yes, complete the following:   1. Will you participate in any of the sub-studies? Choose an item.   If yes, which one(s)? Click or tap here to enter text. | | | | |
| **Does the study involve an investigational drug?** | Choose an item.  If yes, complete the following:   1. Complete the [TGH Drug Information Sheet](https://www.tgh.org/-/media/files/research-and-innovation/tgh_drug_research_information_sheet_version_20_14nov2018_1_0.doc?rev=5906732fb22f46a8aeadd077a1db757c&hash=0A5F45D08058DE84C6F6CD393D6FF69A) 2. Who will administer the drug? Choose an item.    1. Other, specify: Click or tap here to enter text. | | | | |
| **Does the study involve an investigational device?** | Choose an item.  If yes, complete the following:   1. Complete the [TGH Device Information Sheet](https://www.tgh.org/-/media/files/research-and-innovation/tgh_device_procedure_research_information_sheet_version_20_14nov2018.doc?rev=b669f7c7564a4999b8e115f73141b758&hash=46D21E69EE8EF16701AA52CF2F85355C) 2. Does the sponsor require an autopsy, device removal, or data collection in the event of a participant’s death? Choose an item. If yes, specify: Click or tap here to enter text. 3. Will the Sub-Investigator(s) also interact with the device? Choose an item.   If yes, specify the name(s) of the Sub-Investigator(s): Click or tap here to enter text.   1. Will any industry representatives be involved in any procedures involving the device? Choose an item.   If yes, specify who: Click or tap here to enter text.   1. Has this been submitted to FirstCoast on behalf of USF? Choose an item. (This is only applicable to Joint USF/TGH studies) 2. Has this been submitted to FirstCoast on behalf of TGH? Choose an item. | | | | |
| **If this is a device study, is the device currently on the shelf at TGH?** | Choose an item. | | | | |
| **Who will purchase the investigational drug/device/agent?** | Choose an item.  If Other, specify: Click or tap here to enter text. | | | | |
| **Are there any ancillary items that need to be purchased?** | Choose an item.  If yes, specify: Click or tap here to enter text. | | | | |
| **Where will the drug/device/agent be stored?** | Choose an item.  If Other, specify: Click or tap here to enter text. | | | | |
| **Does this study require overnight hospitalization?** | Choose an item.  If yes, are any of the overnight stays outside of Standard of Care (SOC)?  Choose an item.  If there are research-specific overnight hospitalizations, how many nights? Click or tap here to enter text. | | | | |
| **Does this study require an EKG?** | Choose an item.  If yes, answer the following questions:   1. Will the sponsor provide the machine(s)? Choose an item.    * If Other, specify: Click or tap here to enter text. 2. Who will be completing the EKG? Choose an item.    * If Other, specify: Click or tap here to enter text. 3. Where will these be completed and at what visit(s)? Click or tap here to enter text. | | | | |
| **Does this study require a pregnancy test?** | Choose an item.  If yes, how will it be completed? Choose an item. | | | | |
| **Level of TGH Involvement/Engagement**  (select ALL that apply) | TGH employees will engage in the conduct of research activities required by the protocol (including but not limited to, obtaining consent from subjects to enroll in the research, or administration/implantation of investigational research products i.e. study drug/device or obtaining identifiable PHI or specimens for research purposes)  TGH holds the contract  TGH employees will contribute in a substantive way to the scientific development or execution of the research protocol (i.e. employees are designated as research personnel)  There is potential for patentable or copyrightable inventions to be created through the research from activity conducted at TGH  TGH employees will provide goods or services as part of their normal business operations (for which the entity provides similar goods/services to other purchasers) | | | | |
| **What research activities will occur at TGH?** **(select ALL that apply)** | Recruitment  Labs  Drug admin  Surgery | | | Enrollment  Diagnostics  Follow-up  Device Implant | Treatment  Drug dispensing  Data collection  Physical Exams |
| **Select Hospital Units/Location(s) where research activities and education will occur: (select ALL that apply, if known)**  Complete a [TGH Unit Operational Review](https://www.tgh.org/-/media/files/research-and-innovation/unit_and_nursing_administration_operational_review_proposed_research_study_version_6.docx?rev=739418e173ec4fc68800edc723e08b2c&hash=0DB92D0FB7BD80C465805467A73041A3) form and list all floor/units’ involvement. | | | | | |
| Select ImpactedIntensive Care Units  Select ImpactedIntensive Care Units  Select ImpactedIntensive Care Units  Select ImpactedMother/Baby Units  Select Impacted Pediatric Units  Select Impacted Operating Rooms, Pre-Ops, PACUs  Select Impacted Operating Rooms, Pre-Ops, PACUs  Select Impacted Operating Rooms, Pre-Ops, PACUs  Select Impacted Nursing Units/Floors  Select Impacted Nursing Units/Floors  Select Impacted Nursing Units/Floors  Cancer Center  Emergency Department  Infusion Center  Respiratory  Observation Units: 1F1, 1J2, 1J3, 2K7  Rehabilitation  Other, specify: Click or tap here to enter text. | | | **Outpatient Clinics**  Outpatient Laboratory, specify Choose an item.  Outpatient Diagnostics, specify Choose an item.  409 Bayshore CORE Research Office  409 Bayshore Transplant Clinics  Global Emerging Disease Institute  Healthpark  Harborside Transplant Clinics  TGH Sun City Center  TGH Outpatient Center (Previously known as the Brandon Healthplex (BHP))  Other, specify: Click or tap here to enter text. | | |
| **What TGH support will be needed?** (select ALL that apply) | | | | | |
| **Does your study require TGH Clinical Laboratory/Pathology services?** | N/A | Choose an item.  If yes, which service(s)?  Sample Analysis  Pathology/ Slide Preparation  Collection of De-Identified Remnant Specimens  Collection of Identifiable Remnant Specimens | | | |
| **Does your study require imaging services at TGH?** | N/A | Choose an item.  What imaging does the study require?  MRI CT X-Ray Echocardiogram Other  If other, specify: Click or tap here to enter text.  Where will the imaging occur?  TGH Imaging at the main TGH hospital or at the Brandon Healthplex, complete the *TGH Imaging Feasibility Form (TGH main hospital and Brandon Healthplex)* which can be downloaded on our website by click [here](https://www.tgh.org/research-and-innovation/research-professionals))  TGH Imaging Powered by Tower (Outpatient), complete the *TGH Imaging Powered by Tower (Outpatient) Intake Form* which can be downloaded on our website by click [here](https://www.tgh.org/research-and-innovation/research-professionals))  Other If other, specify: Click or tap here to enter text. | | | |
| **Do you need support with specimen processing?** | N/A | Choose an item.  If yes, please check the requested services and provide the lab manual.  Process Store Ship Dry Ice | | | |
| **Do you need support with IRB submissions, regulatory documents, and long-term maintenance?** | N/A | Choose an item. | | | |
| **Do you need Investigational Pharmacy Services?** | N/A | Choose an item.  If yes, please check the requested services and provide the pharmacy manual:  Storage  Randomization  Drug Preparation/Dispensation  Order Set Development | | | |
| **Do you need Clinical Research Staffing support?** | N/A | Study Coordinator  Nurse Coordinator  Data Entry Support  Specimen Processing Support  24/7 Emergency Department Screening Service to identify potential study participants | | | |
| **Do you need TGH IT Support?** | N/A | Choose an item.  If yes, please check the requested services:  Creation of EPIC documentation templates or Smart phrases  Clinical data retrieval/extraction  Best Practice Advisory (BPA)  Other, specify: Click or tap here to enter text. | | | |
| **Does your study require the transfer of images (e.g. CT Scan/MRI, ultrasound)?** | No | Yes  If yes, complete the [Technology Feasibility Worksheet](https://www.tgh.org/-/media/files/research-and-innovation/technologyfeasibilityworksheetversion60.pdf?rev=45d8668896f346978ebd2c29204adeb4&hash=1891866C0D1E4BF2D56E3C190EC8A0AF) | | | |
| **Does the study involve the addition of software and/or hardware to the USF/TGH System?** | No | Yes  If yes, complete the [Technology Feasibility Worksheet](https://www.tgh.org/-/media/files/research-and-innovation/technologyfeasibilityworksheetversion60.pdf?rev=45d8668896f346978ebd2c29204adeb4&hash=1891866C0D1E4BF2D56E3C190EC8A0AF) | | | |
| **Other research support:** | N/A | Specify:Click or tap here to enter text. | | | |
| Enter additional comments here. | | | | | |

**Submitter Signature (type name here):** Click or tap here to enter text.

**Date Signed:** Click or tap here to enter text.

Thank you for your interest in performing/conducting your research project/study at Tampa General Hospital (TGH).

**Reminder: Please submit this form to** [**research@tgh.org**](mailto:research@tgh.org) **as a Word document.**