**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****. Please do not save it as a PDF.**

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| **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 listIf 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** |
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| **Funding:** | Please select a funding source from the listIf 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** |
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| **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.
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| **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 UnitsSelect ImpactedIntensive Care UnitsSelect ImpactedIntensive Care UnitsSelect ImpactedMother/Baby UnitsSelect Impacted Pediatric UnitsSelect Impacted Operating Rooms, Pre-Ops, PACUsSelect Impacted Operating Rooms, Pre-Ops, PACUsSelect Impacted Operating Rooms, Pre-Ops, PACUsSelect Impacted Nursing Units/FloorsSelect Impacted Nursing Units/FloorsSelect 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** **as a Word document.**