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| **GENERAL INFORMATION** |
| **Full Study Title:** | Enter Study Title. |
| **Short Title/Nickname:**  | PI Last Name\_ Protocol ID. |
| **Study Protocol Number:** | Enter PROTOCOL ID or USF IRB Study ID. |
| **Study Type:** | Please select a study type from the list |
| **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 purpose of 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 list |
| **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) | [ ] Attached to email submission |
| Study Protocol | 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 | Choose an item.  |
| **Additional documents required if study is funded** |
| Draft Budget, if applicable | Choose an item.  |
| Draft Contract or Data Use Agreement | Choose an item.  |
| **Additional documents required if study involves FDA monitored investigational drug or device** |
| Investigator Brochure or Instructions for Use | Choose an item.  |
| TGH Drug Information Sheet | Choose an item.  |
| TGH Device Information Sheet | Choose an item.  |
| FDA IND/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 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, Investigator will need to complete the COI Disclosure Form  |
| **Does the study involve intellectual property that needs to be protected?** | Choose an item. |
| **Does the study involve an investigational drug?** | Choose an item. If yes, complete the TGH Drug Information Sheet |
| **Does the study involve an investigational device?** | Choose an item. If yes, complete the TGH Device Information Sheet |
| **Who will purchase the investigational drug/device/agent?** | Choose an item.If Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Where will the drug/device/agent be stored?** | Choose an item.If Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **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)** |
| 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 [ ]  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 [ ]  Brandon Healthplex ED [ ]  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 services?**  | [ ]  N/A | Select Laboratory Service  |
| **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 Screening Service to identify potential study candidates  |
| **Do you need TGH IT Support 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  |
| **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 |
| **Other research support:**  | [ ]  N/A | Specify:Click or tap here to enter text. |
| Enter additional comments here. |

**Submitter Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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