**ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO** [**RESEARCH@TGH.ORG**](mailto:RESEARCH@TGH.ORG)

**Submission Checklist**

* Please provide the following documents with your study submission. For studies submitted via USF BullsIRB only provide documents not available on the portal.

Protocol

Informed Consent (s)

No Consent Requirement

Applying for ICF Waiver to IRB

Research instruments (e.g. Questionnaires, data collection sheets, ect.)

Letters of support from external entities

Grant (s)

Contract(s)

IND/IDE number (experimental uses of drugs or devices)

Investigators Brochure/IFU (for experimental uses of drugs or devices)

Investigator Curriculum Vitae’s for Primary Investigator and Associated Investigators

* Studies requiring unit support will go through feasibility process at Tampa General Hospital prior to any study activity on unit. Please complete the following forms as applicable. For a complete list visit: [TGH Support Request Documents](file:///C:\Users\D42400\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\FU2Z8DJ0\TGH%20Support%20Request%20Documents)

TGH Unit Operational Review of Proposes Research (e.g. Unit(s) impacted, activities)

TGH Imaging Operational Review of Proposed Research (Diagnostic testing, MRI, CT,

etc.)

Technology Operational Review of Proposed Research (Data image transfer/

upload requests)

TGH Drug Research Information Sheet (Investigational Drug Studies)

TGH Device Research Information Sheet (Investigational Device Studies)

* For IRB Submission Document visit Bulls IRB Library page:

[https://arc.research.usf.edu/Prod/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5BACDE0E76FC6AE945B08E9C38DF21F154%5D%5D](C:\\Users\\D42400\\AppData\\Local\\Microsoft\\Windows\\INetCache\\Content.Outlook\\FU2Z8DJ0\\USF Bulls IRB)

| **A. GENERAL STUDY INFORMATION** |
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| Full Study Title: |  |
| Short Title: (descriptive title to be used for study ID in EPIC/EMR and CTMS |  |
| Study Protocol Number: |  |
| IRB Name: | USF IRB  WIRB  Other, specify: |
| IRB #: | Pending available |
| NCT #: | NA  Pending available |
| Principal Investigator (PI) Name: |  |
| PI Affiliation and Department: |  |
| Primary Coordinator Name: |  |
| Study Phase | Pilot  Phase I  Phase II Phase III  Phase IV NA |
| If the study is phase IV or post marketing, is the study required by the FDA? | Yes No NA |
| Are the products FDA approved for use in the indication under study? | Yes No NA |
| Does the study involve stem cells or gene therapy/transfer? | Yes No  If yes, provide a description: |
| Number of Planned Subjects: |  |
| Funding Source(s);  select ALL that apply | TGH directly holds contract with sponsoring agency  Industry-Sponsored  Government Sponsored (e.g. NIH, DOD)  Investigator  Other funding, specify (e.g. industry funding; department funding; government or non-government grant support):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  N/A |
| Level of TGH staff involvement; select ALL that apply | Perform invasive or non-invasive procedures for research purposes outside the scope of standard of care  Manipulate the environment for research purposes  Interact for research purposes  Obtain informed consent  Obtain identifiable private information or identifiable biological specimens from any source for the research  Recruitment of research subjects |

| **B. RESEARCH ACTIVITIES AT TGH** |
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| **What research activities will occur at TGH?** **(select ALL that apply)** | Recruitment  Labs  Drug administration  Surgery  Other\_\_\_\_\_\_\_\_\_\_\_\_ | | Enrollment (consent)  Diagnostics  Follow-up  Device Implant | | Treatment  Drug dispensing  Data collection  Physical Exams |
| **Location(s) where research activities and education will occur: (select ALL that apply)** | | | | | |
| Specialty Surgery Unit  ACE Unit (Acute Care for elderly)  Complex Medicine  Oncology 1 7C1  Oncology 2 7C2  Gynecology Unit  Surgery Trauma 8C2  Primary Care 8A1 & 2  Neuroscience 1 9A1  Neuroscience 2 9A2  Psychiatric  Burn Center  Orthopedic Trauma  Joint Replacement Center  Short Stay Center  GE Center  Operating Rooms 3F  Post Anesthesia Care  Main OR  Cardiac OR  Nursing 4R  Cardiac Cath Lab  Angio/Interventional  Parathyroid Center  Vascular Surgical Acute Care  Complex Medicine  Nursing 3R  Clinical Education  Observation Unit  Endoscopy Center  Mother Baby Unit | | Pathology  Infusion/Cancer Center  ER  ICU—Surgical Trauma  ICU—Neurosciences 1  ICU—Neurosciences 2  ICU—Medical 2D1-2  ICU—Medical ICU 2  Adult Medical Surgical ICU  ICU - Vascular  CTICU  CCU  Cardiac Transition  Cardiac Telemetry Unit 5A1-2  Cardiovascular Telemetry 3H1  3K/CV Center  ICU - Adult Stepdown 5A  Cardiac Care  Transplant - Administration  Transplant 1 (7F & 8F)  Transplant 2 9F1  Pediatric Medical/Surgical  PICU  NICU South  NICU North  Labor & Delivery  Antepartum/Postpartum  Pediatric Dialysis  Rehabilitation  Adult Dialysis – Apheresis Unit  Observation | | Clinics:  30th Street—Pediatrics  30th Street—Genesis  Transplant Thoracic  Physician Services – Specialty Clinic  Kennedy—Family Practice  Outpatient Rehabilitation  Harbourside Medical Tower (HMT)  409 Bayshore Transplant Clinic – 4th floor  CORE: 5th floor 409 Bayshore  Suites:  Surgical Suites  CV Pre and Post Procedure  Outpatient Surgery  Pre-op Center  PACU  Bariatric Center  Outpatient Diagnostics  Outpatient Laboratory  Pediatric Day Hospital  Brandon Healthplex ED  Other, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **C. STUDY SUPPORT INFORMATION** |

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| What TGH support will be needed? (select ALL that apply)  Note: If applicable, a fee schedule will be provided if services are requested. | | |
| Laboratory: | N/A | Sample Collection  If yes, specify:  Identifiable  Non-Identifiable  Process  Store  Ship  Tumor specimen sample prep |
| Regulatory: | N/A | Regulatory Support |
| Pharmacy: | N/A | Storage  Randomization  Dispensing |
| Study Coordinator: | N/A | Study Coordinator Support |
| Nurse Coordinator: | N/A | Study Coordinator Support |
| IT: | N/A | Reports  Data  BPA  Order Set  Other, specify: |
| Does the study involve data transfers (e.g. CT Scan/MRI)? | No | Yes  If yes, provide details: |
| Does the study involve the addition of software and/or hardware? | No | Yes  If yes, provide details: |
| Who will purchase the investigational drug/device/agent? | N/A | Physician/Practice Group  Tampa General Hospital (advanced purchase)  Tampa General Hospital (consigned/leased from sponsor)  Sponsor will provide free of charge  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Where will the drug/device/agent be stored? | N/A | Physician/Practice Group  Tampa General Hospital Investigational Pharmacy  Sponsor will provide on a case-by-case basis  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other research support: | N/A | Specify: |

**List ALL services to be performed at TGH (complete the table below)**

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| Visit #/Name | Location where procedure, test, item, or service to be performed | Description of procedure, test, item or other service:  (ex. informed consent, EKG, imaging, specimen collection and/or processing. Include CPT/HCPCS code(s), if applicable) | Performed by TGH, TGH CORE Staff, or PI/External (non-TGH) Staff? |
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**Submitter Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date of Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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