**ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO** **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%3A%5CUsers%5CD42400%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CFU2Z8DJ0%5CTGH%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

| **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 CollectionIf 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).