# **Research Study Proposal Form**

**ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO** **RESEARCH@TGH.ORG**

Thank you for your interest in performing/conducting your research project/study at Tampa General Hospital (TGH). In order for the Office of Clinical Research (OCR) to efficiently conduct our review, the following study documents are required to begin the process. Please select all documents that are included in your submission:

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| **For ALL studies the following documents must be submitted, as applicable:** |
| [ ]  Research Study Proposal Form[ ]  Study protocol (Version date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[ ]  IRB Application **for Investigator Initiated studies (IIT)**. If there is no informed consent, the request for a waiver of Consent and Authorization must submitted with the application [ ]  **NA**[ ]  Data collection sheet (if applicable) [ ]  **NA**[ ]  Survey, questionnaires and scripts (if applicable) [ ]  **NA**[ ]  Current CV, signed and dated for the principal investigator |

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| **Informed Consent Form:**  |
| [ ]  **NA** Informed Consent Form **If NA, documentation of/request for Waiver of Consent must be included.**[ ]  All Informed Consent/Assent Forms (Version date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[ ]  Documentation of/request for Waiver of Consent[ ]  HIPAA Authorization Forms (if separate document from Informed Consent Form) if applicable [ ]  **NA**  |

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| **Business and Finance:** |
| [ ]  Sponsor’s budget, funding memo/sheet, grant award, etc.  (**Required for all funded studies)** [ ]  **NA**[ ]  CMS Approval Letter (device studies only) [ ]  **NA**[ ]  FDA Approval Letter for IND/IDE studies. Letters from sponsors are not acceptable [ ]  **NA**[ ]  Any agreements/contracts: Clinical Trial Agreement, Contracts, Work Order, Statement of Work (SOW), Material Transfer Agreements (MTA), Facility Use Agreements, Purchased Services Agreements, Purchase Agreements, Device Agreements, etc. [ ]  **NA** [ ]  Purchase Agreement (if applicable) [ ]  **NA**[ ]  Coverage Analysis (if applicable) [ ]  **NA** |

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| **Study Documents - Draft copies from sponsor are acceptable:** |
| [ ]  Investigator Brochure (if applicable) – Drug Studies [ ]  **NA** [ ]  Instructions for Use (IFU) (if applicable) – Device Studies [ ]  **NA**[ ]  Imaging, software or hardware Manual (if applicable) [ ]  **NA**[ ]  Laboratory Manual (if applicable) [ ]  **NA**[ ]  EDC Manual (if applicable) [ ]  **NA**[ ]  Pharmacy Manual (if applicable) [ ]  **NA**[ ]  Other study related documents as available [ ]  **NA** |

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| **For ALL drug and device/procedure studies, the following document must be completed and submitted:** |
| [ ]  TGH Drug Research Information Sheet [ ]  **NA**[ ]  TGH Device/Procedure Research Information Sheet [ ]  **NA** |

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| **The OCR will begin reviewing the research project/study once all required study documents are received by the OCR. If you need clarification on the required documents, please contact** **research@tgh.org****.** |

**Optional Documents for Initial Research Study Proposal Form Submission:**

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| **Studies that involve TGH inpatient/outpatient units or require TGH bedside nursing support** |
| For studies that involve TGH inpatient/outpatient units or require TGH bedside nursing support, a nursing feasibility assessment must be completed. You may submit the Research Study Proposal Form with or without the nursing feasibility assessment completed; however, the nursing feasibility assessment must be completed prior to TGH OCR completing the overall review and approval process. If applicable, submit the following documents:[ ]  **NA**[ ]  Unit Nursing Support and Awareness Worksheet – signed/dated[ ]  TGH Hospital Unit Support of Research Study letter – signed/dated by Mary Kutash (mkutash@tgh.org) |

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| **Nursing Related Research Projects** |
| For any nursing related research projects, notify the TGH Advanced Nurse Research Specialist in TGH Nursing Administration and submit: [ ]  **NA**Instructions: If a study is a nursing study OR contains a survey or questionnaire that involves nursing staff, the PI/designee must submit the study documents to Nursing Administration, Mary Kutash (mkutash@tgh.org), for review and approval. You may submit the Research Study Proposal Form with or without the nursing administration support documentation; however, the letter of nursing approval is required in order to proceed through the TGH review and approval process.[ ]  TGH Nursing Administration Support of a Research Study letter – signed/dated by Mary Kutash |

1. **General 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 #: |  [ ]  Pending available |
| NCT #: |  [ ]  NA [ ]  Pending available |
| Principal Investigator (PI) 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 |
| Study Indication: |  |

**Short Study Description:** (1-2 sentences summarizing the purpose of the study, 200 max character limit)

|  |  |
| --- | --- |
| What research activities will occur at TGH: (select ALL that apply) | [ ] Recruitment [ ] Enrollment (consent) [ ] Treatment [ ] Labs [ ]  Diagnostics [ ]  Drug dispensing[ ] Drug administration [ ] Follow-up [ ] Data collection[ ]  Surgery [ ]  Device Implant [ ]  Physical Exams[ ] Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

 **PI Information**

|  |  |
| --- | --- |
| Affiliation and Department: |  |
| Mailing Address: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |
| Credentialed at TGH? | [ ] Yes [ ] No [ ] Pending |
| Access to TGH’s CTMS? | [ ] Yes [ ] No [ ] Pending |
| Access to VESTIGO (TGH Investigational Product Accountability System)? | [ ] Yes [ ] No [ ] Pending |

1. **Study Support Information**

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| What TGH support will be needed? (select ALL that apply) |
| Laboratory: [ ] NA | [ ] Sample Collection [ ]  Process [ ] Store[ ] Ship [ ] Tumor specimen sample prep |
| Regulatory: [ ] NA | [ ] Regulatory Support (Note: If services are requested, a fee schedule will be provided in the study acknowledgment e-mail, if applicable.) |
| Pharmacy: [ ]  NA | [ ] Storage [ ] Randomization [ ] Dispensing (Note: If services are requested, a fee schedule will be provided in the study acknowledgment e-mail, if applicable.) |
| Study Coordinator: [ ] NA | [ ]  I/E [ ]  ICF [ ]  IP admin [ ]  Questionnaires [ ]  Data entry[ ] Other, specify:  |
| IT: [ ] NA | [ ] Reports [ ] Data [ ] BPA [ ] Order Set[ ] Other, specify:  |
| Does the study involve data transfers (e.g. CT Scan/MRI)? | **[ ] Yes [ ] No** **If yes, provide details:** |
| Does the study involve the addition of software and/or hardware? | **[ ] Yes [ ] No** **If yes, provide details:** |
| Other research support: [ ] NA | 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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**Additional services can be listed on the last page of this application in section B.1.**

**\*\*FOR NON-TGH ENTITIES - PROFESSIONAL FEE INFORMATION:**

**If this study requires any of the services listed below (or other services/groups not listed that perform billing outside of TGH), non-TGH study sites must contact the following entities below for service related agreements.**

**Laboratory:** Please be advised that you may be charged laboratory reading fees by Ruffolo, Hooper and Associates. TGH has no control over the assessment of these fees. Please contact Ruffolo, Hooper and Associates at 813-890-0138 for service related agreement information.

**Radiology:** Please be advised that you may be charged radiology reading fees by Radiology Associates. TGH has no control over the assessment of these fees. Please contact Radiology Associates at 813-253-2721 for service related agreement information. **EKG:** Please be advised that you may be charged EKG reading fees by EKG Interpretation. TGH has no control over the assessment of these fees. Please contact 813-254-2441 for service related agreement information.

**Anesthesiology:** Please be advised that you may be charged anesthesiology professional fees by TeamHealth Anesthesiology. TGH has no control over the assessment of these fees. Please contact 813-258-3444, ext. 306, for service related agreement information. **If your study does not involve any additional professional services, then these fees are not applicable.**

1. **Study Details**

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| Number of Planned Subjects: |  |
| Study Type: (select only one option) | [ ] Drug Study [ ] Device Study – IDE[ ] Device Study – HDE[ ] Device Study [ ] Observational[ ] Procedure[ ] Registry with specimen[ ] Registry[ ] Quality Improvement (QI)[ ] Specimen[ ] Chart Review[ ]  Questionnaire/Survey/Interview[ ]  Emergency Use[ ]  Compassionate Use |
| Drugs/Devices/Agents/Procedures Being Investigated (List by name): |  |
| Therapeutic Area of the Study (select only one option – most relevant area): | [ ]  Allergy, Asthma and Immunology[ ]  Anesthesiology[ ]  Anthropology[ ]  Cardiology and  Cardiothoracic Surgery[ ]  College of Medicine[ ]  Critical Care and Trauma[ ]  Emergency Medicine[ ]  Engineering[ ]  Gastroenterology and  Digestive Diseases[ ]  Genetics and Metabolism[ ]  Hepatology[ ]  Infectious Disease[ ]  Internal Medicine  | [ ]  Infectious Disease[ ]  Internal Medicine[ ]  Laboratory[ ]  Mental Health[ ]  Molecular Medicine[ ]  Neonatology[ ]  Nephrology[ ]  Neurology and  Neurosurgery[ ]  Nursing[ ]  OB/GYN[ ]  Oncology[ ]  Ophthalmology[ ]  Orthopaedics[ ]  Otolaryngology | [ ]  Pastoral Care[ ]  Pathology[ ]  Pediatrics[ ]  Pharmacology[ ]  Pharmacy[ ]  Plastic Surgery[ ]  Poison Center[ ]  Public Health[ ]  Pulmonology[ ]  Radiology[ ]  Surgery[ ]  Transplant[ ]  Trauma Surgery[ ]  Urology[ ] Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| IRB Name: | [ ]  USF IRB[ ]  WIRB[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| Funding Source(s); (select ALL that apply) | [ ]  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 |
| Sponsor/Manufacturer Name: |  |
| Sponsor/Manufacturer Contact Information: | Name:Title:Phone:Email: |
| CRO Name, if applicable: |  |
| CRO Contact Information: | Name:Title:Phone:Email: |
| Are the products FDA approved for use in the indication under study? | [ ] Yes [ ] No [ ] NA |
| IND/IDE/HDE Number: |  OR [ ] NA |
| Who will purchase the investigational drug/device/agent? | [ ]  Physician/Practice Group[ ]  Tampa General Hospital (advanced purchase) [ ]  Tampa General Hospital (consigned/leased from sponsor)[ ]  Sponsor will provide free of charge [ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  N/A |
| Where will the drug/device/agent be stored? | [ ]  Physician/Practice Group[ ]  Tampa General Hospital Investigational Pharmacy [ ]  Sponsor will provide on a case-by-case basis[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  N/A |
| Does the study involve stem cells or gene therapy/transfer? | [ ] Yes [ ] No If yes, provide a description:  |

1. **Study Personnel**

**Sub-Investigators:**

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| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |

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| E-mail: |  |
| Pager/Cell Phone: |  |

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| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |

**Additional Sub-Investigators should be listed in Section D.1.**

**Primary Study Coordinator (SC):**

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| --- | --- |
| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard? | [ ] Yes [ ] No  |

**Study Contact:**

|  |  |
| --- | --- |
| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard? | [ ] Yes [ ] No  |

**Any additional study personnel should be listed in Section D.2.**

**For sponsor studies:** [ ] **NA**

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| Contract Contact Name: |  |
| Contract Contact Telephone: |  |
| Contract Contact E-mail: |  |

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| Budget Contact Name: |  |
| Budget Contact Telephone: |  |
| Budget Contact E-mail: |  |

1. **Education Plan**:

It is the responsibility of the study team and not TGH research staff to notify all affected TGH hospital units of the study. The unit manager and/or educator must approve of the study prior to release of the final TGH approval. This information should be captured in the **Unit Nursing Support and Awareness Worksheet. For any further questions, please contact** **research@tgh.org****.**

Who will execute the education plan?

[ ]  Sponsor [ ]  PI [ ]  Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Describe your Education Plan for training or notifying all affected areas not captured in the Unit Nursing Support and Awareness Worksheet: (e.g. ECHO, Radiology, Lab, etc.)

:

1. **Research Activities at TGH:**

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| Location(s) where research activities and education will occur: (select ALL that apply) | [ ]  Specialty Surgery Unit [ ]  ACE Unit (Acute Care for the elderly) [ ]  Complex Medicine [ ]  Oncology Unit [ ]  Gynecology Unit [ ]  Trauma/Surgery [ ]  Primary Care [ ]  Neurosciences [ ]  Psychiatric [ ]  Burn Center [ ]  Orthopaedics [ ]  Joint Center [ ]  Short Stay Center [ ]  GE Center [ ]  Main OR [ ]  Cardiac OR[ ]  Cardiac Cath Lab[ ]  Angio/Interventional Suites: [ ]  Outpatient Surgery [ ]  Pre-op/Surgical Prep Unit [ ]  PACU [ ]  Bariatric Center[ ]  Outpatient Diagnostics[ ]  Outpatient Laboratory [ ]  Pediatric Day Hospital Services:[ ]  Pathology[ ]  Infusion/Cancer Center[ ]  ER [ ]  ICU—Trauma/Surgical[ ]  ICU—Neurosciences  | [ ]  ICU—Medical[ ]  ICU - Vascular[ ]  CTICU [ ]  CCU[ ]  Cardiac Transition[ ]  Cardiac/Vascular/Telemetry[ ]  3K/CV Center[ ]  Adult Step-Down[ ]  Cardiac Care[ ]  Transplant[ ]  Pediatric Medical/Surgical[ ]  PICU[ ]  NICU[ ]  Labor & Delivery[ ]  Antepartum/Postpartum[ ]  Pediatric Dialysis [ ]  Rehabilitation[ ]  Adult Dialysis[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Clinics: [ ]  30th Street—Pediatrics[ ]  30th Street—Genesis[ ]  Kennedy—Family Practice[ ]  Outpatient Rehabilitation[ ]  Harbourside Medical Tower (HMT)[ ]  409 Bayshore Transplant Clinic – 4th floor[ ]  CORE: 5th floor 409 Bayshore [ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Financial Disclosure**

Does PI or any investigator receive any financial compensation from the study sponsor?

[ ]  YES [ ]  NO

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

**INTERNAL USE ONLY:**

Office of Clinical Research Acknowledgement of Receipt

Received by:

Date Complete Submission Received:

OCR Review Start Date:

Upon review completion, signature and date of reviewer:

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| B.1. Additional services |
| 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) | Performed by TGH, TGH CORE Staff, or PI/External (non-TGH) Staff? |
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**Section D.1. Complete the below information for any additional Sub-Investigators:**

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| Pager/Cell Phone: |  |

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| Section D.2. Complete the below information for any additional study personnel |
| Name: |  |
| E-mail: |  |
| Role: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard | [ ] Yes [ ] No  |

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| --- | --- |
| Name: |  |
| E-mail: |  |
| Role: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard | [ ] Yes [ ] No  |

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| --- | --- |
| Name: |  |
| E-mail: |  |
| Role: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard | [ ] Yes [ ] No  |

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| --- | --- |
| Name: |  |
| E-mail: |  |
| Role: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard | [ ] Yes [ ] No  |

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| Name: |  |
| E-mail: |  |
| Role: |  |
| Require access to TGH CTMS? | [ ] Yes [ ] No  |
| Require access to USF CTMS? | [ ] Yes [ ] No  |
| Require access to VESTIGO? | [ ] Yes [ ] No  |
| Require access to ClinCard | [ ] Yes [ ] No  |