**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). Please follow the instructions for Research Study submission:

| **Submission Instructions** |
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| **INTRODUCTION:**TGH has three research study submission options: * **Option #1 - PRE-SUBMISSION**
* **Option #2 - COMPLETE SUBMISSION**
* **Option #3 – COMPLETE SUBMISSION FOR RETROSPECTIVE CHART REVIEW STUDIES**

[ ]  **Option #3 - COMPLETE SUBMISSION FOR RETROSPECTIVE CHART REVIEW STUDIES*** Any retrospective chart review study with NO informed consent, budget and/or contract allows your study to be submitted under Option #3

**Option #3 Instructions:*** **STEP 1 (STUDY TEAM):** Obtain all study documents and complete **Section A** of the TGH Research Study Proposal Form.
* **STEP 2 (STUDY TEAM):** Complete the entire TGH Research Study Proposal Form **Sections B – D**, including signing and dating the form.
* **STEP 3 (STUDY TEAM):** Submit the completed TGH Research Study Proposal Form and study documents to research@tgh.org.

TGH Office of Cline Research (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 contactresearch@tgh.org**APPROVALS REQUIRED TO START STUDY ACTIVITIES:**For all studies conducted at TGH using any TGH resources, data (e.g., medical record information) and/or facilities, two written approvals are required prior to starting the study: 1. Institutional Review Board (IRB) approval; and
2. TGH OCR approval

**TGH Clinical Research Website: Study Submissions**To obtain further Instructions and Forms:<https://www.tgh.org/more-about-tgh/clinical-research/study-submission-0>***Always go to the TGH Clinical Research website to obtain the current information and forms*** |

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| **SECTION A – STUDY DOCUMENTS** |

Select all documents that are included in your submission:

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| **For ALL studies the following documents must be submitted:** |
| [ ]  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 [ ]  Data collection sheet [ ]  Current CV, signed and dated for the principal investigator |

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| **B. 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 #: |  [ ]  Pending available |
| Principal Investigator (PI) Name: |  |
| Study Indication: |  |

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

**PI Information**

|  |  |
| --- | --- |
| Affiliation and Department: |  |
| Mailing Address: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |
| Credentialed at TGH? | [ ] Yes [ ] No [ ] Pending |

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| **C. Study Details** |

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| Number of Planned Subjects: |  |
| 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[ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

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| **D. Study Personnel** |

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

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

**Primary Study Coordinator (SC):**

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

**Study Contact: (Any additional study personnel should be listed in Section D.1.)**

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

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

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| Section D.1. Complete the below information for any additional study personnel |
| Name: |  |
| E-mail: |  |
| Role: |  |

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