**ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO** [**RESEARCH@TGH.ORG**](mailto: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 two research study submission options:   * **Option #1 - PRE-SUBMISSION** * **Option #2 - COMPLETE SUBMISSION**   **Option #1 – PRE-SUBMISSION**   * The PRE-SUBMISSION is a helpful option that allows your study to be reviewed early on in the TGH intake process. The PRE-SUBMISSION is not mandatory but encouraged. The benefit of this option is to assist in identifying areas and items of clarification that can be addressed early on in the study intake and review process. * **Examples** of studies applicable to PRE-SUBMISSION Option Include: Drug Studies; Device Studies; Sponsor Studies; Pre-Grant Request; Protocol Development; any studies with a contract, budget and/or informed consent.   **Option #1 Instructions:**   * **STEP 1 (STUDY TEAM):** Document in **Section A** the available study documents. At a minimum, a protocol synopsis must be submitted for TGH’s initial review to be completed. * **STEP 2 (STUDY TEAM):** Complete **Sections B-D** of the TGH Research Study Proposal Form with the available information. * **STEP 3 (STUDY TEAM):** Submit the TGH Research Study Proposal Form, and available study documents, to [research@tgh.org](mailto:research@tgh.org). * **STEP 4 (TGH OCR):** Provide a notice to the submitter of study review completion, and feedback, as applicable. * **STEP 5 (STUDY TEAM):** Proceed to COMPLETE SUBMISSION and submit the remaining study documents and complete the TGH Research Proposal Form in its entirety once all documents are available. * If you selected the PRE-SUBMISSION Option, you are required to submit a COMPLETE SUBMISSION package for the study to proceed to TGH full review/start-up processes.   **Option #2 - COMPLETE SUBMISSION**   * The COMPLETE SUBMISSION is required for all studies and must include all documents outlined in Section A of this form. * **Examples** of studies that must go directly to the COMPLETE SUBMISSION Option Include: Retrospective Chart Review; Quality Improvement Studies; or any study with NO informed consent, budget and/or contract. * Studies submitted under Option #1 must proceed to Option #2, Complete Submission, once all study documents are available.   **Option #2 Instructions:**   * **STEP 1 (STUDY TEAM):** Obtain all study documents and complete **Section A** of the TGH Research Study Proposal Form. If you completed Option 1, update **Section A** of the TGH Research Study Proposal Form. * **STEP 2 (STUDY TEAM):** Complete the entire TGH Research Study Proposal Form **Sections B – G**, including signing and dating the form. If you completed Option 1, update the entire TGH Research Study Proposal Form **Sections B – D** and complete **Sections E- G**, and re-sign and date the form. * **STEP 3 (STUDY TEAM):** Submit the completed TGH Research Study Proposal Form and study documents to [research@tgh.org](mailto:research@tgh.org).   TGH 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](mailto:research@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, as applicable:** |
| Research Study Proposal Form  Study protocol (Version date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **Protocol Synopsis (Version Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_) *Applicable to Option #1.***  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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| **SECTION A – STUDY DOCUMENTS** |

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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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| **TGH Unit Awareness & Support**  **NA**  **This Section applies to studies conducted at TGH inpatient /outpatient units/departments (#1 below) and all nursing research studies (#2 below)**  ***(Optional with initial submission; may be completed later in the submission process)*** |
| *You may submit the TGH Research Study Proposal Form with or without the TGH Unit Awareness & Support documentation at initial submission; however, all required documents are needed to proceed through the TGH review and approval process.* |
| 1. **Studies that involve TGH inpatient/outpatient units and/or departments or require TGH bedside nursing support and/or other ancillary support**  **NA** |
| ***For studies that involve TGH inpatient/outpatient units and/or departments or require TGH bedside nursing support*** ***and/or ancillary support, an assessment must be completed***. Submit the following documents:  TGH Unit Awareness & Support Worksheet (refer to worksheet for further detailed instructions)  TGH Unit Awareness & Support letter (*modified as needed for this study*) – signed/dated by Mary Kutash ([mkutash@tgh.org](mailto:mkutash@tgh.org)) |
| 1. **Nursing Research Study (Principal Investigator is a Nurse)**  **NA** |
| ***All nursing research studies must be submitted to Mary Kutash, TGH Advanced Nurse Research Specialist*** ([mkutash@tgh.org](mailto:mkutash@tgh.org)). Submit the following:  Study documents (e.g. Chart Review Studies) **OR**  TGH Unit Awareness & Support Worksheet (e.g. If inpatient/outpatient units are involved. *Refer to TGH Unit Awareness & Support worksheet for further detailed instructions*)  TGH Unit Awareness & Support letter (*modified as needed for this study*) – signed/dated by Mary Kutash |
| **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 |
| 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)

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| 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**

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| 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 |

**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 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) | |
| 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 C.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.**

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| **D. 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: | | |

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| **E. Study Personnel** |

**Sub-Investigators:**

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

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

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| Name: |  |
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| Pager/Cell Phone: |  |

**Additional Sub-Investigators should be listed in Section E.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:**

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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 |

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

**Provide the following for sponsor studies:** **NA- Not a Sponsor study**

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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: |  |

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| **F. 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 **TGH Unit Awareness & Support Worksheet. For any further questions, please contact** [**research@tgh.org**](mailto: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 **TGH Unit Awareness & Support Worksheet**: (e.g. ECHO, Radiology, Lab, ECG. Procedure etc.)

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| **G. 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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| C.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 E.1. Complete the below information for any additional Sub-Investigators: | |
| Name: |  |
| Telephone: |  |
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| Pager/Cell Phone: |  |

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| Section E.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 |