



CLINICAL RESEARCH STUDENT/VOLUNTEER CREDENTIALING APPLICATION

Office of Clinical Research
researchcredentialing@tgh.org

**THE FOLLOWING ITEMS ARE REQUIRED TO BEGIN THE
CREDENTIALING PROCESS. PLEASE FORWARD
THESE ITEMS TO THE ABOVE ADDRESS:**

- Completed Application which includes:
 - Confidentiality Statement
 - Security and Confidentiality Agreement
 - Signed PI Statement of Responsibility
- Resume/CV
- CITI Human Subject Protection Certificate

In accordance with Tampa General Hospital policy, students/volunteers performing any functions related to clinical research **without patient contact** must be credentialed through TGH Office of Clinical Research (OCR). Duties are limited to retrospective data collection and data processing or analysis. Students/volunteers **may not be involved in any patient contact for the purpose of recruitment, consenting or study visit implementation.**

No research activities are to be initiated until credentialing approval has been granted.

The following documentation must be completed in full and sent to the address above:

- Application, completed, signed, and dated,
- Copy of current Resume/CV, signed, and dated with no personal information such as DOB, home address, etc.,

- Protection of Human Subject Education Certificate (completed on-line at <http://www.citiprogram.org/>). Minimum courses required: Biomedical Investigators and Key Personnel Basic Course.
- Completed and signed Investigator Statement of Responsibility from the students/volunteer's investigator or TGH Supervisor. This physician/person will be responsible for the student's actions during their involvement under the proposed research. The physician must be privileged through TGH Medical Staff Services or a TGH employee. All appropriate boxes must be checked, and a time frame included.

Once the above items have been received and reviewed by OCR Credentialing, a research badge is issued and the **required Mindlab courses** (TGH orientation, Epic review, Requirements for Research, and other courses required at the time of the application submission) will be mapped to the student/volunteer's Mindlab account.

Upon completion of the Mindlab courses, the student/volunteer will do the following to pull their transcript.

- a. Log in using your research badge number
- b. Open Mindlab using Google Chrome
- c. Click on Resources/My Transcript
- d. On the right of the screen, you'll see "export/generate PDF"
- e. Click on export again/Download Files – a window will open listing any downloads you may have created in Mindlab
- f. Save this to your desktop or drop directly into an email addressed to researchcredentialing@tgh.org
- g. Send your Mindlab transcript to researchcredentialing@tgh.org immediately. Failure to complete the required courses within thirty-days will result in the expiration of Mindlab access. The credentialing process will then need to be re-opened.

TGH OCR Credentialing will verify completion of the courses and final review of all requirement documents. If everything is in order, an Approval email will be sent.

SPECIAL NOTES:

- All research badges are virtual – no physical badge is issued. The badge number is for Epic access only. Should access be needed to buildings/offices, the credentialing process will need to be completed through TGH HR to obtain an entry badge.
- The maximum time frame a research badge is issued is for 1-year and will expire regardless of time frame listed on the Investigator's Statement of Responsibility. Student/volunteer must notify TGH OCR Credentialing 30-days prior to the expiration to avoid any delay in access. If the Investigator's Statement does not cover the time frame needed, an updated Statement must be submitted to OCR Credentialing before renewal is approved.
- If Epic Remote Access is needed, student/volunteer is to notify TGH IT directly. Please submit an IT request ticket to TGH at <https://helpdesk.tgh.org#pages/ticket/new> or you

can call them at (813) 844-7490. The ticket will require approval and then will be routed to TGH IT for activation.

- Students/volunteers performing research functions that have direct patient contact, must be credentialed through TGH Human Resources. For full details, contact nonemployeeaccess@tgh.org



Will you have direct patient contact such as recruiting, consenting, or performing research functions?

YES: STOP - Contact TGH HR for credentialing requirements.

NO: Move forward and complete all the following information in this application and forward to researchcredentialing@tgh.org

I. Personal Information

Name: _____
First Middle Initial Last

Mailing Address: _____

City: _____ State: _____ Zip: _____

Date of birth: _____ City of birth: _____ Last 4 SS#: _____

E-Mail Address: _____ Cell Phone: _____

Emergency Contact: _____ Phone: _____

Current Position or Year in School: _____ Proposed Date of Graduation: _____

Name of School Currently Attending: _____

Is this research project conducted for a school requirement (for credit)? Yes No

If you already have a TGH badge number, please list here: _____

Please indicate your level of education or credentials:

- Bachelor's Degree
- Master's Degree
- Medical Student
- Doctoral Candidate
- Other _____

II. Professional Information

Affiliation (Name of group or department you will be working under): _____

Work Address: _____

City: _____ State: _____ Zip: _____

Please list the Principal Investigators that you intend to work with:

Please indicate the types of studies that you expect to be involved in:

- _____ Chart Review
- _____ Registry
- _____ Observational
- _____ Survey
- _____ Drug Trials
- _____ Device Trials
- _____ Industry Sponsored
- _____ Investigator Initiated

I understand that my involvement with human research is a privilege that is to be conducted under the ethical principles of respect for all persons, beneficence, and justice. I am committed to protecting the privacy of patient health information during any data collection that I am responsible for and am committed to minimizing risk for any patients during the conduct of the research that I am involved in. I will conduct all research related activities according to the TGH and IRB approved study protocol and will maintain patient safety at the forefront of all research activities with which I am involved.

Applicant Signature

Date



CONFIDENTIALITY STATEMENT

I, _____, will be participating in research studies that are to be conducted at Tampa General Hospital. All TGH related studies that I serve on as a research staff member will be approved by Tampa General Hospital and a TGH affiliated Institutional Review Board.

I realize that, in the course of my work, I may be exposed to confidential information regarding patients.

I understand that all patient information is confidential and protected under State and Federal regulations governing hospitals and patient rights. Violations of the sections may carry penalties.

I further understand that no patient names or data may be abstracted or removed from the hospital other than as identified in the research protocols and approved in the Tampa General HIPAA Authorizations.

I understand the above conditions and agree to comply with them.

Signature

Date

Print Name



INVESTIGATOR'S STATEMENT OF RESPONSIBILITY

Principal Investigator/ TGH supervisor: _____

Institution/ Dept: _____

Student Name: _____

I will be sponsoring the above-named student for a research internship from _____ to _____ (dates)

I understand that the student may not be involved in any patient contact for the purpose of recruitment, consenting, or study visit implementation.

I understand that the student's duties regarding research activities are limited to retrospective data collection and data processing or analysis.

I am requesting remote access for my student. I acknowledge that this is only necessary if chart review will occur off the TGH network. (if this is required, please have the student complete the additional Security and confidentiality agreement on the last page.

By signing below, I agree to be responsible for the student's conduct while under my supervision for this research role.

Principal Investigator/TGH supervisor*

***Student sponsor must be an attending physician privileged through TGH Medical Staff Services or a TGH employee.**

Security and Confidentiality Agreement

TGH* has a legal responsibility to safeguard the confidentiality and security of our patients' protected health information (PHI) as well as operational, proprietary, and employee information. This information may include, but is not limited to, patient health records, human resources, payroll, fiscal, research, and strategic planning and may exist in any form, including electronic, video, spoken, or written. This agreement applies to all members of the workforce, including but not limited to employees, volunteers, students, physicians, and third parties, whether temporary or permanent, paid or not paid, visiting, or designated as associates, who are employed by, contracted to, or under the direct control of TGH. This agreement also applies to users of TGH information systems, and the information contained therein, whether the user is affiliated with TGH or not, and whether access to or use of information systems occurs locally or from remote locations. I hereby agree as follows:

- I acknowledge that TGH has formally stated in policy its commitment to preserving the confidentiality and security of health information in any format. I understand that I am required, if I have access to such health information, to maintain its confidentiality and security.
- I understand that access to health information created, received, or maintained by TGH or its affiliates is limited to those who have a valid business, medical, or professional need to know the information. I understand that TGH has implemented administrative, technical, and physical safeguards to protect the confidentiality and security of PHI, and I agree not to bypass or disable these safeguards.
- I understand that I will be given a unique User ID and password to access electronic health, operational, proprietary, employee or other confidential information. I understand that my User ID and password are confidential, that I am responsible for safekeeping my password, that I am also responsible for any activity initiated by my User ID and password, and that in certain circumstances my User ID and password may be equivalent to my legal signature. If I suspect that my User ID or password has been compromised, I should immediately contact TGH Information Technology (IT).
- I have no expectation of privacy when using TGH's information systems. TGH shall have the right to record, audit, log, and/or monitor access to or use of its information systems that is attributed to my User ID. I agree to practice good workstation security measures on any computing device that uses or accesses a TGH information system. Good security measures include, but are not limited to, maintaining physical security of electronic devices, never leaving a device unattended while in use, and adequately shielding the screen from unauthorized viewing by others.
- I understand that only encrypted and password protected devices may be used to transport PHI or other Restricted Data.
- I understand that smartphones and other mobile devices used to access TGH information systems must be configured to encrypt any Restricted or Sensitive Data, including photographs and videos, in persistent storage. I understand that I may access and/or use TGH confidential or Restricted Data only as necessary to perform my job-related duties and that I may disclose (i.e., share) confidential or Restricted Data only to authorized individuals with a need to know that information in connection with the performance of their job functions or professional duties.
 1. **Restricted Data:** Data in any format collected, developed, maintained, or managed by or on behalf of TGH, or within the scope of TGH's activities, that are subject to specific protections under federal or state law or regulations or under applicable contracts (e.g., medical records, Social Security numbers, credit card numbers, Florida driver licenses, and export-controlled data).
 2. **Sensitive Data:** Data whose loss or unauthorized disclosure would impair the functions of TGH, cause significant financial or reputational loss, or lead to likely legal liability (e.g., financial information, salary information, hospital policies, research work in progress, and copyrighted or trademarked material).
- I understand that upon termination of my employment / affiliation / association with TGH, I will immediately return or destroy, as appropriate, any confidential or Restricted Data in my possession. I understand that my confidentiality obligations under this Agreement will continue after the termination of this Agreement and after termination of my employment or affiliation with TGH.
- I agree to immediately report any known or suspected violation of the confidentiality or security of PHI of patients of TGH to either TGH IT or to the TGH Privacy Office.
- I understand that violations of this Agreement may result in revocation of my user privileges and/or disciplinary action, up to and including termination, and that TGH may seek any civil or criminal recourse and/or equitable relief.

By signing or by entering my name and other identifying information on this Agreement, I acknowledge that I have read this Agreement and agree to comply with all the terms and conditions stated above.

Print Name	Entity or Department	
Signature	Date	Badge # or ID #
E-mail		

*For purposes of this agreement, TGH includes the Florida Health Sciences Center, Inc.'s Board of Directors, Florida Health Sciences Center, Inc., Iminary Healthcare Staffing and The Surgery Center at TGH Brandon HealthPlex