

Monitor FAQS

Thank you for choosing Tampa General Hospital (TGH) for your research needs. Our preference is for remote monitoring because we use electronic records almost exclusively. Our patient records are stored in the Electronic Medical Record (EMR), Epic, and our regulatory documents, non-clinical and clinical patient source documents are stored in our electronic regulatory management system, Florence.

To assist in your visit, please review the following information:

Schedule. Sponsor representatives who are monitoring remotely will have access to the study and patient records 24/7 to make this a more productive experience. However, you should continue to set appointments with the appropriate study team member(s) to meet with you virtually, to review any concerns or items that need responses. Study staff will not be available on an "as needed" basis during the monitoring visits; setting an appointment helps everyone to plan their days more efficiently.

If an in person visit is required, monitors will be permitted on TGH premises from **8am – 5pm** on the days of scheduled monitoring visits.

Florence. Access can take up to two weeks. Please plan accordingly. Please use the following link to complete registration and training: https://academy.florencehc.com/path/eisf-training-for-monitors
Once you have completed the modules, a certificate will be emailed to you. Please forward that certificate to researchregulatory@tgh.org and include the following study information:

- o Principal Investigator
- Sponsor Name
- Study Name
- o Protocol number
- The regulatory team will request your signature on the Training Attestation form within FLO. This
 request will come via an email from Florence. Please be watching for this email as it may arrive in
 your spam folder.
- Once the training form is signed, you will have met the requirements and access to the study will be granted.

For any access issues contact <u>researchregulatory@tgh.org</u>

Epic Access. TGH IT will not provide an Epic Link account or access to records until a monitoring visit is scheduled. Must be requested 2 weeks prior to your visit. Epic access will be requested on your behalf by the coordinator. Once this has been completed you will receive an email with a link to EPIC Link so that you can finish the request. Please see the "Monitor Account Request Tip Sheet". Use this tip sheet once you have been sent the link by our IT dept.

For any access issues contact TGH IT at 813-844-7490

Location. TGH Office of Clinical Research is physically located at 409 Bayshore Blvd Tampa, FL 33606, in the Tampa General Medical Group building. However, please enter 204 W. DeLeon St. Tampa, FL 33606, in your GPS.

Parking. Free parking is available at 409 Bayshore Blvd, please be mindful of patients and do not park on the first floor of the parking ramp.

Wayfinding. Our designated monitoring space is located on the 5th floor of 409 Bayshore in a conference room. This floor is badge access only. Once you arrive to the lobby, please contact your



research coordinator and they will escort you up to the 5th floor.

If your coordinator is unavailable, you may contact the research line at 813-426-4118 and inform them that you are here for a scheduled monitor visit. Please be ready to provide study information and coordinator name.

Investigational Drug Pharmacy. TGH's Investigational Drug Pharmacy is located at 1 Tampa General Circle. There is pharmacy storage of oral investigational drug at 409 Bayshore if needed.

Please contact <u>researchpharmacy@tgh.org</u> prior to your upcoming visit to schedule designated time with our pharmacy team.

Tours & Privacy. In-person tours are discouraged. We have created this virtual tour of the Clinical Research Office: Clinical Research Tour for Monitors

If you would like to request an in-person tour of our patient or lab areas, please notify your research coordinator prior to the visit.

To request a pharmacy tour, please contact researchpharmacy@tgh.org.

Internet Access. Wireless internet (WiFi) is available free of charge from TGH. This service is termed 'TGHGuest'.

Appearance. Please ensure your attire is business appropriate while on site. The temperature of the monitoring space is often chilly, please dress accordingly.

Tardiness. If you are arriving more than 15 minutes after your scheduled time, please contact your research coordinator.



CLINICAL RESEARCH

Tobacco. TGH is a smoke-free campus, this includes vaping and smokeless tobacco. Smoking in the parking ramp is prohibited.

Dining. Vending machines are located on the 4th floor of 409 Bayshore. There is a full-service cafeteria, Starbucks and McDonalds located at the main hospital, 1 Tampa General Circle, and is within walking distance. If you choose to leave campus for lunch, please let the research coordinator know you are leaving and when you plan to return.

COI/Sunshine Act/Anti-Kickback. Precludes sponsors, clinical research organizations, or their designees to provide meals, gifts, or other stipends unless specifically stated in the clinical research contract and budget. Similarly, TGH is precluded from providing the sponsor, clinical research organization, or designee any meals, gifts, or other stipends.

Tampa General Hospital Office of Clinical Research:

Physical Address: 409 Bayshore Blvd. Tampa, FL 33606 **GPS Address:** 204 W. De Leon St. Tampa, FL 33606



Tampa General Hospital:

1 Tampa General Circle, Tampa, Florida 33606

