USF IRB and TGH (Tampa General Hospital) Collaborative FAQs

The USF IRB Supports our Research Community

The USF IRB provides resources and guidance to support our USF and affiliate research community with conducting ethical and scholarly human subjects research. This document is designed to support our USF and TGH researchers with answers to common frequently asked questions. The IRB and researchers work together as a team to develop and cultivate research for a better world.

I am a TGH Investigator. Does my study need to be submitted to TGH IRB?

TGH does not have an internal IRB. TGH accepts central IRBs and the USF IRB. If you are using another institution or organization for oversight of your protocol, TGH may require a one-time reliance agreement. The protocol can be submitted through TGH centralized address research@tgh.org for review and processing.

When do USF Investigators submit studies to the TGH OCR (Office of Clinical Research)?

When USF research is being conducted at a TGH location (e.g TGH CORE, Pharmacy), or when any assistance is required such as pharmacy and coordinator support. Early submission is best. Submit to TGH once the site is identified and you have a research study proposal. This is the time to notify TGH resources. Email: research@tgh.org

How do USF Investigators submit studies to the TGH OCR?

TGH website has information that outlines the requirements for submitting a trial to TGH Office of Clinical Research for review. Email all appropriate documents to research@tgh.org. Required documents include: TGH OCR Research Study Proposal Form, final protocol, informed consent forms, sponsor budget, contractual agreements, FDA communications (i.e. IND or IDE letter and any study manuals [Study manuals (for feasibility, if imaging is involved)] required to conducts the study (e.g. imaging manuals, laboratory, pharmacy, device manuals) For more information, please visit TGH website: https://www.tgh.org/about-tgh/clinical-research/study-submission.

Why would I, as an Investigator, need to add TGH on my BullsIRB application?

If your research is going to be using any TGH resources, data (i.e. medical record information), and/or facilities.

After BullsIRB approval when can TGH research activities begin?

The TGH OCR approval letter is needed to begin research activities at TGH. In addition to IRB approval, all study executed contracts, final budgets and IRB documents are required, in addition to IRB approval to receive TGH OCR approval. The TGH approval letter must be in place before your research can start. This is independent of IRB approval.

After IRB approval, how do I obtain TGH OCR approval to begin research activities?

Once all required documents are received for contracts, budgets and IRB approved docs are received, TGH OCR will provide a TGH OCR approved letter. To check on your study at any time, please reach out to reserch@tgh.org

When I am adding new staff to my USF/TGH study, how do I do this?

When adding staff to the study and/or protocol, the PI or PI proxy will need to submit a modification in BullsIRB and change the personnel. Contact the Reliance Department if you have questions about this: rsch-reliance@usf.edu

Tampa General Hospital | OCR
reserch@tgh.org | (813) 974-5638 |
https://www.tgh.org/about-tgh/clinical-research/study-submission

Department of Research Integrity & Compliance | IRB
RSCH-IRB@usf.edu | (813) 974-5638 |
www.usf.edu/research-innovation/research-integrity-compliance/

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