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| **SECTION 1.0: Instructions** | | | | | |
| **1. Initial submissions to be reviewed by Schulman Associates IRB must be accompanied by this Tampa General Hospital (TGH) signed cover page in order to be processed. TGH Office of Clinical Research (OCR) Staff will review the TGH-specific forms, sign this Institutional Cover Page, and return a scanned copy to the submitting party.** | | | | | |
| |  | | --- | | **2. Tampa General Hospital Submission Requirements: Provide the following information to the TGH OCR:** | | * Completed/Signed *Cover Page* | | * *Tampa General Hospital Study Application* listing all research personnel **>>>** Tampa General Hospital requires training for research personnel in the protection of human research subjects. Documentation of this training is required before any new study will be approved by the reviewing IRB and for all ongoing studies at the time of continuing review. | | * Tampa General Hospital *Informed Consent Form with Required Elements* | |  | | **3. Schulman Associates IRB Submission Instructions:** Upon receiving approval from Tampa General Hospital OCR to submit to Schulman IRB, submit this signed cover page and all required submission documents via Schulman [Secure eSubmission](https://portal.sairb.com/Submission/). Institutional submissions that require Full Board Review should be submitted by 3:00 pm EST one week prior to the desired meeting date. | | **NOTE:** Please visit [www.sairb.com](http://www.sairb.com/)/institutions for submission requirements for [New Study](http://www.sairb.com/institutions/Pages/submitstudy.aspx) Submissions, [Added Site](http://www.sairb.com/institutions/Pages/submitsite.aspx) Submissions, [Federally Funded/FWA](http://www.sairb.com/Investigators/SubmitSite/Pages/fwasite.aspx) and [Transfer of IRB Oversight](http://www.sairb.com/Investigators/SubmitSite/Pages/transferirbsite.aspx) studies. | | | | | | |
| **SECTION 2.0: Contact Information** | | | | | |
| **1. Institutional Information:** | | | | | |
| Institution Name: | Tampa General Hospital | Protocol #: | |  | |
| Principal Investigator: |  | Sponsor Name: | |  | |
| **2. Cover Page Completed by (Site Main Point of Contact for Follow-Up Questions):** | | | | | |
| Name: |  | Title: |  | | |
| Phone: |  | Email: |  | | |
| Research Group:  (if applicable) |  |  |  | | |
| **3. Tampa General Hospital Institutional Contact (AMC) \**For Schulman Associates IRB Internal Use Only*:** | | | | | |
| Names: | Beth Kohl and Jill Kestler | Contact Role(s): | CC (AMC w/ Site Access only) | | |
| Phone: | N/A | Email: | [bkohl@tgh.org](mailto:bkohl@tgh.org) and [jkestler@tgh.org](mailto:jkestler@tgh.org) | | |
| |  | | --- | | **SECTION 3.0: Tampa General Hospital Affiliation** | | **1. Will the research activities for this study take place within Tampa General Hospital facilities?**  Yes  No **>>>**Explain how this research, or what aspects of this research, involves Tampa General Hospital: | | **2. Will Tampa General Hospital personnel (employed physicians and staff) interact with human subjects or their identifiable data for the purposes of this research?**  Yes  No **>>>**Explain how this research, or what aspects of this research, involves Tampa General Hospital: | | **3. Will the intended subject population for this research include Tampa General Hospital patients?**  Yes  No**>>>**Explain how this research, or what aspects of this research, involves Tampa General Hospital: | | **4. Will any research activities take place at non-Tampa General Hospital facilities, require review and approval by an IRB other than Schulman Associates IRB, include non-Tampa General Hospital personnel interacting with human subjects or their identifiable data, or enroll subjects from other entities?**  Yes**>>>**Please complete **a.:**  No | | 1. **If yes, explain:**   This is a multi-center study with each site responsible for obtaining IRB approval for the research under their purview.  The other IRB(s) wish to defer IRB oversight to Schulman. Attached is(are) the [deferral letter(s)](http://www.sairb.com/IRBForms/Sample_Deferral_Letter.docx) for the non-Tampa General  Hospital facilities. (Please note: when involving USF IRB, please include the USF Approval to Proceed Letter from the USF  IRB).  The other IRB(s) wish to retain IRB oversight.  Other: | | | | | | |
| **SECTION 4.0: Informed Consent Template Language** | | | | | |
| **Tampa General Hospital currently has pre-negotiated informed consent language on file with Schulman Associates IRB.** | | | | | |
| **1. Will a waiver of Informed Consent be requested?**  Yes**>>>** Fill out the [Request for Waiver or Alteration of Informed Consent Form](http://www.sairb.com/IRBForms/Request_for_Alteration_or_Waiver_of_Informed_Consent_Form.docx)  No**>>>** Please complete **a. and b.:** | | | | | |
| 1. **If No, please indicate below how the Informed Consent will be submitted:** | | | | | |
| The Informed Consent with the Tampa General Hospital pre-negotiated language inserted is being submitted. | | | | | |
| Please incorporate Tampa General Hospital pre-negotiated language into the submitted Informed Consent. | | | | | |
| The Informed Consent with Tampa General Hospital pre-negotiated language as well as non-template changes not   previously negotiated is being submitted. *Additional site changes to the Informed Consent must be tracked in this submission.*  **Please note: Sponsor approval of Tampa General Hospital Informed Consent language and additional changes must be provided with the initial submission in instances where Schulman Associates IRB is the Central IRB of record for the study.** | | | | | |
| |  | | --- | | **SECTION 5.0: Tampa General Hospital Institutional Deferral** | | |  |  |  |  | | --- | --- | --- | --- | | **This is to confirm that Tampa General Hospital hereby authorized Schulman Associates Institutional Review Board to be the reviewing IRB on the above listed protocol. This institution wants to be copied on correspondence between Schulman Associates IRB and Tampa General Hospital employees as well as granted access to approval documents.** | | | | |  | Beth Kohl, MS, MPH  Manager, Clinical Research  or Authorized Designee: Anna Valencia, MPH, Director, Clinical Research |  | Signature Date (mm/dd/yyyy) | | | | | | | |
| **SECTION 6.0: Questions** | | | | | |
| **Please forward any Tampa General Hospital questions to Beth Kohl, at** [**bkohl@tgh.org**](mailto:bkohl@tgh.org)**. For any Schulman Associates IRB questions, contact Justin Osborne, at** [**JOsborne@sairb.com**](mailto:JOsborne@sairb.com) **or (513) 794-5760 or Maria Stivers, at** [**MStivers@sairb.com**](mailto:MStivers@sairb.com) **or (513) 794-5743.** | | | | |