



*Medical College of Wisconsin  
Institutional Review Board*

**To:** Marc De Moya, MD  
Abdul Hafiz Al Tannir, MD  
**CC:** Elise Biesboer  
Caroline Herdeman  
Krissa Packard

**Date:** 5/9/2023

**Re: Project Title:** Observation of traumatic HTX: A Western Trauma Association Multi-Institutional Trial  
**PRO ID:** [PRO00047518](#)

The MCW Institutional Review Board #5 has granted an exemption from IRB oversight for the above-referenced submission in accordance with 45 CFR 46.104(d) 4. Approval has been granted by the MCW Institutional Review Board #5 and is effective as of 05/08/2023.

The items listed below were submitted and reviewed when the IRB approved this submission. Research must be conducted according to the IRB approved documents listed below:

HTX MCT DCF  
PRO

Given that the current project does not involve direct contact with subjects, an informed consent process is not required.

The IRB granted approval of a waiver of HIPAA authorization requirements at 45 CFR 164 for this project.

Decedent data may be accessed in accordance with 45 CFR 164.512.

The Principal Investigator is responsible for notifying the IRB via Amendment prior to the initiation of any additions or modifications made to this project. On an annual basis, you will be asked to complete an exempt status update report, so that the IRB can maintain an accurate record of all current projects.

**Exempt Category #4 projects no longer require Froedtert Office of Clinical Research and Innovative Care Compliance (OCRICC) review and approval.**

In order to meet the requirement of accounting for all use and disclosures of Protected Health Information (PHI) for the purpose of research without patient authorization, research staff must complete an Accounting Log specific to that project's disclosure. This must be completed electronically via the web-based Accounting Log Form located [here](#). Upon completion, this log will be submitted directly to Froedtert Health Information Management (HIM) and will be considered valid for the length of the IRB Approval of the study. At time of government audit or other administrative request, researchers must be able to produce their less than 50 screening list within 48 business hours, if requested. Principal Investigators are ultimately accountable for the conduct of their research.

**Be advised:**

1. MCW Researchers are required to use the Medical College of Wisconsin (MCW) Clinical Translational Science Institute (CTSI) Clinical Research Data Warehouse (CRDW) resources and tools for obtaining formal Reports of PHI data, images, etc.
2. Requests for financial, cost or other data not yet available through the CRDW: MCW researchers will need to complete an F&MCW Reports, Data & Analysis Request <https://remedy-prod-smartit.s1.fchhome.com/ux/myitapp/#/catalog/home>. Researchers must attach a copy of the project IRB Registration Letter & the Data Collection Form (DCF) to your Report Request. This process does require a Froedtert network account.

To obtain Froedtert network access, work with your Department Administrative personnel.

3. Questions regarding access to FH data or OCRICC review and approval, please contact OCRICC office: [ocricc@froedtert.com](mailto:ocricc@froedtert.com)

Please notify the IRB when all project activities have been completed.

If you have any questions, please contact the IRB Coordinator II for this IRB Committee, Chris Koceja, at 414-955-2603 or [ckoceja@mcw.edu](mailto:ckoceja@mcw.edu).

Sincerely,

Nevin Uysal Biggs, MD  
IRB Chair  
MCW Institutional Review Board #5