TRACK-TBI Biospecimen Sharing Policy

Data sharing and mutual collaboration among research teams to accelerate research in TBI is a fundamental tenet of the TRACK-TBI project, and are core beliefs of its investigators. The TRACK-TBI database and biospecimen repositories can only serve their intended purposes as a current and legacy resource for further research with a robust, transparent, and open-access data and biospecimen sharing plan. Plasma and serum samples from the currently enrolling study (U01NS086090) are a finite resource and governed by this TRACK-TBI Biospecimen Sharing Policy, **which is part of, and incorporates by reference the terms of the TRACK-TBI Research Collaboration Policy and its Data Use/Human Materials Transfer Agreements and Publication and Authorship Guidelines, which agreements must be acknowledged and/or executed as part of any approved request to share TRACK-TBI biospecimens.**

All biospecimen requests must originate with submission of the TRACK-TBI Research Collaboration Request Form and preliminary analysis plan to the TRACK-TBI Administrative Core (Appendix 1). Requests are reviewed by the TRACK-TBI Executive Committee for review and decision.

Study Purpose

- The purpose of TRACK-TBI plasma and serum samples is to serve as a validation cohort. **Requests for samples to be used in a discovery cohort or for an exploratory study will not be entertained.**
- Requests for samples must be accompanied with preliminary data from humans with TBI, showing in small- to moderate-sized cohorts that the biomarker(s) being proposed show promise as a diagnostic or prognostic biomarker for TBI. Preliminary results from animal models or humans with other disorders (i.e., stroke, epilepsy) are not sufficient.
- Due to the complex nature of the clinical data collected and its relationship with the biofluid biomarkers, analysis should be carried out in collaboration with a TRACK-TBI Investigator. This Investigator must be identified on the Research Collaboration Request Form.

Specimen Allocation and Disposition

The minimum volume of sample required for the proposed studies will be provided. Only in exceptional circumstances will more than 0.15 mL be provided, and those will be have be well justified.

Plasma OR serum samples will be provided to collaborators de-identified and blinded.

Samples will be shipped by TRACK-TBI Biorepository staff at University of Pittsburgh Medical Center (UPMC) and will require execution of an MTA with University of Pittsburgh. (Appendix 2)

A shipping and handling fee will be applied to each shipment based on the nature of the request.

Samples are only to be used to run assays on the biomarkers proposed in the collaboration agreement.

Any volume of unused biospecimen must be returned to the TRACK-TBI Biorepository within 120 days. Returning samples to the TRACK-TBI Biorepository should follow the shipping instructions in the TRACK-TBI Biorepository SOP.

Results must be returned to TRACK-TBI and will be deposited together with TRACK-TBI data in the Federal Interagency TBI Repository (FITBIR). Access to this data will be according to FITBIR policies.

Process for Requesting Biospecimen Samples

1. Submit TRACK-TBI Research Collaboration Request Form: 2-page description of analysis plan and amount of plasma/serum requested.
2. Collaboration/biospecimen request considered by TRACK-TBI Executive Committee.
3. Following approval of collaboration/biospecimen request, a worksheet will be completed by the collaborator that will allow the TRACK-TBI Biorepository at University of Pittsburgh to calculate processing, handling, and shipping fees.
4. A Data Use Agreement/Human Materials Transfer Agreement (Appendix 2) then must be fully executed between the collaborator and TRACK-TBI by the UCSF PI (Appendix 1) and independently between collaborator and University of Pittsburgh. (Appendix 2)
5. Biospecimen samples are shipped by TRACK-TBI Biorepository at University of Pittsburgh to collaborator.