

MTBI² Division Capabilities Snapshot

Clinical Operations Division

Email: MTBI2-cod@usuhs.edu

The **Clinical Operations Division** provides a full range of clinical trial support services to investigators and study teams from project proposal to study close-out, including oversight and guidance of clinical trials sponsored by and collaborating with MTBI².

Clinical Operations Capabilities

- Clinical research/project management
- Protocol development (protocol and consent documents)
- Trial feasibility assessment; site identification and qualification
- Outreach, recruitment, and retention
- Quality and safety management and audit preparation
- Regulatory compliance and operations
- Risk-based monitoring (remote and on-site)

Clinical Data Analytics Capabilities

- Statistical analysis
- Statistical study design
- Sample size/power calculations
- Analysis planning
- Machine learning
- Modeling
- Simulation
- Computational statistics
- Methods section drafting

Clinical Data Management Capabilities

- Development of Data Management Plan (DMP)
- Database building in Electronic Data Capture (EDC) systems
- Case Report Form (CRF) design
- User Acceptance Testing (UAT)
- Data cleaning and validation
- Database lock

Biorepository Division

Email: MTBI2-biorepository@usuhs.edu

The **Biorepository Division** receives, processes, catalogs, stores, and ensures the integrity of biospecimens for MTBI² and collaborative studies. The Biorepository Division also provides samples to partners to support well-designed research protocols.

Biorepository Capabilities

- Blood collection and aliquot design consultation
- Specimen receipt, processing, inventory, and storage
- Maintenance of donated samples collected through both internal MTBI² studies and collaborative protocols
- Specimen retrieval for analysis
- Blood kit production
- Vial-level specimen inventory system

Bioanalysis Division

Email: MTBI2-bioanalysis@usuhs.edu

The **Bioanalysis Division** utilizes state-of-the-art, innovative technology to provide quantification of proteomics and transcriptomics biomarkers related to TBI and brain health research. The Bioanalysis Division also supports new methodology development for novel biomarker discovery.

Bioanalysis Capabilities

- Ultra-sensitive neurological and immunological protein detection and quantification: **Quanterix SIMOA HD-X Analyzer, Quanterix SP-X, Meso Scale Discovery**
- Statistical analysis for **SomaScan Proteomics** platform to support SomaScan data analyses (in collaboration with SomaLogic and the MTBI² Informatics Division)
- Transcriptome profiling: **NanoString nCounter Pro** (NanoString)
- Nanoparticle size, concentration, and colocalization analyses: **ZetaView QUATT** (Particle Matrix)
- Pathway, network, and hierarchical clustering analysis on omics data: **Ingenuity Pathway Analyses**
- Biomarker analyses on atypical sample types, such as extracellular vesicle and sweat
- Data reporting and visualization support