

**Data Sharing and Use Agreement**  
**Michigan Trauma Surgery Collaborative (MTSC)**  
**Attachment A**

Under the terms of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. Parts 160-164 (the “Privacy Rule”), two (or more) organizations sharing data involving full or limited protected health information are required to enter into a data sharing agreement that spells out the terms of their interactions. This intent of this document is to describe these relationships and responsibilities for the Michigan Trauma Surgery Collaborative (MTSC).

*1) Overview of the MTSC*

The MTSC is a regional, voluntary consortium of hospitals and surgeons that perform trauma care and surgery in Michigan. The goal of the Michigan Trauma Quality Improvement Program (MTQIP) as conducted by the MTSC is to improve the quality of care for patients who have sustained traumatic injury. To do this, the participating hospitals will submit their trauma registry data to the MTSC clinical outcomes registry. Three times per year the group meets to examine this data and to design and implement changes in care that result in better outcomes for trauma patients. The project is funded by Blue Cross and Blue Shield of Michigan (BCBSM) and coordinated by the MTQIP Coordinating Center at the University of Michigan.

The MTQIP involves the collection data utilizing the existing trauma registry process at each participating center:

a. Trauma Registry

Participating hospitals will submit data from a review of the medical records for all of their trauma patients. As part of the American College of Surgeons Committee on Trauma verification process trauma centers are required to maintain a trauma registry. Each patient in the trauma registry at a participating center is assigned a unique registry identification number by the participating site prior to submission of the data to the coordinating center so that the clinical registry contains no sensitive, identifiable personal information such as name or social security number. This portion of the project is therefore deemed a Limited Dataset under HIPAA which may be used or disclosed for research, public health, and other limited purposes, but only by those who sign a data use agreement.

*2) Organization*

The MTSC involves the coordinated efforts of a number of different parties, each with its own distinct set of responsibilities. The program is organized as follows:

a. The MTSC Executive Committee

The Executive Committee is comprised of representatives of each of the major parties involved and is responsible for:

- Oversight of the program

- Setting standards for operational policies
- Monitoring the performance of all entities involved in the program

#### b. The MTSC Publications Committee

The Publications Committee is comprised of representatives of each of the major parties involved and is responsible for setting policy regarding publications based on MTSC data including:

- Authorship
- Conflict of interest
- Setting processes for proposing and approving research questions within the collaborative

#### c. MTQIP Coordinating Center

The MTQIP Coordinating Center directs the MTSC and oversees the MTSC Data Coordinating Center (DCC) which manages the day to day operations of the MTSC including:

- Project Administration/Coordination
  - Maintenance of project-related regulatory files
  - Planning and running of MTSC meetings
  - Site coordinator training, education, coordination
- Management of data collection
  - Informatics development related to data extraction from the trauma registry
  - Data reliability audits, analysis, feedback
- Reporting/Research
  - Development, generation, updating of MTSC report content
  - Statistical modeling and analysis for reporting and research purposes
  - Distribution of MTSC reports
- Quality Improvement
  - Guide the development and broad implementation of MTSC quality improvement initiatives

#### d. Participating Trauma Surgery Programs

Initially 4 hospitals in the state of Michigan will participate in the MTSC. Each site agrees to:

- Collect and submit data to the MTSC clinical registry according to MTSC standards, definitions, and policies to ensure timely and high quality data capture
- Actively participate in the MTSC meetings and quality improvement initiatives

#### e. Blue Cross Blue Shield of Michigan (BCBSM)

BCBSM has provided funding for the project. The Program Director (Mark Hemmila) is responsible for submitting quarterly progress reports to BCBSM. Data submitted to BCBSM

in the form of progress reports will not identify any patient specific information and participating center anonymity will be preserved.

### *3) Policies Governing Data Sharing and Use*

#### a. MTSC DCC

For the purposes of the project outlined in above, the MTSC DCC will compile, clean, adjudicate, and analyze data submitted by the participating sites/patients to the MTSC clinical registry.

Confidential reports based on analysis of this data will be generated and distributed by the DCC to the participating sites timed to correspond with the MTSC meetings which are held three times each year (on the approximately the first Tuesday of February, June, and October). In the reports, hospitals (trauma centers) will be identified by a unique study identifier only. These reports will allow each surgeon and site to compare their trauma patients, clinical care, and outcomes to the range and average of the collaboration as a whole.

In the course of meeting these responsibilities, the DCC may have varying degrees of access to Protected Health Information (“PHI”), a Limited Data Set or De-identified Information. The DCC may use or disclose PHI on behalf of the participating site only in order to meet these responsibilities as set forth in Section 1 and 3 above and in accordance with Section 3b below. The DCC agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided by this agreement. The DCC will take the following measures to ensure the security of this information:

- Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI that it creates, receives, maintains, or transmits on behalf of the participating site as required by the Security Rule;
- Ensure that any agent, including a subcontractor to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect the PHI; and
- Report to the participating site, in writing, any security incident of which it becomes aware.

#### b. MTSC Participating Site

The DCC agrees to make available to the participating site confidential MTSC data (in electronic format) from the MTSC clinical registry and patient survey data bases that were collected on its own patients. The DCC will also distribute MTSC reports (paper format) that will allow the site to compare its data to the mean and range of the collaborative as a whole. As set forth in Section 3a above, this data will be distributed to the site at the time of the thrice annual MTSC meetings. The participating site owns this data and may analyze it independently, use it for internal purposes or for publication, and report in that context that the data were obtained via participation in the MTSC.

However, the participating site must agree to uphold the collaborative nature of the enterprise by refraining from using MTSC data to compare its experience to that of any of the other consortium members (using aggregate data or data from subsets of participant facilities) in any public manner including but not limited to presentation, publication, publicity, or advertising.

c. BCBSM

The DCC agrees to make available to BCBSM, as the funding agency, data from the MTSC clinical registry on which to judge participating sites' participation in the MTSC clinical registry and quality improvement initiatives. This information may include the timeliness, completeness, and quality of the participating sites data submissions, and their rates of attendance at MTSC meetings, as well as responsiveness to DCC data queries and to resolving patterns of problems with regard to data validity. The DCC will also provide BCBSM Foundation information regarding the average and range of performance within the collaborative as a whole so that it may assess the extent to which the overall effort is succeeding in improving trauma surgery care. The DCC will not however make available to BCBSM confidential information on the performance of individual sites, other than performance/participation in quality improvement initiatives as part of the annual CQI index measures and scoring report.