Participation Agreement

This Participation Agreement is effective the 1st day of June, 2019, by and between _____ located in _____, Michigan (hereinafter referred to as "PARTICIPANT") and the Regents of the University of Michigan, a Michigan constitutional corporation located in Ann Arbor, Michigan for the benefit of the Michigan Trauma Quality Improvement Program, (hereinafter referred to as "MTQIP"),

WHEREAS MTQIP is a quality collaborative initiative ("CQI") between The Regents of the University of Michigan and Blue Cross Blue Shield of Michigan/Blue Care Network ("BCBSM/BCN");

WHEREAS the State of Michigan Department of Health and Human Services (MDHSS) Statewide Trauma System has contracted with MTQIP for data aggregation and reporting purposes to the Statewide Trauma System;

WHEREAS PARTICIPANT desires to participate in the MTQIP collaborative;

NOW, THEREFORE, MTQIP and PARTICIPANT agree as follows:

I. SCOPE OF SERVICES

MTQIP and PARTICIPANT agree to the terms and conditions of participation as outlined in Exhibit A.

II. DATA CONFIDENTIALITY/ DATA MANAGEMENT

A. MTQIP will comply with all relevant state and federal privacy standard. The Parties have entered into a Business Associate Agreement dated _____ (attached as Exhibit B) in compliance with the Health Insurance Portability and Accountability Act ("HIPAA") including the HIPAA Privacy and Security Standards, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and its implementing regulations ("HITECH") including modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules under HITECH.

B. MTQIP and or its designated data aggregator will handle PARTICIPANT data in accordance with HIPAA Privacy and Security Standards. The parties agree each wish to use/or disclose as permitted by this Agreement for research, public health, or health care operations such as quality assurance or benchmarking purposes. The parties, and any Authorized Party on the party's behalf, may use the Data Set for the following purposes:

   a. Benchmarking clinical variables for purposes of quality improvement.
   b. Presenting and publishing results of quality improvement efforts.
   c. Presenting and publishing new findings that are clinically relevant to the treatment of patients.
   d. Creating de-identified extracts (reports or data sets) and using them or disclosing them for outcome evaluation.

C. The MTQIP Coordinating Center will share data and aggregated reports with the MDHSS Statewide Trauma System.

D. Limited Data Sets generated by the MTQIP Coordinating Center may be shared with PARTICIPANTS in accordance with Data Use Agreement (attached as Exhibit C).
E. Full or Limited Data Sets generated by MTQIP Coordinating Center may be shared with other Blue Cross Blue Shield of Michigan/Blue Care Network Collaborative Quality Initiatives (CQI's) for PARTICIPANTS in accordance with Amendments to the Participant Agreement (attached as Amendments).

III. TERM AND TERMINATION

A. This Participation Agreement shall commence on the Effective date and shall automatically renew each year.
B. Either party may terminate this Agreement upon thirty (30) days prior written notice or upon breach by the other party of any material provision of this Agreement, inclusive of its Exhibits; provided the breach continues for thirty (30) calendar days ("Cure Period") after the receipt by the breaching party of written notice of the breach from the non-breaching party. Cure of the breach within the Cure Period shall continue the Agreement inclusive of its Exhibits in full force and effect.

IV. MISCELLANEOUS

A. Independent Contractor. MTQIP shall at all times be acting as an independent contractor.
B. Assignment. PARTICIPANT may not subcontract, assign or transfer this Agreement or interest or claim under this Agreement without prior written approval from MTQIP.
C. No Third Party Rights. Nothing in this Agreement shall be construed as creating or giving rise to any rights in third parties or persons other than the named parties to this PARTICIPATION AGREEMENT.
D. Notices. Any notice or other communications by either party to the other shall be in writing and shall be given, and be effective when received but in no event later than three (3) days after mailing as addressed to the following:

To:

To: MTQIP
Mark R. Hemmila, MD
University of Michigan NCRC
Building 16, Room 139E
2800 Plymouth Road
Ann Arbor, MI 48109-2800
mhemmila@med.umich.edu

V. EXECUTION

In witness whereof, the parties have executed in duplicate this Participation Agreement, intending to be bound hereby as of the Effective Date.

Regents of the University of Michigan:	**PARTICIPANT:**
By: _____	By: _____
Name: Jeanne Strickland	Name: _____
Title: Chief Compliance Officer, Michigan Medicine	Title: _____
Date: _____	Date _____

Exhibit A

ELIGIBILITY AND EXPECTATIONS

Participating Hospital Eligibility Requirements

In order to be considered for participation in MTQIP a hospital must:

I. Operate an adult trauma program.

II. Possess American College of Surgeons (ACS) Level 1 or 2 adult trauma center verification.

III. Use one of the following trauma registry software: Digital Innovations, Inc. V5 or Clinical Data Management TraumaBase. Later MTQIP data submission portal compliant versions will also be accepted as they become available.

IV. Enroll in BCBSM's Participating Hospital Agreement (PHA).

Participating Hospital Expectations

To be deemed an "active PARTICIPANT" in the MTQIP collaborative and receive the associated BCBSM financial support. A PARTICIPANT must:

I. Develop and maintain an organizational commitment of active participation in the MTQIP collaborative with regard to facility administration and MTQIP collaborative staffing levels.

II. Commit to tri-annual complete and timely submission of all trauma registry data. "Timely" defined as within two weeks of request. "Complete" defined as all case-applicable fields populated for the requested time interval.

III. To ensure consistent data analysis across all MTQIP hospitals and MDHSS Statewide Trauma System reporting the PARTICIPANT will transmit all records entered into the PARTICIPANT's trauma registry. Hospitals will not apply any filters when transmitting the trauma registry data other than the requested timeframe. The MTQIP Coordinating Center will apply standardized criteria across all participants to identify eligible cases. Criteria include, but is not limited to, the criteria as outlined in the annual National Trauma Data Standard (NTDS) Data Dictionary issued by the American College of Surgeons Committee on Trauma, specific quality initiatives as defined by the collaborative, future quality initiatives as determined by the collaborative, and assessment of potential interventions to improve the MTQIP collective performance.

IV. Identify a clinical champion that will be a trauma surgeon. The clinical champion will lead the hospital in MTQIP quality improvement (QI) efforts. If the Trauma Medical Director is not the surgeon champion, then the Trauma Medical Director must be fully supportive of the program and the designated surgical champion with regard to collaborative QI efforts.

V. The clinical champion or an assigned trauma surgeon designee will attend three of three tri-annual collaborative meetings.

VI. Identify an administrative lead that will be the Trauma Program Manager (TPM)
    A. The administrative lead will be the administrative lead for MTQIP at the facility.

B. The administrative lead will be the direct supervisor of the trauma registry staff and MTQIP clinical reviewer. No alternate or dual reporting structure is allowed.
C. The administrative lead will also provide institutional support for full project participation.
D. The administrative lead will attend three of three tri-annual collaborative meetings (with the MTQIP Clinical Reviewer (MCR) allowed to serve as an alternate for one meeting).

VII. Assign a dedicated MCR to collect data and assist in trauma program QI:
A. The MCR position consists of 1.0 FTE person per 575 eligible MTQIP trauma cases.
B. The MCR must be a Registered Nurse (BSN preferred) or equivalent (Nurse Practitioner or Physician Assistant).
C. The MCR must physically reside within the trauma program on-site within the hospital.
D. The MCR must be hired by and report directly to the Trauma Program Manager and/or Trauma Medical Director. No alternative or dual reporting structure is allowed.
    a. The MCR should have access to an appropriate computer with high-speed internet connectivity.
    b. The MCR will attend at least two of three tri-annual collaborative meeting.

VIII. Focus on Quality Improvement:
A. Enroll and maintain active program participation in the American College of Surgeons Committee on Trauma's Trauma Quality Improvement Program (ACS TQIP).
B. Actively integrate MTQIP and ACS TQIP into the existing trauma center Performance Improvement Patient Safety (PIPS)/Quality Improvement (QI) program.

IX. Commit to using one of the following trauma registry software platforms: Digital Innovations, Inc. V5 or Clinical Data Management TraumaBase. Later MTQIP data submission portal compliant versions will also be accepted as they become available.

X. Commit to using MTQIP data elements and data definitions that are updated annually on http://www.mtqip.org/.

XI. Commit to using the Association for Advancement of Automotive Medicine (AAAM) 2005 (08 Update) version of the Abbreviated Injury Scale for injury coding in the trauma registry.
A. Transition to future versions of AIS coding (e.g., AIS 2015) will be coordinated and executed in a planned manner within the MTQIP CQI.

XII. Collaborate with the Coordinating Center:
A. Participate in MTQIP Coordinating Center-led site visits and external data validation audits of patient data entered into the MTQIP database.
    a. Commitment to developing and implementing a site-specific quality improvement agenda, linked to the MTQIP quality improvement agenda, and also driven by opportunities specific to the facility based on its own experience.
    b. Provide the Coordinating Center with the individual trauma center's ACS TQIP identification information and reports on request.

XIII. Commitment of members of the facility's MTQIP team in attending tri-annual meetings:
A. The team will include at a minimum the surgeon champion, trauma program manager/coordinator, and MTQIP Clinical Reviewer. While not all members may be able to attend every meeting, we require that at least two team members attend each meeting. While not all members may be able to attend every meeting, we require an equivalent alternate of the same discipline (i.e., a trauma attending surgeon may substitute for another

trauma attending surgeon).

B. The physician alternative must be one of the trauma surgeons from the attending call panel and be fully familiar with the MTQIP CQI.
C. The trauma program manager and the MTQIP Clinical Reviewer may serve as alternates for each other.

XIV. Collaborate with other participating sites.

A. Participation of each site in process improvement is essential to the success of the program, including the sharing of and learning from best practices.
B. Sites must be willing to share data at meetings.

XV. Collaborate with other BCBSM CQI's

A. MTQIP will share data and quality improvement efforts with other BCBSM CQI's under CQI Sharing Amendment agreements agreed to by the PARTICIPANT and MTQIP.
B. These current and future collaborations may involve additional voluntary capture of data by the PARTICIPANT in relation to the specialty of trauma and acute care surgery. Acute care surgery is defined as the specialty encompassing trauma surgery, emergent general surgery, and surgical critical care. Capture of acute care surgery data will involve information technology capability to submit emergent general surgery patient (EGS) information via a HIPAA-compliant designated data aggregator (e.g., ArborMetrix) and/or HIPAA-compliant software licensed to the University of Michigan.

XVI. Confidentiality and collegiality

A. The MTQIP Coordinating Center will provide each participating center anonymity within the program with the following exception:
    a. Trauma centers and their data will be unblinded at MTQIP meetings. All meeting participants will sign a confidentiality agreement prior to meeting entry.
B. BCBSM will only have access to de-identified data.
C. Promote a friendly and collegial atmosphere at all times.
D. Centers may not use MTQIP or ACS TQIP data for competitive advantage or marketing.

MTQIP Collaborative Coordinating Center Expectations

The MTQIP Coordinating Center is responsible for the following:

I. Administrative oversight

A. Provide administrative management of MTQIP.
B. Assist collaborating sites with any participation issues that arise.
C. Provide an annual data submission schedule.
D. Review and modify these data elements and definitions, based on program needs and to keep them synchronized with ACS TQIP and the National Trauma Data Standard-Data Dictionary wherever possible.
E. Organize and lead an MTQIP Advisory Committee that will be responsible for leadership, coordination of continuous quality improvement efforts, development and review of manuscripts, and distribution of the program's findings.
F. Monitor participant performance throughout the year to ensure that participants are meeting expectations. In instances where participants are not meeting the participation expectations established by the MTQIP Coordinating Center, the MTQIP Coordinating Center will alert

participants through verbal and/or written communications of their performance issues as soon as the issue is identified.

II. Facilitation of collaboration
    A. Apply uniform cohort criteria across all centers to protect benchmark report integrity.
    B. Conduct MTQIP-wide meetings to review quality improvement opportunities.
    C. Facilitate self-assessment and self-improvement of participating sites through a rapid cycle Continuous Quality Improvement process.

III. Services
    A. Provide training to data abstraction staff on the data elements, data definitions and methods of data abstraction.
    B. Organize and oversee the external validation site-visits.
    C. Analyze data and generate reports for feedback and discussion at MTQIP meetings.
    D. Develop and maintain collaborative protocols available on www.mtqip.org.
    E. Provide timely and informative feedback to each participating hospital.

Exhibit B

HIPAA BUSINESS ASSOCIATE AGREEMENT

THIS HIPAA BUSINESS ASSOCIATE AGREEMENT ("BAA") is entered into effective the 1st day of June, 2019 ("Effective Date"), by and between _____ ("Covered Entity"), and the Regents of the University of Michigan, a Michigan constitutional corporation for the benefit of the University of Michigan Coordinating Center for the Michigan Trauma Quality Improvement Program ("MTQIP") also referred to as ("Business Associate" "BA" or "UM").

Business Associate may perform functions or activities on behalf of Covered Entity involving the creation, receipt, maintenance, access, transmission, use and/or disclosure of protected health information ("PHI") received from or on behalf of Covered Entity. Therefore, Business Associate agrees to the following terms and conditions set forth in this BAA.

1.0 Definitions. For purposes of this BAA, any terms used herein, unless otherwise defined, shall have the same meanings as used in the HIPAA Privacy and Security Standards, as amended by the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) and its implementing regulations ("HITECH") including modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules under HITECH.

2.0 Scope and Interpretation. This BAA shall apply only if and to the extent UM is considered a BA to Covered Entity. Subject to this limitation, the terms and conditions of this BAA shall provide for Business Associate's creation, receipt, maintenance, transmission, use and/or disclosure of PHI, in any form or medium, including electronic PHI ("ePHI"), in Business Associate's capacity as "Business Associate" to Covered Entity. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with HIPAA.

3.0 Compliance with Applicable Law. Beginning with the relevant effective date, to the extent Business Associate meets the definition of a "business associate" of Covered Entity as such term is defined under HIPAA, Business Associate shall comply with its obligations under this BAA and with all obligations of a business associate under HIPAA, HITECH, as modified, and other related laws, for so long as Business Associate creates, receives, maintains, accesses, or transmits PHI.

4.0 OBLIGATIONS OF BUSINESS ASSOCIATE

4.1 Permissible Use and Disclosure of PHI. In addition to the uses and disclosures permitted by the Participation Agreement or this BAA, Business Associate may use and disclose PHI:

a. For its own proper management and administration,

b. To carry out its legal responsibilities,

c. To aggregate PHI in its possession to provide data aggregation services to Covered Entity as described in 42 C.F.R. § 164.504(e)(2)(i)(B),

d. To create De-Identified Data Sets and/or Limited Data Sets in compliance with the Privacy Rule; and to use or disclose information in such De-Identified Data Sets without further restriction; and to use or disclose information in such Limited Data Sets pursuant to a Data Use Agreement as permitted by the Privacy Rule; and

e. To report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

4.2 **Limitations on Use and Disclosure of PHI.** Business Associate shall not, and shall ensure that its directors, officers, employees, agents, and subcontractors do not, use or disclose PHI in any manner that is not permitted or required by the Participation Agreement(s) or this BAA, or as Required by Law. All uses and disclosures of, and requests by Business Associate for, PHI are subject to the Privacy Standards' Minimum Necessary Rule and shall be limited to the information contained in a Limited Data Set, to the extent practical, unless additional information is needed to accomplish the intended purpose, or as otherwise permitted in accordance with Section 13405(b) of HITECH, and any other subsequently adopted guidance. Additionally, Business Associate shall ensure that neither it nor its directors, officers, employees, agents, or subcontractors, access, store, share, maintain, use or disclose PHI beyond the borders of the United States of America without agreement of Covered Entity.

4.3 **Security.** To the extent that Business Associate creates, receives, maintains, or transmits ePHI on behalf of Covered Entity, Business Associate shall:

a. Comply with the security provisions found at 45 C.F.R. §§ 164.308, .310, .312, and .316 in the same manner as such provisions apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI;

b. Ensure that any agent to whom Business Associate provides ePHI agrees in writing to implement reasonable and appropriate safeguards to protect such ePHI; and

c. Report to Covered Entity promptly after its discovery any Security Incident of which Business Associate becomes aware and which results in a use or disclosure of ePHI in violation of the Participation Agreement(s) or this BAA. For those Security Incidents that do not result in a use or disclosure of ePHI in violation of the Participation Agreement(s) or this BAA, reports may be made in the aggregate on at least a quarterly basis. In this context, the term "Security Incident" shall have the same meaning as such term is defined at 45 C.F.R. § 164.304.

4.4 **Privacy.** To the extent that Business Associate is to carry out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of its obligation(s) under this BAA. Business Associate shall also otherwise implement appropriate safeguards in accordance with the Privacy Standards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this BAA.

4.5 **Mitigation of Harmful Effects.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA, including, but not limited to, compliance with any state law or contractual data breach requirements.

4.6 **Breach of Security or Privacy Obligations.**

a. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a use or disclosure of PHI not provided for in this BAA by Business Associate, its officers, directors, employees, agents, or subcontractors or by a third party to whom Business Associate disclosed PHI.

b. Business Associate shall report to Covered Entity, within ten (10) business days of discovery, a breach of unsecured PHI in accordance with the requirements set forth in 45 C.F.R. §§ 164.400-.414.

Business Associate shall fully cooperate with Covered Entity's breach notification and mitigation activities, and shall be responsible for all costs incurred by Covered Entity for those activities.

4.7 **Agreements by Third Parties.** Business Associate shall enter into an agreement with any agent or subcontractor of Business Associate that will have access to PHI hereunder. Pursuant to such agreement, the agent or subcontractor shall agree to be bound by the same restrictions, terms, and conditions that apply to Business Associate under this BAA with respect to such PHI. Business Associate agrees to provide Covered Entity a list of all its agents or subcontractors upon request.

4.8 **Access to Information.** Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the access provisions of 45 C.F.R. § 164.524.

4.9 **Availability of PHI for Amendment.** Covered Entity acknowledges and agrees that Business Associate does not, within the scope of its services, collect, retain or maintain Designated Record Set information. Accordingly, Business Associate has no obligation to comply with the amendment provisions of 45 C.F.R. § 164.526.

4.10 **Documentation of Disclosures.** Business Associate agrees to document uses and disclosures of PHI and information related to such uses and disclosures as required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528.

4.11 **Accounting of Disclosures.** Within ten (10) business days of notice by Covered Entity to Business Associate that Covered Entity has received a request for an accounting of disclosures of PHI regarding an individual during the six (6) year period prior to the date on which the accounting was requested, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of disclosures of PHI, as required by 45 C.F.R. § 164.528. In the case of an electronic health record maintained or hosted by Business Associate on behalf of Covered Entity, the accounting period shall be three (3) years and the accounting shall include disclosures for treatment, payment, and health care operations, in accordance with the applicable effective date of Section 13402(a) of HITECH. In the event the request for an accounting is delivered directly to Business Associate, Business Associate shall forward such request to Covered Entity within five (5) business days of receipt.

4.12 **Restrictions.** Business Associate shall comply with any restrictions on disclosure of PHI requested by an individual and agreed to by Covered Entity in accordance with 45 C.F.R. §164.522.

4.13 **Judicial and Administrative Proceedings.** In the event Business Associate receives a subpoena, court or administrative order or other discovery request or mandate for release of PHI, Business Associate shall notify Covered Entity in writing prior to responding to such request to enable Covered Entity to object. Business Associate shall notify Covered Entity of the request as soon as reasonably practicable, but in any event within two (2) business days of receipt of such request.

4.14 **Availability of Books and Records.** Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of the Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy Standards.

4.15 **Breach of Contract by Business Associate.** In addition to any other rights Covered Entity may have in the Participation Agreement(s), this BAA, or by operation of law or in equity, Covered Entity may, upon a breach or violation of this BAA, provide a reasonable opportunity for Business Associate to cure

or end any such violation within the time specified by Covered Entity. If cure is not possible or if Business Associate does not cure such breach or violation, Covered Entity may immediately terminate the Participation Agreement(s). Covered Entity's option to have a breach cured shall not be construed as a waiver of any other rights Covered Entity has in the Participation Agreement, this BAA, or by operation of law or in equity.

4.16 Effect of Termination of Agreement(s). Upon the termination of the Participation Agreement or this BAA for any reason, Business Associate shall return all PHI created by Business Associate or received from Covered Entity to Covered Entity or, at Covered Entity's direction, destroy all PHI received from Covered Entity that Business Associate maintains in any form, recorded on any medium, or stored in any storage system. This provision shall apply to PHI that is in the possession of Business Associate, its agents and subcontractors. If it is not feasible for the Business Associate to return or destroy PHI, Business Associate further agrees to extend any and all protections, limitations, and restrictions contained herein to Business Associate's use and disclosure of any PHI retained after termination of this BAA, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of PHI infeasible. Business Associate shall retain no copies of the PHI. Business Associate shall remain bound by the provisions of this BAA, even after termination of the Participation Agreement or this BAA, until all PHI has been returned or otherwise destroyed as provided in this Section.

4.17 Indemnification. Business Associate shall indemnify and hold harmless Covered Entity and its officers, trustees, employees, agents, and subcontractors from any and all claims, penalties, fines, costs, liabilities, or damages, including but not limited to reasonable attorney fees, incurred by Covered Entity arising from a violation by Business Associate of its obligations under this BAA.

5.0 OBLIGATIONS OF COVERED ENTITY

5.1 Notice of Privacy Practices. Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices in accordance with 45 C.F.R. § 164.520, to the extent such limitations affect Business Associate's use or disclosure of PHI.

5.2 Revocation of Authorization of Individual. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, if and to the extent such changes affect Business Associate's use and disclosure of PHI.

5.3 Restrictions on Use and Disclosure. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent such restriction may affect Business Associate's use or disclosure of PHI.

6.0 MISCELLANEOUS

6.1 Third Party Rights. The terms of this BAA do not grant any rights to any third parties.

6.2 Independent Contractor Status. For the purposes of this BAA, Business Associate is an independent contractor of Covered Entity, and shall not be considered an agent of Covered Entity.

6.3 Changes in the Law. The parties shall amend this BAA to conform to any new or revised legislation, rules, or regulations to which Covered Entity is subject now or in the future including, without limitation, HIPAA, HITECH, the Privacy Standards, Security Standards or Transactions Standards.

6.4 Owner of PHI. Under no circumstances shall Business Associate be deemed in any respect to be the owner of any PHI of Covered Entity.

This BAA becomes binding when signed by authorized representatives of both parties.

Regents of the University of Michigan:	**Covered Entity:**
By: _____	By: _____
Name: Jeanne Strickland	Name: _____
Title: Chief Compliance Officer, Michigan Medicine	Title: _____
Date: _____	Date: _____

Exhibit C

Limited Data Use Agreement

This data use agreement (the "Agreement") is by and between The Regents of the University of Michigan on behalf of its_____, ("UM") a Michigan constitutional corporation with its principal place of business in Ann Arbor, Michigan, and _____ ("Entity") and is effective as of _____ (the "Effective Date").

WHEREAS, UM and Entity are both engaged in research, public health, or other purposes permitted under 45 C.F.R. § 164.514(e):

WHEREAS, Entity agrees to use and/or disclose certain information for research, public health, or other purposes as permitted under 45 CFR § 164.514 (e);

AND WHEREAS, the parties agree that UM shall maintain, use or disclose such information shared by Entity for purposes enumerated above;

NOW, THEREFORE, the parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. UM shall provide Entity with access to certain data (the "Limited Data Set") in accordance with the terms and conditions of this Agreement. Under no circumstances shall UM be required under this Agreement to provide the Entity with any information that does not qualify as part of a "limited data set" under 45 C.F.R. § 164.514(e).
2. The Principal Investigator and those under the Principal Investigator's direction (the "Authorized Parties") are authorized to use the Limited Data Set or any part of it on behalf of UM and agree to abide by the terms of this Agreement:

   Name:_____ Signature: _____

   Name:_____ Signature: _____

   The parties, and any Authorized Party on the parties' behalf, may use the Limited Data Set only for the following purposes:

   _____

   _____

   _____

   _____

   Use an attachment to list any additional permitted uses.

3. Entity agrees as follows:
   - ✓ Not to use or further disclose the Limited Data Set or any information contained therein other than as permitted by this Agreement or required by applicable law.
   - ✓ To comply with the security provisions found at 45 C.F.R. §§164.308, 310, 312, and 316 in the same manner as such provisions apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI.
   - ✓ To report to UM any use or disclosure of the Limited Data Set or any part of it not provided for by this Agreement of which the Entity or any Authorized Party becomes aware.
   - ✓ To ensure that any agents, including subcontractors, to whom Entity provides the Limited Data Set or any part of it to agree to the same restrictions and conditions that apply to the Entity under this Agreement.

- ✓ Not to use the information contained in the Limited Data Set to identify the individuals whose information is contained in the Limited Data Set, nor to contact them under any circumstances.

4. The Term of this Agreement shall commence as of the Effective Date and will terminate when the use of the Limited Data Set is no longer needed or upon termination of the Participation Agreement.

5. In the event either party becomes aware of any use of the Limited Data Set or any part of it that is not authorized under this Agreement or required by applicable law, such party may (i) terminate this Agreement upon notice; (ii) disqualify (in whole or in part) the UM and/or any Authorized Parties from receiving protected health information in the future; and/or (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Services. Further sanctions may apply under 45 C.F.R. parts 160 and 164.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

Regents of the University of Michigan:	**Entity:**
By:_____	By: _____
Name: Jeanne Strickland	Name:_____
Title: Chief Compliance Officer, Michigan Medicine	Title: _____
Date: _____	Date: _____

AMENDMENT NO. 1 TO
PARTICIPANT AGREEMENT

This Amendment No. 1 to Participant Agreement (PA) effective the 1st day of June, 2019 by and between the Regents of the University of Michigan, a Michigan constitutional corporation on behalf of its affiliates and _____("Participant") shall be effective the 1st day of June, 2019.

Participant is engaged in MTQIP:

These parties have agreed to amend the Agreement for the purpose of allowing Participant Data in MTQIP to be shared with the Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) a Blue Cross Blue Shield of Michigan (BCBSM) Collaborative Quality Initiatives (CQI's).

1.0 **Overview**. The CQI's are partnerships between BCBSM, participating hospitals, physicians and the coordinating center that leads the program. Hospitals and physicians share data to develop best practices around areas of care with high costs and high variation. Individual CQI's seek opportunities to collaborate with each other and share data, analyses, and reports in ways that enhance the ability of participating hospitals and physicians to improve the care that they provide to patients. BCBSM supports and encourages collaboration between participant CQI's concerning the sharing of data and program information with each other to generate new knowledge and enhance quality improvement efforts.

a. Enhanced feedback reporting. Data exchange creates data synergy for participants and CQI's. Data aggregation allows for identification and feedback of previously undetected signals, trends, and correlations. Enhanced feedback reporting offers a greater understanding of care delivery and promotes the identification of best practices.

b. Greater returns on investment. Expanded dataset capture is associated with additional administrative and staffing expenses for both the participant and the CQI. Data sharing across CQI's allows for symbiotic growth without incurring additional costs. This model also holds the potential to minimize the waste associated with duplicate variable capture across CQI's for variables with high capture reliability.

c. Improved data quality. There is duplication in variable abstraction across the CQI's. The value of this duplication to be used in a blockchain fashion to perform edit checks and identify conflicting data for variables with low capture reliability.

2.0 **Scope**. The scope for use of the MTQIP data includes benchmarking clinical variables for purposes of quality improvement, presenting and publishing results of quality improvement efforts, presenting and publishing new findings that are clinically relevant to either or both CQI's mission, creating de-identified extracts (reports or datasets) and using them or disclosing them for outcome evaluation as noted in the Agreement.

3.0 **Use case**. MTQIP shall share MTQIP aggregated data set data with the Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) for the purpose of perioperative care quality improvement. ASPIRE may use MTQIP data for identification of patient outcomes. In exchange for sharing MTQIP data for the purpose(s) articulated ASPIRE will in turn share ASPIRE data with MTQIP to assist MTQIP to understand the relationship between anesthesia variables and outcome(s) to improve care and will be used in accordance with all uses enumerated in the Agreement.

This Amendment, coupled with the underlying terms and conditions of the Agreement, contains and merges all of the terms and conditions between the parties with respect to the subject matter hereof without modifications.

Participant:

By: _____

Print name: _____

Title: _____

Date of Signature: _____

Address for Notice:

_____

_____

Regents of the University of Michigan:

By: _____

Print name: Jeanne Strickland

Title: Chief Compliance Officer

Date of Signature: _____

Address for Notice:
University of Michigan NCRC

MTQIP

Building 16, room 139E

2800 Plymouth Road

Ann Arbor, MI 48109-2800

AMENDMENT NO. 2 TO
PARTICIPANT AGREEMENT

This Amendment No. 2 to Participant Agreement (PA) effective the 1st day of May, 2019 by and between the Regents of the University of Michigan, a Michigan constitutional corporation on behalf of its affiliates and _____("Participant") shall be effective the 1st day of June, 2019.

Participant is engaged in MTQIP:

These parties have agreed to amend the Agreement for the purpose of allowing Participant Data in MTQIP to be shared with Michigan Surgical Quality Collaborative (MSQC) a Blue Cross Blue Shield of Michigan (BCBSM) Collaborative Quality Initiatives (CQI's).

1.0 **Overview**. The CQI's are partnerships between BCBSM, participating hospitals, physicians and the coordinating center that leads the program. Hospitals and physicians share data to develop best practices around areas of care with high costs and high variation. Individual CQI's seek opportunities to collaborate with each other and share data, analyses, and reports in ways that enhance the ability of participating hospitals and physicians to improve the care that they provide to patients. BCBSM supports and encourages collaboration between participant CQI's concerning the sharing of data and program information with each other to generate new knowledge and enhance quality improvement efforts.

a. Enhanced feedback reporting. Data exchange creates data synergy for participants and CQI's. Data aggregation allows for identification and feedback of previously undetected signals, trends, and correlations. Enhanced feedback reporting offers a greater understanding of care delivery and promotes the identification of best practices.

b. Greater returns on investment. Expanded dataset capture is associated with additional administrative and staffing expenses for both the participant and the CQI. Data sharing across CQI's allows for symbiotic growth without incurring additional costs. This model also holds the potential to minimize the waste associated with duplicate variable capture across CQI's for variables with high capture reliability.

c. Improved data quality. There is duplication in variable abstraction across the CQI's. The value of this duplication to be used in a blockchain fashion to perform edit checks and identify conflicting data for variables with low capture reliability.

2.0 **Scope**. The scope for use of the MTQIP data includes benchmarking clinical variables for purposes of quality improvement, presenting and publishing results of quality improvement efforts, presenting and publishing new findings that are clinically relevant to either or both CQI's mission, creating de-identified extracts (reports or datasets) and using them or disclosing them for outcome evaluation as noted in the Agreement.

3.0 **Use case**. MTQIP shall share MTQIP aggregated data set data with MSQC for quality improvement. MSQC shall share MSQC aggregated data set data with MTQIP for quality improvement. The MSQC data set contains a comprehensive cadre of perioperative variables for patients who undergo an operative intervention. The MTQIP data set contains perioperative variables for patients who may or may not undergo an operative intervention. MSQC-MTQIP data aggregation allows for identification of potential care pathways for patients at high risk of mortality and/or complications in both operative and non-operative instances. This information can be used to aid clinicians in providing the safest care at the safest time.

This Amendment, coupled with the underlying terms and conditions of the Agreement, contains and merges all of the terms and conditions between the parties with respect to the subject matter hereof without modifications.

Participant:

By: _____

Print name: _____

Title: _____

Date of Signature: _____

Address for Notice:

_____

_____

Regents of the University of Michigan:

By: _____

Print name: Jeanne Strickland

Title: Chief Compliance Officer

Date of Signature: _____

Address for Notice:
University of Michigan NCRC

MTQIP

Building 16, room 139E

2800 Plymouth Road

Ann Arbor, MI 48109-2800

AMENDMENT NO. 3 TO
PARTICIPATION AGREEMENT

This Amendment No. 3 to Participation Agreement ("Amendment") by and between The Regents of the University of Michigan for the benefit of the Michigan Trauma Quality Improvement Program (hereinafter referred to as "MTQIP") and _____ ("Participant") shall be effective August 1, 2021.

The parties hereto have entered into a Participation Agreement effective _____ ("Agreement") and agree to amend the Agreement as more fully described below:

1. The following will be added as Section F under Article II:

> F. PARTICIPANT's affiliates who elect to participate in the patient-reported outcomes survey (see Exhibit A to this Amendment No. 3) will provide MTQIP with the name and contact information for PARTICIPANTS patient population for which patient-reported outcomes are to be captured. MTQIP will engage with such patients to complete the patient-reported outcomes survey. MTQIP will link the resulting patient reported outcomes to the Data Set for said patient. MTQIP is not responsible for providing PARTICIPANT with the results of the patient survey other than as set forth in the Agreement. MTQIP has no obligation to follow up with PARTICIPANT's patients as to said patient's responses to the patient-reported outcomes survey. PARTICIPANT will indemnify, defend, and hold MTQIP its board members, officers, employees, agents, and students from and against any costs, losses, damages, liabilities, expenses, demands, and judgments, including reasonable court costs and attorney fees, related to follow up on patient's responses to the patient reported outcomes survey entered and linked to the appropriate Data Set by MTQIP, except to the extent that such costs, losses, damages, liabilities, expenses, demands, and judgments, including reasonable court costs and attorney fees are due to the negligence or willful misconduct of MTQIP in performing its obligations under the Agreement and its Amendments.

This Amendment, coupled with the underlying terms and conditions of the Agreement, contains and merges all the terms and conditions between the parties with respect to the subject matter hereof. Nomodifications or amendments to the Agreement or this Amendment shall be of any force or effect unless reduced to writing and signed by the parties. Except as expressly set forth above in the Amendment, the Agreement shall remain unchanged and shall continue in full force and effect.

Participant:	Regents of the University of Michigan:
By:_____	By:_____
Printed Name: _____	Printed Name: Jeanne Strickland
Title: _____	Title: Chief Compliance Officer
Date of Signature:_____	Date of Signature:_____