**Multicenter perioperative outcomes group**

**DATA USE AGREEMENT**

 This Data Use Agreement (“Agreement”) is by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Participant”) and the Regents of the University of Michigan, a nonprofit educational institution of the State of Michigan (“Michigan”). Throughout this Agreement, Participant and Michigan are individually referred to as “party” and collectively as “parties.” This Agreement will become effective upon execution by both parties to this Agreement as of the date of the first signature affixed below (the “Effective Date”).

 **A. Definitions**

 1. *ASPIRE:* The Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) which is a sub-group of MPOG focused on using MPOG data to assess variationin practice, identify best practices, and measure process adherence and patient outcomes, and create programs for quality improvement.

*2. ASPIRE Project:* The quality improvement initiative submitted by Participant over time and approved by the ASPIRE Quality Improvement Committee and for which Michigan is providing MPOG Data to Participant under this Agreement.

*3. Covered Entity:* Per 45 CFR 160.103 (“Definitions”), is a health plan, health care clearinghouse, or health care provider that is subject to the standards, requirements, and implementation specifications of the HIPAA Privacy Rule.

 4. *Individual:* Per 45 CFR 160.103 (“Definitions”), is the person who is the subject of protected health information and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

 5. *Limited Data Set:* Per 45 CFR 164.514(e)(2) (“Implementation Specification: Limited Data Set”), is protected health information that excludes the 16 direct identifiers specified in that section. A Limited Data Set may contain postal address information, in the form of a town or city, State, or zip code only; age; specific dates, including birth date, admission date, discharge date, and date of death; and any other information, not amongst the listed 16 direct identifiers, that could be used, alone or in combination with other reasonably available information to identify an individual who is a subject of the information.

 6. *MPOG:* The Multicenter Perioperative Outcomes Group (MPOG), which has been established to pool data submitted by anesthesiology departments of institutions with perioperative information systems into a common research and quality improvement database with the hope of accelerating outcomes research by investigating perioperative events to advance knowledge and improve patient care.

7. *MPOG Data:* The Limited Data Set provided by the Michigan data coordinating center to Participant for use a MPOG Project or ASPIRE Project.

 8. *MPOG Participant:* An organization participating in MPOG that has signed a Multicenter Perioperative Outcomes Group Data Use Agreement.

 9. MPOG *Project:* The research study or studies submitted by Participant over time and approved by the Perioperative Clinical Research Committee (“PCRC”) and for which Michigan is providing MPOG Data to Participant under this Agreement.

10*. Participant Data:* The Limited Data Set provided by Participant to Michigan for inclusion in the MPOG centralized research dataset.

 11. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

12. *Protected Health Information or PHI:* Per 45 CFR 160.103 (“Definitions”), means information, maintained or transmitted in any form or medium, that: (i) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and (ii) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

 13. *Required by Law:* Per 45 CFR 164.103 (“Definitions”) means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.

 14. *Secretary* shall mean the Secretary of the Department of Health and Human Services or his designee.

 **B. SCOPE OF AGREEMENT**

This Agreement sets forth the terms and conditions pursuant to which Participant may transfer Participant Data to Michigan for inclusion in the MPOG centralized research and quality improvement repository; Michigan’s obligations and rights to receive, process, use, and distribute Participant Data, as part of MPOG Data, to MPOG Participants for use in Projects; and the Participant’s rights and obligations to receive and use any MPOG Data in Projects.

 **C. COLLECTION OF MATERIALS**

Participant represents and certifies that:

 1. Any Participant Data provided to Michigan by Participant were collected pursuant to and in accordance with any applicable Institutional Review Board (“IRB”) approval and in compliance with all applicable laws, regulations and policies for the protection of human subjects, including, in the case where Participant is a covered entity, 45 CFR Part 46, “Protection of Human Subjects” (the “Common Rule”), and the HIPAA Privacy Rule.

 2. Any relevant informed consents and authorizations permit use, processing, and redistribution of the Participant Data in the manner described in this Agreement.

 3. In addition, Blue Cross Blue Shield of Michigan MPOG Participants agree to have data shared with the Michigan Surgical Quality Collaborative Patient Safety Organization for purposes of quality improvement and research and approved by the ASPIRE Quality Improvement Committee or MPOG PCRC, respectively.

 **D. PARTICIPANT OBLIGATIONS**

Participant agrees:

 1. To provide Participant Data, as applicable, to Michigan, in accordance with frequency, data, and upload specification to be provided by the coordinating center, for the sole and limited purpose of enabling Michigan to receive, process, use, and distribute the Participant Data to MPOG Participants for use in MPOG or ASPIRE Projects. Participant is responsible for ensuring the removal of all prohibited direct identifiers from the Participant Data, such that the Participant Data will be in the form of a Limited Data Set, before transfer to Michigan.

 2. That Participant has the authority and hereby grants Michigan, as the coordinating center, explicit permission to:

 a. Process and use Participant Data for MPOG activities; and

 b. Distribute the Participant Data, as part of MPOG Data, to MPOG Participants upon submission by such MPOG Participants of a MPOG Project or ASPIRE Project.

 3. To not use or disclose MPOG Data other than as permitted or required by the Agreement or as Required by Law, and shall not use or disclose the MPOG Data in a manner inconsistent with the Privacy Rule.

 4. To not use MPOG Data in any research or quality improvement initiative that is not approved as part of the Project, and for a period not to exceed the period of time identified in the Project. Modification of an approved Project requires submission of a Project amendment to, and approval by, the Perioperative Clinical Research Committee (PCRC).

 5. To establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the MPOG Data and to prevent loss, unauthorized access or use, modification or disclosure, and any misuse of the MPOG Data.

 6. To ensure that any agents, including subcontractors, or other third parties to whom it provides MPOG Data which is received from, or created or received by Participant agrees in writing to be bound by the same restrictions and conditions that apply through this Agreement to Participant with respect to such MPOG Data.

 7. To report to Michigan any use or disclosure of MPOG Data not provided for by this Agreement of which the Participant, its officers, employees, or agents become aware, including without limitation, any disclosure of MPOG Data to an unauthorized subcontractor, within five (5) working days of its discovery, and agrees to mitigate to the extent practicable any harmful effect that is known to Participant of any such use or disclosure.

 8. To not identify, attempt to identify, or contact any Individual, or living relative of an Individual, from which the MPOG Data was derived, including through the use of other outside databases or the performance of mathematical or statistical techniques to identify Individuals.

 9. To submit a proposed manuscript to the PCRC prior to submission to academic journals for approval. PCRC submission is to ensure that the previously approved PCRC research hypothesis is addressed and answered and the MPOG Data was used as initially approved. Participant will submit the proposed manuscript within nine (9) months of the Participant receiving the MPOG Data.

 10. To acknowledge that other researchers may have access to MPOG data sets and that overlap of research is a distinct possibility.

11. To review the most current version of the MPOG Bylaws and evidence Participant’s understanding by signing the MPOG Bylaws.

 **E. MICHIGAN Obligations**

Michigan agrees to:

 1. Use or disclose Participant Data only as permitted or required by this Agreement, or for the proper management and administration of Michigan, or as Required by Law, and shall not use or disclose the Participant Data in a manner inconsistent with the Privacy Rule.

2. Use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of the Participant Data other than as provided for by this Agreement.

3. To report to the Participant any use or disclosure of Participant Data not provided for by this Agreement of which Michigan, its officers, employees, or agents become aware, including without limitation, any disclosure of PHI to an unauthorized subcontractor, within five (5) working days of its discovery.

4. Ensure that any third party to whom it provides the Participant Data agrees to the same restrictions and conditions that apply through this Agreement to Michigan with respect to protection of the Participant Data.

 5. To not identify, attempt to identify, or contact any Individual, or living relative of an Individual, from which the Participant Data was derived, including through the use of other outside databases or the performance of mathematical or statistical techniques to identify Individuals.

 6. Transmit MPOG Data to MPOG Participants, including Participant, for use in Projects.

 **F. SHARING AMONG BLUE CROSS BLUE SHIELD OF MICHIGAN (“BCBSM”) COLLABORATIVE QUALITY INITIATIVE (“CQI”)**

1. MPOG and ASPIRE will share Participant Data with the following CQIs:
	1. Michigan Trauma Quality Improvement Project (“MTQIP”)
	2. Michigan Urological Surgical Improvement Collaborative (“MUSIC”)
	3. Michigan Arthroplasty Registry Collaborative for Quality Improvement (“MARCQI”)
	4. Michigan Cardiovascular Consortium (“BMC2”)
	5. Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (“MSTCVS”)
	6. Michigan Bariatric Surgery Consortium (“MBSC”)
	7. Michigan Spine Surgery Improvement Collaborative (“MSSIC”)
	8. Obstetrics Initiative (“OBI”)

The CQIs are partnerships between BCBSM, participating hospitals and 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 CQIs 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 CQIs concerning the sharing of data and program information with each other to generate new knowledge and enhance quality improvement efforts. Reasons for collaboration between the various CQIs include:

1. Data exchange creates data synergy for participants and CQIs. 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.
2. Expanded dataset capture is associated with additional administrative and staffing expenses for both the participant and the CQI. Data sharing across CQIs allows for symbiotic growth without incurring additional costs. This model also holds the potential to minimize the waste associated with duplicate variable capture across CQIs for variables with high capture reliability.

There is duplication in variable abstraction across the CQIs. 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.

1. ASPIRE shall share Limited Data Set from its registry with MTQIP, MUSIC, MARCQI, BMC2, MSTCVS, MBSC, MSSIC, and OBI to help these various CQIs understand perioperative process of care and outcomes that are related to their respective quality initiatives, but not currently captured by these various CQIs.
	1. ASPIRE may share intraoperative glucose data to help MTQIP, MUSIC, MARCQI, BMC2, MSTCVS, MBSC, and MSSIC build glucose related quality measures.
	2. ASPIRE may share neuraxial anesthesia data to help OBI assess how variation in techniques may affect obstetric outcomes.

The purpose of data sharing is to create efficiencies for participating sites in data collection, and spark collaboration amongst ASPIRE and the other CQIs at both the coordinating center and participating site level. ASPIRE would provide feedback to participating sites with this data.

 **G. TERM AND TERMINATION**

 1. *Term*: The Term of this Agreement shall commence as of the Effective Date.

 2. *Termination for Cause*: Upon a Party’s knowledge of a breach of this Agreement by the other Party, the non-breaching Party shall either:

1. Provide an opportunity for the breaching Party to cure the breach or end the violation, and terminate this Agreement if the breaching Party does not cure the breach or end the violation within the time specified by the non-breaching Party; or
2. If cure and termination are not feasible, the non-breaching Party will discontinue disclosure of Materials to the breaching Party and report the breach or violation to the Secretary.

 3. *Termination without Cause*. Either Party may terminate this Agreement in whole or in part for its sole convenience upon thirty (30) days prior notice.

 4. *Effect of Termination*:

a. Except as provided in paragraph (4)(b) of this Article G, upon termination of this Agreement, for any reason, Michigan shall return or destroy all Participant Data received from Participant, or created or received by Michigan on behalf of Participant, and Participant shall return or destroy all MPOG Data received from Michigan, or created or received by Participant on behalf of Michigan. This provision shall apply to Participant Data and MPOG Data that are in the possession of subcontractors, agents, or other third parties.

b. In the event that returning or destroying Participant Data or MPOG Data is deemed infeasible, a Party shall provide to the other notification of the conditions and reasons that make return or destruction infeasible. If the other Party agrees that return or destruction is infeasible, such agreement shall be evidenced in writing and the protections of this Agreement shall be extended to such Participant Data or MPOG Data and further uses and disclosures shall be limited to only those purposes that make the return or destruction infeasible, for so long as the Participant Data or MPOG Data are retained.

 **H. Miscellaneous**

 1. *Breach or Violation*: Neither Party is responsible for the other’s violations of the Privacy Rule unless a pattern of activity or practice that constitutes a material breach or violation of the Privacy Rule is known, in which case the further delivery of Participant Data or MPOG Data will be withheld. If this is not possible, the breach will be reported to the Secretary.

 2. *Amendment*: The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary to comply with the requirements of the Privacy Rule and HIPAA.

 3. *Survival*: The respective rights and obligations of Recipient under Article G and H(4) shall survive the termination of this Agreement.

 4. *Compliance with Laws*: In performing their respective obligations under this Agreement, Parties shall at all times comply with all applicable provisions of HIPAA, the Privacy Rule, and all other applicable state and federal laws and regulations.

 5. *Interpretation:* Any ambiguity in this Agreement shall be interpreted in a manner consistent with the Privacy Rule.

 6. *Disclaimer*: NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

 7. *Intellectual Property*: Parties acknowledge and agree that they do not by virtue of this Agreement acquire any intellectual property rights in the Participant Data or MPOG Data or future inventions or discoveries made by MPOG Participants using MPOG Data distributed by Michigan.

 8. *Relationship of the Parties*: Each Party to this Agreement is an independently contracting party. Nothing in this Agreement shall constitute, be construed, or create an employment relationship, a partnership, or a joint venture among any of the Parties.

 7. *Assignment; Successors and Assigns*: Neither Party may assign its rights or cause to be assumed its obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Subject to the foregoing, this Agreement shall apply to, be binding in all respects upon and inure to the benefit of the Parties hereto and their respective successors and assigns.

 8. *Mutual Indemnity*: Parties shall, to the extent allowed by law, each defend, indemnify and hold harmless the other from and against any and all claims, losses, causes of action, judgments, damages and expenses to the extent caused by any breach of this Agreement or failure to perform its obligations hereunder, by the indemnifying party, its employees, officers, or agents.

 10. *Execution of Agreement*: This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original copy and all of which, when taken together, will be deemed to constitute one and the same agreement. The exchange of copies of the Agreement and of signature pages by facsimile transmission will constitute effective execution and delivery of this Agreement as to the Parties hereto and may be used in lieu of the original Agreement for all purposes. Signatures of the Parties transmitted by facsimile will be deemed to be their original signatures for all purposes.

 11. *Entire Agreement*: This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and replaces all prior agreement, understanding, commitments, communications, and representation made between the Parties, whether written or oral, with respect to the subject matter hereof.

 12. *Severability:* If any provision of this Agreement is declared invalid or unenforceable, such provision shall be limited and construed so as to make it enforceable or, if such limitation or construction is not possible, such provisions shall be stricken from the Agreement. In such event, all other provisions shall remain in full force and effect, unless such enforcement would be inconsistent with the purposes of this Agreement.

13. *Notices:* Legal notices or matters of a contractual nature arising out of the terms and conditions of this Agreement may be directed to:

MICHIGAN:

University of Michigan Health System

Legal Office

300 North Ingalls Bldg, Ste 3B04

Ann Arbor, MI 48109

Attn.: Colleen McClorey

cmcclore@umich.edu

734.764-2178

PARTICIPANT:

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**PARTICIPANT THE REGENTS OF THE**

 **UNIVERSITY OF MICHIGAN**

Authorized Official: Authorized Official:

Title: Title:

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Signature Date Signature Date