**Sight OUtcomes Research CollaborativE (SOURCE)**

**PARTICIPATION AND DATA USE AGREEMENT**

 This Data Use Agreement (“Agreement”) is by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Participant”) and the Regents of the University of Michigan, a State of Michigan Constitutional corporation (“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”).

WHEREAS, Michigan has established the **S**ight **OU**tcomes **R**esearch **C**ollaborativ**E** (“SOURCE”) for the purpose of permitting multi-institutional collaboration to accelerate outcomes research and quality improvement in ophthalmology; and

WHEREAS, Participant seeks to participate in SOURCE and share Participant Data as required;

NOW THEREFORE, the Parties agree to the following:

 **A. Definitions**

 1. *SOURCE-DC:* The Sight OUtcomes Research CollaborativE Data Collaborative (“SOURCE” or “SOURCE-DC”), which has been established to pool data submitted by ophthalmology departments of institutions with health information systems into a common research and quality improvement database with the hope of accelerating outcomes research to advance knowledge and improve patient care.

2. *SOURCE Data:* (a) all patient information shall be fully de-identified pursuant to standards and implementation specifications set forth under 42 CFR § 164.514 (the “De-identified Data Set”); (b) no healthcare provider names are included in such data; and (c) all hospital/center names or other identifying information shall be removed and non-identifying numbers or similar designations will be used.

 3. *SOURCE Participant:* An organization participating in SOURCE-DC that has signed the Sight OUtcomes Research CollaborativE (SOURCE) Participation and Data Collaborative Data Use Agreement.

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

5*. Participant Data:* The de-identified Data Set provided by Participant to Michigan as specified in Exhibit A.

 **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 SOURCE centralized research and quality improvement repository; Michigan’s obligations and rights to receive, process, use, and distribute Participant Data, as part of SOURCE Data, to SOURCE Participants for use in Projects; and the Participant’s rights and obligations to receive and use any SOURCE 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.

 **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 SOURCE-DC Participants for use in SOURCE-DC Projects. Participant is responsible for de-identifying and coding Participant Data 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 SOURCE-DC activities; and

 b. Distribute the Participant Data, as part of SOURCE-DC Data, to SOURCE-DC Participants upon submission by such SOURCE-DC Participants of a SOURCE-DC Project.

 3. To not use or disclose SOURCE-DC Data other than as permitted or required by the Agreement or as Required by Law.

 4. To not use SOURCE-DC 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 Research Committee (RC).

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

 6. To ensure that any agents, including subcontractors, or other third parties to whom it provides SOURCE-DC 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 SOURCE-DC Data.

 7. To report to Michigan any use or disclosure of SOURCE-DC Data not provided for by this Agreement of which the Participant, its officers, employees, or agents become aware, including without limitation, any disclosure of SOURCE-DC 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 SOURCE-DC 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 RC prior to submission to academic journals for review by the RC to ensure appropriate attribution to SOURCE and that the research reflects the original project’s proposal.

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

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

 12. To execute Exhibit B, the Datavant Solution Order Form, which provides de-identification and linking for tools for Participant to use related to Participant Data transfer to Michigan.

 **E. Mutual Obligations**

Michigan and Participant agree to:

1. Not to use or further disclose or re-identify patient protected health information, any healthcare provider or any hospital/center contained in the De-Identified Data Set or any information contained therein other than as permitted by this Agreement, except for Participant identifiers as approved of by the SOURCE Executive Board, or as required by applicable law.
2. To use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement.
3. Not to use the information contained in the De-Identified Data Set to identify the individuals whose information is contained in the De-Identified Data Set, nor to contact them under any circumstances.
4. SOURCE will produce an exhibit, for attachment to this Data Use Agreement, for each project requesting data from Participants. Each project exhibit will explicitly outline the De-Identified Data Set requested and how the data will be used, for review and approval by Participant. Approved exhibits will be signed by Participant’s designated leadership for inclusion in the project. Use of the data sets provided is limited to the approved project exhibit.
5. Data submitted by Participant hereunder shall only be used for the applicable project set forth on Exhibit C hereunder.

 **F. TERM AND TERMINATION**

 1. *Term*: The Term of this Agreement shall commence as of the Effective Date and continue for a period of five (5) years

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

 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.

 **G. Miscellaneous**

 1. *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.

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

 3. *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.

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

 5. *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.

 6. *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 SOURCE-DC Data or future inventions or discoveries made by SOURCE-DC Participants using SOURCE-DC Data distributed by Michigan.

 7. *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.

 8. *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.

 9. *Liability*: Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers or directors, to the extent allowed by law.

 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

Office of the General Counsel

300 North Ingalls, Ste 3B04

Ann Arbor, MI 48109-5476

Attn.: Colleen McClorey

cmcclore@med.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

**Exhibit A**

**DATASET REQUIREMENTS**

**The Participant agrees to prepare the following files which will constitute their contribution to the SOURCE Dataset:**

**Encounter file**

**Patient file**

**Order file**

**Diagnosis file**

**Provider characteristics file**

**Charges files**

**Problem list file**

**Visit summary / HPI file**

**Family history file**

**Review of systems file**

**Ocular Surgery files (supplies / implants)**

**Procedure / imaging notes**

**Medications file**

**Lab test results file**

**Eye exam files**

**Radiology file**

**Pathology file**

**Encounter note file**

**Operative report file**

**Workstation file**