**AMENDMENT \_\_\_\_**

**TO SIGHT OUTCOMES RESEARCH COLLABORATEIVE (SOURCE)**

**PARTICIPATION AND DATA USE AGREEMENT**

 This Amendment (Amendment) to the Sight Outcomes Research Collaborative (SOURCE) Participation and Data Use Agreement (Agreement) by and between The Regents of the University of Michigan (Michigan) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Participant) shall be effective \_\_\_\_\_\_\_\_\_\_\_.

 The parties hereto have agreed to amend the Agreement as more fully described below:

1. The parties agree to remove Section E(5) from the Agreement.
2. The parties agree to replace Section E(4) from the Agreement with the following:
	1. SOURCE will produce a written approval on behalf of the SOURCE Executive Board to be treated as an exhibit, for attachment to this Data Use Agreement, for each project requesting data, submitted by the Participant. Each project exhibit will explicitly outline the applicable data set(s) requested and how the data will be used by Participant. Use of the data sets provided is limited to the approved project exhibit.
3. The parties agree to add the following as Section D(13) as well as the accompanying exhibits which are attached as Appendix 1 to this Amendment:

Participant may elect to provide additional optional data as described in Exhibits D and E by selecting such options below. To the extent such data is provided, the permissions and obligations of this Section D shall extend to those optional data sets as well. If no option is selected, Participant shall only provide Participant Data defined above. In addition to Participant Data, Participant will provide (check any that apply):

1. \_\_\_\_\_ Participant Test Data as defined in Exhibit C, incorporated herein only if this option is selected.
2. \_\_\_\_\_ Participant Free-Text Data Set as defined in Exhibit D, incorporated herein only if this option is selected.
3. \_\_\_\_\_ Participant Consented Data Set as defined in Exhibit E, incorporated herein only if this option is selected.

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.  No modifications 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.

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| --- | --- |
| ParticipantBy: Printed Name: Title: Date of Signature: Address for notices:  Federal Tax ID:  | For the Regents of the University of MichiganBy: Printed Name: Title: Date of Signature: Address for notices:  Federal Tax ID:  |

**Exhibit C**

**Statement of Work**

**A. PURPOSE**

 Integration of key ocular diagnostic tests results (“Test Data”) routinely performed on patients into the SOURCE repository, including, automated perimetry, optical coherence tomography, biometry, keratometry, ocular photography (each a “Device”).

**B. PROCESS**

 SOURCE will work with each participant to guide it on how to extract the Test Data from the Device in a manner that will allow the Test Data to be aggregated into the SOURCE repository.

 The Test Data will be extracted by Participant and Participant will de-identify protected health information (“PHI”) using Datavant software.

 The Test Data will then be transmitted to SOURCE. SOURCE will perform additional cleaning of the Test Data and incorporate it into the SOURCE repository.

SOURCE is not responsible for Participant’s cost in performing the Test Data extraction and de-identification activities.

**C. PARTICIPANT RESPONSIBILITIES AND OBLIGATIONS**

 Participant is not obligated to share its Test Data in order to participate in SOURCE.

 Participant can share Test Data from any Device, but is not obligated to share Test Data for every Device.

 Participant can access Test Data from other SOURCE participants if Participant is sharing its Test Data for the same Device. If Participant ceases sharing its Test Data for a particular Device, it will lose access to the Test Data from other SOURCE participants for that Device. For example, if Participant is willing to share its visual field test data, but not its optical coherence tomography test data, Participant will have access to visual field test data of other SOURCE participants, but will not have access to the optical coherence tomography test data of the other SOURCE participants.

 Continued access to aggregate Test Data for a given Device by the Participant is contingent upon continued sharing of its Test Data for that particular Device.

 If Participant ceases sharing Test Data with SOURCE, SOURCE will return any prior shared Test Data and will not use Participant’s Test Data on new projects. However, for ongoing projects using existing shared Test Data, SOURCE will continue using the Test Data until the project is completed.

**D. COMMERCIALIZATION OF DATA**

The same stipulations outlined in the Sight Outcomes Research Collaborative (SOURCE) Participation and Data Use Agreement will apply.

**Exhibit D**

**Free-Text Data Set Addendum**

* + - 1. This Addendum shall apply to all SOURCE Participants providing a Free-Text Data Set defined in section 2 of this Exhibit D.
			2. The “Free-Text Data Set” is a Limited Data Set, which includes options for operative reports, clinic visit encounter notes, and other free text fields from the electronic health records of Participant after direct identifiers are removed, and covered in accordance with Exhibit D.
			3. A “SOURCE Free-Text Data Set” is the combined individual-level data of Free-Text Data Sets provided by SOURCE Participants who elect to provide such data under the terms of this Exhibit D.
			4. Only SOURCE Participant(s) providing a Free-Text Data Set shall be able to request and receive a SOURCE Free-Text Data Set for a SOURCE Project under the same procedures as those in the Agreement for requests of SOURCE Data.
			5. To the extent of any inconsistencies between this Addendum and the Agreement, this Addendum shall control.
			6. Participant acknowledges and agrees that the SOURCE Free-Text Data Set may be able to be linked to SOURCE-DC Data which Participant receives for SOURCE Projects under the Agreement, and that, as a result, the SOURCE-DC Data received shall be a Limited Data Set as defined in 45 C.F.R. § 164.514(c), and treated accordingly.
			7. If Participant also provide a SOURCE Consented Data Set under Exhibit E, SOURCE Free-Text Data Sets and SOURCE Consented Data Sets may be able to be linked to each other and SOURCE-DC Data and all such data shall be used in compliance with the requirements of the Agreement and all Exhibits.
			8. All reference to the Participant Data provided to SOURCE in the Agreement shall be revised to refer to a Limited Data Set as defined in 45 C.F.R. § 164.514(c). If SOURCE discovers any directly identifiable information included in the Free-Text Data Set, it shall immediately notify Participant, destroy all such identifiers, and cease all use of any identifiable information that would make the Free-Text Data Set anything other than a Limited Data Set.
			9. For all approved projects involving a transfer of Free-Text Data Sets to SOURCE Participant, all references to the SOURCE-DC Data or the De-identified Data Set in the Agreement shall be revised to refer to a Limited Data Set as defined in 45 C.F.R. § 164.514(c).
			10. SOURCE Participant certifies and represents that receipt of SOURCE-DC Data will be in accordance with laws and regulations applicable to SOURCE Participant, including any IRB approval or review requirements.
			11. SOURCE Participant certifies and represents it has the right and authority to transfer the Free-Text Data Set to SOURCE for the purposes of the Agreement, and that such transfer is in accordance with all applicable laws, regulations, and includes any IRB approval or review if such is required by such laws or SOURCE Participant policies.
			12. The parties agree to take such action as is reasonably necessary to negotiate in good faith to amend this Agreement, from time to time, in order for the parties to remain in compliance with applicable requirements of HIPAA.

**Exhibit E**

**Consented Data Set Addendum**

* + - 1. This Addendum shall apply to all SOURCE Participants providing a Consented Data Set defined in section 2 of this Exhibit E
			2. The “Consented Data Set” is a Limited Data Set, which includes options for data from wearables, surveys and other sources of data provided with the explicit consent of subjects of other studies of Participant after direct identifiers are removed, and covered in accordance with Exhibit E.
			3. A “SOURCE Consented Data Set” is (a) the combined individual-level data of Consented Data Sets provided by SOURCE Participants who elect to provide such data under the terms of this Exhibit E; (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.
			4. Only SOURCE Participant(s) providing a Consented Data Set shall be able to request and receive a SOURCE Consented Data Set for a SOURCE Project under the same procedures as those in the Agreement for requests of SOURCE Data.
			5. To the extent of any inconsistencies between this Addendum and the Agreement, this Addendum shall control.
			6. Participant acknowledges and agrees that the SOURCE Consented Data Set may be able to be linked to SOURCE-DC Data which Participant receives for SOURCE Projects under the Agreement, and that, as a result, the SOURCE-DC Data received shall be a Limited Data Set as defined in 45 C.F.R. § 164.514(c), and treated accordingly.
			7. If Participant also provide a SOURCE Free-Text Data Set under Exhibit D, SOURCE Free-Text Data Sets and SOURCE Consented Data Sets may be able to be linked to each other and SOURCE-DC Data and all such data shall be used in compliance with the requirements of the Agreement and all Exhibits.
			8. All reference to the Participant Data provided to SOURCE in the Agreement shall be revised to refer to a Limited Data Set as defined in 45 C.F.R. § 164.514(c).
			9. For all approved projects involving a transfer of Consented Data Sets to SOURCE Participant, all references to the SOURCE Data, or the De-identified Data Set in the Agreement shall be revised to refer to a Limited Data Set as defined in 45 C.F.R. § 164.514(c).
			10. SOURCE Participant certifies and represents that receipt of SOURCE-DC Data will be in accordance with laws and regulations applicable to SOURCE Participant, including any IRB approval or review requirements.
			11. SOURCE Participant certifies and represents it has the right and authority to transfer the Consented Data Set to SOURCE for the purposes of the Agreement, and that such transfer is in accordance with all applicable laws, regulations, and includes any IRB approval or review if such is required by such laws or SOURCE Participant policies.
			12. The parties agree to take such action as is reasonably necessary to negotiate in good faith to amend this Agreement, from time to time, in order for the parties to remain in compliance with applicable requirements of HIPAA.