

**CEDARS-SINAI SOURCEDRIVE
CONSORTIUM MEMBERSHIP AGREEMENT**

This Cedars-Sinai SourceDrive Consortium Membership Agreement (the “Agreement”) is entered into as of the Effective Date set forth on Exhibit “A” between Cedars-Sinai Medical Center, a California nonprofit public benefit corporation (“Cedars-Sinai”) and the Organization named on Exhibit “A” (“Member”).

WHEREAS, Cedars-Sinai owns the cloud-based SourceDrive software program which is a tool for managing clinical trial documents and workflows (“SourceDrive”); and

WHEREAS, Cedars-Sinai has established the SourceDrive Consortium at Cedars-Sinai to further develop and improve SourceDrive through input from users of SourceDrive (the “SourceDrive Consortium”); and

WHEREAS, Cedars-Sinai will license use of SourceDrive software to other research organizations, which license would, for select organizations, include mechanisms for participating organizations to be included in the ongoing evaluation, development and improvement of SourceDrive through involvement in the SourceDrive Consortium, all on the terms of this Agreement; and

WHEREAS, Member wishes to license the SourceDrive software on the terms set forth in this Agreement; and

NOW, THEREFORE, the parties hereto agree as follows:

1. **Member and Member Consortium Elections.** Exhibit “A” sets forth the name and contact information for Member and key contact information of Cedars-Sinai. Exhibit “A” also sets out Member’s elections regarding SourceDrive Consortium participation levels which are described below.

2. **Cedars-Sinai to Operate SourceDrive.** Notwithstanding Member’s involvement with the SourceDrive Consortium, Cedars-Sinai shall be solely responsible for the operation of and any changes to the SourceDrive software. No Member shall obtain any proprietary rights in the SourceDrive software by reason of any contributions Member makes through the SourceDrive Consortium or otherwise.

3. **License of SourceDrive Software.** Cedars-Sinai hereby licenses the SourceDrive software to Member on the terms and conditions set forth in this Agreement and Exhibit “B”.

4. Consortium Participation Levels and Governance Committee.

(a) Membership Levels.

The following are the three current levels of membership participation entitling research organizations to license the SourceDrive software and, at certain levels of membership, participate in the SourceDrive Consortium. Cedars-Sinai reserves the right to add new membership levels and to cease enrollment in existing levels at any time during the term of this Agreement, upon not less than ninety (90) days prior written notice to all Members. If Cedars-Sinai plans to modify the terms of any of the three membership levels described below, Cedars-Sinai shall notify all current Members in writing of the proposed modification not less than one hundred eighty (180) days prior written notice to all Members. If Members choose to renew their agreements and memberships, they will enter into an amended agreement setting out the new membership terms.

- (i) *Academic Member:* Academic Members will be granted a nonexclusive license to the SourceDrive software and access to all upgrades on the terms set forth in this Agreement and Exhibit “A”.
- (ii) *Premium Academic Member:* Premium Academic Members will (A) be granted a nonexclusive license to the SourceDrive software and access to all upgrades on the terms set forth in this Agreement and Exhibit “A”, and (B) have the right, but not the obligation, to participate in any Governance Committee meetings to assist Cedars-Sinai with the establishment of product enhancements and Consortium initiatives. Premium Academic Members will have the option to beta test upgrades and improvements to the SourceDrive software. If desired, Premium Academic Members may have their organization name and logo placed on the Cedars-Sinai SourceDrive website.
- (iii) *Commercial Member:* Commercial Members will be granted a nonexclusive license to the SourceDrive software and access to all upgrades on the terms set forth in this Agreement and Exhibit “A”.

(b) Governance Committee.

(i) *Purpose:* Cedars-Sinai shall convene an annual meeting of a SourceDrive Governance Committee (“Governance Committee”). The Governance Committee purpose shall be to regularly and continuously review the performance of the SourceDrive software and to identify improvements and enhancements to be considered by Cedars-Sinai. All recommendations to Cedars-Sinai by Premium Academic Members shall be considered in good faith. Cedars-Sinai shall provide Premium Academic Members with specific information on its acceptance, timing and prioritization of improvements and enhancements for the SourceDrive software.

(ii) *Participants:* Premium Academic Members may invite up to five (5) individuals to participate in Governance Committee meetings. As a condition to participation, all Premium Academic Members must enter into a Confidentiality

Agreement in the form attached to this Agreement at Exhibit “D”.

(iii) *Meetings*: Meetings shall be handled informally and shall not be subject to requirements for quorums, agendas, meeting minutes and the like, though draft agendas will generally be prepared and distributed in advance of meetings by Cedars-Sinai in order to solicit discussion topics. The Governance Committee will meet at least two times per year by video meeting. Cedars-Sinai shall coordinate meeting dates with Premium Academic Members in order to maximize participation.

5. Fees.

(a) Annual Membership Fees.

The following are the annual fees payable under this Agreement for the different levels of Membership:

Academic Member:	\$20,000
Premium Academic Member:	\$40,000
Commercial Member:	\$60,000

Annual Membership Fees shall be payable by June 15 for the following year of the Term.

(b) Annual Study Fees.

In addition to the Annual Membership Fees, Members shall pay Cedars-Sinai an Annual Study Fee based on the number of studies placed into the SourceDrive software. The Annual Study Fee shall be \$6,000 for every 100 studies. Member shall pay an amount equal to its estimated need for each year of the Term, to be paid by June 15 for the following year of the Term. Within thirty (30) days following the end of each year of the Term, Cedars-Sinai shall invoice Member for the actual Annual Study Fee due, which invoice shall include a refund to Member if the Member overpaid the Annual Study Fee.

6. Cedars-Sinai Funding and Use of Member Funds. Fees collected for licenses of the SourceDrive software and Consortium participation memberships will be used in a manner that is solely in the discretion of Cedars-Sinai. Cedars-Sinai shall not be obligated to account for use of funds and will have no obligation to place the funds in a segregated account. Members acknowledge that Cedars-Sinai is making its own substantial commitment of direct and indirect funding of the SourceDrive software maintenance, support and development and of the operation of the SourceDrive Consortium. Member’s only remedies in the event of Member’s dissatisfaction with Cedars-Sinai’s performance under this Agreement, including funding of SourceDrive efforts, shall be to (i) communicate Member’s concerns to Cedars-Sinai and/or to (ii) terminate or not renew this Agreement.

7. **Membership Years, Term and Termination.**

(a) **Membership Years.** SourceDrive licenses and SourceDrive Consortium participation are run on the basis of the typical healthcare academic year, a twelve (12) month period commencing July 1 and ending June 30 (“Membership Year”).

(b) **Term.** The term of this Agreement shall begin on the Effective Date and shall continue through a full Membership Year. If a Member’s Effective Date is not July 1, the Member’s first term shall be the period commencing the Effective Date and expiring the second June 30 thereafter (meaning a prorated year plus a full Membership Year). Thereafter, this Agreement shall automatically renew each July 1 for the next Membership year unless this Agreement is terminated by either party as provided below. Fees for the initial year shall be prorated, as needed, as set forth on Exhibit “A.”

(c) **Termination.** Either party may terminate this Agreement for breach of the party upon fifteen (15) days prior written notice to the other party, which notice shall specify the nature of the breach. Otherwise notice of early termination or of nonrenewal on expiration of the expiration of the then current term can be given by either party upon one hundred eighty (180) days prior written notice. Additionally, this Agreement shall terminate upon notice to Member if any of the Fees are past due by more than thirty (30) days.

(d) **Return of Fees on Prorated Basis.** If this Agreement is terminated prior to the expiration of its term, if the termination is not the result of Member’s material breach of this Agreement, Cedars-Sinai shall refund any fees paid for the current Term on a prorated basis. If this Agreement is terminated prior to the expiration of its term as a result of Member’s material breach of this Agreement, Cedars-Sinai shall refund any fees paid for the current Term on a prorated basis, less the amount of Cedars-Sinai’s reasonable estimate of its financial damages from such breach.

(e) **Access to SourceDrive Software Following Termination.** Member shall have access to the SourceDrive software for one (1) month following any termination of this Agreement in order for Member to arrange for a transfer of Member’s materials.

8. **Confidentiality and HIPAA Compliance.** Member agrees to fully comply with (and shall cause all its researchers, employees and agents to fully comply with) Federal and state laws and regulations designed to protect the confidentiality of all personal health and other personal information concerning all prospective and enrolled research participants. Without limiting the foregoing, the parties will comply with applicable provisions of the Health Insurance Portability and Accountability Act of 1996, as amended from time to time, and regulations promulgated thereunder, California laws relating to the privacy of patient and individual information and other applicable laws. In order to document Cedars-Sinai’s rights and responsibilities in connection with the information that Member may place in SourceDrive, Member and Cedars-Sinai hereby agree to the provisions of the Business Associate Agreement attached hereto as Exhibit “C”.

9. **Publications.** Cedars-Sinai will be free to publish information about

SourceDrive activities.

10. Copyright, Patents and Other Intellectual Property. Cedars-Sinai shall continue to own the name, copyright, trademark, patents and all other intellectual property relating to the SourceDrive software.

11. WARRANTY DISCLAIMER.

THE SOURCEDRIVE SOFTWARE AND RELATED RESOURCES AND SERVICES PROVIDED BY CEDARS-SINAI IN ACCORDANCE WITH THE TERMS OF THIS AGREEMENT ARE WITHOUT EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND THE PARTIES MAKE NO WARRANTY OR REPRESENTATION THAT THE SOURCEDRIVE SOFTWARE AND RELATED RESOURCES OR SERVICES DO NOT OR WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. SUCH ARE ALL PROVIDED TO MEMBERS "AS IS". CEDARS-SINAI SHALL BEAR NO LIABILITY FOR ANY CLAIM, ACTION, DAMAGE OR INJURY ON ACCOUNT OF MEMBER'S USE OF THE SOURCEDRIVE SOFTWARE AND RELATED RESOURCES AND SERVICES.

IN NO EVENT SHALL EITHER PARTY, ITS TRUSTEES, DIRECTORS, OFFICERS, RESEARCHERS, EMPLOYEES, STUDENTS, AGENTS AND AFFILIATES, BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGES OR INJURY TO PERSONS OR PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER THAT PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING. THIS SECTION SHALL SURVIVE THE EXPIRATION OR ANY EARLIER TERMINATION OF THIS AGREEMENT.

12. Use of Names. Neither party will use the name of the other in any advertising or other form of publicity without the written permission of the other. As an example for Cedars-Sinai, the Member shall not use the names "Cedars-Sinai" or "SourceDrive" or any variation, adaptation or abbreviation thereof, or that of any of its trustees, officers, faculty, students, employees, or agents, or any trademark owned by Cedars-Sinai.

13. Notices. Any notices required to be given or which shall be given under this Agreement shall be in writing and be addressed to the parties as shown on Exhibit "A". Notices shall be delivered by certified or registered first class mail (air mail if not domestic) or by commercial courier service, and shall be deemed to have been given or made as of the date received.

14. Independent Contractors. Cedars-Sinai and each Member is acting as an independent contractor and nothing contained in this Agreement is to be construed as creating a partnership, joint enterprise, or any other agency relationship between the parties.

15. Entire Agreement. Unless otherwise specified, this Agreement and the Exhibits embody the entire understanding between Cedars-Sinai and Member. No amendments or changes to this Agreement or any Exhibit shall be effective unless made in writing and signed by authorized representatives of the parties.

IN WITNESS WHEREOF, the parties have entered into this Agreement as of the Effective Date.

CEDARS-SINAI MEDICAL CENTER

MEMBER

By: _____
Nicole A. Leonard, JD, MBA
Vice President of Research and
Assistant Dean
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

EXHIBIT "A"

Participation Terms

Address and Contact Information for Notices and other Communications to Cedars-Sinai:

Principal Contact, Name and Title: Nicole A. Leonard, JD, MBA
Vice President of Research
And Assistant Dean
Cedars-Sinai Medical Center
8700 Beverly Blvd., Suite NT 2048
Los Angeles, CA 90048
Nicole.Leonard@cshs.org

Address and Contact Information for Notices and Other Communications to Member:

Principal Contact, Name and Title: _____
Name: _____
Title: _____
Street Address: _____

Email Address(es): _____

Accounts Payable Contact, Name and Title: _____
Name: _____
Title: _____
Street Address: _____

Email Address(es): _____

Informational Technology Name and Title: _____
Name: _____
Title: _____
Street Address: _____

Email Address(es): _____

Effective Date: _____

If the Effective Date is not July 1, the prorated fees shall be determined as follows: Number of Days left in the Membership Year/365 x Full Year Fee plus the Full Year fee for the first full Membership Year.

Member Level: _____

EXHIBIT “B”

License Terms

1. **Software License Grant.** Cedars-Sinai grants to Member a non-exclusive, non-transferable, limited license for Member to use the SourceDrive software, solely in connection with Member’s operation of its own human subjects research programs.

2. **Compliance with Standards.** The SourceDrive software may only be used to support Member’s human subjects research programs, which shall be operated in compliance with all applicable laws, regulations and ethical standards for human subjects research. Cedars-Sinai shall not have any responsibility for Member’s human subjects research.

3. **Authorized Users and Access Restrictions.** “Authorized User(s)” will mean the individuals Member authorizes to use the SourceDrive software. Member shall ensure that each Authorized User will receive an individual logon, unique to that user, for purposes of accessing the SourceDrive software. Authorized Users will not share individual logons or their passwords. Member will maintain a list of all Authorized Users and will make such list available to Cedars-Sinai on request. Member will ensure only Authorized Users access the SourceDrive software through Member’s systems and will prevent unauthorized access.

4. **Access/Use Indemnity.** Member hereby agrees to defend, indemnify and hold harmless Cedars-Sinai, its directors, officers, agents, employees, and affiliates, and each of their respective successors and assigns, from and against any and all claims, demands, liabilities, losses, costs and/or expenses, including reasonable attorney’s fees, arising out of any breach of Member’s or its Authorized Users’ obligations to comply with the terms of this Agreement or the Standards or out of unauthorized access to or improper use of the SourceDrive software Items and Services originating within Member’s organization.

5. **Ownership.** This Agreement does not grant to Member any ownership interest in the SourceDrive software Items and Services or the software. Ownership of the SourceDrive software and the software and all intellectual property rights in it will remain at all times with Cedars-Sinai and, as applicable, Cedars-Sinai’s third party suppliers or agents. Any copy, modification, revision, enhancement, adaptation, translation, or derivative work of or created from the SourceDrive software and/or software made by or at the direction of Member will be owned solely and exclusively by Cedars-Sinai, and/or as applicable, Cedars-Sinai’s third party suppliers or agents, as will all patent rights, copyrights, trade secret rights, trademark rights, and all other proprietary rights, worldwide therein and thereto.

6. **Copyright.** The SourceDrive software, including the software, contains material that is protected by United States copyright law and trade secret law, and by international treaty provisions. All rights not granted by Cedars-Sinai and/or as applicable, Cedars-Sinai’s third party suppliers or agents, by this Agreement are expressly reserved by Cedars-Sinai. Member will not remove any proprietary notice of Cedars-Sinai or a third

party from any copy of the SourceDrive software, including the software.

7. **Training and Support.** Member agrees that its Authorized Users will participate in training related to the SourceDrive software, as determined to be necessary by Cedars-Sinai.

8. **SourceDrive Software Modification.** Cedars-Sinai will have the right to eliminate, change, or substantially modify the SourceDrive software or any part of the SourceDrive software as it determines appropriate in its sole discretion. Cedars-Sinai will provide Members reasonable advance notifications of any such modifications to the SourceDrive software released to Members on the cloud.

9. **Prohibited Actions.** This Agreement shall not be construed to confer any rights upon Member by implication, estoppel, or otherwise except as specifically set forth in this Exhibit. Specifically, this Agreement in no way provides Member the rights to do any of the following:

- (a) to reproduce the software in copies;
- (b) to make an archival copy of the software;
- (c) to place the software on a secure server connected to Member's intranet;
- (d) to make modifications to the software;
- (e) to prepare Derivative Works based upon the software;
- (f) to distribute the software;
- (g) to sublicense the software;
- (h) to sell the software;
- (i) to gain a commercial benefit from the use of the software; or
- (j) to reproduce the software, make modifications to the software, or to prepare Derivative Works based upon the software that are not solely for the internal use, research, and development by Member.

EXHIBIT “C”

Business Associate Agreement Terms

THIS BUSINESS ASSOCIATE AGREEMENT (“BAA”) is made and entered into by and between Member as a Covered Entity and Cedars-Sinai as a Business Associate.

RECITALS

A. Member may be placing medical and personal information of Member’s prospective and enrolled research participants in SourceDrive. Such information may constitute Protected Health Information (“PHI”) (further defined below). Member and Cedars-Sinai intend to protect the privacy and provide for the security of PHI disclosed to Cedars-Sinai in compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act (“the HITECH Act”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable laws.

B. This BAA constitutes the Business Associate Agreement contemplated by HIPAA relating to the disclosure of PHI by Member to Cedars-Sinai, as set forth in, but not limited to, Title 45, Sections 164.314(a), 164.502(a) and (e) and 164.504(e) of the Code of Federal Regulations (“C.F.R.”).

In consideration of the mutual promises below and the exchange of information pursuant to this BAA, the parties agree as follows:

1. Definitions

- a. Breach shall have the meaning given to such term under the HITECH Act and HIPAA Regulations [42 U.S.C. Section 17921 and 45 C.F.R. Section 164.402].
- b. Breach Notification Rule shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and D.
- c. Business Associate shall have the meaning given to such term under the Privacy Rule, the Security Rule, and the HITECH Act, including, but not limited to, 42 U.S.C. Section 17938 and 45 C.F.R. Section 160.103.
- d. Covered Entity shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to, 45 C.F.R. Section 160.103.
- e. Data Aggregation shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.

- f. Designated Record Set shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- g. Electronic Protected Health Information means Protected Health Information that is maintained in or transmitted by electronic media.
- h. Electronic Health Record shall have the meaning given to such term in the HITECT Act, including, but not limited to, 42 U.S.C. Section 17921.
- i. Health Care Operations shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- j. Privacy Rule shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and E.
- k. Protected Health Information or PHI means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental 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) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501. Protected Health Information includes Electronic Protected Health Information [45 C.F.R. Sections 160.103, 164.501].
- l. Protected Information shall mean PHI provided by Member to Cedars-Sinai or created, maintained, received or transmitted by Cedars-Sinai on Member's behalf.
- m. Security Incident shall have the meaning given to such term under the Security Rule, including, but not limited to, 45 C.F.R. Section 164.304.
- n. Security Rule shall mean the HIPAA Regulations that are codified at 45 C.F.R. Parts 160 and 164, Subparts A and C.
- o. Services Agreements shall mean the Agreement described above or any similar agreement with Cedars-Sinai enabling Member to create or maintain Protected Information in electronic systems provided by Cedars-Sinai, including without limitation CS-Link and any records hosting application of Cedars-Sinai.

- p. Unsecured PHI shall have the meaning given to such term under the HITECH Act and any guidance issued pursuant to such Act including, but not limited to, 42 U.S.C. Section 17932(h) and 45 C.F.R. Section 164.402.

2. **Obligations of Business Associate**

- a. **Permitted Uses.** Cedars-Sinai shall use Protected Information only as permitted or required under the Services Agreements or this BAA, or as required by law. Further, Cedars-Sinai shall not use Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so used by Member. However, Cedars-Sinai may use Protected Information as necessary (i) for the proper management and administration of Cedars-Sinai and its Health Care Operations; (ii) to carry out the legal responsibilities of Cedars-Sinai; (iii) as required by law; or (iv) for Data Aggregation purposes relating to the Health Care Operations of Member [45 C.F.R. Sections 164.504(e)(2) and 164.504(e)(4)(i)].
- b. **Permitted Disclosures.** Cedars-Sinai shall disclose Protected Information only as permitted or required under the Services Agreements or this BAA, or as required by law. Cedars-Sinai shall not disclose Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so disclosed by Member. However, Cedars-Sinai may disclose Protected Information as necessary (i) for the proper management and administration of Cedars-Sinai; (ii) to carry out the legal responsibilities of Cedars-Sinai and its Health Care Operations; (iii) as required by law; or (iv) for Data Aggregation purposes relating to the Health Care Operations of Member. If Cedars-Sinai discloses Protected Information to a third party, Cedars-Sinai must obtain, prior to making any such disclosure, (i) reasonable written assurances from such third party that such Protected Information will be held confidential as provided pursuant to this BAA and used or disclosed only as required by law or for the purposes for which it was disclosed to such third party, and (ii) a written agreement from such third party to immediately notify Cedars-Sinai of any breaches, suspected breaches, Security Incidents, or unauthorized uses or disclosures of the Protected Information, to the extent it has obtained knowledge of such occurrences [42 U.S.C. Section 17932; 45 C.F.R. Section 164.504(e)].
- c. **Prohibited Uses and Disclosures.** Cedars-Sinai shall not use or disclose PHI other than as permitted or required by the Services Agreements, or as required by law. Cedars-Sinai shall not use or disclose Protected Information for fundraising or marketing purposes. Cedars-Sinai shall not disclose Protected Information to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates [42 U.S.C. Section 17935(a) and 45 C.F.R. Section 164.522(a)(vi)]. Cedars-Sinai shall not directly or indirectly receive remuneration in exchange for Protected Information, except with the prior written consent of Member

and as permitted by the HITECH Act, 42 U.S.C. Section 17935(d)(2), and the HIPAA regulations, 45 C.F.R. Section 164.502(a)(5)(ii); however, this prohibition shall not affect payment by Member to Cedars-Sinai for services provided pursuant to the Services Agreements.

- d. **Appropriate Safeguards.** Cedars-Sinai shall implement appropriate safeguards to prevent the use or disclosure of Protected Information other than as permitted by the Services Agreements, including, but not limited to, administrative, physical and technical safeguards in accordance with the Security Rule, including, but not limited to, 45 C.F.R. Sections 164.308, 164.310, and 164.312. [45 C.F.R. Section 164.504(e)(2)(ii)(B); 45 C.F.R. Section 164.308(b)]. Cedars-Sinai shall comply with the policies and procedures and documentation requirements of the Security Rule, including, but not limited to, 45 C.F.R. Section 164.316. [42 U.S.C. Section 17931].
- e. **Cedars-Sinai's Subcontractors and Agents.** Cedars-Sinai shall ensure that any agents and subcontractors that create, receive, maintain or transmit Protected Information on behalf of Cedars-Sinai, agree in writing to the same restrictions and conditions that apply to Cedars-Sinai with respect to such Protected Information and implement the safeguards required by paragraph 2.d above with respect to Electronic PHI [45 C.F.R. Section 164.504(e)(2)(ii)(D); 45 C.F.R. Section 164.308(b)]. Cedars-Sinai shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation (see 45 C.F.R. Sections 164.530(f) and 164.530(e)(1)).
- f. **Access to Protected Information.** Cedars-Sinai shall make Protected Information maintained by Cedars-Sinai or its agents or subcontractors in Designated Record Sets available to Member for inspection and copying within five (5) days of a request by Member to enable Member to fulfill its obligations under state law [Health and Safety Code Section 123110] and the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.524 [45 C.F.R. Section 164.504(e)(2) (ii)(E)]. If Cedars-Sinai maintains Protected Information in electronic format, Cedars-Sinai shall provide such information in electronic format as necessary to enable Member to fulfill its obligations under the HITECH Act and HIPAA Regulations, including, but not limited to, 42 U.S.C. Section 17935(e) and 45 C.F.R. Section 164.524.
- g. **Amendment of PHI.** Within ten (10) days of a request by Member for an amendment of Protected Information or a record about an individual contained in a Designated Record Set, Cedars-Sinai and its agents and subcontractors shall make such Protected Information available to Member for amendment and incorporate any such amendment or other documentation to enable Member to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.526. If an individual requests an amendment of Protected Information directly from Cedars-Sinai or its agents or subcontractors, Cedars-Sinai must notify Member in writing within five (5)

days of the request and of any approval or denial of amendment of Protected Information maintained by Cedars-Sinai or its agents or subcontractors [45 C.F.R. Section 164.504(e)(2)(ii)(F)].

- h. Accounting of Disclosures.** Promptly upon any disclosure of Protected Information for which Member is required to account to an individual, Cedars-Sinai and its agents and subcontractors shall make available to Member the information required to provide an accounting of disclosures to enable Member to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.528, and the HITECH Act, including but not limited to 42 U.S.C. Section 17935(c), as determined by Member. Cedars-Sinai agrees to implement a process that allows for an accounting to be collected and maintained by Cedars-Sinai and its agents and subcontractors for at least six (6) years prior to the request. However, accounting of disclosures from an Electronic Health Record for treatment, payment or health care operations purposes are required to be collected and maintained for only three (3) years prior to the request, and only to the extent that Cedars-Sinai maintains an Electronic Health Record. At a minimum, the information collected and maintained shall include: (i) the date of disclosure; (ii) the name of the entity or person who received Protected Information and, if known, the address of the entity or person; (iii) a brief description of Protected Information disclosed; and (iv) a brief statement of purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual’s authorization, or a copy of the written request for disclosure. If a patient submits a request for an accounting directly to Cedars-Sinai or its agents or subcontractors, Cedars-Sinai shall within five (5) days of the request forward it to Member in writing.
- i. Governmental Access to Records.** Cedars-Sinai shall make its internal practices, books and records relating to the use and disclosure of Protected Information available to Member and to the Secretary of the U.S. Department of Health and Human Services (the “Secretary”) for purposes of determining Cedars-Sinai’s compliance with HIPAA [45 C.F.R. Section 164.504(e)(2)(ii)(I)]. Cedars-Sinai shall provide Member a copy of any Protected Information and other documents and records that Cedars-Sinai provides to the Secretary concurrently with providing such Protected Information to the Secretary.
- j. Minimum Necessary.** Cedars-Sinai, its agents and subcontractors shall request, use and disclose only the minimum amount of Protected Information necessary to accomplish the purpose of the request, use or disclosure. [42 U.S.C. Section 17935(b); 45 C.F.R. Section 164.514(d)] Cedars-Sinai understands and agrees that the definition of “minimum necessary” is in flux and shall keep itself informed of guidance issued by the Secretary with respect to what constitutes “minimum necessary.”

k. Notification of Possible Breach. Cedars-Sinai shall notify Member promptly of any suspected or actual breach of Protected Information; any use or disclosure of Protected Information not permitted by the Services Agreements or this BAA; any Security Incident (i.e., any attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system) related to Protected Information, and any actual or suspected use or disclosure of data in violation of any applicable federal or state laws by Cedars-Sinai or its agents or subcontractors. Notwithstanding the foregoing, the parties understand that pings and other broadcast attacks on Cedars-Sinai's firewall, port scans, unsuccessful log-on attempts, denial of service attacks and any combination of the above shall not be considered a Security Incident, so long as no such incident results in the defeat or circumvention of any security control, or in the unauthorized access, use or disclosure of PHI provided by Covered Entity. The notification shall include, to the extent possible, the identification of each individual whose unsecured Protected Information has been, or is reasonably believed by the business associate to have been, accessed, acquired, used, or disclosed, as well as any other available information that Member is required to include in notification to the individual, the media, the Secretary, and any other entity under the Breach Notification Rule and any other applicable state or federal laws, including, but not limited, to 45 C.F.R. Section 164.404 through 45 C.F.R. Section 164.408, at the time of the notification required by this paragraph or promptly thereafter as information becomes available. Cedars-Sinai shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to unauthorized uses or disclosures required by applicable federal and state laws. [42 U.S.C. Section 17921; 45 C.F.R. Section 164.504(e)(2)(ii)(C); 45 C.F.R. Section 164.308(b)].

l. Breach Pattern or Practice by Business Associate's Subcontractors and Agents. Pursuant to 42 U.S.C. Section 17934(b) and 45 C.F.R. Section 164.504(e)(1)(ii), if Cedars-Sinai knows of a pattern of activity or practice of a subcontractor or agent that constitutes a material breach or violation of the subcontractor or agent's obligations under the Services Agreements or other arrangement, Cedars-Sinai must take reasonable steps to cure the breach or end the violation.

3. Termination

a. Material Breach. A breach by Cedars-Sinai of any provision of this BAA, as determined by Member, shall constitute a material breach of the Services Agreements and shall provide grounds for immediate termination of the Services Agreements, any provision in the Services Agreements to the contrary notwithstanding. [45 C.F.R. Section 164.504(e)(2)(iii)].

b. Effect of Termination. Upon termination of the Services Agreements for any reason, Cedars-Sinai shall retain all Protected Information that Cedars-Sinai

and its agents and subcontractors still maintain in any form. Cedars-Sinai shall continue to extend the protections and satisfy the obligations of Section 2 of this BAA to such information, and limit further use and disclosure of such PHI to those purposes that make the return or destruction of the information infeasible [45 C.F.R. Section 164.504(e)(ii)(2)(J)].

EXHIBIT “D”

Nondisclosure Agreement Template

MUTUAL CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

This Mutual Confidentiality and Non-Disclosure Agreement (“Confidentiality Agreement”) is made effective as a companion agreement to the Cedars-Sinai SourceDrive Membership Agreement (“Membership Agreement”) by and between Cedars-Sinai Medical Center (“Cedars-Sinai”) and the Member listed on the signature page hereto (“Member”). This Confidentiality Agreement shall be effective as of the Effective Date of the Membership Agreement.

In consideration of the mutual covenants, terms and conditions set forth herein and the Membership Agreement, the Parties agree as follows:

1. Consortium Meetings and Members. This Confidentiality Agreement and other confidentiality agreements using this same template are being entered into by Cedars-Sinai with each Premium Academic Member of the Cedars-Sinai SourceDrive Consortium. This Confidentiality Agreement and the other confidentiality agreements are intended to protect the Confidential Information, as defined below, of all such Premium Academic Members and Cedars-Sinai. Cedars-Sinai and all past, current and future Premium Academic Members of the SourceDrive Consortium are referred to herein as the “Parties” or each individually as a “Party,” and the Party disclosing information shall be referred to as the “Discloser” and the Party receiving information shall be referred to as the “Recipient.”

2. Confidential Information. As used herein, “Confidential Information” shall relate to any Party’s human subjects research programs mean any non-public, confidential or proprietary information disclosed by a Party, whether disclosed orally or in writing, electronic or other form or media, and whether or not marked, designated or otherwise identified as “confidential” or “proprietary” (or could otherwise be reasonably construed as confidential under the circumstances surrounding disclosure) including, without limitation: financial information and records; data and data files and formats; business strategies and plans; information regarding relationships with patients, customers, suppliers, employees, independent contractors, health plans, health plan subscribers or beneficiaries, and other third parties; business methods, protocols, processes, inventions, ideas, know-how and trade secrets; proprietary software, hardware and other information technology; system designs, architecture and operations; requests for proposals and proposals; and pricing information. In addition, the term “Confidential Information” shall include: (a) any notes, analyses, memoranda or other documents prepared by a Party that contain, reflect or are based upon, in whole or in part, any Confidential Information furnished to the Recipient or its Representatives (as defined below); (b) any individually identifiable health information which is protected by the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended, and regulations

promulgated thereunder (“**HIPAA**”); and (c) the existence or status of, and any information concerning, the discussions between the Parties. Confidential Information of a Party shall include Confidential Information of third parties to which the Discloser owes an obligation of confidentiality.

3. Exclusions. Except for individually identifiable health information which is protected by HIPAA, or any other state or federal privacy law, the obligation to maintain the confidentiality of the Confidential Information hereunder shall not apply to such portion of the Confidential Information that can be established by credible evidence: (a) to already be generally available to the public when Discloser discloses it to Recipient or becomes public and generally available (other than as a result of breach of this Agreement) after Discloser discloses it to Recipient; (b) to have been lawfully acquired by the Recipient from a third party without breach of a confidentiality restriction; (c) that the Recipient can demonstrate by written proof was independently developed by the Recipient without use of or reference to Discloser’s Confidential Information; or (d) has been explicitly approved for disclosure by the Discloser. Even if a particular portion of Discloser’s Confidential Information becomes public after Discloser discloses it to Recipient, Recipient shall not use or disclose such portion to third parties along with other portions of Discloser’s Confidential Information disclosed by Recipient hereunder unless the specific combination itself was previously public.

4. Confidentiality Obligation. Recipient will hold and maintain Discloser’s Confidential Information in strictest confidence for a period of three (3) years, exercising at least the same degree of care as Recipient customarily exercises to protect its own like information, but no less than reasonable care; provided that, with respect to Confidential Information that constitutes a trade secret under applicable law, Recipient agrees to hold and maintain such Confidential Information in strictest confidence until it no longer qualifies as a trade secret under applicable law. Without the prior written consent of Discloser, Recipient will not use or disclose any portion of the Confidential Information in any manner whatsoever to any person or entity other than its directors, officers, employees, attorneys, agents, legal counsel, or consultants (each a “*Representative*”) who reasonably need access to the Confidential Information and are bound to protect its confidentiality. Each Party shall take reasonable steps to ensure compliance with this Agreement by its Representatives, and shall be responsible for any breach of this Agreement by its Representatives. Recipient shall not reverse engineer, disassemble, or decompile any prototypes, software, samples or other elements that embody Discloser’s Confidential Information. Each Party agrees that it and its agents, representatives and employees shall not use, reproduce, distribute or disclose the Information in any way that is detrimental to the other Party. Recipient shall have the right to refuse to accept any of Discloser’s Confidential Information under this Agreement prior to any disclosure. Recipient shall promptly notify Discloser of any actual or suspected unauthorized use or disclosure of Discloser’s Confidential Information of which Recipient becomes aware.

5. Compelled Disclosure. Notwithstanding the foregoing, disclosure of

Confidential Information by a Recipient shall not be precluded if such disclosure is legally compelled, provided that Recipient provides prompt written notice to the Discloser sufficiently in advance to permit the Discloser to contest the disclosure or seek an appropriate protective order. If disclosure is required despite the opposition of Discloser, Recipient will disclose only that portion of the Confidential Information that is legally required and will cooperate with Discloser in seeking assurances from the applicable court or agency that the Confidential Information will be afforded confidential treatment and further dissemination thereof restricted.

6. **No License.** All Confidential Information will remain the property of the Discloser. No right or license is granted to Recipient, for any use of or interest in the Confidential Information.

7. **Termination & Survival.** This Agreement is effective as of the Effective Date and shall continue in full force and effect until the three (3) years after the termination of Member’s Membership Agreement.

8. **Remedies.** Without prejudice to the rights and remedies otherwise available to Discloser, Discloser may be entitled to equitable relief by way of injunction if there is a breach or threat of breach of any of the provisions of this Agreement by the Recipient. The Parties acknowledge and agree that damages may not be an adequate remedy in the event of a breach of this Agreement.

9. **IN WITNESS WHEREOF**, intending to be legally bound hereby, and upon due authorization, the Parties have executed this Agreement as of the Effective Date.

CEDARS-SINAI MEDICAL CENTER

MEMBER

By: _____
Nicole A. Leonard, JD, MBA
Vice President of Research and
Assistant Dean
Date: _____

By: _____
Name: _____
Title: _____
Date: _____