

LINKAGE HONEST DATA BROKER AGREEMENT

This linkage honest data broker agreement (the “**Agreement**”) is between the REGENSTRIEF INSTITUTE, INC., (“**Regenstrief**”) a contractor for the U.S. Government, the NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (“**NCATS**”), and (“**Participating Site**”)(together, Regenstrief, NCATS and the Participating Site are the “**Parties**” and each individually are a “**Party**”) and will become effective on the date of the last signature below.

Whereas, NCATS has contracted with Regenstrief for honest data broker services to enhance the NCATS N3C Enclave’s, research capabilities and support compliance with the NCATS N3C Enclave’s Data Transfer Agreement’s prohibition against re-identifying individuals.

Whereas, executing this agreement is voluntary; Participating Site is not required to use Regenstrief’s honest broker services for the Participating Site to contribute their data to the NCATS N3C Data Enclave, formerly known as the NIH COVID-19 Data Warehouse.

Whereas, in executing this Agreement, the Participating Site will have access to Regenstrief’s secure, pseudonymized privacy-preserving Deduplication, Record Linkage, Cohort Discovery and other related services. Participating Site is allowed to utilize all or a limited scope of services offered by Regenstrief.

Participating Site can be assured that Regenstrief and tokenization software vendor will not have access to the Participating Site’s Health Data and NCATS will not have access to the Participating Site’s Tokens.

The Parties therefore agree as follows:

- Section 1. **Definitions.** Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations or the Data Transfer Agreement, as the case may be. The following definitions apply:
- 1.1 **“Cohort Discovery”** means the process for enabling authorized researchers to query the N3C Enclave for de-identified subjects meeting specified inclusion and exclusion criteria.
 - 1.2 **“Deduplication”** means eliminating duplicate or redundant information within a data source.
 - 1.3 **“Health Data”** means the Participating Site’s information related to an individual’s medical history, including but not limited to structured information such as demographics, vital signs, diagnoses, procedures, admission, discharge and transfer information and semi-structured information, including laboratory tests and results, medications, imaging, waveform, variants etc. Health Data that includes real dates and zip codes is a Limited Data Set as defined herein. Health Data is referenced in the Data Transfer Agreement as Data.

- 1.4 **“Limited Data Set”** is Protected Health Information that excludes certain direct identifiers of the individual or of relatives, employers, or household members of the individual as defined by Section 164.514(e)(2) of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and its implementing regulations at 45 CFR Parts 160 and 164 (the “HIPAA Regulations”). If a Participating Site is a Covered Entity as defined under the HIPAA Regulations, the Health Data submitted to the NCATS N3C Enclave per the Data Transfer Agreement is a Limited Data Set.
- 1.5 **“Metadata”** means a set of data that provides a structural or administrative description about the Participating Site’s Health Data. Metadata does not include Health Data.
- 1.6 **“Privacy Preserving Record Linkage (PPRL) or Record Linkage”** means connecting records using secure, pseudonymization processes in a data set that refer to the same individual across different data sources while maintaining the individuals’ privacy.
- 1.7 **“Research”** means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.
- 1.8 **“Token” or “Hash”** mean an encrypted value created by an irreversible conversion algorithm and any underlying Protected Health Information that has been de-identified using the expert determination method as described under HIPAA regulations at 45 CFR 164.514(b)(1).

Section 2. **Regenstrief’s Obligations.**

- 2.1 Regenstrief will only receive and have access to the Participating Site’s Tokens and Metadata. Regenstrief will not receive or have access to any Health Data. If Regenstrief’s tokenization software vendor has access to Health Data, per Section 4.4 of this Agreement its access would be solely through the Participating Site and not Regenstrief or NCATS.
- 2.2 Regenstrief will not use or further disclose the Participating Site’s Tokens or Metadata other than as permitted or required by this Agreement.
- 2.3 Neither Regenstrief nor its tokenization software vendor will disclose the hashing algorithm key used to create the Participating Site’s Tokens.
- 2.4 Regenstrief will secure the Tokens and Metadata from unauthorized access, use or disclosure in the same manner and using the same degree of care as Regenstrief would govern and protect its own information. The unauthorized

access, use or disclosure of information may be subject to criminal or civil penalties, identity theft, personal financial loss or invasion of privacy.

- 2.5 Regenstrief will not attempt to re-identify, nor attempt to contact any communities or populations associated with particular Health Data; or to re-identify or contact individuals, their relatives or relevant groups who are or who maybe the subject of the Participating Site's Health Data.
- 2.6 Regenstrief will not disclose the Participating Site's Tokens to NCATS.
- 2.7 Regenstrief will report the discovery of any unauthorized use or disclosure of or access to the Participating Site's Tokens to both the Participating Site and NCATS at NCATSDataAccessIncidents@nih.gov no later than 2 business days after discovery.
- 2.8 Regenstrief will ensure that its employees, agents, subcontractors and service providers agree to the same obligations and conditions contained in this Agreement and in the N3C Data User Code of Conduct: <https://ncats.nih.gov/n3c/resources/data-user-code-of-conduct> as applicable.
- 2.9 Regenstrief will provide the Participating Site with tools, methods, and support to create Tokens.

Section 3. **NCATS Obligations.**

- 3.1 NCATS will provide Regenstrief the N3C research identifier for the Participating Site's Health Data within the NCATS N3C Data Enclave.
- 3.2 NCATS will not request for access nor access the Participating Site's Tokens.
- 3.3 NCATS will arrange for tokenization software to be provided at no charge to the Participating Site.

Section 4. **Participating Sites Obligations.**

- 4.1 The Participating Site will not transfer, disclose, or provide access to any Health Data under this Agreement to any Party.
- 4.2 The Participating Site will or will have executed a separate Data Transfer Agreement with NCATS facilitating the transfer of its Health Data to the NCATS N3C Data Enclave. A sample Data Transfer Agreement can be found at <https://ncats.nih.gov/n3c/resources/data-contribution>.
- 4.3 The Participating Site shall agree to a version of the tokenization software license, and will be responsible for tokenization software license compliance and tokenization software maintenance (e.g. upgrades, patches, etc.) in accordance with the tokenization software vendor's instructions. A template of

the tokenization software license can be found in Exhibit A. Participating Site will maintain this license so long as the Linkage Honest Broker Agreement is active. Under this agreement, Participating Site will not share Health Data, including a Limited Data Set, with the tokenization software company for N3C related activities.

- 4.4 The Participating Site is responsible for determining if it needs to enter into a Data Use Agreement in accordance with 45 CFR 164.514(e)(4) with the tokenization software company with which it holds a license. If the Participating Site makes such determination, it is responsible for entering into the Data Use Agreement with the tokenization software company and agrees that NCATS and Regenstrief have no role in the tokenization software company's view of or access to Health Data.
- 4.5 The Participating Site will provide Regenstrief with Metadata describing Participating Site's data within the NCATS N3C Data Enclave.
- 4.6 The Participating Site shall securely transmit Tokens and Metadata to Regenstrief.
- 4.7 The Participating Site will coordinate with Regenstrief and its tokenization software vendor for implementing the tokenization process and improving record linkage quality.
- 4.8 At its own expense, the Participating Site will host and maintain an environment with the appropriate specifications and technical requirements to run the tokenization software. The Participating Site will maintain control over this environment at all times.

Section 5. **Permitted Uses.** Except as otherwise limited in the Agreement, Regenstrief may use the Participating Site's Tokens and Metadata for the following purposes:

- 5.1 **Deduplication.** Regenstrief may use the Metadata and Tokens to provide Deduplication services for N3C related projects.
- 5.2 **Privacy Preserving Record Linkage (PPRL).** Regenstrief may use the Metadata and Tokens to provide PPRL services for N3C related projects. "N3C-related projects" shall mean projects and Data Use Requests (DURs) that have been reviewed and approved by NCATS Data Access Committee and/or NIH IRB-approved dataset linkages.
 - (a) PPRL services will be reviewed and recommended by NCATS. NCATS may seek input from the N3C governance committee. Any PPRL services conducted will not result in the re-identification of any data.
- 5.3 **Cohort Discovery.** Regenstrief may utilize Tokens and Metadata at the request of a Participating Site and consistent with the NCATS N3C Data Enclave rules and

policies <https://covid.cd2h.org/PPRL> for possible follow-on clinical research. Please note that contact with individual patients is not permitted except by the Participating Site.

- 5.4 **Mapping.** Regenstrief will map the Tokens to N3C identification numbers in accordance with NCATS standard operating procedures, as may be amended from time to time, which are incorporated by this reference. NCATS shall make these standard operating procedures available upon written request by Participating Site.
- 5.5 **Governance and Compliance.** Regenstrief may use the Metadata and Tokens to ensure compliance with agreements and processes as required by NCATS.
- 5.6 **Technical Services.** Regenstrief may use Metadata and Tokens to improve any of the permitted services in Section 5, and to support and improve the Participating Site's tokenization process.

Section 6. **Term and Termination.**

- 6.1 **Term.** The initial term of this Agreement ends five (5) years following the date of the last signature and may be extended by the Parties' mutual consent.
- 6.2 **Termination.** Any Party may terminate this Agreement with thirty (30) days written notice to the other Parties.
- 6.3 **Effect of Termination.** After termination of this Agreement, Regenstrief will keep a copy of the Participating Site's Tokens and Metadata to ensure N3C related projects already in progress and utilizing such data may continue. Regenstrief will extend the protections of this Agreement to the Tokens and Metadata and limit any further use or disclosure of such Tokens and Metadata other than described in this Section 6.3, as long as Regenstrief maintains such Tokens and Metadata. Regenstrief will archive the Participating Site's Tokens and Metadata after the conclusion of all ongoing N3C related projects utilizing such data. At the request of NCATS, at any time after the termination of this Agreement, Regenstrief will return the Participating Site's Tokens and Metadata to the respective Participating site. The obligations under this Section 6.3. will survive any expiration or termination of this Agreement.

Section 7. **Assignment.** A Party shall not assign any of the Party's rights or delegate any of the Party's obligations under this Agreement to any other person or entity.

Section 8. **Modification; Waiver.** No amendment or waiver of this Agreement will be valid unless in writing and signed by each Party's authorized representatives.

Section 9. **Entire Agreement.** This Agreement constitutes the entire understanding between the Parties with respect to the subject matter of this Agreement and supersedes all other Agreements, whether written or oral, between all three Parties.

Section 10. **Notices.** For a notice or other communication under this Agreement to be valid, it must be in writing and delivered by electronic mail, return receipt requested, or by registered or certified mail, return receipt requested and postage prepaid.

10.1 A valid notice or other communication under this Agreement is effective when the Party receives the notice or communication and as follows:

- (a) If it is delivered electronic mail, return receipt requested, upon receipt as indicated by the date of the electronic receipt returned;
- (b) if it is delivered by registered or certified mail, return receipt requested and postage prepaid, upon receipt as indicated by the date on the signed receipt; or
- (c) if the Party to which it is addressed rejects or otherwise refuses to accept it, or if it cannot be delivered because of a change in address for which no notice was given, then upon that rejection, refusal, or inability to deliver.

10.2 A valid notice must use the information specified below:

To Regenstrief:
Regenstrief Institute, Inc.
1101 W. 10th Street
Indianapolis, IN 46202
Attention: Privacy Officer
Email: riilegal@regenstrief.org

To NCATS:
NCATS
9800 Medical Center Drive
Rockville, MD 20850
Attention: Office of Strategic Alliances (OSA)
Email: ncatspartnerships@mail.nih.gov

To Participating Site:

Attention:

Email:

Participating sites contact/alert email for Honest Broker Services:

Section 11. **Regulatory References.** A reference in this Agreement to a section in the HIPAA Regulations means the section in effect, or as amended.

Section 12. **Publicity and External Communications.** The Parties agree that each Party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other Parties provided that any such statement shall accurately and appropriately describe the relationship of the Parties and shall not in any manner imply endorsement by the other Parties whose name is being used.

Section 13. **Indemnity.** The Parties do not intend or provide indemnification for any loss, claim, damage, or liability under this Agreement.

Each Party is signing this Agreement on the date stated opposite that Party's signature.

Regenstrief Institute, Inc.

Date:

By: _____

Karen L Crow
Chief Financial Officer

National Center for Advancing Translational Sciences

Date:

By: _____

Krishna "Balki" Balakrishnan
Acting Director, Office of Strategic Alliances

Participating Site

Date:

By: _____

Exhibit A: Tokenization Software License Template

DATAVANT SITE LICENSE AGREEMENT

THIS DATAVANT SITE LICENSE AGREEMENT (this "**Agreement**"), is made and entered into as of the last signature date below (the "**Effective Date**") by and between Datavant, Inc. ("**Datavant**"), and LICENSEE ("**Licensee**").

- Section 1. **License.** Subject to the terms and conditions of this Agreement and during the Term (as defined below), Datavant hereby provides Licensee with a non-exclusive, non-sublicensable, non-transferrable, limited license to install and use Datavant's proprietary Datavant Solution (in object code form only) ("**Software**") solely for Licensee's internal use and for the purpose(s) and for the fee(s) set forth in an order form executed by the parties (each, an "**Order Form**") and only in accordance with all Datavant-provided documentation and instructions. Each Order Form is incorporated by reference into this Agreement; in the event of a conflict between the terms of an Order Form and this Agreement, the terms of this Agreement shall govern unless such Order Form explicitly references the section in this Agreement that is being amended for purposes of such Order Form. The Software will only be installed at the Licensee site(s) agreed to by the parties in writing (email is sufficient) ("**Site**"). For clarity, no source code will be provided to Licensee.
- Section 2. **Restrictions.** Licensee will not (and will not allow any third party to): (a) reverse engineer, disassemble, decompile, or otherwise attempt to discover any source code or underlying algorithms of the Software; (b) except as expressly permitted in the applicable Order Form, provide, lease, lend, use for timesharing or service bureau purposes or otherwise use or allow others to use the Software for the benefit of any third party; (c) use the Software to help develop any competitive product or service; (d) use the Software in violation of any laws, regulations, or third party rights, including the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("**HIPAA**"); (e) disclose any Software performance data to any third party (all such performance data is Datavant's Confidential Information (as defined below)); (f) take any action with the purpose of, or having the effect of, re-identifying any data that has been processed using the Datavant Solution; or (g) share its site-specific tokens with a third party or receive a third party's site-specific tokens (*i.e.*, all tokens sent and received by Licensee should be "transit" tokens, as described in the Software documentation). All the limitations and restrictions on the Software in this Agreement also apply to all Datavant-provided documentation.
- Section 3. **Feedback.** Notwithstanding anything else, Licensee grants to Datavant a perpetual, irrevocable, royalty free, paid-up, transferrable, sublicensable, right and license to use, display, reproduce, distribute and otherwise exploit Feedback (as defined below) for any purposes. Datavant agrees that (a) Licensee does not have to provide Feedback, and (b) all Feedback is provided "AS IS." "**Feedback**" means all suggestions for improvement or enhancement, recommendations, comments, opinions, code, input, ideas, reports, information, know-how or other feedback provided by Licensee (whether in oral, electronic or written form) to Datavant related to the Software or any Datavant-provided documentation.
- Section 4. **No Transfer of Protected Health Information; Personally Identifiable Information.** The parties agree and understand that, in order for Licensee to use the Software, Licensee does not share or transfer to Datavant any protected health information (PHI) (as such term is used in HIPAA) or personally identifiable information (PII) (as such term is defined by the National Institute of Standards and Technology Special Publication 800-122) of any third party.
- Section 5. **Confidentiality.** Each party acknowledges that, during the term of this Agreement, such party may be exposed to or obtain information that is proprietary or confidential to the other party and/or its affiliates. "**Confidential Information**" includes all information, written or oral, relating to the business, pricing of its products and services, operations, services, facilities, processes, methodologies, technologies, intellectual property, research and development, employees, patients, faculty and students, other consultants and authorized agents of Datavant, Licensee, or their respective affiliates. Each party shall hold the Confidential Information in strict confidence and not disclose the Confidential Information to third parties or use Confidential Information for any purpose other than for the performance of obligations hereunder. Without limiting the foregoing, each party shall be permitted to disclose Confidential Information to its officers and employees who have an absolute need to know such Confidential Information in order to fulfill such party's obligations hereunder and who are informed of and agree to be bound by the confidentiality obligations of this Agreement. Each party shall prevent any unauthorized use or disclosure of any Confidential Information. Each party shall promptly advise the other party in the event that it learns or has reason to believe that the other party's Confidential Information has been subject to an unauthorized disclosure. Notwithstanding the foregoing, the confidentiality obligations shall not extend to information that: (a) as of the time of its disclosure or thereafter becomes available to the public without breach of this Agreement or any other agreement or contractual obligation; (b) was rightfully known to the receiving party as of the time of its disclosure; (c) is rightfully learned by the receiving party from a third party not under a confidentiality

obligation; or (d) is required to be disclosed pursuant to a subpoena, court order, or government authority, whereupon the disclosing party shall provide prompt written notice to the other party prior to such disclosure, so that the other party may seek a protective order or other appropriate remedy. Upon termination of this Agreement or at such earlier time as the parties may direct, each party shall destroy or delete all of the other party's Confidential Information in its possession, including all copies thereof. Upon written request, such party shall certify to the other party in writing that all Confidential Information has been destroyed or deleted.

Section 6. Term and Termination. This Agreement shall begin on the Effective Date and end on the last day of the then-current Order Form, unless the parties execute a subsequent Order Form or this Agreement and all then-current Order Forms are earlier terminated in accordance with this Section 6 ("**Term**"). In addition, either party may terminate this Agreement if the other party materially breaches this Agreement and fails to cure such breach within fifteen (15) days from receipt of written notice thereof (email is sufficient). Upon any termination, Licensee shall immediately cease all use of the Software (and delete all copies of the Software). The following provisions will survive termination: Sections 2, 3, 5, 6, 7, 8 (with respect to attribution requirements), and 9.

Section 7. Warranties; Disclaimer; Limitations. Each party hereby represents and warrants that: it has the authority to enter into this Agreement, to grant the rights granted by it under this Agreement, and to perform its obligations under this Agreement. During the Term, Datavant represents and warrants that the Software (a) will not infringe any third party's U.S. intellectual property rights, (b) will substantially conform to the written documentation provided by Datavant regarding the Software, (c) will generate tokens that, if the initial identifiable data is properly inputted into the Software in accordance with Datavant's guidelines, will be adequately de-identified (pursuant to HIPAA) as previously certified by a third-party expert statistician, and (d) will, at the time of delivery and to Datavant's knowledge, be free of all viruses, time bombs, Trojan horses, or other malicious code. Use of the Software in breach of Section 2 or the Software Documentation shall void Datavant's warranties in this Section 7. EXCEPT AS PROVIDED IN THIS SECTION 7, THE SOFTWARE IS PROVIDED "AS IS" AND DATAVANT, ITS LICENSORS AND OTHER PROVIDERS DISCLAIM ALL WARRANTIES, BOTH EXPRESS AND IMPLIED. NEITHER PARTY SHALL BE LIABLE WITH RESPECT TO INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF FORESEEABLE AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL PARTY'S MAXIMUM AGGREGATE LIABILITY UNDER THIS AGREEMENT AND ANY ORDER FORM EXCEED THE TOTAL AMOUNT PAID TO DATAVANT PURSUANT TO THIS AGREEMENT AND ALL ORDER FORMS (OR, IF THERE HAVE BEEN NO PAYMENTS, THE CAP WILL BE \$1000). LICENSEE ACKNOWLEDGES THAT IT IS RESPONSIBLE FOR ENSURING THAT ANY DATA SETS USING OUTPUTS FROM THE SOFTWARE ARE DE-IDENTIFIED IN ACCORDANCE WITH APPLICABLE LAWS, INCLUDING, BUT NOT LIMITED TO, HIPAA; EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 7, DATAVANT DOES NOT MAKE ANY WARRANTIES WITH RESPECT TO THE ADEQUACY OR LEGAL COMPLIANCE OF SUCH OUTPUT, AND LICENSEE ACKNOWLEDGES AND AGREES THAT IT, NOT DATAVANT, IS RESPONSIBLE FOR OBTAINING ANY NEEDED CERTIFICATION(S) FROM AN EXPERT.

Section 8. Customer Name and Attribution. During the Term, Datavant may include Licensee's name as part of a general list of customers (on its website and in other marketing materials). Other than uses of Licensee's name and logo in general customer lists, Datavant shall not use the name, logo, insignia, symbol or trademark of Licensee without Licensee's prior written consent. In the event Licensee or a third party acting on behalf of Licensee elects to publish any academic report or other publication that is developed (in whole or part) using the Software (such as a publication that incorporates data processed by the Software), Licensee will ensure such publication contains reasonable attribution to the Datavant Solution.

Section 9. Miscellaneous. Neither this Agreement nor the licenses granted hereunder are assignable or transferable; any attempt to do so shall be void. Notwithstanding the foregoing, Datavant may assign or transfer this Agreement to an affiliate or to a successor entity upon a change of control event (or the sale of all or substantially all assets of Datavant). Any notice, report, approval or consent required or permitted hereunder shall be in writing to a party's address set forth below (except to the extent email is authorized herein). If any provision of this Agreement shall be adjudged by any court of competent jurisdiction to be unenforceable or invalid, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable. This Agreement shall be deemed to have been made in and shall be construed pursuant to the laws of the State of Delaware without regard to conflicts of laws provisions thereof, and without regard to the United Nations Convention on the International Sale of Goods. Jurisdiction and venue for all claims arising hereunder will be the state and federal courts located in San Francisco, California. Any waivers or amendments shall be effective only if made in writing. This Agreement is the complete and exclusive statement of the mutual understanding of the parties and supersedes and cancels all previous written and oral agreements and communications relating to the subject matter of this Agreement.