# Data Exchange and Use Agreement

This Agreement between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("Stanford"), an institution of higher education having corporate powers under the laws of the State of California, and [NAME] ("[COUNTERPARTY]"), a [corporation, LLC, Not-for-Profit, Academic Institution] having a principal place of business at [ADDRESS], is effective on the day of 20 ("Effective Date").

Dr. [NAME] (“Principal Investigator”) of Stanford conducts research in the area of [FIELD of EXPERTISE]. Principal Investigator seeks to collaborate with [CounterParty] in furtherance of the Research Project [Protocol #], titled “[Title of Research Project]” (“Protocol” or “Project” as the case may be). This Protocol or Project is supported by federal grant from the [Government Entity] who is afforded rights dire[COUNTERPARTY]y through a separate agreement from [NAME]. Stanford will [choose: share or receive] certain [Protected Health Information] and other Data. [CounterParty] will make certain [describe Data if not De-Identified] De-identified Data available to Principal Investigator. This Agreement sets forth the terms and conditions under which data will be exchanged, shared and used. The parties hereby agree as follows:

# DEFINITIONS

# “Applicable Law” shall mean all Federal, state and local laws and regulations to the extent applicable to the terms of this Agreement, including without limitation, (i) Federal Food, Drug, and Cosmetic Act (“FDCA”), (ii) HIPAA and the HITECH Act, in each case as the same may be amended or supplemented from time to time.

# "Breach" shall have the meaning set forth in 45 C.F.R. 164.402

# “De-identified Data” or “Limited Data Set,” as the case may be, means that subset of data and information subject to transfer in accordance with this Agreement that constitutes an individual’s information that has been de-identified pursuant to the HIPAA Privacy Rule, (45 CFR 160 and 164), provided by the [COUNTERPARTY] to Stanford under an [IRB] approved Protocol and which is/was collected in accordance with the standard patient informed consent procedures of the [COUNTERPARTY] in effect at the time of collection and/or pursuant to approval by the IRB.

# "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), Title XIII of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), and implementing regulations promulgated by the United States Department of Health and Human Services, including, but not limited to the Privacy, Security, Breach Notification and Enforcement Rules (45 C.F.R. Parts 160, 162 and 164), as may be amended from time-to-time.

# "Individually Identifiable Health Information" means information that is a subset of health information, including demographic information collected from an individual, and; is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and 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.

# Intellectual Property Rights” means patents, copyright and similar rights under the applicable laws of any government authority, domestic or foreign, including without limitation all applications and registrations relating to any of the foregoing.

# “Institutional Review Board” or “IRB” means, including an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), which is/are committee(s) designated to safeguard ethical conduct of studies using human subjects by monitoring and reviewing biomedical and behavioral research under certain national and international laws, regulations, codes and/or norms.

# "Protected Health Information" or "PHI" means Individually Identifiable Health Information that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA regulations; or transmitted or maintained in any other form or medium as defined in 45 C.F.R. § 164.501. Protected Health Information excludes Individually Identifiable Health Information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g, and records described at 20 U.S.C. § 1232g(a)(4)(B)(iv).

# "PII" means information or data that (i) identifies an individual, including by name, signature, address, telephone number or other unique identifier, (ii) can be used to identify or authenticate an individual, including passwords, PINs, biometric data, unique identification numbers (e.g., social security numbers), answers to security questions or other personal identifiers, (iii) PHI under HIPAA and the HITECH Act and/or (iv) can be used in combination with other information or data to identify an individual, including but not limited to the individual's gender, race, income, date of birth, geographic location, school or workplace name, group affiliations, mental, emotional or physical characteristics, or other indirect identifiers.

# “Protocol” means the parameters and deliverables of the Research Project, as set forth in Schedule 1 appended to Exhibit A, attached hereto and made a part hereof.

# “Purpose” means use as part of and in furtherance of the Research Project and in all cases including not-for-profit research and educational use.

# “Research Project” means the project/protocol set forth on Exhibit A, attached hereto and made a part hereof.

# “Results” means all data and information developed in the performance of the Research Project and/or developed using the Data within the terms of the Agreement.

* 1. **“Security Incident”** means any actual or reasonably suspected: (i) loss or theft of Stanford Materials or Data; or (ii) unauthorized use, disclosure, alteration, destruction, acquisition of, unauthorized access to, or breach of confidentiality of, Stanford Materials or Data.

# “Stanford Materials” means data, information, intellectual property, analysis, methods, algorithms, processes, Protected Health Information, and Results which may be provided by Stanford in identifiable form, related to Data or this Agreement, including without limitation, that data set forth in the approved Protocol.

# “Study Data” means data and information collected for purposes of conducting the Research Project [and collected in accordance with the standard patient informed consent procedures of the [COUNTERPARTY] in effect at the time of collection and/or pursuant to approval by the IRB.]

# GRANT OF RIGHTS; FEES

* 1. **License Grants.** 
     1. **[COUNTERPARTY] Grant**. Subject to the terms and conditions of this Agreement, [COUNTERPARTY] hereby grants Stanford a non-exclusive right and license to use the Data to advance the objectives of Research Projects and that fall within the general purpose of the approved Protocols. For use of the Data for objectives that fall outside of the general purpose of the approved Protocol, an amendment to this Agreement will need to be subject to IRB approval, if required by law, and signed by the both parties.
     2. **Stanford Grant**. Subject to the terms and conditions of this Agreement, Stanford hereby grants to [COUNTERPARTY] a nonexclusive right and license to use the Stanford Material solely for the purposes described in the Protocol.
  2. **Rights Reserved.** Rights not conferred are expressly reserved. All rights in Stanford Materials not expressly granted to [COUNTERPARTY] are reserved by Stanford; all rights to Data not expressly granted to Stanford are reserved by [COUNTERPARTY] including any right: (i) to sell, sublicense, or rent Data, Results or Stanford Material to third parties; or (ii) of one party to permit access to the databases of the other party or to anyone other than authorized employees or contractors of such party unless otherwise provided hereunder. Furthermore, notwithstanding Section 2.1, this Agreement does not constitute, grant nor confer any license under any patents or proprietary interests of either Party to the other except Stanford may freely publish Results in accordance with the terms of Section 7 as well as permit access to Data to anyone agreeing to be bound by these terms and to the extent furthering the aims of the Research Project, including authorized current and former employees, visiting faculty, students and/or fellows, collaborators or contractors to the extent necessary to complete the Research Project.
  3. **Fees.** Fees payable for Data use are set forth in the table contained in Exhibit B, attached hereto and made a part of this Agreement.

# SCOPE OF USE; RESTRICTIONS

# Scope of Use. Data may be used for the Research Project and for purposes of advancing science, deriving outcomes, and generating the Results. The Parties acknowledge that the Data [and Stanford Materials] is/are valuable and that except as expressly permitted only authorized personnel, contractors and agents agreeing to abide by the protections set forth herein are the only persons permitted to use the Data under this Agreement. Each party agrees to use the non-owning or non-controlling party’s Data and/or Stanford Materials, as the case may be, only in connection with this Agreement and to hold the other party’s data and materials in strict confidence otherwise. The Parties agree not to disclose, share, sell or allow access to any of the Data except as expressly permitted by this Agreement. Furthermore, with regard to PII/PHI received in connection with the Data transfer, Stanford [or COUNTERPARTY, as the case may be] shall (i) ensure that all appropriate technical and organizational safeguards are taken to protect the Data against unauthorized disclosure or access and (ii) notify [COUNTERPARTY] promptly of any communication received from an individual who is the subject of such Data.

# Restriction on Scope. Subject to Section 3.1, researcher may use the Data only in connection with the Research Project solely for the following Purpose: (i) academic research and publication of academic papers in accordance with Section \_\_(Publications) hereof.

# PRIVACY AND SECURITY

* 1. **Privacy Rule.** The Data may be used for the Research Project pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164 and sets forth the terms and conditions under which [COUNTERPARTY] will disclose certain Protected Health Information (PHI) to Stanford. All terms used in this agreement are as defined in the Privacy Rule.
  2. **Standards that Apply:**
     1. Stanford’s use the Data solely for the Research Project and in accordance with the terms of this Agreement; and
     2. retain ultimate control over Data received from [COUNTERPARTY] regardless that Stanford may share the Data with authorized personnel, contractors, agents and third parties on a need to know basis to further the aims of the Research Project.
  3. **Privacy Related Restrictions on Data Use.** Stanford agrees that it, its personnel or any third party acting for or on Stanford’s behalf or in conjunction with the research, including but not limited to, any visiting faculty, graduate students, research assistants or subcontractors shall not:
     1. use the Data to establish the individual identities of any of the subjects from whom the Data were obtained.
     2. publish any Data in a manner that would allow it to be directly re- identified, de-anonymized or disaggregated in whole or part from the Data;
     3. take any action with or make any use of the Data not otherwise permitted under Applicable Law.

# Data Overlays. Notwithstanding anything to the contrary in the foregoing, Stanford agrees not to perform linkages of any De-Identified Data which would result in the re-identification of a particular individual or entity. However, Stanford shall not be prohibited from overlaying data on any De-Identified Data set or subset thereof so long as the same is solely for purposes reasonably contemplated by, and for purposes of furthering the aims of, the Research Project.

* 1. **Appropriate Security Safeguards.** Stanford will use appropriate physical, technical and administrative safeguards to prevent use or disclosure of the information other than as provided for by this Agreement.
  2. **Breach Notification.** Stanford will promptly report to [COUNTERPARTY], and at least within five (5) days of Stanford’s discovery of a breach, any use or disclosure of the Data not allowed by this Agreement (for purposes hereof, “discovery” shall have the meaning ascribed to it in 45 CFR § 164.404(a)(2)). The parties will promptly confer and agree on legally required steps Stanford should take to minimize the harm (if any) resulting from such breach. [COUNTERPARTY] will cooperate with Stanford in complying with such steps. In the event of actual or suspected unauthorized disclosure of, access to, or other breach of the Data, Stanford will comply with all state and Federal laws and regulations related to such breach, and will cooperate with [COUNTERPARTY] in assisting it to fulfill its legal obligations.
  3. **Industry Standards for Data Transmittal.** [COUNTERPARTY] represents to Stanford that [COUNTERPARTY] will use the standards generally accepted in the data processing industry to transmit the Data as required by this Agreement in a protected and secure manner.
  4. **Transmittal and Processing of Stanford Materials.** Stanford, as mutually agreed upon, will commence transferring Stanford Materials to [COUNTERPARTY] and, as mutually agreed upon, will continue to provide Stanford Materials to [COUNTERPARTY], including any historical Stanford Materials to the extent available, on a per request basis, by delivery of a mutually agreed electronic means (e.g., magnetic tapes, internet protocol, CDs, etc.).
  5. **No Guarantee of Transmittal by Stanford.** In the event Stanford in good faith reasonably believes that Stanford is prohibited by Stanford policy or applicable law, rule, regulation, court action, or contract from providing all or any part of the Stanford Materials to [COUNTERPARTY] in the form described herein, then Stanford may withhold such Stanford Materials to the extent of such prohibition. The parties agree, upon the occurrence of any such withholding, to cooperate as may be necessary to provide to [COUNTERPARTY] as much of the Stanford Materials as may lawfully be provided as soon as that may practicably be accomplished, which cooperation may include such measures as modifications to the methods and/or process by which Stanford Materials is transferred.
  6. **Combining Data Sets.** Stanford may combine the Data with other data to be used in an aggregated, de-identified and consolidated form as may be contemplated by the Protocol.

# [COUNTERPARTY] USE OF STANFORD MATERIALS

* 1. **[COUNTERPARTY] Representations.** [COUNTERPARTY] represents to Stanford that:
     1. **Appropriate Safeguards.** [COUNTERPARTY] is required to comply with all Applicable Law, including the HITECH Act and HIPAA. [COUNTERPARTY] will ensure that any authorized agents and contractors, to whom it provides the Stanford Materials to agrees to the same restrictions and conditions that apply to the [COUNTERPARTY] with respect to such information.
     2. [COUNTERPARTY] certifies that (i) the Data and information was collected in accordance with the informed consent provided by the individuals to whom it relates and that such informed consents do not prevent the use of the Data or subject information for the Purpose set forth herein or (ii) there is no informed consent and [COUNTERPARTY]'s IRB has determined that no such consent is required. Stanford is responsible for obtaining and complying with any review or approval required by Stanford's IRB or by Recipient's policies. [COUNTERPARTY]'s obligation to provide the Data or subject information shall be subject to approval of this transfer by the [COUNTERPARTY] IRB.
     3. [COUNTERPARTY] certifies that the Information does not contain any human subject data that will allow a subject to be identified. If any Data or information that constitutes or includes PHI, is transferred unintentionally, upon discovery by Stanford or notification to Recipient by [COUNTERPARTY], the PHI shall be destroyed to the extent allowable by Applicable Law.
     4. **Breach Notification.** [COUNTERPARTY] will promptly report to Stanford, and at least within five (5) days of [COUNTERPARTY]’s discovery of such breach, any use or disclosure of the Stanford Materials not provided for by this Agreement (for purposes hereof, “discovery” shall have the meaning ascribed to it in 45 CFR § 164.404(a)(2)). The parties will promptly confer and agree on legally required steps [COUNTERPARTY] shall take to minimize the harm (if any) resulting from such breach. Stanford will cooperate with [COUNTERPARTY] in complying with such steps. In the event of actual or suspected unauthorized disclosure of, access to, or other breach of the Data, [COUNTERPARTY] will comply with all state and Federal laws and regulations related to such breach, and will cooperate with Stanford in fulfilling its legal obligations.
  2. **[COUNTERPARTY] Use of Stanford Materials.** [COUNTERPARTY] agrees that it (or any third party acting for or on the [COUNTERPARTY]’s behalf) shall not:
     1. Further disclose the Stanford Materials other than as permitted by the Protocol or as otherwise required by law.
     2. Use or disclose Stanford Materials, including all Protected Health Information, for any other reason than to perform its functions identified in the Protocol.
     3. Except as allowed by the Protocol, combine Stanford Materials with other data that may reasonably allow for the re-identification, de-anonymization or disaggregation of the Stanford Materials or
     4. publish any identifiable Protected Health Information, re-identified, de-anonymized or disaggregated data derived in whole or part from the Stanford Materials.

# INTELLECTUAL PROPERTY

* 1. **Ownership of Data; Ownership of Results.** 
     1. All Data shall be owned exclusively by [COUNTERPARTY]. To the extent Stanford has or acquires any rights in or to the Data, Stanford and Stanford’s researcher each hereby irrevocably assigns, transfers and conveys to [COUNTERPARTY] all of its right, title and interest in and to the Data, excluding any modifications, enhancements or derivative works developed by Stanford using the Data. For clarity, summaries, analyses and interpretations of the Data generated by Researcher pursuant to this Agreement shall not be considered "Data" and rights with respect to such summaries, analyses and interpretations shall be the property of Stanford. Furthermore, and notwithstanding anything to the contrary herein, to the extent Data cannot be segregated from the Results generated under the Protocol, [COUNTERPARTY] hereby grants to Stanford a fully paid, perpetual unrestricted right and license in and to that subset of Data necessary to fully exploit its rights in the Research Project and Results generated therefrom.
     2. As between [COUNTERPARTY] and Stanford, and subject to the various rights granted in this Agreement, Stanford owns and shall own all Intellectual Property Rights in and to the Stanford Materials, including without limitation any and all derivative work, as well as copyrights in the publications and materials prepared for academic use, excluding underlying original Data otherwise not critical to Stanford’s ownership rights in the Results.
     3. Use of Results. Patents and inventions shall be handled in accordance with Patent Rights Clause of 37 CFR 401.14. Stanford hereby grants to [COUNTERPARTY] an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use and reproduce any Results, for commercial purposes. Any transfer or sub-license of the Results to a third-party, including the federal government, requires the prior approval of Stanford.
  2. **No Other Intellectual Property Rights.** Except as specifically provided in this Agreement, neither party shall have any right or license by virtue of this Agreement to use or exploit any Intellectual Property Rights of the other party.

# PUBLICATION

# It is the intent of the Parties to freely publish and disseminate Results in the public interest. Consistent with its status as a non-profit educational and research institution, and its policies, Stanford may freely publish the Results of the Research Project and/or extrapolations or derivative work in academic journals, unpublished working papers, posters, academic presentations and reports so long as the Data used in the Results is de-identified and the Results do not contain raw data or data that may reasonably be re-identified.

# Stanford shall submit any proposed publication for review by [COUNTERPARTY] at least thirty (30) days prior to the publication date. Stanford agrees that if [COUNTERPARTY] reasonably determines that the proposed publication contains Confidential Information belonging to the [COUNTERPARTY], Stanford will remove any such Confidential Information if requested to do so before publishing. If [COUNTERPARTY] determines that the proposed publication contains patentable subject matter desires to have such subject matter protected by a patent application, Stanford agrees to delay publication for up to fifteen (15) additional days in order for a patent application to be filed. No right of manuscript approval is implied by this Section.

Language for Joint Rights to Publish:

[Alternative for Joint] **Publications**. It is expected that each Party may wish to publish separately or together the Results of the Research Project. Each Party shall have the right, consistent with academic standards, to publish or present the Results of the work performed in accordance with this Research Project. Each Party shall disclose to the other such publications and each agree to provide appropriate acknowledgment of the source of the Data or, in the case of materials, the Stanford Materials, in all publications. In order to safeguard intellectual property rights, the Party wishing to publish or otherwise publicly disclose the results of such research shall first submit a draft of the proposed manuscripts to the other for comment and consideration of appropriate patent action at least forty five (45) days prior to any submission for publication or other public disclosure. The parties will cooperate in good faith to determine mutually agreeable timing and content of any such publications, removing any Confidential Information as well as preserving the Intellectual Property Rights of the non-publishing party.

Notwithstanding the foregoing, in the event a joint publication was contemplated by the Parties hereunder and there has been no joint publication submitted within twelve (12) months of completion of the Research Project, each Party reserves the right to publish independently, so long as the Party wishing to publish or otherwise publicly disclose the Results shall first submit a draft of the proposed manuscripts to the other for comment and consideration of appropriate patent action at least forty five (45) days prior to any submission for publication or other public disclosure. The parties will cooperate in good faith to determine mutually agreeable timing and content of any such publications, removing any Confidential Information as well as preserving the Intellectual Property Rights of the non-publishing party. No right of manuscript approval is implied by this Section.

# CONFIDENTIALITY AND SECURITY

* 1. **Definition of Confidential Information.** “Confidential Information” means in relation to a party, confidential and proprietary information (whether in written, oral, or electronic form) that:
     1. is by its nature confidential; and
     2. if written, is designated by a “confidential” or “proprietary” marking; if verbally disclosed, identified as confidential at the time of disclosure and followed up with a written confirmation of confidentiality within ten (10) days of disclosure
  2. **Exceptions to Confidential Information.** Confidential Information shall not include information which can be demonstrated:
     1. to have been rightfully in the possession of the receiving party from a source other than the disclosing party prior to the time of disclosure of said information to the receiving party hereunder (“Time of Receipt”);
     2. to have been in the public domain prior to the Time of Receipt;
     3. to have become part of the public domain after the Time of Receipt by a publication or by any other means except an unauthorized act or omission by, or breach of this Agreement on the part of, the receiving party or its employees or agents;
     4. to have been supplied to the receiving party after the Time of Receipt without restriction by a third party who is under no obligation to the disclosing party to maintain such information in confidence; or
     5. is independently developed by the receiving party without the use of or reference to Confidential Information of the disclosing party.
  3. **Protection of Confidential Information.** Except as permitted in this Agreement, each party covenants and agrees that it shall hold (and shall cause its faculty, students, research assistants, employees, agents and subcontractors to hold pursuant to written agreements substantially similar to the confidentiality provisions set forth in this Agreement) confidential all Confidential Information (defined below) of the disclosing party and shall not use or disclose such Confidential Information, except as authorized in this Agreement, without the express written consent of the disclosing party. Each party shall take reasonable measures and efforts to provide protection for the disclosing party’s Confidential Information, including measures at least as strict as those the receiving party uses to protect its own Confidential Information of similar importance. The confidentiality obligations of the parties shall survive the termination or expiration of this Agreement.

[COUNTERPARTY] shall handle Stanford Materials, Protected Health Information and other Confidential Information with a standard of care at least as rigorous as the standard for which it maintains Protected Health Information or Confidential Information of other HIPAA covered entities for which it maintains PHI, which shall be materially similar to those specified in Stanford’s Minimum Security Standards for high risk data, located at https://itservices.stanford.edu/guide/securitystandards#security- standards-endpoints and in no case of a lesser standard of care as is reasonable and/or required by Applicable Law. This certification is a material representation of fact upon which reliance was place when this transaction was made or entered into. [COUNTERPARTY] will not handle or process any such Stanford Materials, Protected Health Information or other Confidential Information until such security standards are in place. [COUNTERPARTY] shall maintain and implement a comprehensive information privacy and security program that complies with HITECH, HIPAA, and the regulations and guidance’s issued thereunder by the U.S. Department of Health and Human Services (“HHS”). Without limitation, this includes administrative, technical and physical safeguards that are appropriate to the size and complexity of [COUNTERPARTY]’s operations and the nature and scope of its activities involving Protected Health Information.

* 1. **Employees and Agents.** Each party shall have the right to disclose the other party’s Confidential Information to those of its employees and agents who have a need to know such Confidential Information in order to exercise the receiving party’s rights or perform the receiving party’s obligations pursuant to this Agreement.
  2. **Preventing Unauthorized Use and Notice of Violation.** Each party shall use reasonable efforts to assist the other party in identifying and preventing any unauthorized use or disclosure of any Confidential Information. Without limiting the foregoing, each party shall immediately advise the other party in the event that it learns or has reason to believe that any person who has had access to the Confidential Information of such party has violated or intends to violate the terms of this Agreement, and shall cooperate if the disclosing party seeks injunctive relief against any such person.
  3. **Security Incident.** [COUNTERPARTY] shall notify Stanford of any Security Incident. Such notice shall summarize in detail the Security Incident and the corrective action taken or to be taken by the [COUNTERPARTY]. In the event of a Security Incident, [COUNTERPARTY] agrees to keep Stanford informed of progress and actions taken to resolve the Security Incident. Unless such disclosure or notification is mandated by law, Stanford in its sole discretion will determine whether to provide explicit notification to study participants concerning Security Incidents involving Stanford Materials or Protected Health Information. [COUNTERPARTY] will cooperate with Stanford in fulfilling all obligations. In the event of a Security Incident, the [COUNTERPARTY] shall:
     1. conduct a reasonable investigation of the reasons for and circumstances of the Security Incident;
     2. use reasonable and promptly take all necessary actions to rectify, prevent, contain and mitigate the impact of the Security Incident, and remediate the Security Incident; and
     3. collect, preserve and document evidence regarding the discovery and cause of, and vulnerabilities, response, remedial actions and impact related to the Security Incident, using means that shall meet reasonable expectations of forensic admissibility; and provide such documentation to Stanford upon request.
     4. cooperate fully with Stanford’s efforts to carry out the notification and mitigation requirements and will indemnify and reimburse Stanford for all of Stanford’s reasonable costs of complying with and carrying out such requirements.
  4. **Court Order.** If the receiving party receives a subpoena, court order or other validly issued administrative, regulatory or judicial notice requesting the disclosure of the disclosing party’s Confidential Information, the receiving party shall (to the extent legally permitted):
     1. promptly notify the disclosing party in writing to allow the disclosing party a reasonable opportunity to resist such disclosure and/or seek a protective order before the required time for disclosure; and
     2. if requested, provide reasonable assistance, at the disclosing party’s expense, to the disclosing party in resisting the disclosure and/or seeking a protective order to govern the disclosure. The receiving party shall be entitled to comply with such subpoena, court order or notice, but shall in doing so make every reasonable effort to secure confidential treatment of any Confidential Information it is compelled to disclose and shall not disclose any more Confidential Information than is necessary to comply with the subpoena or other process.

# REPRESENTATIONS AND WARRANTIES

# Stanford Representations. Stanford represents to [COUNTERPARTY] that:

# Stanford’s use of Data will not violate any applicable law, rule or regulation;

# the execution delivery and performance of this Agreement by Stanford will not violate any applicable law, rule or regulation;

# Stanford will comply with, and will cause its faculty, graduate students and research assistants and any party to which it provides access to Data to acknowledge and be aware of the applicable terms of this Agreement.

# [COUNTERPARTY] Representations. [COUNTERPARTY represents and warrants

# that it has full power and authority to enter into this Agreement and grant the rights and licenses hereunder.

# warrants that the Data does and will substantially conform and be transferred to Stanford in accordance with the Protocol and any other specifications set forth in research plans under the Research Project.

# it will perform, hereunder exceeding but in no event lesser than is consistent with generally accepted industry standards and in all cases pursuant to Applicable Law.

# INDEMNIFICATION AND DISCLAIMERS

* 1. **[COUNTERPARTY] Indemnification of Stanford.** [COUNTERPARTY] shall defend, indemnify and hold Stanford and its directors, officers, employees, students, agents, successors and assigns harmless, to the full extent permitted in law or equity, from and against any and all third party losses, claims, actions, damages, regulatory actions or investigations, liabilities, costs and expenses (including reasonable attorneys' fees and expenses), fines, penalties, judgments, and costs (including but not limited to the costs of providing appropriate notice to all parties and credit monitoring, credit rehabilitation, or other credit support services to individuals with information impacted by the actual or suspected breech, to the extent procured by [COUNTERPARTY]) (collectively, “Losses”) to the extent that Losses: (i) arise out of a breach of [COUNTERPARTY]’s obligations, (ii) arise out of [COUNTERPARTY]’s use, handling or storage of Stanford Material in a manner not permitted by the Protocol, or (iii) relate to gross negligence or intentional acts under this Agreement.
  2. **Stanford Indemnification of [COUNTERPARTY].** Stanford shall defend, indemnify and hold [COUNTERPARTY] and its directors, officers, employees, agents, successors and assigns harmless, to the full extent permitted in law or equity, from and against any and all direct third party Losses to the extent caused by or resulting from Stanford’s grossly negligent or intentional acts under this Agreement.
  3. **Disclaimer of Warranties.** Except as expressly set forth in this Agreement, Data, Stanford Materials and Results are provided “AS IS” without representation or warranty of any kind, either express or implied, and the parties hereby disclaims any and all representations and warranties, including without limitation any representations or warranties of merchantability or fitness for a particular purpose.

# INSURANCE

* 1. [COUNTERPARTY] will procure and maintain during the term of this Agreement comprehensive general liability insurance and cyber-insurance, including coverage for intellectual property and product liability, to the full amount of [COUNTERPARTY]’s

insurance limits, but in no event less than $2,000,000 per occurrence, with a reputable and financially secure insurance carrier. This insurance will be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. If [COUNTERPARTY]’s insurance is written on a claims-made basis, as opposed to an occurrence basis, [COUNTERPARTY] will purchase the coverage necessary to ensure continued and uninterrupted coverage of all claims, including those made after the policy expires or is terminated.

# RELATIONSHIP MANAGEMENT

* 1. **Contact Persons.** Each party will designate in writing a contact person to facilitate, coordinate, and oversee the performance of the parties’ respective obligations under this Agreement. Each party may replace its contact person by written notice to the other party. The initial contact persons will be designated by each party within a reasonable time after the Effective Date.
  2. **Ongoing Adaptation.** Both parties agree to cooperate in good faith with each other on an ongoing basis to adapt the parties’ arrangements under this Agreement to accommodate future changes in applicable law, relevant technology, or other changes in the relevant industry or environment. The parties shall cooperate in good faith to make any conforming amendments or modifications to this Agreement to accommodate the provision of Data to Stanford and the provision of Stanford Materials to [COUNTERPARTY].
  3. **Dispute Resolution.** In the event of a dispute arising out of or relating to this Agreement, the Parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. Either Party may, by written notice to the other Party, refer the dispute to the other Party for attempted resolution by formal good faith negotiation within thirty (30) days after such notice is received. If the dispute remains unresolved after the good faith negotiation period provided in the previous sentence, either Party by written notice to the other Party may have such issue referred for resolution to the [COUNTERPARTY NAME AND TITLE] and the Associate Vice President for Sponsored Research at Stanford (collectively, the "Executive Officers"). The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Executive Officers fail to resolve the dispute within thirty (30) days after it is referred to them, each Party shall have the right to pursue any other remedies legally available to resolve the dispute, including the right to terminate the Agreement, and the matter may be brought by a Party as a suit in a court of competent jurisdiction in accordance with Section 15.3 (Governing Law).
  4. **Remedies.** Each party shall be entitled to seek equitable relief, for the other party’s actual or threatened failure to abide by these provisions, in addition to all other rights and remedies available at law or in equity. Notwithstanding the procedure described in Section 6.2, each party shall be entitled to seek preliminary injunctive relief in any court of competent jurisdiction for the other party’s actual or threatened breach of this Agreement.
  5. **Limitation of Liability**. UNLESS OTHERWISE STATED IN THIS AGREEMENT, NEITHER PARTY WILL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES OF THE OTHER ARISING OUT OF ANY PERFORMANCE OF THIS AGREEMENT OR IN FURTHERANCE OF THE PROVISIONS OR OBJECTIVES OF THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

# PUBLICITY

Neither party will use the name or trademark of the other party in any publicity, advertising or announcement related to this Agreement without the prior written consent of the other party.

# TERM AND TERMINATION

# Initial Term; Renewal Term. This Agreement shall be effective as of the Effective Date, and the initial term thereof shall be one (1) year (“Initial Term”). At the end of the Initial Term, this Agreement may be renewed for successive renewal terms of one (1) year each, upon the written authorization of both parties. The Initial Term, along with any renewal term, shall be referred to as the “Term.”

* 1. **Term for Transfer of Data.** [COUNTERPARTY] will make the Data available to Stanford during the Term of this Agreement [or as otherwise agreed from [Date] to [Date].
  2. **Termination for Convenience.** Either party may terminate this Agreement for convenience with thirty (30) days’ written notice.
  3. **Termination for Cause.** Either party may terminate this Agreement by written notice if the other party has defaulted in any material obligation under this Agreement and failed to cure such default within thirty (30) days after written notice of the default from the terminating party, including, (i) breaches of its obligations under Section 2, 4, 5, 6, 8 or 9 of this Agreement, or (ii) violates any Intellectual Property Rights of the non- breaching party. Either party may terminate this Agreement immediately upon written notice if the other party (i) becomes insolvent or if a court of competent jurisdiction enters an order or decree in respect of such party under any bankruptcy or similar law approving a petition for reorganization or appointing a custodian for all or substantially all its assets or ordering the liquidation of such party.
  4. **Discontinuation of Use.** The parties acknowledge and agree that termination shall not affect rights accrued and/or surviving, subject to the terms of this Agreement. Upon termination or expiration of this Agreement, [COUNTERPARTY] will return or, at Stanford’s election, destroy all individual identifiers, included in Stanford Protected Health Information or other identifiable Stanford Materials immediately upon termination or conclusion of the Agreement.
  5. **Effect of Termination. Expiration of License.** With respect to Protected Health information or other materials subject to consent of the research subjects, the License expires automatically on [date], and [COUNTERPARTY] shall cause all agents, representatives, subcontracts, and collaborators to cease any such use and access after expiration of the license. For other Stanford Materials excluding Protected Health Information or other materials subject to consent of the research subjects, the License expires automatically on [date].

# GENERAL PROVISIONS

* 1. **Authority.** Each party represents and warrants to other that it has the full power and authority to enter into and perform this Agreement and all necessary legal, corporate, contractual, and other power and authority to grant the rights contemplated by this Agreement.
  2. **All Notices.** All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All notices to [COUNTERPARTY] are emailed or mailed to:

[ADDRESS]

[Attention]

All notices to Stanford are e-mailed or mailed to: Stanford University

Office of Sponsored Research 3160 Porter Drive, Suite 100 Palo Alto, CA 94304

Attn:

osr\_intake@stanford.edu; [hoac@stanford.edu](mailto:hoac@stanford.edu)

* 1. **Training.** [COUNTERPARTY] shall provide Stanford with reasonable training and support at its request for purposes of optimizing use of Data, including how Data may optimally be interpreted, as well as trouble-shooting technical questions of access and any other or further assistance as is reasonably necessary for Stanford to exercise its rights hereunder as well as to effectively and efficiently carry out the aims and goals of the Research Project.
  2. **Waiver, Amendment or Modification.** The waiver, amendment or modification of any provision of this Agreement or any right, power or remedy hereunder shall not be effective unless made in writing and signed by the Party against whom enforcement of such waiver, amendment or modification is sought. The terms of this Agreement shall not be added to, amended or modified by the terms of any purchase order, acknowledgement, or other form. No failure or delay by either Party in exercising any right, power or remedy with respect to any of its rights hereunder shall operate as a waiver thereof.
  3. **No Implied Obligations**. Nothing herein shall obligate either Party (or its respective representatives or appointees) to reach agreement on issues that are left open to the subsequent agreement of such Party (or its respective representatives or appointees). In addition, neither Party shall, by reason of any failure to reach agreement under the terms and conditions of this Agreement, be liable to the other for compensation, reimbursement or damages on account of any loss of prospective profits or on account of expenditures, investments, or other commitments made in connection with this Agreement or the anticipation of extended or expanded performance hereunder. Except as expressly provided, nothing in this Agreement is intended to prevent either Party from entering into agreements with Third Parties.
  4. **Governing Law; Severability.** The validity, construction and performance of this Agreement and the legal relations among the Parties hereto shall be governed by and construed in accordance with the laws of the State of California, excluding that body of law applicable to choice of law and the Parties consent to the jurisdiction of the courts of California State in connection with the resolution of any dispute among them arising from the validity, construction or performance hereof. If any provision of this Agreement or the application of any such provision shall be held by a tribunal of competent jurisdiction to be unenforceable or contrary to law, the remaining provisions of this Agreement shall continue in full force and effect.
  5. **Accrued Rights; Surviving Obligations**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, and shall not relieve either Party from its obligations which are expressly indicated to survive expiration or termination of this Agreement, including, without limitation, those under [Sections \_\_], shall survive any expiration or termination of this Agreement, unless otherwise stated not to survive the termination for cause or breach.
  6. **Integration.** This Agreement, including the attached Exhibits, supersedes all prior oral and written proposals and communications, if any, and sets forth the entire agreement of the parties with respect to the subject matter hereof, and may not be altered or amended except in writing, signed by an authorized representative of each party.
  7. **Headings.** No headings in this Agreement affect its interpretation.
  8. **Electronic Copy.** The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

[signature page to follow]

The duly authorized party representatives execute this Agreement, including all its terms and conditions.

|  |  |
| --- | --- |
| THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY | [COUNTERPARTY] |
| Signature | Signature: |
| Name: | Name: |
| Title: | Title: |
| Date: | Date: |

I acknowledge that I have read this Agreement in its entirety and will use reasonable efforts to uphold my obligations and responsibilities under this Agreement.

|  |
| --- |
| PRINCIPAL INVESTIGATOR |
| Signature: |
| Name: |
| Title: |
| Date: |

# Exhibit A

**Research Project**

**Schedule-1 to Exhibit A**

**Protocol**

**Exhibit B**

**Fees and Payment**