

CTSA Data Transfer and Use Agreement (“Agreement”)

Provider:	Recipient:
Provider Investigator: Name: Email:	Recipient Investigator: Name: Email:
Agreement Term: Start Date: Date of last execution below End Date: years after the Start Date	Project Title: Data Type:

Terms and Conditions

- 1) Provider shall provide the data described in Attachment 1 (the “Data”) to Recipient for the purpose set forth in Attachment 1 (the “Project”). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.
- 2) If applicable, reimbursement of any costs associated with the transfer of the Data to the Recipient will be addressed in Attachment 1.
- 3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project, and solely by Recipient Investigator, and Recipient’s faculty, employees, fellows, and students who are under obligations of use consistent with the terms of this Agreement (“Recipient Personnel”). No other use and or disclosure is permitted without Provider’s prior written consent.
- 4) Except as otherwise authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, without the prior written consent of Provider. The Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other obligations as may be set forth in Attachment 2.
- 5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research, including, as applicable, U.S. Public Health Service and National Institutes of Health regulations and guidelines such as those relating to use of data from human subjects.
- 6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days to review proposed manuscripts and ten (10) days to review proposed abstracts to ensure that the Data is protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.

- 7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards.
- 8) Unless terminated earlier in accordance with this section, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall promptly return to Provider or, at Provider's option, destroy all copies of Data as instructed by the Provider or in Attachment 2, provided, however, that Recipient may retain such copy of the Data (not to include Protected Health Information ("PHI") as defined in the Health Insurance Portability & Accountability Act of 1996, as amended) to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification. Upon Provider's request, Recipient shall confirm such destruction in writing.
- 9) Except as provided below, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding the foregoing, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.
- 10) Subject to the limits of, and without waiving any immunities provided under applicable law [including constitutional provisions, statutes and case law, regarding the status, powers and authority of the Institution or the Institution's principal(s)], the Parties agree to be responsible for their own negligent acts or omissions in the performance of their duties hereunder and shall be financially and legally responsible for all of their expenses, liabilities, and attorney fees resulting from or attributable to any such acts or omissions. Neither Party shall have an obligation to indemnify the other hereunder. The terms of this paragraph shall survive expiration of this Agreement.
- 11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. 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 party, 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 party whose name is being used.
- 12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:
 - I. Attachment 1: Project Specific Information
 - II. Attachment 2: Data-specific Terms and Conditions
- 13) The Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that their respective undersigned Authorized Officials are duly authorized to sign this Agreement on behalf of their institution.

<p>By an Authorized Official of Provider:</p> <p>_____</p> <p>Name: _____ Date _____</p> <p>Title: _____</p> <p><u>Contact Information for Formal Notices:</u></p> <p>Name: _____</p> <p>Address: _____</p> <p>Email: _____</p> <p>Phone: _____</p>	<p>By an Authorized Official of Recipient:</p> <p>_____</p> <p>Name: _____ Date _____</p> <p>Title: _____</p> <p><u>Contact Information for Formal Notices:</u></p> <p>Name: _____</p> <p>Address: _____</p> <p>Email: _____</p> <p>Phone: _____</p>
<p>READ and UNDERSTOOD:</p> <p>_____</p> <p>Name: _____</p> <p>Title: Provider Investigator</p> <p>Date: _____</p>	<p>READ and UNDERSTOOD:</p> <p>_____</p> <p>Name: _____</p> <p>Title: Recipient Investigator</p> <p>Date: _____</p>

Attachment 1

Project Specific Information

1. Description of Data:

Instructions to the drafter – complete to the level of detail required by your institution; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the information that will be transmitted under this DTUA. Examples of information that may be provided include:

- *Whether the data is obtained from human subjects and, if so, a description of the population included in the data.*
- *If the data is from animal subjects, the species of animal the data was obtained using.*
- *If not from human or animal subjects, a description of the focus of the data.*
- *The number of subjects and/or experiments included*
- *Name of the study that the data was obtained under*

If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here. Also include here reference to any specific method that will be used to transfer the data to the Recipient.

2. Description of Project:

Instructions to the drafter – complete to the level of detail required by your institution; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the project that the Recipient will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that may be provided include:

- *Objective or purpose of the Recipient's work*
- *A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results*

3. Reimbursement of Costs:

- None
- As governed by a separate written agreement between the parties
- As set forth herein:

Attachment 2

Data Transfer and Use Agreement Terms and Conditions for Limited Data Set

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of 45 CFR 164.514(e) if done by the Provider.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
3. Recipient shall promptly report to the Provider any acquisition, access, use or disclosure of the Data not provided for by this Agreement after becoming aware of any such acquisition, access, use or disclosure in breach of this Agreement. Should Recipient commit a breach of this Agreement, which is not cured within thirty (30) days of notice, then Provider will discontinue disclosure of Protected Health Information ("PHI") as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and will, when required, report the breach to the Secretary, Department of Health and Human Services.
4. Provider is a Covered Entity, and the Data will be a Limited Data Set as defined by HIPAA. The Data shall not contain any of the identifiers set forth in Section 164.514(e)(2) of the HIPAA regulations. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code. All PHI shall be kept in strict confidence without limitation of time.
5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Recipient and Provider shall use reasonable efforts to encrypt all PHI in transit or in storage.
6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB review or approval that may be required.
7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA, the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations (45 C.F.R. Parts 160-164).

Attachment 2
Data Transfer and Use Agreement
Terms and Conditions for
De-identified Data about Human Subjects

1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.
2. If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").
3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.
4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.
5. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware or as otherwise required by law.