***Text in red are instructions to the drafter and should be deleted prior to completion of the DTUA.***

***\*\*Please note that this DTUA is intended for use with de-identified data and Limited Data Sets from US-based Providers. If all or a portion of the data originates from outside of the US, this DTUA should only be used with fully anonymized data. \*\****

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| **FDP COVID-19 Data Transfer and Use Agreement (“Agreement”)** | |
| **Provider**: | **Recipient**: |
| Provider Scientist:  Name:  Email: | Recipient Scientist:  Name:  Email: |
| **Agreement Term:**  Start Date: Date of last signature below  End Date: *[Please insert a specific end date]* | **Project Title**: |
| **TERMS AND CONDITIONS**   1. Provider shall provide the COVID-19 related data set 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. 2. 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 Scientist and Recipient’s faculty, employees, fellows, students, agents, contractors, subcontractors, and collaborators who have a need to access the Data for the Project (“Authorized Users”). Recipient will ensure that any agent, contractor, subcontractor, or collaborator to whom Data is disclosed agrees to restrictions and conditions at least as restrictive as those that apply to Recipient under this Agreement. 3. Except as 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, except Authorized Users, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within five (5) business days of when it becomes aware of such use or disclosure. 4. Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such public health efforts and/or research. The Provider agrees that the transfer of the Data for this Project is compliant with its obligations under all applicable laws and regulations. 5. Recipient is encouraged to make publicly available the results of the Project. The parties will together make decisions on authorship of jointly authored publications, if any. Authorship will be in accordance with academic and/or scholarly standards. Recipient shall adhere to the following, if checked (*check at most one of the below*):   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 from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected.  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 ten (10) days from receipt to review proposed manuscripts and abstracts to ensure that the Data is appropriately protected.  Recipient shall notify Provider Scientist of each publication resulting from use of the Data upon acceptance for publication.   1. Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient’s research using the Data, as appropriate in accordance with applicable scholarly standards. 2. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code. 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. 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. 3. If checked, the Data constitutes a Limited Data Set as that term is defined by the 1996 Health Insurance Portability and Accountability Act, Public Law 104-191 (“HIPAA”), and the following terms apply: 4. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514. 5. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set. In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv)Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images. 6. 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. 7. If checked, the Data is, in whole or in part, from sources outside of the United States and has been anonymized or otherwise rendered not readily identifiable under all applicable laws and regulations. 8. This Agreement shall expire as of the End Date set forth above. Upon expiration of this Agreement, Recipient shall destroy or return the Data to Provider; provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under applicable law or regulation. 9. Except as provided below or prohibited by law, 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. 10. No assumption of liability or indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement. 11. Neither party shall use the other party’s name, trademarks, or other logos in any publicity, advertising, or news release. 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, 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 Attachment 1 embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project. 13. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly- authorized representatives of both parties. 14. The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution. 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. | |
| By an Authorized Official of Provider:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_  Name: Date  Title:  Contact Information for Formal Notices:  Name:  Address:  Email:  Phone: | By an Authorized Official of Recipient:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_  Name: Date  Title:  Contact Information for Formal Notices:  Name:  Address:  Email:  Phone: |

**Attachment 1**

Project Specific Information

**Description of Data**: *Please describe the Data in sufficient detail below (type of data, amount of data, source of data) so that each party understands the information that will be transmitted under this Agreement.*

**Description of Project**: *Please describe the Project in sufficient detail below so that each party understands the Project to be undertaken using the Data.*