NIH COVID-19 Data Warehouse
Data Transfer Agreement ("Agreement")

This Data Transfer Agreement ("Agreement") is between the National Center for Advancing Translational Sciences (NCATS) a component of the National Institutes of Health ("Recipient") and _____ ("Provider") and will become effective on the date of the last signature below.

The NIH COVID-19 Data Warehouse is an NIH data sharing resource, operated under a contract containing clinical and imaging data from individuals who have received a Coronavirus Disease 2019 ("COVID-19") test or whose symptoms are consistent with COVID-19. Data will also be collected from individuals infected with pathogens such as SARS 1, MERS, and H1N1 to support comparative studies. Addressing the COVID-19 pandemic requires that researchers, clinicians, and heath care providers have available and can make use of all relevant data needed to address this unprecedented crisis. Therefore, this data warehouse will accelerate discovery using near real-time data and observational research, clinical studies and clinical trials, and will bring these data to bear on COVID-19. This solution requires a single computational environment to support public health actions, clinical care, policy, and science underpinning vaccines, prophylaxis, and treatment. The data warehouse is a highly interoperable, secure, clinical data research environment that will harmonize clinical and patient data.   The NIH COVID-19 Data Warehouse will serve as a national resource to address the COVID-19 pandemic, as well as demonstrate coordination of clinical and patient data, setting an example for how to approach urgent research needs during future healthcare challenges.

The NIH COVID-19 Data Warehouse is being created by NIH as part of the government response to fight the COVID-19 pandemic and protect the public health. NIH intends to provide access to and use by researchers for public health purposes and decision making, including conducting and supporting research to define the clinical natural history of COVID-19 infection and assess therapeutic responses and outcomes, and conducting and supporting a broad range of studies, including the identification of COVID-19 risk factors and development of effective countermeasures and diagnostics.

Terms and Conditions

1)   Provider shall provide the data set described in Attachment 1 ("Data") to Recipient.

2)   Provider agrees that it has the legal authority to provide the Data to Recipient for the uses of the NIH COVID-19 Data Warehouse described in this agreement.

3)   Recipient shall not use the Data except as authorized under this Agreement. The Data will be deposited in the NIH COVID-19 Data Warehouse and made accessible to users

under a separate data use agreement to support the response to the COVID-19 pandemic. Users who access the Data will:

- only analyze the Data within the NIH COVID-19 Data Warehouse platform.
- not be able to download or remove the Data from the NIH COVID-19 Warehouse in any form.
- share the results of analyses within the platform to the extent possible
- make no effort to contact or identify individuals who are or may be the sources or subjects of the Data
- agree to acknowledge the NIH COVID-19 Data Warehouse in all publications and oral disclosures that rely on the Data
- be used only for research purposes and public health activities related to the COVID-19 pandemic

4)   Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations.

5)   Provider agrees to be identified as a data contributor on the NIH COVID-19 Data Warehouse website.

6)   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.

7)   Except to the extent prohibited by law, the Recipient is responsible for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

8)   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.

9)   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

10) The term of this Agreement is five (5) years from the date of last signature and may be extended upon mutual consent of both parties. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

11)   Should the Provider no longer be able to or willing to participate in the NIH COVID-19 Data Warehouse, Provider may request to terminate this agreement with 30 days written notice. Once Data has been ingested and uploaded into the NIH COVID-19 Data Warehouse, it cannot be destroyed and must be retained. Recipient agrees to keep a copy of Data and will generate a new version of the data set for use that no longer contains the Provider's withdrawn Data. For clarification purposes, researchers who have previously utilized the Data, prior to Provider's termination, will be allowed to continue their ongoing research as well as validation and confirmation of future findings.

12) Provider acknowledges that once data are uploaded to the NIH COVID-19 Data Warehouse, the data will be protected from disclosure by a Certificate of Confidentiality per Section 301(d) of the Public Health Service Act (42 USC 241(d)), as amended by Section 2012 of the 21st Century Cures Act, P.L 114-255", and the NIH Policy on Certificates of Confidentiality. Recipient will be bound by the terms of the Certificate and will be unable to redisclose the data except as permitted by the terms of the Certificate, including to Provider. Provider acknowledges that even if a copy of the data is provided by Recipient, the copy of the data is still protected by the Certificate.

13) 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.

<div align="center">Signatures Begin on Next Page</div>

For NCATS (Recipient)	For Provider
Authorized Signature:	Authorized Signature:
Printed Name and Title: Krishna "Balki" Balakrishnan Ph.D. M.B.A Acting Director, Office of Strategic Alliances (OSA)	Printed Name and Title: _____ _____ _____
Date:	Date:
Mailing Address for Notices:	**Mailing Address for Notice:**
Name/Address: NCATS Attn: Office of Strategic Alliances (OSA) 9800 Medical Center Drive Rockville MD 20850	Name/Address: _____ _____ _____ _____ _____ _____
Email: ncatspartnerships@mail.nih.gov	Email:
Tel: 301-827-7155	Tel:
N/A	Scientific POC: Printed Name Title Email
N/A	Legal Reviewer/Sponsored Research: Printed Name Title Email

Attachment 1

Description of Data

Please provide a description of what is being submitted to the NIH COVID-19 Data Warehouse:

Attachment 2
Terms and Conditions for Limited Data Set

Additional Terms and Conditions:

1.   Recipient shall not use or further disclose the Limited Data Set (LDS) other than as permitted by this Agreement or as otherwise required by law.

2.   Recipient shall report to the Provider any use or disclosure of the LDS not provided for by this Agreement within fifteen (15) business days of when it becomes aware of such use or disclosure.

3.   To the extent the Provider is a HIPAA Covered Entity, and the data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the LDS 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.

If the LDS being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

4.   Recipient will not use the LDS, 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 LDS 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.

5.   Recipient agrees to ensure that any agent, including a subcontractor to whom it provides the LDS agrees to the same restrictions and conditions that apply through this Agreement to the Recipient with respect to such information. For clarification purposes, the prior sentence does not alter the restrictions and conditions of the Certificate of Confidentiality.

6.   By signing this Agreement, Recipient and Provider provide assurances 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.

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 the HIPAA rules.