

NCATS N3C DATA ENCLAVE INSTITUTIONAL DATA USE AGREEMENT

This Institutional Data Use Agreement ("Agreement") is between the National Center for Advancing Translational Sciences (NCATS), a component of the National Institutes of Health and

("Accessing Institution") which will become effective on the date of the last signature below.

WHEREAS, the National COVID Cohort Collaborative, or N3C, aims to build a centralized national data resource, the NCATS N3C Data Enclave, formerly known as the NIH COVID-19 Data Warehouse, that the research community can use to study COVID-19 and identify potential treatments and interventions as the pandemic continues to evolve.

WHEREAS, the N3C will enable the rapid collection and analysis of clinical, laboratory and diagnostic data from hospitals and health care plans that have transferred this Data via a Data Transfer Agreement to the NCATS N3C Data Enclave. The NCATS N3C Data Enclave will aggregate and harmonize clinical data on a recurring basis from COVID-19 tested patients, or those with related symptoms, to support data analytics and statistics that require a large amount of data. Clinical data from individuals with SARS, MERS, and H1N1 influenza will also be available to support comparative studies via the NCATS N3C Data Enclave.

WHEREAS, the N3C Data Enclave is built upon a state-of-the-art analytics platform that protects data security, patient privacy, and recognizes investigator contributions, it will empower investigators to work together to demonstrate the potential of innovative collaborative technologies and fuel novel analyses.

WHEREAS, Accessing Institutions whose User(s) wish to access and use the Data for public health purposes and research to inform decision making, including but not limited to conducting and supporting research to define the clinical natural history of COVID-19 infection, assessing 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 will need to execute this Institutional Data Use Agreement (DUA) and for every proposed project, submit a Data Use Request (DUR). This Institutional Data Use Agreement establishes the permitted uses of the Data by the User(s) as assured by the signatory Accessing Institution.

I. Definitions

1. **Accessing Institution** means the institution, entity, organization, or Citizen/Community Scientist that will be signatory of this agreement and the responsible party for the conduct of its User(s) approved to access Data under this agreement.
2. **Citizen/Community Scientist** refers to any member of the public not affiliated with a research organization who may submit a Data Use Request outlining a proposed COVID-19 Related Research project utilizing Synthetic Data after execution of a Data Use Agreement with NCATS.
3. **COVID-19 Related Research** means Data preparation and management or general research including but not limited to, health/medical/biomedical research, statistical methods, algorithms development, behavioral, public health and social-sciences research related to COVID-19 and COVID-19 response planning for public health and safety and other related research.

4. **Data** collectively means source Data Sets including clinical data related to COVID-19, or SARS, MERS, and H1N1 influenza to support comparative studies, provided or received herein:
 - a. **Limited Data Set** (as defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and in accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule),
 - b. **De-identified Data** means patient data that is health information from a medical record that has been stripped of all protected health identifiers—that is, all information as defined by HIPAA that can be used to identify the patient from whose medical record the health information was derived.
 - c. **Synthetic Data** means an artificial, statistically-comparable, computational derivative of the original Data. Synthetic Data does not contain Personal Health Information as defined under HIPAA.
5. **Data Access Committee (DAC), referred to as the NCATS N3C DAC**, is composed of representatives from the NIH or other Federal Agencies and is responsible for reviewing Data Use Requests (DUR) and verifying that conditions for accessing Data are met.
6. **Data Access Incident** is defined to include any access to or use of N3C Data outside the bounds of a DAC-approved Data Use Request. The term is also inclusive of any violation (intentional or not) of any of the Data Use Terms and Conditions in this agreement, or responsible data use expectations defined within the N3C Data User Code of Conduct.
7. **Data Contributor** – Institution that transferred Limited Data Sets to the NCATS N3C Data Enclave under a separate Data Transfer Agreement.
8. **Data Use Request (DUR)** a document that User(s) must complete and submit to the DAC for review prior to accessing the NCATS N3C Data Enclave. For each individual project, the DUR, outlined in Appendix A, will contain overarching use objectives and designs, scientific goals, any testable hypotheses, and an outline of plans for using the Data.
9. **HIPAA Privacy Rule** refers to the Health Insurance Portability and Accountability Act (HIPAA) of 2000, the Health Information Technology for Economic and Clinical Health Act, and all implementing regulations, as may be amended from time to time.
10. **Human Research Protection Program (HRPP)** is defined as the overarching program at an Accessing Institution charged with the responsible oversight of human subjects research and compliance with federal regulations (e.g., the Federal Policy for the Protection of Human Subjects (45 CFR 46) by Users from that institution
11. **NCATS N3C Data Enclave** is an NIH-managed cloud-based data repository and investigational platform used to capture, integrate, and make available Data for research analysis purposes.
12. **Research Project** means the COVID-19 Related Research described in the approved DUR.
13. **User(s)** are authorized by the NCATS N3C DAC to access and/or analyze Data for COVID-19 Related Research.

II. Data Use Terms and Conditions

1. Research Use

- a. For each proposed Research Project, User(s) agree(s) to submit a Data Use Request (DUR) to the NCATS N3C DAC for review and approval to access the Data.

- b. User(s) agree(s) to use the Data exclusively for the Research Project proposed, and/or comparative studies using data from individuals infected with pathogens such as SARS, MERS, and H1N1 to support comparative studies, described in the DUR. Any other use of the Data is prohibited.
- c. For Research Projects that involve individuals from more than one Research Institution, a DUA must be executed by all Accessing Institutions for a DUR to be approved.
- d. User(s) agree(s) to use Data in compliance with all applicable federal, state, local, and tribal laws, regulations, and policies.
- e. If requesting access to the Limited Data Set, the User(s) agree(s) to provide documentation of Accessing Institution's Human Research Protection Program (HRPP) approval for the Research Project as described in the DUR. If requesting access to De-identified Data, the User(s) agree(s) to adhere to the Accessing Institution's HRPP policies regarding oversight expectations for research with this data type.
- f. Accessing Institution confirms that its Users(s) will have completed prior to the approval of a DUR and will maintain training in human subjects research protection for the duration of a DUR, unless requesting access only to Synthetic Data.
- g. If a User leaves the Accessing Institution, the User must notify the NCATS N3C DAC. User's new institution must have an active DUA and be affiliated with the current DUR before continuing the Research Project.

2. Confidentiality and Data Security

- a. Users of the NCATS N3C Data Enclave shall have their identity authenticated and their research activities shall be regularly audited and tracked for data security.
- b. Users agree to not attempt to re-identify or contact any individuals who are the subjects of the Data or any known living relatives unless required by law to maintain public health and safety.
- c. Users agree not to attempt to use the Data to identify or contact any Data Contributors or healthcare providers unless such identification is needed for Data preparation and management purposes and only at the request of NCATS or required by law to maintain public health and safety.
- d. Data access approval is not transferable.
- e. Except as required by law, User(s) shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party without the prior written permission of the NCATS N3C DAC. If the Accessing Institution believes it is required by law or legal process to use or disclose the Data, the Accessing Institution will promptly notify the NCATS N3C DAC to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill Accessing Institution's legal obligations.
- f. Users agree to not photograph, create screen shots, nor download Data viewed on the NCATS N3C Data Enclave. Furthermore, Users' access to the NCATS N3C Data Enclave will be terminated after 1 year. Users' access to their analyses and findings on the NCATS N3C Data Enclave may continue with DAC approval of DUR renewal.
- g. Accessing Institution and its Users agree to report any unauthorized access use(s) or disclosure(s) of the Data not provided for under this Agreement or other Data Access Incident(s) to NCATS at NCATSDataAccessIncidents@nih.gov no later than 2 business days after discovery. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in

- place to define and fully remediate the situation. The occurrence of a Data Access Incident may be grounds for termination or suspension of this agreement and any access to Data. NCATS may also seek injunctive relief against the Accessing Institution to prevent any disclosure of Data to anyone other than NCATS.
- h.** Data in the NCATS N3C Data Enclave is made available to the research community for their use, through their analysis and findings, to further the research and development of ideas and knowledge that will benefit and improve public health. NCATS encourages the development of new analytical tools, models, diagnostics, therapeutics, or other interventions building on basic discoveries enabled through Data obtained from the NCATS N3C Data Enclave. The Accessing Institution and its User(s) are free to pursue patent protection on any inventions or discoveries developed through their approved use of NCATS N3C Data Enclave.
 - i.** Data residing in NCATS N3C Data Enclave is protected by a Certificate of Confidentiality pursuant to section 301(d) of the Public Health Service Act. The Certificate of Confidentiality prohibits disclosure, including in any federal, state, or local criminal, civil, administrative, legislative, or other proceeding, of identifiable, sensitive information collected or used during research unless disclosure is made pursuant to a statutory exception. The Certificate of Confidentiality also protects all copies of Data from the NCATS N3C Data Enclave in perpetuity as explained in the NIH Policy for Issuing Certificates of Confidentiality <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>.
 - j.** Accessing Institution and Users agree to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements, such as completing appropriate required NIH IT training, relating to safeguarding of the Data as may be set forth in the NIH website <https://irtsectraining.nih.gov/public.aspx>. Note that NCATS may request evidence of completion of the NIH IT training from Users (i.e., a screenshot or copy of the Certificate of Completion provided at the end of the course). Users will not share their NCATS N3C Data Enclave log-in credentials with others at any time.

3. Dissemination of Research Descriptions, Results and Acknowledgements

- a.** Users are encouraged to make the results of their research publicly available, ideally in an open access format and consistent with scientifically accepted publication or dissemination practices. In recognition of the effort that Data Contributor(s) made in collecting and providing the Data, User(s) who publish their results, or otherwise publicly present findings, agree(s) to acknowledge the NCATS N3C Data Enclave as the source of these Data and Data Contributors per guidelines in the NCATS N3C Data Enclave website.
- b.** Accessing Institution and User(s) agree(s) to allow the following information in the approved DUR to be made publicly available: non-confidential research statement of the Research Project, Project Title, Users' names and Accessing Institution(s).

4. Liability

- a.** Data Contributors shall retain ownership of any rights they may have to the Data, and neither NCATS nor Accessing Institution and/or Users obtain any rights to the Data other than as set forth herein.

- b. Users creating a NCATS N3C Data Enclave workspace(s) are expected to ensure that external data, files, or software that they import into the NCATS N3C Data Enclave are conducted in accordance with all applicable national, tribal, and state laws and regulations as well as relevant institutional policies, procedures and agreements. NCATS assumes no responsibility and/or liability regarding all imported data, files, or software.
- c. NCATS must pre-approve all software that will be imported by the User(s) into the NCATS N3C Data Enclave. The User(s) may only import the software after NCATS provides written approval. NCATS has the right to remove all unapproved software from the User's NCATS N3C Data Enclave workspace at any time.
- d. The Data and software are made accessible "AS IS" and NCATS and the Data Contributor(s) make no representations or warranties, expressed or implied, regarding the Data and software, including but not limited to the marketability, use or fitness for any particular purpose, or that such Data and software do not infringe upon any third party property rights. Furthermore, neither NCATS nor the Data Contributors shall be liable for special consequential or incidental damages.
- e. The Accessing Institution will not claim, infer, or imply endorsement by the United States Government, the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), or the NCATS of the Research Project, the entity or personnel conducting the research, or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

5. Term and Termination

- a. This DUA may be terminated by mutual written agreement between NCATS and the Accessing Institution. Either NCATS or the Accessing Institution may terminate this DUA without cause by providing 30 days written notice to the other party. Upon termination, all access for Users from the Accessing Institution will be terminated. Failure to comply with the NCATS N3C Data Enclave User Code of Conduct by Accessing Institution and/or User(s) may result in a suspension of access to the Data for **ALL** Users until NCATS completes an investigation into the specific Data Access Incident. After this time, NCATS may either reinstate or terminate, in whole or in part, User's access to the Data.
- b. This DUA will remain in effect for a period of five (5) years from the DUA Effective Date and will automatically expire at the end of this period unless terminated or renewed. The Accessing Institution may request that the DUA be renewed one (1) year prior to the expiration date. Access to the NCATS N3C Data Enclave workspace(s) for DAC approved DUR(s) will be effective for a period of one (1) year starting from the date access is granted. A DUA must be in place for the entire term of a DUR. At any time, Users may indicate that they no longer need access to their N3C Data Enclave workspace.
- c. All legal notices related to this agreement will be sent to the below listed contact information. Amendments to this DUA must be made in writing and approved and signed by the Accessing Institution and NCATS Office of Strategic Alliances (OSA).
- d. The following terms and conditions of the DUA, 1b, 1d, 1e, 2b, 2c, 2e, 2i, 3 in its entirety and 4a, 4b, 4d, 4e in its entirety will survive expiration or termination of this agreement.

Signatures Begin on Next page

AGREED AND UNDERSTOOD by the parties through their authorized signatures.

Authorized Signatory: On behalf of the Accessing Institution and its User(s), the undersigned individual hereby attests that he/she/they is/are authorized to legally bind the Accessing Institution and its User(s) to the terms of this Agreement and agrees to all the terms specified herein.

Accessing Institution:

Name: _____

Title: _____

Address: _____

Signature: _____ **Date:** _____

Email of Authorized Signatory: _____

Legal Notice Contact (email or address): _____

Scientific Point of Contact:

Name: _____

Title: _____

Email: _____

Legal Contract/Tech Transfer Reviewer:

Name: _____

Title: _____

Email: _____

For: National Center for Advancing Translational Sciences (NCATS)

Name: Lili Portilla MPA

Title: Director, Office of Strategic Alliances (OSA)

Signature: _____ **Date:** _____

Email for Legal Notices: NCATSPartnerships@mail.nih.gov

Appendix A

Sample of Electronic Data Use Request (DUR) for Accessing Data from the NCATS National COVID Cohort Collaborative (N3C) Data Enclave

*Not to be completed, reference only

N3C Enclave Registration Information:

If not yet registered, requesting Users can find registration information at <https://ncats.nih.gov/n3c/>. An ORCID ID is required for registration (see <https://orcid.org/> for more information). Please note that User Name and User's Accessing Institution will be made publicly available.

Accessing Institution:
User Name:
Email:
ORCID:

Data Use Request Information:

Each DUR will be reviewed by the N3C Data Access Committee (DAC) on a project-specific basis. Requesting Users must submit a DUR for each different proposed Research Project.

Please note that Project Title and the Non-Confidential Research Statement will be made publicly available.

Research Project Title:
Project personnel or collaborators on this DUR¹
Non-Confidential Research Statement:² (250 word max)
Proposed Research Project Plan:³ (500 word max)

Data Being Requested ⁴	Selected Data Set(s)	Local Human Research Protection Program (HRPP) Oversight ⁵
Synthetic Data (Level 1)		N/A
De-identified Data (Level 2)		Follow local institutional policies
Limited Data Set (LDS) (Level 3)		Local HRPP Determination Letter Uploaded

¹ Name all project personnel and their institutional affiliations. Note that collaborating Users from different Accessing Institutions will need to confirm execution of a DUA between their respective institution and NCATS. If joining a previously submitted DUR, you will need to be approved by the originating User prior to N3C DAC review.

² Provide a high-level description of the proposed Research Project suitable for public posting on an N3C website. The description should include the Data type requested along with the COVID-19 Research questions to be addressed.

³ Provide sufficient information for the NCATS N3C DAC to understand the research and analyses proposed in the proposed Research Project, including the COVID-19 Research question(s) to be addressed, the required level of access to Data necessary to conduct the work proposed, a general outline for the anticipated analyses, and any software that is expected to be utilized within the N3C Data Enclave in the course of the Research Project. As stated in the DUA, any software used within the N3C Data Enclave must be approved in writing by N3C prior to being uploaded.

⁴ Note that Citizen/Community Scientist(s) may only request access to Synthetic Data (Level 1 Data)

⁵ Per the DUA, User(s) requesting access to De-identified Data (Level 2 Data) are expected to follow their institution's HRPP policies with regard to oversight of research with this data.

Users requesting the full N3C Limited Data set (Level 3 Data) are expected to upload a local HRPP Determination Letter for the proposed research to accompany the DUR.

Other Information:

In addition to the above, prior to submitting a DUR Users requesting access to the N3C Data Enclave will:

1. Confirm that their Accessing Institution(s) has executed an Institutional Data Use Agreement (DUA) with NCATS, Citizen/Community Scientist(s) who wish to request access to the Synthetic Data (Level 1) must execute a DUA directly with NCATS.
2. Attest to their review of the DUA https://ncats.nih.gov/files/NCATS_N3C_Data_Use_Agreement.pdf and an understanding of the Terms and Conditions for use of all Data and any software utilized within the N3C Data Enclave.
3. Attest to the N3C Data User Code of Conduct [<https://ncats.nih.gov/n3c/resources/data-user-code-of-conduct>] and compliance with all expectations therein.
4. Complete the standard NIH IT training at <https://irtsectraining.nih.gov/public.aspx>, provide the date the training was completed, and retain evidence of completion to provide to NCATS upon request (i.e., a screenshot or copy of the Certificate of Completion provided at the end of the course).
5. When requesting De-identified Data (Level 2) or the Limited Data Set (Level 3), complete human subjects research protection training, provide the date the training was completed, and retain evidence of completion to provide NCATS upon request.

User(s): By clicking submit, requesting User(s) state their agreement with the information contained within the DUR and attest to understanding their responsibilities and obligations for N3C Data use under the DUA https://ncats.nih.gov/files/NCATS_N3C_Data_Use_Agreement.pdf, the N3C Data User Code of Conduct <https://ncats.nih.gov/n3c/resources/data-user-code-of-conduct> and any applicable institutional, local, state, federal, or tribal laws, regulations, and policies.