

**NCATS' National Clinical Cohort Collaborative (N3C) Enclave
DATA TRANSFER AGREEMENT**

This Data Transfer Agreement ("Agreement") is between the National Center for Advancing Translational Sciences (NCATS) ("Recipient"), a component of the National Institutes of Health (NIH) and _____ ("Data Contributor") (each a "Party" and collectively, the "Parties") which will become effective on the date ("Effective Date") of the last signature below.

WHEREAS the NCATS mission is to turn research observations into health solutions through translational science.

WHEREAS the N3C Enclave ("N3C Enclave") facilitates information dissemination and research through data sharing. The N3C Enclave contains clinical data sets including but not limited to data derived from a Limited Data Set originating from records of individuals who have received longitudinal care from Data Contributors and/or, when available, synthetic data product(s) derived from the Limited Data Set.

WHEREAS the N3C Enclave is built upon a state-of-the-art analytics platform that protects data security, patient privacy, and recognizes investigator contributions, it will facilitate Approved User investigators' collaborative research efforts on an array of innovative technologies and novel analyses.

WHEREAS the N3C Enclave will support research by enabling the rapid collection and analysis of data such as clinical, laboratory, and diagnostic data from Data Contributors that have transferred Data via a Data Transfer Agreement to the N3C Enclave. Within the N3C Enclave, disease agnostic clinical data will be aggregated and harmonized on a recurring basis from participating Data Contributors to facilitate Approved User research.

WHEREAS, Data Contributors will have the ability to preset approved Phenotypes as well as exercise control over how their Data are used consistent with this agreement and applicable NCATS policies and/or determinations.

I. Definitions

1. **Agreement** refers to this Data Transfer Agreement.
2. **Approved User(s)** is an investigator approved by the relevant NIH Data Access Committee to access Data or more datasets contained in N3C Enclave Data for a specified period and only for the purposes outlined in the correlating Data Access Request and Data Use Agreement.
3. **Data**, collectively "Data Sets" (that may be source or harmonized Data Sets), includes clinical data such as:
 - a. Limited Data Sets (as defined by HIPAA, e.g., 45 CFR § 164.514 (e)(2)) and/or
 - b. Datasets, libraries, and registries that may enrich the value of the Limited Data Set.
4. **Data Access Committee (DAC)** refers to the NIH Data Access Committees (DACs) that review requests from extramural and intramural researchers to use the N3C Enclave Data for proposed secondary research uses as an Approved User. DACs may approve, decline, or table such requests. DACs are formed based on topic expertise and are not necessarily specific to an NIH Institute, Center, or Office (ICO).
5. **Data Access Request (DAR)**, previously referred to as a Data Use Request (DUR), is a request submitted to a NIH Data Access Committee for approval related to a specific research use and

specifying the Data to which access is sought, the planned research use, and the names of the proposed Approved Users.

6. **Data Contributor** is an Institution that transfers Data to the N3C Enclave through this Agreement.
7. **Data Use Agreement (DUA)** refers to written terms and conditions applicable to an Approved User that is required to be executed prior to an Approved User's access to Data.
8. **HIPAA** collectively refers to the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, the HIPAA Privacy Rule of 2000, all modifications, and implementing regulations, as may be amended from time to time.
9. **Linkage Honest Broker Agreement (LHBA)** refers to the agreement executed by Data Contributor and N3C's Honest Broker to enable PPRL services for the Data Contributor.
10. **National Clinical Cohort Collaborative (N3C) Enclave** is a secure, controlled environment for storage, management, and analysis of Data. The underlying architecture, compute resources, and infrastructure used to support the environment may evolve over time to meet future operational and research needs while still preserving the highest standards of data protection and patient privacy.
11. **Phenotype(s)** are precise, computable definitions of patient populations based on clinical features such as diagnoses, procedures, medications, lab results, and temporal patterns, and are central to real-world data research. In N3C Clinical, phenotypes are used to define cohorts for each dynamic tenant and serve as the basis for data provisioning, ensuring alignment between the research question and the dataset delivered.
12. **Privacy Preserving Record Linkage (PPRL)** refers to the methodology of connecting records using secure, pseudonymization processes in a data set that refer to the same individual across different data sources while maintaining the individual's privacy.
13. **Protected Health Information (PHI)** is defined as individually identifiable health information transmitted or maintained by a covered entity or its business associates in any form or medium (45 CFR 160.103). It can include any individually identifiable health information, including demographic data, that relates to an individual's past, present, or future physical or mental health or condition, or the provision of healthcare.
14. **Recipient or "NCATS"** refers to The National Center for Advancing Translational Sciences.

II. Terms and Conditions

1. Data Contributor shall provide the Data Set described in Attachment 1 to Recipient.
2. Use of PPRL is required for Data submitted to the N3C Enclave. Data Contributor will execute an LHBA to enable PPRL.
3. Data deposited in the N3C Enclave will be made accessible to applicable Approved Users after approval of the DAC and once a Data Use Agreement has been executed between Recipient and Approved Users. In the Data Use Agreement, Approved Users will agree to the following concepts:
 - a. only access Data approved for use by Recipient.
 - b. use the Data only for research purposes and as limited by the research proposal outlined in an approved Data Access Request.

- c. request approval for alterations in scope regarding the Data Access Request research proposal prior to accessing N3C Enclave Data for such purposes.
 - d. only analyze the Data within the N3C Enclave.
 - e. not be authorized to download or remove the Data from the N3C Enclave in any form.
 - f. comply with any and all restrictions and obligations set forth by Recipient
 - g. make no effort to contact or identify individuals who are or may be the subject of the Data.
 - h. share the results of analyses as broadly as possible.
 - i. agree to acknowledge the N3C Enclave in all publications and presentations that rely on the Data.
4. Data Contributor will be able to exercise control over how their Data are used, consistent with this agreement and applicable NCATS policies and/or determinations.
5. Authorized Users will have a one (1) year term of access to Data in the N3C Enclave and will be eligible for two (2) additional 1-year term renewals.
6. Recipient agrees to use the Data in compliance with all applicable laws, rules, regulations, and policies.
7. Data Contributor represents that its provision of Data is compliant with relevant institutional policies and applicable federal, state, or local laws and regulations have been followed, including the completion of any IRB or ethics review or approval that may be required. Data Contributor acknowledges that Recipient is not a Covered Entity or a Business Associate under HIPAA and therefore is not subject to HIPAA.
8. Unless otherwise requested by Data Contributor and consistent with applicable NCATS policies, Data Contributor agrees to be publicly identified as a Data Contributor
9. Data Contributor represents and warrants that: (1) to its knowledge, it will not provide Protected Health Information to Recipient beyond that information permitted in a Limited Data Set (as defined in 45 CFR § 164.514(e)(2)); (2) it has obtained the consent or authorization of the individual to provide the Data to Recipient, if required by applicable law; (3) it has notified individuals of the use of the individual's data, if required by applicable law; and (4) it has authority (including, but not limited to, under applicable law and any contractual obligations) to make the Data available to Recipient for use within the N3C Enclave and as described in this Agreement.
10. Recipient will make no effort to contact or determine the identity of individuals who are or may be the sources or subjects of the Data. Data Contributor acknowledges that Recipient has no obligation to review Data provided by Data Contributor to determine if such Data contains Protected Health Information beyond that information permitted in a Limited Data Set. Periodic scans may be conducted by the Recipient. If Protected Health Information is identified, Data Contributor will work with Recipient to remove Protected Health Information.
11. Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." DATA CONTRIBUTOR 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.

12. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement.
13. 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. Notwithstanding the foregoing, Data Contributor shall not use the names, symbols, logos, or identifying marks of NIH, NCATS, HHS, or the Federal Government or their employees in any advertising, promotional, or sales literature without the prior written approval of the IC.
14. This Agreement includes the below listed Attachments, which are incorporated by reference:
 - Attachment 1: Description of Data
 - Attachment 2: Terms and Conditions for Limited Data Set
15. This Agreement shall remain in effect for five (5) years and will be automatically renewed in the absence of a prior written objection to such renewal by either Party. Each automatic renewal shall be in effect for one (1) year with a limit to 5 renewals.
16. Either Recipient or Data Contributor may terminate this agreement with thirty (30) days written notice to the other Party. Once Data has been ingested and uploaded into the N3C Enclave, it cannot be destroyed and must be retained. Recipient will generate a new data set that does not contain the Data Contributor's withdrawn Data. Authorized Users who have been approved to use Data Contributor's Data prior to Data Contributor's termination will be allowed to continue to use the Data until the end of the applicable term of use and any renewal(s) and may be authorized by Recipient to add new Approved Users (as approved by the DAC) for the purpose of supporting Authorized Users' research, validation, and/or confirmation of future findings.
17. Data Contributor acknowledges that Data will be protected from disclosure by a Certificate of Confidentiality per Section 301(d) of the Public Health Service Act, as amended (42 USC 241(d)) 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 Data Contributor.
18. The undersigned Authorized Officials of Data Contributor 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.
19. This Agreement constitutes the entire understanding between the Institutions with respect to the subject matter of this Agreement and supersedes all other agreements, whether written or oral, between the Institutions.
20. This Agreement supersedes all prior agreements between the Parties, if any, with respect to the subject matter hereof.
21. A Party shall not assign any of its rights or delegate any of its obligations under this Agreement to

any other person or entity unless agreed to in writing by the Data Contributor and Recipient.

22. No amendment or waiver of this Agreement will be valid unless in writing and signed by each Party's authorized representatives.

Signatures Begin on Next page

AGREED AND UNDERSTOOD by the Parties through their authorized signatures.

Authorized Signatory: On behalf of the Data Contributor the undersigned individual hereby attests legal authorization to bind the Data Contributor to the terms of this Agreement and agrees to all the terms specified herein.

Data Contributor: _____

Signatory Name: _____

Signatory Title: _____

Address: _____

Signature: _____ **Date:** _____

Email of Authorized Signatory: _____

Agreement Notice Contact (email): _____

For: _____

Name: _____

Title: _____

Signature: _____ **Date:** _____

Email for Agreement Notices: _____

Please cc NCATSPartnerships@mail.nih.gov with final agreement.

Attachment 1
Description of Data

1. Data that qualify for inclusion in the N3C Enclave will be limited and must include at least two encounters, spaced at least 30 days apart, and contain clinically relevant data. This data may include vital signs (e.g., blood pressure or weight), laboratory measurements, procedures, or diagnoses.
2. Data Contributors will use the NCATS-provided phenotype to extract their Data in accordance with N3C Enclave data types and structures. The Phenotype generates a Limited Data Set (LDS) which contains dates of service and zip codes. Extracted Data elements encompass a wide range of clinical data, including but not limited to demographics, vital signs, diagnoses, procedures, medications, and admission, discharge, laboratory tests results, and transfer information.
3. Data will be extracted by Data Contributors on a recurring basis, with serial updates provided to N3C Enclave for the included records to create a longitudinal cohort including historical information dating back to January 1, 2016.
4. Data Contributors will create a Limited Data Set (LDS) using an NCATS-provided phenotype and retain dates and ZIP codes.
5. Additional datasets, such as but not limited to, ancillary linked data, such as patient registries, monitoring devices, and wearables, may be provided with the agreement of the Data Contributor and the Recipient.

Attachment 2
Terms and Conditions for Limited Data Set

Additional Terms and Conditions for Limited Data Set(s) provided through this Agreement:

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 Data Contributor 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. If the LDS being provided is coded, the Data Contributor will not release, and the Recipient will not request, the key to the code.
4. 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.