

Dear DUA Signee!!!

NCATS and the National COVID Cohort Collaborative (N3C) are pleased to announce the official opening of the N3C Data Enclave on September 1, 2020!

An [NCATS N3C webpage](#) was created to provide program resources and governance documents, such as the [Data Transfer Agreement \(DTA\)](#), [Data Use Agreement \(DUA\)](#), [User Code of Conduct](#), and frequently asked questions relating to governance, as well as information on [required NIH security training](#), [acknowledging N3C in publications and presentations](#), and [guiding principles for engaging with the community](#).

In parallel, the [N3C website](#) provides information for [registering to N3C/CD2H](#); [creating an account and entering the N3C Data Enclave](#); individual workstream, subgroup, and task team information; as well as [frequently asked questions for data access and use](#). There are also dashboards and N3C project lists currently being created to allow for collaboration and engagement.

N3C has also made materials available for public view through Zenodo, a general-purpose open-access repository: the [N3C IRB protocol](#), [Community Guiding Principles](#), [Attribution and Publication Principles for N3C](#) among others with more to come.

CD2H and NCATS have partnered to quickly build this important national resource to study the COVID pandemic. We are enormously grateful for the communities across the CTSA and the common data models that have rallied with us to make this possible. We are excited about what we and our partners can learn from this shared resource and are confident that this can advance our collaborative efforts to address this health crisis.

Sincerely,

NCATS N3C TEAM

Getting Access to the data

The NCATS N3C Data Use Agreement is now available, allowing researchers to submit or join a project in the N3C Data Enclave—one of the largest, most secure clinical data resources for accelerating and collaborating on COVID-19 research. Below is a brief overview of the process, along with additional resources to help get started. Please consider forwarding this message to researchers within your community who may also wish to access the N3C Data Enclave for COVID-19 research.

Data Use Request

In order to get access to the N3C data investigators need to submit an online application called a Data Use Request or DUR. This guide outlines the steps for an investigator to submit a DUR for a new project or submit a DUR to join an existing project.

Overview of the Data User Request (DUR) Process

1. Investigator submits a Data Use Request.
2. Data Access Committee (DAC) Reviews and Approves the research project

3. Investigators are given access to the analytics workbench

IMPORTANT! READ the checklist before starting the Data Use Request (DUR) process

First time user prerequisites



1. Register at
N3C



2. Signed
DUA



3. HSP / Security
Training

Step 1: Data Access Preparation

- a. [Register with N3C](#) and request an N3C Data Enclave account. (approval 1-3 days)
- b. Confirmation your [institution \(see list\)](#) has an executed [Data Use Agreement \(DUA\)](#)
- c. Acquire an [ORCID ID](#) (free and quick) to assure author attribution

Step 2: Two Factor Authentication

- d. NCATS requires two factor authentications for access to the N3C data enclave so before you apply for a DUR downloaded a two-factor authentication app on your smartphone, or tablet [DUO](#), [Free OTP](#), [Google Authenticator](#), or [Microsoft Authenticator](#)

Step 3: Current (last 3 years) Training Requirements

- e. Completion of [NIH Information Security and Information Management Training](#).
- f. Completion date of **Human Subjects Research training** (LDS or DeID only) (consult your Institution's Human Subjects Research Office for training guidance).

Returning Users



1. Submit
DUR



2. Data Access
Committee Approval



3. Work Bench
Access

Step 4: Submit the Data Use Request (DUR) Form:

When you are ready to propose a project or join an approved project, complete and submit the data user request form within the [NCATS N3C Data Enclave](#). We recommend researchers review the DUR (see Images below) to ensure that you are [\(see\)](#) prepared to provide the requested information.

- During this process, researchers will read and attest to the [NCATS N3C Data Use Agreement \(DUA\)](#) and the [N3C Data User Code of Conduct](#). If requesting access to the limited dataset, they will need to upload their institution's IRB determination letter either stating approval of your

Draft your Data Use Request Application

Research Projects Require:

- Title:**
- Project Description** (must be COVID-19 Related)
- Project Rationale:**

- The project rationale is used by the Data Access Committee, (DAC) to assess the level of data/data tier being requested (Limited Data Set (LDS), De-Identified (DeID), or Synthetic. User should describe the minimum necessary level of data needed to conduct research

Data Level	Data Description	Eligible Users	Access Requirements*
Synthetic Data Set	Artificial, statistically-comparable, computational derivative of the original data; it does not contain individually identifiable health information, also known as protected health information (PHI) as defined by the Health Insurance Portability and Accountability Act (HIPAA)	<ul style="list-style-type: none"> • Researchers from U.S.-based institutions • Researchers from foreign institutions • Citizen scientists 	<ul style="list-style-type: none"> • N3C registration • N3C Data Enclave account • Data Use Agreement (DUA) executed with NCATS • NIH IT training completion • Approved Data Use Request (DUR)
De-identified Data Set	Patient data that has been stripped of PHI identifiers as defined by HIPAA	<ul style="list-style-type: none"> • Researchers from U.S.-based institutions • Researchers from foreign institutions 	<ul style="list-style-type: none"> • N3C registration • N3C Data Enclave account • DUA executed with NCATS • NIH IT training completion • Approved DUR • Human Subjects Research Protection training completion
Limited Data Set	Patient data that includes only two of the 18 elements defined as PHI by HIPAA (dates of service and patient zip code)	<ul style="list-style-type: none"> • Researchers from U.S.-based institutions 	<ul style="list-style-type: none"> • N3C registration • N3C Data Enclave account • DUA executed with NCATS • NIH IT training completion • Approved DUR • Human Subjects Research Protection training completion • Local Human Research Protection Program IRB determination letter

*Data access requirements may change over time

Data Levels

IV. RB Letter of Determination (LDS Only)

- a. If requesting access to the limited dataset, you must upload a PDF copy of your institution's **IRB determination letter** for your project

Step 5: Begin Research

If the DUR is approved by the N3C Data Access Committee (DAC), the user will receive an email with instructions for accessing the [NCATS N3C Data Enclave](#). . Approved DURs are valid for 1 year.

More Information

- [Data types and levels of access](#)
- [N3C Data Enclave registration](#) and [checklist](#)
- Frequently Asked Questions regarding the [N3C program](#) and [account registration](#)
- [N3C Forms and Resources](#)

Contacts

- For DTA or DUA questions: NCATSPartnerships@mail.nih.gov
- For registration and account creation: NCATSAuthSupport@mail.nih.gov
- For N3C Data Enclave technical support: NCATSN3CSupport@mail.nih.gov
- For general support: data2health@gmail.com

Data Use Request Form

Step 1: Fill our DUR Project Title, Description and Rationale for request data tier DUR Step 1: Project Description

New Data Use Request

Each Data Use Request (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.

Your Name and Accessing Institution will be made public.

User *John Doe Investigator*

Accessing Institution

Please enter your new project title.
Project Title (Public)

Research Project Abstract (Public)

Research Project Rationale (Confidential to N3C DAC)

Allow other researchers to join this project?
 Allow Do not allow

DUR Project Title, Description and Rationale for request data tier

Step 2: Add the name of Collaborator/s to your project (Optional)

Step 2: Collaborators

Collaborators	
<small>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. Please note that N3C Usernames and institutional affiliations will be made publicly available on the N3C website.</small>	
Collaborator's First Name	Collaborator's Last Name
<input type="text"/>	<input type="text"/>
<input type="checkbox"/> This collaborator belongs to my institution	Collaborating institution
Collaborator Email	<input type="text"/>
<input type="text"/>	
<input type="button" value="Add Additional Collaborators"/>	

Project Collaborator/s form (Optional)

Step 3:

Attest to DUA, Code of Conduct and Up to date training Security/HSP

Upload Letter of Determination for local IRB if requesting LDS

Step 3: Attestations

Data Tier Access
What level of data are you requesting?
<input type="radio"/> Limited Data Set (Level 3) <input type="radio"/> De-Identified Data (Level 2) <input type="radio"/> Synthetic Data (Level 1)
<small>Patient-level records scrubbed of name and birth date, but other potentially identifiable information intact.</small>
Please complete your N3C Data Enclave Institutional DUA Attestation.
Please read and attest that you will abide by the N3C Data Enclave Institutional DUA
<input type="radio"/> I attest that I have read and agreed to the terms of use outlined in the DUA
I have completed the Information Security and Information Management Training within the last year
<input type="radio"/> Yes <input type="radio"/> No
I have completed Human Subjects Research Protection Training within the last three years
<input type="radio"/> Yes <input type="radio"/> No
Completion of Human Subjects Research Protection Training Date
<input type="text" value="MM/DD/YYYY"/>
Please complete your N3C Code of Conduct Attestation.
Please read and attest that you will abide by the N3C Data User Code of Conduct
<input type="radio"/> I attest that I have read and agreed to abide by the N3C Code of Conduct.
Letter of Determination
Upload a PDF of your HRPP determination letter
<input type="text" value="Choose file"/> <input type="button" value="Browse"/>

Attestation: DUA, Code of Conduct, Security/HSP training, Letter of Determination LDS only