CCTS

National COVID Cohort Collaborative

The gates to the amusement park are open

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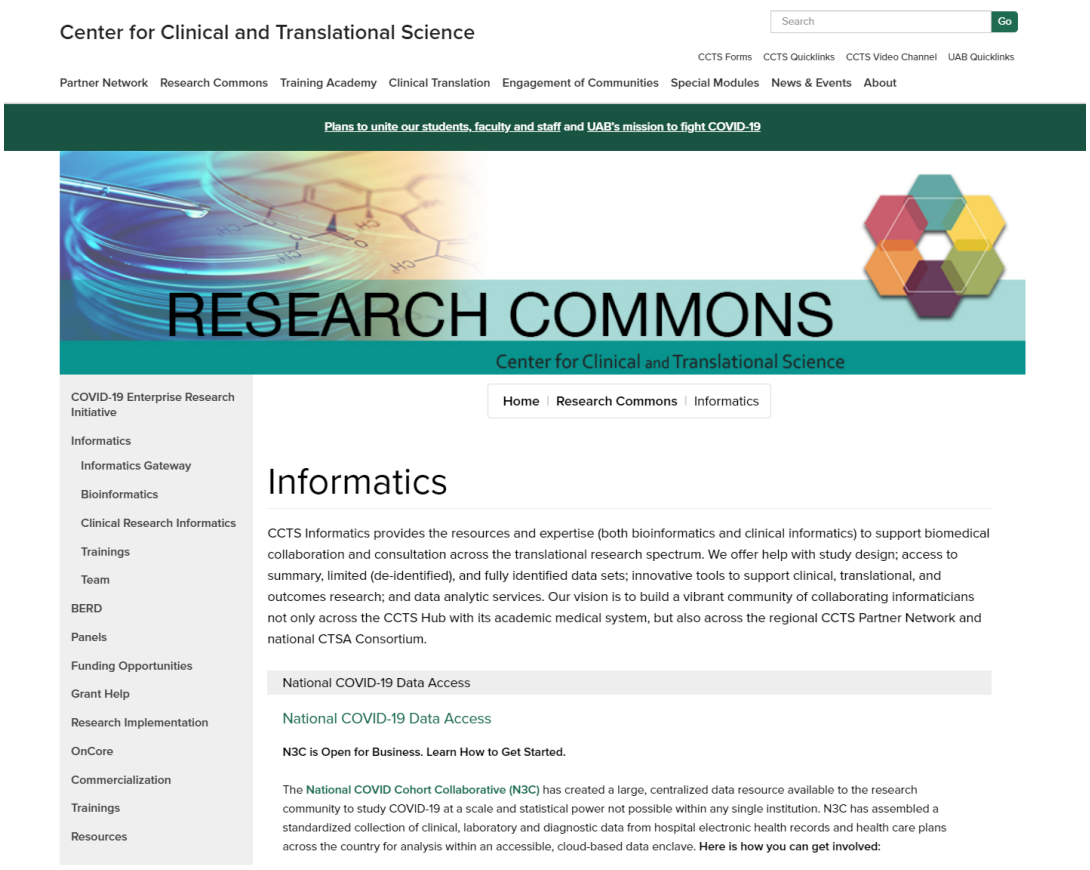
https://www.uab.edu/ccts/research-commons/informatics



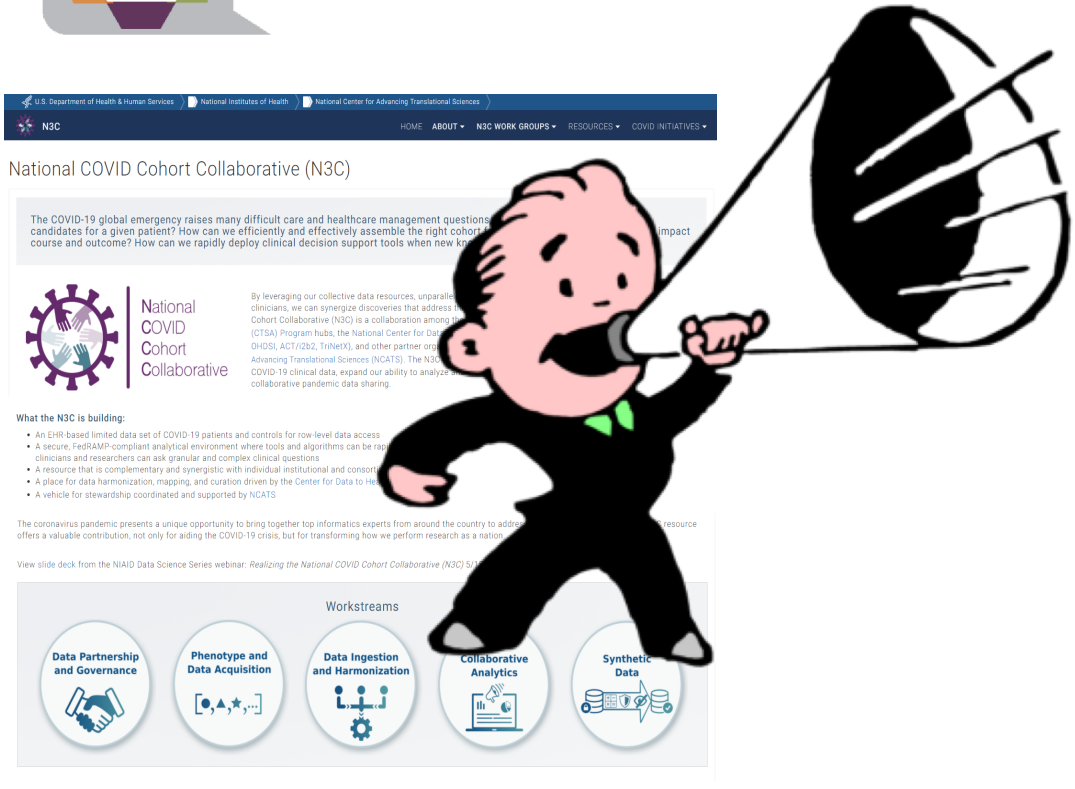
Data levels or tier

National COVID Cohort Collaborative

Access Level	Level 1 – Synthetic	Level 2 – Deidentified		Level 3 - LDS
Data Type	**Synthetic Data**	**Aggregate Data (i.e., summary statistics)**	**HIPAA Safe Harbor**	**HIPAA Limited Data Set**
Description	Computational data derivative statistically resembles original data	Counts and summary statistics representing 10+ individuals	Data stripped of 18 direct identifiers called out in the HIPAA Privacy Rule	Data that is stripped of all PHI under HIPAA except dates and zip codes

Borrowed from Ken Gersing

https://covid.cd2h.org/N3C
https://ncats.nih.gov/n3c



CALLING ALL…

Population Health Scientists
Outcomes Researchers
Data Wranglers
Biostatisticians
Epidemiologists
Clinical Informaticists
Coding Experts (R a/o Python)
AI / Machine Learning Leads

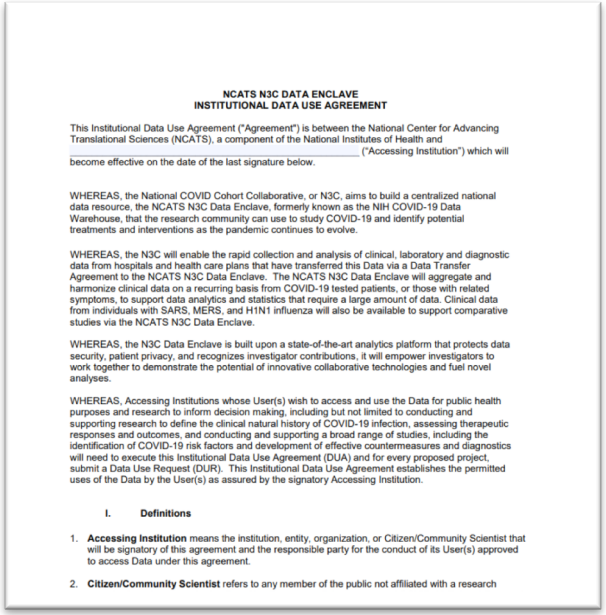
For more information, connect with
Bob Kimberly (rpk@uab.edu) or
Jennifer Croker (jcroker1@uabmc.edu)
Jim Cimino (ciminoj@uab.edu)

N3C Data Use Agreements

https://ncats.nih.gov/n3c

(N3C Forms and Resources Tab > N3C Data Access > NCATS N3C Data Use Agreement Form)

An **N3C Data Use Agreement (DUA)** is executed by NCATS and a research institution (or directly with a researcher in the case of a citizen/community scientist who is not affiliated with an institution). It is strongly recommended that researchers ensure that their home institution has executed a DUA with NCATS before they begin the process of applying for data access.



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

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

First time user prerequisites

1. Register at N3C

2. Signed DUA

3. HSP / Security Training

1. Data Access Preparation

Register at N3C
Confirmation your institution has an executed Data Use Agreement (DUA)
Acquire an ORCID ID (free and quick) to assure author attribution

2. Two Factor Authentication

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

3. Current (last 3 years) Training Requirements

Completion of2020 Information Security, Counterintelligence, Privacy Awareness, Records Management Refresher, Emergency Preparedness Refresher.
Completion date of **Human Subjects Research training** (LDS or DeID only)

4. IRB Approval

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

5. Draft your Data Use Request Application

Overview of the Data User Request (DUR) Process

1. Submit DUR

2. Data Access Committee Approval

3. Work Bench Access

1. **Draft your Data Use Request Application**

   Research Projects Require:

   Title: (xxx)

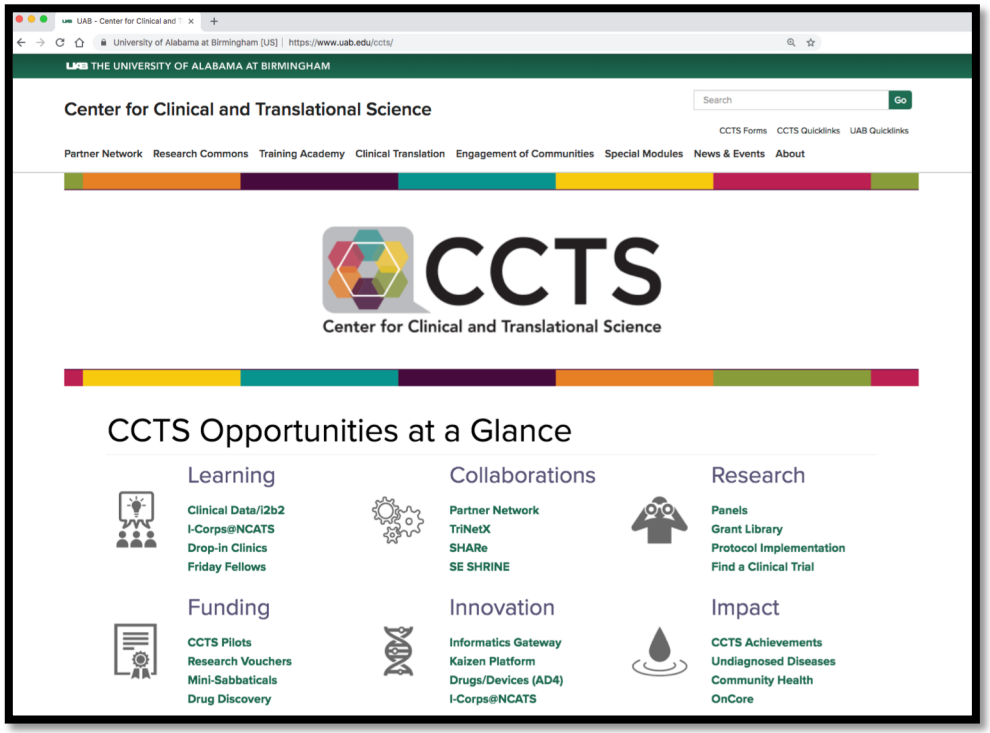
   Project Description: (must be COVID-19 Related)

   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

   Upload IRB Approval, if applicable

2. **Investigator submits a Data Use Request.**
3. **Data Access Committee (DAC) Reviews and Approves the research project**
4. **Investigators are given access to the analytics workbench**

Stay Connected



Science through Synergy

CCTS

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