

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 Participant 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.