

NeuroCOVID

Data Fields Overview & Data Access

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I. Study Summary

The COVID-19 Neuro Databank-Biobank (The NeuroCOVID Project), funded by the National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health, was initiated at NYU Langone Health in 2020. The objective of this project is to create and maintain an international resource of de-identified data and biospecimens for documenting and studying neurological complications experienced by patients in association with SARS-CoV-2 infection.

The NeuroCOVID database receives, curates, and stores de-identified clinical data from multiple participating USA and international study sites.

II. Eligibility Criteria

Non-Pregnant Adult Patients (18 years old and over):

- Diagnosed with SARS-CoV-2 infection on or after January 1, 2020, by laboratory testing
AND
- New neurological condition or worsening of pre-existing neurological conditions associated with SARS-CoV-2 infection

III. Data Summary List

De-identified data are abstracted from medical records. The data dictionary indicates where branching logic was used and which fields were considered Core vs. Non-Core. Changes/addition/hiding of data elements were made according to evolving scientific interest, especially considering post-acute conditions and symptoms, and timing of their onset and resolution.

The data dictionary includes detailed information on all data elements and changes.

Patient Characteristics

- Demographic information
- Medical setting patient was last seen
- Insurance
- Education / Employment
- Language
- Living arrangements
- Physical limitations/restrictions

Medical History

- BMI
- COVID-19 and influenza Immunization
- Comorbid medications prior to COVID-19 infection
- Comorbid neurological conditions prior to COVID-19 infection
- Non-neurological comorbid conditions

Covid19 Related Information

- New or worsening of pre-existing neurological conditions associated with COVID-19, and associated details
 - Neurological condition categories:
 - Demyelinating white matter disease
 - Encephalitis/meningitis
 - Stroke & associated
 - Ischemic
 - Hemorrhagic
 - TIA
 - Intracerebral/ intraventricular hemorrhage
 - Subarachnoid hemorrhage
 - Cerebral venous thrombosis
 - Myopathy
 - Neuropathy
 - Neuromuscular junction disorder

- Anosmia/ageusia
- Neurocognitive disorder or condition
- Mood disorders
- Thought disorders
- Fatigue disorders
- Headache
- Neuro-ophthalmic
- Hearing
- Dysautonomia
- Seizures
- Traumatic brain Injury
- Toxic metabolic encephalopathy
- Hypoxic Ischemic injury
- Movement disorder
- Brain tumor
- Myelopathy
- Non-neurological conditions
- World Health Organization Clinical Progression Score
- Substance use
- Medications
- Post-acute conditions
 - Month and year of COVID19 illness onset (or first positive test) were collected.
 - Timing of subsequent events (first neurologic condition onset, hospitalization, etc) was recorded as number of days after illness onset (or first positive test).
 - More specific data fields about the timing (number of days) associated with onset/worsening and resolution of each individual neurological condition were added to database as noted in data dictionary.
 - Neurological and non-neurological associated **symptoms** recorded in the medical record (variables with prefix “sym_”) were added to emulate, as closely as possible the patient-reported symptoms listed on the “WHO Case Report Form (CRF) for Post COVID conditions;” see data dictionary for timing.
 (https://cdn.who.int/media/docs/default-source/3rd-edl-submissions/who_crf_postcovid_feb9_2021.pdf?sfvrsn=76afd14_1&download=true).
 - Clinical trial participation
 - Substance overuse
 - Medications for acute illness (< 4 weeks from onset of COVID-19 illness)
 - Post-acute medications and treatments

Hospitalization Information

- Hospitalization details: (e.g. admission timing, LOS, ICU, etc)
- Hospital-associated relevant scales
- Interventions/procedures/complications
- Disposition

Testing

- COVID-19 testing
- Imaging/angiography
- Neuropsychological testing
- Smell testing
- Laboratory testing
 - Inflammatory markers
 - Hematology/CSF/coagulation
 - Rheumatologic tests
 - Chemistries
 - Serology
 - Culture
- EEG/EMG
- Ultrasound/DaTSCAN
- Autopsy

Specimens may be available by request depending on availability and investigator interest. Contact us for more details at cecile.norris@nyulangone.org

IV. Data/Specimen Request

Researchers interested in access to the NeuroCOVID dataset must submit an application for review by the NeuroCOVID Review Committee.

1. Submission Guidelines

Submission should be submitted using the online application:

<https://app.smartsheet.com/b/form/ef4a25f39260452a9ffbe6e9627b3b4d>

An administrative review of the application will be conducted for completeness prior committee review.

Application Elements

- Request type
- Applicant/PI information
- NIH format biosketch for PI & key personnel
- Institution information
- Funding source
- IRB status
- Lay Summary
- Name of Project/Title
- Abstract (400 words)

The scientific abstract should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study for the general scientific audience

- Protocol (not to exceed 3 pages single-spaced)
 - Hypothesis
 - Specific aims
 - Rationale
 - Design
 - Analysis plan
 - Bibliography (excluded from the 3 pages)

After NeuroCOVID Review Committee approval of the proposal, details, including but not limited to approval date, title, lay summary, Institution name, lead Investigator, and status of the project , (approved, in progress, published) will become public information, and will be shared on the NeuroCOVID website. Therefore, please do not submit a title or information that includes proprietary/confidential information.

Biospecimen requests

For proposals requesting biospecimen access, additional criteria will be evaluated:

- Rationale of biospecimen request
- Size of request for biospecimen (sample size should be appropriate for the research aims)
- Laboratory proposed for the biospecimen analysis

2. Proposal Review

Proposals will be reviewed on a quarterly basis by members of the NeuroCOVID review committee.

Applications will be reviewed on the quarterly basis on the following scheduled:

Cycle	Open for application	Close for application
Fall	October 1st	November 15th
Winter	January 1st	February 15th
Spring	April 1st	May 15th
Summer	July 1st	Aug 15th

Review criteria

Proposals will be reviewed against criteria including:

- Impact / priority
- Significance
- Innovation
- Approach
- Investigator
- Quality of research environment
- Value to the scientific community

Members of the review committee will evaluate and rate each proposal using a scorecard (appendix 1).

3. Duplicate and overlapping proposals

The review committee will assess the degree of overlap between proposals that may have similar project scopes, as part of the review process. If more than one researcher is requesting the data for a similar project already approved/submitted by another researcher, the researcher will be notified that there is a project that has an overlapping request.

Note: No confidential information will be shared. If there is substantial overlap, an effort will be made to encourage collaboration without revealing the identity of the researchers.

V. Data/Specimen Access

Upon proposal's approval from the NeuroCOVID review committee, the researcher will execute a Data Use Agreement and obtain IRB approval for the approved project. The researcher will then gain access to the data within the NeuroCOVID Researcher Portal. The NeuroCOVID Research Portal is a secured environment that contains several analytics tools (i.e. SPSS, SAS, Anaconda, R,..) for the research to conduct the research analysis.

VI. Questions

For any questions related to data and/or specimen access, please email Cecile Norris, NeuroCOVID Project Manager, at cecile.norris@nyulangone.org