

NCATS N3C Data Enclave & Data Access Requirements

To complete a Data Use Request (DUR), you must first sign and return this certification to the ORSP (orsp@osteo.wvsom.edu). Additionally, provide the enumerated elements identified in this document (these are required for the NCATS N3C access, already). Return this form and requested documents as part of the ORSP-1 research project initiation request (or in an email identifying the NCATS resources as part of a new/amended specific aim of an already approved project).

Data Use Request (DUR) process, including WVSOM requirements

1. Provide a copy of the Data Use Request to be submitted to NCATS N3C.
2. Provide a copy of the Certificate of Completion of [NIH Information Security and Information Management Training](#).
 - a. Each individual data user must complete *only the first course* on the list titled: [2020 Information Security](#) consisting of these 5 modules: *Information Security, Counterintelligence & Insider Threat, Privacy, Records Management, Emergency Preparedness*. (Allow 60-90 minutes to complete all 5 modules inside the *first course only*.)
 - b. After completing the 5th module of the 2020 Information Security course (only), a button will appear on the top bar that says "Print Certificate."
 - c. Users may be asked to provide this certificate to NCATS upon request.
3. Ensure completion of Human Subjects Research Protection training through CITI, as provided in the training requirements email from the ORSP, *if you intend to access the de-identified or limited datasets*. (This training requirement does not apply to investigators who will only access the synthetic dataset.)
 - a. Users will be asked to provide the date the training was completed to NCATS, and retain evidence of completion to provide NCATS upon request.
4. ORCID: Provide the ORSP your ORCID. Your personal ORCID will be required to create an account with NC3. If you do not have an ORCID, you may create one at their [webpage](#).
5. Sign and return this certification. By signing this certification, you agree to the following (in addition to the NIH NCATS Data Use Request you have attached):
 - a. Data will only be used for the specified project as described in the DUR. Each project requires a separate DUR to NIH. Data will be used exclusively for the Research Project proposed, and/or comparative studies using data from individuals infected with pathogens such as SARS, MERS, and H1N1 to support comparative studies, described in the DUR. Any other use of the Data is prohibited.
 - b. Any access of the NCATS N3C data shall occur only with a WVSOM issued encrypted device. No access using the WVSOM affiliation may occur from a personal device.
 - i. The WVSOM Investigator agrees to review the [WVSOM Acceptable Use of Information Technology Resources policy](#) (GA-31).
 - c. Any collaborators from a different institution, who will access the data, must have their own Data Use Agreement and Request forms in place through that collaborating institution
 - d. Investigators from WVSOM will adhere to [WVSOM's Human Research Protections Program](#) regarding the use of de-identified and Limited Data sets.
 - i. Note that for these types of data requests, the Investigator must have an IRB approval/determination letter to submit with the Data Use Request to NIH.
 - ii. Note that the IRB approval must be in effect for the entire duration of the DUR.

- e. If the Investigator separates from WVSOM, the Investigator must notify the NCATS N3C DAC.
- f. WVSOM Investigators agree to not attempt to re-identify or contact any individuals who are the subjects of the Data, or their known relatives. Additionally, WVSOM investigators agree to not attempt to re-identify or contact Data contributors or healthcare providers.
- g. WVSOM Investigators shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party without prior written permission of NCATS N3C DAC.
 - i. If received, such written approval must be provided to the ORSP prior to the disclosure of the Data to the third party.
- h. WVSOM Investigator agrees to use Data in compliance with all applicable federal, state, local, and tribal laws, regulations, and policies.
- i. The WVSOM Investigator agrees not to photograph, create screen shots, print, nor download Data viewed on the NCATS N3C Data Enclave.
- j. Any unauthorized access, use or disclosure must be reported to both NCATS *and* WVSOM IT. WVSOM IT must be notified first, within 4 hours of discovery of the incident, so that an appropriate remediation plan may be developed.
 - i. To report an unauthorized access, use, or disclosure incident to WVSOM IT, complete and submit an [INCIDENT REPORTING FORM](#). This report must be filed within 4 hours of discovery of the incident, in order to ensure that the NCATS requirement, as below, is addressed by the time a report is filed with NCATS (as below). Please choose the Incident Type as “HIPAA Breach” in the form.
 - ii. Once WVSOM IT and the ORSP have communicated with the Investigator, the WVSOM Investigator must report the unauthorized access, use, or disclosure to NCATS. To do so, the WVSOM Investigator must email NCATSDataAccessIncidents@nih.gov no later than 2 business days after discovery. Notification should include any known information regarding the incident and a general description of the activities or process in place to define and fully remediate the situation. Copy orsp@osteo.wvsom.edu on the email to NIH.
- k. WVSOM Investigators are encouraged to make the results of their research publicly available, ideally in an open access format and consistent with scientifically accepted publication or dissemination practices. In recognition of the effort that Data Contributor(s) made in collecting and providing the Data, User(s) who publish their results, or otherwise publicly present findings, agree(s) to acknowledge the NCATS N3C Data Enclave as the source of these Data and Data Contributors per guidelines in the NCATS N3C Data Enclave website.

By signing this document, I agree to follow the processes described above, and I attest to my understanding of my responsibility and obligations to WVSOM and for N3C Data use under the WVSOM Data Use Agreement.

Printed Name

Signature

Date

ORCID