UNIVERSITY of VIRGINIA
Vice President for Research
Institutional Review Board for Health Sciences Research

May 26, 2023

To NCATS N3C Data Access Committee,

This letter is being provided as follow-up to an earlier letter given the expansion of the current National **COVID** Cohort Collaborative (N3C) enclave to include clinical tenants under a broader data sharing agreement for the renamed National **Clinical** Cohort Collaborative (N3C). The acronym is the same but the scope is expanding. We also understand that although the cohort is expanding, the data elements in the expanded enclave are the same as the prior enclave from a regulatory perspective in that the following points remain the same as National **COVID** Cohort Collaborative:

1. National **Clinical** Cohort Collaborative includes a limited dataset of health record data from contributing sites with site ID anonymized.
2. National **Clinical** Cohort Collaborative includes Patient Privacy Preserving Linked (PPRL) data such as CMS data and death data, and public datasets such as census data. NCATS will continue to add other PPRL datasets over time, none of which will include identifiers beyond those in limited datasets.

As before, the Institutional Review Board for Health Sciences Research (IRB-HSR) at the University of Virginia (UVA) has determined that research studies using ONLY data available in the N3C enclave (including health record data, PPRL data, and public datasets) will be considered non-human subject research if the following criteria are met:

1. Study does not require submission to the FDA.
2. All data collected for the project, were entirety collected for purposes other than this project.
    a. The investigator will not obtain information through intervention or interaction with the individual.
    b. The investigator will not obtain data for this project via a process like a chart review where identifiable health information will be viewed, used or analyzed.
3. The research does not require access to any data that are readily identifiable and/or contain HIPAA identifiers exceeding the criteria of a Limited Dataset per HIPAA regulations. In addition, the research will not involve importing additional information into the dataset that would make the data within the N3C identifiable per HIPAA regulations. The research does not require access to any individuals as subjects of the research.
4. A contract is in place covering institutional access to N3C data that includes HIPAA Data Use Agreement (DUA) language. The researchers will each submit a Data Use Request (DUR) or DUR Collaborator form for new access to data within N3C. As part of the DUR the researcher will attest to having reviewed the institutional DUA as well as agreeing to the N3C Data User Code of Conduct.

In cases where the criteria above **are not met**, IRB review or oversight will be required since the project may then meet the federal definitions of human subject research.

Sincerely,

DocuSigned by:
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Eileen Sembrowich
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