UNIVERSITY of VIRGINIA
OFFICE of the VICE PRESIDENT for RESEARCH
IRB for Health Sciences Research

October 8, 2020

To NCATS N3C Data Access Committee,

The Institutional Review Board for Health Sciences Research (IRB-HSR) at the University of Virginia (UVA) has determined that research studies using ONLY N3C data 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 will meet the federal definitions of human subject research.

Sincerely,

Susie Hoffman

Susie R. Hoffman BSN CIP
Director, IRB for Health Sciences Research