



December 20, 2021

Dear Tribal Leader and Urban Indian Organization Leader:

I am writing to initiate a formal Tribal Consultation and Urban Confer on the National Center for Advancing Translational Sciences (NCATS) National COVID Cohort Collaborative (N3C) Data Enclave, **on February 11, 2022, at 1:30 p.m. EST.**

NCATS is one of 27 Institutes and Centers within the National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services (HHS). The purpose of this letter is to request input from Tribal Nations about *whether and how* to appropriately make contributed American Indian or Alaska Native (AI/AN) data available to Tribal researchers and to the broader scientific research community.

The onset of the COVID pandemic raised many concerns with few answers. Access to real-world data from COVID-treated patients is necessary to gain clinical insights that may help in preventing and treating COVID-19. The N3C Data Enclave is a national electronic health record (EHR) data research resource to address these COVID-19 needs. Existing EHR data from hospitals and health care organizations are collected and harmonized to a common data format (e.g., recording height in centimeters) to make information comparable across the different health systems and over time. These data are refreshed on a regular basis to understand the pandemic as it progresses, including the entry of viral variants and gaining knowledge about long-COVID. The clinical data in the N3C reflect the U.S. population and its diversity when considering such factors as race and ethnicity, age, and geographic location. NCATS has a deep commitment to data sharing and inclusiveness so that knowledge gained can be used to bring more treatments to all people more quickly.

As the pandemic took hold in early 2020, NCATS quickly partnered with health care organizations across the United States to provide patient EHR data for the N3C Data Enclave, specifically for research on COVID-19.¹ NIH and NCATS worked carefully to align processes of data transfer and data use so they conformed to the provisions of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Federal Policy for the Protection of Human Subjects (“Common Rule”), balancing the need to keep patient information confidential alongside the public benefit of making this information available for research. All data must remain in the protected Enclave and can be used only for COVID-19-related research after approval from the NCATS N3C Data Access Committee.

Participants are not recruited for the N3C. Rather, contributing sites de-identify existing data from individuals who are COVID-19 positive along with two matched COVID-19-negative individuals. Under the HIPAA privacy regulations for a [limited data set](#),² de-identified health

¹ The N3C Data Enclave is a secure platform through which the harmonized clinical data provided by our contributing sites is stored. The data itself can be accessed only through a secure cloud portal hosted by NCATS and cannot be downloaded or removed.

² Refers to protected health information that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement. [HIPAA Privacy Rule and Its Impacts on Research \(nih.gov\)](#)

information may be used and disclosed for research purposes. The N3C received a waiver of consent from the NIH Institutional Review Board, and NIH is taking care to ensure the highest privacy and security requirements are met and adhered to for housing and protecting these data in the NIH-managed N3C Enclave.

The NCATS team has been working toward a Tribal Consultation for more than a year, because contributing sites provide existing race and ethnicity categories and five-digit ZIP code data to the N3C as part of a data set collected from patient EHRs. Concurrently, Tribal Consultations were underway or in process for several other NIH COVID-related programs. In the meantime, the NCATS team has been in constant communication with the NIH Tribal Health Research Office leadership, has sought input from other NIH colleagues who have experience with Tribal data and Consultations, and has met with the Tribal Epidemiology Centers to discuss ideas. Through these discussions, and until NCATS can consult with the Tribal Leaders, NCATS took two key steps to protect the AI/AN submitted data.

- Race and ethnicity information from health care settings is generally self-identified or assigned by health care providers and does not relate to Tribal enrollment and does not include Tribal affiliation. All AI/AN submitted data are aggregated in the “other” category.
- The five-digit ZIP codes that overlap with Tribal communities and/or refer to a population of 20,000 people or fewer are currently not accessible for studying specific research questions.

N3C is under ongoing development, and thus, the agency is seeking input from Tribal Nations about *whether and how* to appropriately make AI/AN data available to Tribal researchers and to the broader scientific research community.

A “Framing Letter” with additional information about N3C has been provided along with this letter. Suggested topics for your consideration include the following:

- Should AI/AN data be unobscured and made available for COVID-19 research?
- What steps would the N3C need to take to consider making these data available?
- If Tribal Nations identify benefits to using the N3C data resource, what outreach is needed to better engage AI/AN researchers?

In accordance with the NIH’s implementation of the HHS Tribal Consultation Policy, NIH is announcing a one-hour virtual NIH Tribal Consultation and Urban Confer on the National COVID Cohort Collaborative (N3C) Data Enclave on **February 11, 2022, from 1:30 p.m. to 2:30 p.m. EST**. We encourage you to participate in this discussion. A recorded informational webinar about the N3C Program is available for your review prior to the Tribal Consultation on the NCATS Tribal Consultation Event page, <https://ncats.nih.gov/n3c/about/tribal-consultation>.

Participant Information

What: NIH Tribal Consultation on the National COVID Cohort Collaborative (N3C) Program

Date: Friday, February 11, 2022

Time: 1:30–2:30 p.m. EST | 12:30–1:30 p.m. CST | 11:30 a.m. –12:30 p.m. MST |
10:30–11:30 a.m. PST | 9:30–10:30 a.m. AKST

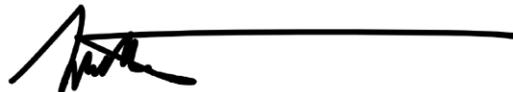
Live videocast link: Will be available on <https://ncats.nih.gov/n3c/about/tribal-consultation>, closer to the date of the Consultation. If you have any technical questions related to connectivity or audio/visual matters regarding the meeting, please contact Dr. Penny Burgoon at N3CConsultation@nih.gov.

If you are unable to attend, we invite you to send written testimony and comments to NIHTribalConsultation@nih.gov by April 11, 2022.

The NIH remains committed to engaging and partnering with Tribal Nations to use the power of biomedical research to support healthier communities. Thank you for your continued partnership as we work together during this public health emergency to improve the health of American Indians and Alaska Natives. We look forward to this opportunity to listen and learn from you.

If you have any additional questions, please feel free to contact **Dr. Penny Burgoon**, Director, Office of Policy, Communications, and Education, National Center for Advancing Translational Sciences, NIH, at N3CConsultation@nih.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joni L. Rutter', followed by a long horizontal line extending to the right.

Joni L. Rutter, Ph.D.
Director, National Center for Advancing Translational
Sciences