Tribal Consultation: National COVID Cohort Collaborative (N3C)

Meeting will begin shortly

- Please stay muted with your camera off unless you are speaking.
- This meeting will be recorded and broadcast on NIH Videocast. (Zoom chat will not display in videocast)
  - Closed Captioning is available.
- In the event of technical difficulties, please email N3CConsultation@nih.gov.
Tribal Consultation: National COVID Cohort Collaborative (N3C)

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February 11, 2022
https://ncats.nih.gov/n3c/about/tribal-consultation
Purpose of Consultation: Engaging Tribes for Use of N3C to study COVID-19 Health Outcomes

- Describe the NCATS National Covid Cohort Collaborative (N3C) electronic health records (EHR) data resource
- Describe current and future status of American Indians and Alaska Natives (AI/AN) data in N3C
- Understand Tribal Leaders' perspectives on benefits/risks of N3C
  - Consider how N3C can directly benefit Tribal communities
  - Engage Tribes to use N3C for COVID-19 health research, for example research to understand long COVID or Post-acute sequelae of COVID-19 (PASC).

https://ncats.nih.gov/n3c/about/tribal-consultation
Working to Understand Tribal Perspectives

• Working with THRO
  • Monthly Meetings since September 2020

• Conversations with external experts
  • Johns Hopkins Center for American Indian Health (August 2020)
  • Southcentral Foundation (September 2020)
  • Tribal Epidemiology Center Directors (September & November 2020)

• Learning from NIH COVID-19 Tribal Consultations
  • May 2020 – NIH Tribal Consultation on COVID-19 Research
  • July 2021 – NIH Tribal Consultation on Rapid Acceleration of Diagnostics (RADx) Tribal Data Repository
  • April 2019 – NIH Tribal Consultation on Draft Policy for Data Management and Sharing
What the N3C Database Resource Is and Is Not

**Overarching Purpose and Duration:**
- N3C was built because of the urgency to understand clinical course of COVID-19
- N3C is a 5-year program that can be renewed (ability to extend with renewed agreements)

**N3C:**
- **Is** de-identified health data from existing EHRs
- **Does** utilize existing data
- **Is** provided by health care organizations, specifically for researching COVID-19 with the goal of improving health outcomes
- **Is** a secure resource; data cannot be downloaded or removed
- **Does** contain obscured AI/AN information (self- or provider-reported) and zip codes

**N3C:**
- **Is not** a resource that contains Tribal affiliation information; nor IHS data
- **Is not** the same as the RADx Tribal Data Repository
- **Is not** inclusive of biospecimens
- **Is not** engaging with participants
- **Is not** consented (waiver of consent obtained)
- **Is not** a repository for human genomic data; human genomic data are not allowed
When the pandemic began, there were so many questions and few answers: Need for holistic approach

- How does it spread?
- Why are symptoms so variable?
- Which diseases or conditions (e.g., diabetes, heart disease, cancer, hypertension) increase the risk for severe COVID-19?
- What are COVID-19 symptoms?
- What are best treatments for COVID-19?
Need: Standardized electronic health records to aid information sharing

• Electronic health records (EHRs) are not standardized
  • No standard process to collect and manage EHR data
  • No standard way to use patient EHRs for research or help make or inform public health decisions using near real-time data
N3C Project: What, How, Why, and Impact

**Important Public Health Questions**

- What are COVID-19 symptoms?
- What are risk factors for severe COVID?
- What are risk factors for Long COVID?
- What are best treatments for COVID-19?

**Potential Impacts**

- Better prevention & treatment
- Long COVID
- Optimized care for specific communities
- Improved health equity
- Save lives
N3C Database Controlled Access

1. Data Provided to N3C
   Institutions Sign Data Transfer Agreement

2. Data Access & Use
   1. Institutions Sign Data Use Agreement for their researchers
   2. Researchers Register & Submit Data Use Request
      a. Human Research Participant Protections (HRPP) Training
      b. NIH IT Security Training
      c. User Code of Conduct

3. NIH Data Access Committee (DAC)
   Reviews data use requests
   • Ensure COVID-19 related research
   • Assess that requested level of access is justified
   • Confirm compliance with training requirements
   • Ensure that certification of institutional review board (IRB) approval is provided if needed

Additional N3C Security
• Data cannot be removed
• Platform has several layers of security
• Adheres to Federal and NIH policies & regulations
• Privacy protections
• Security testing & monitoring
We are seeking consultation to inform Tribes of this COVID-19 resource and to seek input on whether or how these data could be made most useful for Tribal interests

**Approach Pending Tribal Consultation**

- AI/AN is currently obscured in an aggregated category with other data
- 2,659 zip codes overlapping Tribal lands are not available, to block any inference of Tribal affiliation

**Tribal Consultation**

- NCATS has posted relevant materials on its website: [https://ncats.nih.gov/n3c/about/tribal-consultation](https://ncats.nih.gov/n3c/about/tribal-consultation)
- After the Consultation, Tribal Nations will have time to submit written testimony to NIH and NCATS
- NCATS will prepare a report and action plan based on the Tribal Consultation
How can the N3C contribute to our understanding of COVID-19?

**N3C’s Utility**
- Largest EHR research resource

**Evolution of COVID**
- Viral variants
- Long COVID
The tremendous amount of data within the N3C enables researchers to characterize long-COVID and predict who may be vulnerable.

- Difficulty breathing associated with higher risk of PASC
- Vaccination associated with lower risk of PASC

N3C Data Enclave Statistics
Release Set: January 27, 2022
Production version: Release-v61-2022-01-27

- Sites: 69
- Persons: 11.0 million
- COVID+ Cases: 3,923,853
- Clinical Observations: 1.1 billion
- Lab Results: 5.9 billion
- Medication Records: 1.8 billion
- Procedures: 579.2 million
- Visits: 597.5 million
Learning and Training Resources in the N3C

- Help Desk
- Weekly office hours
- 20+ Training Videos
- 31 Domain teams (support from subject matter experts)
- Personal Trainer

Support Desk

If you need assistance with the N3C Data Enclave, the following options are available:

- Attend Support Desk office hours on Tuesdays & Thursdays at 10-11 am PT/1-2 pm ET. Register here.
- Submit a Support Request.
- Consult the Frequently Asked Questions (FAQs).
- A quick start tour is available inside the Enclave.
- Video tutorials will be uploaded as they are created.

Tutorials

The following tutorials provide information for researchers to learn about the tools, vocabulary, and resources available within the N3C Data Enclave. For those users with a current N3C Data Enclave account, more detailed tutorials can be found within the internal Training Portal (Log in required). For additional support options, please visit the N3C Support Desk.

Enclave Orientation Session B

This session is for analysts, statisticians, data scientists, or anyone who wants to gain a broader understanding of the tools needed to work with the

Enclave Orientation Session A

This session is for those who want to learn about N3C, as well as how to engage with project teams and access the data. Learning objectives: (1) Provide

Privacy Preserving Record Linkage

Learn about hashing and how it allows for privacy-preserving record linkage (PPRL) within the N3C Data Enclave. A demonstration of these linkages is
How can we make this resource more useful to the Tribal communities?

• How should AI/AN data be shared responsibly for COVID-19 research?
  • How would Tribal communities want to be involved in governance, access, use, etc.?

• What steps should NCATS consider in making AI/AN data available?
  • Which aspects of governance would be particularly important for incorporating Tribal?

• How can ongoing partnerships with Tribal communities and researchers be enhanced?
### How should AI/AN data be shared responsibly: Examples* of options

<table>
<thead>
<tr>
<th>Model</th>
<th>Access to AI/AN data</th>
<th>Impact of this model</th>
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<tbody>
<tr>
<td>Current Model</td>
<td>AI/AN data are obscured.</td>
<td>Demographics and zip codes remain obscured for research purposes, limiting community-specific benefits.</td>
</tr>
<tr>
<td>Tribal Data Access Committee (TDAC)</td>
<td>Tribal Data Access Committee (TDAC) as part of the current DAC process</td>
<td>Allows strict control for AI/AN data with relatively low administrative burden. Only researchers with specific approvals could access unobscured data, broadening community-specific benefits</td>
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<tr>
<td>Tribal Data Use Request (TDUR) for data</td>
<td>One TDUR for all Tribal research</td>
<td>One overarching TDUR with locus of control at lead researcher level. Higher burden for few people.</td>
</tr>
<tr>
<td>Tribal Data Space</td>
<td>Create a protected Tribal-specific space within the N3C?</td>
<td>Allows strict control for AI/AN data with moderate administrative burden. Only researchers with specific approvals could access unobscured data, broadening community-specific benefits</td>
</tr>
<tr>
<td>All open</td>
<td>Unobscure all AI/AN and zip code data</td>
<td>Allows the broadest level of access for all researchers.</td>
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*Not mutually exclusive or exhaustive*
Q&A

Please submit questions through the Zoom chat box.

Tribal Leaders may also send written testimony to NIH Tribal Consultation@nih.gov before Friday, March 18, 2022.
NCATS

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To learn more about N3C, visit us at https://ncats.nih.gov/n3c
### Four Pillars of Data Protections

<table>
<thead>
<tr>
<th>Regulatory &amp; Policy</th>
<th>Privacy Measures</th>
<th>Security Testing and Monitoring</th>
<th>Researcher Responsibilities</th>
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| - Data- Contributing Sites abide by the HIPAA Privacy Rule  
- N3C research is subject to the Federal Policy for the Projection of Human Subjects in research ('Common Rule')  
- Data are provided as HIPAA-defined Limited Data Set  
- NIH IRB oversight & waiver of consent  
- For COVID-19 related research only  
- No genomic data  
- No emergency public health authorities were used to obtain the data under these conditions. | - Certificate of Confidentiality  
- Data stays within the Enclave: No download or capture of raw data  
- Privacy Impact Assessment  
- Review of project requests by Data Access Committee  
- Additional Tribal data privacy measures (while seeking a consultation with Tribal Nations) | - Federal Government Compliant Enclave managed by NCATS  
- Meets government security controls for cloud security and privacy  
- Data encryption in transit and at rest, without exception  
- Scheduled penetration testing  
- Active monitoring and logging by NIH and HHS  
- Auditing of activities in the N3C Enclave | - A User’s organization signs a Data Use Agreement with NCATS for terms and conditions of use  
- Users Adhere to a Code of Conduct  
- Required NIH IT Security Training  
- Required Human Subjects’ Protections Training  
- Follow Community Guiding Principles |
Harnessing resources of the Clinical and Translational Sciences Awards (CTSA) Program institutions, CTRs in IDeA States, and the Center for Data to Health (CD2H), the goals are to:

- Generate a secure, national resource of electronic medical record data from COVID-19 tested patients
- Make available real-world clinical data for speeding COVID-19 research and improving patient care