INSTITUTE FOR TRANSLATIONAL MEDICINE

**Request for National COVID Cohort Collaborative (N3C) Project Applications
for April 1, 2022-June 30, 2022**

Full Applications due March 1st 2022 by the EOD CST through an online application form at
https://redcap.uchicago.edu/surveys/?s=AXFATW9PNJDFP3HD.

About the unit: The Institute for Translational Medicine (ITM) connects researchers and community organizations with funding, education, and resources to find effective ways to prevent and treat disease in real-world settings.

As part of the National Institutes of Health/National Center for Advancing Translational Science-funded Clinical and Translational Science Awards (CTSA) program, ITM works with a consortium of 60 institutions toward advancing medicine in innovative ways. Their mission is to train scientists and health care providers at its partner institutions, and in the community to determine the molecular underpinnings of disease and disease predisposition, and to develop, test, and implement the most effective personalized therapies that are rigorous, valid, efficient, ethical, and respectful of our communities' needs and values. Learn more about ITM on our website **here**.

Context: The importance of timely, good quality, open and disaggregated data and statistics has never been as clear as during the COVID-19 crisis. Such data are critical in understanding, managing and mitigating the human, social and economic effects of the pandemic. From a clinical perspective, they are also essential for designing new treatments and accelerated actions to address the health crisis. During public health emergencies like COVID-19, science- and the process of turning observations into new therapies- must be faster than ever. The National COVID Cohort Collaborative (N3C) is addressing this urgent need by building a centralized national COVID-19 analytics platform that can turn all these data into new knowledge, with the goal of speeding research efforts across the country. The N3C is a partnership among the NCATS-supported **Clinical and Translational Science Awards (CTSA) Program** hubs, the **National Center for Data to Health (CD2H)**, and NIGMS-supported **Institutional Development Award Networks for Clinical and Translational Research (IDeA-CTR)**, with overall stewardship by NCATS. Collaborators will contribute and use COVID-19 clinical data to answer critical research questions to address the pandemic.

The ITM is committed to support data driven initiatives that advance COVID-19 knowledge. ITM is funding projects that seek to answer meaningful research questions using the National N3C Data Enclave. **The funds will be used entirely to cover analyst time to work with the N3C Data Enclave**. The maximum number of analyst hours for a given project should be proposed by the applicant, and then may be revised during the proposal review through discussions among reviewers and/or applicants. The final maximum number of analyst hours for a given project will not exceed 400, but could be much less, and final allocation will depend on the overall pool of applications and the review processes. The number of projects awarded (likely between 1 and 2) will be determined based on the number of hours requested by each project and the total hours available. The analytical support will be provided by a Senior Research Analyst (SRA) from the University of

Chicago Center for Health and the Social Sciences' Methods Core (more information [here](#)) who is trained in the core programming skills necessary for N3C work, and is gaining proficiency in the use of the N3C data enclave specifically. Project leads will also receive feedback and guidance from the ITM-N3C review committee members and support in dissemination and extramural application development if applicable.

Call for applications: We are currently accepting projects for the period April 1, 2022 through June 30, 2022. Information on eligibility, research focus areas, and application criteria are described below.

Application deadline: Please submit via the online form by March 1st 2022, EOD CST.

ITM-N3C project priority areas and special considerations:
- All projects must use data collected through the N3C Data Enclave. The NCATS N3C Data Enclave contains nationwide real world data from patients who were tested for COVID-19 or whose symptoms are consistent with COVID-19, as well as data from individuals infected with pathogens such as SARS 1, MERS and H1N1, which can support comparative studies. The data includes information such as demographics, lab test results, encounters, procedures, medications, medical conditions, physical measurements and more; see the **full list** of data. Please note that the N3C Data Enclave is focused only on retrospective electronic health record data.
- All projects must use the full amount of the award to cover research analyst time from the University of Chicago Center for Health and the Social Sciences. **Note that analyst time will be paid directly by the ITM as awarded projects use these services. Awardees will not receive funds to spend.**
- Projects are expected to leverage access to granular line level real patient data from the N3C Data Enclave.
  There are 3 tiers of data available for analysis:
  - **Limited Data Set (LDS):** Consists of patient data that are void of all 18 protected health information personnel identifiers that are identified in the [Safe Harbor Method](#) of the HIPAA Privacy Rule de-identification standard, except the following
    - Dates of service (dates of birth are not present, but year of birth is)
    - Patient 5-digit ZIP code
  - **De-identified Data Set:** Consists of patient data from the LDS with the following changes
    - Dates of service are algorithmically shifted to protect patient privacy
    - Patient ZIP codes are truncated to the first three digits or removed entirely if the ZIP code represents fewer than 20,000 individuals
  - **Synthetic Data Set:** Consists of data that are computationally derived from the LDS and that resemble patient information statistically but are not actual patient data.
  Priority will be given to projects using LDS or De-Identified Data Sets from the N3C Data Enclave.
- Projects are expected to conduct all data analyses related to the project within N3C Data Enclave, using programming languages and data analytics tools including R, Python, SQL, Contour.
- All projects must leverage population-based research to study COVID-19 related topics, particularly: a) research that identifies effective interventions as the pandemic continues to evolve; b) research that seeks to understand long-term health impact of COVID-19; and c) research that enables novel analyses and methods that will serve to address COVID-19 and other diseases in the future.
- In addition to advancing COVID-19 core research, all projects are expected to describe a plan for dissemination of the project findings.
- Projects should propose a research plan that can be completed in 3 months with a max of 400 total hours of analyst time (150-250 hours suggested). The services that the analyst can provide to the awarded project are limited to:
  - preliminary discussion and study design
  - N3C data management and data preparation (external data cannot be merged into the N3C enclave, and post-hoc analysis of N3C data with non-N3C data from the PI, e.g., might be

considered feasible for analyst work but should not be expected until the application is approved)
- o N3C data analysis and presentation of N3C data analysis outputs; such as table and figure creation
- o writing, compiling, and/or editing the portions of a manuscript's Methods section and/or Results section that covers the methods that the analyst used and/or the results that those methods generated
- Dissemination activities may extend past the award timeframe, but this award does not reserve analyst time for dissemination activities after the timeframe; other funding sources would be needed to fund analyst effort after the timeframe of this award is finished.

Eligibility of project applicants:
- Faculty at all levels at any of the ITM partner institutions are encouraged to apply.
- Research staff at ITM partner institutions are also eligible to apply if they have PI eligibility.
- Postdoctoral researchers at any ITM partner institutions may apply with a faculty mentor/supervisor (and with a LOS from that mentor confirming continued support for the fellow during the project period).
- Investigators may apply from any department or field as long as the project advances COVID-19 population based research.

If selected for funding, project PIs agree to:
- Submit an application for N3C data access in a timely fashion after receiving the award notice (timeline described below); this includes: (1) confirming their institution has an active N3C Data User Agreement (DUA), (2) registering with N3C, (3) completing the required N3C registration training, which consists of a refresh of your institution's human subjects research training if not completed in the past 3 years, and the 60-90 minute 2021 NIH Information Security and Management Refresher (through the NIH public portal), and (4) submitting an online Data Use Request (DUR) through NCATS N3C Data Enclave for their new awarded project. See **FAQs about DURs**. The N3C Data Access Committee (DAC) reviews and approves DURs. Once the DAC approves a DUR, access to the N3C Data Enclave workspace will be effective for one year starting from the date access is granted. A DUA must be in place for the entire term of a DUR. DURs are renewable. When users renew their DURs, they will need to attest at that time that their training for access to the N3C Data Enclave is up to date. The entire process for N3C data access usually takes 15 business days. There is no fee to access the data. Learn more about the **process for accessing** the N3C Data Enclave.
- Submit human subjects protocol for IRB review in a timely fashion (timeline described below) after receiving notice of being selected as a finalist. If the members of the study team are from an ITM institution other than UChicago, the awardee will have to work with their local IRB to obtain their approval as well as a letter of reliance from the UChicago IRB. Note, if the project works with only the N3C De-identified or Synthetic data, many IRBs will likely have a less-involved and quicker review than if the project would work with the N3C Limited Data.
- Work closely with the assigned Senior Research Analyst, providing direction to the study and intellectual input to the study design. PIs agree to make time and create opportunities for working collaboratively with the SRA for timely completion of the proposed research plan.
- Join the ITM N3C user group and regularly attend its meetings.
- Present at least once in a workshop at their home institution or multi-site workshop with other ITM partner institutions.
- Contingent on positive outcomes from the workshop presentation and sufficient quality of the findings, disseminate the findings of the at a national conference and/or in a peer-reviewed journal.

Full application – due March 1st, 2022, by the EOD CST

Applications are submitted through the online application form found here:
https://redcap.uchicago.edu/surveys/?s=AXFATW9PNJDFP3HD

Applications should include:
- PI and collaborators' NIH biosketches (5 pages maximum per biosketch)
    - See here for blank biosketch and instructions
- Specific aims/hypotheses to be tested (1 page)
- Research plan (3 pages)
    - background and significance of the proposed research
    - relevant preliminary data (if applicable)
    - study design and methods;
    - analytic plan;
    - a timeline for project completion
        - Please note that the project period is April 1, 2022, through June 30, 2022, although it's acceptable for some activities, like research dissemination, to extend past the project period
- References/bibliography
- Names of all key personnel involved in the project
- Budget and Justification
    - Applicants may request up to 400 hours of analyst time per project, although we expect to fund projects that each require a maximum of 150-250 hours of analyst time.
    - Applicants are expected to submit an estimate for the number of analyst hours for their project with each application, and a justification that describes how that estimate will be allocated to specific tasks (see below for a description of the required contents of the budget justification for each application submitted). After a submission, the review committee may reach out to the applicant during the review process to invite the applicant to schedule a consultation with reviewers to discuss and perhaps suggest revisions to the estimated hours needed, the research plan, and the budget justification for the proposed research plan. The decision by the review committee of whether to reach out to a given applicant with this invitation will depend in general on the merit of the application and other applications; in general, meritorious applications that seem to require small adjustments to the hours or research plan according to the reviewers will be more likely to receive such invitations.
    - Budget justification will consist of a simple narrative/table describing estimate of analyst time needed for project execution tasks. **Use the form below to complete and submit your budget request.** Acceptable analyst tasks that will be eligible for analyst time are:
        - preliminary discussion and study design
        - N3C data management and data preparation (external data cannot be merged into the N3C enclave, and post-hoc analysis of N3C data with non-N3C data from the PI, e.g., might be considered feasible for analyst work but should not be expected until the application is approved)
        - N3C data analysis and presentation of N3C data analysis outputs; such as table and figure creation
        - writing, compiling, and/or editing the portions of a manuscript's Methods section and/or Results section that covers the methods that the analyst used and/or the results that those methods generated

If awarded, the final research plan, scope of work, and budget will be reviewed and approved by the Review Committee.

Selection and notification of award
Projects will be reviewed and scored by review committee members and subject area experts.

Applications will be scored in line with NIH scoring guidelines in the following categories, on a scale of 1 (exceptional) to 9 (poor): overall impact, significance, investigator(s), innovation, approach, and other review criteria/considerations.

Timeline of key dates

- *Application deadline*: Please submit via the online form by the EOD CST, March 1, 2022.
- *Review for merit and feasibility:* March 2-14, 2022.
- March 15, 2022 *award finalists are notified of their status and given suggested revisions to their projects based on reviews*
- *Deadline for providing completed DUR and IRB/SMART IRB applications to ITM by* EOD, March 21, 2022.
- *Project selection and submission of DUR in N3C Data Enclave and IRB applications,* March 22, 2022.
- *Projects start on* April 1, 2022

Contacts

Please contact Andrea Flores at aflores@bsd.uchicago.edu with any questions. You may also contact Tom Best (tbest3@bsd.uchicago.edu) and Sonja Johnson-Hall (sjohnso2@bsd.uchicago.edu)

BUDGET

For each task that the N3C Data Analyst will complete for this project, please provide an estimated number of hours and a detailed explanation of the work to be done. Please see the RFA for a more detailed description of the analyst services available.

Function	Hours	Description/Justification
Preliminary Discussion		
Study Design		
Query Preparation		
Data Management		
Data Analysis		
Data Outputs		
Manuscript Preparation and Editing		
TOTAL HOURS		