HSC Application (Version 1.0)

1.0 General Information

*Enter the full study title:		
Investigating the epidemiology of SARS-CoV-2 and influenza A co-infection among pediatric patients in the United States using the National COVID Cohort Collaborative (NC3)		
***Enter a short title for quick reference:**		
Epidemiology of pediatric SARS-CoV-2 and influenza A co-infection, US An abbreviated version of the full study title		

2.0 Add departments

2.1 Add all departments associated with this study:

Is Primary?	Department Name
◉	**HSC** - *HSC* - Dept. of Biostatistics & Epid
○	**HSC** - *HSC* - HSC Student

3.0 ■ Assign Key Study Personnel (KSP) to access the study

3.1 * Add a Principal Investigator (PI).
See SOP 801: Investigator Qualifications and Responsibilities for specific qualifications for serving as PI.:

Name	Role	Training Record
Wendelboe, Aaron, PhD	**Principal Investigator**	View Training Record

3.2 Add Research Staff.
IMPORTANT: Individuals who are no longer faculty or staff at OU/OUHSC, OU Health, VA, or Dean McGee should be listed as Non-OU Collaborators. Indicate if Non-OU Collaborators are involved in Section 100, Question 5.4, and add the collaborator(s) to Section 150. 5/17/2023

A) Additional Investigators

Name	Role	Training Record
Naqvi, Ozair Hassan	**Sub-Investigator**	View Training Record

B) Research Support Staff

Name	Role	Training Record
No Research Support Staff have been added		

3.3 *Please add a Study Contact:

Name	Role	Training Record
Naqvi, Ozair Hassan	Study Contact	View Training Record
Wendelboe, Aaron, PhD	Study Contact	View Training Record

Study contact(s) will receive all automatic system notifications, study correspondence messages, iRIS home screen task reminders, and outcome letters. It is recommended that KSP charged with submitting forms and responding to stipulations are added as study contacts. Usually, study coordinators and the PI are listed as study contacts.

3.4 Norman Campus only: If applicable, add a faculty advisor

Name	Role	Training Record
No Faculty Advisor has been added		

4.0 50-HSC Type of Submission

4.1 IRB to review study:

- (●) Health Sciences Center IRB
- ( ) (not used)

4.2 Select the type of submission you wish to complete:

- ( ) Study Application / Research Application
- (●) Determination of Human Research Worksheet
- ( ) Investigator Representation for Research on PHI of Decedents, Privacy Form 7 (Privacy Board Review)
- ( ) Investigator Representation for Review of PHI - Preparatory to Research, Privacy Form 6 (Privacy Board Review)
- ( ) One-Time Emergency Use of a Test Article (5-Day Notice of Use)
- ( ) CIRB (No longer in use)

5.0 2800-Determination of Human Research Worksheet

6.0 5000-Exit Application Interview

6.1 Use the text box below to add any other information you would like to include in this application.

The N3C systematically and regularly collects data derived from the electronic health records of people who were tested for COVID-19 or who had related symptoms, as well as data from individuals infected with pathogens that can support comparative studies, such as SARS 1, MERS and H1N1. The data set includes such information as demographics, symptoms, lab test results, procedures, medications, medical conditions, physical measurements and more.

I will request access to the limited dataset. A data use agreement is already in place between OUHSC and the NC3.

A limited data set is defined as protected health information that excludes certain direct identifiers of an individual or of relatives, employers or household members of the individual — but may include city, state, ZIP code and elements of dates. A limited data set can be disclosed only for purposes of research, public health or health care operations.
Three levels of data are available for analysis:

• Limited Data Set (LDS): Consists of patient data that retain the following protected health information —
o Dates of service
o Patient ZIP code

NC3 has a central IRB:

Central IRB Approval Letter for the National Covid Cohort Collaborative (N3C)

Link:
https://zenodo.org/records/4010824

The National COVID Cohort Collaborative (N3C) opted to submit a single IRB at one of the organizing sites (Johns Hopkins University) to minimize the burden of participation for each site contributing clinical data to the N3C Secure Data Enclave. The N3C community collaboratively contributed to the core protocol. However, respecting site autonomy, the central IRB was not required; each site could opt to submit the core protocol to their own local IRB. For more information about N3C visit covid.cd2h.org

6.2
Principal Investigator Certification

☑ I certify that all information provided in this submission, including support materials, is complete and accurate.

For studies/research applications:

☑ I certify that all investigators have completed the education requirements of the OU Health Sciences Center Campus IRB ("HSC IRB"), as applicable and required for conducting human subjects research.

☑ I assure that I have obtained all necessary approvals from external entities, as applicable and required for conducting human subjects research.

☑ I assure compliance of all investigators to this submission as approved; relevant OU IRB policies and procedures; applicable federal, state and local laws; and, ethical conduct of the research and protection of the rights and welfare of human participants, as applicable and required for conducting human subjects research.

☑ I agree to obtain legally effective informed consent and HIPAA Authorization from research participants, as applicable.

☑ I agree to promptly report protocol deviations and/or unanticipated problems as defined by OU IRB policy to the OU IRB, as applicable.

☑ I assure that I have documentation of encryption for all electronic devices used in conducting human subjects research.

Click the "Save and Continue to Next Section" button to move to the next step.