MUSC IRB Tips and Language for N3C Enclave access (draft v1, 9/16/2020):

Tips and Language for Non Human Subject Research (NHSR) or Exempt IRB Applications

How should I complete the screening questions section?

Screening Questions # 2 & 3	For the HIPAA Safe Harbor Dataset/NHSR Applications: Select "No" to both. For the HIPAA Limited Dataset/Exempt Application: Select "No" to Screening Questions #2 and "Yes" to Screening Question #3.

How should I complete section A.9 Identifiers?

A.9.1.	For the HIPAA Safe Harbor Dataset/NHSR Applications: Select "None of the above." For the HIPAA Limited Dataset/Exempt Application: Select "Any elements of dates…" and "Any geographic subdivisions…"

How should I complete section C.1. Data Sources?

C.1.1.	Select "Other". N3C Description: The National COVID Cohort Collaborative (N3C) is a centralized, secure data repository of clinical data housed at and managed by the NIH National Center for Advancing Translation Science (NCATS). It is designed to support collaborative COVID-19 secondary data analyses. N3C is a HIPAA-limited dataset, which includes a variety of clinical data (demographics, encounters, diagnosis, procedures, medications, vitals, labs, etc.) about millions of patients who meet the N3C COVID-19 phenotype. Data are both retrospective and prospective. Data are collected as part of routine medical care, and entered into the N3C database under a HIPAA waiver. Data originate from dozens of health care institutions across the United States (including UNC), who have each executed a Data Transfer Agreement with NCATS and have an IRB application to cover the data contribution activity. Researchers may access the N3C data through the N3C Data Enclave, which meets federal data security standards. Researchers may request access to either the HIPAA-limited dataset or a HIPAA Safe Harbor version of the dataset. No patient data may be downloaded or removed from the environment.
C.1.2.	Per the N3C guidelines, I will submit a Data Use Request describing my intended research activity and requesting access to the [*select as appropriate:* HIPAA-limited or HIPAA Safe Harbor] dataset. The NCATS Data Access Committee reviews and approves DUR provided basic criteria are met.

	NC-Chapel Hill has previously executed an overarching Data Use Agreement with NCATS to allow UNC researchers to access the N3C data.
C.1.3.	Yes – It is not necessary to attach the DUA. You can reference the N3C Master DUA in your cover memo.

How should I complete section C.2. Coding and Data Use Agreements?

C.2.1.	
When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."	Yes
Will any of the personnel involved in this study (this includes collaborators providing data or specimens, personnel listed on grants, co-authors, and faculty advisors) have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples?	No
Answer the questions below to identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:	
Data use agreement with custodian of data (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	Yes – Master DUA with Institution
Data are publicly available?	No
Honest broker (centralized custodian who controls data and will not release codes or IDs)?	Yes
Other	No
Do ALL of these data, records or specimens exist at the time of this application?	No
If no, explain how prospective data collection will occur.	See below

In section C.2, how should I say prospective data collection will occur?

Contributing sites will submit weekly refreshes of clinical data including new patients and new data about existing patients. These data will then be made available to users in the N3C Enclave.

Exempt IRB Application Tips and Language

Which exemption should I request?
The most appropriate exemption is Category 4(ii).
Here is some boilerplate text for the explanation: “We will request access to the National COVID Cohort Collaborative HIPAA Limited Dataset, which dates and location information but none of the other HIPAA identifiers.”

How should I complete section A.2. Subjects?

A.2.1.	9999
A.2.2.	9999
A.2.3.	The National COVID Cohort Collaborative (N3C) will continue to grow over time as more sites contribute data and more patients are added to each site's dataset. As of 9/9/2020, there are about 482,000 patients in the dataset but this is expected to grow into the millions.
A.2.4.	Select “Children,” because the dataset will include children.
A.2.7.	0 – 99

How should I complete section A.2.A Children?

A.2.A.1	The N3C dataset includes children; therefore, data about children will be exposed to the researcher. COVID-19 often manifests differently in children than adults; thus it is important to study COVID in both adults and children.
A.2.A.2	There is no direct benefit to participants. [Provide additional information about how your research is likely to yield generalizable information about the condition.]
A.2.A.3	There are no unique risks to children. Data for children's records will include the same protection as all records.