



**Office of Human Subjects Research  
Institutional Review Boards**

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**Date:** May 1, 2020

**APPLICATION APPROVAL**

**Review Type:** Convened  
**Principal Investigator:** Christopher Chute  
**Number:** IRB00249128  
**Title:** National COVID Cohort Collaborative (N3C): A national resource for shared analytics  
**Committee Chair:** Richard Moore  
**IRB Committee:** IRB-3

**Date of Approval:** May 1, 2020

**Date of Expiration:** May 1, 2021

The JHM IRB approved the above-referenced Application.

IRB review included the following:

**45 CFR 46.116:** A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

**Progress Report Required:**

The Board determined that this research meets the criteria for submission of a Progress Report as an alternative to a Continuing Review Application. The Progress Report must be submitted using a Further Study Action and selecting progress report at least 6 weeks prior to the expiration date. Please note, the Progress Report **must** be submitted prior to the expiration date shown on this notice. If the Progress Report is not submitted prior to the expiration date all activity must stop. Before any research activity can resume, you must submit the progress report.

**45CFR46.404 and/or 21 CFR 50.51:** This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of parents/guardians is waived.

Assent is waived for all children.

**Changes in Research:** All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately,

and promptly reported to the JHM IRB.

**Unanticipated Problems:** All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive or alter authorization for the above-referenced project. The IRB determined that all specific criteria for a waiver or alteration of authorization were met, as follows:

(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) the research could not practicably be conducted without access to and use of the protected health information.

**Study documents:**

**HIPAA Form 4:**

FINAL\_Chute\_IRB00249128\_HIPAA Form 4\_05012020.pdf

**Additional Supplemental Study Documents:**

DRAFT-N3C-Data Use Agreement.docx

Coordinating Center Description.docx

Final version - NCATS Data Transfer agreement 04-23-2020.docx

OMOP CDM v5 COVID Data Dictionary.docx

**Protocol:**

National COVID Cohort Collaborative V4.docx

**Johns Hopkins Study Team Members:**

Richard Zhu, Dazhi Jiao, Xiaohan Zhang, Stephanie Hong, Harold Solbrig, Harold Lehmann, Davera Gabriel

The Johns Hopkins Institutions operate under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, Johns Hopkins Health System and Johns Hopkins Hospital - FWA00006087