University of Pennsylvania
Institutional Review Board
3800 Spruce St., First Floor Suite 151
Philadelphia, PA 19104
Ph: 215-573-2540
(Federalwide Assurance # 00004028)

26-Mar-2020

MARK D NEUMAN
neumanm@pennmedicine.upenn.edu
cc: Lakisha.gaskins@pennmedicine.upenn.edu

PRINCIPAL INVESTIGATOR	: MARK D NEUMAN
TITLE	: COVID Airway Provider PPE Use and Outcomes Registry
SPONSORING AGENCY	: NO SPONSOR NUMBER
PROTOCOL #	: 842827
REVIEW BOARD	:

Dear DR. MARK NEUMAN:

The quality improvement/quality assurance application submitted for the above-referenced protocol was reviewed and acknowledged on 26-Mar-2020. It was determined that this project qualifies as a quality improvement initiative that does not meet the definition of human subjects' research and therefore further IRB review is not required.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

NOTE REGARDING THE CONDUCT OF RESEARCH AND THE COVID-19 PANDEMIC:
While the IRB is permitting and processing submissions, approval by the IRB at this time DOES NOT constitute authorization to initiate this protocol, protocol amendment, or continue research procedures (as applicable). Please see details below depending on your affiliated school.

Penn Medicine
During the COVID-19 Pandemic, permitted clinical trial activity is limited to **essential clinical trials. Essential clinical trials are those that enroll or follow patients with life threatening or serious conditions** for which participation in the clinical trial **holds out the clear prospect of the patient directly benefiting**. Patients already enrolled into clinical trials who are undergoing safety assessments fall into this definition. Please review the Message from Emma Meagher, MD - Clinical Research Update #3 on the IRB website here for further details: https://irb.upenn.edu. **Please consult with Emma Meagher at emma@upenn.edu for non-oncology trials or Bob Vonderheide at rhv@upenn.edu for oncology trials for guidance if you wish to open a new trial, or if you are unclear whether your protocol constitutes essential research.**

Other Schools
Only research studies with procedures that may be conducted remotely or virtually may be conducted at this time (e.g., electronic survey research, record reviews, secondary data analysis). Please also refer to any guidance provided by your school.

Sincerely,

Jessica L. Yoos

Digitally signed by Jessica L. Yoos
Date: 2020.03.26 13:54:29 -04'00'

IRB Administrator