

**Determination of Non-applicability of Human Subjects Regulations**  
**National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)**

Project title **COVID Evaluation of Risk for Emergency Departments (COVERED) Project**

Primary contact **Preeta Kutty, MD, MPH**

Division/Branch **DHQP/PRB**

*The purpose of this form is to document NCEZID's determination that the above-listed protocol does not require submission to CDC's Human Research Protection Office. This authority is delegated to the CDC Centers, Institutes, and Offices under CDC Policies SSA-2010-01 and SSA-2010-02.*

**Determination**

- ☐ Project is neither conducted nor supported by a Common Rule agency. IRB review is not required. [45 CFR 46.101(a)]
- ☐ Project does not meet the definition of research under 45 CFR 46.102(l). IRB review is not required.
- ☒ Project is deemed not to be research under the following provision. IRB review is not required.
- Public health surveillance activities, 45 CFR 46.102(l)(2)
- ☐ Project does not involve human subjects under 45 CFR 46.102(e). IRB review is not required.
- ☐ CDC's role in the project does not meet the threshold requiring submission to HRPO. *Investigator has provided documentation of appropriate local review.*

**Rationale**

The purpose of this activity is to monitor and assess the burden and risk factors associated with COVID-19 for emergency healthcare workers in the United States. The project will recruit healthcare personnel at high-volume centers within the EMERGENCY ID Net and National Emergency Airway Registry networks. Personnel will have serum regularly tested along with regular surveys to monitor and assess the risk of exposures related to COVID-19. Results will be used to inform the ongoing response to the COVID-19 pandemic and may be published. As this activity involves the collection of data and biospecimens supported by a public health authority and is limited to allow the identification and assessment of the onset of a disease outbreak, including trends and risk factors, to provide priority setting during the course of an event, it is consistent with non-research public health surveillance.

**Additional considerations**

Participants will be asked to provide informed consent.

This determination applies specifically to "Project 1" and does not apply to either "Project 2" or "Project 3".

**Additional requirements**

Changes in the nature or scope of this activity may impact the regulatory determination. Please discuss any changes with your NC Human Subjects Advisor before they are implemented.

Reviewed by **James Peterson, PhD**

Title **Human Subjects Advisor**

Signature **S** James M. Peterson - Digitally signed by James M. Peterson -S  
Date: 2020.04.09 10:26:55 -04'00'

Date **4/9/2020**



**Human Subjects Office/  
Institutional Review Board (IRB)**

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600 Newton Road  
Iowa City, Iowa 52242-1098  
319-335-6564 Fax 319-335-7310  
[irb@uiowa.edu](mailto:irb@uiowa.edu)  
<http://research.uiowa.edu/hso>

April 13, 2020

TO: Nicholas Mohr  
Cmed-Emergency Med  
Kari Harland  
Catherine Fairfield  
Kelli Wallace  
Hafeez Rajwani  
Kelly Percival  
Julie Weeks  
Zita Sibenaller

FROM: J. Andrew Bertolatus, BA, MD  
IRB Chair or Chair Designee

RE: Not Human Subjects Research Determination

I have reviewed the information submitted with your project titled 202004285 COVID Evaluation of Risk for Emergency Departments (COVERED) Project. I have determined that the project described in the application *does not* meet the regulatory definition of human subjects research and does not require review by the IRB, because this has been determined to be a public health surveillance activity by the CDC IRB (and this project will be supported by CDC)

We appreciate your care in submitting this application to the IRB for review. If the parameters outlined within this Human Subjects Research application request change, re review and/or subsequent IRB review may be required.

Please don't hesitate to contact me if you have any questions. The Human Subjects Office can be reached via phone (319)-335-6564 or email [irb@uiowa.edu](mailto:irb@uiowa.edu).



**Olive View/UCLA Education & Research Institute, Inc.**

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Website [www.ovuclaeri.com](http://www.ovuclaeri.com)

DATE: April 16, 2020

TO: David Talan, MD

FROM: Olive View-UCLA Education & Research Institute - Institutional Review Board

PROJECT TITLE: [1594068-1] COVID Evaluation of Risk for Emergency Departments  
(COVERED) Project

REFERENCE NUMBER:

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF NOT RESEARCH (**SURVEILLANCE PROJECT**)

DECISION DATE: April 16, 2020

Thank you for your submission of New Project materials for this project. The Olive View-UCLA Education & Research Institute - Institutional Review Board has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

**The IRB acknowledges and accepts the Centers for Disease Control and Prevention (CDC) surveillance project determination.**

We will retain a copy of this correspondence within our records.

If you have any questions, please contact Denise Tritt at 747-210-3434 or [denisetrutt@ovuclaeri.com](mailto:denisetrutt@ovuclaeri.com). Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Olive View-UCLA Education & Research Institute - Institutional Review Board's records.