Project PREVENT

UCLA
University of Iowa

PReventing Emerging Infections through Vaccine EffectiveNess Testing

EmergencyIDNet-PREVENT@uiowa.edu

November 10, 2020

Dear Project PREVENT Investigators,

We have recently received important news from CDC: the project is funded and our project has received a Public Health Surveillance determination from the Institutional Review Board at the Centers for Disease Control and Prevention (CDC), the University of Iowa, and at Olive View-UCLA (the coordinating sites for Project PREVENT). We are providing documentation for you to share with your IRB to make an independent determination about whether Project PREVENT qualifies as Public Health Surveillance (meaning that it is NOT human subjects research).

We have included the following documents for your application:

1. Project PREVENT Protocol
2. University of Iowa Human Subjects Research Determination
3. Olive View – UCLA Human Subjects Research Determination
4. CDC Human Subjects Research Determination – *Please note that the project reviewed by CDC as Project PREVENT was submitted as a modification to a related vaccine effectiveness project (see page 4 of that document that lists Project PREVENT as part of that overall project). The approval from CDC indicates that our proposed methods are consistent with the methods in the prior project and that an independent review of our methods met the determination that this is NOT human subjects research.*

This is a critical and time-sensitive step! Now that all of the central regulatory hurdles have been cleared, we need to move quickly to launch this project at all sites. We need to finalize procedures and staff at each site, and we need to firm up our site selection.

For right now:

1. Please submit the attached documentation to your IRB **this week**. As soon as you receive an IRB determination, please e-mail that documentation to EmergencyIDNet-PREVENT@uiowa.edu and idnet@ucla.edu as soon as possible.
2. Please complete and return the Case Finding and Recruitment Plan and send to the above email addresses **by November 18th**. It's okay if you don't have every detail worked out—*we need to know what procedures you have set up and how we can help you.*
3. You will be receiving details about subcontracts from Olive View-UCLA ERI (including site budgets) soon. Subcontracting will be expedited from our side, because this is one of the parts of the project that could delay your local launch.
4. We will be scheduling weekly calls to detail next steps as we move toward our rapid launch schedule. These calls will include training, regulatory details, and approvals.

Thank you for your interest in Project PREVENT, and we look forward to working with you! Please reach out if you have any questions.

THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

November 4, 2020

TO: Nicholas Mohr
Cmed-Emergency Med
Cole Wymore
Kari Harland
Catherine Fairfield
Zita Sibenaller
Aaron Tyagi
Archit Sharma
Muska Nataliansyah
Allison Schuette
Julie Weeks
Kelli Wallace
Hafeez Rajwani

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

RE: Not Human Subjects Research Determination

I have reviewed the information submitted with your project titled 202011047 PReventing Emerging infections through Vaccine EffectiveNess Testing (Project PREVENT). 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 is a public health surveillance activity that has been proposed and (potentially) funded by a public health authority (US CDC). Note that documentation of this determination from CDC has been attached to this form.(It is very helpful that those letters from CDC re: no IRB review are attached)

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.

E R I

Olive View/UCLA Education & Research Institute, Inc.

14445 Olive View Drive - Research Administration Office
Sylmar, CA 91342-1495
Telephone 747-210-3434 Fax (747) 210-3465
Website www.ovuclaeri.com

DATE:	November 10, 2020
TO:	David Talan, MD
FROM:	Olive View-UCLA Education & Research Institute - Institutional Review Board
PROJECT TITLE:	[1680686-1] PReventing Emerging infections through Vaccine EffectiveNess Testing—COVID (Project PREVENT)
REFERENCE NUMBER:	
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF NOT RESEARCH
DECISION DATE:	November 10, 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 CDC's public health surveillance determination. This project does not meet the regulatory definition of human subjects research and does not require IRB review.

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 denisetritt@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.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 10/23/20

Title:	Emerging Infections Program Tracking of SARS-CoV-2 Infections and Assessing Vaccine Effectiveness among Healthcare Personnel
Project Id:	0900f3eb81b25a55
Accession #:	NCEZID-ET-4/16/20-25a55
Project Contact:	Magill_Shelley S. (fxe9)
Organization:	
Status:	**Pending Clearance : Amendment**
Intended Use:	**Project Determination**
Estimated Start Date:	04/27/2020
Estimated Completion Date:	12/31/2021
CDC/ATSDR HRPO/IRB Protocol #:	Previously determined to be a non-research activity. Therefore, we are not continuing to update the list of non-CDC project staff and co-investigators.
OMB Control #:	Currently approved under 0920-1296; expiration date 10/31/2020. We are now applying for PRA waiver. See attached documents.

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	4/17/20	Peterson_James M. (iyr1) CIO HSC
PRA: **PRA Applies**		4/17/20	Samuel_Lee (llj3) OMB / PRA

ICRO: **Returned with No Decision**		4/17/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Urgent
Date Needed:	10/23/2020
Priority Justification:	This project is part of the COVID-19 response activities. Delay in review of this protocol will result in delay in availability of reliable data to support response activities.
Determination Start Date:	10/14/20
Description:	This project is a collaboration with the Emerging Infections Program (EIP) to track and interview healthcare personnel (HCP) who tested positive for SARS-CoV-2 (HCP cases) and HCP who tested negative for SARS-CoV-2 (HCP non-cases) to determine the burden of infections and identify factors associated with SARS-CoV-2 infection. We have updated the EIP project protocol to incorporate an evaluation of the post-introduction effectiveness of a complete schedule of the SARS-CoV-2 vaccine in preventing laboratory-confirmed symptomatic COVID-19 among HCP. The project will be performed in healthcare facilities within EIP catchment areas. Other, non-EIP collaborators will participate in the vaccine effectiveness (VE) project only, using a specific VE protocol which has been added to this STARS submission. Please refer to the protocols for details. NCEZID/DHQP staff have oversight and responsibility for EIP activities related to the burden of infections and identification of factors associated with SARS-CoV-2 infections in HCP. Vaccine Task Force/NCIRD staff have oversight and responsibility for EIP and other collaborator activities related to the VE evaluation.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	Yes
IMS Activation Name:	2019 Novel Coronavirus Response
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The goals of this information collection are to: 1) inform public health and healthcare facility guidance for protecting the healthcare workforce from the effects of SARS-CoV-2 infection; 2) evaluate the effectiveness of SARS-CoV-2 vaccines in preventing symptomatic COVID-19 and learn how these vaccines work in a real-world setting before widespread distribution to the general public.
Objective:	DHQP objectives for EIP tracking and interview of HCP cases and non-cases: 1) Determine the incidence of SARS-CoV-2 infection among HCP working in participating healthcare facilities; 2) Describe characteristics of HCP exposed to or infected with SARS-CoV-2, including clinical activities and personal protective equipment (PPE) use; 3) Compare exposures and other characteristics of HCP cases and HCP who tested negative for SARS-CoV-2 infection to identify potential risk factors or protective factors. Vaccine Task Force/NCIRD objectives for VE evaluation: Evaluate post-introduction effectiveness of a complete schedule of the SARS-CoV-2 vaccine in preventing laboratory-confirmed symptomatic SARS-CoV-2 infection among HCP. Secondary objectives for the VE

	evaluation include: 1) Evaluate post-introduction effectiveness of the SARS-CoV-2 vaccine in preventing severe disease among HCP with laboratory-confirmed symptomatic SARS-CoV-2 infection; 2) Evaluate effectiveness by HCP age groups and in subgroups with comorbidities; 3) Evaluate effectiveness by various groups of HCP job categories and clinical practice settings; 4) Evaluate effectiveness by vaccine product (if more than one product is in use) and for a single dose (if a 2-dose schedule is recommended).
Activities or Tasks:	New Collection of Information, Data, or Biospecimens, Secondary Data or Specimen Analysis
Target Populations to be Included/Represented:	Pregnant Women, American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, White, Female, Male, Transgender, Adult 18-24 years, Older adults > 64 years, Healthcare Provider, Impaired hearing or deaf, Immigrants or Refugess
Tags/Keywords:	Coronavirus, Hospitals, Nurses, Nursing Homes
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided, CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens, CDC employees will participate as co-authors in presentation(s) or publication(s), CDC employees will provide substantial technical assistance or oversight, CDC is providing funding, CDC is recipient of private data /specimens FROM an institution
Method Categories:	Analytic Services (can be data/specimen TA for non-research,research,investigations); Case-Control; Convenience Sample; Exposure Investigation; Individual Interview (Quantitative); Individual Interviews (Qualitative); Public Health Assessment; Record Review; Secondary Data Analysis; Surveillance Support
Methods:	All EIP sites will conduct prospective surveillance for HCP who test positive for SARS-CoV-2. EIP staff will obtain line lists of HCP cases from state or local health departments, or from occupational health departments or infection control programs in participating healthcare facilities. A subset of EIP sites will work with selected healthcare facilities that can identify HCP who test positive and negative for SARS-CoV-2 infection to perform a HCP case-non-case comparison that involves interviews of both HCP cases and non-cases to identify risk factors for infection. All EIP sites will also perform a VE evaluation in HCP as described in the EIP protocol. Additional collaborators, such as non-EIP academic centers, will also participate in the VE evaluation in HCP using the VE-specific protocol included in this submission. Please refer to the protocol for details.
Collection of Info, Data or Biospecimen:	Data will be collected from HCP via telephone interviews or self-administered electronic questionnaire. For the VE evaluation, project staff will also perform review of HCP medical records and vaccination history records.
Expected Use of Findings/Results:	The data collected from this project will be used to: 1) determine the extent of SARS-CoV-2 infection among HCP working in U.S. healthcare facilities; 2) describe characteristics of HCP cases and non-cases, including clinical activities and personal protective equipment (PPE) use; 3) compare exposures and other characteristics of HCP cases and non-cases to identify risk factors or protective factors for SARS-CoV-2 infection; 4) evaluate post-introduction effectiveness of a complete schedule of the SARS-CoV-2 vaccine in preventing laboratory-confirmed symptomatic COVID-19 among HCP.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers?	Yes
Is an assurance of confidentiality in place or planned?	No
Is a certificate of confidentiality in place or planned?	No

Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Cooperative Agreement	Emerging Infections Program	CK17-1701	2017	2
CDC Cooperative Agreement	EMERGEncy ID NET Project PREVENT	NOFO # RFA-CK16-001, Grant #U01 CK000480	2017	1
CDC Contract	Safety and Healthcare Epidemiology Prevention Research Development (SHEPheRD)	RFTOP 2017 Domain 7-G001	2017	1

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	
Population - Children	N/A
Population - Minors	N/A
Population - Prisoners	N/A
Population - Pregnant Women	N/A

Population - Emancipated Minors	N/A

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested documents of informed consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
University of Iowa Carver College of Medicine					NOFO # RFA-CK16-001, Grant #U01 CK000480
California Emerging Infections Program					
Colorado Emerging Infections Program					
Connecticut Emerging Infections Program					
Georgia Emerging Infections Program					
Tennessee Emerging Infections Program					
Maryland Emerging Infections Program					
Minnesota Emerging Infections Program					
New Mexico Emerging Infections Program					
Oregon Emerging Infections Program					
New York Emerging Infections Program					

Olive View-UCLA Educ & Rsch Inst	FWA00000495	07/17/24	Olive	09/01/23	NOFO # RFA-CK16-001, Grant #U01 CK000480

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Ashley Fell	n/a	n/a	n/a	n/a	Project Officer	ashley.g.fell@state.mn.us		Minnesota Emerging Infections Program
Cathleen Concannon	n/a	n/a	n/a	n/a	Project Officer	Cathleen_Concannon@URMC.Rochester.edu		New York Emerging Infections Program
Chris Czaja	n/a	n/a	n/a	n/a	Co-Investigator	christopher.czaja@state.co.us		Colorado Emerging Infections Program
Christina Felsen	n/a	n/a	n/a	n/a	Project Officer	Christina_Felsen@URMC.Rochester.edu		New York Emerging Infections Program
Erin Phipps	n/a	n/a	n/a	n/a	Co-Investigator	EPhipps@salud.unm.edu		New Mexico Emerging Infections Program
Ghinwa Dumyati	n/a	n/a	n/a	n/a	Co-Investigator	Ghinwa_Dumyati@URMC.Rochester.edu		New York Emerging Infections Program
Helen Johnston	n/a	n/a	n/a	n/a	Project Officer	helen.johnston@state.co.us		Colorado Emerging Infections Program
James Meek	n/a	n/a	n/a	n/a	Co-Investigator	james.meek@yale.edu		Connecticut Emerging Infections Program
Jennifer Loo	01/22/2022	07/18/2022			Project Officer	ihi4@cdc.gov	404-639-4735	Epidemiology Team
Joelle Nadle	12/17/2021		12/20/2021		Co-Investigator	jnadle@ceip.us		California Emerging Infections Program
Katherine Fleming-dutra	01/02/2022	11/28/2020	12/03/2022	11/29/2022	Co-Investigator	ftu2@cdc.gov	404-639-4243	Epidemiology Team
Linda Frank	n/a	n/a	n/a	n/a	Project Officer	lfrank@ceip.us		California Emerging Infections Program

Lucy Wilson	09/26/2022				Co-Investigator	wilsonl@umbc.edu		Maryland Emerging Infections Program
Marla Sievers	12/17/2021		12/20/2021		Co-Investigator	marla.sievers@state.nm.us		New Mexico Emerging Infections Program
Meghan Maloney	12/17/2021		12/20/2021		Project Officer	meghan.maloney@ct.gov		Connecticut Emerging Infections Program
Monica Brackney	09/26/2022				Co-Investigator	monica.brackney@yale.edu	203--	Connecticut Emerging Infections Program
Nicola Thompson	01/28/2023	02/21/2022			Co-Investigator	dvq0@cdc.gov	404-639-1668	Epidemiology Team
Nora Chea	09/30/2023	01/10/2022	01/11/2022		Principal Investigator	xdc7@cdc.gov	404-639-0025	Epidemiology Team
Pamela Talley	12/17/2021		12/20/2021		Co-Investigator	Pamela.Talley@tn.gov		Tennessee Emerging Infections Program
Patricia Ryan	12/17/2021		12/20/2021		Co-Investigator	patricia.ryan@maryland.gov		Maryland Emerging Infections Program
Paula Clogher	12/17/2021		12/20/2021		Project Officer	paula.clogher@yale.edu		Connecticut Emerging Infections Program
Rebecca Perlmutter	12/17/2021		12/20/2021		Project Officer	rebecca.perlmutter@maryland.gov		Maryland Emerging Infections Program
Rebecca Pierce	12/17/2021		12/20/2021		Co-Investigator	rebecca.a.pierce@dhsoha.state.or.us		Oregon Emerging Infections Program
Ruth Lynfield	12/17/2021		12/20/2021		Co-Investigator	ruth.lynfield@state.mn.us	651-201-5422	Minnesota Emerging Infections Program
Ryan Gierke	02/26/2022	04/30/2022	04/30/2022	04/30/2022	Project Officer	ipe3@cdc.gov	404-639-0805	Epidemiology Team
Sandra Pena	n/a	n/a	n/a	n/a	Project Officer	Sandra.Pena@tn.gov		Tennessee Emerging Infections Program
Sarah Lim	n/a	n/a	n/a	n/a	Project Officer	Sarah.Lim@state.mn.us		Minnesota Emerging Infections Program

Sarah Shrum Davis	n/a	n/a	n/a	n/a	Project Officer	Sarah.Shrum@state.nm.us		New Mexico Emerging Infections Program
Scott Fridkin	n/a	n/a	n/a	n/a	Co-Investigator	sfridki@emory.edu		Georgia Emerging Infections Program
Shelley Magill	n/a	n/a	n/a	n/a	Program Lead	fxe9@cdc.gov	404-639-0291	Epidemiology Research and Innovations Branch
Stepy Thomas	12/17/2021		12/20/2021		Project Officer	smthomas@gaeip.org		Georgia Emerging Infections Program
Tamara Pilishvili	09/10/2022				Principal Investigator	tdp4@cdc.gov	404-639-3585	Epidemiology Team
Taniece Eure	09/26/2022				Project Officer	xge9@cdc.gov	404-639-4101	Epidemiology Team
Valerie Ocampo	12/17/2021		12/20/2021		Project Officer	VALERIELEIGH.S.OCAMPO@dhsoha.state.or.us	971-673-2793	Oregon Emerging Infections Program
Vivian Leung	12/17/2021		12/20/2021		Co-Investigator	Vivian.Leung@ct.gov		Connecticut Emerging Infections Program

Data

DMP

Proposed Data Collection Start Date: 4/27/20

Proposed Data Collection End Date: 12/31/21

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact:	Nora Chea
Public Access Justification:	Data contain PII. Data can be requested via a data use agreement
How Access Will Be Provided for Data:	Fulfillment of requests for data or isolates is subject to approval of CDC and EIP site staff. Requestors with project proposals approved by CDC and EIP sites will be provided with a dataset that meets applicable privacy and data security requirements.
Plans for Archival and Long Term Preservation:	Data will be stored securely and indefinitely on CDC share drives with restricted access and appropriate encryption as determined by ITSO.

Spatiality

Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									