THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
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irb@uiowa.edu
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June 28, 2022

TO: Nicholas Mohr
Cmed-Emergency Med
Kari Harland
Catherine Fairfield
Zita Sibenaller
Kelli Wallace
Archit Sharma
Karin Nielsen
Shannon Landers
Alexander Peebles
Cameron Williams
Julie Weeks

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 202206139 PReventing Emerging infections through Vaccine EffectiveNess Testing (Project PREVENT) II. 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 we concur with the CDC opinion that this is a public health surveillance activity not subject to IRB review. This determination applies only to the work carried out by the Univ of Iowa.

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.

University of California Los Angeles
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095-1406

http://ora.research.ucla.edu/ohrpp
General Campus IRB: (310) 825-7122
Medical IRB: (310) 825-5344

NOT HUMAN SUBJECTS RESEARCH
DETERMINATION: UCLA IRB REVIEW NOT REQUIRED

DATE:	6/28/2022
TO:	DAVID TALAN, M.D. EMERGENCY MEDICINE
FROM:	Anthony Saldaña Administrator, MIRB 1
RE:	IRB#22-000962 PReventing Emerging infections through Vaccine EffectiveNess Testing II —COVID (Project PREVENT II) Version: V1.0

Funding Source(s)	1) DHHS-CDC CENTERS FOR DISEASE CONTROL AND PREVENTION *Grant PI*: DAVID TALAN *Grant Title*: RFA-CK-22-003, Emerging Infections Sentinel Networks (EISN) Research - 2022 *Grant Number*: 1 U01CK000643-01-00

This project is a public health surveillance activity performed in collaboration with the Centers for Disease Control and Prevention. This project meets the following criteria, per draft guidance "Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements"

• The activity is a public health surveillance activity (45 CFR 46.102(l)(2));
• The activity is conducted, supported, requested, ordered, required, or authorized by a

public health authority (45 CFR 46.102(k) and 46.102(l)(2)); and
• The activity is limited to that necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products) (45 CFR 46.102(l)(2)).

https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html

Based on the information provided in the webIRB application, the UCLA Office of the Human Research Protection Program has determined that the above-named project does not meet the definition of human subjects research. The workspace for this project is now located in your archive folder.

Project Determination

Emerging Infections Program Tracking of SARS-CoV-2 Infections and Assessing Vaccine Effectiveness among Healthcare Personnel

Project ID:	0900f3eb81b25a55
Accession #:	AES -AES -5/31/22-3aae9
Project Contact:	Ian Plumb
Organization:	NCIRD
Status:	Pending Clearance : Amendment
Intended Use:	Project Determination
Estimated Start Date:	04/27/20
Estimated Completion Date:	12/31/21
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	No OMB Control Number issued.

Description

Priority
Urgent
Date Needed
10/26/20
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
05/26/22
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/Lab-Aid/Chemical Exposure Submission

Yes

IMS Activation Name

2019 Novel Coronavirus Response

Select the primary priority of the project

Protection of healthcare personnel and patients

Select the secondary priority(s) of the project

Transmission of SARS-CoV-2

Select the task force associated with the response

Health Systems and Worker Safety; Vaccine Task Force

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Lab-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. To minimize duplication of data collection activities, we consulted with other task force colleagues (e.g., the Epi Data Analysis Unit of the Healthcare Infection Prevention and Control Team within the Health Systems and Worker Safety Task Force) and scanned the literature. Vaccine effectiveness evaluations are being conducted with multiple CDC partners, with efforts coordinated by the Vaccine Task Force.

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).

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?

No

Project does not incorporate elements of health equity science

Not selected

Measuring Disparities

Yes

Studying Social Determinants of Health (SDOH)

Not selected

Assessing Impact

Not selected

Methods to Improve Health Equity Research and Practice

Not selected

Other

Not selected

Activities or Tasks

New Collection of Information, Data, or Biospecimens; Secondary Data or Specimen Analysis

Target Population 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 Refugees-

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 Bio specimens

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. For a detailed burden estimate, please see the PRA waiver justification. Based on the time needed for generation of line lists of HCP tested for SARS-CoV-2 (5 to 15 minutes x 2,040 responses), completion of HCP interviews (50-60 minutes x total of 4,267 HCP), plus review of medical records and vaccination histories (10-45 minutes x total of approximately 270 responses each), plus completion of denominator data collection (20 minutes x 300 responses), the total estimated burden is 5,061 hours.

Expected Use of Findings/Results and their impact

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 (including coded data)?

Yes

Is this project covered by an Assurance of Confidentiality?

No

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?
No
Is there a formal written agreement prohibiting the release of identifiers?
No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Contract	Safety and Healthcare Epidemiology Prevention Research Development (SHEPheRD)	RFTOP 2017 Domain 7-G001	2017	1	
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	

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office
No

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #
California Emerging Infections Program					
Colorado Emerging Infections Program					
Connecticut Emerging Infections Program					
Georgia 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					
Tennessee Emerging Infections Program					
University of Iowa Carver College of Medicine					NOFO # RFA-CK16-001, Grant #U01 CK000480
Olive View-UCLA Educ & Rsch Inst	FWA00000495	08/10/26	Olive	09/01/23	NOFO # RFA-CK16-001, Grant #U01 CK000480

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
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

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
James Meek	n/a	n/a	n/a	n/a	Co-Investigator	james.meek@yale.edu		Connecticut Emerging Infections Program
Jennifer Loo	01/13/2025	07/18/2022			Project Officer	ihi4@cdc.gov	404-639-4735	Epidemiology Team
Joelle Nadle	n/a	n/a	n/a	n/a	Co-Investigator	jnadle@ceip.us		California Emerging Infections Program
Katherine Fleming-dutra	01/29/2025	11/17/2023	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	n/a	n/a	n/a	n/a	Co-Investigator	wilsonl@umbc.edu		Maryland Emerging Infections Program
Marla Sievers	n/a	n/a	n/a	n/a	Co-Investigator	marla.sievers@state.nm.us		New Mexico Emerging Infections Program
Meghan Maloney	n/a	n/a	n/a	n/a	Project Officer	meghan.maloney@ct.gov		Connecticut Emerging Infections Program

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Monica Brackney	n/a	n/a	n/a	n/a	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	12/06/2024	12/06/2024	12/06/2024	Principal Investigator	xdc7@cdc.gov	404-639-0025	Epidemiology Team
Pamela Talley	n/a	n/a	n/a	n/a	Co-Investigator	Pamela.Talley@tn.gov		Tennessee Emerging Infections Program
Patricia Ryan	n/a	n/a	n/a	n/a	Co-Investigator	patricia.ryan@maryland.gov		Maryland Emerging Infections Program
Paula Clogher	n/a	n/a	n/a	n/a	Project Officer	paula.clogher@yale.edu		Connecticut Emerging Infections Program
Rebecca Perlmutter	n/a	n/a	n/a	n/a	Project Officer	rebecca.perlmutter@maryland.gov		Maryland Emerging Infections Program
Rebecca Pierce	n/a	n/a	n/a	n/a	Co-Investigator	rebecca.a.pierce@dhsoha.state.or.us		Oregon Emerging Infections Program

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Ruth Lynfield	n/a	n/a	n/a	n/a	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	09/07/2024	06/24/2024			Program Lead	fxe9@cdc.gov	404-639-0291	Epidemiology Research and Innovations Branch
Stepy Thomas	n/a	n/a	n/a	n/a	Project Officer	smthomas@gaeip.org		Georgia Emerging

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
								Infections Program
Tamara Pilishvili	09/10/2022	09/14/2024			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	n/a	n/a	n/a	n/a	Project Officer	VALERIELEIGH.S.OCAMPO@dhsoha.state.or.us	971-673-2793	Oregon Emerging Infections Program
Vivian Leung	n/a	n/a	n/a	n/a	Co-Investigator	Vivian.Leung@ct.gov		Connecticut Emerging Infections Program

DMP

Proposed Data Collection Start Date	04/27/20
Proposed Data Collection End Date	12/31/21
Proposed Public Access Level	Restricted
Data Use Type	Data Sharing Agreement
Data Use Type 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 of the data	Data will be stored securely and indefinitely on CDC share drives with restricted access and appropriate encryption as determined by ITSO.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States		

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	06/07/22	Legardy-Williams_Jennifer (yzl3) CIO HSC
PRA: **PRA Applies**	**Qualifies for a statutory Waiver:** Vaccine Waiver *Justification:* Objectives are: Determine the incidence of SARS-CoV-2 infection among HCP working in participating healthcare facilities; Describe characteristics of HCP exposed to or infected with SARS-CoV-2, including clinical activities, personal protective equipment (PPE) use, and SARS-CoV-2 vaccine status;Describe SARS-CoV-2 infections that occur after HCP have completed COVID-19 vaccination; 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; Evaluate post-introduction effectiveness of a complete schedule of the SARS-CoV-2 vaccine(s) in preventing laboratory-confirmed symptomatic COVID-19 among HCP.Secondary objectives for component 2b (VE): Evaluate post-introduction effectiveness of the SARS-CoV-2 vaccine(s) in preventing severe disease among HCP with laboratory-confirmed symptomatic COVID-19; Evaluate effectiveness by HCP age groups and in subgroups with comorbidities; Evaluate effectiveness by various groups of HCP job categories and clinical practice settings; 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). Therefore, NCIRD has determined the information collection activities conducted under this project qualify for the NCVIA-conferred PRA waiver as they come under the activities authorized under the NCVIA at section 2102(a)(6)-(7) of the Public Health Service Act (42 U.S.C. 300aa-2(a)(6)-(7)).	07/29/21	Hynes_Ansley (xia0) OMB / PRA

ICRO: **PRA Applies**	OMB Approval date: 07/12/21 OMB Expiration date: 12/31/99	07/12/21	Zirger_Jeffrey (wtj5) ICRO Reviewer