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Kaiser Washington Vaccine and Treatment Evaluation Unit - DMID 21-0012

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
3UM1AI148373-02S5	5UM1AI148373-02	JACKSON, LISA A	KAISER FOUNDATION RESEARCH INSTITUTE

Description

Abstract Text

This Supplemental Funding application requests funding for the Kaiser Washington **Vaccine** and Treatment Evaluation Unit (VTEU) to function as a clinical site for DMID study 21-0012, a Phase 1/2 study of delayed heterologous SARS-CoV-2 **vaccine** dosing (boost) after receipt of EUA vaccines. This clinical trial will evaluate the safety and immunogenicity of different heterologous delayed doses (boosts) in those who received an EUA **vaccine** (either prior to participation in this trial, or as part of this trial). Since the 1960s the VTEUs have conducted trials of vaccines and therapeutic candidates for infectious diseases of public health importance (other than HIV) including, for example, influenza, malaria, smallpox, anthrax, and pneumococcal infection. Kaiser Washington has been continuously funded as a VTEU site since 2007, and in 2019 was awarded a seven-year cooperative agreement as one of ten VTEU sites in the newly formed NIAID Infectious Diseases Clinical Research Consortium (IDCRC). In 2020, the NIH and the IDCRC responded to the COVID-19 pandemic by launching the first trial (20-0003) of a candidate COVID-19 **vaccine** (**mRNA**-1273), an **mRNA vaccine** co-developed by the NIH **Vaccine** Research Center and Moderna, Inc, in March 2020. The Kaiser Washington VTEU was originally the sole site for that trial which was later expanded in terms of enrollment and sites, to also include the Emory University School of Medicine VTEU and the NIH **Vaccine** Research Center sites. **mRNA**-1273 has been granted Emergency Use Authorization, as has an **mRNA vaccine** from Pfizer and an adenovirus-vectored **vaccine** from Janssen. Knowledge of the safety, tolerability, and immunogenicity of a boost **vaccine** using a heterologous platform with the homologous or variant spike lineage administered after an EUA primary dosing is a critical piece of information needed to inform public health decisions. The heterologous boost strategy will also provide an opportunity to thoroughly evaluate innate, cellular, and humoral immune responses elicited from the multiple prime boost combinations using very similar immunogens, utilizing **mRNA**, adenovirus- vectored, and protein- based platforms. As new vaccines are manufactured to emerging variants, these foundational data will be key to the evaluation of future variant and heterologous prime-boost strategies.

Public Health Relevance Statement

The NIAID Vaccine and Treatment Evaluation Units (VTEUs) provide the ability to respond quickly to emerging infectious disease threats by conducting clinical trials and research studies of candidate vaccines, therapeutics and diagnostics. This application requests supplemental funding for the Kaiser Washington VTEU to participate as a clinical site for the 21-0012 Phase 1/2 protocol, which will evaluate delayed heterologous SARS-CoV-2 vaccine boosting of persons who previously receive an EUA vaccine series. This will provide an opportunity to thoroughly evaluate innate, cellular, and humoral immune responses elicited from the multiple prime boost combinations using very similar immunogens, utilizing mRNA, adenovirus- vectored, and protein-based platforms.

Project Terms

Adenovirus Vector | Anthrax disease | Antigens | Award | COVID-19 pandemic | COVID-19 **vaccine** | Clinical Research | Clinical Trials | Communicable Diseases | Conduct Clinical Trials | Data | Diagnostic | Dose | Emerging Communicable Diseases | Enrollment | Evaluation | FDA Emergency Use Authorization | Foundations | Funding | Future | Grant | HIV | Immune response | Influenza | Knowledge | Malaria | Messenger RNA

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Kaiser Washington Vaccine and Treatment Evaluation Unit - DMID 21-0012

Project Number
3UM1AI148373-02S5

Former Number
5UM1AI148373-02

Contact PI/Project Leader
JACKSON, LISA A

Awardee Organization
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Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Research Institutes

State Code
CA

Congressional District
13

Other Information

FOA
PA-20-272

Study Section

Award Notice Date
12-August-2021

Fiscal Year
2021

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
150829349

CFDA Code
855

Project Start Date
12-August-2021

Project End Date
30-November-2025

Budget Start Date
12-August-2021

Budget End Date
30-November-2021

Project Funding Information for 2021

Total Funding
$2,014,564

Direct Costs
$1,393,490

Indirect Costs
$621,074

Year	Funding IC	
2021	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$2,014,564

Sub Projects

No Sub Projects information available for 3UM1AI148373-02S5

Publications

Thank you for your feedback!

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Kaiser Washington Vaccine and Treatment Evaluation Unit - DMID 21-0012

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
3UM1AI148373-02S5	5UM1AI148373-02	JACKSON, LISA A	KAISER FOUNDATION RESEARCH INSTITUTE

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 3UM1AI148373-02S5

Clinical Studies

No Clinical Studies information available for 3UM1AI148373-02S5

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Related News Releases

No news release information available for 3UM1AI148373-02S5

History

No Historical information available for 3UM1AI148373-02S5

Similar Projects

No Similar Projects information available for 3UM1AI148373-02S5