Back to Search Results

Description
Details
Sub-Projects
Publications
Patents
Outcomes
Clinical Studies
News and More
History
Similar Projects

Immunogenicity and Efficacy of SARS-CoV-2 stabilized prefusion Spike protein vaccines in infant rhesus macaques

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
3P01AI117915-06S1	2P01AI117915-06	PERMAR, SALLIE R.Other PIs	DUKE UNIVERSITY

Description

Abstract Text

ABSTRACT The emergence of the highly-transmissible novel coronavirus SARS-CoV2 has led to a global pandemic of severe respiratory disease. While elderly individuals and adults with co-morbidities are high risk populations, coronavirus disease (**COVID**-19) can occur in individuals across all age groups, including infants. Therefore, it will be important to develop a **vaccine** that can be administered in early life and generate long term immunity to end the COVID19 pandemic. While initial safety testing of **vaccine** candidates will occur in adult populations, there are many potential advantages of targeting the **vaccine** to the pediatric **vaccine** schedule including high rates of pediatric **vaccine** coverage and potential for lifelong immunity. In fact, infants can respond remarkably well to protein antigens, including the hepatitis B and candidate HIV envelope vaccines, and there is evidence that HIV-infected infants are better equipped to generate HIV-neutralizing antibodies. Moreover, our previous work in human and rhesus monkeys has established that infants are able to generate HIV Env **vaccine** responses of comparable or higher magnitude to that of adults that persist for months and are able to be boosted. The parent grant P01 AI117915-06 “Early Life Vaccination to Prevent HIV Acquisition in Adolescence” aims to assess candidate HIV envelope mRNA and SOSIP trimer vaccines in infant rhesus monkey nonhuman primate model and determine their efficacy against HIV acquisition in adolescence. As related complementary studies, we propose to assess the immunogenicity and efficacy of candidate SARS-CoV2 spike (S) protein and mRNA **vaccine** candidates in infant rhesus monkeys. We hypothesize that infants can mount effective and persistent systemic and mucosal antibody responses to SARS-CoV-2 vaccination that will protect against virus challenge. This work will provide preclinical safety, immunogenicity, and efficacy data on leading SARS-CoV2 **vaccine** platforms that can de-risk human trials in pediatric populations and justify bypassing time consuming and expensive age de-escalation studies. The end of the SARS-CoV2 pandemic will require high global coverage with a **vaccine** that prevents viral spread and generates long lasting immunity, which may best be achieved with a pediatric targeted **vaccine**.

Public Health Relevance Statement

PUBLIC HEALTH NARRATIVE The global spread of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and its associated coronavirus disease (COVID-19) of 2019-2020 has led to pandemic of unprecedented scale that requires immediate action for countermeasures. A vaccine is considered the best option to contain the virus and to prevent further outbreaks. This work will provide preclinical data on leading SARS-CoV2 vaccines platforms that can de-risk human trials in pediatric populations. The end of the SARS-CoV2 pandemic will require high global coverage with a vaccine that prevents viral spread and generates long lasting immunity, which may best be achieved with a pediatric targeted vaccine.

Project Terms

2019-nCoV **Adolescence** **Adult** **Age** **Antibodies** **Antibody Response** **Antigens** **Award** **B-Lymphocytes** **Birth** **Bypass** **COVID-19** **COVID-19 pandemic** **Cell Lineage** **Cessation of life** **Childhood** **Complement** **Consumption** **Coronavirus** **Data** **Development** **Disease** **Disease Outbreaks** **Elderly** **Exhibits** **HIV** **HIV vaccine** **Hepatitis B** **Human** **Immune** **Immune response** **Immune system** **Immunity** **Immunoglobulin G** **Immunology** **Individual** **In**

Back to Search Results

Description
Details
Sub-Projects
Publications
Patents
Outcomes
Clinical Studies
News and More
History
Similar Projects

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Contact PI/ Project Leader

Name
PERMAR, SALLIE R.

Title
CHAIRMAN OF PEDIATRICS

Contact
sallie.permar@duke.edu

Other PIs

Name
DE PARIS, KRISTINA

Program Official

Name
SINGH, ANJALI

Contact
anjalisingh@niaid.nih.gov

Organization

Name	Department Type	State Code
DUKE UNIVERSITY	PEDIATRICS	NC

City
DURHAM

Organization Type
SCHOOLS OF MEDICINE

Congressional District
04

Country
UNITED STATES (US)

Other Information

FOA
PA-20-135

Study Section

Award Notice Date
10-August-2020

Fiscal Year
2020

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
044387793

CFDA Code
855

Project Start Date	10-August-2020
Project End Date	30-November-2020
Budget Start Date	10-August-2020
Budget End Date	30-November-2020

Project Funding Information for 2020

Total Funding	Direct Costs	Indirect Costs
$1,227,827	$1,145,234	$82,593

Year	Funding IC	
2020	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$1,227,827

Sub Projects

No Sub Projects information available for 3P01AI117915-06S1

Publications

No Publications available for 3P01AI117915-06S1

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Back to Search Results

Description
Details
Sub-Projects
Publications
Patents
Outcomes
Clinical Studies
News and More
History
Similar Projects

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No Outcomes available for 3P01AI117915-06S1

Clinical Studies

No Clinical Studies information available for 3P01AI117915-06S1

News and More

Related News Releases

No news release information available for 3P01AI117915-06S1

History

No Historical information available for 3P01AI117915-06S1

Similar Projects

No Similar Projects information available for 3P01AI117915-06S1