



## PRESS RELEASE

### Harmonizing efforts to conduct large scale COVID-19 vaccine efficacy trials

*COVID-19 Prevention Network named*

SEATTLE, JULY 9, 2020 – A clinical trial called CoVPN 5001 will help the newly formed COVID-19 Prevention Network (CoVPN) understand early SARS-CoV-2 infection and the body’s early immune responses to the virus that causes COVID-19 illness. Gathered from diverse populations worldwide, the data obtained through this study will describe viral progression and immunological characteristics of early infection with SARS-CoV-2. Information about the clinical course of SARS-CoV-2 infection, especially during its early stage, is needed to close knowledge gaps and will potentially suggest markers of protection that could be used in evaluating the efficacy of future COVID-19 vaccine candidates.

“The CoVPN 5001 study is the first study conducted under the aegis of the CoVPN, and is designed to develop the clinical and laboratory pipelines for the rapid implementation of future COVID vaccine efficacy trials while conducting groundbreaking scientific investigations,” said Will Hahn, M.D., Protocol Chair for CoVPN 5001 and staff scientist at Fred Hutchinson Cancer Research Center. “The protocol is explicitly designed to be a ‘dry run’ for pivotal trials testing the efficacy of a COVID vaccine,” Hahn concluded.

CoVPN 5001 is designed to follow an estimated 800 study participants aged 18 years or older who have tested positive for SARS-CoV-2 infection. Study participants will be enrolled into one of three groups: those showing no symptoms, those showing mild symptoms, and those showing severe symptoms that require hospitalization. Participants may move between groups if their symptoms worsen over the course of the study.

Six study visits spread over one month will be conducted at either a participating trial site, hospital, or at the place where the study participant resides. Samples to be collected from participants include blood samples, nasal samples, saliva samples, and urine samples. The collection of stool samples will be optional. These sample collections may be done either by clinic staff or the study participant themselves. Blood samples will only be collected by clinic staff. A final study visit to check on the health of study participants will be conducted approximately two months after enrollment.

SARS-CoV-2 is the most infectious of three coronaviruses that have caused recent epidemics resulting in significant morbidity and mortality in humans in the past 20 years. Since declared a pandemic by the World Health Organization on March 11, COVID-19 has claimed a significant number of lives. A safe and effective vaccine [to prevent the acquisition and transmission of SARS-CoV-2] is necessary to reduce morbidity and mortality and aid the global community to return to a thriving social and economic global infrastructure.

“The participants in this study will give us a unique opportunity to understand the natural immune responses in the early stage of infection. Without the community’s support, science can’t move forward,” said Gail Broder, MHS, Community Engagement Lead for CoVPN 5001 and CoVPN Senior Community Engagement Project Manager at Fred Hutch.

The CoVPN will use existing clinic and laboratory infrastructure to capture clinical and immunologic information among persons with acute SARS-CoV-2 infection. CoVPN 5001 will take place across more than 58 participating trial sites in the United States, South America and sub-Saharan Africa.

**Table 1:** List of clinical trial sites (17) in the US participating in CoVPN 5001

City /Town	Clinical Research Site	City /Town	Clinical Research Site
<b>Atlanta</b>	Ponce de Leon Center	<b>New Orleans</b>	Adolescent Trials Unit
	The Hope Clinic of the Emory Vaccine Center	<b>Newark</b>	New Jersey Medical School
<b>Baltimore</b>	Johns Hopkins University	<b>New York</b>	NY Blood Center
<b>Boston</b>	Brigham and Women's Hospital Vaccine		Columbia Physicians & Surgeons
	Fenway Health	<b>Philadelphia</b>	University of Pennsylvania
<b>Birmingham</b>	University of Alabama - Birmingham	<b>San Francisco</b>	Bridge HIV
<b>Chapel Hill</b>	University of North Carolina -Chapel Hill	<b>Seattle</b>	Seattle Vaccine Trials Unit
<b>Cleveland</b>	Case Western Reserve/University Hospital	<b>St. Louis</b>	St. Louis University
<b>Miami</b>	University of Miami		

**Table 2:** List of clinical trial sites (12) in South America participating in CoVPN 5001

Country	City / Town	Clinical Research Site
<b>Argentina</b>	Buenos Aires	Balvanera, Ramos Mejia
		Almagro
	Rosario	Instituto CAICI
<b>Brazil</b>	Belo Horizonte	FUMG
	Rio de Janeiro	IPEC-Fiocruz
<b>Mexico</b>	Merida	Unidad de Atención Medica e Investigacion en Salud (UNAMIS)
	Mexico City	Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán /Clínica Especializada Condesa Iztapalapa
<b>Peru</b>	Iquitos	Asociacion Civil Selva Amazonica
	Lima	Impacta - Barranco
		San Marcos
		Impacta - San Miguel
Via Libre		

**Table 3:** List of clinical trial sites (31) in sub-Saharan Africa participating in CoVPN 5001

Country	City / Town	Clinical Research Site
South Africa	Cape Town	Groote Schuur Clinical Research Site
		Khayelitsha - eKhayaVac Clinic
		Masiphumelele Desmond Tutu HIV Foundation
	Durban	Botha's Hill Clinical Research Site
		Chatsworth Clinical Research Site
		Isipingo Clinical Research Site
		CAPRISA
		Tongaat Clinical Research Site
		Verulam Clinical Research Site
		Vulindlela Clinical Research Site
	Elandsdoorn	Ndlovu Research Centre
	Klerksdorp	The Aurum Institute Klerksdorp Clinical Research Site
	Ladysmith	Qhakaza Mbokodo Research Clinic
	Medunsa	MeCRU Medunsa
Mthatha	Nelson Mandela Academic Clinical Research unit (NeMACRU)	
Rustenburg	The Aurum Institute Rustenburg Clinical Research Center	
Soweto	Soweto Bara	
	PHRU-Kliptown	
Soshanguve	Setshaba RC	
Tembisa	Aurum, Tembisa Clinic 4	
Botswana	Gabarone	Botswana Harvard AIDS Institute Partnership
Kenya	Kisumu	KEMRI CGHR Clinical Research Centre
Mozambique	Maputo	Polana Canico Health Research and Training Center Network
Malawi	Lilongwe	UNC Project Lilongwe
Tanzania	Mbeya	National Institute for Medical Research Centre-Mbeya Medical Research Centre (NIMR-MMRC)
Zambia	Lusaka	Matero
	Lusaka	ZEHRP Lusaka
	Ndola	ZEHRP Ndola
Zimbabwe	Harare	Milton Park
		Seke South
		St. Mary's

CoVPN 5001 is sponsored by NIH's National Institute of Allergy and Infectious Diseases. Interested individuals can email [CoVPN.SBS-CEU@fredhutch.org](mailto:CoVPN.SBS-CEU@fredhutch.org) for more information.

**About The COVID-19 Prevention Network (CoVPN)**

The COVID-19 Prevention Network (CoVPN) was formed by the National Institute of Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health to respond to the global pandemic. Through the CoVPN, NIAID is leveraging the infectious disease expertise of its existing research networks and global partners to address the pressing need for vaccines and antibodies against SARS-CoV-2. CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of vaccines and antibodies for the prevention of COVID-19. The CoVPN is headquartered at the [Fred Hutchinson Cancer Research Center](#).

**About Fred Hutch:**

At [Fred Hutchinson Cancer Research Center](#), home to three Nobel laureates, interdisciplinary teams of world-renowned scientists seek new and innovative ways to prevent, diagnose and treat cancer, HIV/AIDS and other life-threatening diseases. Fred Hutch's pioneering work in [bone marrow transplantation](#) led to the development of [immunotherapy](#), which harnesses the power of the immune system to treat cancer. An independent, nonprofit research institute based in Seattle, Fred Hutch houses the nation's first National Cancer Institute-funded cancer prevention research program, as well as the clinical coordinating center of the Women's Health Initiative and the international headquarters of the NIAID-funded [HIV Vaccine Trials Network](#) and the newly formed COVID-19 Prevention Network (CoVPN).

**CoVPN Media relations:**

**Aziel Gangerdine**

- Cell: +1 206.384.0945
- [azielg@fredhutch.org](mailto:azielg@fredhutch.org)

**Claire Hudson**

- [crhudson@fredhutch.org](mailto:crhudson@fredhutch.org)