



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, MD 20892

August 11, 2020

Dear Tribal Leader and Urban Indian Organization Leader:

During these unprecedented times, we are writing to introduce the “COVID-19 Prevention Network (CoVPN),” and its upcoming research studies of products that might prevent COVID-19 (Coronavirus Disease of 2019), and how we might partner with you and your community. We want to ensure that Native and indigenous people are appropriately represented in our studies. In addition to your potential participation, we have convened a panel of 11 AIANNH experts with diverse tribal affiliations, areas of expertise, and geographic locations. These experts are meeting to review each of the study protocols, informed consent forms, and early phase study data to assist in identifying materials and information essential to Tribal participation.

About the CoVPN

The **CoVPN** was formed by the National Institutes of Health (NIH) to help respond to the global COVID-19 pandemic. It relies on existing research networks and global partners to address the pressing need for vaccines and other prevention methods, specifically monoclonal antibodies, against SARS-CoV-2. (Antibodies are proteins made by the body to fight infections and disease, and monoclonal antibodies are those that are made in a laboratory and given to people, rather than the antibodies made naturally.)

The mission of the CoVPN is to conduct Phase 3 clinical trials for COVID-19 vaccines and monoclonal antibodies. Phase 3 trials look at research questions regarding the continued safety and efficacy of the study intervention: does the product prevent infections or help to reduce the severity of disease? The CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of US government-sponsored COVID-19 vaccines and monoclonal antibodies for the prevention of COVID-19 disease. To find out more about the network, please visit <https://www.coronaviruspreventionnetwork.org/>

Upcoming Research Studies and Identifying Study Locations

In the coming months, the COVID-19 Prevention Network (CoVPN) plans to assist in five vaccine studies and three antibody studies. The table below lists the studies in order of the planned start date.

Sponsor	Study Type	Tentative Study Opening Date	Region	# of Participants
Regeneron	Antibody	July 6 th	US	2,000
Moderna	Vaccine	July 27 th	US	30,000
Lilly	Antibody	August 2 nd	US	1,700 - 2,400

AstraZeneca	Vaccine	Mid-August	US	30,000
Janssen	Vaccine	Late September	Argentina, Brazil, Chile, Columbia, Mexico, Peru, South Africa, US	60,000
NIAID	Observational SARS-CoV-2 antibody prevalence study	Early October	US	80,000
Novavax	Vaccine	Mid-October	US (possible international sites)	30,000
Sanofi	Vaccine	Mid-November	US	30,000

To successfully partner with AI/AN peoples, we will need to identify study sites conveniently located near communities that want to participate.

If you know of any investigators with experience conducting clinical research, an interest in conducting any of these trials, and an established clinical research site, please ask them to reach out to Danna Flood (dflood@fredhutch.org).

Sharing Information and Engaging Your Community

We plan to develop materials with guidance from our Native and Indigenous Expert panel, a group of Native researchers from across the country to ensure that information is clear, culturally appropriate, and addresses concerns unique to Tribal communities. We're also prepared to convey information through television, radio, print media, webinars, listening sessions, and other channels that communities find most effective.

We are striving to ensure that Tribal Nations and community members have all the necessary information needed to make informed decisions about study participation, and the opportunities to safely participate in these studies. To that end, we welcome any guidance you may have as we work towards increased inclusion in the research and access to approved products once efficacy is established. If you have any questions please reach out to the CoVPN team: Michele Andrasik (Director of Community Engagement) mandrasik@fredhutch.org or Jasmin Aina (Project Coordinator) jaina@fredhutch.org

Sincerely,



Anthony S. Fauci, M.D.
 Director
 National Institute of Allergy
 and Infectious Diseases