

COVID-19
Prevention Network

COVPN COMMUNITY AND STAKEHOLDER ENGAGEMENT STRATEGIC PLAN



A publication by the COVID-19 Prevention Network

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WHAT IS THE COVPN?

The COVID-19 Prevention Network (CoVPN) was established by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, to enroll thousands of volunteers for large-scale Phase 3 clinical trials testing a variety of investigational vaccines and monoclonal antibodies to protect people from COVID-19. The network merges four existing NIAID-funded clinical trials networks: the **HIV Vaccine Trials Network (HVTN)**, based in Seattle, WA; the **HIV Prevention Trials Network (HPTN)**, based in Durham, NC; the **Infectious Diseases Clinical Research Consortium (IDCRC)**, based in Atlanta, GA; and the **AIDS Clinical Trials Group**, based in Los Angeles, CA. The individual networks will continue to perform clinical trials for HIV vaccines and prevention and other infectious diseases, in addition to their new COVID roles.

The existing clinical trials networks that form the CoVPN



Structural Factors Drive COVID-19 Disparities

COVID-19 can affect anyone, and the disease can cause symptoms ranging from mild to very severe. Some people may be more likely to have severe illness than others because they have characteristics or medical conditions that increase their risk. (<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/assessing-risk-factors.html>).

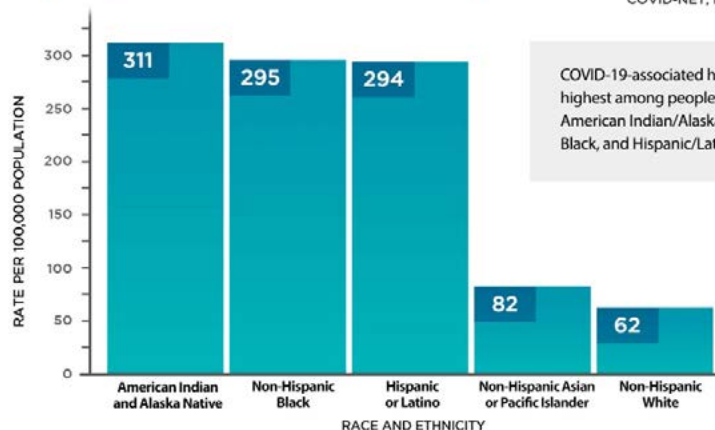
- Lack of access to healthcare
- Density of households
- High rate of unemployment
- Pervasive discrimination



COVID-19 Cases are rising across the United States and around the world. **American Indian/Alaska Native, Black, Latinx, essential workers and older adults (65+) are by far the hardest hit, with higher rates of COVID infections, hospitalizations and death.**

Age-adjusted COVID-19-associated hospitalization rates by race and ethnicity

COVID-NET, MARCH 1 - AUGUST 8, 2020



COVID-19-associated hospitalization rates are highest among people who are non-Hispanic American Indian/Alaska Native, non-Hispanic Black, and Hispanic/Latino.

cdc.gov/coronavirus



C3317989-A

Rates are statistically adjusted to account for differences in age distributions within race/ethnicity strata in the COVID-NET catchment area. Rates are based on available race and ethnicity data which is now complete in 94.3% of cases from COVID-NET sites. COVID-19-associated hospitalization rates for American Indian and Alaska Natives may be impacted by recent outbreaks among specific communities within this population and the small numbers of American Indian and Alaska Natives cases included in COVID-NET.

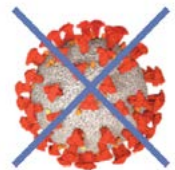
What's the Answer? A vaccine that works for everyone.



HOW DOES A VACCINE WORK?

By teaching the body to recognize and fight invaders.

Vaccines work by teaching your body to recognize an invading virus, which sends your immune system into action. Ultimately, they help your body prevent or control infections as well as reduce the severity of a disease.



The vaccine gives your body advance information about the virus. You are not given the actual virus. Vaccines are made using synthetic copies of pieces of the virus.

Body sounds the alarm.

Fighter cells and proteins go into action.

GOAL: Your body can block or control the virus if it comes into contact with it in the future.

WHAT ARE THE PHASES OF CLINICAL RESEARCH?

There are 3 main stages of clinical trials, and we're in phase 3.

With SARS-CoV-2, we are working as quickly as possible.

No phases are skipped. Instead, we overlap the phases, starting the next phase as quickly as we have the necessary safety data collected and analyzed from the earlier phase.

The new phase can start while the long-term follow-up of people in the earlier phases continues. Other steps can be done in parallel, instead of one after the other.

Stages of Clinical Trials



Phase 1

A small number of healthy volunteers are tested for safety and immune responses



Phase 2

Hundreds of volunteers help identify the best dose and vaccine administration schedule



Phase 3

Several thousand volunteers test the safety and efficacy of the vaccine

HOW DID WE GET TO PHASE 3 SO QUICKLY?

Usually when this effort is undertaken by individual pharmaceutical companies, they start production when all hurdles have been cleared and government reviewers have seen the results of all phases of the study and evaluated effectiveness.

For COVID-19, the US Government began **investing billions of dollars** to start producing vaccines after early study phases, and are **reducing the bureaucracy** that usually holds up review of later phase results, cutting significant amounts of time, without cutting corners.

WHAT'S THE CHALLENGE?

We need **thousands** of volunteers ready to roll up their sleeves by the end of 2020!



Engagement and Participation of Priority Populations

PRIORITY POPULATIONS

- People with underlying medical conditions
- People with greater chances of exposure at their job
- People who live or work in elder-care facilities
- People over age 65
- People who work in jails or prisons
- People from racial and ethnic groups that have been hardest hit by the pandemic, such as Black/African Americans, Latinx, and American Indian/Alaska Natives.

COMMUNITY ENGAGEMENT

All activities are tailored to each of these vital populations.

Priority populations require varying outreach, engagement, and recruitment approaches.

We continue to build and maintain relationships with experts working with these groups.

What Stands in Our Way?

- People are bombarded with myths and misinformation.
- People who want to help don't know how.
- Volunteers may be stigmatized by a vocal anti-vax movement.
- A higher than normal number of US citizens are doubting the vaccine development process for COVID-19.
- Politics are interfering with science like never before.

WHAT IS THE COVPN COMMUNITY ENGAGEMENT MODEL?

At the top left of the graphic, you will notice the term Community Education, which then flows into Recruitment, which flows into Retention, and then flows back to Community Education. Community Education, Recruitment, and Retention are not synonymous with each other, and are distinct concepts and processes that fall under the umbrella of Community Engagement, and operate in a cyclical fashion supporting each other.

- **Community Education:** sets the foundation for awareness, literacy, and support of COVID-19 prevention and COVID-19 clinical research locally
- **Recruitment:** builds upon community education to engage and support clinical trial participation
- **Retention:** builds upon community engagement and recruitment, to support continued study engagement by the local community and a positive trial experience by participants



Community members are at the heart of the CoVPN, and we know that without community, science could not move forward because we would have no one participating in our research studies. At our research sites, community engagement is a collective responsibility that is shared by everyone including investigators, community staff, clinicians, and community advisory board members.

CoVPN sites are required to develop annual work plans that outline their processes and goals for community engagement, and these work plans have to be approved by the CoVPN

Community Engagement team. These work plans are developed in partnership with all key site staff, including investigators, clinicians, CAB members, and community staff members. The work plans describe community education, recruitment, and retention efforts focused on the surrounding community.

Good Participatory Practice is a framework used in the CoVPN, and it is one of the key components at the heart of the CoVPN Community Engagement Program. Additionally, various behavioral theories guide the work we do as a Network in order to ensure that we are truly engaging community members at each phase in the clinical trial process.

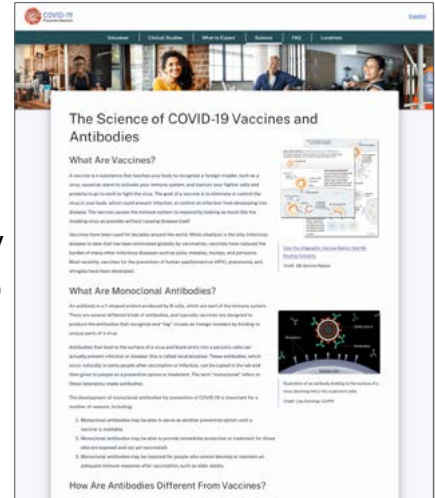
As part of our commitment to meaningful community and stakeholder engagement, we have developed a strategic plan to provide an overview of our strategies and efforts, which involves developing tools and materials for potential participants and participants, tools and materials for clinical trials sites, and community education programs focused on engaging stakeholder groups to ensure that communities have the resources they need to make informed decisions.

MATERIALS FOR PARTICIPANTS/ POTENTIAL PARTICIPANTS

These materials are created centrally by the CoVPN and provided to the CoVPN research sites for distribution to potential participants through education activities and the informed consent process, as well as to participants during the study.

- **The Bill of Rights and Responsibilities for Research:** a detailed description of the rights and responsibilities of participants and site staff in CoVPN research studies.
- **Injuries Sheet:** a handout for US sites regarding study-related injury compensation provided under the Public Readiness and Emergency Preparedness (PREP) Act and the Countermeasures Injury Compensation program (CICP).
- **Participant Experience Brochure:** General overview of what participants can expect when they sign up for a vaccine trial, including study and follow-up visits, how to sign up for the registry, and what to expect after completing the registry.

- **The CoVPN website, www.CoronavirusPreventionNetwork.org or www.PreventCOVID.org**, is the website used to provide resources and to support recruitment efforts for these clinical studies. The site provides educational information on vaccines and monoclonal antibodies, answers frequently asked questions, and most importantly, allows volunteers to register in a Volunteer Screening Registry through a secure portal. To volunteer, visit www.PreventCOVID.org, click on “Volunteer Now” and complete the survey. Local study sites will contact volunteers in their area who are a good match for a particular study that they have available.



CoVPN website

- **Frequently asked questions about COVID-19 Clinical Studies** with detailed answers to these questions: posted on the CoVPN website.

MATERIALS/SUPPORT FOR CLINICAL TRIAL SITES

Materials are created centrally by the CoVPN and are provided to the CoVPN research sites for their use in community engagement activities. These materials include, but are not limited to: PowerPoint slide sets to explain each study in language that is accessible to laypersons; slides that explain the racial and ethnic inequities regarding COVID-19 that include links to assist with keeping the slides updated; materials for use in reaching particular populations, such as large print materials for use with older adults; and videos that can be used to debunk myths and correct misinformation. Additional support is also provided, such as regular conference calls where research sites can share their best practices and help each other to mitigate challenges.

PRIORITY POPULATION EXPERT PANELS

We have convened 4 Expert Panels, each comprised of 10-12 scientists representing diverse areas of expertise including biomedical and social and behavioral sciences, biostatistics and ethics. The expert panelists are members of and working with and within priority communities (Native/Indigenous, Latinx, African American/Black, Older Adults/VA). These panel members are common across all COVID trials and are helpful in building and maintaining relationships with the priority communities. They provide guidance and direction to the CoVPN and partners regarding engaging priority population members, and strategies to mitigate barriers to participation.



CoVPN Native & Indigenous Expert Panelists



Alika Maunakea (Native Hawaiian), PhD
Associate Professor-Department of Native Hawaiian Health Epigenomics, University of Hawai'i



Matthew Anderson (Eastern Band Cherokee Nation), PhD
Assistant Professor, Microbiology and Microbial Infection & Immunity The Ohio State University



Bonnie Duran (Co-Chair, Opelousas/Coushatta descendent), Dr.PH
Professor, Schools of Social Work and Public Health, University of Washington



Michelle Johnson-Jennings (Choctaw Nation Tribal Member), PhD
Tenured Associate Professor, Scientific Director, and Canada Research Chair Indigenous Community Engaged Research



Dave Wilson (Ex-Officio, Dine'), PhD
Director, National Resource Center on Native American Aging, Center for Rural Health University of North Dakota School of Medicine & Health Sciences



Naomi Lee (Seneca Nation), PhD
Assistant Professor, Department of Chemistry and Biochemistry Northern Arizona University



Denise Dillard (Inupiaq Eskimo), PhD
Research Director, Southcentral Foundation (SCF)



Rodney C. Haring (Beaver Clan), PhD, MSW
Director, Center for Indigenous Cancer Research, Roswell Park Comprehensive Cancer Center



Karina L. Walters (Co-Chair, Choctaw Nation of Oklahoma), PhD, MSW
Professor, School of Social Work, University of Washington



Tommi Lynn Gaines (Navajo/ Dine'), DrPH
Associate Professor, Department of Medicine, University of California San Diego



Lonnie Nelson (Eastern Band of Cherokee descent), PhD
Assistant Professor, Department of Nursing, Washington State University

CoVPN African American & Black Expert Panelists



Cyril Engmann, M.D., FAAP
Clinical Prof, Global Health; Clinical Prof, Pediatrics - Neonatology Global Prog Leader/Director; Maternal, Newborn, Child Health & Nutrition; PATH, Attending Neonatologist, Pediatrics, School of Medicine, UW & Seattle Children's Hosp



Orlando Harris, PhD, FNP, MPH
Associate Professor, Department of Community Health Systems, School of Nursing University of California, San Francisco.



Ernest Hopkins
Director of Legislative Affairs, San Francisco AIDS Foundation (SFAF) Founder & Board Chair of the National Black Gay Men's Advocacy Coalition



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CoVPN LatinX Expert Panelists



Adrian Dominguez, MS
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Urban Indian Health Institute



Julie Levison, M.D., MPhil, MPH
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Souhail Malavé-Rivera, PhD Adjunct
Professor & Co-Director, Sex+ TEAM
Center for Evaluation and Sociomedical
Research School of Public Health,
University of Puerto Rico-Medical
Sciences Campus

CoVPN Older Adult & VA Expert Panelists



Amy C. Justice, M.D., PhD CNH Long Professor of Medicine and Public Health, Yale University Staff Physician, VA Connecticut Healthcare System



Arun Karlamangla, PhD, M.D. Professor of Medicine in Residence, Division of Geriatrics UCLA School of Medicine



Collette Adamsen, PhD Director, National Resource Center on Native American Aging, Center for Rural Health University of North Dakota School of Medicine & Health Sciences



Fayron Epps, PhD, RN Assistant Professor at Emory University, Nell Hodgson Woodruff School of Nursing



Jan Busby-Whitehead, M.D. Division Chief; Professor; Director, Division of Geriatric Medicine Center for Aging and Health, UNC Chapel Hill



Janiece Taylor, PhD, MSN FAAN, Assistant Professor Center for Innovative Care and Aging, Johns Hopkins School of Nursing



Kathryn E. Callahan, M.D., MS Geriatrician, Winston Salem, NC



Keith Whitfield, PhD President, University of Nevada Las Vegas



Marianne Shaughnessy, PhD Director, Geriatric Research, Education and Clinical Centers (GRECC), VA Office of Geriatrics & Extended Care, Veterans Health Administration



Michi Yukawa, M.D. Professor of Medicine Department of Medicine Division of Geriatrics, San Francisco VAMC



Sandra Crouse-Quinn, PhD Professor and Chair, Department of Family Science Senior Associate Director, Maryland Center for Health Equity School of Public Health, University of Maryland



Tanya R. Gure, M.D. Associate Professor of Clinical Medicine, Section Chief of Geriatrics, Ohio State University Wexner Medical Center



Tara A. Cortes, PhD, RN, FAAN Executive Director Professor, Hartford Institute for Geriatric Nursing, New York University Rory Meyers College of Nursing



Ugochi Ohuabunwa, M.D. Associate Professor of Medicine, Emory University Division of General Medicine and Geriatrics



Wayne McCormick, M.D., MPH Professor of Medicine at the University of Washington, Department of Medicine, Division of Gerontology and Geriatric Medicine, Harborview Medical Center

COVPN COMMUNITY WORKING GROUP

Consistent with the principles of Good Participatory Practice, a community working group was convened to provide guidance on the development, implementation, and results dissemination of COVID-19 research studies. The goals of the COVID-19 Community Working Group include, but are not limited to: adapting sample informed consent forms for local use and reviewing study-related materials, helping to inform recruitment and retention strategies, assisting in monitoring any emerging community issues while research is ongoing, and informing the facilitation of accurate study results dissemination.



CoVPN Community Working Group



Jonathan Lucas, MPH
Community Research Project
Manager, CoVPN, FHI 360



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Community Engagement Manager
UNC Global HIV Prevention &
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Community Advisory Board
Member
Fred Hutch/Seattle Vaccine Trials
Unit



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Co-Chair



Ro Yoon
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Vaccine Trials Unit



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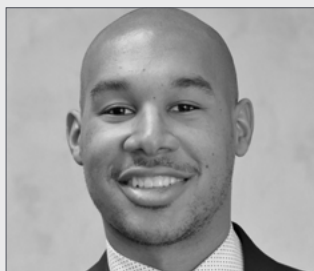
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Community Advisory Board
Member, George Washington
University Public Health
Research Clinic

WHAT IS STAKEHOLDER ENGAGEMENT IN THE COVPN?

Stakeholder engagement supports the community education component of the CoVPN community engagement model by focusing on the development and maintenance of partnerships and quality relationships with a variety of stakeholders to develop trust and engage those partners in a shared vision. Stakeholder engagement requires a commitment to a process of shared principles and values for the mutual benefit of all parties. Community and stakeholder education are critical components of the community engagement efforts of the CoVPN and set the foundation for awareness, literacy, and support of COVID-19 prevention and COVID-19 clinical research. To effectively engage stakeholders, we have engaged in:

Listening Sessions

These offer opportunities to share relevant information to stakeholders and hear input and feedback about the design and implementation of the CoVPN trials. These sessions are ongoing and iterative, and involve partnering with stakeholder groups who host these activities for their networks and constituents.

Virtual Webinars/Town Hall Events

These events, like the listening sessions, provide opportunities to share relevant information about the CoVPN trials, but also include opportunities to engage in meaningful dialog about other related topics including medical mistrust, racism, vaccine hesitancy, research ethics, among other topics. These sessions are ongoing and iterative, and involve partnering with stakeholder groups who host these activities for their networks and constituents.

Stakeholder Outreach

Through our direct communication, listening sessions, and virtual meetings, as well as through our stakeholder partners, we have engaged key industries to establish and enhance partnerships in support of broader information dissemination. These industries include unions associated with the essential workforce (e.g., correctional staff, meat/poultry unions, restaurant unions, factories), grassroots organizations focused on COVID-19 and social justice organizations, national organizations, and political entities. These efforts at the network level also work in tandem with the outreach and education efforts conducted by the CoVPN sites at the local level.



Some of the regional and national organizations we are partnering with include *(not an exhaustive list)*:

- AARP, Washington, DC
- Abounding Prosperity, Dallas, TX
- AIDS Project of the East Bay, Oakland, CA
- Black AIDS Institute, Los Angeles, CA
- Community Campus Partnerships for Health, Raleigh, NC
- House of Blahnik, Philadelphia, PA
- Keeping Ballroom Community Alive Network, New York, NY
- Latino Commission on AIDS, New York, NY
- NMAC, Washington, DC
- National Black Justice Coalition, Washington, DC
- National Urban League, New York, NY
- POCAAN, Seattle, WA
- Southern AIDS Coalition, Birmingham, AL
- ThriveSS, Atlanta, GA
- Treatment Action Group, New York, NY
- Tribal and Urban Indian Health Immunization Coalition, American Indian Health Commission for Washington State
- UnidosUS, Washington, DC
- Urban Indian Health Institute, Seattle, WA
- Brothers United, Indianapolis, IN
- Tru Evolution, Riverside, CA

Our regional and national organizational partnerships continue to grow as we continue to connect and build relationships with new groups.

COVPN FAITH INITIATIVE

It is important to acknowledge and foster the critical role that faith and religious institutions play in nurturing hope, healing, and health in communities, and to support broad awareness and support of COVID-19 research studies. It is also important to meaningfully engage diverse communities, including faith communities, in conversations about COVID-19 and the associated research studies. When effective products are found, the engagement efforts will result in greater acceptability and reduced costs associated with bringing communities along¹.

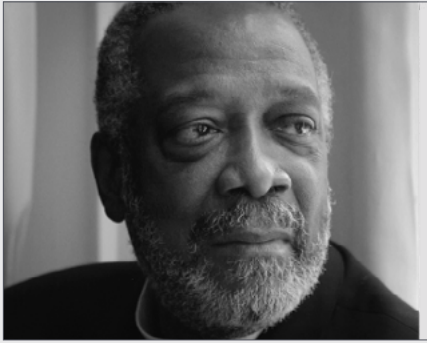
CoVPN Faith Initiative Purpose

The initiative seeks to address the impact of COVID-19 in faith communities, particularly faith communities that are comprised largely of Black, Latinx, and American Indian/Alaskan Native people, by mobilizing faith leaders nationally, to provide leadership and support in the conduct of COVID-19/CoVPN education and awareness activities. These activities integrate anti-racist, anti-xenophobic, anti-homophobic and Good Participatory Practice principles, along with the inclusion of common values found in the sacred texts of various religions.



¹MacQueen, K. M., & Cates Jr, W. (2005). The multiple layers of prevention science research. *American Journal of Preventive Medicine*, 28(5), 491-495.

CoVPN Faith Initiative Team



Rev. Edwin Sanders, Senior Servant and Founder of Metropolitan Interdenominational Church in Nashville, Tennessee (initiative leader)



Khadijah Abdullah, Executive Director of Reaching All HIV+ Muslims in America (RAHMA), Washington, District of Columbia



Dr. Ulysses W. Burley III, Founder of UBtheCure, Chicago, Illinois



Bishop Oliver Clyde Allen III, Senior Pastor and Founder of The Vision Cathedral of Atlanta, Georgia



Dr. Bambi W. Gaddist, CEO and Founder, Executive Director of the South Carolina HIV Council – Wright Wellness Center in Columbia, SC



Rev. Kamal Hassan, Pastor of Sojourner Truth Presbyterian Church, Richmond, California



Rev. Bertram G. Johnson, Union Theological Seminary, New York, New York



Activities

The CoVPN Faith Initiative team, trusted within their communities and having long-term relationships with the scientists in the research networks, conduct education sessions intersecting faith and science with faith leaders and groups around the country. This bridges any gaps that may exist by assuring communities that participation in the clinical trials is the best way to ensure that study results accurately represent the entire population and that approved vaccines are effective for all people. The team will conduct these educational sessions virtually and in-person (where appropriate) to enhance trust and support meaningful engagement in key communities, and provide accurate and updated information about COVID-19 and CoVPN clinical trials. The CoVPN Faith Ambassadors also partner with 42 faith leaders to assist in information dissemination and hosting education sessions to enhance networks of faith leaders and meaningfully engage communities.

Contact Us

For more information about the **CoVPN**, visit us at: www.PreventCOVID.org.

Follow us on Facebook and Instagram at [@PreventCOVID19](https://www.instagram.com/PreventCOVID19).

For more information about **CoVPN Community Engagement activities**, email us at: CoVPN.SBS-CEU@fredhutch.org.

For more information about **CoVPN Stakeholder Engagement activities**, email Stephaun Wallace, Ph.D. at: sewallac@fredhutch.org.