

DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research

Moving Swiftly to Combat the COVID-19 Global Health Crisis

COVID-19 Vaccine Research, Recruitment, and Testing

Moderator: A. Mariel Jais, PharmD, RBP

Manager of the Office of Laboratory Safety
Office of the Vice President for Research. George Washington University

10:35 - 11:35 AM EST



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Moving Swiftly to Combat the COVID-19 Global Health Crisis

COVID-19 Vaccine Research, Recruitment, and Testing



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Co-Director, Including Diverse Populations
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Diversifying Clinical Trials and Clinical Research

Best Practices from VA Research

Presenter: Molly Klote, MD, COL, USA, Ret.
Director of Office of Research Protections, Policy, and Education
April 23, 2021



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of Veterans Affairs

Integrated Healthcare



The Veterans Health Administration is America's largest integrated health care system, providing care at 1,255 health care facilities, including 170 medical centers and 1,074 outpatient sites of care of varying complexity (VHA outpatient clinics), serving **9 million** enrolled Veterans each year.

<https://www.va.gov/health/>



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Research at VA

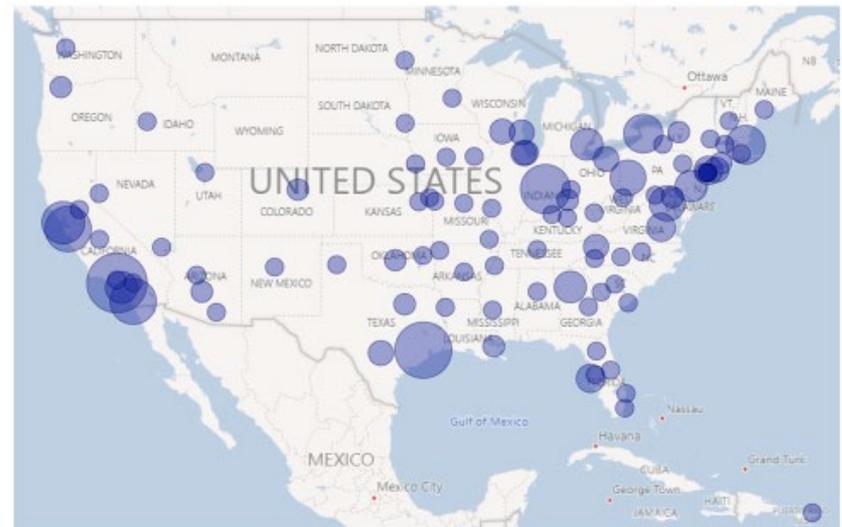
- Over **90 years of research**
- **Multi-site clinical research** in the United States began in the VA health care system
- VA's ability to oversee and manage research across the enterprise provides a rapid way to implement **large-scale national studies**.
 - Additionally, our electronic medical records provide access to an immense amount of information to facilitate high-quality research studies.



What do you get for your investment in VA research?

- 22,000 ongoing studies (2020)
- A national platform for research studies – currently in use for Federal COVID-19 Response
- Collaborations with the best Academic Medical centers in the country
- Training the next generation of scientists and providers
- 70% of all medical providers in the US have trained in a VA medical facility

10/13/2020



VA
HEALTH CARE
Defining
EXCELLENCE
in the 21st Century

DISCOVERY * INNOVATION * ADVANCEMENT

VA
U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research and Development

VA Research Advances



Implantable pacemaker (1950s)



1st Liver transplant (1967)



Antihypertensive medication use (1970s)



Aspirin reduces heart attacks & death (1983)

When we heard that 1 out of 3 people 60 years old and older get shingles...

we got the shingles vaccine!

What is shingles?

- Shingles is a disease that causes a painful, blistering rash. One in three people with shingles will have serious, long-term pain after the rash heals.
- Almost all older adults can get shingles. About one in three people will develop the disease during their lifetime.
- Shingles is more common and more serious in older adults. Nearly 1 million Americans get shingles every year and about half of them are 60 years old and older.

How can the risk of shingles and long-term pain from shingles be reduced?

- A new vaccine against shingles has been developed and is recommended for people 60 years old and older.
- You can reduce your risk of shingles and long-term pain by getting the vaccine.
- In a clinical trial involving people 60 years old and older, the shingles vaccine prevented long-term pain in two out of three people who got vaccinated and prevented the disease in about half of them.

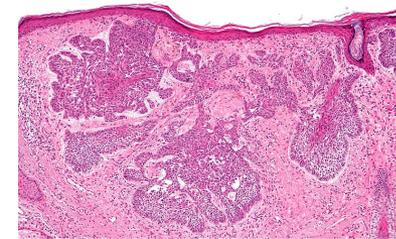
Reduce YOUR risk of shingles. GET VACCINATED.

For more information, ask your healthcare provider, call 800-CDC-INFO (800-232-4636), or visit www.cdc.gov/vaccines/imz/advs/shingles/default.htm

ZostaVax Shingles Vaccine (2011)



VA-DEKA Arm (2014)



Flourouracil 5%-Skin Cancer (2018)

VA Research Strategic Priorities

Work as an enterprise to:

-  Increase Veterans access to high quality clinical trials
-  Increase the substantial real-world impact of VA research
-  Put VA data to work for Veterans

 Actively promote diversity, equity, and inclusion within our sphere of influence

 Build community through VA research

New in FY 2021



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Diversity & Inclusion (D&I) Advisory Sub-committee

- Formed in October 2020 under the National Research Advisory Committee
- Informs strategic outreach, recruitment, and education of minority and underserved volunteers into VA clinical trials and research



D&I Advisory Sub-committee

Committee members are from across VA and beyond:

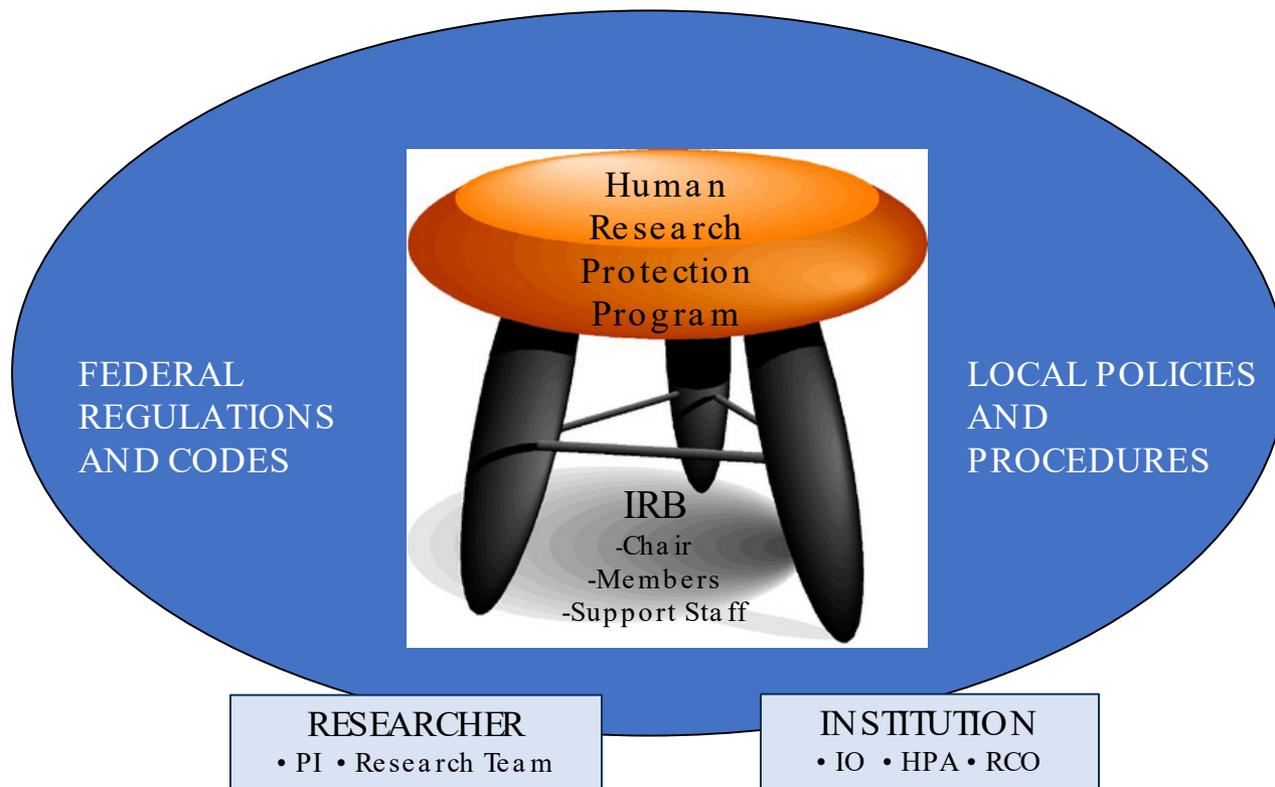
Center for Minority Veterans (VA)	Volunteer and Community Relations (VA)
Center for Faith and Opportunity Initiatives (VA)	Women's Health Practice-Based Research Network
Office of Resolution Management, Diversity & Inclusion (VA)	VA Homeless Program
Office of Tribal and Intergovernmental Affairs (VA)	Office of Public and Intergovernmental Affairs (VA)
Office of Community Engagement (VA)	Center for Women Veterans (VA)
National Chaplain Services (VA)	VHA Social Work
Coronavirus Prevention Network (CoVPN)	National VA Chaplain Service



Outward Facing Program



Human Research Protections Plan



Office Of Research Oversight

- Office established by Congress to ensure VHA has adequate oversight of research
 - Risk to research participants
 - Risk to the Agency
- Office dedicated to protecting research subjects through compliance visits
- A network of Research Compliance Officers across VHA



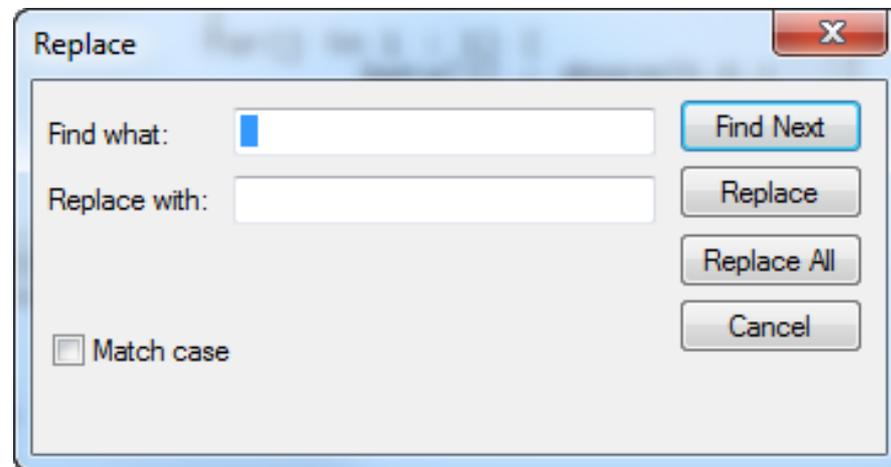
Words Matter

Research

- No longer “on”
- **In** and **With** the community

• Subject

- **Participant/volunteer**



Coronavirus Research Volunteer List

WHAT: The VA coronavirus volunteer list is a nationwide pool of diverse volunteers available to be contacted if there's a COVID-19 clinical trial or study that's right for them.

Coronavirus research at VA

Join the effort to prevent and treat COVID-19



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Diversity in the Registry

- The Registry currently has over 56,000 volunteers – **23% minority, 18% women**
- National and local outreach campaign included:
 - PSA with Drs Jerome Adams and Anthony Fauci with prominent Black and Hispanic Veterans
 - Print and digital collateral featuring non-white researchers and Veterans, with input from D&I sub-committee
 - Podcasts
 - Human-interest stories on Black and Hispanic Veteran volunteers



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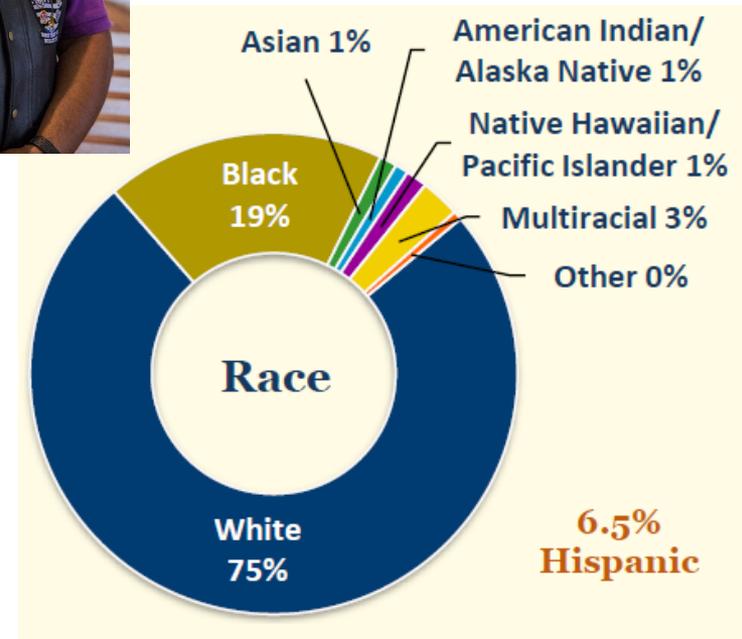
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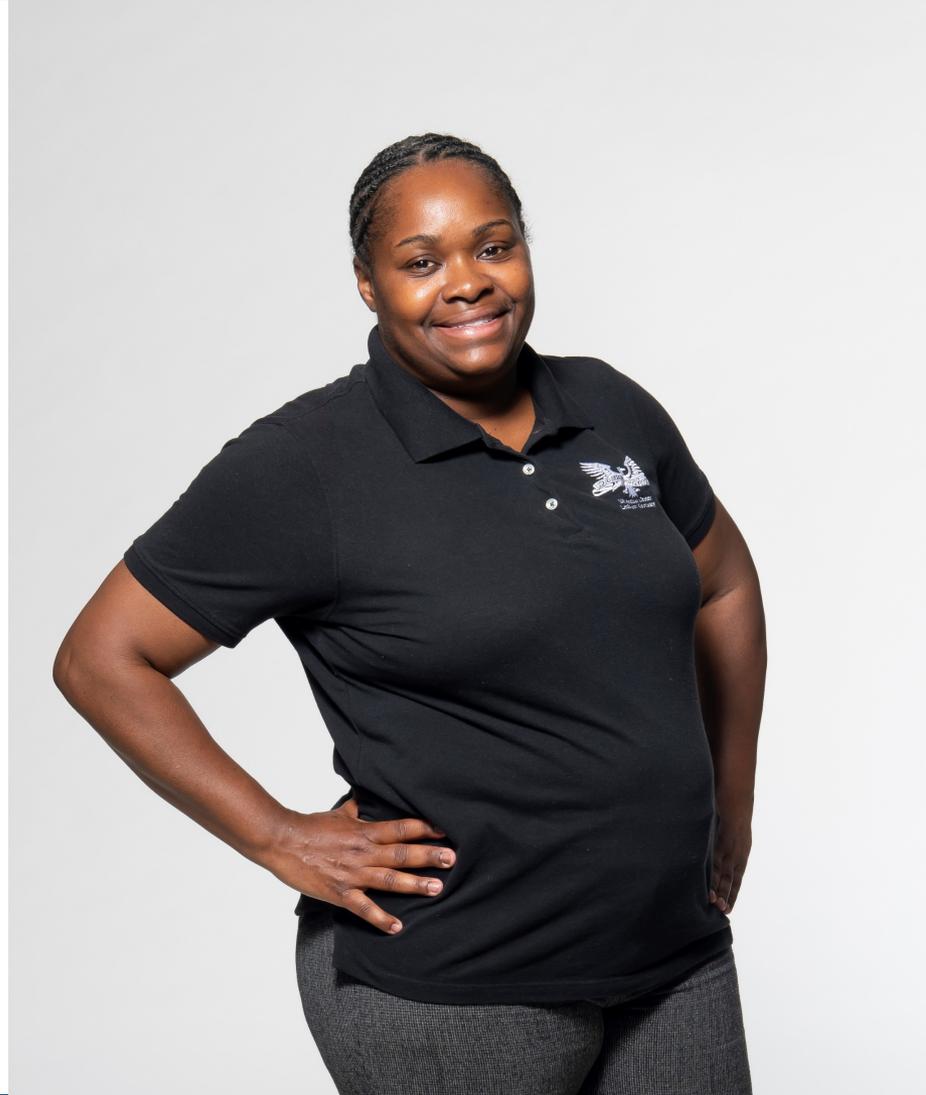
MVP Cohort Overview

- Over 831,000 Veterans enrolled as of March 2021
- Largest African American cohort of any genetics research program
- MVP's goal: At least one million Veterans enrolled by 2022, with a focus on diversity and inclusion



Focus on Women Veterans

- Women reflect **9%** of all Veterans in MVP (**75,000** of **830,000** Veterans enrolled)
 - Women in MVP are more diverse than men (40% vs. 27% non-White, respectively)
 - There are roughly 2 million living women Veterans



Inward Facing Efforts

- ORD formed the DEI Workgroup:
 - Address Inequity in funding of research
 - Collect baseline data
 - Monitor success over time
 - Assist minority and underrepresented researchers in writing (grants, abstracts, manuscripts, presentations)
 - Held a seminar last month
 - Survey of writing needs



Thank you!

Contact:

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Novavax Phase 3, Randomized, Observer-Blinded, Placebo- Controlled Study Howard University



Presenters:

Florencia Gonzalez, MPH
Co-director, Inclusion of Diverse Populations
GHUCCTS

Megan Ware
Peer Support Specialist
Center for Infectious Disease Management and
Research (CIDMAR)

About the COVID Vaccine Trial



- Howard University was selected as a site for the Novavax Phase 3 vaccine study by the National COVID Prevention Network (CoVPN).
- Novavax is a biotech company located in Rockville, MD.
- The Novavax study, a placebo-controlled Phase 3 trial, was initiated to evaluate the safety, efficacy, and immunogenicity of the Novavax vaccine and to provide protection against COVID-19 disease.

Novavax Phase 3 Clinical Trial for COVID-19 Vaccine at HUH

Principal Investigator:

Siham M. Mahgoub, MD

Medical Director

Center for Infectious Disease
Management and Research
(CIDMAR)



Photo Credit: WJLA

Collaborations & Study Team

- Center for Infectious Disease Management and Research (CIDMAR)
- Georgetown-Howard Universities Center for Clinical and Translations Science (GHUCCTS)
 - HUH Clinical Research Unit
 - Administrative Core
 - Community Engagement & Inclusion of Diverse Population Cores
- HU College of Medicine
 - Associate Dean for Strategy, Outreach, and Innovation
- (HU-ACTS) community advisory board (CAB)
- HU Communications Team
- HU College of Pharmacy
- Matrix Medical Network
- MedStar Washington Hospital Center
- (HU-ACTS) community advisory board (CAB)

Trial Overview

- Phase 1-2 trials conducted in Australia and South Africa
- Phase 3 trial enrolled in 119 sites
 - 111 U.S, 6 Mexico, 2 Puerto Rico
- 2:1 randomization
- 2 shots, 21 days apart
- Up to 2 years follow-up (up to 10 visits)
- Primary outcomes – COVID cases and severe COVID cases
- Inclusion/Exclusion



Recruitment Priority Groups



COVID-19 Prevention Network

IRB Approved at the Study Level Nov 30, 2020

HELP FIND A VACCINE FOR COVID-19!

WE'RE LOOKING FOR:

- Adults aged 18 and older
- People who are more likely to be exposed to COVID-19, including:
 - 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 impacted in greater numbers by the pandemic, such as Black/African American, Latinx, American Indian/Alaska Native/Native Hawaiian

If you decide to join a COVID-19 prevention study, you will be compensated for your time.

You **CANNOT** get infected with SARS-CoV-2 or get COVID-19 illness from the study vaccine.

Learn more



HU Site Code: HOWU



Howard University
HUCOVID@howard.edu
202-865-7743

- Adults aged 18 and older
 - People from racial and ethnic groups that have been impacted in greater numbers by the pandemic such as Black/African American, Hispanic, American Indian/Alaska Native/Native Hawaiian)
 - People more likely to be exposed to COVID-19 (Including people with underlying medical conditions)
 - People with increased chance of exposure at job
 - People who live or work in elder-care facilities
 - People over the age of 65
 - People who work in jails or prisons
- Sites were asked to enroll 15% Black/African American participants, 20% Hispanic participants, and 1-2% American Indian/Alaska Native/Native Hawaiian

Study Accrual



All sites

- Study received FDA approval Dec 27, 2021
- Close to 30,000 enrolled site wide
- Active recruitment from Dec 28, 2020 to February 16, 2021
- Originally told we would recruit end of Feb 2021

Howard University

- 150 participants enrolled in six weeks.
- Recruitment goal was 300 participants.
- 56% participants enrolled from diverse ethnic and racial background (30% Black/African- Americans, 21% Hispanic 5% Asian)
- 64% Male, 36% Female

Recruitment Strategies

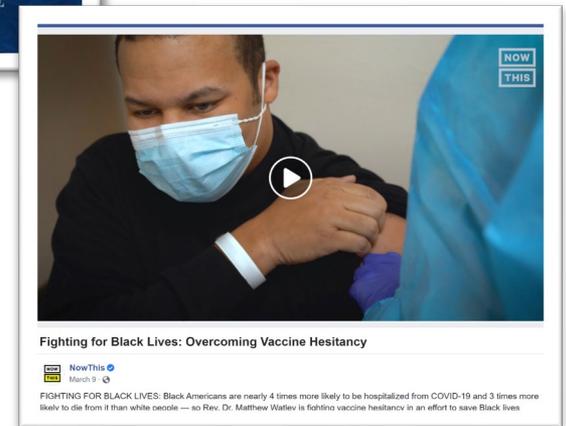
Community Engagement

- Study Community Advisory Board
 - Key to our community engagement efforts
- Community engagement events- Dissemination of study info & educational material
 - Kingdom Fellowship Food Drive
 - Pennsylvania Avenue Baptist Church
- Community focused webinars/ town hall meetings
 - *Making it Plain: A Conversation with Dr. Fauci and the Black Community*
- Mobile Van



Pennsylvania Avenue Baptist Church

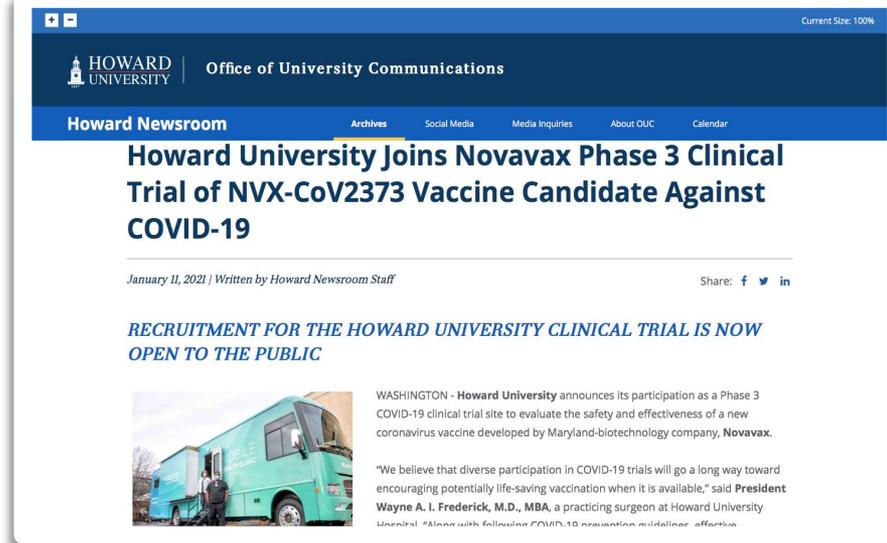
[NowThis - Fighting for Black Lives: Overcoming Vaccine Hesitancy](#)



Additional Recruitment Strategies



- COVID-19 Prevention Network (CoVPN) Screening Registry
- Press Release
- Word of mouth (Referrals from Vaccine Trial team & participants in the trial)
- Radio station advertisements (Radio Zol & WHUR)
- ClinicalTrial.Gov
- Allowing for meaningful engagement during screening process



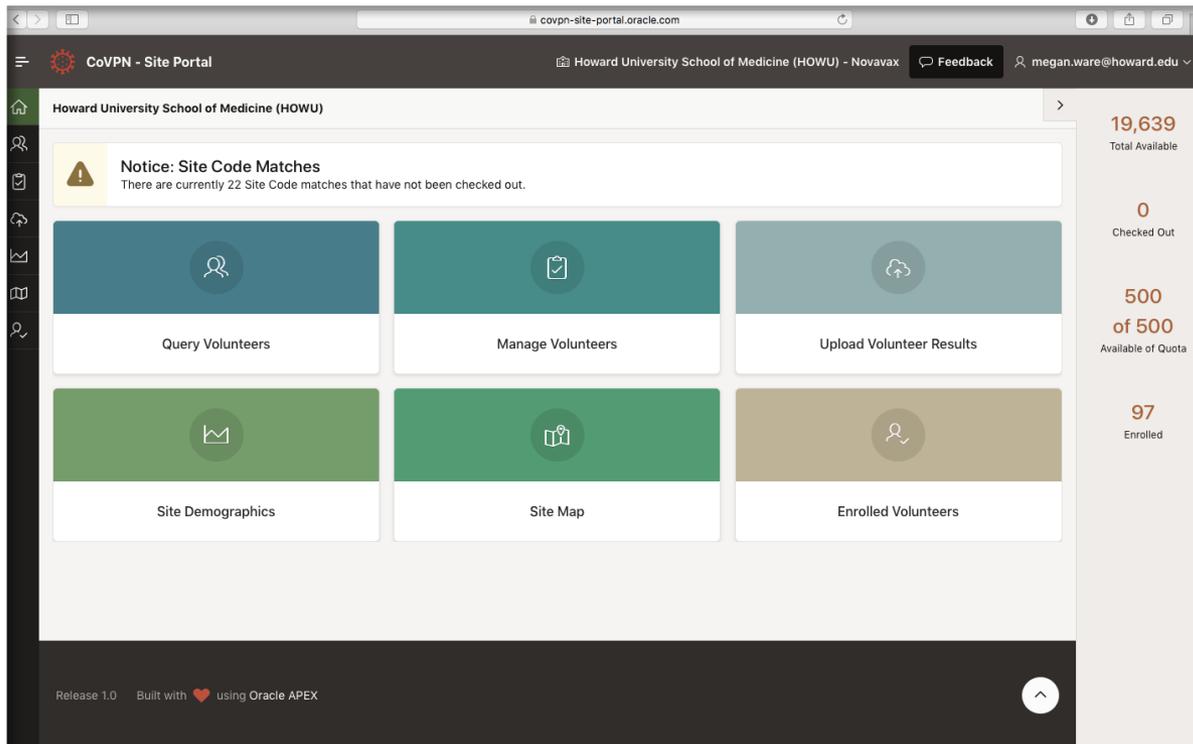
Successful Recruitment Strategies



Meaningful engagement during screening

- Listened attentively (ex: participant concerns/fears)
- Shared personal experience with vaccination
- Encouraged participants to do what is best for them
- Took time to provide education about the trial
- Be ready to provide Research 101 information

Successful Recruitment Strategies (



CoVPN - Site Portal

Howard University School of Medicine (HOWU) - Novavax

Feedback

megan.ware@howard.edu

Howard University School of Medicine (HOWU)

Notice: Site Code Matches
There are currently 22 Site Code matches that have not been checked out.

19,639
Total Available

0
Checked Out

500
of 500
Available of Quota

97
Enrolled

Query Volunteers

Manage Volunteers

Upload Volunteer Results

Site Demographics

Site Map

Enrolled Volunteers

Release 1.0 Built with ❤️ using Oracle APEX

- The COVID-19 Prevention Network (CoVPN) Screening Registry brought in most participants
- Registry included list of interested potential volunteers for COVID-19 prevention clinical trials.
- Participation involved completing a 10 min online survey including several eligibility criteria and demographic questions
- HU enrolled **97 participants** from the registry

Inclusion of People with limited English Proficiency



- Worked closely with CAB to:
 - Identify study specific interpreters
 - Community Health Workers (outreach)
 - Provide input on recruitment material
- Trained bilingual (Spanish/English)
- Translated study material: recruitment flyers, consent, app
- Participants not asked to provide immigration status, SS#, or any financial information



Important Screening Considerations Vulnerable Populations

Understand context of person's experience:

- Is this study a right fit given their life context?
- Is potential participant going to be able to follow-up (retention)?
- What do I need to emphasize so that potential participant can make an informed decision? (i.e. study time commitment)
 - What could potentially impact your ability to make the study appointments?
 - Where do you live? (proximity to study site)
 - Do you have transportation?
 - Work – income loss?

Retention Strategies

- Being culturally sensitive
- Meeting participants halfway by demonstrating a caring attitude
- Being responsive to participants needs
- Offering unblinded participants the opportunity to stay in the trial for safety follow-up



Thank you!

Q & A