DIVERSITY IN CLINICAL TRIALS IN THE STATE OF NEVADA 2024 BIENNIAL REPORT –



IMPLEMENTATION OF ASSEMBLY BILL 214

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EXECUTIVE SUMMARY

Existing law requires the Division of Public and Behavioral Health of the Department of Health and Human Services to establish various programs relating to the provision of health care and the improvement of public health in this State. (NRS 439.263, NRS 439.495, 439.501, 439.517, 439.5295). As provisioned in Assembly Bill 214 passed in the 79th legislative session, the division is tasked with establishing and promoting programming around clinical trial diversification in furtherance of the health and wellbeing of Nevadans. In response to this, The Division of Public and Behavioral Health's Office of Chronic Disease Prevention and Health Promotion (CDPHP) has worked with the Nevada Office of Minority Health and Equity (NOMHE) to provide a response/update to AB214 passed in the 79th legislative session:

Actions to be completed include the following.

- Review the most recent versions of Clinical Trial Guidance for Industry and Food and Drug Administration (NOMHE and CDPHP)
- Establish programs/outreach to encourage participation in clinical trials, especially with persons who are members of underrepresented demographic groups. (NOMHE)
- Identify barriers to participating in clinical trials. (NOMHE and CDPHP)
- Update and maintain website that provides information about methods for identifying and recruiting persons and access/links to websites maintained by entities performing research in Nevada. (CDPHP)

ABOUT ASSEMBLY BILL 214 (NRS 439.263)

During the Nevada Legislature's 79th session (2017), then <u>Assemblywoman Dina Neal</u> introduced <u>Assembly Bill (AB) 214</u>, which was passed by the Legislature and signed by Governor Brian Sandoval. This bill, codified in NRS 439.263 requires the Division of Public and Behavioral Health (DPBH) to submit a report to the Director of the Legislative Counsel Bureau for transmittal to the legislature a report concerning the status and results of the program established in paragraph (a) of NRS 439.263.

The specific deliverables of NRS 439.263 include:

- The State is to:
 - o Improve the completeness and quality of data concerning diverse demographic groups that is collected, reported and analyzed for the purposes of clinical trials of drugs and medical devices.
 - Identify barriers to participation in clinical trials by persons who are members of demographic groups that are underrepresented in such trials and employ strategies recognized by the United States Food and Drug Administration to encourage greater participation in clinical trials by such persons; and
 - Make data concerning demographic groups that is collected, reported and analyzed for the purposes of clinical trials more available and transparent.

The Division of Public and Behavioral Health is to:

 Review the most recent version of "Collection of Race and Ethnicity Data in Clinical Trials—Guidance for Industry and Food and Drug Administration Staff," published by the United States Food and Drug Administration.



- Establish, using existing infrastructure and tools, a program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such clinical trials. The program must include, without limitation:
 - Collaboration with medical facilities, health authorities and other local governmental entities, nonprofit organizations and scientific investigators and institutions that are performing research relating to drugs or medical devices to assist such investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and
 - The establishment and maintenance of an Internet website that:
 - provides information concerning methods recognized by the United States Food and Drug Administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and
 - Contains links to Internet websites maintained by medical facilities, health authorities and other local governmental entities, nonprofit organizations and scientific investigators and institutions that are performing research relating to drugs or medical devices in this State.
- Apply for grants from any source, including, without limitation, the Federal Government, to fund the program established pursuant to paragraph (a), with the assistance of the Office of Federal Assistance
- Submit a report to the Director of the Legislative Counsel Bureau for transmittal to the Legislature a report concerning the status and results of the program established pursuant to paragraph (a) during each even numbered year.
- All state or local government entities that conduct clinical trials of drugs or medical devices, including without limitation, the Board of Regents of the University of Nevada is to:
 - Adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in those clinical trials. Such a policy must include, without limitation, requirements that:
 - investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States Food and Drug Administration to identify and recruit such persons to participate in those clinical trials.

In actioning the legislation established by NRS 439.263, the Division of Public and Behavioral Health identified the Nevada Office of Minority Health and Equity (housed within the Director's Office of the Department of Health and Human Services) as the optimal partner in collaborating to establish and complete actions identified.



Figure 1.

Provider meeting with patient in clinic setting.

NRS 439.263 WEBSITE OVERVIEW

Soon after the approval of AB 214, DPBH created a website for Nevadans interested in learning about clinical trials in the state. This website is located at:



http://dpbh.nv.gov/Resources/Clinical_Trials/. The webpage provides information on clinical trials as well as the different types of clinical research. It links both national and Nevada specific clinical research opportunities. In alignment with the legislative intent of AB214 the website provides an explanation on why diversity in clinical research is important. In addition to this, the website provides resources for local researchers to use in maintenance of cultural competency and sensitivity. The current webpage format was expanded in 2024 to provide additional context and resources for Nevadans. The following section lists the current information found on the DPBH clinical trial webpage.

What is a Clinical Trial

Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.

Clinical research is studies in which people participate as patients or healthy volunteers. The idea for a clinical research study often starts as a clinical trial in the laboratory. The main two types of clinical research are called Observational Studies (also known as Non-Interventional Studies) and Clinical Trials (also known as Interventional Studies).

<u>Non-Interventional or Observational Studies:</u> Non-interventional studies are
often known as observational studies. Observational studies occur when
research is focused on identifying or analyzing changes that occur over time
through monitoring habits, medical data, and biological samples.
Observational studies do not test medical interventions, like a drug or device,
but may help identify treatment or prevention strategies.



• <u>Interventional Studies or Clinical Trials:</u> Interventional studies are often known as clinical trials. Clinical trials are research studies that test the safety and effectiveness of medical, surgical, or behavioral intervention in people. They require people of every age, health status, race, gender, ethnicity, and cultural background to participate. Both healthy and those with diagnosed medical conditions can take part in clinical trials.

Learn more about different types of clinical research here:

- 1. Clinical Trials: What Patients Need to Know | FDA
- 2. What Are Clinical Trials and Studies? | National Institute on Aging (nih.gov)

Find Clinical Research Opportunities in Nevada

Interested in participating in a clinical research opportunity? Check out a few Nevadan organizations that conduct clinical research below.

- Northern Nevada
 - o Current Clinical Trials | Renown Health
- Southern Nevada
 - Current Studies | AB Clinical Trials
 - Office of Clinical Trials | Division of Research | University of Nevada, Las Vegas (unlv.edu)
- Rural and Frontier Nevada:
 - o Clinical Trials | Cleveland Clinic
 - Nevada ADRC Alzheimer's Disease Research Center Nevada
 Exploratory ADRC Alzheimer's Disease Research Center (nvadrc.org)

Interested in learning about national clinical research opportunities? Learn more about national opportunities below.

NIH All of Us Research Program

 The All of Us Research Program funded through the National Institutes of Health is working to improve health care through research. Unlike research studies that focus on one disease, All of Us is building a diverse database that can inform thousands of studies.

• Clinicaltrials.gov

- <u>Clinicaltrials.gov</u> is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. This website not only shows open studies, but all clinical trials that have been conducted. Use the following tips to navigate the website to learn more about research opportunities available in Nevada.
 - Type in the condition or disease you want to learn more about.
 (Ex: Alzheimer's, Heart Attack)
 - If you have additional search criteria you would like to search, type in under "Other Terms". (Ex: "heart attack" treatment).



- If you would like to learn about a specific kind of intervention/ treatment, type the treatment under "Intervention/treatment" (Ex: Aspirin, Exercise).
- If you want to see all trials done in Nevada (even those that have concluded), type Nevada or a city or address under "Location."

Assembly Bill 214 (NRS Chapter 439.263)

During the 79th (2017) session of the Nevada Legislature, <u>Assembly Bill (AB) 214</u> was passed. This bill requires the Division of Public and Behavioral Health (DPBH) to establish a program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such trials. This bill also requires each state or local governmental entity that conducts such trials to adopt a policy concerning the identification and recruitment of such persons to participate in those trials.

Diversity in Clinical Research

Health and wellness are shaped by our physical and mental well-being. Our physical and mental wellbeing is influenced and defined by our biology, behavior, environment, society, social policies, and lived experiences. The lived experiences of people vary based on many factors like race, age, socioeconomic status, sexual orientation, gender identity, geographic location and more. Simply put, we are all different in many ways and similar in others. It is this diversity that clinical researchers should consider and include when creating, modifying, and studying medical initiatives, interventions, and therapeutics.

Diseases, disorders, therapeutics, and medications affect different populations differently. Historically, clinical trials did not always recruit participants who represented the individuals most affected by a particular condition. Often, clinical research relied almost exclusively on white male study participants leading to gaps in understanding of diseases, conditions, preventative factors, and treatment effectiveness. In addition to this, historical atrocities and incidents have led to many communities developing and maintaining mistrust in clinical research and medical institutions.

This clinical research history has led to gaps in knowledge that impede comprehensive public health and medical understanding of medical conditions, preventative measures, and treatment effectiveness. As a result, many initiatives and policies have been established to reduce inequities, discrimination, and mistrust while increasing accountability and diverse involvement.

This is reflected in the following national policies:

o 1974 National Research Act

 On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.



- The Belmont Report created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
 - A report that establishes the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.
- Establishment of Institutional Review Boards (IRB) by the National Research Act
 - o Institutional Review Boards, also known as IRB, are groups that have been formally designated to review and monitor research involving human subjects. The purpose of IRB review is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.

1993 NIH Revitalization Act

The NIH Revitalization Act of 1993, PL 103-43 (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2), signed into law on June 10, 1993, directed the NIH to establish guidelines for inclusion of women and minorities in clinical research The statute requires NIH to ensure that clinical trials are carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other trial participants

21st Century Cures Act

- The 21st Century Cures Act, PL 114-255, enacted December 13, 2016, requires entities conducting applicable clinical trials submit results of valid analyses by sex/gender, race, and ethnicity in Clinicaltrials.gov. The statute further requires that NIH consider, as appropriate, whether the entity has complied with this reporting requirement when awarding any future grant to that entity; and that NIH encourage the reporting of the results of valid analysis through any additional means determined appropriate.
- 2024 Revisions to the Statistical Policy Directive No.15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity
 - o In March 2024, the U.S. Office of Management and Budget (OMB) published a set of revisions to the Statistical Policy Directive (SPD) No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity providing significant changes to data collections established and utilized since 1997. The revisions incorporated culturally mindful practices and changes to the standardized language established nationally.



Within the State of Nevada, it is also acknowledged that it is only when the populations included in clinical research are fully reflective of the diversity of the country can we ensure that public health and medical interventions are mindful of manifestation differences. As such, Assembly Bill 214 was established to encourage the intentional diversification of clinical research within Nevada. To learn more about why it is important to diversify clinical research, please visit the websites linked below.

- Collection of Race and Ethnicity Data in Clinical Trials Guidance for Industry and Food and Drug Administration Staff
- Diversity in Clinical Trials (Food and Drug Administration)
- <u>Lack Of Diversity In Clinical Trials Presents Possible Health Consequences</u> -National Public Radio
- Are Racial and Ethnic Minorities Less Willing to Participate in Health Research? |
 PLOS Medicine
- Sexual and Gender Minority Research Office (Food and Drug Administration)
- <u>Diversity & Inclusion in Clinical Trials (nih.gov)</u>
- <u>Diversity Plans to Improve Enrollment of Participants from Underrepresented</u>
 Racial and Ethnic Populations in Clinical Trials Guidance for Industry (fda.gov)
- <u>Diversity & Inclusion in Clinical Trials (National Institute on Minority Health and</u> Health Disparities)
- Why Diverse Clinical Trial Participation Matters | New England Journal of Medicine (nejm.org)
- Clinical Trial Diversity (phrma.org)

Resources for Nevadans interested in learning more about Clinical Trials

Interested in learning more about clinical research and opportunities available? Check out the resources linked below.

- Information for Research Subjects | Division of Research | University of Nevada, Las Vegas (univ.edu)
- Human Research Volunteer Informational Videos | HHS.gov
- <u>Learn About Studies | ClinicalTrials.gov</u>
- Informed Consent for Clinical Trials | FDA
- How Vaccines are Developed and Approved for Use | CDC
- Protecting Data and Privacy | All of Us Research Program | NIH
- PhRMAPrinciples-of-Clinical-Trials-FINAL.pdf
- FDA and Clinical Drug Trials: A Short History
- Advancing Healthcare in Nevada Through Research | Renown Health
- Clinical Center Patients' Bill of Rights (nih.gov)
- The Belmont Report | HHS.gov
- Institutional Review Boards Frequently Asked Questions | FDA



Resources for Researchers in Nevada

There are many organizations conducting clinical research within the State of Nevada. This section of the webpage is designed to provide researchers with resources that will aid in being culturally aware, responsive, sensitive, and literate. The State of Nevada is full of diversity. This diversity includes geographic location, socioeconomic status, race, ethnicity, age, language and more. The following resources take these factors into account.

- DHHS Language Access Plans
 - o ADSD Language Access Plan ADA (nv.gov)
 - Nevada Medicaid Language Access Plan (nv.gov)
 - o DPBH Language Access Plan 2022 (Final) (2) (nv.gov)
 - o <u>DWSS Language Access Plan (nv.gov)</u>
- Division of Public and Behavioral Health -Office of Analytics Webpage
 - o OFFICE OF ANALYTICS DATA & REPORTS (nv.gov)
- Nevada Office of Minority Health and Equity Webpage
 - o General Webpage: https://dhhs.nv.gov/nomhe
 - Minority Health Report
 - Nevada Minority Health Report 2023 (nv.gov)
 - Health Equity Action Plan
 - https://dhhs.nv.gov/uploadedFiles/dhhs.nv.gov/content/Programs/CHA/MH/Health%20Equity%20Action%20Plan%202(1).pdf
- UNR Larson Institute
 - o https://makinghealthhappen.org/about/
- Nevada Minority Health and Equity Coalition Webpage
 - Community Based Participatory Research Toolkit
 - A Step-by-Step Guide to CBPR (nmhec.org)
 - o Additional Reports and Publications
 - Reports and Publications Nevada Minority Health and Equity
 Coalition (nmhec.org)
- CDC Places: Local Data for Better Health
 - o https://www.cdc.gov/places/index.html
- U.S. Office for Human Research Protections
 - Upcoming Educational Events | HHS.gov

2023-2025 IMPLEMENTATION TIMELINE OF NRS 439.236

Description

Nevada Office of Minority Health Equity has worked with the Division of Public and Behavioral Health Chronic Disease Prevention and Health Promotion Office to provide a response/update to AB214 passed in the 79th legislative session since 2023.

Actions to be completed include the following.

- Review the most recent versions of Clinical Trial Guidance for Industry and Food and Drug Administration (NOMHE and CDPHP)
- Establish programs/outreach to encourage participation in clinical trials, especially with persons who are members of underrepresented demographic groups. (NOMHE)



- Identify barriers to participating in clinical trials. (NOMHE and CDPHP)
- Update and maintain website that provides information about methods for identifying and recruiting persons and access/links to websites maintained by entities performing research in Nevada. (CDPHP)

Learning Objectives

- Identification of Ways to advocate for reducing stigma around discussing, identifying, or seeking treatment for health issues, concerns, or challenges related to clinical research.
- Identification of Ways to provide culturally humble services to specialized populations such as communities of color.
- Provide a forum for providers to elevate current and projected studies and research in their community or communities, share experienced barriers to accessing or providing culturally humble, and engage in a conversation of how to identify solutions to overcome barriers.
- Empower communities to come together to identify issues related to clinical research diversification, solutions to these issues, and supports needed to implement those solutions, and to serve as equal participants in the design of culturally and linguistically appropriate services for their communities.

Identification of Barriers to Clinical Research Access Timeline

Completion Date	Task	Responsible Party	Notes/Details	Status
Ongoing	Review of Federal Clinical Trial Guidelines	NOMHE/CDPHP	Purpose is to have a general awareness of the diversity requirements.	In Process
	Interns		NOMHE has an intern project that requires the following:	
			The intern(s) will attend webinars and collect attendee information and provide it to the preceptor and highlight key points of the webinar.	
Ongoing investigate trends of clinical research diversity	NOMHE	The intern will assist in identifying resources and research data on one of the following topics.	In Process	
			 Clinical Trial Diversification, Standards, recommendations 	
			The Intern shall complete a content review and create a summary of trends	



			utilizing the gathered information. This trend analysis will be used to identify barriers and recommendations to health equity. Trend analysis is key to	
			informing the work of NOMHE in terms of programs, events, initiatives, and creation of materials.	
Ongoing	Review of current federal clinical research outreach recommendations	NOMHE/CDPHP	Purpose is to have a general awareness of the outreach recommendations	In Process
Ongoing	Identification of barriers by current researchers in Nevada	NOMHE		In Process
Ongoing	Periodic report outs on barriers identified	NOMHE		In Process
On going	Review State Language Access Plans and other plans that impact diversity equity and inclusion within the state that is relevant to clinical research	NOMHE		In Process
Ongoing	Plan to address barriers to clinical research	NOMHE		In Process

Establishment and Continuation of Outreach Task and Timeline

Date	Task	Responsible Party	Notes/Details	Status
Ongoing	Connect and establish partnerships with organizations in Nevada tat conducts clinical research and CBPR	NOMHE to establish and report to CDPHP	This continues actions already in progress.	In process



Ongoing	Establish media educational opportunities like with Podcasts or interviews	NOMHE to establish and report to CDPHP	This continues actions already in progress.	In Process
Ongoing	Development of NOMHE's health advocacy event series on Clinical Research Diversification including but not limited to community events, education fairs, and tabling with partners	NOMHE to establish and report to CDPHP	This continues actions already in progress.	In process
Ongoing Expand NOMHE newsletter opportunities to promote clinical research diversification		NOMHE to establish and report to CDPHP	This continues actions already in progress.	In process
Ongoing	Build a distribution of Community Partners (and their respected target audiences) to coordinate promotion of clinical research diversification opportunities	NOMHE to develop, CDPHP to report progress to LCB	This continues actions already in progress.	In process
Ongoing validate trends seen in clinical		NOMHE to facilitate development	This continues actions already in progress.	In process
2/28/2024	NOMHE to provide information to CDPHP for annual legislative report	NOMHE		In process
2024 Creation of Annual Report		CDPHP, NOMHE to review		In process
		CDPHP		In Process

Website Update and Development Tasks and Timeline

Completion Date	Task	Responsible Notes/Details Party		Status
8/2/2023 Establish timeline for Website Updates NOMHE and CDPHP		Update webpage twice a year	Complete	
1 4/30/2024		CDPHP/ DPBH PIO	Revise current 5 sections to become 6 sections:	In Process
2/28/2024	Identify webpage sections and	NOMHE and CDPHP	 What is a Clinical Trial? Find Clinical Trials in Nevada 	In process



	designs through meetings		a. feature a local research opportunities – for those members of the public interested in finding trials to join 3. Assembly Bill 214 4. Diversity in Clinical Trials 5. Resources for Nevadans interested in learning more about clinical trials 6. Create a SIXTH section for local researchers that (a) aids them with better promotion of trials to diverse patients (b) provide sources for diverse candidates for their research - for example All of Us Research Program DURA form. Example – link (DPBH's) Language Access Plan info	
Ongoing	Select webpage resources and content to showcase	NOMHE and CDPHP	Requires meetings between NOMHE and CDPHP	In process
3/30/2024 then ongoing	Finalize webpage content			In process
4/30/2024	Link relevant DHHS resources (if any)	CDPHP	Reflected by the following options.	In process



HEALTH EQUITY DATA

To allow researchers and clinicians who conduct clinical trials to further understand the breakdown of Nevada residents who are disproportionality affected by diseases and conditions in the state, DPBH updated the Minority Health Report to include data through 2023. The purpose this report is to highlight existing health disparities by race/ethnicity in Nevada, with a focus upon the most current state and national data available. The race/ethnic groups represented in this report are White, Black, American Indian/Alaskan Native (AI/AN), Asian, Native Hawaiian/Pacific Islander (NH/PI), Hispanic, and Unknown/Other/Multiple. Racial and ethnic minorities are disproportionately affected by health problems and disease in Nevada and throughout the nation. Minorities often have higher rates of infectious and chronic diseases due to a variety of reasons and disparities in access to healthcare. It is the intention of DPBH that this data will be used by health professionals, policy makers, community members, and researchers to improve health disparities among Nevada's minority population and improve access to health care services, including clinical trials.

This report is broken down by topic with narratives highlighting important data points, followed by supporting figures and data tables. The comparisons made in this report are conducted between individual race/ethnic categories, Nevada's overall population, and Nevada versus the United States. An example graph is presented below related to leading causes of death by race.

The reports can be accessed on the DPBH website at: https://dhhs.nv.gov/Programs/Office_of_Analytics/OFFICE_OF_ANALYTICS_-
__DATA___REPORTS/

Additionally, as a standard, DPBH includes demographic details in most data requests and reports prepared by the agency when that level of data is collected. This includes data related to sex, gender, age, race, ethnicity, and address. This is done to allow all health data to highlight disparities and better direct resources.

To help the community understand what data is accessible and the residents disproportionately affected by various conditions, DPBH staff have presented at various events, including presenting minority health data.

In addition to this, recent legislative changes to data collection standards within the state of Nevada coupled with federal policy changes to the Statistical Policy Directive No. 15 provides hope for further aggregated data in the future. The passage of Senate Bill 109 from the 2021 Legislative Session, NRS 239B.022-239B.026 now requires the collection of sexual orientation and gender identity and expression data by state and local governmental agencies on forms that include questions about race and ethnicity. This legislation seeks to identify and better serve members of the LGBTQ+ population utilizing governmental services so that agencies may better serve this historically marginalized and underrepresented group. Following the passing of this legislation, Assembly Bill 139 (AB139) from the 2023 Legislative Session, NRS 239B, now requires non-criminal justice governmental agencies that collect information from a person related to the race or ethnicity of the person to include a separate category for persons of Middle Eastern or North African descent. In addition to this change, In March 2024, the U.S. Office of Management and Budget (OMB) published a set of revisions to the Statistical Policy Directive (SPD) No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity providing significant changes to data collections established and utilized since 1997. All of these policy changes are impactful to the future of health equity data.



OFFICE OF MINORITY HEALTH AND EQUITY

In addition to AB 214 that focused on minority health and equity in clinical trials, during the same legislative session, AB 141 was passed. This bill broadened Nevada's Office of Minority Health to now be the Office of Minority Health and Equity and the definition of minority to include members of the LGBTQ and disabled communities. The Nevada State Legislature initially created the Office of Minority Health with passage of Assembly Bill 580 during the 2005 legislative session. Included in the bill was the creation of an Advisory Committee, composed of nine members reflecting the ethnic and geographical diversity of the state.

The mission of the State of Nevada Office of Minority Health and Equity (NOMHE) is:

- To improve the quality of health care services for members of minority groups;
- To increase access to health care services for members of minority groups;
- To disseminate information to and to educate the public on matters concerning health care issues of members of minority groups.

Additionally, the NOMHE provides guidance on implementing initiatives addressing health disparities, contributes to policy development on minority health, increases public awareness of racial and ethnic disparities in health outcomes and health care, and provides technical assistance to minority communities and faith-based organizations interested in improving the status of minority health in Nevada.

This mission aligns with those actions set forth in AB 214, and the NOMHE will continue to be an integral part in implementing the bill.

For more information on NOMHE, please visit the website at: https://dhhs.nv.gov/nomhe

Outreach Activities

Northern Nevada AOU Experience: Oct 25 – 26, 2022

The NOMHE event occurred on October 25th and 26th, 2022, from 10 am to 3 pm both days, with a virtual practice run on October 24th. Hosted at the NV Health Center in Carson City, the event aimed to bring together various organizations including DHHS Chronic Disease Prevention and Health Promotion Unit, NV Indian Commission, NV Health Center, Renown, High Sierra AHEC, ACCEPT, Reno/Sparks NAACP, and N NV Hopes. The event introduced the All of Us Research Program, highlighting its purpose and the role of the Montage Team. The two-day itinerary included mobile units for screenings, vendor and Community Partners tabling, educational resources, and activities such as food trucks and DJ/radio simulcasts. The event also featured a virtual practice run on October 24th and a pre-event awareness/promotion webinar, which engaged All of Us Research Program Virtual Ambassadors and local experts. Partnering in Northern Nevada with Sierra Nevada Health Center in October of 2022 to bring this event to this region, the NOMHE team secured 15 community partners to join, providing related resources to community members to create a Health Fair / sample collection event. An estimated 150 people participated during the N NV excursion.

Education and Resource Partners
All of Us Research Program
Nevada Health Centers



DHHS Division of Public and Behavioral Health Chronic Disease Prevention and Health Promotion Unit
NV Indian Commission
ACCEPT
High Sierra AHEC
Renown Clinical Research
Renown Cancer Institute
Reno/ Sparks NAACP

Southern Nevada AOU Experience November 17, 2022

The All of Us Research Program Research Program is an initiative on clinical trial diversification funded by the National Institute of Health. The goal of this initiative is to help build one of the most diverse health databases in history by including participants from all backgrounds. The outcome is to find ways to treat and prevent diseases, including those that disproportionately impact minority populations, by adding one million (diverse) samples to the database. . The S NV excursion took place in November 2022 at Pearson Community Center with 25 community partners and approximately 200 people participated. On November 17, 2022, the Southern Nevada All of Us Research Program Kickoff event was held at the Pearson Community Center. The event aimed to introduce the All of Us Research Program and other local clinical trial and medical engagement opportunities, providing participants with valuable insights into the science and impacts of these initiatives. The event began at 10:00 am and featured a series of brief presentations, including welcomes from NOMHE and OASH, an introduction to the program, and a community perspective on the initiative. Overall, attendees learned about clinical trial opportunities and resources available in Southern Nevada.

Education and Resource Partners

Nevada Office of Minority Health and Equity

Hot 702.5 FM

Southern Nevada Health District Chronic Disease/Barbershop Initiative

Southern Nevada Health Center

Nevada Partners

Intermountain Healthcare

Cleveland Clinic

Nevada Faith and Health Coalition

Southern Nevada Asian Community Development Council

Nevada Donor Network

Puentes

The Center

DHHS Aging Disability Services Division – Office for Consumer Health Assistance

DHHS Aging Disability Services Division - Adult Protective Services Program

R.E.D. Rose Program

Nevada Health Centers

Leaders in Training

Bridging the Gap Adult Sickle Cell Disease Foundation



Northern Nevada Insights and Interactions Forum: May 18, 2023

Insights and Interactions, a panel discussion and networking reception, took place at Bethel AME Church Sparks on May 18th, 2023, featuring community engagement implementation strategies. The event aimed to introduce the All of Us Research Program alongside local clinical trial and medical engagement opportunities and education. Attendees gained insights into the science and impacts related to All of Us Research Program and clinical trial diversification efforts. Through panel discussions, participants explored the importance of community engagement in research and its application in clinical trials. Interactive activities, including evaluation question worksheets, enabled attendees to experience the core principles of community-based participatory research. The event also educated Northern Nevadans about clinical trial opportunities, regional resources, and community partners. Interactive sessions allowed attendees to work on scenarios related to developing community outreach plans with a focus on clinical trial awareness. Volunteers from various institutions, including UNR School of Public Health and UNR Medical School Clinical Research team, supported the event, contributing to its success and impact. This event had approximately 60 attendees from community organizations, partners, and general public.

Panelists

Jessie H Clark

• Provided commentary on Community Based Participatory Research and how it Is applicable for all community organizations. Dr. Clark is a Associate Professor at University of Nevada, Reno with the Department of Geography. Dr. Clark is also a member of the Nevada Minority Health and Equity Coalition and has subject matter expertise in Community Based Participatory Research.

Victoria Rios

Provided commentary on Community Based Participatory Research and how
it Is applicable for all community organizations. Victoria Ross is a staff member
at the University of Nevada, Reno with the Department of Geography. She is
also a member of the Nevada Minority Health and Equity Coalition and has
subject matter expertise in Community Based Participatory Research.

Danielle Eaton

 Provided commentary on the clinical trial process and why clinical trials are important. Danielle Eaton is the Director of Clinical Research with UNR Med and Renown Health. She provided information about the clinical research professional workforce needed to bring cutting edge diagnostics, therapeutics, and preventatives to the Northern Nevadan Community.

Shaun Dabe

 Provided commentary on the clinical trial process and why clinical trials are important. Shaun Dabe is the Healthy Nevada Project Supervisor of Research



Genetics Renown Institute for Health Innovation. He discussed current clinical trials within the State of Nevada that community organizations may promote, and community members may participate in.

Kadie Zeller

 Provided commentary on Community Based Participatory Research and how it is applicable for all community organizations. Kadie Zeller is the executive director of Om Namo, a non-profit focused on increasing community wellness in tribal communities in Nevada.

Education and Resource Partners Nevada Office Of Minority Health and Equity All of Us Research Program Renown **UNR School of Medicine** High Sierra AHEC Northern Nevada Asian Community Development Council

Southern Nevada Maya Cinemas Health Fair: October 14, 2023

The NOMHE event took place at the Maya Cinemas in North Las Vegas and hosted a Health and Education Resource Fair on October 14th, 2023, from 11 am to 4 pm, aimed at introducing the All of Us Research Program and local clinical trial opportunities. This fair showcased various community engagement opportunities and health resources, targeting primarily Spanish-speaking, multi-generational families in the area. Partner organizations like CVS Pharmacy, UNLV, Touro University, SNHD and Roseman University were invited to table and offer health screenings, resources, and educational materials. Attendees had the chance to learn about the All of Us Research Program Research Program and participate in free DNA testing. With a focus on advancing equitable healthcare, this event was an enriching experience for all involved. Approximately 200 people attended this event.

Education and Resource Partners

Nevada Office Of Minority Health and Equity Puentes Promotoras Las Vegas Integrity Law Firm DHHS Division of Welfare and Supportive Services UnitedHealthcare - Health Plan of Nevada Medicaid Silver Summit HealthPlan The Lou Ruvo Center at Cleveland Clinic Nevada Health Link UNLV The Practice Loving embrace home care Immunize Nevada Senator Dina Neal Senate District 4 Humana



Farm Fresh to you Girl Scouts of Southern Nevada All of Us Research Program Research Program

Southern Nevada Tabling Opportunity: East Las Vegas Community Center: October 7, 2023

NOMHE participated in an event at The East Las Vegas Community Center which hosted a Resource Fair on October 7, 2023, from 10 am to 2 pm, organized in partnership with All of Us Research Program, the Mexican Consulate, and REACH. This fair introduced the All of Us Research Program and local clinical trial opportunities while providing various community engagement resources and educational materials. With over 20 indoor tabling vendors and outdoor mobile units, approximately 500 people attended the event. Attendees gained insights into the science and impacts related to All of Us Research Program and other clinical trials in Nevada. The event will feature informative sessions, interactive activities, Zumba classes, and the presence of key figures like Las Vegas Councilwoman Olivia Diaz and the consul to the Mexican Consulate.

Southern Nevada Breaking Barriers Forum: October 17, 2023

Insights and Interactions was an event that took place at Lou Ruvo Center at the Cleveland Clinic on October 17, 2023, from 4:00 to 7:30 pm PST, aimed to introduce the All of Us Research Program and local clinical trial opportunities concerning Alzheimer's and Dementia in BIPOC communities. The event featured networking discussions followed by a panel presentation and interactive community dialogue. Highlighting the significance of Alzheimer's and Dementia screening and diagnosis in clinical trial diversity, the panel discussion and networking reception offered insights for community advocates and organizations. Emphasizing BIPOC communities, the event intended to raise awareness and encourage participation in clinical trials. Approximately 60 people attended the event.

Panel Members

Dr. Charles Bernick

 Provided commentary on the clinical trial process and why clinical trials are important in the care and treatment of Alzheimer's and dementia. Dr. Bernick is a neurologist with Cleveland Clinic Lou Ruvo Center for Brain Health. Dr. Bernick has been involved in the field of Alzheimer's disease research and treatment for over 30 years and is currently leading multiple studies at the Lou Ruvo Center for Brain Health.

Dr. Dylan Wint (pronounced Die-Lyn) -

 Provided commentary on Alzheimer's and dementia statistics in Nevada, within BIPOC communities and, the diagnosis and treatment rates. Dr. Wint is the Director of Cleveland Clinic Lou Ruvo Center for Brain Health. In addition to caring for patients, Dr. Wint oversees the center's clinical, research and educational initiatives.

Dr. Atoya Adams



 Provided commentary on why diversity in clinical trials is important, challenges for sourcing diverse candidates, and why physicians should mention or recommend research involvement with their patients. Dr. Adams has been a member of the Las Vegas medical community since 2005 when she moved here as a hospitalist. Her involvement in research started during her college days at Yale university and has continued throughout her career. She conducts phase 2-4 trials within her specialty of Internal medicine.

Brenda Harris

• Speaking of her experience participating in a clinical trial and having a family member with Alzheimer's disease. Brenda is a longtime Las Vegas resident. She is a participant in the AHEAD trial, which looks at whether the newly FDA-approved anti-amyloid drug, lecanemab, can delay or prevent Alzheimer's in people who have one or more risk factors for the disease but have not been diagnosed.

Josh Perez

Provided commentary on why diversity in clinical trials is important, what is
the NIH funded All of Us Research Program, community-based participation
for the All of Us Research Program Research Program. Josh Perez, a resident
of Dallas Texas is the lead tour manager of the All of Us Research Program
Journey, the mobile engagement asset for the All of Us Research Program
Research Program. Josh works to ensure that the All of Us Research Program
Journey reaches a diverse group of individuals from all walks of life, while
fostering a deeper understanding of the program's mission and inviting
people to participate. With his expertise, Josh is leading the charge on
making a positive impact on public health, through community-based
participation at events nationwide.

Education and Resource Partners

Nevada Office Of Minority Health and Equity Lou Ruvo Center at the Cleveland Clinic Alzheimer's Association UNLV School of Public Health Nevada Minority Health and Equity Coalition

Funding Opportunities

The Office of Grant Procurement, Coordination and Management has been actively researching funding opportunities to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in such trials. To date, there has been one funding opportunity released in January of 2018 through the National Institute of Health (NIH) somewhat related to this topic, but not specifically for clinical trials (PA-18-



586). This funding opportunity was a supplemental award for projects already funded under the main awards. The Office of Grant Procurement, Coordination and Management sent this funding announcement out to their listserv of 71 recipients, but there were no applications put forth.

Their office receives regular updates through the Federal Funds Information for States (FFIS) and reviews the newly released opportunities to determine if any could support implementation of AB 214 and will provide updates on progress biennially through this report.

Further, the Office of Grant Procurement, Coordination and Management and DPBH staff presented to the Nevada Minority Health and Equity Coalition in Las Vegas, Nevada in November of 2017 on how to apply for grants and state resources to assist them in grant applications and trainings. Since then, the Office of Grant Procurement, Coordination and Management has been providing the coalition with grant opportunities that are focused on minority health issues.

BARRIERS

The intent of AB 214 is to promote diversity within clinical research in Nevada. With the legislative intent in mind, the barriers identified in outreach activities fall under two categories. While historical events within clinical settings continue to have influence on research involvement the following focuses on additional barriers identified in Nevada.

Barriers to Research Integration within Clinical Care

The Nevada Office of Minority Health and Equity (NOMHE) learned of the following concerns from conversations with researchers at Renown/UNR School of Medicine, Cleveland Clinic Lou Ruvo Center, UNLV Medical School Office of Clinical Trials, and AB Clinical Trials.

- Primary Care Providers lack of connection and knowledge with current Clinical Trials within the State of Nevada
- Lack of community understanding, knowledge, and engagement of current clinical research opportunities for diverse participants
- Breakdowns within public health and health care access for rural and frontier Nevadan patients that are interested in participating in Clinical research.
- Physicians' time to research clinical research opportunities is limited with current patient load and requirements.
- Increased misinformation about clinical research.

Barriers to Community Interest and Understanding

The Nevada Office of Minority Health and Equity learned of the following concerns from community engagement forums across Nevada.

• Primary care physicians do not share information about clinical research opportunities.



- In this digital age many clinical trial opportunities are facilitated by internet access. Broadband difficulties and transportation difficulties have resulted in reduced clinical research opportunities.
- Breakdowns within public health and health care access for rural and frontier Nevadan patients that are interested in participating in Clinical research.
- Mistrust with medical providers based on perceived or actual discrimination cases.
- Lack of cultural understanding with medical provider team.
- Medical provider shortage.
- Lack of knowledge of what is a clinical research opportunity.
- Increased misinformation across various platforms.
- Educational Information is not shared across digital spaces like social media.