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Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Health Subcommittee of the Committee on Energy and Commerce, thank you for the opportunity to testify today on behalf of the National Alliance for Hispanic Health (the Alliance) and our community-based members delivering health and human services to over 15 million in underserved communities annually and the Healthy Americas Foundation (HAF), the supporting organization of the Alliance.

The Alliance is the nation's premier science-based and community-driven organization that focuses on the best health for all. We work to ensure that health incorporates the best of science, culture, and community. The Alliance achieves this by listening to the individual, investing in leading community-based organizations, working with national partners, examining and improving the resources and systems available, and designing solutions to make health a part of each person's life. We continually work to improve the quality of care and its availability to all.

Our goal is to close the gaps in three key areas:
- research, services, and policy;
- scientific discovery and benefit for the individual; and,
- community services and medical practice.

Since its founding in 1973, the Alliance has advocated for inclusion of underrepresented population groups, including Hispanic communities, in the nation's health research enterprise to deliver on the promise of personalized medicine. We are grateful to the Committee for once again looking at the role of adequate inclusion of underrepresented groups in research in order to advance good science and the future of biomedicine.

Adequate inclusion of underrepresented population groups in health research is a long-standing but unfulfilled mandate for good science and personalized health care. The implications of refining health information systems with more granular information are enormous. The Alliance is proud to have been an early and consistent advocate for adequate inclusion of women and racial and ethnic groups in research. The issue of inclusion is not new and was a central recommendation of the US Department of Health and Human Services (DHHS) 1985 Report of Secretary Heckler's Task Force on Black and Minority Health. Based on that report and the advocacy of many of those individuals and organizations that served on the Secretary's Task Force, a Hispanic identifier was added to the model death certificate in 1989. Up until then, there was no information on how many Hispanics died in a given year. The new data fundamentally changed the view of Hispanic health. Regardless of country of heritage, Hispanics live longer than non-Hispanic whites. That's true despite additional risk factors like

diabetes, excess weight, lack of health insurance. Measuring success of new treatments, requires definitions not based on general population metrics, but measures that represent more granular information that support personalized health care.

The one size fits all model never served anyone; all it did was create distorted models of health. Good science, good epidemiological practice, and the development of safe products make clear that adequate inclusion of underrepresented population groups should be the standard for how health data are collected, analyzed, and reported. DHHS knows this to be true and yet they reluctantly have moved to gather these basic data.

For the most part, current medical therapies, as well as most of those in development, have been tested inadequately — or not at all — in women, children, older adults, individuals with multiple chronic conditions, low-income individuals, and racially and ethnically diverse populations. For example –

- While Hispanics represent almost one in five persons (19%) in the U.S. they represent 5% of participants in clinical trials;
- An analysis of a decade (2008 to 2018) of clinical trials leading to cancer drug approvals found that only one in ten reported data for Hispanics; and
- Hispanics represent only 1.13% of individuals in genome-wide association studies (GWAS) despite the fact GWAS findings may not generalizable across ethnic groups.

A lack of inclusion in research not only limits our ability to translate biomedical research into personalized health care for all Americans; when it comes to clinical trials, DHHS is actually ignoring the law. The NIH Revitalization Act of 1993 (PL 103-43) requires that clinical trials be designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial. That standard is not being met today.

Existing Community Based Participatory Research models can eliminate barriers to inclusion of underrepresented population groups in biomedical research. Since 2005, NIH has detailed a set of Community Based Participatory Research (CBPR) standards that should be the basis for all federally funded research. Those standards call for scientific researchers and community members to collaborate as equal partners in the design of research, adequate recruitment in order to report specific data for underrepresented groups, involving community members in the analysis of findings and reporting back to communities, and frameworks that consider the multiple medical and non-medical domains of influence that result in health outcomes. Using CBPR standards have produced important advances in our understanding of health across American communities and advanced progress to personalized health care.

For example, differences in prevalence of some chronic diseases or their risk factors among different heritage groups in the U.S. Hispanic population have been described by the CBPR landmark study, the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). That study has enrolled over 16,000 Hispanic adults from four diverse communities in a long-term study of health as well as the protective factors that may have implications for the broader understanding of the factors that create health. By co-developing a study design with community members, funding trusted research partners, and an investment that has allowed for recruitment of a significant number of participants; the HCHS/SOL study is making a significant contribution to understanding health. However, as leadership of that study have stated, the

underlying mechanisms mediating such differences are yet to be determined. A key study currently in the field that seeks to build a diverse database that will support the biomedical research community, among other objectives, to understand those underlying mechanisms is the NIH's *All of Us* Research Program. The program was developed as a response to the September 2015 Report of the Precision Medicine Initiative Working Group of the Advisory Committee to the NIH Director.

All of Us is working to improve health care through research. Unlike research studies that focus on one disease or group of people, *All of Us* is building a diverse database that can inform thousands of studies on a variety of health conditions. This creates more opportunities to:
- know the risk factors for certain diseases;
- figure out which treatments work best for people of different backgrounds;
- connect people with the right clinical studies for their needs; and,
- learn how technologies can help us take steps to be healthier.

Like the HCHS/SOL study, *All of Us* is founded on principles of CBPR. The goal is ambitious. The program is inviting one million people across the U.S. to participate over 10 years to help build one of the most diverse health databases in history.

As part of the *All of Us* CBPR design, the program has funded over 100 program partners, including Community Engagement Partners of which the Alliance is proud to have competitively received an award. Community Engagement Partners conduct a wide range of activities, including engaging and facilitating enrollment and retention of communities historically underrepresented in biomedical research and contributing to the body of knowledge supporting the science of community engagement. As a Community Engagement Partner, the Alliance also engages researchers from diverse backgrounds to utilize the *All of Us* data resources to advance precision medicine and health care providers who serve historically underrepresented communities to promote *All of Us*. In addition to utilizing community partners in outreach, *All of Us* collaborates with community partners in all aspects of the program design and implementation as well as developing community report back initiatives. The program also collaborates with community partners in the design and tracking of metrics for the program, including metrics for participation and collaboration with communities underrepresented in biomedical research.

The benefit of a strong CBPR grounding in design and implementation, is clearly demonstrated by the *All of Us* metrics to date. For example, as of December 4, 2021, –
- a majority of the 438,00 *All of Us* participants are from racial and ethnic communities underrepresented in biomedical research, including Hispanics representing 17% of the overall program participants to date, and over half (59.5%) of participants are women;
- the participants are spread across adult age categories and US geography; and
- participants are engaged and building the database with over 330,000 biosamples collected and over 262,000 participants linking their electronic health record (EHR) to the *All of Us* Research Program.

This is an extraordinary accomplishment since the program officially launched on May 6, 2018.

Furthermore, as the program advances to its goal of engaging over 1 million people, we are already seeing important research and scientific advancement. With the Researcher Workbench beta launched in May of 2020, more than 1,000 researchers have registered and are carrying out

over 900 active research projects ranging from Alzheimer's disease to vaccine hesitancy with numerous projects exploring the role of health care access and social determinants of health and producing findings for various racial and ethnic, gender identity, and socio-economic groups.

Perhaps one of the best examples of the importance of building a national database that reflects use of CBPR models and has inclusion at its core, is how *All of Us* delivered on the quick response need to support COVID-19 research. For example, the program --

- between January and March 2020 tested over 24,000 participant samples to look for antibodies against SARS-CoV-2, the virus that causes COVID-19;
- between May 2020 and February 2021, *All of Us* deployed the COVID-19 Participant Experience (COPE) survey six times to ask questions about mental health, well-being, and everyday life to help researchers understand how COVID-19 impacted experience over time with over 100,000 participants completing the survey one or more times; and,
- since the beginning of the COVID-19 pandemic has leveraged over 200,000 *All of Us* participant EHRs, using privacy and security safeguards including removal of direct identifiers, in order to make COVID-19 EHR data available to researchers.

These efforts not only produced critical and timely information to form an early response to COVID-19, they also have produced an important resource to understand COVID-19 and its impact in population groups that continue to experience a disproportionate impact of the COVID-19 pandemic.

While it is clear that inclusion is central to good science and advancing the promise of personalized health care, inclusion is the exception rather than the norm in biomedical research. The following actions would advance the effort to make inclusion the norm.

1. **Pass the bipartisan Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act (H.R. 5030/S. 2706).** Lack of inclusion in clinical trials is limiting advances in biomedical research and personalized health care. For example one in five cancer clinical trials fail due to insufficient patient enrollment. On November 15, 2021, the Energy and Commerce Committee received a letter from a diverse group of 156 health organizations calling for passage of the DIVERSE Trials Act. Recognizing the increasing role that decentralized clinical trials play in biomedical research, the Act would allow trial sponsors to provide patients with technology necessary to facilitate remote participation in clinical trials; create a statutory safe harbor so that patients may get financial support for ancillary costs (e.g. transportation, childcare, lodging) associated with their clinical trial participation; and, require DHHS to issue guidance on how to conduct decentralized clinical trials to improve inclusion of populations underrepresented in biomedical research. This is an urgent action needed to address the crisis in clinical trial enrollment.

2. **Mandate inclusion of CBPR standards as a part of FDA review of new drug applications and NIH review of research funding proposals.** The importance of inclusion of underrepresented populations for advancing biomedical research was made clear when the New England Journal of Medicine (NEJM) announced an inclusion policy. Starting January 1, 2022 authors of all research studies accepted for publication by NEJM must include information and a table, to be posted with the article at the time of

publication, that describes representativeness of the study group. The FDA and NIH should follow suit in advancing inclusion and transparency of inclusion in research.

While the FDA has issued guidance on inclusion, implementation of that guidance has varied widely by drug trial sponsor. Congress should call on FDA to create an explicit "relevance score" in review of new drug applications that includes measures of: (1) utilization of a CBPR model for conduct of the research; and, (2) powering of the study design to produce findings that can demonstrate safety and efficacy at a minimum by sex/gender, race, ethnicity, and age. To ensure inclusion goals are met, FDA should implement a system with industry to ensure real-time tracking of inclusion, such as monthly reporting through FDA-TRACK, and mandated enhanced recruitment strategies in clinical trials where adequate inclusion goals are not being met. Furthermore, the FDA should issue a revised FDASIA Section 907 Report to Congress updating the 907 Action Plan for Inclusion of Demographic Subgroups in Clinical Trials.

Similarly, while NIH has issued standards for Review of Inclusion by Sex/Gender, Race, Ethnicity, and Age in Clinical Research, those standards should be revised to: (1) explicitly include a measure of use of CBPR standards in the research plan; and, (2) mandate reporting findings by sex/gender, race, ethnicity, and age in any peer review research along with an inclusion in research table building on the NEJM model. These changes would make clear to the research community that CPBR standards are central to good science and approved research must include those standards.

3. **Require establishment of a taskforce and report by DHHS on efforts for collecting and analyzing data for populations underrepresented in biomedical research**. It is critical to know the status of DHHS data collection and analysis by at least race, ethnicity, and sex/gender to undergird policy and program development across all agencies to advance inclusion in health research. Without a full understanding of current efforts and gaps, adequate inclusion will not be achieved. The DHHS Secretary should establish a taskforce and the Assistant Secretary for Planning and Evaluation should be asked to provide the taskforce with a report within 90 days on DHHS data collection and analysis by at least race, ethnicity, and sex/gender. Based on the findings the work of the task force should be to address gaps and develop solutions for fully addressing the health of the nation. It has been 36 years since the Report of Secretary Heckler's Task Force on Black and Minority Health. The time for an update is long overdue.

The past two years of the COVID-19 pandemic have shown the critical role that inclusion of all communities must play, as they did in COVID-19 vaccine trials, in advancing biomedical research and achieving the promise of personalized health care. The Alliance and HAF stand ready to support the Subcommittee in your continued leadership efforts to advance inclusion in biomedical research and I thank you for the opportunity to offer our perspective today.