American Society of Human Genetics
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The Honorable Diana DeGette
Chairwoman, Subcommittee on Oversight and Investigations
House Energy and Commerce Committee
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
Ranking Member, Subcommittee on Energy
House Energy and Commerce Committee
United States House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton,

The American Society of Human Genetics (ASHG), the world's largest organization for human genetics and genomics professionals, appreciates this opportunity to provide comments on the discussion draft for the reauthorization of the *21st Century Cures Act* (Cures 2.0). Our approximately 8,000 members are researchers, medical geneticists, genetic counselors, and others who share the common goal of encouraging people everywhere to realize the full potential and benefits of human genetics and genomics.

21st Century Cures changed the way that biomedical research is translated from the bench to the bedside, including through the creation of flagship research programs at the National Institutes of Health (NIH) such as the *All of Us* precision medicine program. Shortly after the law was implemented, NIH enhanced its reporting requirements for individuals in agency-funded Phase III clinical trials based on their gender, ancestry and/or ethnic background, building on the commitment to enhanced research cohort diversity exemplified by the *All of Us* program. **We are excited for Cures 2.0 to build on the successes of its predecessor, specifically with respect to increasing diversity in biomedical research.** ASHG's commitment to diversity, equity and inclusion is a core component of our most recent strategic plan and organizational culture, and we support efforts to increase recognition and incorporation of human genetic diversity in research.

While human beings are 99.9 percent identical in our genetic makeup, the variation in the remaining 0.1% can influence a person's risk of disease or how the body responds to medications, stress, or environmental factors. It is imperative for participation in genetics and genomics research to reflect humanity's diversity so that all people can enjoy its benefits. This will take a concerted effort by the research community and research funders and must include greater engagement with individuals and communities underrepresented in research. Congress should, in legislation such as Cures 2.0, support NIH institutes and programs that emphasize diversity and equity in research and clinical trials participation by the public. Congress should also provide sufficient funding for researchers to do the work of engaging populations underrepresented in research.

In a recent blog post, National Institutes of Health (NIH) Director Dr. Francis Collins emphasized the value of participant diversity within biomedical research in the context of the ongoing COVID-19 pandemic. Dr. Collins highlighted a study recently published in the journal *Nature* that was conducted as part of the COVID-19 Host Genetics Initiative. The study identified thirteen regions of the human genome associated with either a person's risk of becoming infected with SARS-CoV-2 or developing a serious illness as a result of being infected, including two only discovered because of the inclusion of individuals who were of East Asian ancestry. Dr. Collins highlighted the inclusion of these participants as contributing to a more comprehensive understanding of the biology of COVID-19 infection, which in turn can lead to better patient outcomes and stronger public health responses.

The NIH has made important steps in broadening research participation in federally funded research, including human genetics and genomics research. Notably, diversity is a core value of its *All of Us Research Program*, NIH's historic effort established by Congress to collect and study data from one million or more people living in the United States. Through partnerships with community organizations, health care providers and genome centers, the program works to increase cohort diversity and simultaneously reduce barriers to participation. Such efforts to broaden participation in research are essential for the findings from biomedical research to be translated to clinical advances. Industry has also made strides in addressing and removing barriers to participation in clinical trials, such as forming community stakeholder partnerships and placing trial sites in diverse communities. This goes a long way to help the foundational research on which clinical studies are based, represents humanity's diversity. **We applaud your commitment to increasing clinical trial diversity in the Cures 2.0 discussion draft and urge you to expand the proposed GAO study on barriers to clinical trial participation beyond just clinical trials to all federally funded work involving research participants.** An expanded GAO study would help funders and researchers identify the most effective ways to diversify research cohorts in biomedical research to, for example, expand our understanding of the human genome and its application to advancing human health.

Another federal program seeking to increase diversity in research participation is NIH's Community Engagement Alliance (CEAL) initiative Against COVID-19. The CEAL initiative, established recently by Congress, promotes community engagement and outreach efforts to diverse communities hit hardest by the COVID-19 pandemic. Through this program, NIH is also coordinating with local organizations to reach underserved communities. We believe the design and core values of the CEAL initiative model is how NIH and its researchers can approach all research involving individuals as participants, especially specialties such as human genetics and genomics where some individuals are hesitant to become involved. **Cures 2.0 should authorize the expansion of existing programs at NIH like CEAL or create a new program focused on increasing research participant diversity and building trust with communities, including providing dedicated funding for these activities.** Such a program could encourage an emphasis on diversity and inclusion within biomedical research through providing grants for outreach and engagement to underrepresented or historically excluded communities. In this way, NIH could apply the successes and lessons learned from the *All of Us* program, specifically those connected to participant outreach, more broadly across its portfolio.

Thank you for your ongoing support for biomedical research, and the opportunity to comment on this draft. We welcome the opportunity to work you and your staff as you further consider how to increase cohort diversity in biomedical research. Please feel free to contact Dr. Derek Scholes, Senior Director of Policy and Advocacy (dscholes@ashg.org) with any questions.

Sincerely,

Gail P. Jarvik, M.D., Ph.D.
2021 President, ASHG

Mona V. Miller
Chief Executive Officer, ASHG