THOUGHT LEADERS IN PRECISION MEDICINE ROUNDTABLE: The role of the All of Us Research Program in creating a research paradigm that models the future rather than mirrors the maladaptive past
June 21, 2018

BRIEFING DOCUMENT

The NIH All of Us Research Program launched on May 6, 2018, commencing the nationwide recruitment of at least 1 million participants whose clinical and behavioral information will be collected, cross-tabbed, and analyzed for decades. NIH and All of Us leadership estimated that 50%-70% of these participants will represent populations that are underrepresented in biomedical research, including racial and ethnic population groups other than those of European or non-Hispanic descent. Participants will share information over the life of the program through surveys, electronic health records, physical measurements, blood and urine samples, and wearable technologies.

These data, in concert with the nationwide partnership infrastructure created by the All of Us Research Program, have the potential to serve as a foundation for the disruption and inculcation of plasticity into extant maladaptive policies, practices, or norms. What is also required, however, is broadened inclusion and leadership drawn from underrepresented researchers in academic research centers and private sector research entities who bring a new vision and new knowledge to the design of research and clinical trials, analysis of the findings, and translation of the new evidence into guidelines, treatment processes and quality metrics.

Roundtable Objectives and Discussion Framework

The All of Us Research Program is continuing to seek input from community and provider leaders to help assure that the program maximizes its potential and returns value to the participants and their communities. This second National Thought Leaders in Precision Medicine Roundtable is being convened to focus specifically on the infrastructure and resources needed to create and sustain pathways and opportunities for the underrepresented researchers whose knowledge and experience are the sine qua non of a 21st century research paradigm. The objectives of the Roundtable are:

- To increase transparency and understanding of the databases and resources that will be established and maintained by the NIH All of Us Research Program;
- To clarify the processes that will be in place to curate access to these data and resources, to describe anticipated All of Us timelines and/or benchmarks for opening access to the data, and to shed light on any criteria for approval or prioritization of requests for access;
- To refine and/or expand upon the recommendations and issues regarding database access and use that were identified during the February 7, 2018 Thought Leaders in Precision Medicine Roundtable; and
• To define specific and actionable recommendations that *All of Us* can implement during the next 18-24 months.

Research Recommendations from the February 7 Thought Leaders Roundtable

The following recommendations regarding database access and use were an outcome of the February 7, 2018 Thought Leaders in Precision Medicine Roundtable:

**ACHIEVING REPRESENTATIVE DIVERSITY**

• Implement diversity and inclusion standards for researchers who are granted data access. Researchers who use the *AoU* database should meet the same standards of inclusion for women and minorities as research funded by or undertaken by the NIH.

• Update and diversify the lexicon. Use disruptive messaging. The term “minority” does not convey inclusiveness or empowered collaboration. In addition, many groups labeled “minority” do not consider themselves minorities. The new lexicon must be flexible, sensitive to differences in perception, and of service to the disruptive positioning.

• Assist HUBR physicians in communicating research. Physicians who treat HUBR communities often see more patients. *AoU* must provide resources to prepare providers to discuss results and have conversations with participants. Train them on how to address the *AoU* program when people have questions. Increase education in genetics.

**RESOURCES AND SUPPORT**

• All of Us should provide resources to assist with data mining. If this is a database that we are advocating for our constituents, we would like to have resources to do our own mining of the data. Clarify whether community groups will be able to research specific areas. Note that HUBR researchers will want to choose topics that interest them and analyze the data through the lens of science and evidence.

• Consider partnerships with the private sector to increase data access. Explore options for a public/private partnership to engage commercial interests to support use of the *AoU* database.
Training and Mentoring

- *AoU* should dedicate resources to the mentorship and training of young HUBR researchers and clinicians and create leadership programs and messaging for this segment. This intergenerational approach will help assure sustainability of the *AoU* Research Program and benefits to HUBR communities.

- *AoU* should provide training and support to HUBR researchers in the use of the *AoU* database and incorporation of the data into research design and create partnerships with public health programs at historically black colleges & universities (HBCUs). This will help the HUBR research community access the data and answer questions about HUBR populations, ensure HUBR communities are represented in findings, and to hold *AoU* accountable to participants and researchers. This is of particular importance for HUBR researchers of Asian and Pacific Islander, Black/African American, Native American/American Indian, and Hispanic/Latino identities.

Discussion Questions

These discussion questions are suggested in the interest of triggering a robust exchange.

- As researchers what are our concerns regarding our ability to access or use the *All of Us* data set? What steps can *All of Us* take to address those concerns?

- Do our institutions and organizations have the capacity to incorporate into clinical or applied research the types of data that the *All of Us* Research Program will collect? If not, what additional capacity is needed in our communities, institutions, or organizations?

- When will the information in the *All of Us* database be available for use by academic and/or commercial researchers? Will priority be given to certain categories of researcher or *All of Us* partner (public, private, not-for-profit)? Will access to the *All of Us* database be available without constraints or costs? Will the research questions or protocols be subject to review or approval before access is granted? If yes, by whom?

- How have the protections outlined in the Common Rule been factored into the *All of Us* research protocol?
• Is there anything that *All of Us* can or should do to create incentives for research that will accrue to the benefit of populations that are historically underrepresented in biomedical research? What should *All of Us* do to facilitate the translation of that research into therapeutic options that are reimbursable by CMS and/or commercial insurers?

If you have any questions or comments regarding this Briefing Document or the Thought Leaders in Precision Medicine Roundtable, please contact Gretchen C. Wartman, Vice President for Policy and Program, National Minority Quality Forum, at gwartman@nmqf.org.