All of Us Research Program
Ethical, Legal, and Social Implications (ELSI)
Research Priorities Workshop
June 24–25, 2019

Executive Summary

The *All of Us* Research Program's Ethical, Legal, and Social Implications (ELSI) Research Priorities Workshop was held on June 24–25, 2019. The workshop convened ELSI professionals and *All of Us* participant ambassadors to help identify ELSI research opportunities using the *All of Us* Research Program, provide feedback on how to advance ELSI research by using the program and its data resources, and suggest ELSI-related research use cases.[1]

On Day 1, attendees received information on the program's research platform, scientific framework and priorities, commitment to diversity, participant engagement strategy, data access and privacy policies, and new activities that are being planned. They also received a demonstration of the *All of Us* public data browser. Attendees then divided into working groups organized around three themes: (1) genomics; (2) social determinants of health; and (3) legal, regulatory, and policy issues. In these groups, attendees participated in a facilitated activity where they discussed and recorded ELSI research questions of interest and the data needed to answer them, including data with planned availability through the program's Research Hub.

During an open discussion on Day 2, attendees raised significant concerns about the structure of Day 1 and asserted that the program could make better use of their deep and varied expertise by reframing the workshop to allow for exploration of some important ELSI considerations that the program raises, including protecting participants' rights and privacy and ensuring that participants have a real voice in the program. Many attendees expressed concerns about what they see as missed opportunities by the program to work with ELSI experts on developing key policies and protocols for the program.

Attendees also said that many ELSI questions are legal and/or normative and do not rely on collecting data or identifying use cases; use cases would not get to the heart of the ELSI issues that the program should consider.

In response to this feedback, staff—with input from attendees—revised the workshop agenda for Day 2 to elicit feedback on the ELSI issues that the attendees deemed most important. Ten themes emerged from this discussion:

- Preventing bad outcomes
- Concerns about what is already happening
- Participant- and community-driven research and power dynamics
- Legal and normative questions not answered by data
- Promoting good outcomes
- Informed consent
- Tensions between individual, community, and group frameworks
- Gaps in legal and policy protections
- Concerns moving forward with this resource (stewardship)

[1] A use case is a hypothetical study designed to answer an important research question. It lists the types of data needed to answer the research question, the possible methods for obtaining the data types, and the final specification of the methods to be used.

- Use cases for social determinants of health

Attendees engaged in small-group breakouts based loosely on these themes. The groups then reported out the highlights of their discussions and suggestions for the program, including considerations for enrolling children, explaining the risks and benefits of participation to participants, clearly informing participants about how their data may be used, and ensuring that the program reflects participants' research priorities and addresses health disparities. Other suggestions included conducting a legal analysis of participants' rights, creating a participant review board, and providing greater clarity about the Data Use Agreement (DUA) and what happens if the DUA is violated.

The workshop concluded with program staff summarizing the proceedings; thanking the attendees for the frank and open discussion that resulted in a rich conversation on Day 2; thanking workshop funders, planners, facilitators, and partners; and welcoming submission of additional feedback, questions, and research questions by email. The program staff said they will continue to foster dialogue on ELSI, including addressing many of the gaps and concerns that were raised by the attendees, and answer specific questions about program operations and policies. The program staff said AoU will also compile a white paper on topics discussed at this workshop and make the document public.

Workshop Summary

DAY 1

Dr. Katherine Blizinsky, *All of Us* Policy Director, opened the workshop by welcoming everyone to the event, noting that ELSI has always been an integral part of *All of Us* but that with the workshop, ELSI would now be ensconced in the public face of the program. She expressed her gratitude to the attendees for sharing their time, trust, and expertise. After her welcome, staff and members of *All of Us* gave a series of presentations to provide an overview of the program to attendees.

Dr. Subhashini Chandrasekharan, *All of Us* ELSI lead, provided an overview of the workshop's goals, including to aid the program in identifying opportunities for ELSI research using the *All of Us* data repository and to convene a diverse group of ELSI experts to ensure representation from a variety of communities. Attendees included ELSI researchers, both experienced and early career; *All of Us* participant ambassadors; and members of the *All of Us* consortium, the National Institutes of Health (NIH), and the Department of Health and Human Services. Dr. Chandrasekharan concluded with three framing questions for the workshop:

- What are the essential ELSI questions the community would like to study using *All of Us* as a research platform?
- What data types do we have, and what do we need in terms of analytical tools and logistical support to enable ELSI researchers to address these lines of inquiry?
- What additional tools or features could the program provide to help ELSI researchers?

Dr. Stephanie Devaney, *All of Us* Deputy Director, gave a keynote presentation describing the *All of Us* mission and core values and a brief history of the program. She noted that more than 209,000 people have signed up as participants from all 50 states and that about 162,000 have completed the full protocol. Dr. Devaney especially emphasized the importance of diversity for *All of Us* and the program's efforts to recruit individuals from populations that have been historically underrepresented in biomedical research (UBR). Currently, more than 80% of participants fall under this designation, with 51% self-identifying as having a minority racial or ethnic background.

Dr. Devaney described current and future data collection in the program. The program currently collects data from electronic health records (EHRs) and surveys, and participants will soon be able to contribute data from wearable devices (such as Fitbit) and digital applications on mood and cardiorespiratory fitness. *All of Us* also plans to conduct genotyping and whole genome sequencing for 1 million participants and to return genomic results to them. The program aims to have additional opportunities to return information of value to participants in the future, an important part of supporting participant engagement and long-term participation.

Dr. Kelly Gebo, *All of Us* Chief Medical and Scientific Officer, discussed the scientific priorities of the program and described the potential of a large cohort to accelerate health research and medical breakthroughs. She described some of the innovative aspects of the program, including the level of representation from UBR populations; the development of a widely available, cloud-based database that will use open-source software and analytical tools; and the foundational concept that participants are equal partners in research. Dr. Gebo went on to present the scientific framework of *All of Us*, which outlines the need to enable research that will:

- Increase wellness and resilience and promote healthy living

- Reduce health disparities and improve health equity in UBR populations
- Develop improved risk assessment and prevention strategies to preempt disease
- Provide earlier and more accurate diagnosis to decrease illness burden
- Improve health outcomes and reduce disease impact through improved treatment and development of precision interventions

Dr. Gebo also spoke about the "Big 8" health areas that *All of Us* aimed to prioritize for data collection based on feedback from the *All of Us* Research Priorities Workshop. The list took into account top causes of death and major areas of health disparities, among other factors, and included cancer, cardiovascular disease, and chronic kidney disease. Next, she described the participant journey, provided an overview of research tools that will be available in the Research Hub, and described the curation of salient variables from collected data. Lastly, Dr. Gebo asked the meeting attendees for their help in thinking about ELSI-related questions, variables, and methods to incorporate into the protocol roadmap and the next version of the protocol.

Dr. Consuelo H. Wilkins, Vanderbilt University Medical Center Vice President for Health Equity, Meharry-Vanderbilt Alliance Executive Director, and *All of Us* Engagement Core Director, spoke about the importance of engaging participants as partners to make research relevant for participants and communities. She defined "engagement" and noted that it is distinct from recruitment and retention; the goal of engagement is to involve stakeholders in the selection, design, conduct, and dissemination of research rather than simply to enroll people or retain people. Dr. Wilkins said that *All of Us* is exploring many strategies for engagement. Until now, the program has been focused on enrollment, but it is time to turn toward retention and engagement.

Dr. Wilkins described some of the engagement steps that *All of Us* has taken so far, including activities of the *All of Us* Engagement Core that she leads. The Engagement Core is composed of national leaders in medicine, engagement, and ethics and works with the *All of Us* engagement team to ensure that the program succeeds in elevating participants' voices throughout the program. Part of the engagement strategy has included partnering with community-based organizations to increase awareness, and the formation of a participant ambassador program to ensure involvement of participants in program governance and decision-making.

Lastly, Dr. Wilkins conveyed some of the upcoming engagement plans for the engagement core, including a participant-partner retreat. She also introduced a plan for evaluating engagement in the program based on intermediate and long-term outcomes.

In the discussion that followed Dr. Wilkins' presentation, attendees asked about the links between participant ambassadors and research participants, as well as how engagement activities have influenced *All of Us* governance. Dr. Wilkins responded that participant ambassadors are connected to communities and organizations in their local areas and are individuals who want to be champions and advocates for the research. Dr. Wilkins also provided some examples of changes that were made in response to participant feedback. These included compensating participants to offset the inconvenience of participation, planning for more return of information than initially considered, and having in-person consent options rather than a digital-only model for consent.

Drs. Dikshya Bastakoty, *All of Us* Data and Research Center (DRC) project manager and Weiyi Xia, DRC postdoctoral fellow, made presentations about data access and data privacy for *All of Us*. Dr. Bastakoty began by explaining the goal to provide broad and open access to

data for academic researchers and community scientists without sacrificing participant privacy. The program's access policies, privacy protections, and other safeguards have been designed to strike a balance between these two principles. The *All of Us* data repository will reside in three tiers, with tier assignment varying by level of sensitivity: a public tier; a registered tier; and a controlled tier. To access the registered and controlled tiers, data users will have to follow a series of steps:

1. Verify their identity.
2. Register for a data passport, for which users provide their name and institutional affiliation (if applicable), among other information.
3. Take the *All of Us* research ethics training.
4. Attest to the *All of Us* DUA, a legally binding document.

Individuals who wish to access controlled tier data will have additional requirements that have yet to be determined.

Dr. Bastakoty discussed the safeguards that protect the data resource. This includes limiting data access and analysis to the *All of Us* research platform, oversight of data use by the Resource Access Board, and a data identity protection system embedded within the data.

Next, Dr. Xia went into detail about how decisions are made regarding which data to share with users in the registered tier and some of the specific rules that *All of Us* is using to protect data in this tier. This includes shifting dates and removing explicit identifiers, free-text fields, and geolocation information beyond the level of U.S. state. Dr. Xia also described the analyses used to assess the likelihood that a bad actor could reidentify someone by combining individual-level data with public information. In this way, *All of Us* is able to determine which data types are acceptable to maintain in the registered tier, which need to be altered in some way, and which should be excluded from this tier. Dr. Xia emphasized the importance of protecting participants' sensitive information, especially given the amount of data collected from each person.

During subsequent discussion, attendees asked about the risks of withholding granular information from the registered tier. Dr. Bastakoty acknowledged that this is a consideration for *All of Us* and that one way to mitigate this risk is by releasing the controlled tier as soon as possible. Lastly, an attendee highlighted the importance of talking with communities about their fears, concerns, and priorities, including privacy.

Mr. John Wilbanks, Sage Bionetworks Chief Commons Officer and Ms. Ericka Thomas, *All of Us* participant priorities lead, Policy Office presented on policy implementation in the program. Mr. Wilbanks highlighted the philosophy behind the core protocol as a structurally complex document that has more in common with a software development project than with a typical research protocol. This is because of its format, which includes a national core protocol with additional site-specific elements that allow bugs to be isolated and fixed. The format also allows the core protocol to be modified as best practices emerge and to evolve based on outcomes of workshops such as this one.

Mr. Wilbanks discussed how the program's informed consent process was created, including consultation with multiple stakeholders, careful consideration of vocabulary, and formatting of the consent in a way that conforms to how people read pages on a screen. All content is written at a fifth-grade reading level.

Mr. Wilbanks presented data about the informed consent process. For example, one can observe where consent drop-offs occur and can monitor the results of assessments showing

how well users comprehend the information. Data indicates that 67% of individuals who begin any section of the consent complete all of the consent components.

Ms. Thomas spoke about the laws, policies, and regulations that apply to *All of Us*, as well as how policy is developed and implemented within the program. *All of Us*, for example, must follow the Common Rule, the 21st Century Cures Act, and the Health Insurance Portability and Accountability Act as they pertain to different parts of the program; the program also voluntarily complies with the Federal Information Security Management Act. To help guide and inform additional policies, *All of Us* has various governance bodies, which include staff, consortium members, and participant ambassadors, who, in collaboration with the Policy Office, define and inform the policies that the program implements.

Subsequent discussion led to clarification of certain aspects of the program. An attendee asked what happens in the event that stigmatizing research is published and disseminated. Though actions that the program can take once stigmatizing research is published and disseminated are limited, Dr. Blizinsky noted that *All of Us* aims to raise awareness of actions that researchers can take to prevent their work from being used in a stigmatizing way. An attendee asked who can access data and how intellectual property will be handled. Dr. Devaney responded that the data resource will be open to a range of researchers, including citizen scientists and industry researchers. The data platform will be open to any authorized user to use in conducting research or developing intellectual property.

A Q&A session followed this discussion. Attendees asked about the following:

- Challenges involved with integrating EHR data into the data resource. Dr. Blizinsky explained that this is a laborious and high-touch process and that efforts to help automate the data integration process through the Sync for Science initiative are underway.
- Actions that *All of Us* is taking to handle the profound ethical challenges involved in enrolling children, prisoners, and decisionally impaired individuals. Dr. Devaney noted that *All of Us* is still thinking through these ethical challenges. The protocol and policies will be modified to support these groups. Staff are already thinking about how surveys and other aspects of participation will evolve for children from the time they are infants until they reach the age of majority.
- Consequences for individuals who violate the program's DUA. Dr. Devaney responded that Vanderbilt University is hosting the data in the cloud and that program staff are working with NIH's Office of General Counsel to explore possible enforcement actions.
- How tribal consultations are being undertaken. An attendee raised significant concerns about this and noted that a consultation is different from engagement and is a government-to-government interaction that takes place between tribal nations and, in this case, *All of Us*. Dr. Devaney stated that program staff have been working with the NIH Tribal Health Research Office for consultation and engagement planning. *All of Us* is waiting until the consultation process is complete before taking further actions.

Dr. Jennifer Ayala, *All of Us* DRC project manager, provided the day's last presentation, which was about current and upcoming data types within the *All of Us* database. These include planned surveys on mental health, social determinants of health, and diet; data from Fitbit and other wearables; data from the National Death Index and cancer registries; and free-text notes and images from EHRs.

Dr. Ayala went on to provide a demonstration of the public data browser, where individuals have access to a curated subset of aggregate data stored in the database. She also described the life

cycle of data, which includes steps to perform security checks, quality control, and privacy transformation. Lastly, she provided a sneak peek at the upcoming, cloud-based Researcher Workbench, which will have custom tools for studying user-defined subsets of data. For example, researchers will be able to use an integrated, web-based Jupyter Notebook environment within the Researcher Workbench for powerful, interactive analyses.

In the discussion that followed, attendees asked clarification questions about the types of data that *All of Us* is collecting and provided suggestions about data collection. Attendees noted that researchers need individual- and societal-level variables and indicated that *All of Us* should consider gathering data from participants' communities and local hospitals. Attendees also expressed concerns about survey fatigue and how questions are prioritized. They recommended collecting data about survey drop-off and carefully considering the order in which questions are asked. Dr. Ayala noted that the program has survey methodologists who consider these types of questions. One attendee asked whether it is possible to link a participant's data to metadata about survey completion. Dr. Blizinsky said yes, it would in theory, but it would be helpful to hear about the types of metadata that ELSI researchers are interested in before giving a more concrete answer.

For the remainder of the day, meeting attendees were asked to work in small groups with the aim of developing ELSI use cases. Within each breakout, attendees were asked to first record their ideas for research questions in the templates provided and to next decide as a group which research questions they would develop into use cases over the next two days. When developing use cases, attendees were asked to record the existing *All of Us* data elements that could be used, as well as the additional data types and resources (e.g. data analysis tools) they would need to carry out their proposed research projects. To support use case development, all small groups were provided with brief descriptions of *All of Us* program components, a data dictionary listing data elements collected by the program, and links to the Research Hub to explore publicly available *All of Us* data. Attendees were assigned to one of the workstreams below based on preferences they indicated in advance of the workshop.

- **The Genomics Workstream** focused on issues related to the design and translation of genomics research, including return of genomic research results to participants, genomic privacy, and collection and analysis of DNA from vulnerable and UBR populations.
- **The Legal/Regulatory Policy Workstream** concentrated on the influence of the legal and regulatory framework on the practice of research.
- **The Social Determinants of Health Workstream** was asked to cover the influence of social, environmental, and other factors on health outcomes, including such topics as accurate collection of data on social and lifestyle variables, ethical considerations in the study of health disparities, and the effects of research on vulnerable populations.

DAY 2

After Dr. Blizinsky welcomed everyone back, **Megan Doerr, Sage Bionetworks principal scientist, Governance and Ethics,** recapped the first day of the meeting and the work that was done in the breakout sessions. Attendees had the opportunity to record their initial thoughts and questions, identify interest groups within the breakout sections, and brainstorm use cases. Ms. Doerr suggested that Day 2 be used to flesh out these use cases by using the templates provided.

However, attendees expressed significant concerns about the format for the meeting and the way in which the breakout sessions were structured and operationalized. An attendee noted that

many questions about the program are not driven by data but are rather legal and normative questions. Simply obtaining more data would not answer the most critical questions.

In an open discussion period with all attendees, individuals raised many other concerns about the workshop proceedings and the program itself. Concerns about workshop proceedings included the following:

- Most ELSI research is not conducted using large-scale data. The expertise assembled in the room was not being put to good use, and the program should listen to the voices in the room regarding their concerns and input on different aspects of the program, rather than simply asking researchers what kinds of data they would like to see and use in the data resources.
- It is important to adopt the viewpoint of a research participant when conducting these discussions. It is not currently clear in what ways the program is driven by participants. *All of Us* must work on this and must protect communities if the program is asking so much of them.
- Breakout sessions were conducted disrespectfully, with a harsh code of conduct and an implication that ELSI experts are not good at collaborating.
- There was a misunderstanding about the goals of the workshop due to unclear communication; in addition, the recommended readings covered a broad set of normative, policy, and legal questions, but the workshop itself was not dedicated to exploring these questions.
- The ELSI community's recommendations will not be taken into consideration.

Concerns about the program included that ELSI considerations have not been adequately discussed or addressed. Attendees provided the following examples:

- The program is pulling in intrusive data about participants, such as reproductive history and drug and alcohol use. This gives *All of Us* serious legal and ethical responsibilities to protect the privacy of participants.
- Many people in rural locations do not have enrollment centers or access to mobile phones and the Internet. *All of Us* needs to address how it will provide these individuals with the opportunity to participate.
- Participant ambassadors have not been interviewed for qualitative research even though they are embarking on something that has never been done before and could provide valuable insights.
- Benefits from taxpayer-funded programs have not historically been distributed equitably across groups, and this is a risk for *All of Us* as well. Individuals in many communities do not even have health insurance. *All of Us* needs to consider how to benefit communities in an equitable way.
- There has been a lack of expediency in reaching out to and consulting tribes, and there is concern that tribal voices will not be heard. *All of Us* has not responded to a document from the Tribal Collaboration Working Group, a group of tribal leaders and indigenous researchers convened by the program, called *Considerations for Meaningful Collaborations with Tribal Populations* that was finalized in April of 2018.

Drs. Devaney and Blizinsky took some time to respond to these concerns. They explained that *All of Us* has become more seriously involved in tribal engagement in the past couple of months and will continue this work. The program takes its role as a custodian of taxpayer funds very seriously. It is interested in ELSI input into all aspects of the program and sincerely desires to incorporate feedback into future planning for the program's scientific framework. Drs. Devaney and Blizinsky asked for patience, as bringing ideas to fruition takes time.

In subsequent discussion, attendees reiterated that *All of Us* has not been adequately engaging with all of the communities represented in the room, including participants and ELSI

researchers. Attendees called for genuine and direct engagement across the spectrum from data collection all the way to normative research.

The workshop reconvened after a break. In response to the concerns articulated by attendees, the workshop organizers and facilitators decided to continue the large-group discussion before breaking out into subgroups with new themes decided on as a group.

Ms. Doerr first recapped the morning's discussions, accompanied by live note taking, and reiterated the above points. She brought out the fact that attendees wish to have a broader array of conversations, and then she asked for attendees to express other questions and concerns so that they could be documented. Additional input included the following:

- The program's decision-making process is a black box, and there is a need for more transparency.
- Community-based participatory research is not efficient but is necessary for understanding what is important to communities. *All of Us* should have a greater emphasis on this.
- *All of Us* should think carefully and prospectively about enrolling children and individuals with decisional impairments. The program also has to consider those who will lose decisional capacity over the course of the research (which has likely already happened) and should have dynamic mechanisms to handle this.

Next, Ms. Doerr facilitated the creation of 10 themes for further discussions, and after a series of exchanges, the group agreed upon the following list:

- **Theme 1: Preventing bad outcomes:** Taking preemptive action to protect groups of people who are not yet eligible for enrollment (e.g., children, decisionally impaired adults, incarcerated populations); taking care in the generation of genomic data and return of results; preventing stigmatizing research; preventing "biologization" of social categories.
- **Theme 2: Concerns about what is already happening:** How the program should address access to data, equity, and intellectual property.
- **Theme 3: Participant- and community-driven research (3a) and power dynamics (3b):** The meaning of "community;" the return of information/value tailored to communities and to individuals; ascertainment that the program is collecting the right data; the importance of feedback loops to understand how participants are using the results returned to them and whether it affects the health care that they receive.
- **Theme 4: Legal and normative questions not answered by data:** Is the program complying with current law? Is the current law adequate to protect participants and communities? How is the program interacting with Tribal nations?
- **Theme 5: Promoting good outcomes:** More transparency of the review processes of the *All of Us* Institutional Review Board; the return of value to communities and individuals based on their preferences; driving value in terms of research questions and ideas of interest to communities; researching the researchers to understand who is using program data and for what purpose.
- **Theme 6: Informed consent:** Effectiveness of the informed consent process (an overarching issue to be taken up by all groups).
- **Theme 7: Tensions between individual, community, and group frameworks:** How to prioritize these frameworks when considering the distribution of risks and benefits.
- **Theme 8: Gaps in legal and policy protections:** Identifying gaps and communicating them to participants.
- **Theme 9: Concerns moving forward with this resource:** How *All of Us* governance ensures good stewardship of resources; how to ensure the sustainability of the resource.
- **Theme 10: Use cases for social determinants of health:** Returning to the task from Day 1 to develop use cases in this area.

There were additional messages that emerged during this process:

- One attendee suggested further consideration of this passive model of research. There is an assumption that if the data are available, research will happen. Other datasets, such as the database of Genotypes and Phenotypes, have been underutilized.
- *All of Us* must be careful to ensure that participants adequately understand the risks and benefits of participating in the program and must carefully manage the tension that exists in all research projects between recruitment and accurate portrayal of what people are likely to get from participation.
- The program should clarify the term "stigmatizing research" and ensure that it does not prevent useful and important research, especially research that is important to groups considered vulnerable.
- *All of Us* must keep an eye toward improving health equity and ensuring that access to data is also equitable.

After attendees came to agreement on the themes, Ms. Doerr adjourned the workshop for lunch and noted that attendees would later break into small group discussions. After lunch, Dr. Blizinsky made brief remarks and oriented attendees prior to small group discussions. She acknowledged that the program needs to do a better job of communicating with the ELSI community. She requested that breakout groups record their discussion points to share with *All of Us* and said that program staff will follow up on concerns and questions noted by the groups.

Over the next two hours, attendees organized themselves into small groups loosely based on the 10 themes and then came back together as a full group to report on their discussions. Some of the groups chose to focus more narrowly on a topic within their theme or to modify a theme; these modifications are reflected in the titles below. The following are major points from each discussion group.

Group 1: Preventing bad outcomes (this group focused solely on pediatric enrollment)

- Group 1 stressed that pediatric enrollment should begin with duos or trios (a child plus one or two parents) and should be done by health care provider organizations rather than the direct volunteer mechanism. When children are enrolled, there is a need to understand parents' and adolescents' motivations for enrolling or declining to participate.
- In addition, Group 1 suggested the program think about pediatric issues across the spectrum of recruitment and enrollment, assent and consent, participation, and specific issues related to genomic testing, return of results, and downstream uses of the data. In addition, the program must think about reconsent and explaining how adolescents' rights change when they become adults.
- Finally, Group 1 urged the program to carefully consider identity verification for pediatric populations.

Group 2: Concerns about what is already happening (access to data, equity, and intellectual property)

- Group 2 noted that the program should be careful about overpromising results; understating risks, potential harms, and the likelihood of data breaches; and potential for therapeutic misconception. The group encouraged the program to look to existing best practices for returning results.
- Group 2 emphasized that legal recourse for misuse of data is important and that the program should develop tools for levying penalties.
- In addition, Group 2 suggested that the program analyze outcomes from secondary uses of data and bring this information back to participants to see whether this is what they anticipated when they consented to participate.

- Furthermore, Group 2 felt that part of the ELSI research agenda should be to iteratively study the consent process to see how effective it has been.
- Finally, Group 2 stated that the program will need compelling and substantial justification for enrolling decisionally impaired individuals and other vulnerable populations. The program must develop safe processes for such enrollment.

Group 3: Participant- and community-driven research

- Two participant ambassadors took part in this group discussion and felt that ambassadors had not been involved in constructing the value proposition for the program; for example, they did not know where the "Big 8" health areas for the science vision came from.
- Group 3 felt that there is a need to understand what value means to *All of Us* participants and that there is substantial existing literature on this topic to which the program should refer.
- Participants want to feel that their participation is worthwhile. Group 3 articulated that researchers should be required to post summaries of their research.
- Finally, Group 3 stressed the importance of bidirectional communication between the program and its participants to learn what participants want and expect from this experience.

Group 4: Power dynamics, programmatic decision-making, and governance

- Group 4 felt that *All of Us* can learn from the Patient-Centered Outcomes Research Institute (PCORI) to ensure that the program reflects participants' research priorities and is set up to address health disparities. They noted that one way to achieve this is by creating seed grants for researchers from underrepresented groups to enable community-driven projects.
- The group felt that *All of Us* should explore new forms of engagement for setting priorities (e.g., setting up a peer-to-peer network for participants that would let them communicate and push forward research agendas). The group thought that this could also help researchers locate new groups of communities and potential cohorts.
- Group 4 emphasized that return of value presents opportunities to recontact participants and understand their desire for receiving information and how they are using this information.
- Lastly, Group 4 noted that there is a need for strategies to help participants navigate the digital design of the program to help those who may find it difficult to do on their own.

Group 5: Legal and normative questions not answered by data (this group also discussed gaps in legal protections)

- Group 5 discussed how to address gaps in the law to protect the rights and protections of participants whose data are in the system, as well as the duties, obligations, and rights of the researchers who use the data.
- The group emphasized the importance of third-party enforcement for the DUA; for example, participants could be third-party beneficiaries with the right to take legal action if the DUA is violated. The group also noted that the DUA should outline what enforcement would look like (e.g., dispute resolution such as arbitration), and there should be enforcement provisions, including injunctive relief. Data users should also have due process rights.
- Group 5 felt that expectations of data users should include:
  - An obligation to report breaches and to agree to audit by *All of Us* or third parties
  - An agreement not to attempt to reidentify individuals or redistribute data in prohibited ways
  - Submission of research summaries for possible peer review
- The group thought that *All of Us* should consider the PCORI model of expecting researchers to engage with participants.

- Group 5 also felt that *All of Us* should consider offering education to data users to help protect participants' rights, since data users will include traditional and nontraditional researchers.

Group 6: Promoting good outcomes and use cases for social determinants of health

- Group 6 felt that the program could yield better data through interviews with participants from the beginning to learn about their expectations and through community engagement by researchers.
- The group suggested development of a methods core to teach researchers about de-identifying qualitative data to make it available for others and to ensure data quality generally.
- Group 6 felt it important to invest in research that looks at disparities and inequities.
- Lastly, Group 6 suggested creating a participant review board and exploring other ways of capturing the social values of communities in order to deliver on them.
- In addition to these suggestions, the group captured several use cases to submit to the program.

Group 7: Tensions among individual, community, and group frameworks

- Group 7 noted that individuals, communities, and groups are fluid constructs. They encouraged the program to carefully consider the allocation of benefits among these constructs.
- The group also thought that *All of Us* should consider these constructs in recruitment, enrollment, and return of results and use precise language when discussing these constructs.
- Furthermore, Group 7 thought that *All of Us* should consider the group and community views of benefit, in addition to the individual.

Group 8: Gaps in legal and policy protections

Group 8 focused on posing a series of questions and suggestions:

- Do participants understand that *All of Us* is research and not health care? The program needs to communicate fully about potential harms and lack of legal rights if privacy breaches occur. Participants should also understand the ramifications in the event that the Patient Protection and Affordable Care Act is invalidated.
- How will the DUA be enforced? Who will monitor data use, and at what level? The burden should not be on the participant.
- *All of Us* should put in place a regular, periodic reconsenting process, since harms and benefits may change over time.
- *All of Us* should put limits on certain uses by insurers or financial companies.
- When it comes to rights and expectations, what is the weight of an individual versus a community?

Group 9: Concerns moving forward with this resource (stewardship)

- Group 9 described a need for more transparency in *All of Us* governance, particularly with respect to the following:
  - How was this governance structure decided, and what does it look like?
  - What is the governance structure, what do governance processes look like, and who is serving in governance roles? There should be representation of all key stakeholders.
  - What is the process for changing *All of Us* policies and procedures?
  - There should be an iterative and ongoing evaluation of the governance structure and processes to achieve adaptive governance.

- In addition, Group 9 had questions about the program's long-term sustainability:
  - Where will the data go once the program ends?
  - What will program tell data users and participants if funding is not sustainable?

Closing Remarks

Dr. Blizinsky thanked the workshop participants for their flexibility, patience, and perseverance in working through important and sometimes difficult conversations. She expressed confidence that the program will be improved as a result of the workshop. Dr. Blizinsky also expressed her sincere gratitude to the *All of Us* team members and *All of Us* partners—Sage, Leidos, and Palladian—that helped to organize and run the workshop, as well as colleagues in the NIH Office of Science Policy for their financial and logistical support.

Lastly, Dr. Blizinsky noted that the information from the workshop will be disseminated, and program staff will follow up about the ideas advanced during the meeting.

Attendees

Tori Allen
Research Associate
Sage Bionetworks

Megan Allyse, Ph.D.
Assistant Professor of Bioethics
Mayo Clinic

Paul Appelbaum, M.D.
Dollard Professor of Psychiatry, Medicine, and Law
Columbia University

Jennifer Ayala, Ph.D.
Project Manager
Vanderbilt University Medical Center

Lottie Barnes, Ed.D.
Assistant Director of Operations and Community Engagement
Community Health Coalition

Dikshya Bastakoty, Ph.D.
Project Manager
Vanderbilt University Medical Center

Adam Berger, Ph.D.
Director, Division of Clinical and Healthcare Research Policy
NIH Office of Science Policy

Benjamin Berkman, J.D., M.P.H.
Bioethicist
National Institutes of Health

Maya Bernstein, J.D.
Senior Advisor, Privacy Policy
U.S. Department of Health and Human Services

Katherine Blizinsky, Ph.D.
Policy Director
All of Us Research Program

Vence Bonham, Jr., J.D.
Investigator, Senior Advisor to the Director
National Human Genome Research Institute

Lawrence Brody, Ph.D.
Director, Division of Genomics and Society
National Human Genome Research Institute

Kyle Brothers, M.D., Ph.D.
Endowed Chair of Pediatric Clinical and Translational Research
University of Louisville School of Medicine

Charlisse Caga-anan, J.D.
Program Director
National Cancer Institute

Angela Carrigan, M.P.H.
Clinical Program Manager
Leidos

Lara Cartwright-Smith, J.D., M.P.H.
Associate Professor
George Washington University

Mark Caulder, M.S., M.P.H.
All of Us Research Program Biobank and Federally Qualified Health Center Team Lead
All of Us Research Program

Subhashini Chandrasekharan, Ph.D.
Health Scientist Administrator, ELSI Research
All of Us Research Program

Mildred Cho, Ph.D.
Professor
Stanford University

Kurt Christensen, Ph.D.
Instructor in Medicine
Brigham and Women's Hospital and Harvard Medical School

Wendy Chung, M.D., Ph.D.
Kennedy Family Professor of Pediatrics and Medicine
Columbia University

Bobby Clark, M.P.P.
Principal, Health Innovation Team
HCM Strategists

Ellen Clayton, M.D., J.D.
Professor, Pediatrics, Law, and Health Policy
Vanderbilt University Medical Center

Elaine Collier, M.D.
Senior Advisor to Director
National Center for Advancing Translational Sciences

Melissa Creary, Ph.D., M.P.H.
Assistant Professor
University of Michigan

Curt DellaValle, Ph.D.
Program Officer
All of Us Research Program

Stephanie Devaney, Ph.D.
Deputy Director
All of Us Research Program

Denise Dillard, Ph.D.
Director of Research
Southcentral Foundation

Meg Doerr, M.S., LGC
Principal Scientist
Sage Bionetworks

James DuBois, D.Sc., Ph.D.
Director, Bioethics Research Center
Washington University School of Medicine in St. Louis

Debra Duquette, M.S.
Associate Director
Northwestern University, Graduate Program in Genetic Counseling

Barbara J. Evans, Ph.D., J.D.
Mary Ann and Lawrence E. Faust Professor of Law; Professor, Electrical and Computer Engineering
University of Houston

Miguel Flores, LISAC, CSOTS
Chief Executive Officer
Holistic Wellness Counseling and Consultant Services

Stephanie Malia Fullerton, D.Phil.
Associate Professor, Bioethics and Humanities
University of Washington School of Medicine

Isabel Gabel, Ph.D.
ELSI Postdoctoral Fellow
University of Pennsylvania

David Galey, Ph.D.
Program Coordinator
Leidos

Ibrahim Garba, M.A., J.D., LL.M.
Research Fellow
Morehouse School of Medicine

Nanibaa' Garrison, Ph.D.
Assistant Professor
Seattle Children's Research Institute

Kelly Gebo, M.D., M.P.H.
Chief Medical and Scientific Officer
All of Us Research Program

Aliza Gersing
Policy Intern
All of Us Research Program

Mark Gerstein, Ph.D.
Professor
Yale University

Amos Glenn, Ed.D.
Instructional Designer-Technologist
University of Pittsburgh

Aaron Goldenberg, Ph.D., M.P.H.
Associate Professor
Case Western Reserve University

David Grande, M.D., M.P.A.
Associate Professor, Medicine
University of Pennsylvania

Shira Grayson, M.S., M.P.H.
Graduate Student
University of Washington

Christi Guerrini, J.D., M.P.H.
Assistant Professor
Baylor College of Medicine

Michael Hahn
Scientific Program Analyst
National Human Genome Research Institute

Catherine Hammack, M.A., J.D.
Associate in Health Policy
Vanderbilt Center for Bioethics and Society

Kristin Harris, M.S.
Operations
Leidos

James Hazel, Ph.D., J.D.
Research Fellow
Vanderbilt University Medical Center

Gail Henderson, Ph.D.
Professor
University of North Carolina, Chapel Hill

Vanessa Hiratsuka, Ph.D., M.P.H.
Senior Researcher
Southcentral Foundation

Sara Hull, Ph.D.
Director, Bioethics Core
National Human Genome Research Institute

Rosario Isasi, J.D., M.P.H.
Assistant Professor
University of Miami

Elodie Jean-Philippe, J.D., M.A.
Legal Policy Intern
All of Us Research Program

Karen Johnson-Webb, Ph.D.
Associate Professor
Bowling Green State University

Nancy Jones, Ph.D.
Program Officer
National Institute on Minority Health and Health Disparities

Jennifer Jones, M.P.H.
Executive Director, TEC
University of Pittsburgh
National Network of Libraries of Medicine

Sonya Jooma, M.A.
Policy Analyst
All of Us Research Program

Galen Joseph, Ph.D.
Associate Professor University of California, San Francisco

Aleek Kahramanian, M.P.A.
Policy Project Manager
All of Us Research Program

Dave Kaufman, Ph.D.
Program Officer
Division of Genomics and Society
National Human Genome Research Institute

Martine Lappé, Ph.D.
Assistant Professor
California Polytechnic State University

Risa Lavizzo-Mourey, M.D., M.B.A.
Robert Wood Johnson Foundation PIK
Professor of Population Health and Health Equity
University of Pennsylvania

Gabriel Lazaro-Munoz, Ph.D., J.D., M.B.E.
Assistant Professor
Baylor College of Medicine

Allison Lea, M.A.
Special Assistant to Deputy Director
All of Us Research Program

Sandra Lee, Ph.D.
Chief, Division of Ethics
Columbia University

Nicole Lockhart, Ph.D.
Program Director
National Human Genome Research Institute

Rosayma Lopez-Ramirez, M.A.
Privacy Officer
All of Us Research Program

Holly Fernandez Lynch, J.D., M.B.E.
Assistant Professor
University of Pennsylvania

Mary Madden, M.A.
Research Lead, Health and Data
Data & Society

Mary Majumder, Ph.D., J.D.
Associate Professor
Baylor College of Medicine

Bradley Malin, Ph.D.
Professor
Vanderbilt University

Castilla McNamara, Ph.D., M.P.A.
Inclusion Officer
National Institute of Deafness and Other Communication Disorders

Mollie Minear, Ph.D.
Health Scientist Administrator
National Heart, Lung, and Blood Institute

Sarah Moore
Senior Research Associate
Sage Bionetworks

Francisco Moreno, M.D.
Associate Vice President for Diversity and Inclusion
Professor of Psychiatry
University of Arizona

Melanie Myers, Ph.D., M.S.
Associate Professor and Director, Genetic Counseling Graduate Program
Cincinnati Children's Hospital and University of Cincinnati

Sarah Nelson, Ph.D., M.P.H.
Research Scientist
University of Washington

Carolyn Neuhaus, Ph.D.
Research Scholar
The Hastings Center

Sally Okun, RN, M.M.H.S.
Vice President, Policy and Ethics
PatientsLikeMe

P. Pearl O'Rourke, M.D.
Director, Human Research Affairs
Partners HealthCare

Ruth Ottman, Ph.D.
Professor, Epidemiology
Columbia University

Brad Ozenberger, Ph.D.
Program Director, Genomics
All of Us Research Program

Taunton Paine, M.A., M.Sc.
Senior Policy Analyst
NIH Office of Science Policy

Erin Paquette, Ph.D., J.D., M.B.E.
Assistant Professor, Pediatrics
Northwestern University Feinberg School of Medicine

Lisa Parker, Ph.D.
Professor and Director, Center for Bioethics and Health Law
University of Pittsburgh

Holly Peay, Ph.D.
Senior Researcher
RTI International

Jodyn Platt, Ph.D., M.P.H.
Assistant Professor
University of Michigan

Irene Prabhu Das, Ph.D.
Health Scientist Administrator
All of Us Research Program

Ramya Rajagopalan, Ph.D.
Assistant Research Scientist
University of California, San Diego

Edward Ramos, Ph.D.
Participant Center Program Director
All of Us Research Program

Rona Margaret Relova, M.D.
Research Health Scientist
VA Palo Alto Health Care System

Dara Richardson-Heron, M.D.
Chief Engagement Officer and Scientific Executive
All of Us Research Program

Lainie Ross, M.D., Ph.D.
Professor, Pediatrics, Medicine, and Surgery
University of Chicago

Elizabeth Rubinstein
Transplant Lifestyle Education, Patient Advisor
Henry Ford Health System

Peter Scully, Ph.D.
All of Us Research Program Consortium Operations
Leidos

Richard Sharp, Ph.D.
Director, Biomedical Ethics
Mayo Clinic

Stephen Sodeke, Ph.D., M.A.
Bioethicist and Professor, Bioethics
Tuskegee University

Paul Spicer, Ph.D.
Professor
University of Oklahoma

Karl Surkan, Ph.D.
Participant Representative and Lecturer in Women's and Gender Studies
Massachusetts Institute of Technology

Derrick Tabor, Ph.D.
Health Scientist Administrator
National Institute on Minority Health and Health Disparities

Meredith Temple-O'Connor, Ph.D.
Director of Science Policy
National Center for Advancing Translational Sciences

Tyrone Thigpen
Data Project Manager
Jackson-Hinds Comprehensive Health Center

Ericka Thomas, M.S.
Policy Analyst
All of Us Research Program

Alyssa Tonsing-Carter, Ph.D.
Science and Technology Policy Fellow
American Association for the Advancement of Science
National Institutes of Health

Wendy Uhlmann, M.S.
Genetic Counselor and Clinical Professor
University of Michigan

Vilma Velez
Director, Health Promoter Program
Hudson River HealthCare

Alexis Walker, Ph.D.
Postdoctoral Fellow
Johns Hopkins University

Carol Weil, J.D.
Program Director, Ethical and Regulatory Affairs
National Cancer Institute

John Wilbanks
Chief Commons Officer
Sage Bionetworks

Benjamin Wilfond, M.D.
Director and Division Chief
Seattle Children's Hospital, University of Washington

Consuelo Wilkins, M.D., M.S.C.I.
Vice President for Health Equity and Executive Director, Meharry-Vanderbilt Alliance
Vanderbilt University Medical Center

Amanda Wilson, M.S.L.S.
Head, National Network Coordinating Office
National Library of Medicine

Susan Wolf, J.D.
McKnight Presidential Professor of Law, Medicine, and Public Policy
University of Minnesota

Weiyi Xia, Ph.D.
Postdoctoral Fellow
Vanderbilt University

Joon-Ho Yu, Ph.D., M.P.H.
Research Assistant Professor
University of Washington School of Medicine