Ethical, Legal, and Social Implications in the *All of Us* Research Program

Learnings, Vision, and Approach for Addressing Current and Emergent Issues

All of Us Research Program

November 2020

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Acknowledgements

Executive Summary

The *All of Us* Research Program hosted its [Ethical, Legal, and Social Implications (ELSI) Research Priorities Workshop](#) in June 2019. Invited ELSI professionals, National Institutes of Health (NIH) staff, and participant ambassadors identified and discussed ELSI considerations for the program and opportunities for ELSI research using the program's data resources. This document presents the lessons learned from, and the outcomes of, that workshop as detailed below.

This white paper details the role of ELSI in shaping the [*All of Us* Research Program](#) from its inception; key takeaways from the open and constructive feedback received during the ELSI Research Priorities Workshop; the program's vision and approach for integrating ELSI going forward; and the specific activities the program will implement to engage, communicate with, and integrate ELSI stakeholders' perspectives.

Using thematic coding, program staff also grouped the feedback on ELSI considerations for program design and implementation into overarching and cross-cutting areas, detailed in the companion document (*Key Insights*). Attendees generated several ELSI research questions (Appendix A) about the program and using the program's scientific data resource. They also developed potential research use cases based on data from the program (Appendix B).

The insights resulting from the workshop have complemented and shaped the vision and approach for integrating ELSI within the program through design, policy, processes, and stakeholder engagement. The program will work on building additional pathways for transparent, bidirectional communications with its stakeholders and continue to solicit timely feedback from relevant stakeholders using the "right-sized" approaches. Addressing current and emergent ELSI issues thoughtfully in the development and implementation of its activities remains a critical part of the program's commitment to fostering ethically sound and socially responsible research.

1. Introduction

The [*All of Us* Research Program](#) hosted its Ethical, Legal, and Social Implications Research Priorities Workshop on June 24–25, 2019, in Bethesda, Maryland. Invited ELSI professionals, NIH staff, and participant ambassadors identified and discussed ELSI considerations for the program and opportunities for ELSI research using the program's data resources. The full [summary](#) of the workshop is available on the *All of Us* website. Videocasts of the workshop are available on the NIH website, one each for [Day 1](#) and [Day 2](#). This report details key insights from the workshop and the program's plan to incorporate the lessons learned moving forward.

1.1. Overview of the *All of Us* Research Program

The *All of Us* Research Program, administered by NIH, is a key element of the [Precision Medicine Initiative](#) (PMI), established to build a robust scientific resource with biomedical, behavioral, and social data from one million or more participants that reflect the diversity of the United States (*All of Us* Research Program Investigators, 2020). Currently, participation is open to individuals residing in the United States who are at least 18 years old with the decisional

capacity to consent and who are not currently incarcerated.[1] The enrollment of children, prisoners, and persons with decisional impairments will begin after the program has developed appropriate processes, policies, and protections.

The program aims to make its scientific resources (data and biospecimens) and its participants, when appropriate, accessible to a wide range of researchers, including nontraditional researchers like citizen scientists.

1.2. The Role of ELSI in the *All of Us* Research Program

Recent studies have described important ELSI challenges and areas for further research on the design and implementation of large-scale precision medicine research initiatives, including the *All of Us* Research Program (Hammack et al., 2019; Beskow et al., 2018; Sankar et al., 2017). From its inception, the *All of Us* Research Program has looked critically at the ELSI of the program itself, as well as implications arising from use of its resources. The reflection on ELSI has shaped the program's core values (Figure 1) that guide its decisions and activities. ELSI has also influenced the program's stance toward participant engagement and diversity in important ways.

- The program's commitment to inclusion and diversity is anchored in its mission to advance precision medicine research that can be applied to a broad range of individuals from all walks of life and help address health disparities. The program therefore strives to include participants from different races, ethnicities, age groups, and regions of the country, as well as to increase diversity of participants in terms of gender identity, sexual orientation, socioeconomic status, educational attainment, and disability and health statuses.
- The program is acutely aware of historical inequities and harms to groups and communities from biomedical research. The program takes seriously the need to mitigate harm to individuals, groups, and communities; to increase transparency; and to ensure participants are informed. To this end, the *All of Us* Research Program has partnered with community groups and representatives and is devoting resources to connecting with participants, communities, and the general public to ensure open lines of communication between these groups and the program. In this way, the program hopes to build trusting and lasting relationships around the program and precision medicine research.

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[1] The age of majority is 19 in Alabama (AL Code § 26-1-1) and 21 in Puerto Rico (31 L.P.R.A. § 971).

Figure 1. *All of Us* Research Program Core Values

ALL OF US CORE VALUES

Participation is open to all. Enrollment is open to all eligible adults who live in the United States. People of every race, ethnicity, sex, gender, and sexual orientation are welcome. No health insurance is required. You can be healthy or have health issues. You can sign up directly through JoinAllofUs.org or through participating health care provider organizations. In the future, children will be able to join.

Participants reflect the rich diversity of the United States. To develop individualized plans for disease prevention and treatment, researchers need more data about the differences that make each of us unique. Having a diverse group of participants can lead to important breakthroughs. These discoveries may help make health care better for everyone.
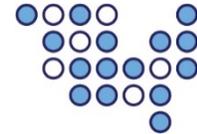
Participants are partners. Participants shape the program with their input and contribute to a project that may improve the health of future generations. They may also learn about their own health.

Transparency earns trust. We inform participants about how their data are used, accessed, and shared. Participants can choose how much information to share.

Participants have access to their information. *All of Us* lets participants see their own information and records.

Data are broadly accessible for research purposes. *All of Us* makes information about participants as a group available in a public database. Everyone can explore the database or use it to make discoveries. Data from individual participants are also available, but only for researchers who apply and are approved. Any personal information that identifies a participant, such as name or address, is removed from data that researchers can access.

Security and privacy are of highest importance. Data are stored in a secure, cloud-based database. All systems meet the requirements of the Federal Information Security Management Act. Ongoing security tests help protect participant data. Learn more about how the *All of Us* Research Program protects data and privacy.

The program will be a catalyst for positive change in research. Working together, *All of Us* researchers, partners, and participants can build a better future for health research and care.

The *All of Us* Research Program is committed to the PMI [Privacy and Trust Principles](#), which provide broad guidance on responsible approaches for sustaining public trust and maximizing the benefits of precision medicine research. Research is conducted with oversight by an independent [institutional review board](#) (IRB) that carefully deliberates ethical and regulatory requirements for inclusion of a diverse participant population. The model of the *All of Us* IRB and the breadth of ELSI expertise its members bring allows for in-depth and timely deliberations on ELSI considerations and ongoing, substantive ELSI input for the program. The [electronic informed consent](#) is modular, designed with careful attention to ensure comprehension across participants with varying levels of educational attainment and digital literacy (Doerr, 2019).

The program's Data Access Framework defines the tiered structure (Figure 2) of the data resource. The requirements for accessing each tier balance the needs of protecting participant privacy and enabling broad access for scientific research. The program is developing policies and implementation strategies for accessing its [data](#), biospecimens, and participants. The *All of Us* Research Program has established [governance bodies](#) to ensure that use of data and biospecimens respects the interests of research participants and safeguards their privacy and security. Participants serve on the *All of Us* Research Program's governance bodies to ensure participant voices and opinions are included in program decisions.

Figure 2. *All of Us* Research Program Data Access Structure
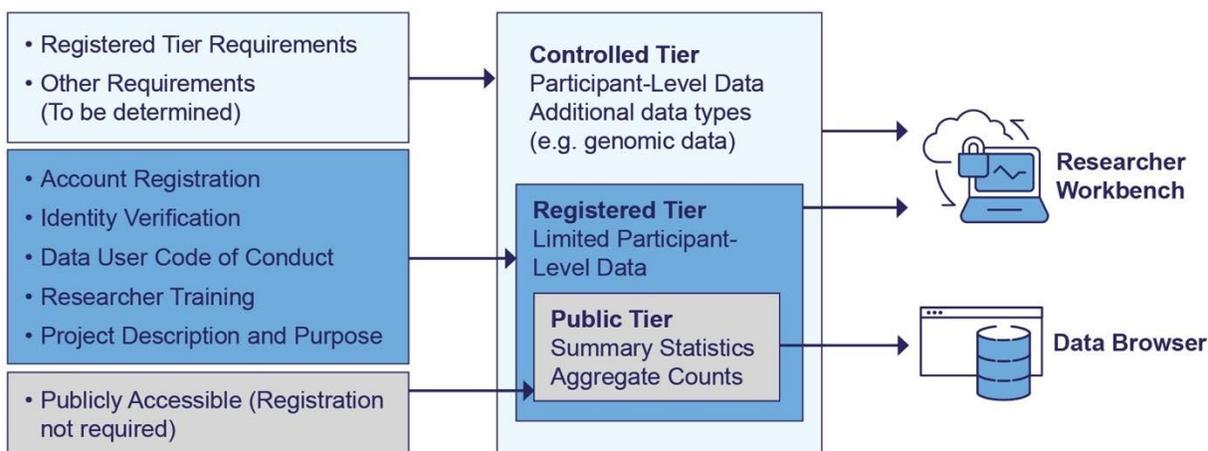
The June 2019 workshop brought together ELSI professionals, *All of Us* Research Program participant ambassadors, investigators from awardee institutions, *All of Us* program staff, and NIH staff. Attendees were asked to help identify ELSI research opportunities using the *All of Us* data resources, provide feedback on how to advance ELSI research through the program, and suggest ELSI-related research questions and use cases.[2]

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[2] A "use case" outlines and describes a research question and includes the following requirements: (1) the data types needed to answer the research question; (2) the methods to obtain the data types and to analyze the data; and (3) the specifications for using the methods.

Attendees had the opportunity to explore publicly available program data, learn about data types (and their definitions) that will be available in the registered and controlled tiers, and identify data and infrastructure needs to enable ELSI research.

2. Lessons Learned from the *All of Us* ELSI Research Priorities Workshop

2.1. Overview of the ELSI Workshop

Attendees were asked to describe ELSI research questions, detail data and infrastructure needed to answer these questions, and develop ELSI research use cases on Day 1. Responding to strong concerns voiced by attendees at the beginning of Day 2 on the purpose and the structure of the workshop, program staff and attendees revised the agenda to shift the focus to identifying key ELSI considerations for the design and implementation of the program itself. Small group work concentrated on topical areas that emerged organically from these open discussions. Each group presented the key points of these discussions to all attendees at the end of the workshop and provided written summaries to the program. A synthesis of the substantive feedback received is detailed in the companion document *Key Insights: ELSI Considerations for the* All of Us *Research Program and Opportunities for ELSI Research.*

2.2. Lessons Learned

The workshop was an opportunity to hear directly from the ELSI community regarding its concerns about the program, particularly around engagement with ELSI stakeholders. The *All of Us* Research Program deeply appreciates and respects the constructive feedback received from workshop attendees. The list below identifies critical areas for fostering meaningful integration of ELSI considerations into the *All of Us* Research Program.

2.2.1. Improve Communications with ELSI Stakeholders

Attendees felt strongly that the program needs to communicate clearly and more frequently with all ELSI stakeholders. They emphasized timely and intentional interactions with ELSI stakeholders that allow for open dialogue, which can help the program address and anticipate critical ELSI issues. Importantly, the program was encouraged to continue to engage actively with participants and communities in settings where they are most comfortable, share information, solicit feedback, and hear concerns. They noted that the program should be cognizant about how information is communicated to stakeholders for broad accessibility and avoid "marketing" or "promotional" style messaging to foster meaningful dialogue and trust.

2.2.2. Leverage and Integrate ELSI Subject Matter Expertise

The attendees pointed out that the workshop could have been planned more intentionally to tap into the deep ELSI expertise gathered there. They emphasized the need to proactively leverage

the varied and rich expertise within the ELSI research community to inform how the program evolves. The potentially new terrain of ELSI encountered by the program as it grows would benefit from insights of cutting-edge ELSI research and, conversely, provide an opportunity to inform ELSI research that may help fill key knowledge gaps. At the same time, the range of expertise within the *All of Us* consortium on ELSI, health disparities, community engagement, digital health, and other topics should be brought to bear more directly on program design, implementation, and policy development.

2.2.3. Increase Transparency

Noting that some aspects of the program are perceived as a "black box," attendees encouraged the program to be transparent about its policies, processes, governance, and decision-making structures with all stakeholders, especially its participants. The program should consider multiple approaches to provide up-to-date information to ELSI stakeholders. These could include peer-reviewed publications that allow for critical evaluation by domain-specific ELSI experts. The program should also create dissemination products directed at general audiences, participants, and community partners.

2.2.4. Seek Participant Feedback on ELSI Issues

The program was encouraged to directly solicit participant perspectives on ELSI issues, including their perceptions of risks and benefits of the program and their preferences for, and experiences with, different aspects of the program, such as return of results. Although the program's participant ambassadors are and will continue to be valuable sources for feedback, the program is well positioned to gather broader and timely input from its participants, particularly for capturing diverse perspectives across groups underrepresented in biomedical research.[3] Furthermore, this information can enable ELSI research by centralizing the collection of participant perspectives. The program was encouraged to collect both qualitative and quantitative data on participant experiences and seek to understand why those perceptions are held. This would be essential for improving participant recruitment, retention, and engagement and for building long-term trust in the program.

2.2.5. Adopt a Broader Vision of ELSI Research

The attendees raised concerns that the approach adopted for the workshop conveyed a preference only for empirical ELSI research. They noted that much of ELSI research was normative, philosophical, legal, or other scholarly work and would not depend on the program's data resources. They further noted that some of the most important ELSI questions would involve studying the program itself, and precluding opportunities to do so could undermine trust in *All of Us.* The program could also benefit from, and is well positioned for, conducting ELSI

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[3] The populations the program considers underrepresented in biomedical research include the following categories: race, ethnicity, sex, age, sexual orientation, gender identity, income, educational attainment, disability, geography, and access to care. A detailed description is available on the *All of Us* Research Hub.

research internally that is timely, not dependent on external funding preferences, and targeted toward high priority questions for the program.

2.3. Considerations for American Indian/Alaska Native Participants

Significant ELSI concerns were also raised about the *All of Us* Research Program's approach for inclusion of self-identified American Indian/Alaska Native (AI/AN) participants. Attendees raised concerns about the lack of expediency in reaching out to and consulting with tribal nations and that tribal voices will not be heard. Attendees noted that the *All of Us* Research Program had not yet formally responded to the 2018 report [Considerations for Meaningful Collaborations with Tribal Populations](#) from the [Tribal Collaboration Working Group](#), a group of tribal leaders and indigenous researchers convened by the program.

Out of respect for tribal sovereignty, the *All of Us* Research Program began a formal tribal consultation process in May 2019 to better understand the views and concerns of tribal leaders and to find ways to partner in the future. This period of tribal consultation consisted of several consultations nationwide and concluded on November 30, 2019. *All of Us* has prepared a [draft report](#) summarizing the comments and questions received during consultation and sharing plans for addressing the issues raised by tribal leaders. After tribal leaders' review of the draft report, an updated report and plain language summary will be publicly posted on the *All of Us* [Tribal Engagement website](#).

Currently, the *All of Us* Research Program has participants who self-identify as AI/AN, but the program does not actively recruit participants from within the AI/AN community or on tribal lands. All data from self-identified AI/AN participants, including those who self-identify as AI/AN alone or in combination with one or more other categories, are currently withheld from data made available for research, including the public data browser and within the registered tier of the *All of Us* Researcher Workbench. Their biospecimens will not be sequenced or used for research until tribal consultation is complete and the program has shared the consultation report and a plain language summary of its plans with AI/AN participants and communities. Once the report and summary are shared, AI/AN participants will be given a period of time to consult with their respective tribes and determine whether they wish to continue participating in the program.

3. ELSI Vision and Next Steps for *All of Us*

Feedback received from attendees made clear the need for deeper and sustained interactions between the *All of Us* Research Program and ELSI stakeholders. Building on the insights from the workshop, the program has adopted a broad vision focused on meaningful engagement and communication with ELSI stakeholders with the following overarching objectives:

- Integrate ELSI stakeholder perspectives into program policy and processes
- Increase communication and transparency with stakeholders
- Enable ELSI research on the program and its data resources

The *All of Us* Research Program has initiated some activities and plans to undertake several more to help meet these objectives (detailed in Sections 3.1–3.3). The program acknowledges that the timing of these activities will vary, with some activities requiring more time and resources to implement and ensure programmatic alignment. The program will therefore continue to explore ways to prioritize these activities in consultation with consortium partners, governance bodies, and the ELSI community.

3.1. Approach for Anticipating and Integrating ELSI Considerations into *All of Us* Research Program Policies and Processes

3.1.1. Engage and Interact with the ELSI Research Community

The *All of Us* Research Program will explore ways to continue to receive input from the research community on integrating ELSI issues in practice, anticipating emerging ELSI issues, and enabling ELSI research, particularly when there are gaps in knowledge. As opportunities arise, program staff will use a variety of fora (e.g., trans-NIH bioethics working groups and seminars, national scientific conferences, national ELSI working groups) to engage with and solicit feedback on program activities and policies from ELSI researchers and other subject matter experts (SMEs).

3.1.2. Integrate ELSI Subject Matter Experts in Governance Bodies

Given its scope, the program must ensure ELSI experts are involved in programmatic planning and policy development. The program has been working to assess and recommend, where appropriate, ELSI expertise for various program governance bodies in which policies and program implementation are determined. The *All of Us* Research Program Policy Office has also facilitated *ad hoc* consultations for program task forces with ELSI SMEs from outside the program for development of policies (e.g., biospecimen access), participant surveys (e.g., disability and cognitive function survey module), and other program components. *All of Us* continues to rely on its IRB; participant ambassadors, who serve on governance bodies; ELSI expertise within awardees; and its community partners to help integrate participant and community perspectives into policy and process development. The program will also continue to use other avenues for participant input already in place, including participant experience surveys, open-ended feedback on activities, inquiries and feedback received by the participant support center, and feedback received through participant and community advisory boards of *All of Us* program partners such as the health care provider organizations and federally qualified health centers.

3.1.3. Solicit Guidance on ELSI and Policy Issues

To better leverage internal ELSI expertise, the program has established the ELSI Brain Trust, which is an internal working group composed of SMEs from the *All of Us* consortium and various NIH Institutes, Centers, and Offices (ICOs). The ELSI Brain Trust will help identify and

consult on ELSI issues for priority activities of the program, working closely with the *All of Us* Research Program Policy Office. Members help inform the program's broader ELSI and policy development activities and proactively address current and emerging policy and ELSI issues affecting participants, groups, communities, and society. The group will also help identify external SMEs who can provide feedback and guidance on different ELSI issues, including relevant research findings. The ELSI Brain Trust will advise on development of ELSI frequently asked questions, topical background research, white papers, and policy documents.

3.1.4. Identify ELSI Issues Proactively

The *All of Us* Research Program acknowledges the need for participants and other stakeholders to provide prospective and ongoing input on ELSI and policy issues. The program will explore options within the participant portal and the *All of Us* Research Hub that will allow for the collection of input—for example, by administering mini-surveys to participants and users—on key issues or when new elements of the program are planned, such as new surveys or return of different types of results. The program has established an email inbox, AOUELSI@od.nih.gov, for feedback on ELSI issues; stakeholders are welcome to reach out with questions, comments, and suggestions.

3.2. Approach for Increasing Transparency and Communicating with ELSI Stakeholders

3.2.1. Disseminate Products of the ELSI Workshop

Attendance at the ELSI workshop was by invitation only due to limited seating capacity. To increase transparency and reach a broader audience, the sessions were streamed live. Furthermore, a detailed summary of the days' events and copies of the presentations are available on the ELSI workshop website. Attendees submitted questions about the program's current approach or plans for addressing specific issues across several ELSI-related themes. These questions were compiled from written attendee feedback provided during the breakout sessions, as well as from emails submitted following the workshop. In addition to the workshop summary, program responses to the questions are available on the ELSI workshop website. This report will be shared publicly on the *All of Us* website and internally with consortium partners and NIH ICOs.

3.2.2. Scientific Meeting Panel Discussions

All of Us also recognizes the importance of national conferences for engaging SMEs, learning about the latest research findings, and anticipating ELSI issues. The program plans to participate in and organize panel discussions on key ELSI and policy issues at various national and international conferences to share experiences and perspectives and solicit feedback from ELSI researchers and other stakeholders to inform the program and its policies.

3.2.3. ELSI-Related Publications by the *All of Us* Research Program

To increase the program's transparency and allow for comments and responses, program staff and consortium members plan to submit papers, commentaries, review articles, and other peer-reviewed publications to relevant scientific journals. These pieces will focus on policies and a broad range of ELSI topics important to the program and to precision medicine research in general. The program will also continue to communicate about ELSI and policy issues to general audiences through articles (e.g., in *[Scientific American](#)*), blog posts, op-eds, and other formats in established science and media outlets.

3.2.4. Webinars

Attendees expressed interest in opportunities to dialogue with *All of Us* staff, IRB members, and participants. The program plans to host webinars on relevant ELSI topics, tailored for a broad range of stakeholders, and bring together SMEs from within the program. These webinars will be used to inform stakeholders and answer questions on program policies and their implementation. The live sessions will be recorded and archived on the *All of Us* Research Program website. The program will reach out to ELSI stakeholders through different communication networks (*All of Us* program communications, NIH mailing lists, consortium partner networks) to notify them about these events and similarly disseminate products of the webinars.

3.2.5. Listening Sessions

All of Us plans to organize thematic or topic-based listening sessions with participants, community partners, researchers, and other stakeholders periodically, to better understand their perspectives (e.g., on data privacy), concerns (e.g., about group harms), group and community priorities for research and data uses, and other emerging ELSI issues. These listening sessions may be held at national scientific conferences and organized in coordination with the meetings' scientific committees or ELSI interest groups. *All of Us* will explore holding public listening sessions across the United States to hear from a broader range of stakeholders. These listening sessions may be held in partnership with community partner organizations and may focus on broad ELSI issues or on specific aspects, such as the return of different types of results and inclusion of children and individuals with decisional impairment. Feedback from these listening sessions will be conveyed to *All of Us* leadership and relevant governance bodies in order to inform the design and implementation of the program.

3.2.6. Workshops

To collect input from the bioethics and ELSI community inside and outside of NIH, the *All of Us* Research Program will explore ways to convene mini-workshops with researchers, community partners, participant ambassadors, and SMEs to share findings of ELSI research about or relevant to the program. These workshops, potentially held in collaboration with other ELSI convenings or scientific conferences, would be organized around specific themes to allow *All of Us* to learn about the latest ELSI research and policy findings and to allow robust dialogue

between researchers and program investigators, staff, and leadership about different policies, processes, and planned program elements.

3.3. Approach for Enabling ELSI Research on the *All of Us* Research Program and Using Program Resources

The primary objective for convening the ELSI workshop was to assess ELSI researchers' interest in and the feasibility of using the *All of Us* Research Program's scientific resources for ELSI research. Although the program itself does not fund independent ELSI research, it is important to make available resources from *All of Us* that are useful to ELSI researchers in order to ensure the program's success and to enrich ELSI research overall. The program hoped that feedback from workshop attendees would help identify data types or functionalities needed to foster such ELSI research. Attendees provided valuable input on these needs but also stressed that a meaningful ELSI research agenda required *All of Us* considerations beyond data and tools.

3.4. Program Infrastructure Needed to Enable ELSI Research

The *All of Us* Research Program recognizes and appreciates the need for normative, philosophical, legal, and other types of scholarship to address the complex and evolving ELSI implications of longitudinal precision medicine research. These types of research may not need scientific data but could be informed by other types of program information, such as system metrics or metadata, details of operational practices, governance processes, or program policies. *All of Us* remains committed to exploring ways to share information with researchers and improve transparency and accountability to stakeholders.

The range and types of ELSI research questions submitted by the attendees (Appendix A) and the use cases they developed (Appendix B) demonstrate opportunities for ELSI research using program data, as well as the need for additional data, guidance, and capabilities offered by the program. The following common needs were articulated across many of the ELSI research topics proposed.

3.4.1. Policy Guidance

Many of the ELSI research questions involved gathering participants' perspectives and experiences using quantitative (surveys) or qualitative (interviews, focus groups) approaches. In many cases, this would be possible only when specific cohorts or groups of participants could be invited to participate in researchers' studies. Although recontact of program participants is currently not permitted, *All of Us* is developing policies for recontact and for ancillary studies; these policies will provide clear guidance on requirements from study investigators. The program currently has guidance on independent parallel studies, where prospective participants may choose to join *All of Us* and another research study at the same time. The interim dual consent policy provides guidelines for sites that plan to enroll participants in an unrelated but IRB-approved research study during the same visit as an *All of Us* encounter. *All of Us* is committed to ensuring that all interactions with prospective participants encourage people to

make informed decisions about participation in the program, independent of factors (incentives or risks) related to other research engagements. The program will ensure that ELSI experts' input is integrated into the development of policies for re-contacting participants for secondary or ancillary research.

3.4.2. Data Types

Attendees identified additional data types needed to enable ELSI research. For example, ELSI research exploring health disparities, health inequities, and benefits or harms to groups and communities may require geocoded data on social determinants of health at different levels (e.g., community, health system). *All of Us* is exploring ways to enhance the data in the future by linking to external data sources, such as the National Death Index and Census tract data. The program will continue to consider other sources of community and health system data, based on researcher, community, and participant feedback. The program has developed guidance about the types of data and tools that researchers can safely bring into their workspaces, including software packages for statistical analyses, phenotype algorithms, and information in public knowledge bases. Any external data or software uploaded into the workspaces must be compliant with the *All of Us* Data User Code of Conduct (DUCC). The DUCC prohibits the upload of personally identifiable information, protected health information, and identifiable private information, as well as the re-identification of participants, stigmatizing research, or any other malicious uses.

3.4.3. Technology

ELSI researchers would desire additional data collection, access to qualitative and unstructured data, and analysis tools, particularly as many studies involve collection and analysis of qualitative data. The *All of Us* Research Program requires that data collected from its participants through ancillary studies be shared back with the program and deposited in the program's data stores (e.g., raw and/or curated data repositories). The program is still exploring ways to make unstructured data available (e.g., electronic health record notes, open text responses from surveys) and carefully considering the risks of identifiability, potential impact on participant privacy, and other issues before hosting qualitative data (Dubois et al., 2018; Antes et al., 2018). *All of Us* anticipates that such data may be made available only in the controlled tier of the Researcher Workbench. The requirements for accessing the controlled tier are still being developed.

The program also recognizes the need for tools to collect and conduct qualitative analysis on data for ELSI research and is exploring options for data users to bring their own tools for analysis into their authorized workspaces. The program will also investigate integration of standard qualitative analysis tools (e.g., NVivo) into the Workbench. Other functional capabilities requested by workshop attendees included distribution of additional surveys directly through the program and chat features where qualitative data could be collected directly and anonymously from participants.

4. Conclusion

The ELSI Workshop was a valuable and productive forum in which the *All of Us* Research Program received candid and constructive feedback from diverse stakeholders. The discussion highlighted a range of viewpoints and the insights the program gained have complemented and shaped its vision and approach for integrating ELSI within *All of Us* through design, policy, processes, and stakeholder engagement. As a result, the program has begun developing and will continue to build additional pathways for transparency, engage in bidirectional communications with its stakeholders, and solicit feedback on the development and implementation of its activities in a thoughtful way. The program will also proactively seek insights from both anticipatory and translational ELSI research to address current and emergent ELSI challenges to improve the program and build a better future for health research and care.

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Glossary

AI/AN   American Indian/Alaska Native

CAPS   Committee on Access, Privacy, and Security

dbGAP   database of Genotypes and Phenotypes

DUCC   Data User Code of Conduct

DV   direct volunteer

EHR   electronic health record

ELSI   Ethical, Legal, and Social Implications

HHS   Department of Health and Human Services

HPOs   health care provider organizations

ICOs   Institutes, Centers, and Offices

IRB   institutional review board

NIH   National Institutes of Health

PCORI   Patient-Centered Outcomes Research Institute

PMI   Precision Medicine Initiative®

RAB   Resource Access Board

SGM   sexual and gender minority

SME   subject matter expert

UBR   underrepresented in biomedical research