Innovation in Large-Scale Research Programs: Elevating Research Participants to Governance Roles Through the All of Us Research Program Engagement Core

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Abstract

Problem

Despite the successes of community-engaged research in advancing research relevance and health equity for diverse communities, the impact of this research has been limited to local and regional programs. Engaging diverse community voices in large-scale, national research programs represents a paradigm shift in biomedical research. Still, disconnects remain between research decision makers and the communities they serve, impeding richer, bidirectional engagement.

Approach

An engagement core team was established within National Institutes of Health All of Us Research Program (AoURP) in 2018 to synthesize community-engaged research practices and establish infrastructure

that operationalizes diverse research participant engagement. The authors integrated research participants as "participant partners" within the AoURP governance, an approach that is embedded into the engagement core's 3 aims: (1) integrate a diverse pool of participants into the program, (2) identify and meaningfully engage a cadre of diverse participants into program governance, and (3) assess the impact of such engagement on research. Participant partners are compensated as consultants at approximately $50/hour.

Outcomes

As of August 2022, more than 515,000 individuals consented to participate in the AoURP, with more than 49% representing racial/ethnic minorities. The authors invited participants to self-nominate if interested in

engaging in research working groups, decision making, and governance. Also, consortium partners nominated individuals on AoURP community advisory and/or participant advisory boards to serve as participant ambassadors. Ten individuals were selected as participant partners for the 2022–2025 term. Eight serve on the steering committee; of those, 4 serve on the executive committee; 2 more serve on the advisory panel. An additional 23 serve as participant ambassadors.

Next Steps

The authors continue to increase the number of research participants serving as engaged partners in the program. Engagement approaches will be systematically evaluated with the goal of adoption by other large-scale research programs.

Problem

The perspectives of participant stakeholders outside of academia and local power structures offer unique insights to researchers. Researchers co-learn with diverse community

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participants and gain valuable feedback salient to and informed by members of marginalized communities.[1–3] Community-engaged research (CEnR) goes beyond treating research participants as enrollment targets to engaging them as partners, encompassing shared decision making and ownership of the processes and products of research.[1–3]

The infrequent and narrow use of a participatory approach in research is insufficient and problematic. Participant engagement is typically limited solely to unidirectional recruitment procedures or study-finding dissemination, creating lost opportunities for bringing participant perspectives into the operating aspects of a research study.[4] Furthermore, engagement goals must differentiate from recruitment goals, which focus on study enrollment and are incongruent with a community-centric, bidirectional approach. Enabling broader engagement can give rise to collaboration among the research

participants and researchers and increase research relevance.

The All of Us Research Program (AoURP), a component of the National Institutes of Health (NIH) Precision Medicine Initiative, is a longitudinal cohort study designed to accelerate health research by exploring the relationship between health, lifestyle, environment, and genetics. Research participants are asked to share their health information, including biospecimens and medical records, for use in precision medicine studies.[5] Precision medicine is individualized treatment that takes into consideration genetics, geography, sexuality, and other factors that make us individuals.

The AoURP has prioritized recruitment to address the lack of participants from populations historically underrepresented in biomedical research, endeavoring to establish a pool of 1 million research participants from diverse cohorts. As of August 2022, more than 515,000 individuals have enrolled in the AoURP, with more than

49% representing racial/ethnic minorities. The program aims to transcend recruitment efforts alone to ensure meaningful engagement. Key to this is the development of sustained engagement across the research lifecycle of a select subset of individuals from the larger pool of research participants. This smaller group of research participants also serve in governance roles in the program and contribute across the research spectrum, including study operations, selection of priority topics and research questions, decision making, study oversight, development of data collection materials and analytical strategies, and drafting and disseminating the publication of findings.[1] This level of engagement is rarely implemented in large research programs, limiting their scale and the value of the data collected.[6]

Approach

Embedding engagement practices within the AoURP presented 2 challenges: (1) creating infrastructure to coalesce the science of CEnR and (2) emphasizing engagement strategies as distinct from recruitment strategies. In this Innovation Report, we briefly describe the formation in 2018 of an engagement core, a team employed to synthesize CEnR practices and establish an infrastructure to facilitate the full integration of a representative cohort of participants as partners into the governance and oversight of research programs. We then detail how the engagement core identified a cadre of "participant partners" to serve in governance roles across the research enterprise and the methods used to bring the participants' voice into the public-facing research program initiatives.

The engagement core, consisting of a total of 6 researchers and staff at Vanderbilt University Medical Center, implements national engagement efforts with participant partners for the AoURP. The aim of our core is the cocreation of research programs that reflect the diverse needs, preferences, and priorities of the AoURP participants, inclusive of the range of age, racial, ethnic, geographical, sexuality, and health statuses of individuals in the United States. Our core includes leaders with experience in CEnR, health equity, precision medicine, biomedical ethics, engagement methodology, and impact evaluation techniques.

We employed a multilevel engagement plan engendering participant involvement across the engagement continuum from brief, targeted input to in-depth, ongoing participation in governance. Successful integration of stakeholders into the governance structure required deliberate strategies to overcome inherent barriers to the partnership process (e.g., subtle group norm differences, lack of common language, power differentials).[7]

We built the engagement infrastructure using sequential steps, with each step conditional upon the previous step. These steps were (1) identify a national cadre of participant partners to serve on governance groups; (2) provide the participant partners clear expectations, robust resources, and appropriate compensation; (3) provide adequate preparation (onboarding) to ensure meaningful engagement and effective bidirectional communication; and (4) convene participant partners through forums that provide a supportive environment for an ongoing exchange of ideas. We describe the various governance groups in Table 1.

To ensure participant partners reflect the diversity of the AoURP,[8] best practices included job descriptions emphasizing the importance of diversity, application and nomination forms with items for individuals to identify the communities and perspectives they represent, and established selection criteria prioritizing diversity and inclusion of perspectives not already represented in the program.

Participant partners were invited to nominate themselves if they were interested in engaging in research working groups, decision making, and governance roles. Nominations were made using an online form disseminated via the February 2018 AoURP participant

Table 1
Terminology, Abbreviations, and Definitions: Research Participant Partner Engagement Methods in the All of Us Research Program

Governance group	Participant partner representation; term; compensation	Function and role for the self-nominated participant partners
Steering committee	8 of ~200 voting members; 3-year term; $5,000 per year	These individuals serve on the primary governance body comprising awardees and National Institutes of Health (NIH) representatives. With other stakeholders, they: set strategic directions for research programs and coordinate overall operations; oversee governance groups established to develop, recommend, and implement policies and processes adopted through the governance structure; and troubleshoot difficult issues.
Executive committee	4 of ~20 voting members; 3-year term; $8,000 per year	4 of the 8 individuals on the steering committee also serve on the executive committee. With other stakeholders, they ensure that the AoURP effectively meets its objectives and mission to address and find solutions to challenges and obstacles and to provide the senior leadership (chief executive officer, chief operating officer, chief engagement officer) with options and information to help make final programmatic decisions.
Advisory panel	2 of ~19 external advisors; 3-year term; $5,000 per year	These individuals serve on this external advisory group that develops options, gives feedback, and evaluates AoURP activities. Members are selected by the chief executive officer of AoURP based on expertise in areas relevant to the goals of the program's mission. Advisory panel members may also set up smaller working groups to consider and provide feedback on specific topics.
Participant ambassadors	20 to 30 nonvoting advisors; 3-year term; $4,200 per year	These individuals are nominated from community advisory boards at regional community or provider organizations that participate in AoURP. Service includes providing feedback on tools, processes, and applications; also serving on governance groups including committees, boards, task forces, and brain trusts.

Abbreviation: AoURP, All of Us Research Program.

newsletter. Concurrently in February 2018, individuals who were on AoURP community advisory boards and/or participant advisory boards were nominated by consortium partners to serve as participant ambassadors. The individuals who were selected as participant partners served on the steering committee, executive committee, and advisory panel. Participant ambassadors only served on governance groups and not the steering committee or executive committee. Two current advisory panel members were a part of the participant ambassador cohort formed in 2018, which reinforces the idea of sustained engagement and ongoing growth.

The engagement core performed a blind review of the essay portion from all applications. Reviewers rated applicants highly if their essay included experience and/or interest in working with diverse populations. Applicants were then ranked with preference for diversity with respect to race and ethnicity, geography, and age. The top-ranked candidates participated in interviews and were scored using a scale ranging from 0 to 4: not able to assess (0), poor (1), fair (2), good (3), excellent (4). Interviews were conducted by 1 engagement core member and 1 staff member from the AoURP division of engagement. The overall score was an average of ranking on the following 6 domains:

- Enthusiasm about their own health and that of future generations

- Experience working with people from different backgrounds

- Experience in governance/oversight committees

- Representation of a diverse population

- Background/life experience fit to participant partner responsibilities

- Leadership potential

Once participant partners were selected, we followed a careful onboarding process. We provided the participant partners: (1) documents detailing roles and expectations, (2) documents about the AoURP, and (3) engagement liaisons experienced with patients and individuals from underserved communities.[9] The liaisons serve as colleagues to participants in governance, with a liaison–participant partner ratio of 2:33. They maintain

consistent contact and are available before and after meetings to answer questions, explain technical jargon and acronyms, and identify issues that would benefit from participant perspectives.

During the orientation sessions, we reviewed the roles and expectations of the engagement core members and the participant partners, and we reviewed the core values of the AoURP. Then we discussed how we were prepared to meet the respective needs and preferences for each participant partner with resources such as training on web conferencing or providing documents with large print or Section 508-compliant materials. The orientation lasted 1 hour and included time for question and answers.

Participant partners are compensated for the time they spend preparing for and participating in meetings and reviewing materials on behalf of the program. Appropriate compensation is a key component of effective engagement. Lack of compensation undervalues participant contributions to the research.[2] Best practice for community members serving on governance and advisory boards for research programs suggests compensating each based on role and on the frequency of meetings. Participant partners are currently compensated as consultants at approximately $50/hour; the amount of compensation is reviewed annually.

Members of the AoURP consortium also ask the participant partners to conduct reviews to assess a variety of tools, documents, and messaging. For example, they may be asked to review protocols, procedures, communications materials, and imagery; materials written in Spanish; and mobile applications. These reviews leverage the diversity of the research participants' accumulated experiences and knowledge, threading cultural congruency throughout all activities. Vital to this engagement strategy is the inclusion of different perspectives based on geography, gender and sexual orientation, age, race, ethnicity, ancestry, environments, and health status.

We appreciate that few, if any, research participant partners are as informed as the staff on the research teams who are deeply involved in the AoURP activities; to fill this knowledge gap, the engagement core employs strategies to share key program information to enable

participant partners to meaningfully contribute their perspectives. Indeed, as voting members of governing panels, the participant partners are expected to share ideas freely as peers.

To facilitate such an environment, the participant partners also convene in separate sessions with their cohort to discuss any barriers to engagement and consider solutions to overcoming challenges. These activities include monthly web-based meetings led by 2 participant ambassadors as elected cochairs and 1 engagement core member; regular, plain-language program updates; a session solely for all participant partners at the annual AoURP meeting; and funds to support participant-led innovations and activities. These activities enhance communications, strengthen trust, and increase perceptions value.

Outcomes

There have been 2 selection processes for participant partner and participant ambassador positions: one for individuals serving a 3-year term starting in 2018 and another for individuals serving a 3-year term starting in 2022.

In 2018, the top 6 candidates of 21 interviewed were offered participant partner positions with 3-year terms (2018–2021). Four joined the steering committee and, of those, 2 served on the executive committee. The other 2 joined the advisory panel. All 6 completed their terms, validating the selection and onboarding processes and demonstrating the underlying value of tapping into the commitment of the participant partners. An additional 19 individuals were selected as participant ambassadors.

In 2021, in response to increasing need for participant involvement in governance groups, the AoURP chief executive officer called for an increase in participant partner representation. We repeated the selection process, drawing the cadre of participant partners from a pool of 150 individuals who participated in the research program and responded to an invitation to self-nominate, and doubled representation on the steering and executive committee. Eight new participant partners joined the steering committee, and 4 of those 8 also joined the executive committee. Two existing participant ambassadors who had

Table 2
Impact of Engagement on All of Us Research Program Processes and Materials

Area of impact	General examples of change	Specific changes from participant partner input[a]
Infrastructure and preresearch activities	• Create policies to enable engagement • Prioritize research topics and questions • Develop capacity to engage • Identify priority populations	Input led to implementation of required "Responsible Conduct of Research" training for All of Us researchers and module revisions to key themes (harms to groups and communities, cultural sensitivity, and race and genetics).
Research design	• Select tools, comparators, and outcomes • Provide input on research methods • Input on cultural appropriateness and relevance • Increase the diversity/representativeness of participants • Create and refine guidelines and policies with the Access to Participant Policy Task Force	Feedback on Social Determinants of Health Survey tool led to changes to mitigate mistrust and health literacy concerns.
Implementation of research	• Tailor materials to specific populations • Identify best approaches to recruitment and retention • Refine enrollment and consent processes • Guide development of return of information process • Create participant-centric awareness campaign	Feedback on the All of Us *COVID Participant Experience* (COPE) survey led to recasting the offer of a cloth mask as a thank-you for survey participation rather than as a nonmonetary incentive.
Analysis of data	• Provide an alternative interpretation of the research results (especially those that are counterintuitive) • Bring attention to factors (confounders) that may not have been measured or documented in the literature • Interpret/assess the plausibility of the results • Provide context for relevance to stakeholders	Input led to changes in the appearance and details of the genetic, health-related, and ancestry results in the patient portal.
Dissemination and use of research	• Advise on audiences and venues for dissemination • Create companion materials for dissemination (e.g., videos, newsletters, brochures, handouts) • Increase social media engagement • Provide input on appropriate message delivery • Coauthor manuscripts • Use program in public health programs, community organizations, and citizen scientists	Two participant partners who served on the Steering Committee coauthored and published a paper with All of Us leadership.[5]
Researchers, participant representatives, and communities	• Build perception that participant and community input is needed • Build perceptions that participating in research is valuable • Improve trust in research and academia • Increase diversity and representativeness of teams • Researcher knowledge and attitudes on engagement • Willing to collaborate	The Participant Feedback on the Value of Research Information assessment, which was developed by participant partners, was completed by over 20,000 All of Us participants, increasing understanding of the specific preferences for receiving health-related program data.

[a]Specific examples of change based on direct participant partner input as part of the bidirectional model of engagement to improve biomedical research.

completed the 2018–2021 term advanced to the advisory panel. An additional 23 individuals were selected as participant ambassadors.

So, for the 3-year term 2022–2025, the engagement core identified and onboarded 33 diverse study participants to serve in governance roles through the AoURP, ensuring inclusion of diverse and underrepresented cohorts. Many of these 33 individuals were between 51 and 65 years old when they started in their roles (n = 14; 42.4%). More than half of the group members self-identified as female (n = 18; 54.5%), 13 (39.4%) as African Americans, and 5 (15.1%) as a sexual gender minority. Thus, as of 2022, at the highest level of governance in the research program,

8 research participants served as full voting members of the 200-member steering committee, and 4 of those 8 served on the 20-member executive committee; 2 more served as members of the 19-member advisory panel. The remaining 23 served as participant ambassadors.

We have identified areas of impact[10] and examples of changes that resulted from participant engagement (Table 2). We devised a process for consortium members to bring critical program-related issues to the participant ambassadors to solicit their perspectives, ideas, and feedback on possible solutions to these issues. Between February 2019 and April 2022, 45 requests for review were submitted

and completed by the participant ambassadors.

Some of the reviews included:

• Offering strategies to improve the communications between the NIH and the AoURP participants around data privacy and rights.

• Providing feedback on campaign materials being used in the public space to maximize engagement and inclusiveness.

• Evaluating English and Spanish genomics public health campaign assets (fact sheets, infographics, and videos) aimed to encourage AoURP participants to allow the program to study their DNA and to

select whether they want to receive information about their DNA.

- Engaging in COVID-19 efforts through the COPE (The *COVID Participant Experience*) survey to better understand the effects of the pandemic on participants' physical and mental health.

- Reviewing content feedback on the accessibility, tone, message, and clarity of the genomics return-of-results assets.

The incorporation of the feedback of research participants—who are experts in their lived experiences and their community's needs—is authentic, not performative. It has the long-term potentiality to transform sound biomedical science to more informed understandings of health disparities to achieve health equity and the identification of future actions (e.g., interventions, policies, clinical practices) that are relevant and culturally congruent.

Next Steps

We will continue to offer additional opportunities for governance engagement. We are developing and implementing a process to measure engagement across the infrastructure, which is critical to assess the impact of participant engagement in the AoURP; specifically, we want to directly assess participant involvement in the governance, implementation, and dissemination of research, as well as the perceptions of the value of engagement and trust.[4] The engagement core team has implemented an innovative and comprehensive engagement model that has integrated participants as stakeholders across the engagement continuum, with a focus on equity and upstream inclusion. This engagement

contribution has the critical mass to inform future research in precision medicine and genomics. Plans include developing, testing, and scaling the model as a potential intervention component of evidence-based engagement. Our early successes demonstrate the feasibility of engaging participants as partners in research, thus helping to narrow existing gaps in engagement.

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