Participants as Partners in the All of Us Research Program

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Overview

- *All of Us* has a comprehensive approach to engaging participants, communities, health care providers, and other stakeholders.
- Engagement is distinct from recruitment and retention.
- Engaging **participants as partners** is expected to make the research more relevant to participants and communities and speed the translation of discoveries into practice.
Engagement
Involve stakeholders in study selection, design, conduct, and/or dissemination

Recruitment
Enroll in study
The Recruitment Continuum

Awareness  Acceptance  Consent  Enrollment  Retention  Return of Results

Wilkins 2016
Vanderbilt Recruitment Innovation Center
All of Us Research Program Engagement Core

Mission:
Engage “participants as partners” in the oversight, design, and conduct of the All of Us Research Program
AoU Engagement Core

Consuelo H. Wilkins MD, MSCI  Karriem S. Watson, DHSc, MS, MPH  Laura Beskow, PhD, MPH  Elizabeth G. Cohn, PhD, RN  Alecia Fair, DrPH

Selena McCoy Carpenter, MEd  Juan Escarfuller, MA, MDiV  Kathleen Brelsford, PhD, MPH  Catherine M. Hammack, MA, JD  Melinda Aldrich, PhD

All core members are at Vanderbilt University Medical Center – except for Dr. Watson at University of Illinois in Chicago and Dr. Cohn at CUNY and Columbia.
All of Us Engagement Core Aims

Create infrastructure to fully integrate participants in all aspects of All of Us

Identify and meaningfully engage diverse participants in governance

Assess impact of engagement in All of Us Research Program
Engagement Core Guiding Principles and Domains

- Participants reflect the broad **diversity** of the US: geographic, racial, ethnic, gender, cultural, health status, and sexual identity.
- We provide **clear expectations and resources** to participate fully.
- We provide **communications and resources** based on participants’ needs and preferences.
- Participant representatives receive **appropriate compensation** for their time.
- We use **engagement strategies** that are distinct from enrollment and recruitment, reflecting **mutual respect, trust, and cultural humility**.
- We arrange **travel and pay in advance** to reduce participants’ burden.
All of Us Research Program Engagement Core

Current Initiatives
- Steering Committee
- Executive Committee
- Participant Ambassadors
- Advisory Panel
- Director’s Think Tank

Planned initiatives
- Participant Polling
- Engagement Studios
Participants as Partners
Steering Committee, Executive Committee, Advisory Panel

- Steering Committee: 4; Executive Committee: 2; Advisory Panel: 2
- Full members – attend meetings, vote, etc.
- Selection Process
  - Announced in participant newsletter February 2018
  - Full participants self-nominated
  - Blind review of personal statements
  - Interviewed 15 participants
  - Selections prioritized to include diverse backgrounds
Participant Ambassadors

- Individuals from 15 states: FQHCs (6), Health Provider Organizations (10), VA (3), DV (3)
- Nominated by engagement leads; from their respective Community and/or Participant Advisory Boards
Participant Partners in Governance

1. Participant Provided Information
   - Modules
   - Survey Completion
   - Pediatric Operations

2. Special Populations
   - Digital Health Technologies

3. Access, Privacy, and Security
   - Biospecimen Access Policy
   - Omics
   - Science

4. Steering Committee
   - Executive Committee
   - Assay IRB Submission

5. Director

6. Participants Eval & Assessment
6. Resource Access
6. Publications
6. Incident Notifications

KEY

- Committee
- Board
- Task Force
In Planning Process

Modified June, 2019
Director’s Think Tank

• **Purpose**
  - Small group of individuals who live in DC area to provide feedback directly to AoU leadership
  - Help shape new approaches
  - Overcome challenges
  - Advance AoU mission

• **Selection Process**
  - Engagement Core performed blind review of nominator’s short essay
  - Nominees ranked with preference to diversity and experience with working with diverse populations
October 2018

- Participant Partner Retreat
- Director’s Think Tank in-person meeting
- Joint session with AoU Steering Committee
Multi-pronged approach to evaluation: quantitative, qualitative, objective

- Participant Partner evaluation of engagement
- Leaderships’ evaluation of engagement
- Mentorship evaluation (Steering Committee)

- Assessing AoU leaders, researchers, staff readiness for engagement
- Assessing Working Group Chairs’ perceived need for engagement

- Blind review of meeting minutes
- Tracking timestamp of when participants receive meeting materials
- Pre-post comparison of how documents change after engagement
3-5 questions

1. How can we ensure that perspectives of participants are proactively sought and considered at all levels of AoU?

2. When measuring the success of participant engagement, what are the most important outcomes to assess?

3. How can we work together to get researchers to value the science of engagement – not just the impact on recruitment/retention?
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**CONTEXTS**
- Socio-Economic, Cultural, Geography & Environment
- National & Local Policies/Trends/Governance
- Historic Collaboration: Trust & Mistrust
- Community/Individual Capacity & Readiness
- Researcher/Organization Capacity & Reputation
- Health Issue/Program Importance
- Fairness/Equity in Prior Research

**PARTNERSHIP PROCESSES/DYNAMICS**
- Individual Characteristics
- Relationships
- Partnership Structures

**ENGAGEMENT**
- Processes
- Outputs
- Integrating Cultural Knowledge
- Empowering Processes
- Partnership Synergy
- Culturally-centered Program
- Appropriate Research Design

**OUTCOMES**
- Intermediate
  - Community/Participant-Centric Research
  - Meaningful and Effective Partnerships
  - Empowered Communities & Participants
  - Individual, Community & Researcher Capacity
  - Research Productivity
- Long-term
  - Community Transformation
  - Research Transformation
  - Health/Health Equity

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**Conceptual Framework Engagement in Precision Medicine.** Adapted from Wallerstein and Duran by Menon, Szalacha, Cohn, Watson, Wilkins 2017
A comprehensive approach to evaluating engagement

Table 5. Evaluation Plan: Indicators of Success

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<tr>
<th>Aim</th>
<th>Successful Processes</th>
<th>Successful Outcomes</th>
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| Establish the infrastructure to fully integrate participants and advocates into the governance and oversight of the *All of Us* Program. | • Engaged a representative sample of Program members in the nomination, selection, onboarding, mentoring and succession planning for the outcomes  
• Provided appropriate compensation for representatives  
• Ensured equitable opportunities to participate that account for time and effort of representatives | • Appointed participants and advocates to key positions through a participatory process  
• Established and implemented an on-boarding plan for appointees  
• Developed a succession plan for alternate and renewal appointments |
| Facilitate ongoing input from diverse participant representatives to enhance the design, implementation, and use of the *All of Us* Program. | • Jointly identified engagement strategies and populations  
• Engaged expert advisors to identify individuals from underrepresented groups to participate in activities  
• Ensured equitable opportunities to participate that account for time and effort of representatives  
• Provided appropriate compensation for representatives  
• Implemented course-corrections as necessitated | • Established and implemented onboarding plan  
• Implemented engagement of individuals from pool of diverse representatives in activities such as input on protocols and communications  
• Implemented process for convening panels to assist with language translations; and providing feedback on tools, processes and applications. |
| Assess the impact of participant engagement on *All of Us* Program design, conduct, and use, and on participant representatives, advocates and partner organizations. | • Consistently measured engagement over the 5 years.  
• Track changes to the Program based on engagement of participant representatives and partner organizations  
• Provided compensation for representatives  
• Measured the expectations of engagement of the Program team and participant representatives  
• Measured changes in capacity & personal development for participants, researchers, and organizations | • Documented positive impacts (such as higher trust, culturally-congruent protocol processes) on the Program and participant representatives,  
• Developed and disseminated a tool-kit for engagement plans for future endeavors such as the *All of Us* Program.  
• Documented that expectations and aspirations were met for Program staff |
**All of Us Engagement Core Aims**

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| • Core  
  • Steering Committee  
  • Executive Committee  
  • Participant Ambassadors  
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  • Director’s Think Tank |

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| • Monthly meetings  
  • Participants voting members of SC and EC.  
  • Participant Ambassadors on 11 governance groups  
  • Continuous input and evaluation on AoURP processes, products and engagement experience. |

| Specific Aim 3  
Assess impact of engagement on research; develop metrics to inform *All of Us* as well as future large-scale research programs |
| --- |
| • Readiness to Engage measure  
  **Future Initiatives**  
  • Return of Results Survey  
  • Community Engagement Studios |