

ELSI Workshop
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All of Us
RESEARCH PROGRAM | The
Future of
Health Begins
With You

Engagement Priorities for the *All of Us* Research Program



Consuelo H. Wilkins, MD, MSCI
Vice President for Health Equity
Vanderbilt University Medical Center
@DrCHWilkins

Overview – *All of Us* Engagement Priorities

- *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.

Core Values Mandated Engagement

1. Participation is **open** to all.
2. Participants reflect the rich **diversity** of the U.S.
3. Participants are **partners**.
4. Trust will be earned through **transparency**.
5. Participants will have **access** to their information.
6. Data will be accessed **broadly** for research purposes.
7. Security and privacy will be of **highest** importance.
8. The program will be a catalyst for positive **change** in research.



Comprehensive Engagement Strategy

- ***All of Us* is engaging organizations across the U.S.**
 - **Engagement Partners:** Trusted national and regional community organizations and health care provider organizations
 - Increase awareness of *All of Us*; some educate providers
 - **Champions:** Community and health advocacy organizations
 - Increase awareness of *All of Us*

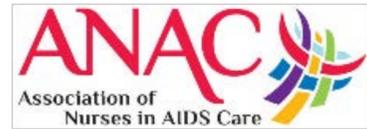


*Dara Richardson-Heron, MD
Chief Engagement Officer*



Photo: CPGI meeting May 2019

All of Us Community and Provider Partner Network



Comprehensive Engagement Strategy

Key Engagement Partners

- HCM Strategies, LLC
- Delta Research and Educational Foundation
- FiftyForward
- National Alliance for Hispanic Health
- PRIDEnet (Stanford, formerly SFGH)
- Engagement leads at all enrollment sites
- Vanderbilt Engagement Core





Engagement

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Recruitment

Engagement is Distinct from Recruitment and Retention

Goal of Engagement: Involve stakeholder in some aspect of study selection, design, conduct or dissemination

Goal of Recruitment: Enroll in study

Goal of Retention: Keep participant in study until completion

Although the goal of engagement is recruitment, engagement often enhances recruitment and retention

The Recruitment Continuum



Wilkins and Johnson 2016

What is engagement?

Engagement: A bidirectional relationship/interaction that results in informed decision-making about matters that affect or have the potential to affect the stakeholder group.

Engagement requires trust, respect, and cultural humility

Why engage the communities?

There is no substitute for the lived experience.

Community members, health care consumers and patients provide unique and invaluable insights, which can make all aspects of care, research, and medical education more relevant, credible, and effective.



Engagement

Patient collaboration

Co-design

Participatory research

User-centered design

HOW CAN I PARTICIPATE?

..... varying terms used for engagement, but not all are created equal.....

Partnership

1 RECONTACTABLE. PROVIDE YOUR CONTACT INFORMATION:

Community Design

2 Public and patient involvement

GET A MEDICAL SCREENING. SIGN UP FOR HEALTH ASSESSMENT VISIT.

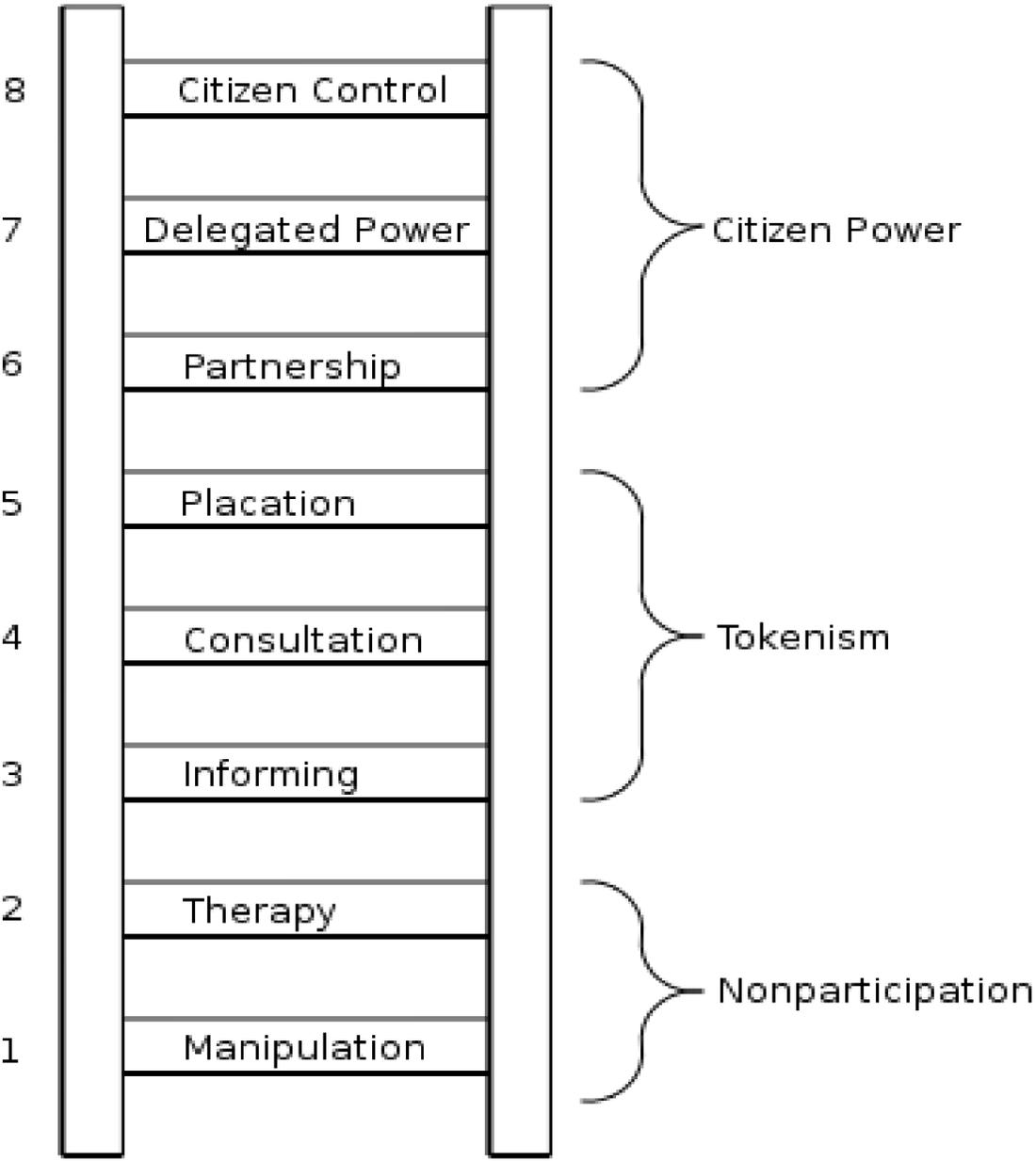
3 Co-production

SUBMIT BIOSPECIMEN. FIND A LOCAL COLLECTION SITE.

Empowerment

4 AUTHORIZE MEDICAL DATA EXCHANGE WITH INFORMATION FROM YOUR DOCTOR'S OFFICE.

The history of community engagement



Increasing Level of Community Involvement, Impact, Trust, and Communication Flow

<i>Outreach</i>	<i>Consult</i>	<i>Consult</i>	<i>Collaborate</i>	<i>Shared Leadership</i>
<p><i>Some Community Involvement</i></p> <p><i>Communication flows from one to the other, to inform</i></p> <p>Provides community with information.</p> <p>Entities coexist.</p> <p>Outcomes: Optimally, establishes communication channels and channels for outreach.</p>	<p><i>More Community Involvement</i></p> <p><i>Communication flows to the community and then back, answer seeking</i></p> <p>Gets information or feedback from the community.</p> <p>Entities share information.</p> <p>Outcomes: Develops connections.</p>	<p><i>Better Community Involvement</i></p> <p><i>Communication flows both ways, participatory form of communication</i></p> <p>Involves more participation with community on issues.</p> <p>Entities cooperate with each other.</p> <p>Outcomes: Visibility of partnership established with increased cooperation.</p>	<p><i>Community Involvement</i></p> <p><i>Communication flow is bidirectional</i></p> <p>Forms partnerships with community on each aspect of project from development to solution.</p> <p>Entities form bidirectional communication channels.</p> <p>Outcomes: Partnership building, trust building.</p>	<p><i>Strong Bidirectional Relationship</i></p> <p>Final decision making is at community level.</p> <p>Entities have formed strong partnership structures.</p> <p>Outcomes: Broader health outcomes affecting broader community. Strong bidirectional trust built.</p>

DHHS. Principles of community-engagement. 2nd Ed. 2011.
http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf

Sherry R. Arnstein, Ladder of citizen participation. 1969.

Engagement prior to *All of Us* launch

Precision Medicine Initiative Pilot Community Engagement Studios (4/29/16 – 10/31/16)

- **77 Studios**
 - 60 were part of the Pilot
 - 17 with FQHCs (CT, TN, SC, NY, MS, CA)
- **654** community members
- Avg **8.5** community members/studio
- **46%** self-identified as a racial/ethnic minority
- **9%** self-identified as a sexual or gender minority



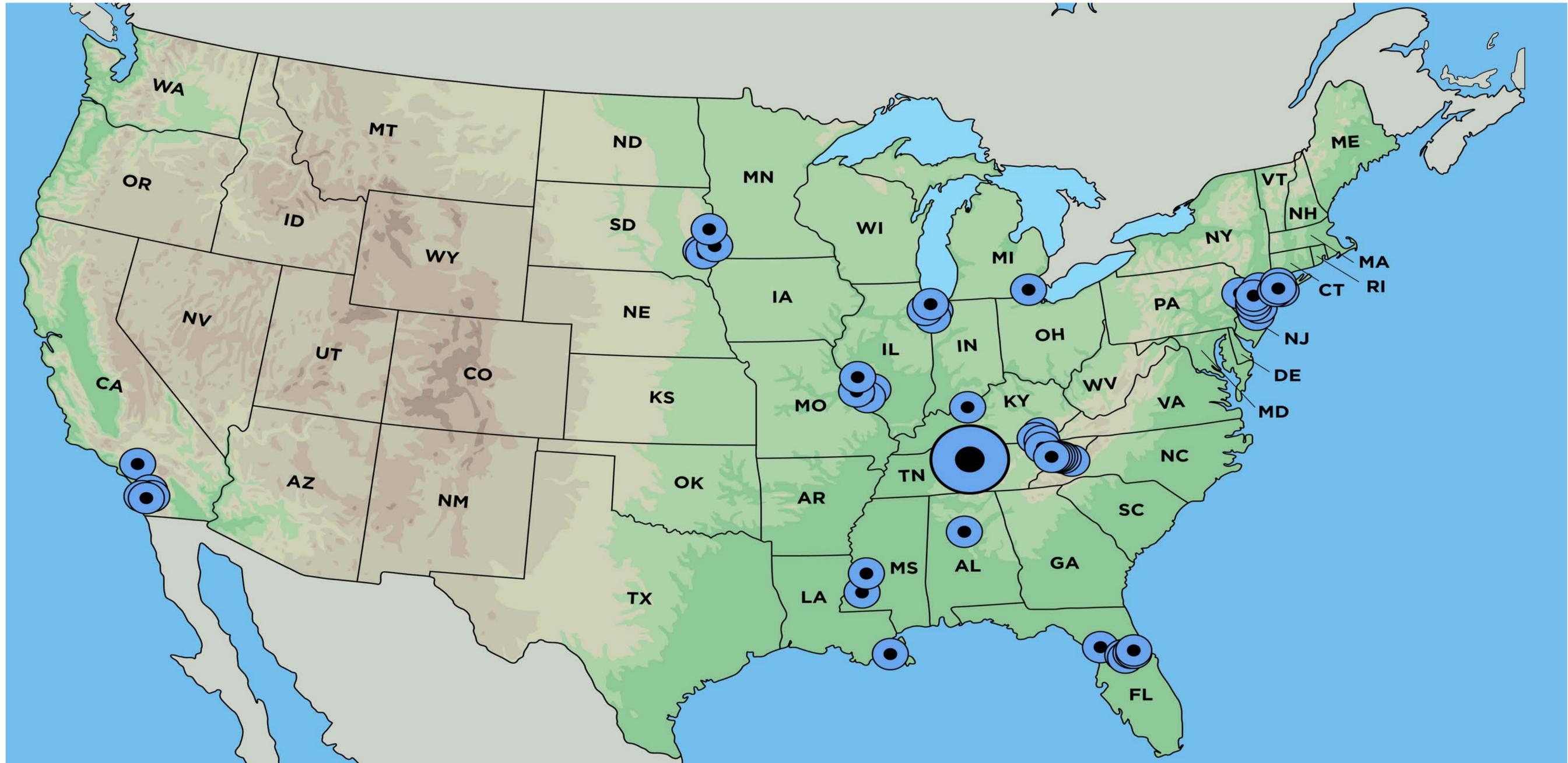
Joosten YA, Israel T, Williams NA, Boone LR, Schlundt D, Mouton CP, Dittus RS, Bernard G, Wilkins CH. Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input from Stakeholders to Inform Research. *Academic Medicine*. 2015 Dec; 90(12): 1646–50.

Johnson DA, Joosten YA, Wilkins CH, & Shiao CA. (2015) Case Study: Community Engagement and Clinical Trial Success: Outreach to African American Women. *Clinical and Translational Science*. 2015 Aug; 8: 388–390.

Vanderbilt PMI Pilot Community Engagement Studios

77 Studios; N= 654; Racial/Ethnic Minorities: 46%

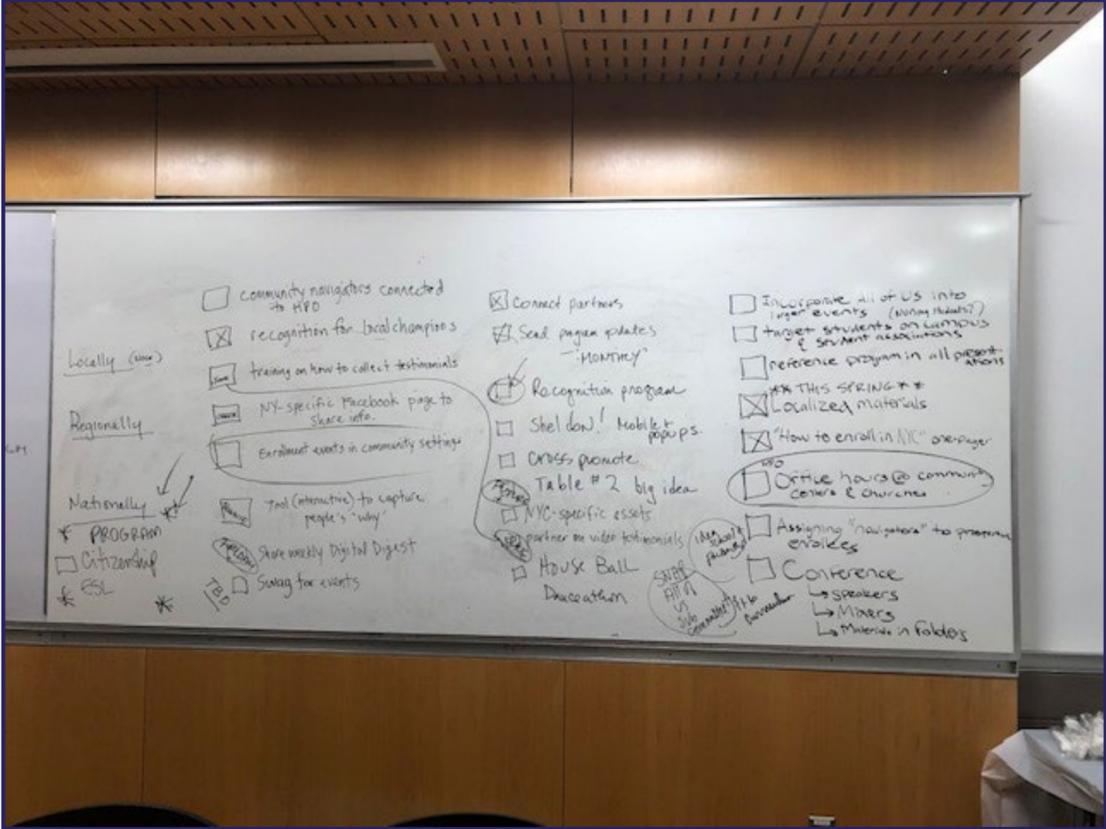
April 29, 2016 - October 31, 2016



Engagement prior to *All of Us* launch

September 2016 – National Community Partners meeting

Lead by: HCM Strategies and NYC Precision Medicine Consortium



Engagement prior to *All of Us* launch

Inaugural Steering Committee members
Selection process November 2016
Appointed early 2017



Patricia Butts



Steve Mikita



Karl Surkan

AoU Engagement Core– PI: Consuelo H. Wilkins, MD, MSCI



Consuelo H. Wilkins MD, MSCI



Karriem S. Watson, DHSc,
MS, MPH



Laura Beskow, PhD, MPH



Elizabeth G. Cohn, PhD, RN



Kathleen Brelsford,
PhD, MPH



Alecia Fair, DrPH



Catherine M.
Hammack, MA, JD



Selena McCoy
Carpenter, MEd



Juan Escarfuller, MA, MDiV

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 Research Program Engagement Core

Mission:

Engage “participants as partners” in the oversight, design, and conduct of the *All of Us* Research Program



All of Us Research Program Engagement Core

Specific Aims:

- . Create infrastructure to fully integrate participants in all aspects of the research
- . Identify and meaningfully engage diverse participants in governance
- . Assess impact of engagement on research; develop metrics to inform *All of Us* as well as future large- scale research programs

Current Participant Partner Initiatives



Future initiatives



Participants as Partners: Multi-level Engagement

Engagement Method	Role	Key Dates
<i>All of Us</i> Steering Committee (n= 4)	Member of <i>All of Us</i> Steering Committee; provides participant perspective	Selected 4/6/18
<i>All of Us</i> Executive Committee (n= 2)*	Member of <i>All of Us</i> Executive Committee; provides participant perspective	Selected 4/6/18
<i>All of Us</i> Advisory Panel (n=3)	<i>All of Us</i> Advisory Panel; provides participant perspective	Selected 4/6/18
Participant Ambassadors (n=24)**	Participant representatives from each HPO and FQHC, four from VA and four from DV**; provide input in overall engagement	Panel established by 4/10/18**

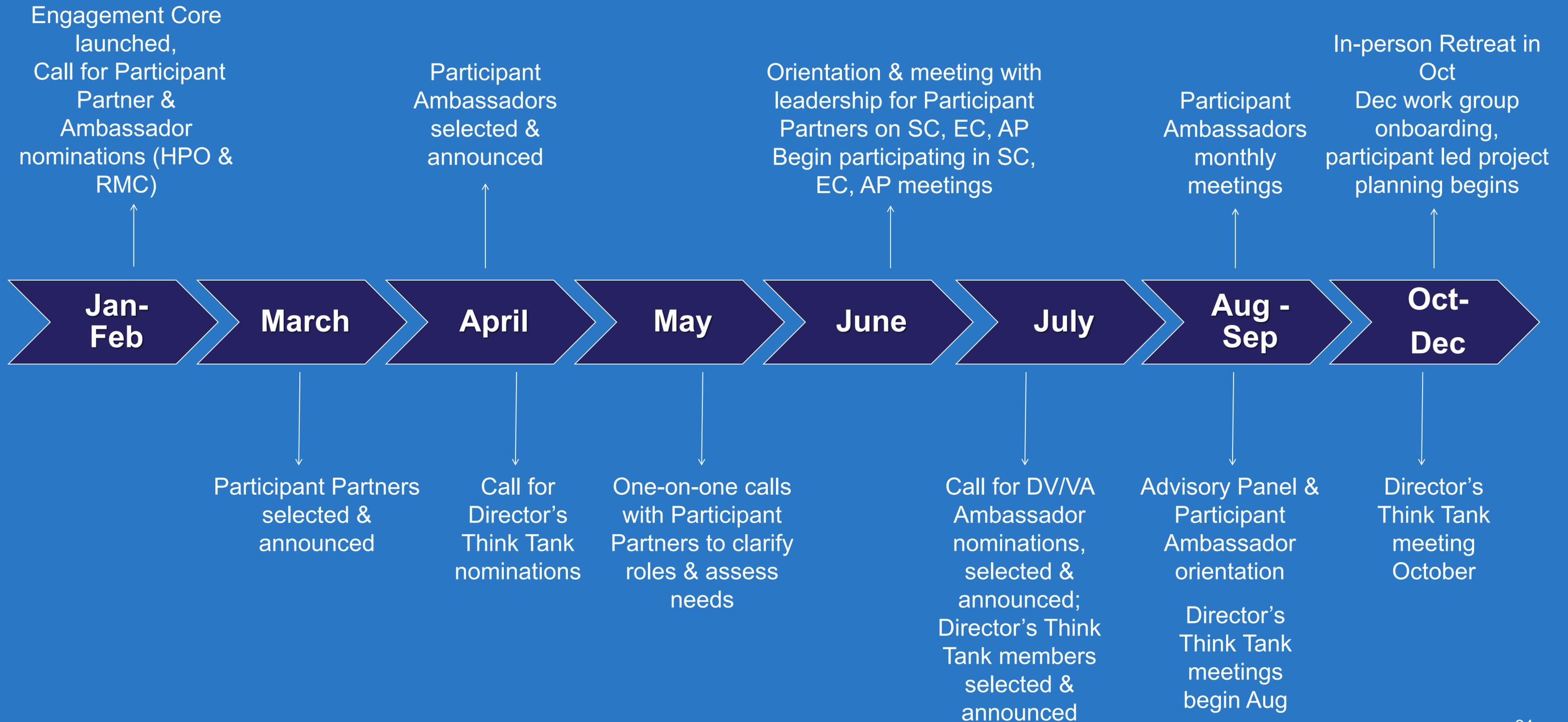
*Two of the four participants on the Steering Committee will also serve on the Executive Committee.

**Participant Ambassadors from HPOs will form the initial panel. Participants from the VA and DV will be added by July 2018.

Participants as Partners: Multi-level Engagement

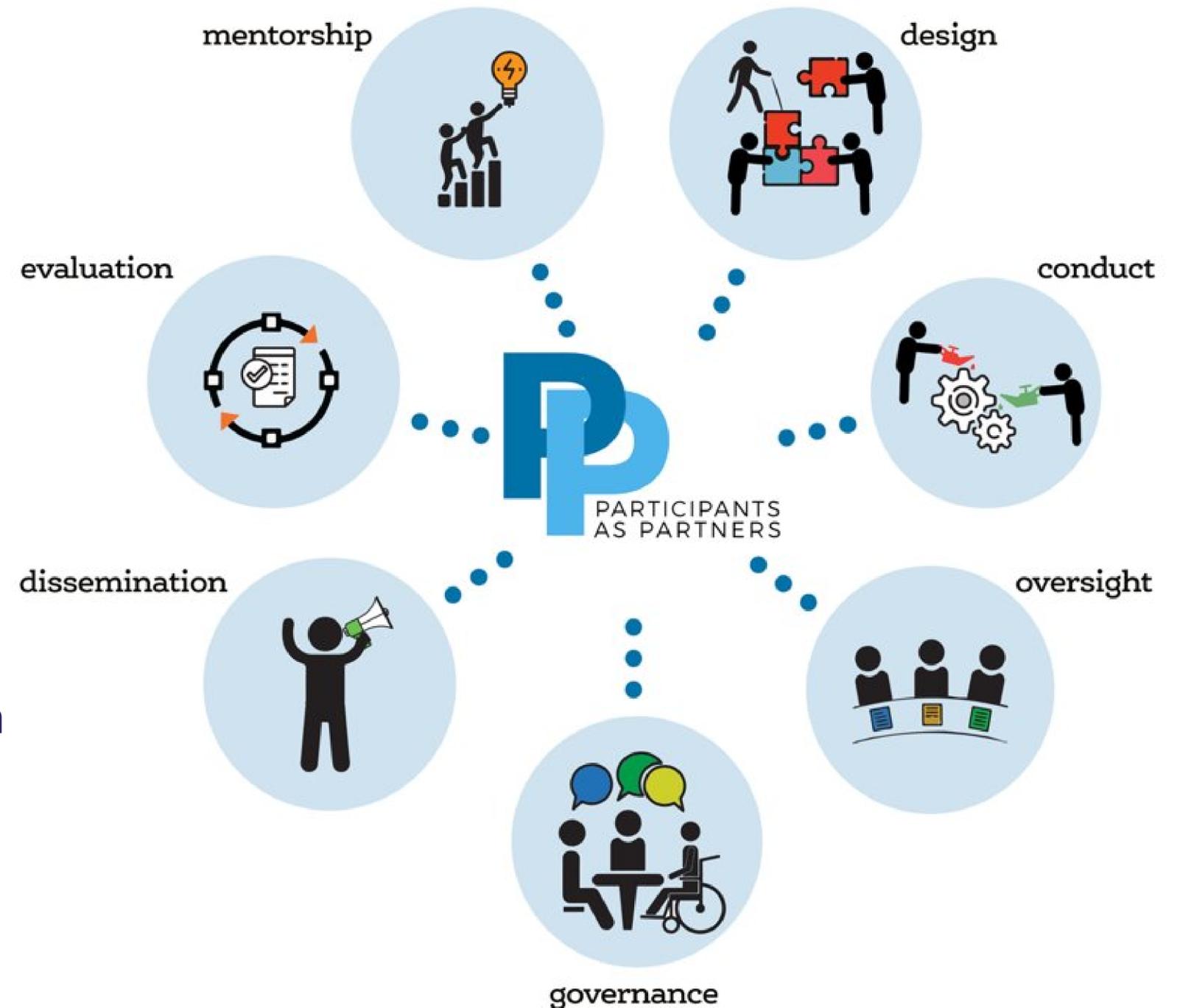
Engagement Method	Role	Key Dates
Director's Think Tank (n= 5-7)	Community representatives provide critical feedback to shape new approaches, solve problems, and advance All of Us mission	Think Tank selected by 5/30/18
Community Engagement Studios (n= 8-10/studio)	Panels of participants convened to provide specific-input; one-time commitment.	Convened on demand, for specific input.
Participant polling (n= 500+)	Participants invited via portal to provide feedback, answer questions. Polls will require 5-10 minutes.	Goal: first invitation July 2019 ongoing invitations
Peer mentors and participant speakers (n= 10)	Prior members of Steering Committee, Advisory Panel, or Think Tank; provides peer guidance to new members;	Begin identifying potential participants 7/1/2018

2018 Engagement Core Timeline



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.



Participants as Partners

Steering Committee, Executive Committee, Advisory Panel



- Steering Committee: 4; 2 of which also serve on Executive Committee; 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 top candidates
 - Selections prioritized to include diverse backgrounds

Participant Ambassadors



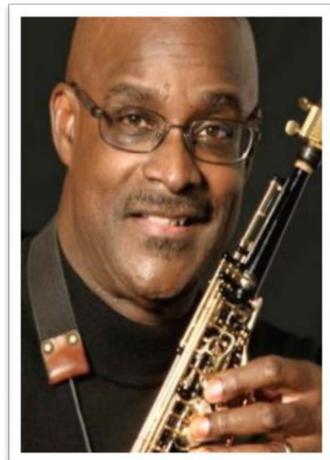
- Individuals from 15 states: FQHCs (6), Health Provider Organizations (10), VA (3), DV (3)
- Nominated by engagement leads; from their respective Community and/or Participant Advisory Boards



Participant Ambassador Placement in Workgroups

Governance Group	Participant Ambassador
Participant Evaluation and Assessment Board	Lottie Barnes and Gus Prieto
Omics	JD Bean
Special Populations Committee	Miguel Flores and Hugo Campos
Participant Provided Information (PPI)	José Iraheta
Science	Keisha Bellamy
Committee on Access Privacy and Security (CAPS)	Vilma Velez and Evelyn Ortiz
Electronic Health Records Committee	Tyrone Thigpen and Ana Pavon
Incident Notification Board (INB)	Michael Miller
Publications Board	Beth Rubinstein
Resource Access Board	Karen Wall and Marilyn Roman

Director's Think Tank



- Purpose

- Small group of mid-level professionals from DC area to provide feedback directly to AoU leadership
- Help shape new approaches
- Overcome challenges
- Advance AoU mission

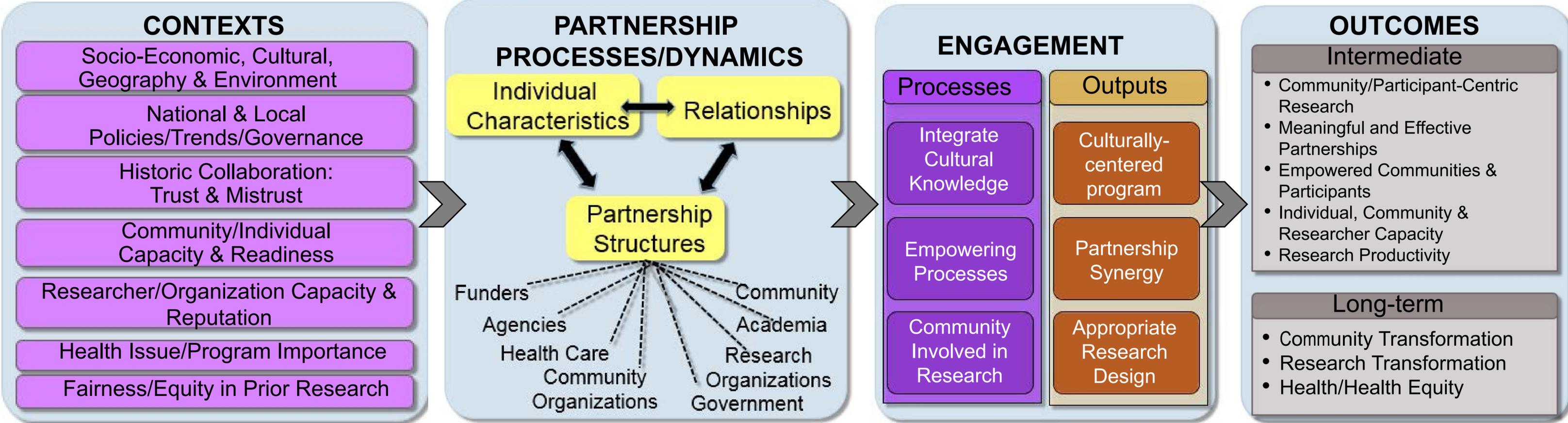
- Selection Process

- 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





CONTEXTS	PARTNERSHIP PROCESSES/DYNAMICS		ENGAGEMENT	OUTCOMES
<p>CONTEXTS</p> <ul style="list-style-type: none"> • Social-economic, cultural, geographic, political-historical, environmental factors • Policies/Trends: National/local governance & political climate • Historic degree of collaboration and trust between researchers & community • Community capacity & readiness • Researcher/Organization: capacity, readiness, reputation • Perceived severity of issues or importance of program • Historic degree of fairness in use of information & findings 	<p>Structural Dynamics:</p> <ul style="list-style-type: none"> • Diversity • Formal Agreements • Real power/resource sharing • Alignment with principles • Length of time in partnership <p>Individual Dynamics:</p> <ul style="list-style-type: none"> • Core values • Motivations for participating • Personal relationships • Cultural identities/humility • Individual experiences • Individual beliefs, spirituality • Reputation & trustworthiness of researchers/organization 	<p>Relational Dynamics:</p> <ul style="list-style-type: none"> • Safety, fairness • Dialogue, listening & mutual learning • Leadership & stewardship • Influence & power dynamics • Flexibility • Self & collective reflection • Participatory decision-making & negotiation • Integration of local/community beliefs to group process • Task roles and communication 	<p>ENGAGEMENT</p> <ul style="list-style-type: none"> • Processes that honor cultural knowledge, local settings and organizations; and use both academic & community language • Empowering co-learning processes lead to partnership synergy & trust • Community members involved in research activities leads to research/evaluation designs that reflect community priorities, needs & preferences • Bidirectional translation, implementation & dissemination 	<p>OUTCOMES</p> <p>Intermediate Outcomes:</p> <ul style="list-style-type: none"> • Policy changes: in academia & communities • Effective partnerships and projects • Empowerment – multi-level • Shared power relations in research/knowledge democracy • Growth in individual & community capacities • Researcher knowledge and attitudes • Research productivity: research outcomes, papers, applications, awards <p>Long-Term Outcomes:</p> <ul style="list-style-type: none"> • Community transformation: policies/programs/conditions • Research transformation: culture, teams • Optimal health/health equity

Questions?

A comprehensive approach to evaluating engagement

<i>Aim</i>	<i>Successful Processes</i>	<i>Successful Outcomes</i>
<p>Establish the infrastructure to fully integrate participants and advocates into the governance and oversight of the <i>All of Us</i> Program.</p>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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
<p>Facilitate ongoing input from diverse participant representatives to enhance the design, implementation, and use of the <i>All of Us</i> Program.</p>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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.
<p>Assess the impact of participant engagement on <i>All of Us</i> Program design, conduct, and use, and on participant representatives, advocates and partner organizations.</p>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 <i>All of Us</i> Program. Documented that expectations and aspirations were met for Program staff