Appreciation to our Liaisons Coordinating Team (LCT) Members Across NIH

- **Co-chairs**
  - Robert Carter, NIAMS
  - Stephanie Devaney, AOU
  - Carolyn Hutter, NHGRI

- **Members**
  - AOU: Joni Rutter, AOU
  - ECHO: Carol Blaisdell
  - NCATS: Anne Pariser
  - NCCIH: Robin Elizabeth Boineau
  - NCI: Montserrat Garcia-Closas
  - NEI: Ellen Liberman
  - NHLBI: Gina S. Wei
  - NIA: Marie Bernard
  - NIAAA: Joanne Fertig
  - NIAID: Robert Eisinger
  - NIBIB: Edward Ramos
  - NICHD: Catherine Spong
  - NIDA: Maureen Boyle
  - NIDCD: Bracie Watson, Jr.
  - NIDCR: Jane C. Atkinson
  - NIDDK: Judith Fradkin
  - NIEHS: Janet Hall
  - NIGMS: Rochelle Long
  - NIMH: Shelli Avenevoli
  - NIMHD: Regina James
  - NINDS: Clinton Wright
  - NINR: Michelle Hamlet
  - NLM: Dianne Babski
  - OAR: Stacy Carrington-Lawrence
  - OBSSR: Dana Wolff-Hughes
  - ODP: Sheri Schully
  - ORWH: Denise Stredrick

- **Non-voting Members**
  - Allison Lea, OSP
  - Stephen Mockrin, AOU
  - Debbie Winn, NCI

Appreciate Jonathan Epstein, Terry Magnuson, & Sachin Kheterpal for AOU service, as well!
A time capsule from one year ago…

Sept 9, 2016 Agenda for this forum

Key Developments

- Awardees selected
- New HPO funding opportunity issued
- Governance established
- Survey findings published

Where we are today

Count of enrollment status by date

- Registered
- Member
- Full Participant
For today’s agenda…

- Overview of program as refresher and “first exposure” to new COC members
- Share purpose & status of our current “Closed Beta Phase” & Recent Announcements
- Discussion
Overview of Program
### Program Development Timeline – To Beta Phase

#### Vision
January–September 2015
- SOTU by President Obama (Jan. 2015)
- ACD (Advisory Committee to the (NIH) Director)
  - Precision Medicine Initiative Working Group formed (Mar. 2015)
  - Report/recommendations (Sept. 2015)

#### Planning & Prototype Piloting
Fall 2015–Fall 2016
- NIH wrote implementation papers, began staffing up
- Vanderbilt pilot project: Built prototype infrastructure & group of 5000+ for feedback on enrollment/engagement, consent, surveys, and return of results (awarded Feb. 2016)
- Sync for Science pilot (awarded Feb. 2016)
- Communications awardees began research, campaign planning, and content development (awarded Mar. 2016)
- Director (Eric Dishman) started (June 2016)

#### Implementation & Development Phase
Fall 2016–Spring 2017
- Establishment of network of health care provider organizations to support enrollment & retention
- Direct volunteer partners in place
- Establishment of Support Center for participants (toll-free number/email, etc.)
- Biobank building/robots & 24-hour shipping process

- Development of Version 1 protocol/IRB approval
- Development of website and participant portal, with mobile app development in progress
- Development of data warehouse
- Development of software for providers/assistants to transmit data from participants’ in-person visits
- Security testing & usability testing

- Congress passes H.R.34, 21st Century Cures Act, in Dec with bipartisan support. Provides funding, strengthens data sharing & privacy provisions

#### Closed Beta Phase for Version 1 Platform & Protocol
Spring–Fall 2017
- Real infrastructure, protocol, people—approx. 10K or more participants

#### National Launch
*Timing TBD based on beta testing. Anticipated late 2017 or early 2018.*

---

Where we are now…

Kickoff Meeting w/Implementation Awardees July 6–8, 2016

WE ARE HERE
All of Us Mission and Objectives

Nurture relationships with one million or more participant partners, from all walks of life, for decades

Our mission
To accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us

Catalyze the robust ecosystem of researchers and funders hungry to use and support it

Deliver the largest, richest biomedical dataset ever that is easy, safe, and free to access
Summary of the All of Us program

- **Rich, Longitudinal Resource**: Deliver a national resource of deep clinical, environmental, lifestyle, & genetic data from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)

- **Diversity of Participants**: Reflect the broad diversity of the U.S.—all ages, races/ethnicities, gender, SES, geographies, & health status—by over-recruiting those underrepresented in biomedical research

- **Diversity of Researchers**: Build the tools & capabilities that make it easy for researchers from citizen scientists to premier university labs to make discoveries using the data & biosamples and through ancillary studies w/ the cohort
Major building blocks of the research program

**DATA AND RESEARCH CENTER (DRC)**
Big data capture, cleaning, curation, & sharing in secure environment

*Vanderbilt, Verily, Broad Institute*

**BIOBANK**
Repository for processing, storing, & sharing biosamples (35+M vials)

*Mayo Clinic*

**PARTICIPANT CENTER**
Direct volunteer participant enrollment, digital engagement innovation, & consumer health technologies

*Scripps Research Institute (with multiple partners)*

**PARTICIPANT TECHNOLOGY SYSTEMS CENTER**
Web & phone-based platforms for participants

*Vibrent Health*

**HEALTH CARE PROVIDER ORGS (HPOs)**
Clinical & scientific expertise network, enrollment & retention of participants

*30+ regional med centers, FQHCs, VA, future awards to grow network*

**COMMUNICATIONS & ENGAGEMENT**
Comms, marketing, & design expertise; Engagement coordination & community partners network

*Wondros, HCM, 4 community partner orgs, future awards to grow network*
# Current Consortium Members

## DV Network
(Direct Volunteers)

- Scripps Translational Science Institute
- National Blood Collaborative
- QTC
- Quest Diagnostics
- Emsi Health
- Walgreens
- PatientsLikeMe
- WebMD
- BlueCross BlueShield
- WONDROS

## HPO Network
(Health Care Provider Organizations)

<table>
<thead>
<tr>
<th>RMCs</th>
<th>Illinois Precision Medicine Consortium</th>
<th>New England Precision Medicine Consortium</th>
<th>Trans-American Consortium for the Health Care Systems Research Network</th>
<th>New York City Precision Medicine Consortium</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Precision Medicine Consortium</td>
<td>UC San Diego Health</td>
<td>Northwestern University</td>
<td>Partners Medical Group</td>
<td>Columbia University Medical Center</td>
</tr>
<tr>
<td>UC Davis Health</td>
<td>Keck Medical Center of USC</td>
<td>NorthShore University</td>
<td>Essentia Health</td>
<td>New York Presbyterian</td>
</tr>
<tr>
<td>UC Irvine Health</td>
<td>UC Health</td>
<td>The University of Illinois at Chicago</td>
<td>Baylor Scott &amp; White</td>
<td>Well Cornell Medicine</td>
</tr>
<tr>
<td>UC Health</td>
<td>Rush Medical Center</td>
<td>John Hopkins University</td>
<td>Spectrum Health</td>
<td></td>
</tr>
<tr>
<td>Southern All of Us Network</td>
<td>University of Arizona</td>
<td>University of Pittsburgh</td>
<td>FQHCs (Federally Qualified Health Centers)</td>
<td>University of Florida Medical Center</td>
</tr>
<tr>
<td>SouthEast Enrollment Center</td>
<td>All of Us, Wisconsin</td>
<td>VA Medical Centers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Community Partners

- Delta
- National Alliance for Hispanic Health
- Fifty Forward
- San Francisco General Hospital Foundation
- WONDROS
- HGM

## Communication & Engagement

- WONDROS
- HGM

## Platform Development

- Scripps Translational Science Institute
- Sage
- Vanderbilt University
- WONDROS
- Vibrent
Summary: Approved Version 1 of Protocol

Enroll, Consent & EHR
- Recruit 18+ years old initially; plan to include children in next iteration
- eConsent or paper long-form
- Participants complete additional consent to share EHR data

Surveys
- Three initial participant provided information modules: The Basics, Overall Health, & Lifestyle

Physical Measurements
- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

Biosamples
- Blood (or saliva, if blood draw is unsuccessful)
- Urine
- 28 aliquots of blood and 6 of urine stored in Biobank

See “Backup” section for more details. Full protocol published at allofus.nih.gov.
Portfolio of Actions & Investments to Achieve Diversity

Design Principle 1
“All healthcare is local!”
So build local capacity & buy-in.

- Incentivize National Network of Health Provider Organizations
- Build Up FQHC Research Capacity as Valuable HPO Partners
- Invent Network of Direct Volunteer Partners
- Grow a Network of National & Local Community Partners
- Develop Specific Plans for Special Population Engagement
- Build a User/Participant-Centered Design Culture & Process

Design Principle 2
“Meet people where they are!”
Physically, culturally, socially.
Other Recent Announcements

- **Children’s Enrollment Scientific Vision WG**
  - Announced on 7/17
  - 4 meetings so far; report expected 10/1

- **Initial Community Partner Awards**
  - 4 community partner awards announced on 7/25
  - Additional awards expected in September timeframe

- **Protocol**
  - Posted on allofus.nih.gov on 8/4

- **Genomics WG**
  - Announced on 8/15
  - 4 meetings so far; report expected 10/1

Purpose & Status of “Closed Beta Phase”
What is the purpose of the “Closed” Beta Phase?

- Enroll initial 10-15,000 participants who can give feedback on all aspects before national launch
- Ramp over 100 locations around the country slowly, carefully week by week
- Test the initial protocol, call center, online tools & interfaces, language of consent & questionnaires, workflow for staff at each location, biobank shipments, etc.

“Closed” means only those given a special code can enroll right now—will be removed for nat’l launch
So, how is it going so far?

- **Participants** are joining, going through the protocol on the participant portal, & giving useful feedback in beta

- **Local staff** learning & ramping fast, finding ways to improve as they “get into it”

- Good progress on **rolling out locations**, but schedule is hard to predict
  - Site specific amendments take time
  - Need more “old IT systems” to test against
  - State requirements require consent revisions

- Limited ability to test engagement methods in a closed beta & no local PR

Beta is doing what it’s supposed to do—and consortium progress is good with terrific collaboration!
Closed Beta Phase Enrollment Status (as of 8/29)

Count of enrollment status by date

Total registered: 2508;  Members: 2153;  Full Participants: 1844
Closed Beta Timeline—rolling out the 100+ locations around the country

Schedule depends on data security & IRB approvals for each local partner & any unique state laws.
So, the million-person question: when will the National Launch be?

**Timeline:**
- We are still on track to launch nationally later this year or early next year.
- Our commitment is still to “launch when ready and right.”

**Considerations For Early Vs. Later in our Window:**
- Do we feel confident about our **engagement “engine”** being able to reach communities?
  - Have we sufficiently tested our recruitment messages & methods?
  - Do our new and forthcoming community partners have enough time to beta test?
  - For Direct Volunteer & HPO partners, can we enable them to test open campaigns?
- **Is the participant experience** simple, clear, & rich enough yet to scale nationally?
  - Want time to incorporate participant feedback from the Closed Beta Phase.
  - Many new tools that are coming need end to end testing: wearables, participant apps.
- Have we **sufficiently stress-tested** our infrastructure for opening up to all?
  - Should we test “burst capacity” by removing participant code for a month or so?

Currently weighing pros & cons of different launch windows
Thank You!
Backup
Participation in the *All of Us* Research Program will be **open** to interested individuals.

The Program will reflect the rich **diversity** of America.

Participants will be **partners** in the Program.

Trust will be earned through robust **engagement** and full **transparency**.

Participants will have **access** to information and data about themselves.

Data from the Program will be broadly **accessible** to empower research.

The Program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.

The Program will be a catalyst for **innovative research** programs and policies.
All of Us: Acceleration of Knowledge Turns >>> Health Breakthroughs!

Questions, Problems, & Hypotheses

Capture, Secure, Clean, & Share Data

Unleash Science & Diverse Scientists

Translate Into Action, Practice, & Meaning
All of Us is building a Resource for others to drive their science

**SECONDARY DATA ANALYSES**
- PILOT environmental risk study
- PILOT a new survey instrument

**ANCILLARY/SUB STUDIES**
- PILOT a disparities study
- PILOT a biomarker study
- PILOT whole genome seq
- PILOT utility of phone/GIS data

**V1 platform**
- Data
- Samples
- Analyses
- Tools
- Cohort

**V2 platform**
- Data
- Samples
- Analyses
- Tools
- Cohort

**V3 platform**
- Data
- Samples
- Analyses
- Tools
- Cohort

**Vx platform...**
- ...
- ...
- ...
- ...
- ...
Our current scientific framework – still a work in progress

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Cardio-Respiratory</th>
<th>Chronic Pain</th>
<th>Immunologic &amp; Inflammatory</th>
<th>Infections</th>
<th>Mental Health</th>
<th>Digestive &amp; Metabolic</th>
<th>Musculoskeletal</th>
<th>Sensory, Neurologic, &amp; Cognitive</th>
<th>Human Development Across the Lifespan</th>
<th>Health &amp; Resilience</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Risk Factors, Prevention & Wellness
- Health Disparities, Health Care Quality & Access
- Genomics and Other –Omics
- mHealth
- Therapeutic & Preventive Interventions
- Environmental & other Contextual Effects
- Informatic, Methodologic, Ethical/Legal, & Statistical Research

Developed with IC Input

Verticals = High level condition/disease areas; Horizontals = Cross cutting areas of interest / themes
Protocol Details
Two Methods of Enrollment

You learn about the Research Program

Participant Portal

Direct Volunteers

Health Care Provider Organizations
Kinds of Research Activities Participants Are Invited To Do…

1. Enroll & Consent
2. Surveys
3. Physical Measurements
4. Biosamples
5. Apps, Phones & Wearables
Consent / e-Consent

- Recruit 18+ years old initially; plan to include children in next iteration
- eConsent or paper long-form
- 5th grade reading level; English & Spanish initially
- eConsent process includes modules on:
  • Participant Provided Info (PPI) + Linkage + Re-contact
  • Physical Measurements (PM) + Biospecimen
  • Sensors or wearable devices
  • EHR
  • Genetic information
- Separate opt-in & signature for some modules, including EHR and genetics (state laws)
Participant Provided Information

Proposed Enrollment Surveys
1. The Basics
2. Overall Health
3. Lifestyle

In Development
4. Personal Health History
5. Medications
6. Family History
7. Health Care Access and Utilization
8. Sleep
9. Environment and exposures

Participant dashboard on their progress

Surveys came from NIH resources & external researcher input; leveraging trusted, known instruments.
Electronic Health Records

- Participants will be asked to authorize linkage of their EHR information.
- Participants must sign a separate informed consent to authorize access to their complete EHR.

<table>
<thead>
<tr>
<th>Initial Data Types</th>
<th>Expanded Data Types (May Include)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Demographics</td>
<td>• Physician Notes</td>
</tr>
<tr>
<td>• Visits</td>
<td>• Mental Health Data</td>
</tr>
<tr>
<td>• Diagnoses</td>
<td>• HIV Status</td>
</tr>
<tr>
<td>• Procedures</td>
<td>• Substance Abuse &amp; Alcohol use/misuse</td>
</tr>
<tr>
<td>• Medications</td>
<td>• Genomic Information</td>
</tr>
<tr>
<td>• Laboratory Visits</td>
<td></td>
</tr>
<tr>
<td>• Vital Signs</td>
<td></td>
</tr>
</tbody>
</table>

Clinic Visit

Check-In

5-10 minutes
Verify Address/key personal information
Verify consent is e-signed before visit
Summarize what to expect of the visit; answer any questions
Instruct participant to remove bulky clothing

Pre-Measurement Verifications

5-10 minutes
Verify completion of PPI
Collect limited information relevant to the measurements / bio-specimen collection (i.e. transfusion?)

Physical Measurements

15-20 minutes
Conduct Program Core Physical Measurements to include:
• Blood Pressure & Pulse
• Height & Weight
• Hip & Waist Circumference
• Re-dressing

Bio-Specimen Collection

10 minutes
Perform blood draw
Collect urine specimens
Collect saliva samples (instead of blood)

Check-Out

5-10 minutes
Verify the completion of measurements and bio-specimen collection
Provide print out and/or digital measurement data to the participant, with $25 compensation
Discuss what to expect post-visit; answer any questions.
Version 1 Physical Measurements & Biospecimen Collection

Physical Measurements
- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

Biospecimen Collection
- Blood and/or saliva
- Urine
- 34 aliquots stored in Biobank
- 24 hour courier nationwide
- Nights & weekend collections
## Biospecimens: Blood and Urine

### Table: PMI Sample Collection

44 ml blood, 34 aliquots to save

<table>
<thead>
<tr>
<th>Type of sample and collection tube (Collection priority)</th>
<th>Volume Collected (ml)</th>
<th>Transport T°C</th>
<th>Fraction and (number) of aliquots created</th>
<th>Aliquots -80°C</th>
<th>LN2</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) EDTA</td>
<td>4</td>
<td>4</td>
<td>(2) DNA</td>
<td>0.5 ml</td>
<td>--</td>
</tr>
<tr>
<td>(2) EDTA</td>
<td>10</td>
<td>4</td>
<td>(5) Plasma (1) WBC (2) RBC (+glycerol)</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
<tr>
<td>(3) Clot Activator (SST)</td>
<td>8</td>
<td>4</td>
<td>(4) Serum</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
<tr>
<td>(4) Plasma Separator (PST)</td>
<td>8</td>
<td>4</td>
<td>(4) Plasma</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
<tr>
<td>(5) EDTA</td>
<td>10</td>
<td>4</td>
<td>(5) Plasma (1) WBC (2) RBC (+glycerol)</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
<tr>
<td>(6) Na-Heparin</td>
<td>4</td>
<td>4</td>
<td>(2) WB (+DMSO)</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
<tr>
<td>Urine</td>
<td>10</td>
<td>4</td>
<td>(6) Urine</td>
<td>1.0 ml</td>
<td>--</td>
</tr>
</tbody>
</table>

- Selected processing steps to be done at collection sites
- Samples shipped same day of collection; received at Mayo within 24 hours and processed within 40

### Minimum amounts of biospecimen collection to be considered enrolled:

- 4 mL of blood for DNA + spot urine sample, OR
- Saliva sample + spot urine sample, if needle sticks unsuccessful after 2 attempts or in very rare cases when it may not be possible to draw blood
All of Us Data & Specimen Flows

1 = Subject to Common Rule or IRB review
2 = Subject to or follows HIPAA Privacy and Security Rule
3 = Covered by Certificate of Confidentiality
4 = Subject to FISMA security review or Interconnection Security Agreement
5 = Subject to review and conditions of access

PTC = Participant Technologies Center
DRC = Data & Research Center
HPO = Healthcare Provider Organization
DV = Direct Volunteers
PPI = Participant Provided Information
S4S = Sync4Science
The Participant Portal is:

- The core public-facing program enrollment & communications tool
- Provides Program updates and messaging to participants
- Access of individual-level information

Future Portal Version will:

- Include a dashboard where participants can view their data compared to the aggregated data generated through the All of Us Research Program.