Accelerating Precision Health for All of Us

The All of Us *Research Program*

Council of Councils
September 1, 2017

Eric Dishman
Entrepreneurial Patient, Advocate, Caregiver
Director, *All of Us* Research Program

National Institutes of Health

#joinallofus

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!

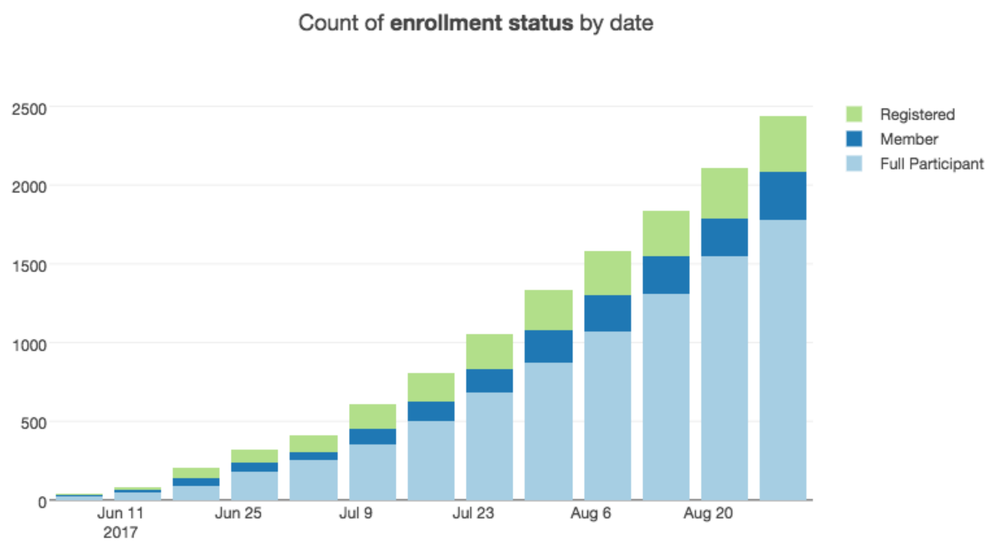
A time capsule from one year ago…

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



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

Where we are now…

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

WE ARE HERE

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.

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

Deliver the largest, richest biomedical dataset ever
that is easy, safe, and free to access

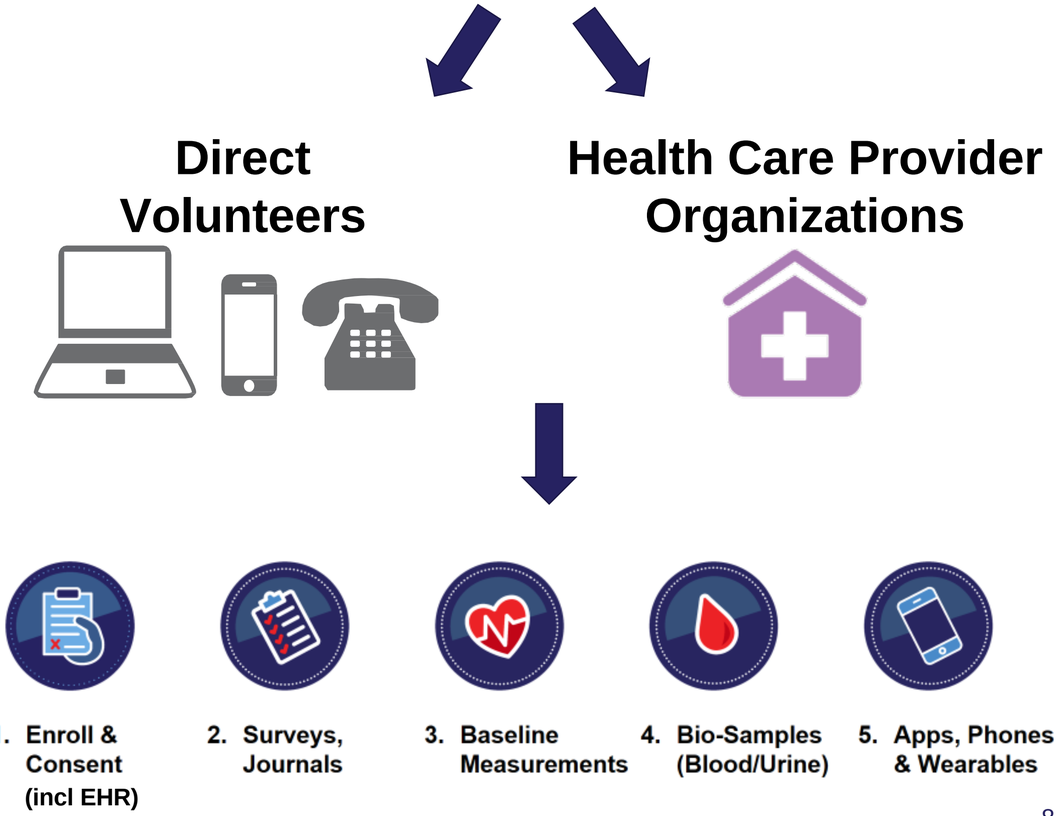
Catalyze the robust ecosystem
of researchers and funders hungry to use and support it

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 A Leidos Company
Walgreens
BlueCross BlueShield
WONDROS
DXC.technology
Quest Diagnostics
EMSI HEALTH
patientslikeme
WebMD
HCM STRATEGISTS

HPO Network

(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium

UC San Diego Health
UCDAVIS HEALTH
Keck Medical Center of USC
UC Irvine Health
UC HEALTH
UCSF University of California San Francisco
San Diego Blood Bank
CEDARS-SINAI

Illinois Precision Medicine Consortium

Northwestern University
THE UNIVERSITY OF CHICAGO
NorthShore University HealthSystem
RUSH
THE UNIVERSITY OF ILLINOIS AT CHICAGO
uic

New England Precision Medicine Consortium

PARTNERS HEALTHCARE
MASSACHUSETTS GENERAL HOSPITAL
BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL
BU Boston University School of Medicine
BOSTON MEDICAL CENTER
University of Massachusetts Medical School

Trans-American Consortium for the Health Care Systems Research Network

Henry Ford Health System
Essentia Health
BaylorScott&White HEALTH
SPECTRUM HEALTH

New York City Precision Medicine Consortium

COLUMBIA UNIVERSITY MEDICAL CENTER
NYC HEALTH+ HOSPITALS
NewYork-Presbyterian
Weill Cornell Medicine

Southern *All of Us* Network

LSUHealth
TUSKEGEE UNIVERSITY
The University of Mississippi MEDICAL CENTER
Tulane University
Cooper Green Mercy HEALTH SERVICES
HUNTSVILLE HOSPITAL
University Medical Center
USA UNIVERSITY OF SOUTH ALABAMA HEALTH SYSTEM

SouthEast Enrollment Center

UNIVERSITY OF MIAMI
EMORY UNIVERSITY
MOREHOUSE SCHOOL OF MEDICINE
UF UNIVERSITY of FLORIDA

All of Us, Wisconsin

Marshfield Clinic
CLEMENT J. ZABLOCKI VA MEDICAL CENTER
THE UNIVERSITY of WISCONSIN MADISON
MEDICAL COLLEGE OF WISCONSIN
BLOODCENTER of WISCONSIN

University of Arizona

THE UNIVERSITY OF ARIZONA
Banner Health

University of Pittsburgh

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

Cherokee HEALTH SYSTEMS
JACKSON-HINDS COMPREHENSIVE HEALTH CENTER
SAN YSIDRO HEALTH
HRHCare COMMUNITY HEALTH
Community Health Center, Inc.
Eau Claire

VA Medical Centers

VA | U.S. Department of Veterans Affairs

Community Partners

DELTA RESEARCH AND EDUCATIONAL FOUNDATION
National Alliance for Hispanic Health
Fifty Forward
SAN FRANCISCO GENERAL HOSPITAL FOUNDATION

Communication & Engagement

WONDROS
HCM STRATEGISTS

Platform Development

Scripps Translational Science Institute
Sage BIONETWORKS
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

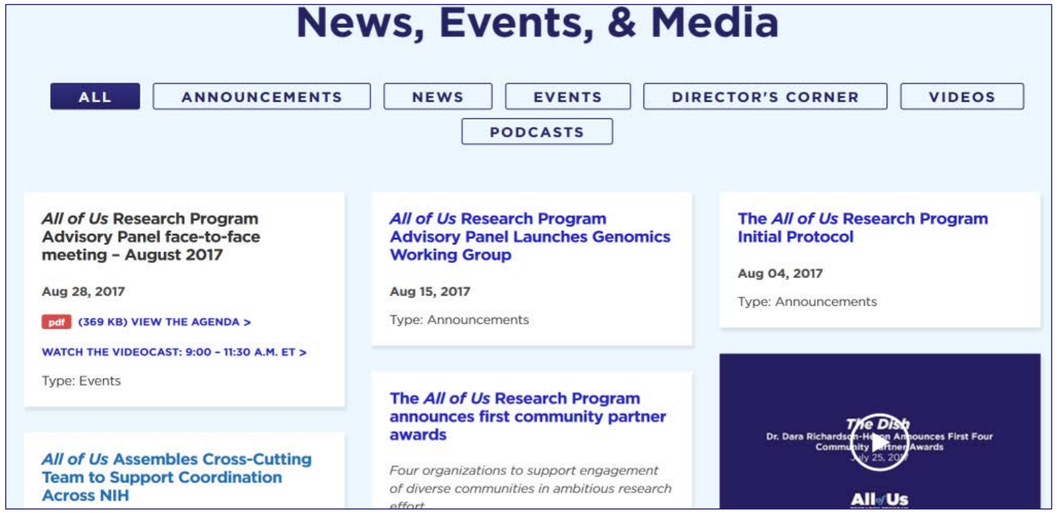
Build a User/Participant-Centered Design Culture & Process

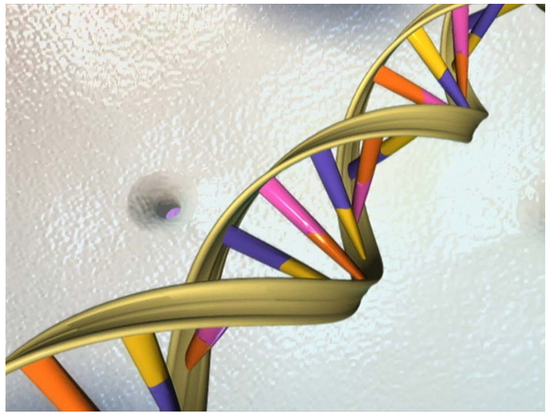
Design Principle 2

“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



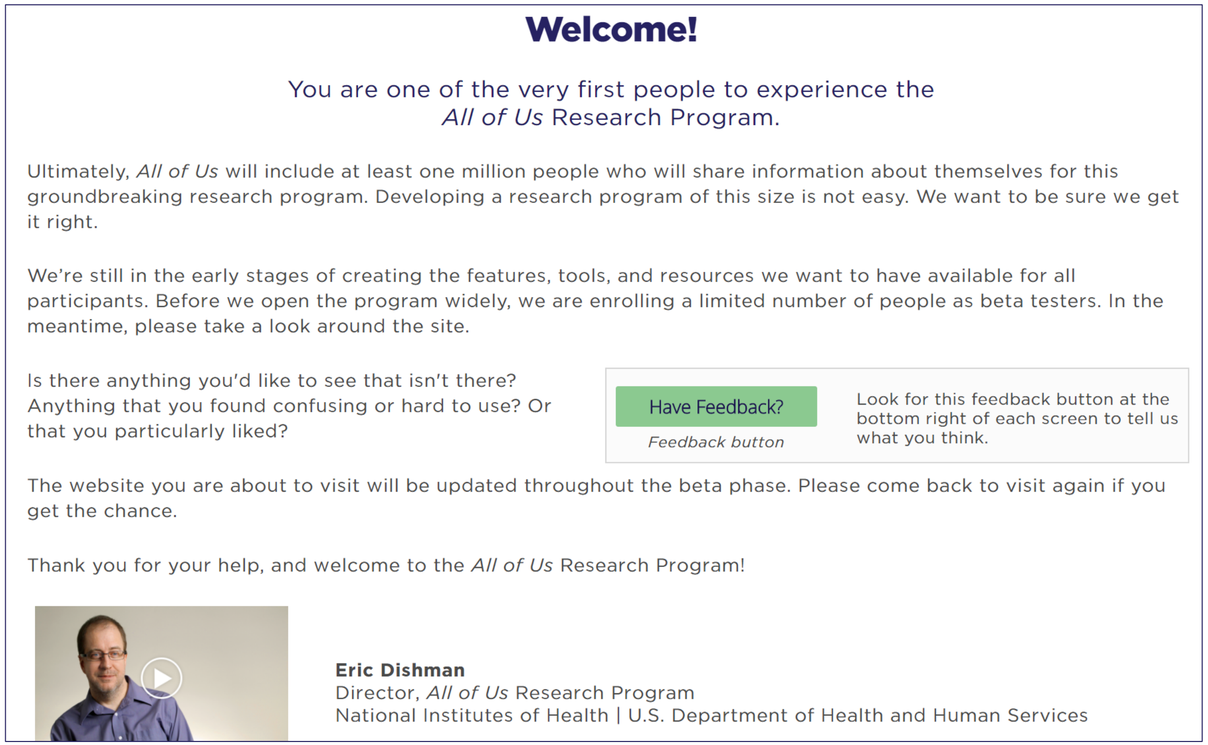


https://allofus.nih.gov/news-events-and-media

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.



Welcome!

You are one of the very first people to experience the *All of Us* Research Program.

Ultimately, *All of Us* will include at least one million people who will share information about themselves for this groundbreaking research program. Developing a research program of this size is not easy. We want to be sure we get it right.

We're still in the early stages of creating the features, tools, and resources we want to have available for all participants. Before we open the program widely, we are enrolling a limited number of people as beta testers. In the meantime, please take a look around the site.

Is there anything you'd like to see that isn't there? Anything that you found confusing or hard to use? Or that you particularly liked?

Have Feedback?

Feedback button

Look for this feedback button at the bottom right of each screen to tell us what you think.

The website you are about to visit will be updated throughout the beta phase. Please come back to visit again if you get the chance.

Thank you for your help, and welcome to the *All of Us* Research Program!

Eric Dishman
Director, *All of Us* Research Program
National Institutes of Health | U.S. Department of Health and Human Services

Click “We’re in beta” at top of https://www.joinallofus.org/

“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?

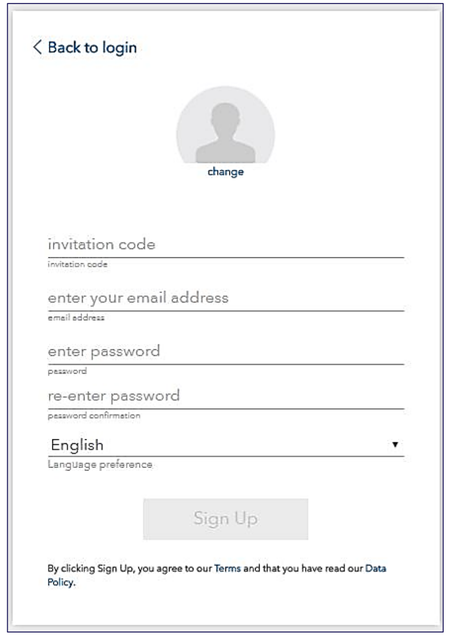
- **Participants** are joining, going through the protocol on the participant portal, & giving useful feedback in beta

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

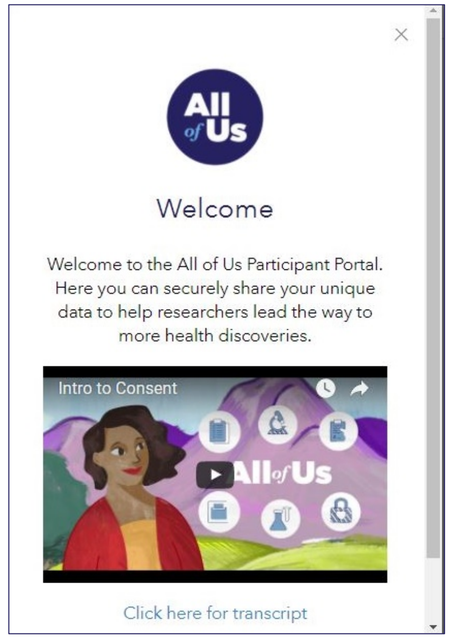
- Good progress on **rolling out locations**, but schedule is hard to predict
  - Site specific amendments take time
  - Need more “old IT systems” to test against
  - State requirements require consent revisions

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

Login Page

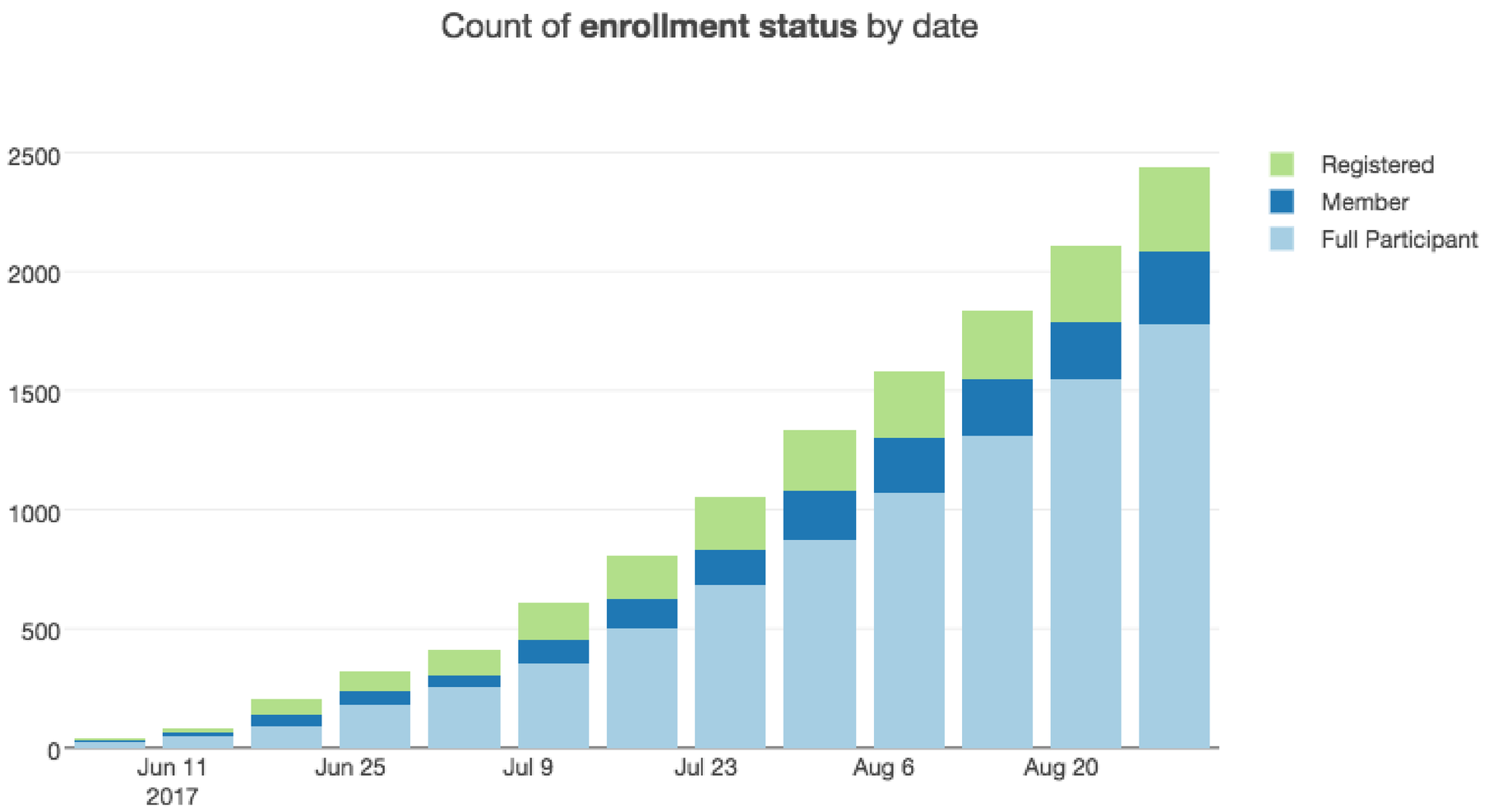


Consent
with consent videos



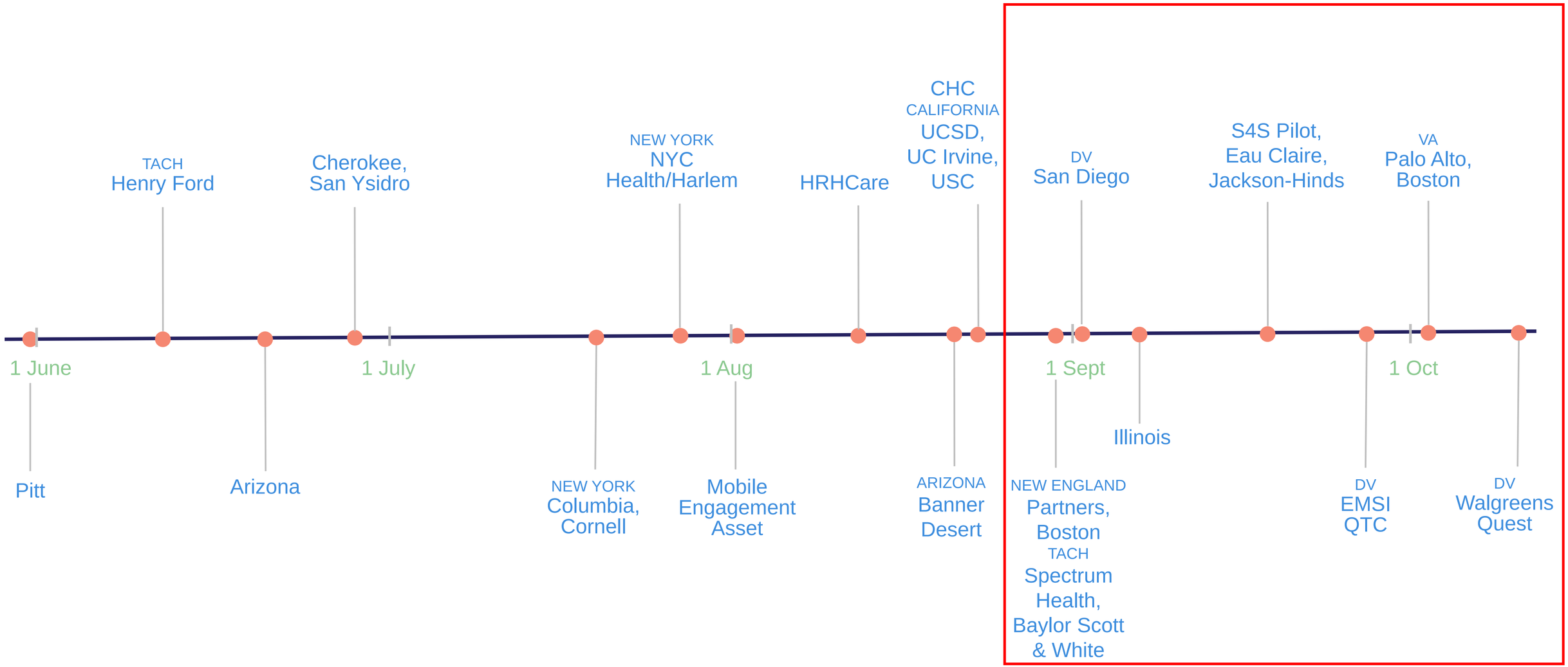
Beta is doing what it’s supposed to do—and consortium progress is good with terrific collaboration!

Closed Beta Phase Enrollment Status (as of 8/29)



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

Core Values

- 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!

All of Us is building a Resource for others to drive their science

SECONDARY DATA ANALYSES

ANCILLARY/SUB STUDIES

PILOT
environmental risk study

PILOT
a disparities study

PILOT
a biomarker study

PILOT
a new survey instrument

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…
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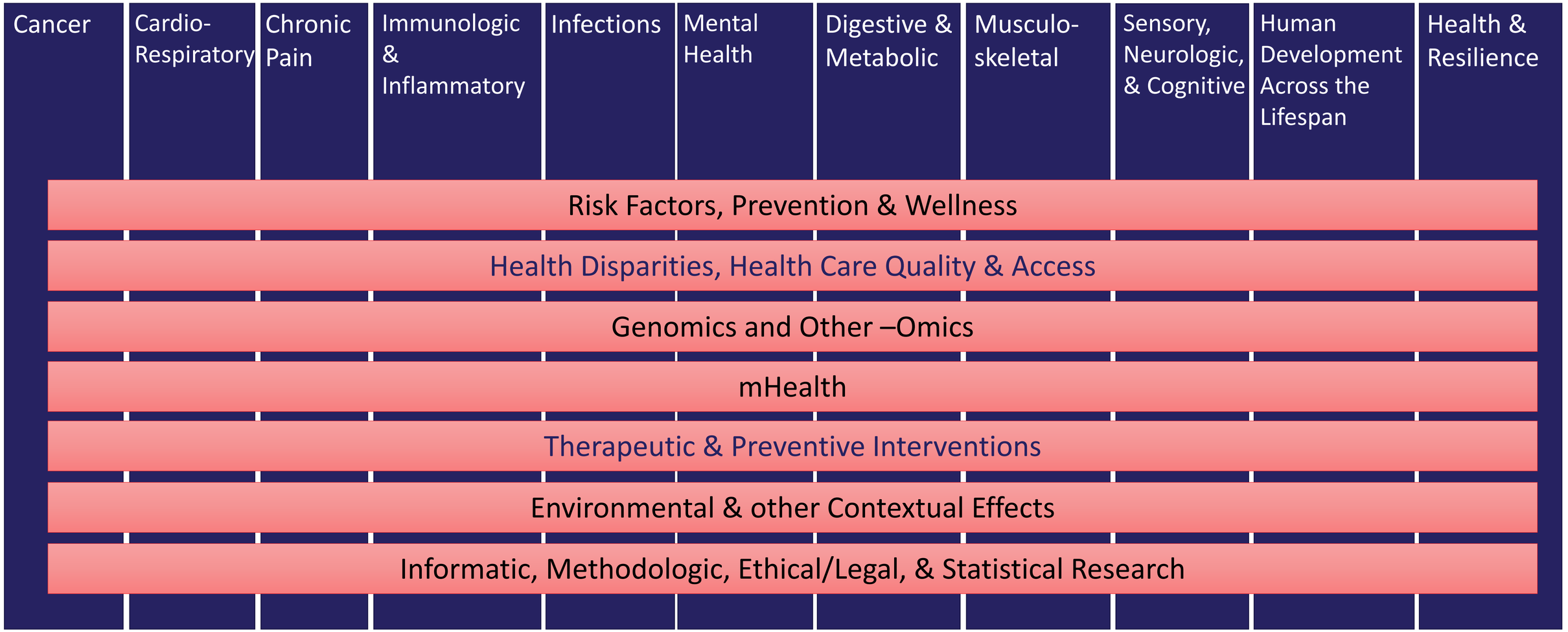
Our current scientific framework – still a work in progress



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

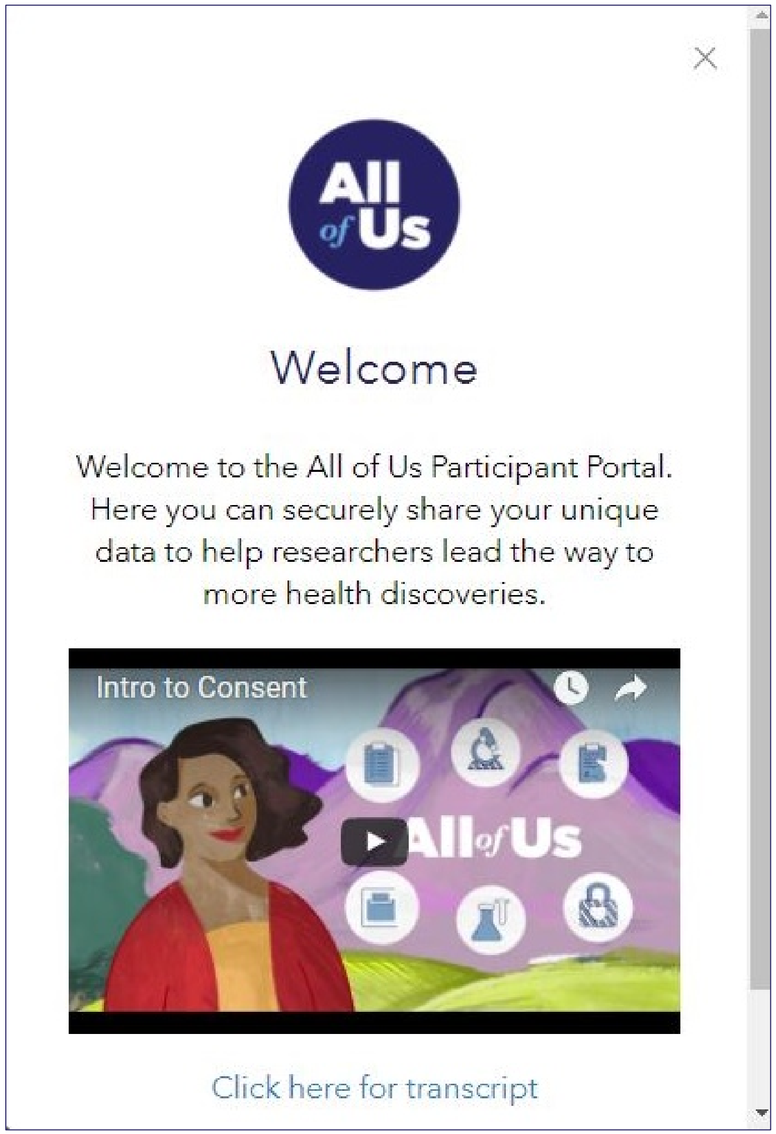
3. Physical Measurements

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

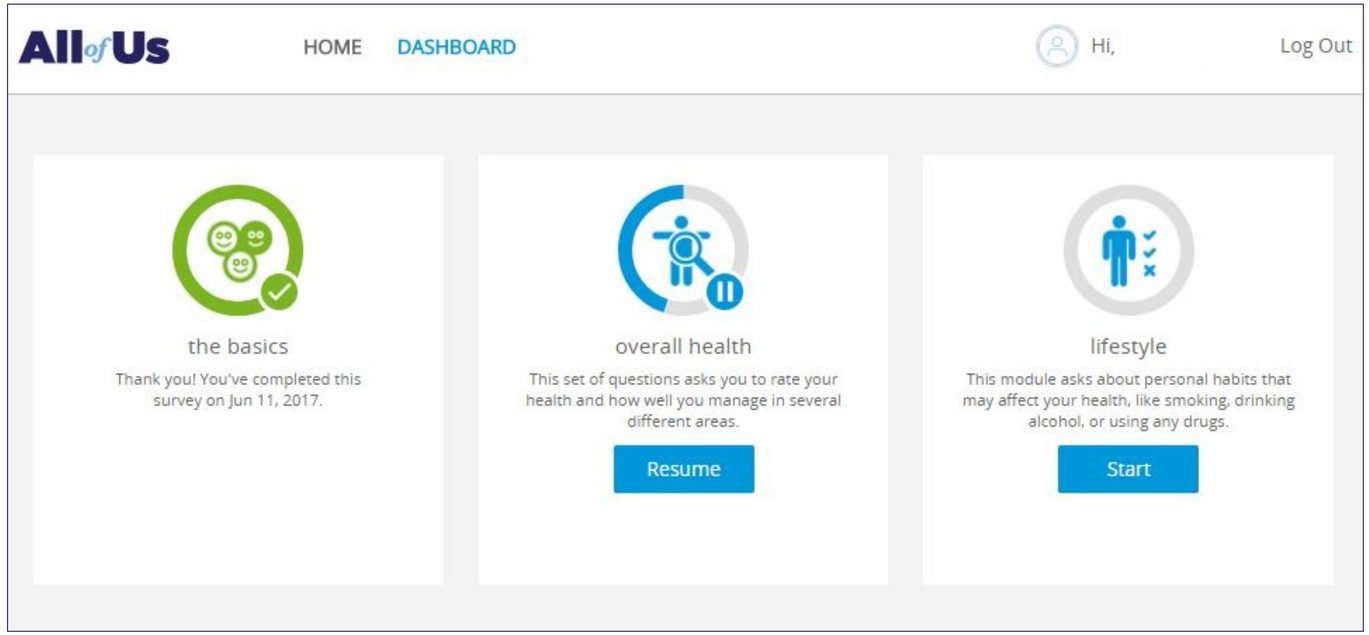
Proposed Enrollment Surveys

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

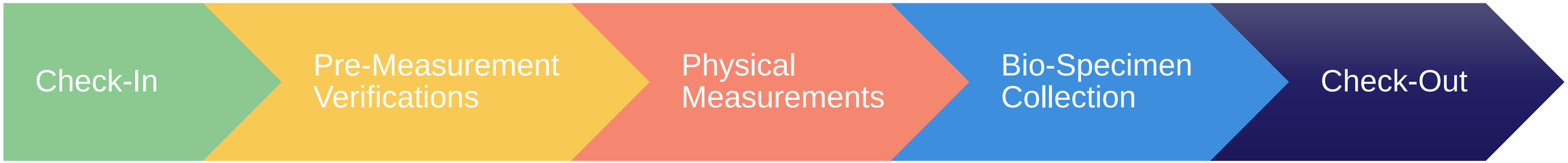
Electronic Health Records

- 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.

Initial Data Types	Expanded Data Types (May Include)
• Demographics • Visits • Diagnoses • Procedures • Medications • Laboratory Visits • Vital Signs	• Physician Notes • Mental Health Data • HIV Status • Substance Abuse & Alcohol use/misuse • Genomic Information

SYNC FOR SCIENCE

Clinic Visit



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

5-10 minutes

Verify completion of PPI

Collect limited information relevant to the measurements / bio-specimen collection (i.e. transfusion?)

15-20 minutes

Conduct Program Core Physical Measurements to include:

- Blood Pressure & Pulse
- Height & Weight
- Hip & Waist Circumference
- Re-dressing

10 minutes

Perform blood draw

Collect urine specimens

Collect saliva samples (instead of blood)

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.

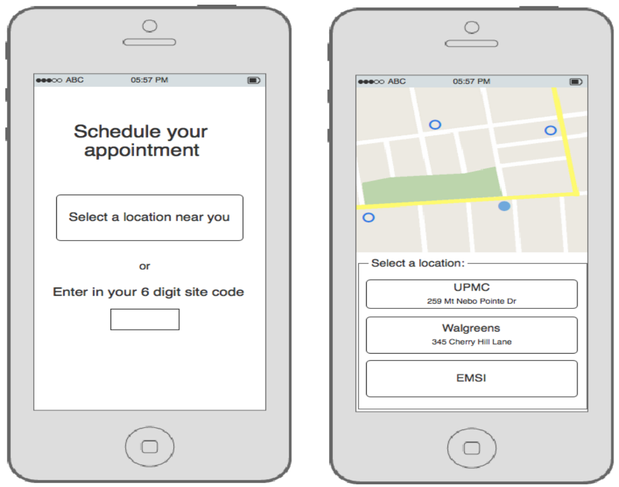
Version 1 Physical Measurements & Biospecimen Collection

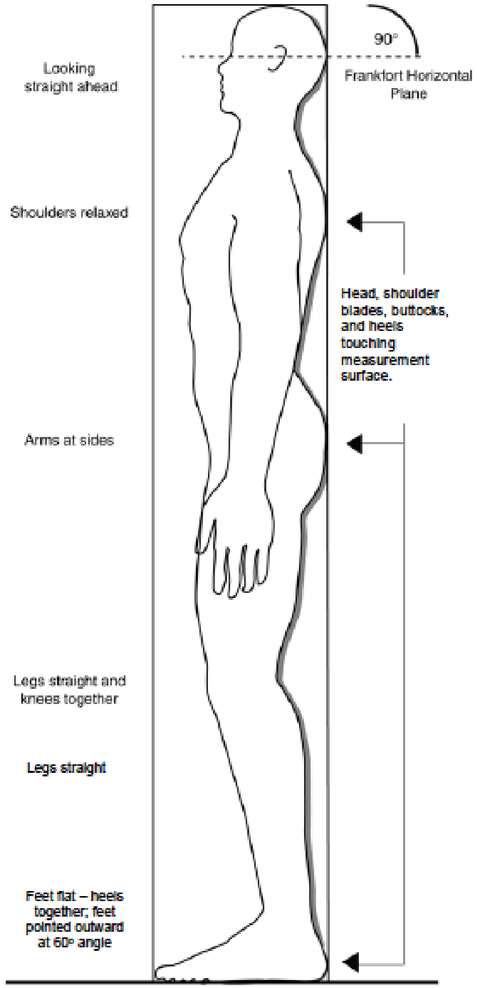
Physical Measurements

- 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

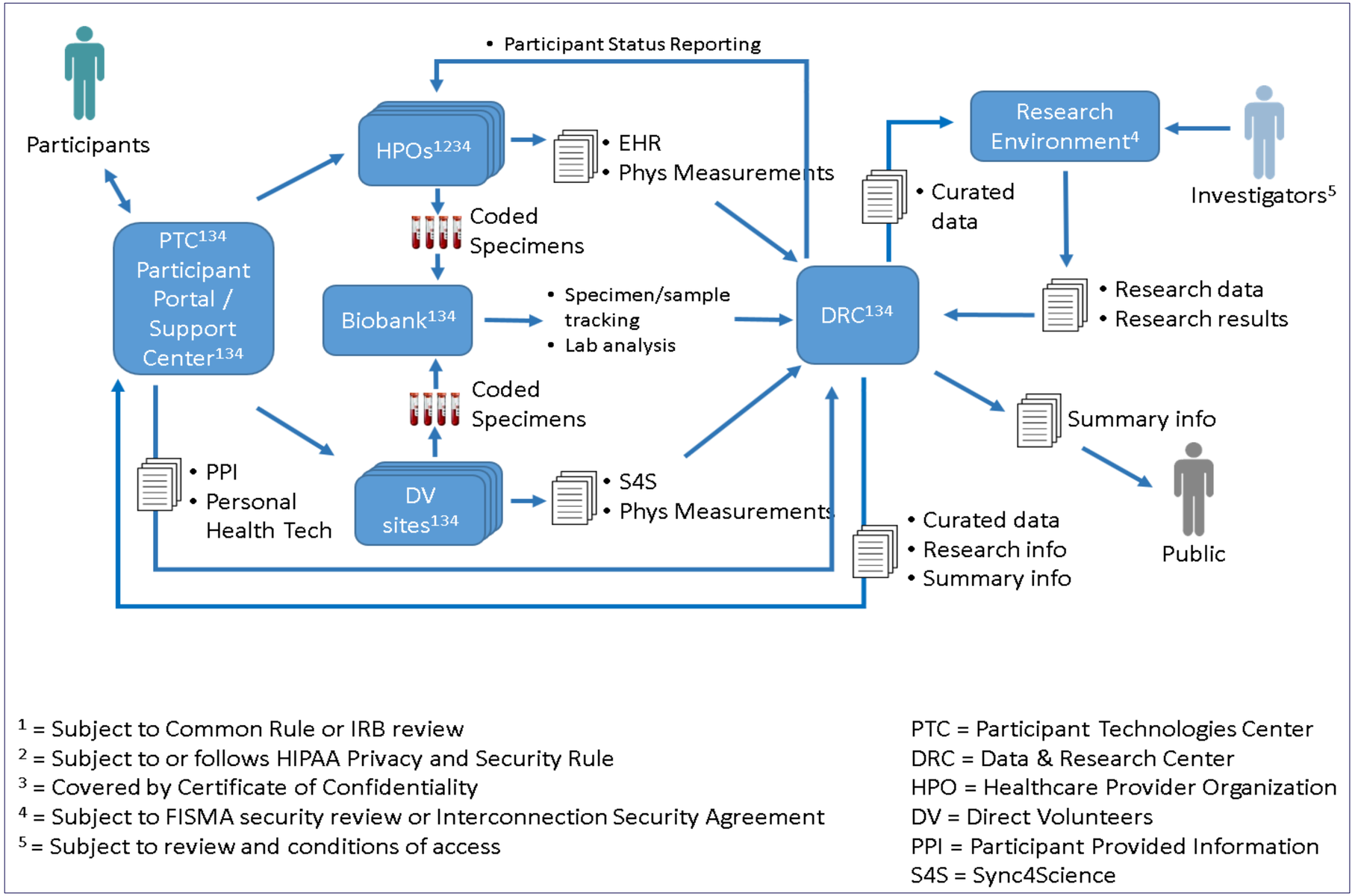
Type of sample and collection tube (Collection priority)	Volume Collected (ml)	Transport T°C	Fraction and (number) of aliquots created	Aliquots -80°C	LN2
(1) EDTA	4	4	(2) DNA	0.5 ml	--
(2) EDTA	10	4	(5) Plasma (1) WBC (2) RBC (+glycerol)	1.0 ml	--
(3) Clot Activator (SST)	8	4	(4) Serum	1.0 ml	--
(4)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

- 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

All of Us Participant Portal …

- 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.

Figure 10–2: Data Flow for Participants and HPO Staff