

Participant Technology Systems Center Informational Webinar

All of Us
RESEARCH PROGRAM



National Institutes
of Health

December 16, 2019

@AllofUsResearch #JoinAllofUs

AGENDA

- Introduction to the *All of Us* Research Program
- Timeline for the funding announcement
- Application components and process
- Objectives of the funding announcement
- OT award background
- Q & A session

Introduction to the *All of Us* Research Program

All of Us Mission and Objectives

Nurture relationships

with one million or more participants, 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 data set ever

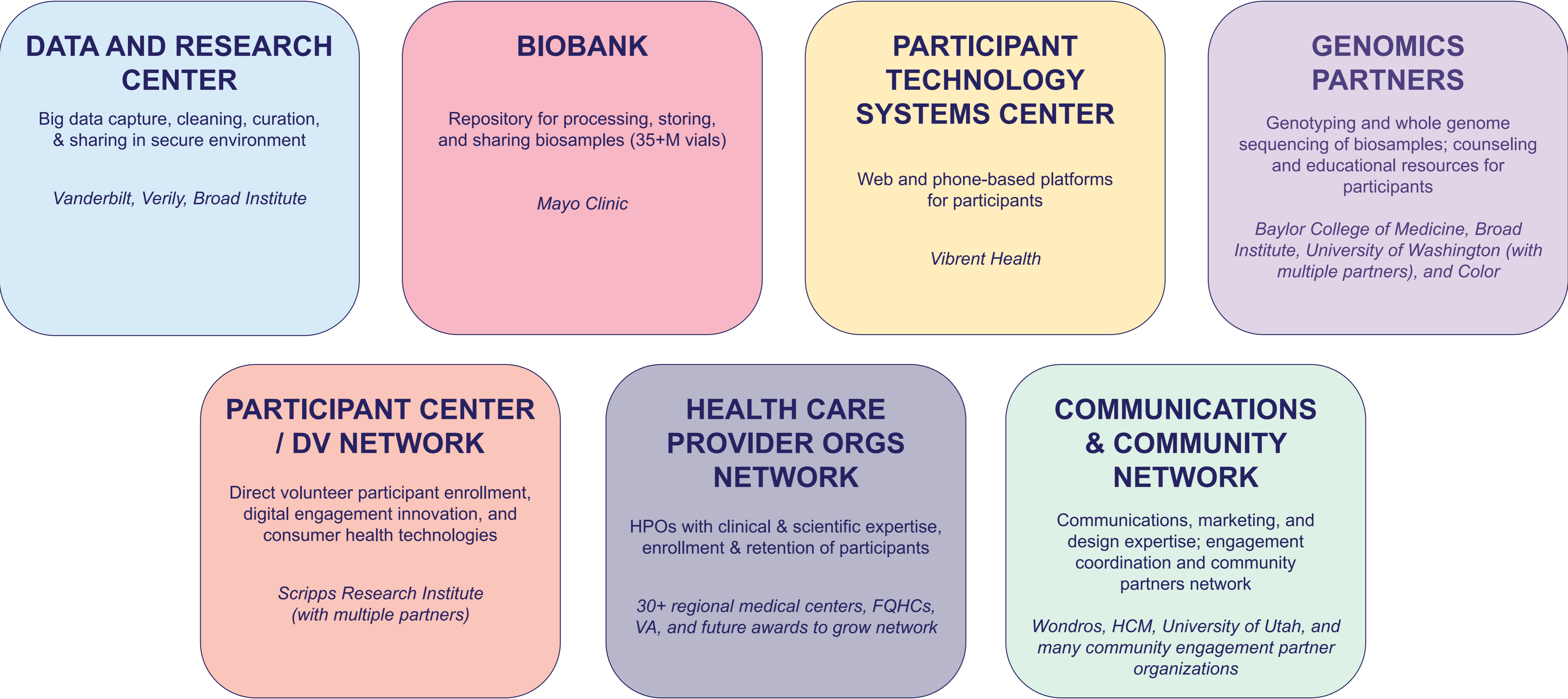
that is easy, safe, and free to access

Catalyze a robust ecosystem

of researchers and funders hungry to use and support it



Major building blocks of the *All of Us* Research Program consortium



All of Us Consortium Members (beyond community partners)

The Participant Center

Scripps Research
Translational Institute

BlueCross.
BlueShield

COMMUNITY
BLOOD CENTER
of the Carolinas

DXC.technology

EMSI
HEALTH

MONTAGE MARKETING

NATIONAL
BLOOD
COLLABORATIVE
BLOOD SOLUTIONS | TRUSTED SOURCE

patientslikeme

Qualcomm

Quest
Diagnostics

QTC
A Leidos Company

Sage
BIONETWORKS

San Diego
Blood Bank

Walgreens

WebMD

Communications
& Engagement

WONDROS

HCM
STRATEGISTS

THE UNIVERSITY
OF UTAH

HPO Network
(Health Care Provider
Organizations)

RMCs

All of Us California

UC San Diego Health

UCI Health

UCSF
University of California
San Francisco

UCDAVIS
HEALTH

COS CEDARS-SINAI

USC University of
Southern California

San Diego
Blood Bank

ECRMC
El Centro Regional Medical Center
An Agency Of The City Of El Centro

All of Us Wisconsin

Marshfield Clinic
Health System

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

Froedtert & MEDICAL
COLLEGE OF WISCONSIN

Illinois
Precision
Medicine
Consortium

Northwestern
Medicine

THE UNIVERSITY OF
CHICAGO

NorthShore
University HealthSystem

RUSH

COOK COUNTY
HEALTH

THE UNIVERSITY OF
ILLINOIS
COLLEGE OF MEDICINE
PEORIA CHICAGO ROCKFORD URBANA

UI Health | UIC

All of Us New England

BRIGHAM HEALTH
BRIGHAM AND
WOMEN'S HOSPITAL

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S
Faulkner Hospital

MASSACHUSETTS
GENERAL HOSPITAL

NEWTON-WELLESLEY
HOSPITAL

McLean HOSPITAL
HARVARD MEDICAL SCHOOL AFFILIATE

PARTNERS
HEALTHCARE

BOSTON
MEDICAL
CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

All of Us Pennsylvania

University of
Pittsburgh

TEMPLE
UNIVERSITY

Trans America
Consortium

Henry Ford
HEALTH SYSTEM

Essentia Health

BaylorScott&White
HEALTH

SPECTRUM HEALTH

RELIANT
MEDICAL GROUP
Part of OptumCare

University of Arizona and
Banner Health

THE UNIVERSITY
OF ARIZONA

Banner Health

New York City
Consortium

COLUMBIA UNIVERSITY
MEDICAL CENTER

NYC
HEALTH+
HOSPITALS

NewYork-Presbyterian

Weill Cornell
Medicine

FQHCs (Federally Qualified Health Centers)

Cherokee
HEALTH SYSTEMS

JACKSON-HINDS
COMPREHENSIVE HEALTH CENTER

SAN YSIDRO
HEALTH

Community
Health Center, Inc.

Eau Claire
People in Care of Others

HRHCare
COMMUNITY HEALTH

All of Us Southern Network

UAB SCHOOL OF
MEDICINE
The University of Alabama at Birmingham
Selma Family Medicine

UAB SCHOOL OF
MEDICINE
The University of Alabama at Birmingham
Montgomery Regional Medical Campus

THE UNIVERSITY OF MISSISSIPPI
MEDICAL CENTER

UAB MEDICINE

Tulane
University

LSU Health
NEW ORLEANS

UAB SCHOOL OF
MEDICINE
The University of Alabama at Birmingham
Huntsville Regional Medical Campus

THE UNIVERSITY OF ALABAMA
University
Medical Center

USA HEALTH

Cooper Green Mercy
HEALTH SERVICES

All of Us SouthEast
Enrollment Center

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

EMORY
UNIVERSITY

MOREHOUSE
SCHOOL OF MEDICINE

UNIVERSITY of
FLORIDA

VA Medical Centers

VA

U.S. Department
of Veterans Affairs

Participant Technology Systems
Center (PTSC)

vibrent

ALL of US
RESEARCH PROGRAM

Biobank

MAYO
CLINIC

Data & Research
Center (DRC)

VANDERBILT UNIVERSITY
MEDICAL CENTER

COLUMBIA UNIVERSITY
MEDICAL CENTER

SCHOOL OF
PUBLIC HEALTH
UNIVERSITY OF MICHIGAN

Northwestern
Medicine

UTHealth
The University of Texas
Health Science Center at Houston

Genomics
Partners

BROAD
INSTITUTE

color

Baylor
College of
Medicine

JOHNS HOPKINS
MEDICINE

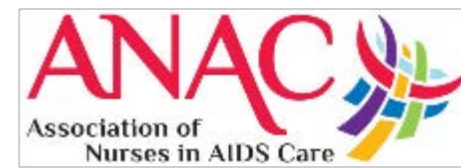
PARTNERS
HEALTHCARE

UTHealth
The University of Texas
Health Science Center at Houston

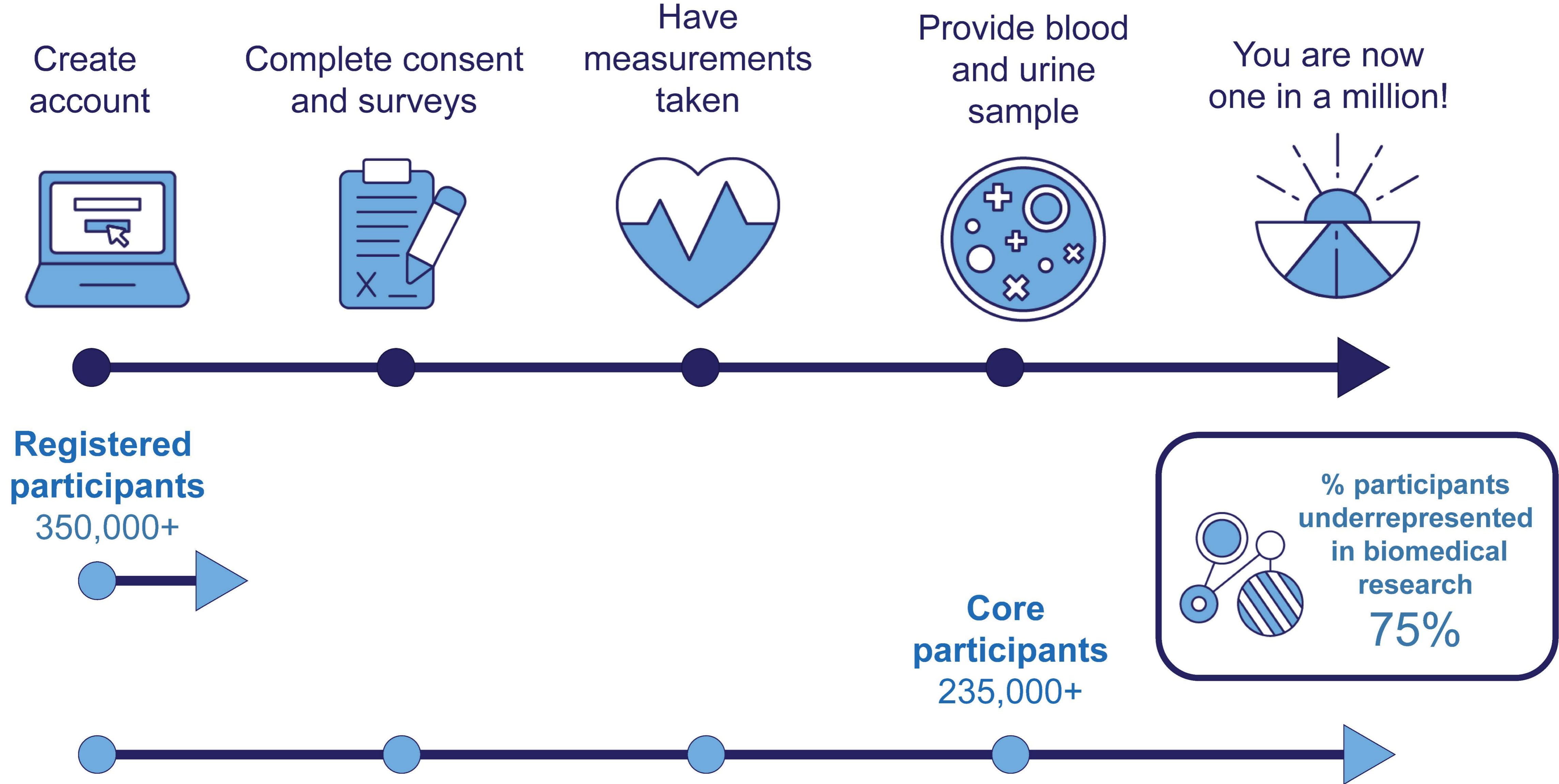
UNIVERSITY of
WASHINGTON

6

All of Us Community Engagement Partners (as of October 2019)

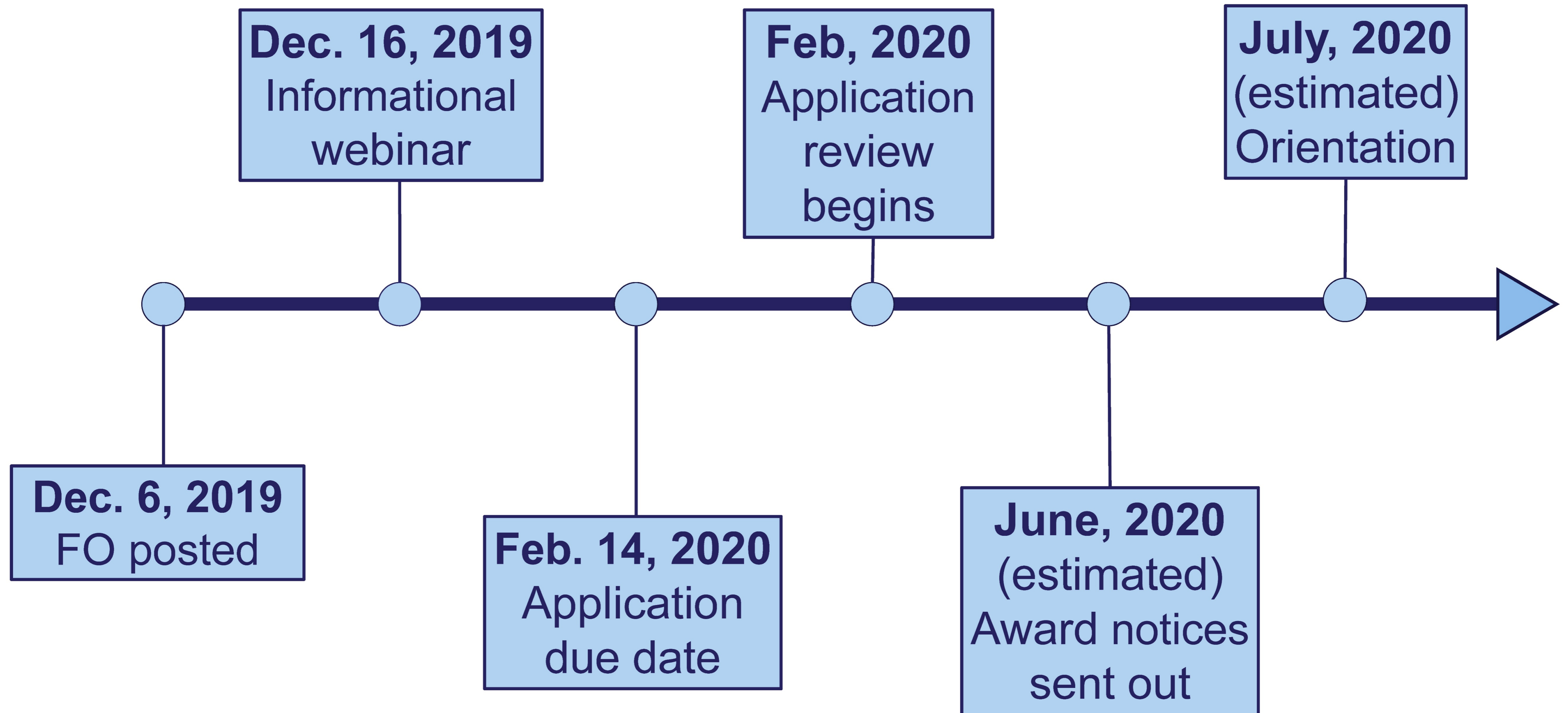


How to become one in a million



Timeline for the funding announcement

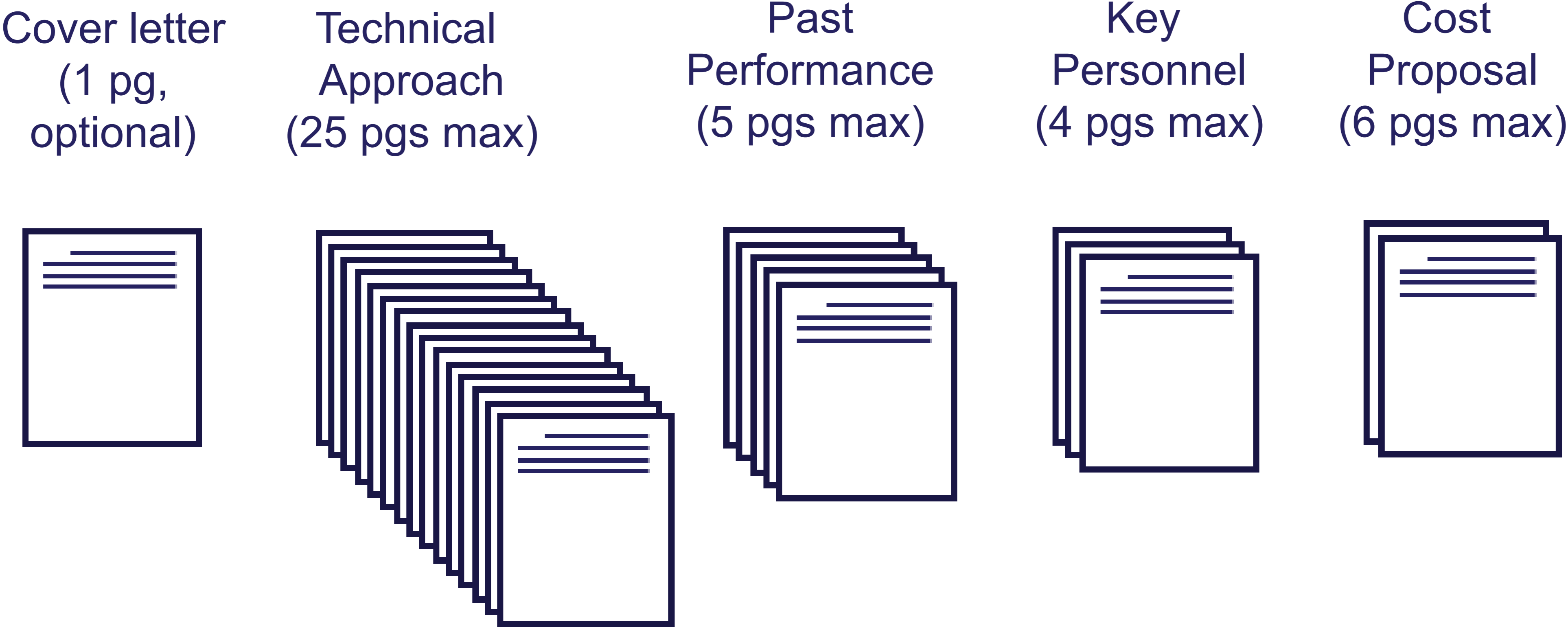
Important dates



Application components and process

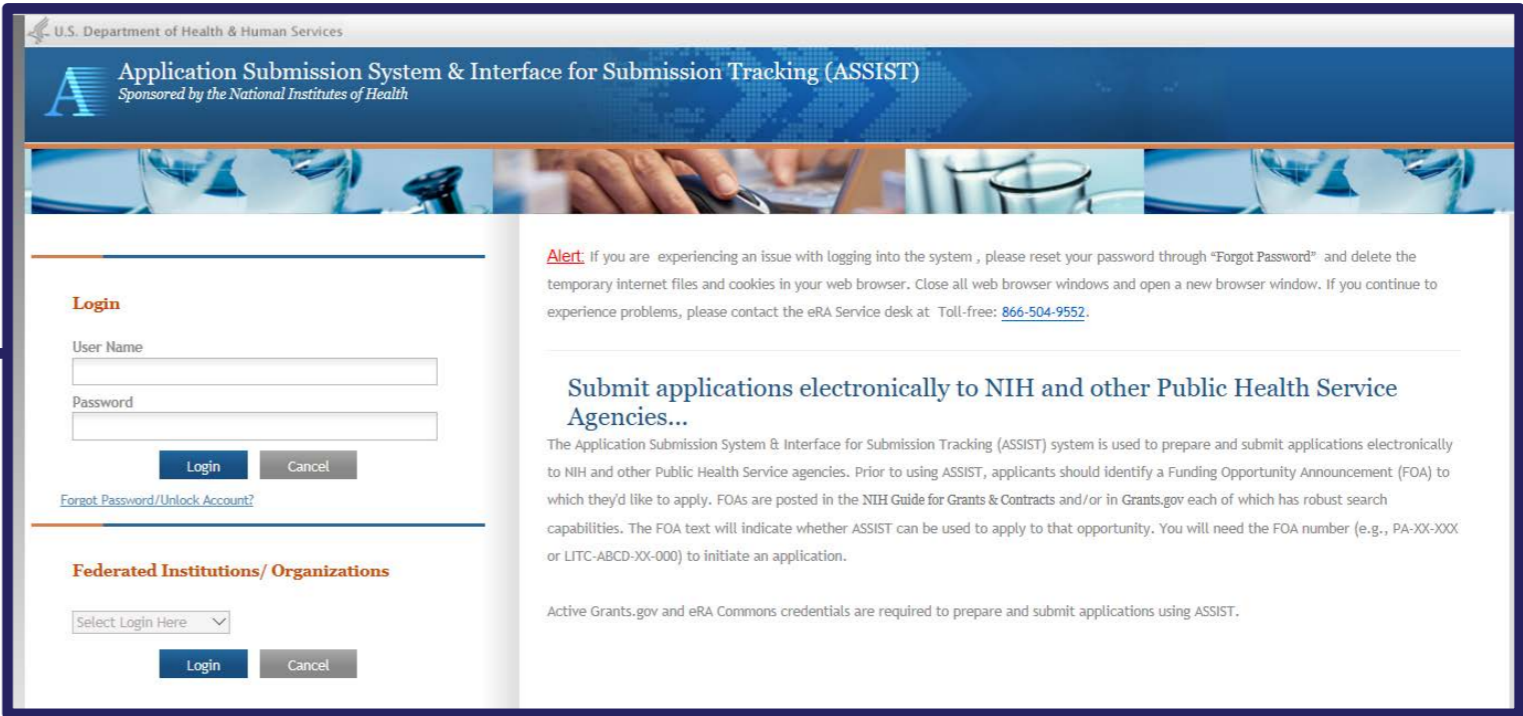
Application components (“Required Application Instructions”, pg. 2-3)

Page limit = 40 (excluding an optional cover letter)

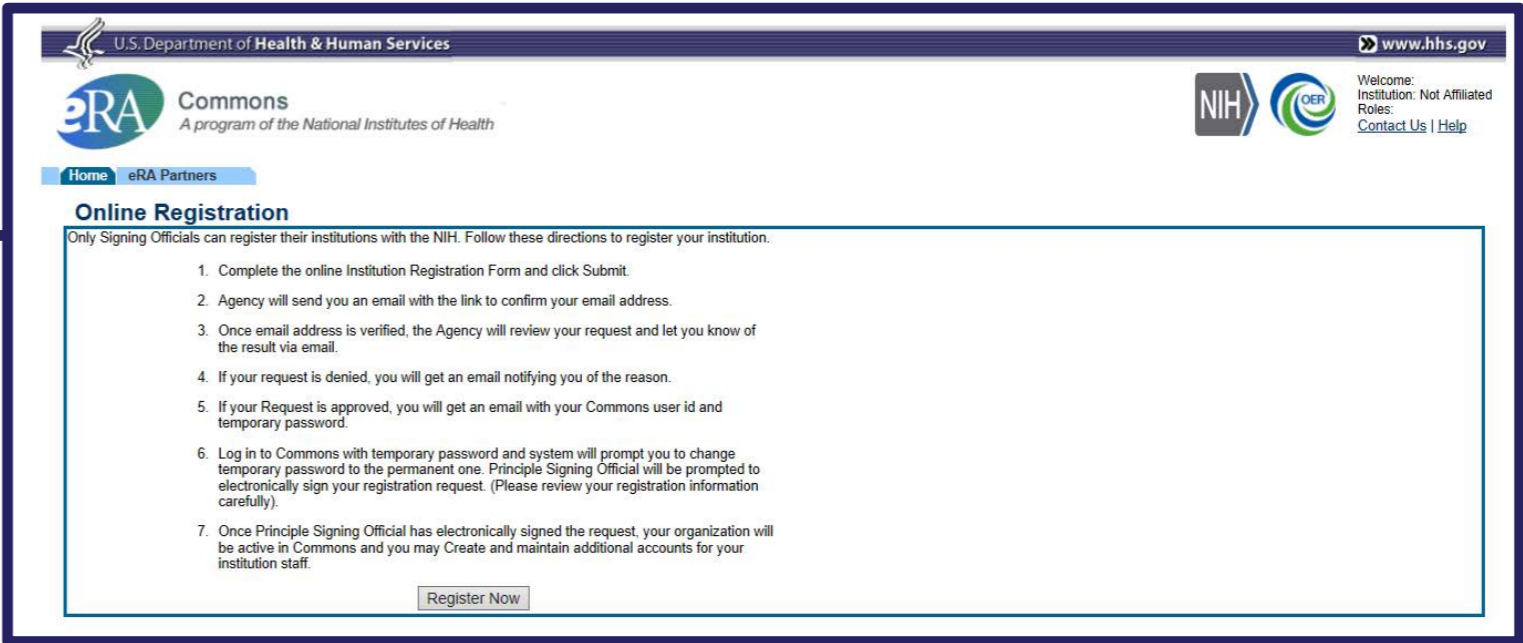


Submission process (“Instructions for Application Submission”, pg. 3-4)

Applications must be submitted via **NIH eRA ASSIST System**



Applicant must be **registered in eRA Commons**



Review “Instructions for Application Submission” section of FO

- Use **OTA-20-001** in the field requesting Funding Opportunity Announcement

Instructions for Application Submission	Applications must be submitted via the NIH eRA ASSIST System by February 14, 2020 (5:00 p.m. local time). To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (see instructions). Organizations already registered in eRA Commons do not need to reregister.
	Once the organization is registered, the individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process. Use OTA-20-001 in the field requesting Funding Opportunity Announcement.

Review process (pg. 5)

1. Evaluate: Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH



2. Select: Top applications will be selected



Objectives of the funding announcement

Purpose and Objectives of the funding announcement (pg. 8)

- ◎ The PTSC has multiple areas of responsibility for the *All of Us* Research Program, including;
 - Platform operations and maintenance
 - Systems integration and support
 - Participant services development
 - Partner services development and support
 - Operational analytics and reporting.

- ◎ Provide technology systems to support program participation from individuals across a broad spectrum of age, cultural background, digital access, educational attainment, health status, socioeconomic status, and technical expertise.

Award Components and Functions for the PTSC (pg. 8-11)

● Component 1: Platform Operations and Maintenance

- Demonstrate awareness of and capabilities to operate, maintain, monitor, and assess a cost-efficient, privacy- and security-compliant cloud environment for All of Us systems development and operations
 - Supporting platform operations and maintenance (O&M,) including security operations, privacy and security compliance (see Data Security and Privacy Management)
 - Supporting development operations and managing commercial cloud platform and software
 - Implementing quality assurance systems and processes to manage the software development life cycle.
 - Support O&M services for partners, to leverage shared resources among integrated systems.

Award Components and Functions for the PTSC (pg. 8-11)

● Component 2: Systems Integration and Support

- Demonstrate awareness of and capabilities to support system integrations and accelerate assessment, onboarding, and operational integration for technology or research service partners for the *All of Us* Research Program.
- The vision of the *All of Us* Research Program is to ultimately open application development opportunities to broader research and software development communities by leveraging an innovation ecosystem to
 - Expand research data collection methods
 - Enhance engagement and return of information to participants
 - Support customized user experiences for specific populations or research protocols

Award Components and Functions for the PTSC (pg. 8-11)

☉ Component 3: Participant Services Development

- Propose solutions to support participation from diverse populations and settings. A few key items highlighted below.
 - Implement current and future protocols for the *All of Us* Research Program, including informed consent materials, surveys, educational content, return/visualization of participant information, customization of content or experience based on participant profile or preferences, and user authorizations management for data sharing.
 - Consider user experience optimization and innovation for both facilitated and unassisted participant interactions in order to improve efficiency and effectiveness of enrollment, engagement, and long-term retention of participants.
 - Support a testbed for rapid user testing and piloting of tools not yet deployed but in development or consideration for use.
 - Consider the needs of the program to support additional user populations (e.g., children and adolescents), protocol-based substudies, and ancillary studies.

Award Components and Functions for the PTSC (pg. 8-11)

◎ Component 4: Partner Services Development and Program Support

- Propose solutions to support engagement, enrollment, and retention of diverse participants within a variety of settings. Tools should support program staff for protocol implementation, facilitation, and management, including
 - Appointment scheduling and management.
 - Multi-channel (e.g., email, SMS, push notifications, direct mail, phone) participant communications and communications workflows.
 - Case management, including cohort, sub-cohort, and individual analytics data access associated with participant status/demographics/region/et cetera.
 - Participant account management and user support.
- Provide support for or coordinate implementation of essential services necessary for PTSC or partner/integrated systems including
 - UI/UX testing for iOS, Android, and web applications.
 - Section 508 compliance auditing and mitigation for PTSC-provided tools.
 - Training and support resources for all PTSC-managed software/services.

Award Components and Functions for the PTSC (pg. 8-11)

● Component 5: Operational Analytics and Reporting

- Propose approaches and solutions to support and enhance capability for the *All of Us* Research Program to leverage rapid and iterative data science methods to increase the performance and efficiency of program components, including strategies for awareness, education, and recruitment, and participant communications for engagement and retention.
 - Analytics tools and services to support real-time visibility for study staff into cohort, sub-cohort, and individual participant status, activity, and engagement with the *All of Us* protocol(s).
 - Curated web and/or mobile platform analytics to optimize the program's ability to monitor and iteratively enhance content and experience to improve enrollment, engagement, progression, and retention of participants.

Data Security and Privacy Management (pg. 11-12)

- Design and implement technical and policy safeguards necessary to ensure data security including compliance with NIST standards to a Federal Information Security Management Act (FISMA) Moderate requirement.
 - The NIH *All of Us* may require additional security measures not included in the FISMA moderate standards.
- Prior to system use in *All of Us*, an Authority to Operate (ATO) from NIH will be required along with documentation describing the current security monitoring/practices in place in accordance with FISMA review standards.
- The NIH *All of Us* ISSO will request an annual independent review of security controls, in addition to continual review and testing, to ensure overall effectiveness against evolving threats and consistent implementation as a requirement of renewal of the ATO.

OT award background

Other Transactions Authority

- The Other Transactions (OT) award mechanism is not a grant, cooperative agreement, or contract.
- For *All of Us*, the National Center for Advancing Translational Sciences (NCATS) manages the OT awards.
- All applicants should read and be familiar with the Other Transaction Award Policy Guide for NIH Precision Medicine Initiative Research Programs. (The NIH Grants Policy Statement does not apply to OT awards.)
- OT allows NIH the flexibility to alter the course of projects in real time to meet the overarching programmatic goal. This means awarded activity can be expanded, modified, partnered, not supported, or later discontinued based on program needs.
- If selected for award, applicants should expect significant ongoing NIH involvement.

Submission Process

- All applicants must submit their application via the NIH eRA ASSIST System.
- To complete the application process, you must complete the NIH Commons Registration first. If you already have a Commons Registration, you do not need to reregister.
- The deadline for application submission is February 14, 2020 by 5pm local time.

Please start the registration and application submission process early to avoid a late application submission due to technical issues.

Late applications will NOT be accepted!

Next steps

1. Submit additional questions to AllofUsFOAInquiries@nih.gov
2. Release slide deck, questions, and answers
3. Application due date: February 14th, 2020
4. Review applications: March 2020
5. Send out award notices: June 2020
6. Hold orientation event (estimated): July-August

Q & A session

Q&A – Open Session

Please use the Q&A box to submit additional questions.



Thank You!
