



Accelerating Discovery through Partnered Research with *All of Us* to Analyze Participant Biospecimens

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Concept Clearance

Concept Clearance: Issue a new PAR for access to *All of Us* biospecimens

Title: Accelerating Discovery through Partnered Research with *All of Us* to Analyze Participant Biospecimens (X01 Resource Access Award)

Objective / Purpose: To enable high-impact research leveraging *All of Us* participant biospecimens to generate new data that will be added to the program's rich dataset

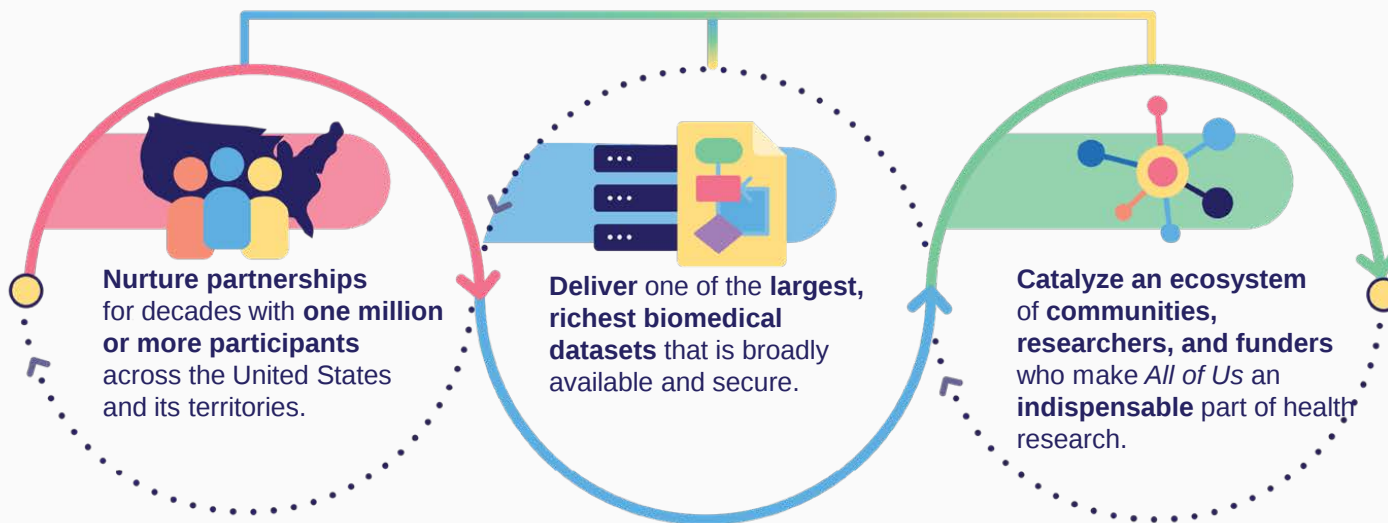
Funds Available & Anticipated Number of Awards: The X01 requires no funding from *All of Us*. We anticipate approximately 5 projects.

Award Project Period: 1-3 years

Council Action: Vote for approval of the concept for the issue of X01 PAR above

Our mission

Accelerate health research, enabling individualized prevention, treatment, and care for all of us.



Enrolled 865K+ Participants With Continued Growth

Participant Enrollment

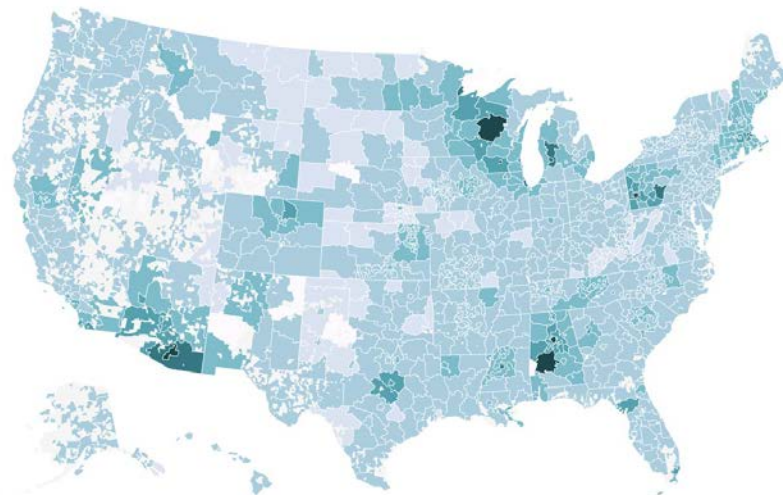
865,000+
Participants

470,000+
Electronic
Health Records

594,000+
Participants who
have completed
initial steps of the
program

609,000+
Biospecimens

Map of Consented Participants



US map of *All of Us* participant density; covers
98.1% of US zip3 codes

Numbers current as of July 31, 2025

Data Types Collected from *All of Us* Participants



Electronic Health Records

Demographics
Vital signs
Diagnoses

Procedures
Medications
Doctor & Laboratory Visits



Participant Surveys

The Basics
Overall Health
Lifestyle

Health Care Access & Utilization
Personal and Family Medical History
Social Determinants of Health

Mental Health and Well-Being



Physical Measurements

Blood pressure
Heart rate
Height
Weight

BMI
Hip circumference
Waist circumference



Biospecimens

Blood
Saliva (for DNA only)
Urine

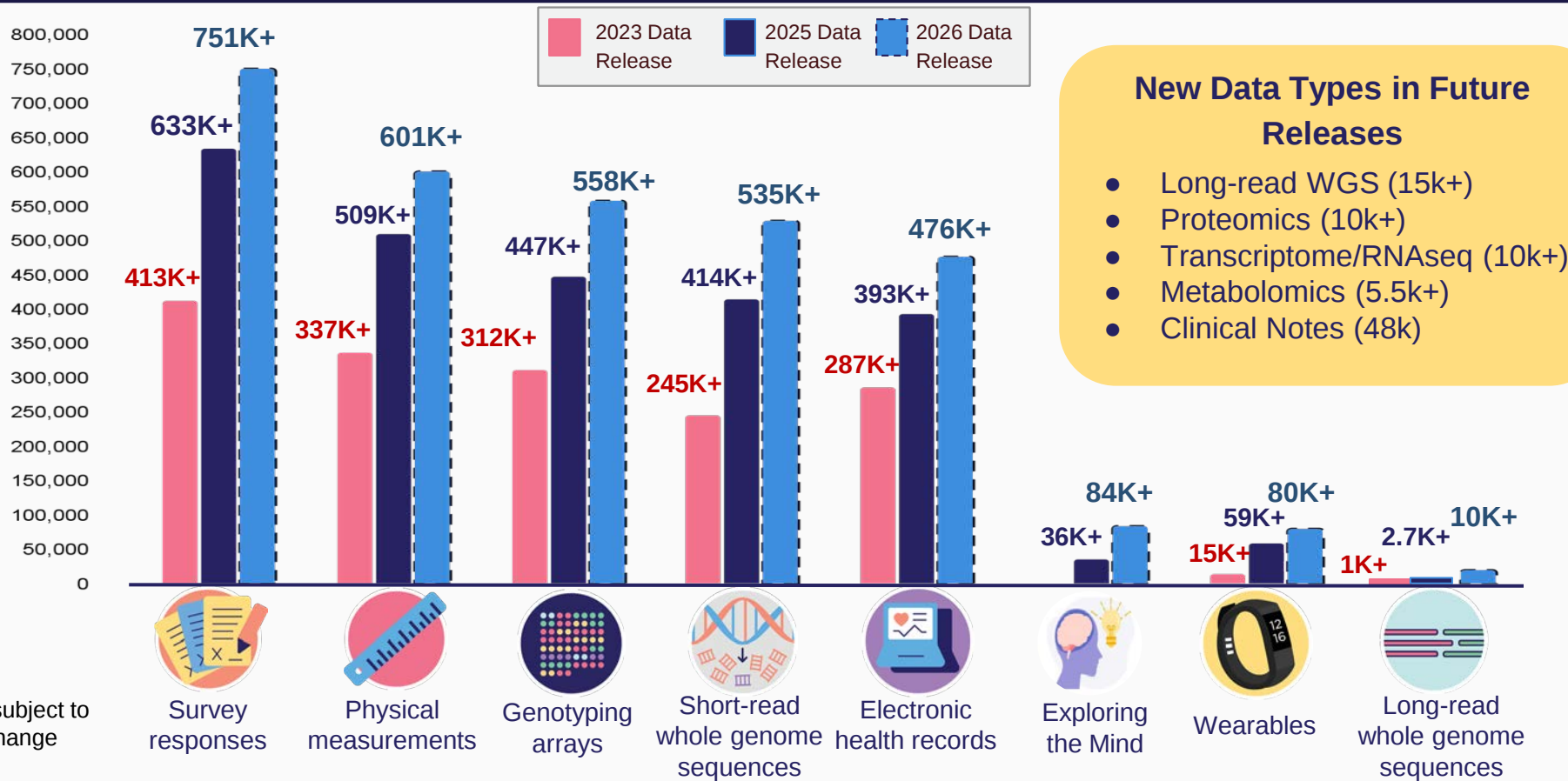


Wearable Data

Fitbit data, including:
Heart Rate
Activity (Daily Summary)

Activity Intraday Steps
Sleep data

Major New Data Releases Every 1 to 2 Years with Projected 2026 Data

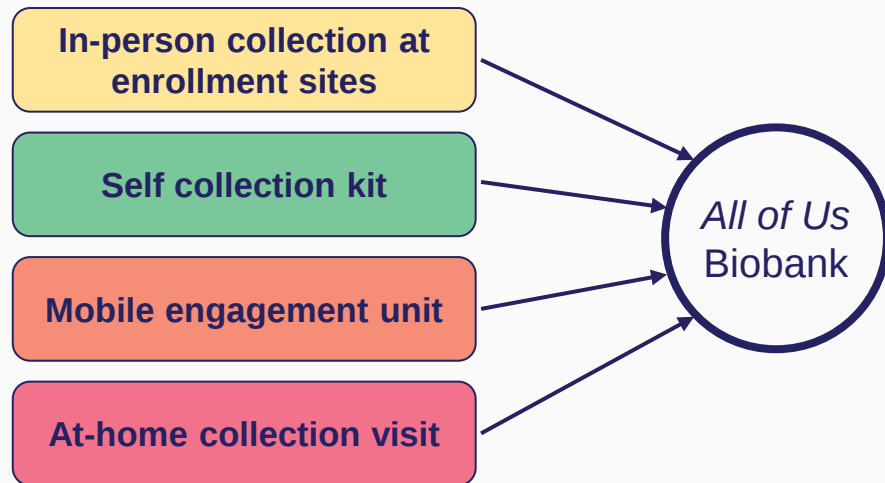


The *All of Us* Biobank

The *All of Us* Biobank, managed by Mayo Clinic, is a national resource supporting collection, analysis, storage, and distribution of biospecimens that the program collects for broad research use.



Total # of aliquots stored: 14,650,000+

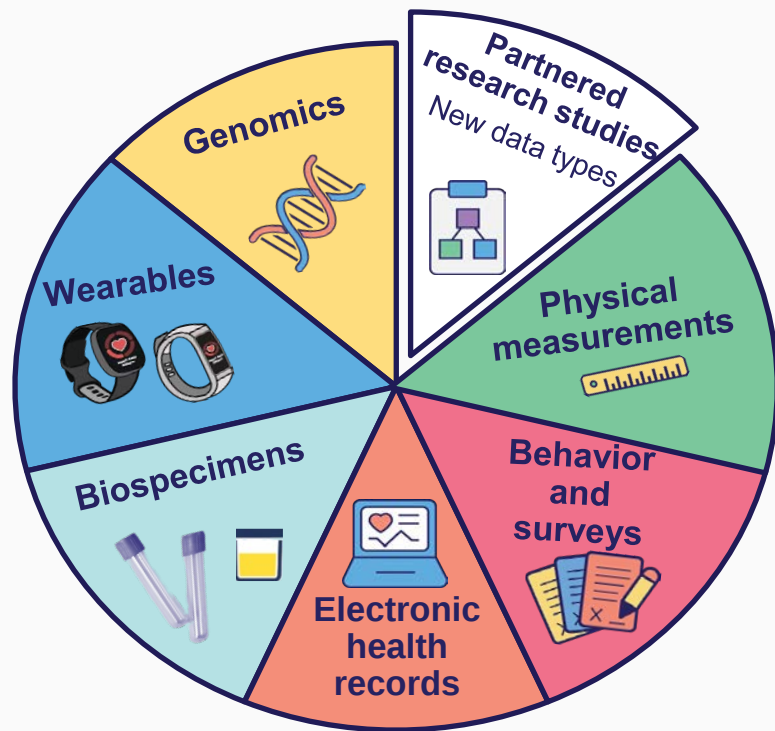


The program uses multiple methods to collect biospecimens from participants across the U.S.

Collection Tube	Parent Tubes Received	Aliquots Stored
Serum Separator (SST)	483,000 +	1,806,000 +
Plasma Separator (PST)	489,000 +	1,877,000 +
Sodium Heparin	482,000 +	956,000 +
EDTA (DNA, plasma, WBC, RBC)	1,000,000 +	5,148,000 +
PAXgene cfDNA	451,453 +	445,000 +
PAXgene RNA (RNA, whole blood)	450,000 +	449,000 +
Urine	488,828 +	3,780,000 +

All of Us Partnered Research Studies

Research projects funded by entities outside of *All of Us* that collect and integrate new data into the *All of Us* data ecosystem enriching it for all users



How do *All of Us* partnered research studies differ from typical ancillary studies?

Make new data available through the Researcher Workbench

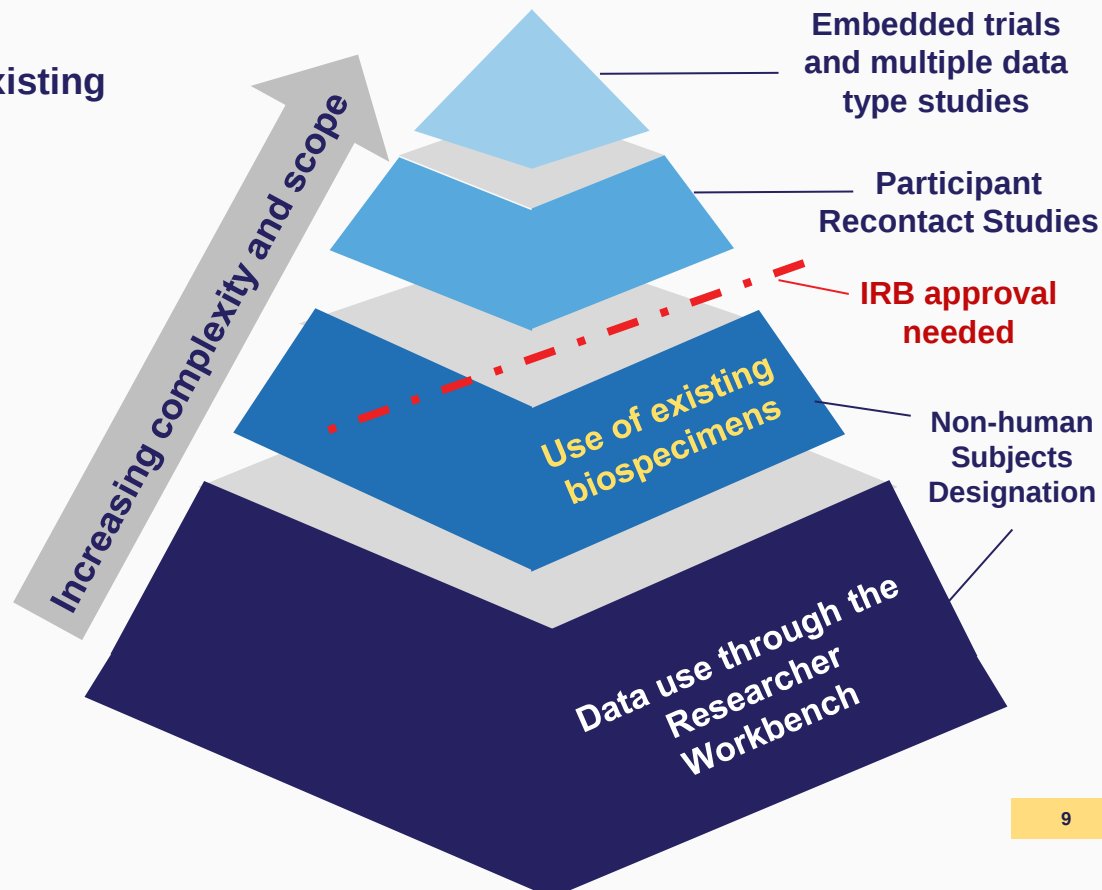
Return value to participants while reflecting participant priorities

Strategy to Enhance Resources through Partnered Research Studies

Partnered research studies build on the existing data in the Researcher Workbench.

All of Us supports many partnered research study designs and methodologies including:

- New assays of previously collected biospecimens
- New surveys
- Digital health technology and wearable data collection methods
- Multi-data type, trial-like studies which test interventions and collect multiple new data types



Broader Launch of Partnered Research Studies



**6 studies already launched
16 studies currently in the
pipeline with NIH partners**

**Call for large-scale study
proposals that leverage
collected biospecimens.**

**Partnering with NIH ICO's to launch initial partnered
research studies**

**Opening access to researchers
outside of the NIH**

2024

2025

2026

2027

Preparing tools and resources for partnered research studies

Today's Concept: PAR for Resource Access via X01

Utilizing the X01 Mechanism for Access to *All of Us* Biospecimens

- X01 mechanism is a Resource Access Award that enables eligible investigators to apply for **access to NIH resources to conduct research**
- *All of Us* proposes to leverage the X01 mechanism by issuing a PAR to allow extramural investigators access to:
 - Stored de-identified biospecimens
 - *All of Us* research infrastructure
- Funding to be supplied by NIH, other government agencies, non-profit or for-profit partners, or through the applicant's existing research budget
- All data generated will be returned to the *All of Us* Researcher Workbench

The X01 will Accelerate Discovery

Biospecimen partnered research studies via the X01 will:

- **Enable cost-effective new research** that will add valuable data back to the *All of Us* resource for broad use (including but not limited to: proteomics, metabolomics, transcriptomics, methylome, immuno-assays, exposomics)
- **Return value** to participants
- **Ensure fairness and transparency** in the application and review process
- **Make progress** towards achieving precision medicine for all

PAR to Support an Initial Biospecimen Release

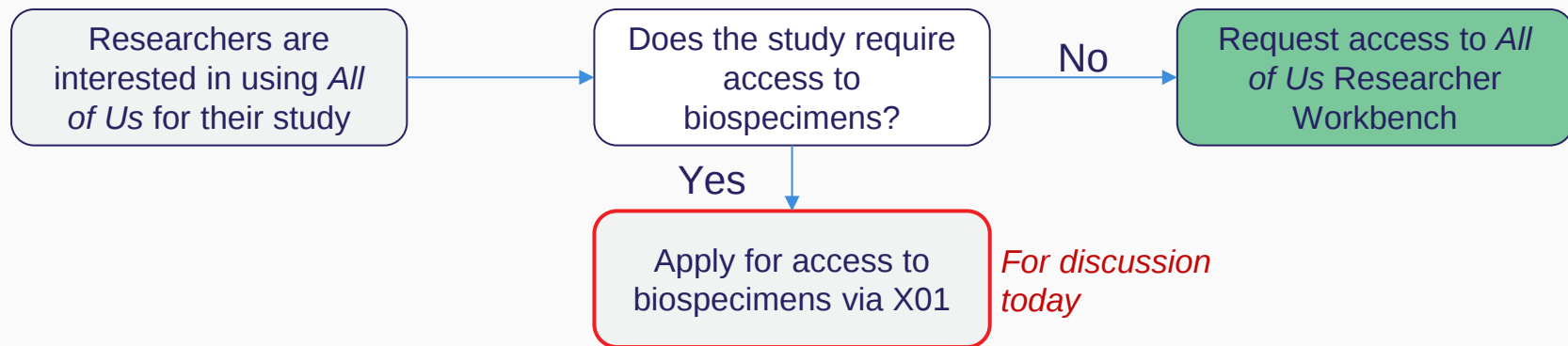
Target: Two receipt dates

Review: Programmatic Review by *All of Us* Research Program for:

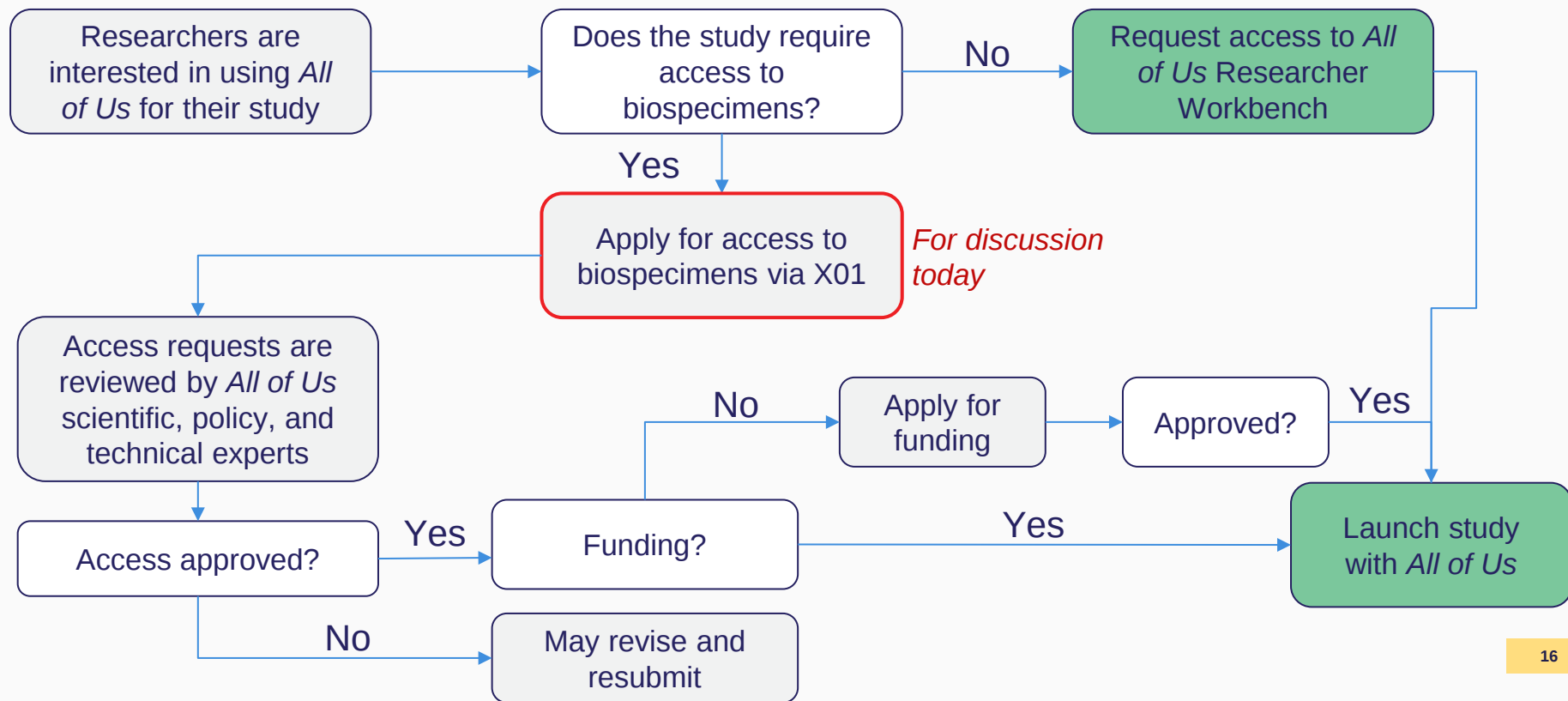
- Scientific & technical merit
- Alignment with *All of Us* mission, core values, and scientific framework
- Potential impact of data returned to *All of Us* dataset
- Return of value to participants

Project support: 1 year to demonstrate funding or supply proof of funding

All of Us will Support Meritorious New Studies



All of Us will Support Meritorious New Studies *(continued)*



Summary

All of Us Research Program:

- Makes de-identified data available to the broad scientific community through the *All of Us* Researcher Workbench
- Allows partnered research studies to expand the cohort data sponsored by the NIH partners
- Intends to open biospecimen access to researchers funded outside of *All of Us* via X01 and leverage the partnered research studies infrastructure

Making Health Discoveries Possible

The *All of Us* Research Program wouldn't be possible without the generosity of our participants and the dedication of our researchers.



Requested Council Action

Vote for concept approval for *All of Us* to issue a X01 PAR for biospecimen access.