

University of Arizona & Banner Health seed grant request for proposals using *All of Us* Research Program data

Dates:

Informational Meeting/Q&A: October 28, 2 p.m. MST (Optional) Zoom link register

Submission Deadline: December 2, 2024; 5 p.m. MST

Award Announcements: December 20, 2024

Award Period (Up to 6 months): January 1, 2025–August 31, 2025

Award Amount: Not to exceed \$40,000 per award, inclusive of indirect costs

Details:

Administrators: University of Arizona (UArizona)-Banner Health

Seed Grant Coordinator: Jennifer Smith, Program

Manager at UArizona-Banner Health

Category: UArizona-Banner Health NIH-Funded OTA Award

Multi-PI applications allowed: Yes

Submit proposals via email to: aou-research@email.arizona.edu

Introduction and Background:

Supported by the National Institutes of Health's *All of Us* Research Program, the University of Arizona-Banner Health, seeks to identify and empower research projects that use *All of Us* data through seed grants. UArizona-Banner Health intends to fund up to three seed grant proposals providing up to \$40,000 (inclusive of indirect costs) per award to cover personnel, computational, and data storage costs associated with scientific aims that leverage *All of Us* data. These seed grants are open to investigators from institutions in the United States and its territories that have a Data Use and Registration Agreement (DURA) in place with the *All of Us* (see "About the *All of Us* Researcher Workbench" below). The seed grants are designed to jump-start projects that leverage and interrogate *All of Us* data.

About the All of Us Research Program

The National Institutes of Health's *All of Us* Research Program is a historic effort to collect and study data from a million or more people living in the United States and its territories. The goal of *All of Us* is to speed up health research discoveries, enabling new kinds of individualized health care. To make this possible, the program is building one of the world's largest and most diverse databases for health research. The program seeks for its participant cohort to reflect the diversity of the United States and its territories and to include individuals from groups that have been underrepresented in health research in the past.

About the All of Us Researcher Workbench





The *All of Us* dataset is stored on the Researcher Workbench, a secure, cloud-based platform. The program offers tiered access to the data. There are three tiers of access: 1) Public Tier through the interactive <u>Data Browser</u>; 2) Registered Tier, which includes individual-level data from electronic health records (EHR), wearables, and surveys, as well as physical measurements; and 3) Controlled Tier, which includes data available on the Registered Tier, as well as genomic data and expanded demographic, survey, and EHR data. In the Researcher Workbench's Controlled Tier, registered researchers can combine genomic data shared by the participant cohort with data from other sources to launch a wide variety of studies.

Researchers' institutions must first have DURAs in place with *All of Us* before they can register to use the Researcher Workbench's Registered and Controlled Tiers. **Your institution must have a DURA in place with** *All of Us* **Research Program before you apply for a seed grant.** You can search or browse the list of registered institutions to confirm if your institution has a DURA in place and the data available to you based on Registered or Controlled Tier access

This grant announcement solicits proposals to pursue seed grants to inform two objectives:

- 1) Encourage investigators to leverage All of Us data to:
 - Conduct studies using All of Us data relevant to investigator-specific research question(s) and study aims, including both clinical and/or omics studies using the Controlled and/or Registered Tiers
 - b. Prepare peer-reviewed publications and disseminate findings
 - c. Engage and develop an active research investigator cohort in our region and with community partners
- 2) Participate as research partners in continuous improvement regarding access to and use of the *All of Us* support resources. Findings and feedback from seed grant study investigators will inform *All of Us* staff in further developing resources for technical assistance. We will conduct monthly meetings with all awardees and support staff to facilitate a community around *All of Us*-based research and discovery.

Description:

UArizona-Banner Health intends to fund up to three seed grant proposals across a range of clinical and public health subtopics associated with scientific aims that leverage the Researcher Workbench. These seed grants may be single or multi-investigator awards providing up to \$40,000 (inclusive of indirect costs) per competitive grant awarded. Our expectation at the conclusion of the award is for the seed grants to lead to peer-reviewed publications and dissemination. (See some example publications resulting from All of Us data.) Possible approaches include, but are not limited to:

- The use of participant-provided health information (validated survey instruments) and EHR data
 to investigate original research questions, to validate existing epidemiological and/or clinical
 evidence, and to demonstrate potential for novel approaches and analyses in the diverse All of
 Us dataset
- The discovery of new genetic variants, genome-wide and phenome-wide association studies, and/or polygenic risk scores
- Studies of genetic influences versus social influences and how those impact health





Proposals to support lines of inquiry on health questions for/with underserved, vulnerable, and minoritized populations, such as racial and ethnic minoritized groups and sexual and gender minoritized groups

Eligibility

Seed grant applicants must be investigators from any institution in the United States and its territories with a DURA in place with All of Us. Collaborative grants that include investigators from multiple institutions with DURAs are allowed. A list of institutions with active, approved DURAs can be found here. Applications will be peer-reviewed and scored using the following criteria:

- a) Commitment to advance scholarly research and dissemination of results through peer-reviewed publication in keeping with the aims of All of Us
- b) Feasibility assessment of study question(s)/aims relative to identification of All of Us descriptive statistics/data categories from Public Tier summary data
- c) Overall significance and merit of proposal
- d) Consistency of project with All of Us core values, data security policies, and privacy and trust principles, including prohibition of stigmatizing research and re-identification of participants
- e) Evidence key personnel are experienced and qualified to conduct the study

Use of the Funds

Funds for awarded seed grant projects will be distributed as subawards to the NIH-funded UArizona-Banner Health researcher engagement award (OT2OD036485-01s1). Time required to establish a subaward may delay the initial start of projects. Collaborative grants that include investigators from multiple institutions with DURAs are allowed, but additional subaward processing times may be encountered. As funds originate from NIH, institution-specific NIH rates for indirect costs apply unless exemptions are acquired. The \$40,000 grant amount includes institutional indirect costs, which should be reflected in the submitted budget.

The following provides a list of generally allowable costs:

- Indirect costs at Institution-specific NIH rates (inclusive of \$40,000 total award amount)
- Effort for PI(s) (Current NIH Salary Cap Applies)
- Effort for other key personnel and non-key personnel supporting research aims
 - Please note that, if needed, statistical analyst, bioinformatician, and/or health informatician effort will be available at no cost to the seed grant award budget and available effort distributed based on need across funded projects (approximately 0.25 FTE per project during the budget period). This support will aid seed grant awardees to navigate Researcher Workbench operations, data availability, programming, computational cost estimation and reduction, and other services. Additionally, UArizona-Banner Health staff, program management staff, and individuals experienced in the Researcher Workbench are available for consultations throughout the award period.
- Computational and data storage costs
 - Example costs are included in the draft budget (see example budget). \$300 in computational credits are currently provided to all new Researcher Workbench users.

The following provides a partial list of **nonallowable** costs:

Experimental reagents and consumable research supplies





- Due to the nature of research on the Researcher Workbench, these costs are not expected and will not be permitted without sufficient and compelling justification.
- Graduate tuition remission
 - Graduate student effort is allowable.
- Equipment
- Domestic and international travel costs
- Cost for personnel from additional external institutions
- Peer review publication or open access fees
- Any unallowable costs listed in NIH Grants policy 14.10.2
 (https://grants.nih.gov/grants/policy/nihgps/html5/section_14/14.10_allowable_and_unallowable_costs.htm)

Funds should be expended between January 1 and August 31, 2025.

Timeline:

December 2, 2024 Proposals due by 5 p.m. MST
December 20, 2024 Funding decisions communicated

January 1, 2025 Earliest budget period start date; funds available for expenditure August 31, 2025 Latest budget period end date; all funds must be expended.

Proposal Format

Proposal narratives **must not exceed four** (4) pages (single-spaced, 11-point font (smallest), 0.5-inch margins). Suggested fonts: Arial, Times New Roman, Calibri, or Tahoma. Reduced, legible font sizes in figures and legends are acceptable. All documents, except the budget sheet, should be saved and submitted as PDF files. The budget sheet should be submitted as an editable Excel document.

Full Proposal

Proposals require the following:

- 1) Cover sheet (not counted against page limit)
- 2) Proposal summary (1 page limit)
- 3) Proposal narrative (3 page limit)
- 4) Required supplemental documents listed below (not counted against page limit)
- 5) Award Requirements and Reporting

1) Cover Sheet:

- a) Descriptive title of proposal
- b) Principal Investigator(s): Name, position, department, institution, contact information
- c) Co-Investigators/Key personnel: Name, position, department, institution, contact information (student assistants and non-key personnel should be noted on the budget)
- d) Keywords/Key phrases: Include up to five keywords or key phrases

2) Proposal Summary (up to 1 page):

- a) Summary or abstract of your proposal
- A self-contained description of the proposed work and outcomes that would result if funded should be included. This should be understandable to a scientifically or technically literate lay reader





3) Proposal Narrative (up to 3 pages):

- a) Brief description of the specific aims and/or objectives
- b) The scope of the project should be reasonable, feasible, and managed within the study timeframe.
 - i) Please note: It is important to review and briefly describe the descriptive statistics (or data categories) using the public <u>Data Browser</u>. These data should be used to assess evidence of target participant population(s), condition(s) of interest, and related data domains relevant to the feasibility of your research question and aims within the Researcher Workbench.
- c) Significance, expected outcomes, and description of how such outcomes may enrich *All* of *Us* and contribute advances to scholarly research in precision medicine and health
- d) Methods and description of how the work will be carried out
- e) Brief description as to why the PI and key personnel are qualified to conduct the study

4) Required Supplemental Documents:

- a) References cited (Suggest a reference style used when submitting a journal article in your field)
- b) PI's CV or biosketch (Multi-PI applications are allowed)
- c) Key personnel CV or biosketches
- d) Budget (see example <u>budget</u>)
 - i) Please file > download > Microsoft Excel to save your own editable version to your device. Create budget justification notes only as needed for clarity. As funds originate from NIH, institution-specific NIH rates for indirect costs apply unless exemptions are acquired. The \$40,000 grant amount includes institutional indirect costs. If an indirect cost exemption has been granted, evidence of this exemption is required before award processing.
- e) Funded proposals are expected to comply with applicable institutional research policies, including but not limited to human subjects, conflict of interest, HIPAA, and *All of Us* data security and privacy policies
 - i) Please note: All of Us data and extracted data cohorts are kept in secure cloud spaces; access does not require IRB approval. We require that all PIs and key personnel attest to their compliance with data security and participant data privacy by including a signed statement that includes the text below: "I have reviewed the All of Us data security policies. I will ensure that any row level data in the All of Us Researcher Workbench will not be downloaded off of the Researcher Workbench and all analyses accessing row-level data will be conducted in the Researcher Workbench. I will not attempt reidentification at the person level and I will report any accidental/incidental reidentification of All of Us participants. I will take extreme care to avoid stigmatizing All of Us participants or groups of participants as a result of the study results and interpretation of findings."

5) Award Requirements and Reporting:

a) Submit a final report (two pages) as a pdf within 30 days of the award period conclusion





- i) The report will be shared with institutional leadership at UArizona-Banner Health and *All of Us* staff and investigators
- ii) Faculty receiving awards, their projects, and/or publications may also be featured in NIH, University of Arizona, and/or Banner Health media outlets
- b) Participate in brief surveys every six months for a period of two years following the seed grant end date to report abstracts, publications, presentations, and other dissemination of results relevant to the funded seed grant
- c) Acknowledge funding in abstracts, publications, and presentations with the following statement: "This research was funded in part by the National Institutes of Health Office of the Director through the University of Arizona-Banner All of Us Researcher's Collective (award OT2OD036485)."
- d) Submit the <u>All of Us Publication and Presentation Reporting Form</u> for any article, presentation, or other product that uses <u>All of Us</u> data
- e) Post relevant workspace(s) as <u>community workspaces</u> in the Researcher Workbench upon publication of research
- f) Participate in the monthly community-building meeting between *All of Us* staff, PIs, and support staff on the usefulness and growth of research infrastructure as well as lessons learned

Submit proposals to <u>aou-research@email.arizona.edu</u> with the subject line: *All of Us* seed grant proposal PILastName

For questions, feedback, support contact:

- Jason Karnes, PharmD, PhD, BCPS, FAHA, FCCP, Director of Scientific Programs, *All of Us* University of Arizona-Banner Health, <u>karnes@arizona.edu</u>
- Vignesh Subbian, PhD, Associate Director of Health Data Science and Research, Center for Biomedical Informatics & Biostatistics, vsubbian@arizona.edu
- Jennifer Smith, MS, Program Manager, aou-research@email.arizona.edu