Technical Assistance Webinar for NOT-MD-22-015 Notice of Special Interest (NOSI): Administrative Supplements to Support "All of Us" and Health Disparities-Related Pilot Research Projects at NIMHD-Funded Research Centers in Minority Institutions (RCMI)

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All of Us Research Program

Gage Rion, ME

All of Us Research Program

May 20, 2022

Webinar Begins at 3:30 PM EST

Webinar Tips

Participants may ask questions using the chat feature. Questions will be answered during the Q&A session at the end of the webinar as time permits.

These slides and a recording of today's webinar will be <u>available at https://www.nimhd.nih.gov/funding/nimhd-funding/webinars.html</u>



Agenda

- NOSI background and research objectives
- II. All of Us Research Hub and Researcher Workbench
- III. Application and submission information
- IV. Review of applications
- V. Timeline for application submission
- VI. Questions



Part I NOSI Background and Research Objectives



Background

❖ Purpose: Administrative Supplements to RCMIs to support pilot research that use the All of US Research Program dataset.

Background:

- ❖ All of Us Research Program- Diverse dataset
- ❖ Data collected include physical measurements, lifestyle questions, electronic health records, social determinants of health (available summer 2022)
- ❖ NIMHD RCMI Program- institutions with a commitment to educating underrepresented students and for institutions that provide clinical services to the medically underserved.



Research Objectives

- All of Us Research Program and NIMHD RCMIs to support pilot projects let by ESIs using the All of Us dataset
 - Address minority health or heath disparities for NIHdesignated United States populations with health disparities
 - Pilot project investigations that align with the NIMHD framework are a priority.
 https://www.nimhd.nih.gov/about/overview/research-framework/nimhd-framework.html
 - Cross-discipline collaborations
- Research topics (may include but are not limited to)
 - CVD risk, COVID-19, chronic conditions, mental health, injuries, sleep, substance use, social determinants influencing access and quality of care



Part II

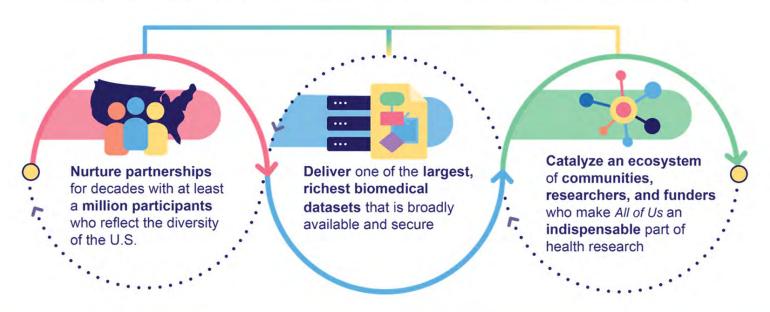
The *All of Us* Research Hub and Researcher Workbench



All of Us Mission

Our Mission

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



Made possible by a team that maintains a culture built around the program's core values

The All of Us Research Program: An Innovative Research Effort

- . Diversity at the scale of 1 million people or more
- . Focus on participants as partners
- . Longitudinal design, ability to recontact



- Multiple data types: EHR, surveys, baseline physical measurements, biospecimens, genomics
- National, open resource for all: Broadly accessible to all researchers with open-source software & tools
- Security and privacy safeguards for all participant data

All of Us Consortium Members (beyond community partners, as of October 2021)



All of Us Community and Provider Partner Network (as of October 2021)













































































































Current protocol



Enroll, Consent and Authorize EHR

Recruiting 18+ years old initially; plan to include children in future

Online, interactive consent

Includes authorization to share EHR data



Answer Surveys

The Basics Health Care Access & Utilization

Overall Health Personal and Family Medical History

Lifestyle Social Determinants of Health

Additional surveys will be released on an ongoing basis



Provide Physical Measurements

BIOOD pressure Height

Heart rate Weight Waist circumference

Hip circumference

Based on diverse sampling and capacity



Provide Biosamples

Blood (or saliva)

Urine specimen

Biosamples will be stored at the program's biobank

Based on diverse sampling and capacity



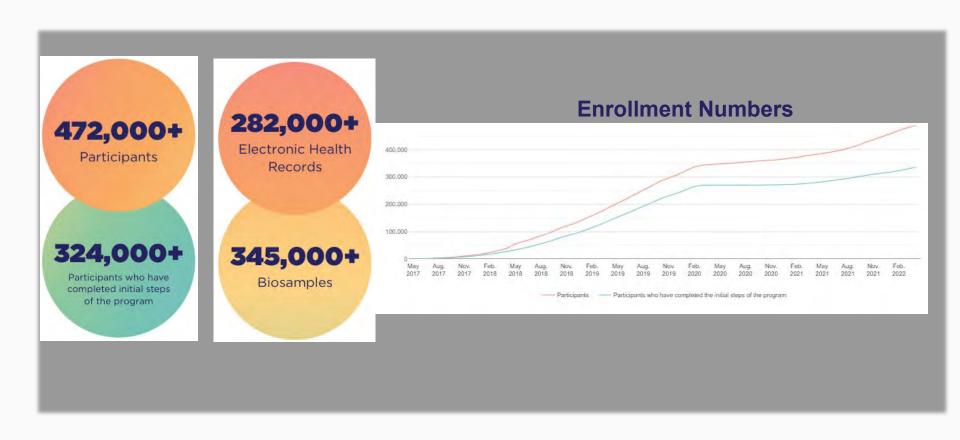
Share data from Wearables/Digital Apps

Share data from wearable fitness devices, starting with Fitbit

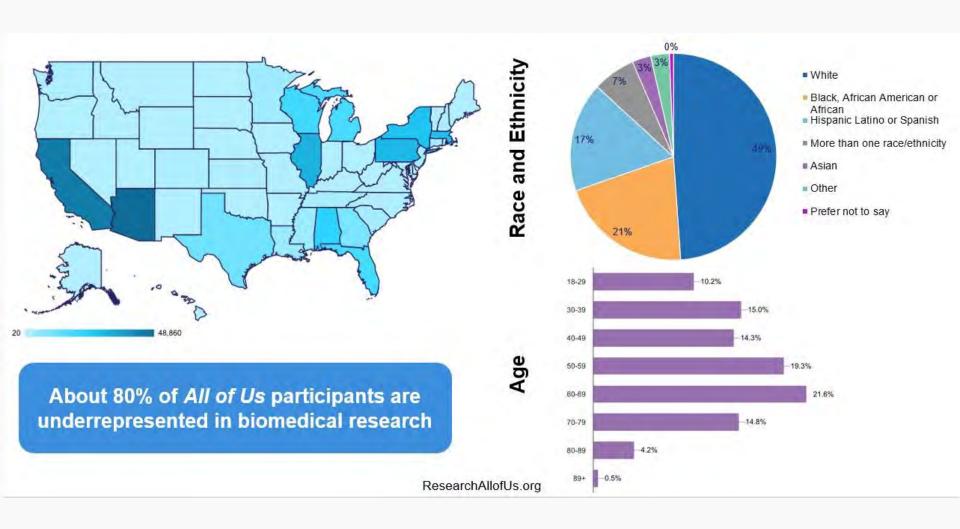
Coming soon:

Integrated apps to track mood & cardio-respiratory fitness

Selected Data Snapshots: Enrollment Progress



Commitment to All of Us Participant Diversity



Researcher Workbench

By The Numbers -



Data available in the researcher workbench



267,600+ Physical Measurements



214,200+ Electronic Health Records (EHR)



329,000+ Survey Responses



98,600+ Whole Genome Sequences

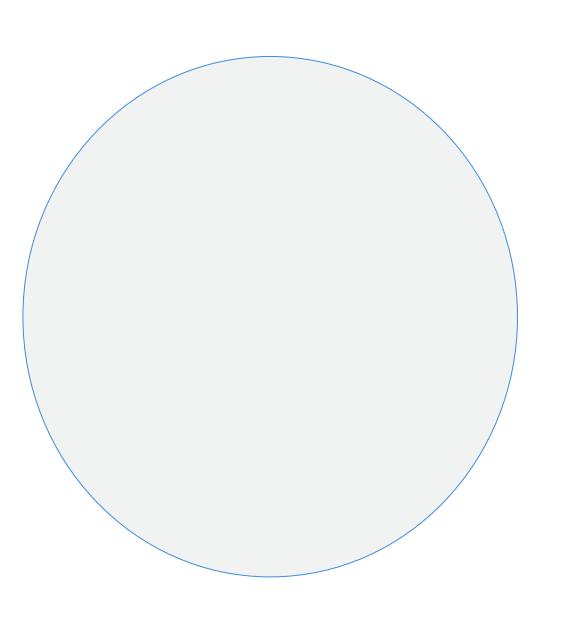


165,000+ Genotyping Arrays

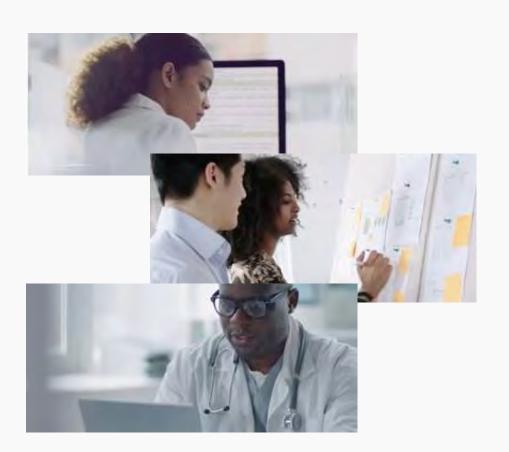


11,600+ Fitbit Records

Research Allof Us.org

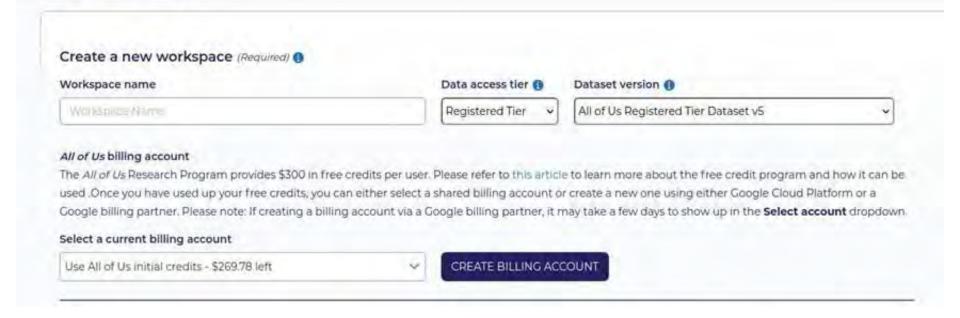


Building a Diverse Researcher Cohort



- Creating a demographically diverse
 researcher cohort that promotes responsible
 and ethical use of data, returns value to
 participant communities, and accelerates
 research impact.
- Encouraging student assemblies and early-stage investigators to bring fresh, creative perspectives & innovative research outcomes.
- Ensuring access for researchers from various institutions/organizations to establish a truly equitable resource for all.





- Billing is set at the workspace level
- All registered researchers receive an initial \$300 in free compute credits
- Workspaces can be connected to billing accounts

92% of all researchers use < \$100 in compute credits 88% use < \$50 80% use < \$25

How to develop a research question using the NIMHD framework and AoU data

Step 1: Review the framework and select topic

National Institute on Minority Health and Health Disparities Research Framework Levels of Influence* Individual Interpersonal Community Societal Community Illness Sanitation Caregiver-Child Interaction Biological Vulnerability Biological Exposure Immunization and Mechanisms Family Microbiome Herd Immunity Family Functioning Domains of Influence Behavioral Community Functioning Policies and Laws Coping Strategies School/Work Functioning Physical/Built Household Environment Community Environmen Personal Environment Societal Structure School/Work Environment Community Resources Environment Sociodemographics Social Networks Community Norms Social Norms Limited English Sociocultural Family/Peer Norms Local Structural Societal Structural Environment Cultural Identity Interpersonal Discrimination Discrimination Discrimination Response to Discrimination Insurance Coverage Health Care Patient-Clinician Relationship Availability of Services Quality of Care Health Literacy Medical Decision-Making Safety Net Services Health Care Policies System Treatment Preferences Population Health **Health Outcomes**

Step 3: Modify research question as needed based on data availability

Step 2: Review Public Tier of the *All of Us* Research Hub to confirm data
availability in the *All of Us* data set

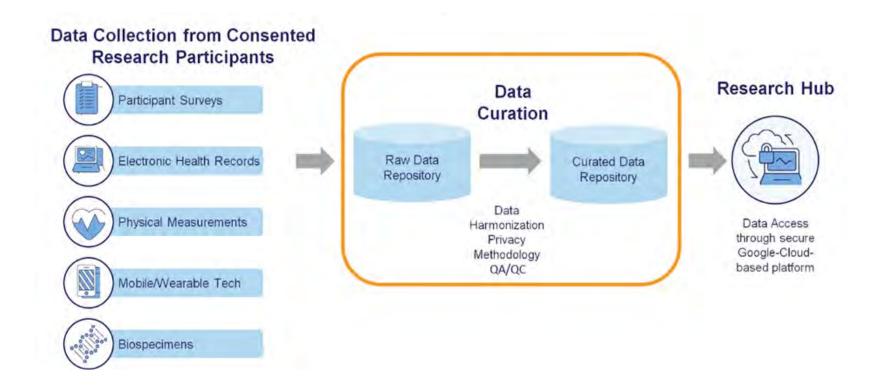


Step 4: Register for the Researcher Workbench for Registered and/or Controlled Tier data access (depending on the research question)





All of Us Research Data Pipeline



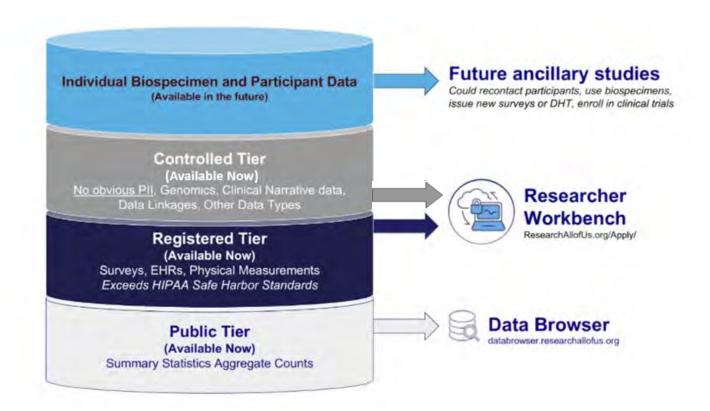


Principles of access & privacy: "Share widely and wisely."





Data and resource access is tiered.







Distinguishing between the Registered and Controlled Tier



Registered Tier

Registered users can access curated, individual-level data and a variety of research tools to conduct a wide range of studies.







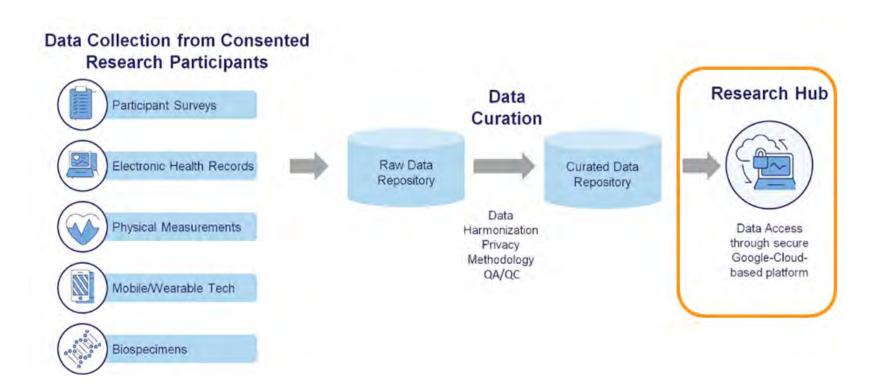
Data have been processed to protect participant privacy

Controlled Tier

Registered users with amended institutional agreements can access all of the data in the registered tier plus expanded and NEW data including:

- Expanded demographics
- Responses to entire COPE Survey
- COVID-19 EHR data
- Unshifted event dates
- Genomic data derived from WGS (~100k participants) and array genotyping (>165k participants)

All of Us Research Data Pipeline





The All of Us Research Hub

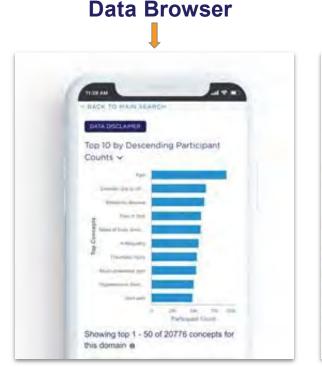


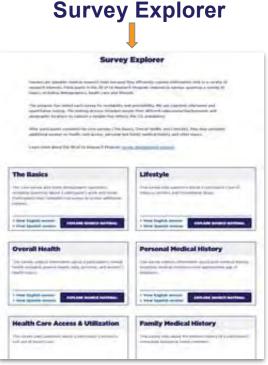
Learn. Discover. Connect.

https://www.researchallofus.org/



Public tools enable researchers to learn about data.





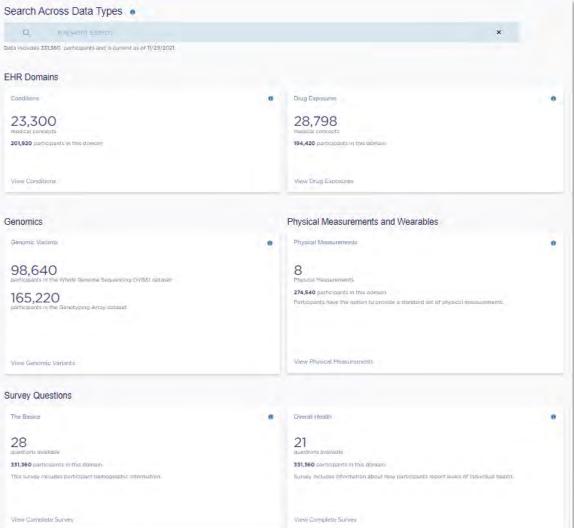
Research Projects Directory



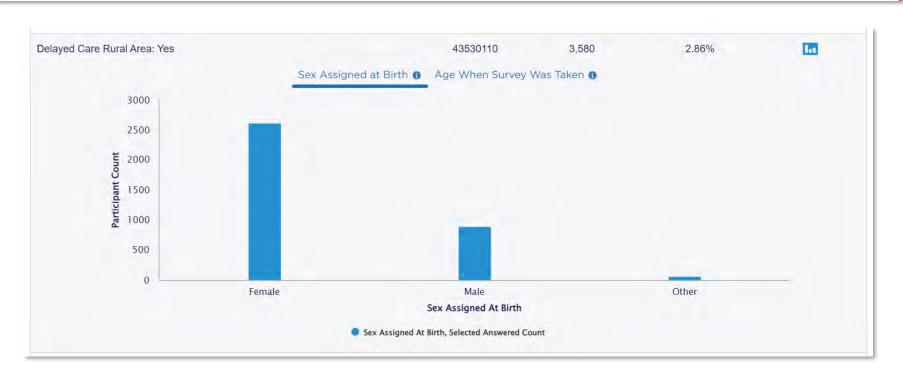
https://www.researchallofus.org/

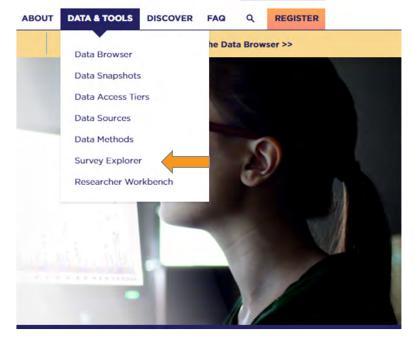






Answer	Concept Code 6	Participant Count 6	% Answered out of 125200	
Delayed Care Rural Area: No	43529416	116,560	93.10%	ПпП
Skip	903096	4,700	3.75%	Ilnn
Delayed Care Rural Area: Yes	43530110	3,580	2.86%	Nnn
Dont Know	903087	400	0.32%	Ilon
Did not answer	Ö	≤ 20	0.02%	





Survey Explorer

Surveys are valuable medical research tools because they efficiently capture information vital to a variety of research interests. Participants in the Alf of Us Rewarch Program respond to surveys spanning a variety of topics, including demographics, health care, and lifestyle.

The program has tested each survey for readability and accessibility. We use cognitive interviews and quantitative testing. This testing process anduded people from different educational backgrounds and geographic locations to capture a sample that reflects the U.S. population.

After participants complete the core surveys (The Basics, Overall Health, and Lifestyle), they may complete additional surveys on health care access, personal and family medical history, and other topics.

Learn more about the All of Us Research Program survey development process.

The Basics

This core survey asks basic demographic questions including questions about a participant's work and home. Participants must complete this survey to access additional

> View Spanish version

> View English version EXPLOSE SOURCE HATERIAL

Lifestyle

This survey asks questions about a participant's use of tobacco, alcohol, and recreational drugs.

> View English version > View Spanish version

EXPLORE SOURCE MATERIAL

Overall Health

This survey collects information about a participant's overall health including general health, daily activities, and women's

> View English version
> View Spenish version

Personal Medical History

This survey collects information about past medical history, including medical conditions and approximate age of

> View English version
> View Spanish version

Health Care Access & Utilization

This survey asks questions about a participant's access to and use of health care.

View English version

EXPLORE SOURCE MATERIAL

Family Medical History

This survey asks about the medical history of a participant's immediate biological family members.

> View English version

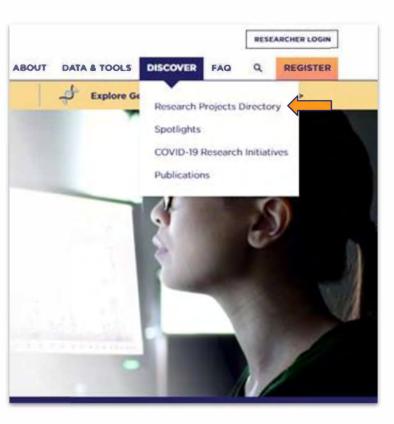
EXPLORE SOURCE MATERIAL

COVID-19 Participant Experience (COPE) Survey

This survey asks questions about the impact of COVID-19 on a participant's mental health, well-being, and everyday life. This survey was deployed to participants multiple times, beginning in May 2020.

> View English version > View Spanish version

EXPLOSE SOURCE MATERIAL



Research Projects Directory

1,497 ACTIVE PROJECTS

This information was updated 5/19/2022

The Research Projects Directory includes information about all projects that currently exist in the Researcher Workbench to help provide transparency about how the Workbench is being used. Each project specifies whether Registered Tier or Controlled Tier data are used.

Note: Researcher Workbench users provide information about their research projects independently. Views expressed in the Research Projects Directory belong to the relevant users and do not necessarily represent those of the All of Us Research Program. Information in the Research Projects Directory is also cross-posted on AllofUs.nih.gov in compliance with the 21st Century Cures Act.

Search By: V Project title: sdoh

4 projects have 'sdoh' in the project title

< Go back to All Projects View or enter a new search query

Effect of SDOH for septic patient 30 days readmisison & Survival

Within our previous study using Dataset registered tier v4 we found that Social determinants of health can improve the model accuracy for predicting power for 30 days readmission among septic patient and survival factors. Within this study i want to...

SDOH Spine

Evaluate the prevalence of orthopaedic pathologies across different sociodemographic populations Investigate social determinants of health (SDOH) in patients receive orthopaedic care and potential disparities Identify risk factors associated adverse events/negative treatment outcomes in orthopaedic patients Evaluate if health literacy and/or...

COVID SDoH

COVID-19 shed light on how socioeconomic disparities disproportionately increased susceptibility, morbidity, and mortality among racial and ethnic populations. Clinical risk factors can only partially explain the difference in hospitalizations and mortality observed in populations of varying socioeconomic status. It...



Participants at a Glance

Enrollment Numbers Enroll

Almospectures at the University of Phane lever upon the

diversity and use of the All of Ut dataset to test the theory that Latina Individuals have seniar or better

health outcomes than their non-subne openbessets.

Spotlights Applicating published findings on hypertension greateness in diverse propulations. Abovin II distili Advin II distili Advin II distili Advin II distili Applications and Applications on the Advin II the distiliant distiliant of the Advin II distiliant of the II d

All of Us Publications

Read program-related publications through the links below.

There are currently 36 publications and counting.

Last updated March 2022

Featured Publications



Hypertension prevalence in the All of Us Research Program among groups traditionally underrepresented in medical research

Hypertension prevalence in the All of Us Research Program among groups traditionally underrepresented in medical research.

Chandler PD, Clark CR, Zhou G, Noel NL, Achilike C, Mendez L, Ramirez AH, Loperena-Cortes R, Mayo K, Cohn E, Ohno-Machado L, Boerwinkle E, Cicek M,

Qian J, Schully S, Ratsimbazafy F, Mockrin S, Gebo K, Dedier JJ, Murphy SN, Smoller JW, Karlson EW; All of Us Research Program Investigators.

Sci Rep. 2021 Jun 22;11(1):12849. doi: 10.1038/s41598-021-92143-w. PMID: 34158555; PMCID: PMC8219813.

Browse or Search all Publications

SEARCH by TITLE		SEARCH	
SORT BY:	DATE	TITLE 1	

Racial and ethnic disparities in cost-related barriers to medication adherence among patients with glaucoma enrolled in the National Institutes of Health All of Us Research Program

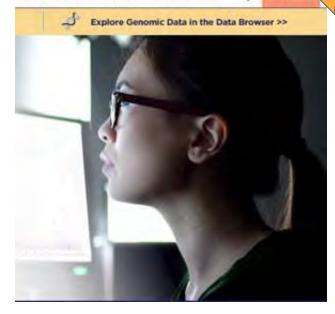
Racial and Ethnic Disparities in Cost-Related Barriers to Medication Adherence Among Patients With Glaucoma Enrolled in the National Institutes of Health All of Us Research Program

Delavar A, Radha Saseendrakumar B, Weinreb RN, Baxter SL. JAMA Ophthalmol. 2022 Mar 3. doi: 10.1001/jamaophthalmol.2022.0055. Epub ahead of print.

PMID: 35238904.

March 3, 2022

ABOUT DATA & TOOLS DISCOVER FAQ Q REGISTER



How to Register



LEARN MORE ABOUT THE DATA AVAILABLE

Explore the data available through the <u>Data Browser</u>, which provides arteractive views of upgregate-level participant data. Learn about individual-level data appears from and the <u>Reference</u>

Workbench tooks



CHECK FOR YOUR INSTITUTION'S AGREEMENT

Before you can register, your entitution must have a Cata Use and Resistration Assembly in place with Air of Us to ensure data security.



CREATE A RESEARCHER WORKBENCH ACCOUNT

Complete your researcher profile, sign the Terms of Service, and agree to the Privacy Policy.



VERIFY YOUR IDENTITY USING LOGIN.GOV

Verify your identity using Login gov. You may need to provide on SSN and a stateissued ID. Your institution may also require you to use an eRA Commons account. If so, contact your institution directly. Boad more about Login gov.



COMPLETE ALL OF US RESEARCH TRAINING

The markstory training provides education on conducting responsible and ethical research with data from Alf of Us participants. Please allow at least one hour to correlate.

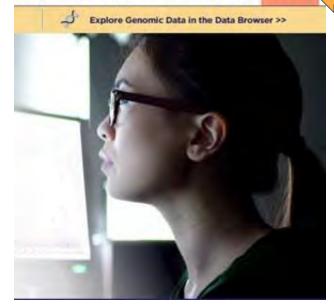


SIGN THE DATA USER CODE OF CONDUCT

The Data User Code of Conduct is an agreement that outlines the program's expectations for researchers.

RESIDENTER

ABOUT DATA & TOOLS DISCOVER FAQ Q REGISTER



Institutional Agreements

Access to the All of Us Researcher Workbench Controlled and Registered Tier data is available to researchers with an institutional agreement in place. Any U.S.-based academic, nonprofit, or health care institution can enter into our Data Use and Registration Agreement. Below is the growing list of organizations that have already signed.

If your institution currently has an agreement that includes access to your preferred data tier, create an account.

If your institution does not have an agreement that includes access to your preferred data tier or requires individual agreements, submit a request

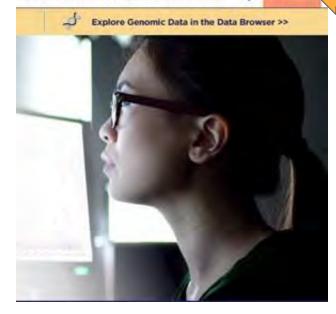
O District seconds - control areas (control accords prime)

308 Institutions Have Agreements in Place

Key: Registered Fier Controlled Fier	Individual agreements required by institution	Figured by institution	
Institution	Access Level	Contact at Institution	
A.T. Still University of Health Sciences	0 0	Gayla Sublette	
Alabama Agriculture and Mechanical University	0	Dámian Clárke	
Albany State University	0 0	Louise Wrensford	
Albert Einstein College of Medicine	0	John M. Greatly	
Allergy & Asthma Network	0 0	Tanya Winders	

Institution	DURA	Registered Tier	Controlled Tier
UNIVERSITY OF HAWAII AT MANOA	Pending		
UNIVERSITY OF PUERTO RICO MED SCIENCES	Yes	X	
MEHARRY MEDICAL COLLEGE	Yes	X	X
CLARK ATLANTA UNIVERSITY	Pending		
XAVIER UNIVERSITY OF LOUISIANA	Yes	X	X
CHARLES R. DREW UNIVERSITY OF MED & SCI	Yes	X	
UNIVERSITY OF CALIFORNIA RIVERSIDE	Yes	X	X
NORTHERN ARIZONA UNIVERSITY	Pending		
NORTH CAROLINA CENTRAL UNIVERSITY	Pending		
MORGAN STATE UNIVERSITY	Yes	X	X
FLORIDA INTERNATIONAL UNIVERSITY	Pending		
SAN DIEGO STATE UNIVERSITY	Yes	X	X
UNIVERSITY OF TEXAS EL PASO	Yes	X	X
TEXAS SOUTHERN UNIVERSITY	Pending		
PONCE SCHOOL OF MEDICINE	Yes	X	X
MOREHOUSE SCHOOL OF MEDICINE	Yes	X	X
JACKSON STATE UNIVERSITY	Pending		
HOWARD UNIVERSITY	Yes	X	X
FLORIDA AGRICULTURAL AND MECHANICAL UNIV	No		
TUSKEGEE UNIVERSITY	Yes	X	X
UNIVERSITY OF HOUSTON	Pending		

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Complete your researcher profile, sign the Terms of Service, and agree to the Privacy Policy



VERIFY YOUR IDENTITY USING LOGIN.GOV

Verify your identity using Login gov. You may need to provide on SSN and a stateissued ID. Your institution may also require you to use an eRA Commons account. If so, contact your institution directly. Boad more about Login gov.



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SIGN THE DATA USER CODE OF CONDUCT

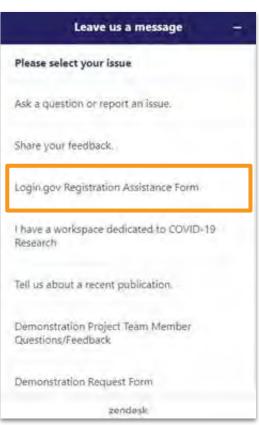
The Data User Code of Conduct is an agreement that outlines the program's expectations for researchers.

RESPISTER

Assistance with Registration



Accessing Researcher Workbench via login.gov Tutorial





Benefits of Registration



Available to all registered users

Resources

All of Us offers data and more.

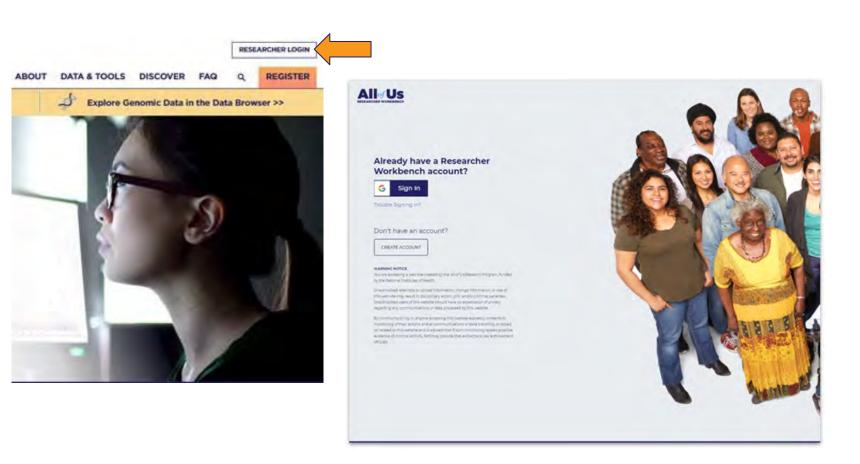
Registered users have access to:

- Platform and tools
- \$300 in initial credit
- User support materials and staff
- Opportunities to showcase work

Platform Uses

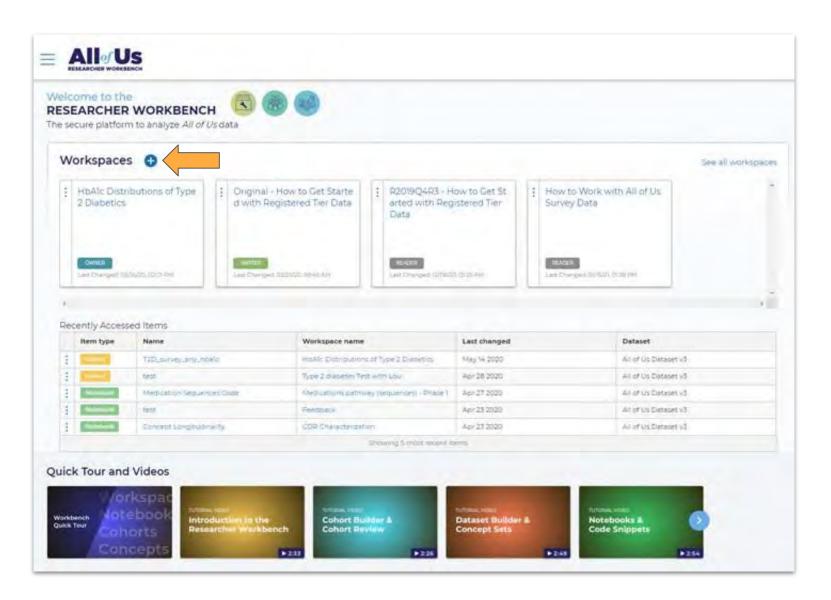
All of Us is for publishing and more.

- Team science
- Dissertation
- Thesis
- Poster presentations
- Class projects
- Self-practice (especially data science)

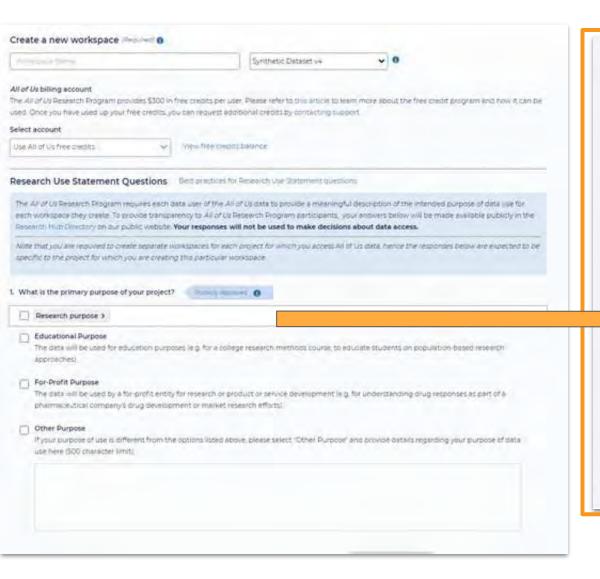


https://www.researchallofus.org/









COPE Covid-19 Mitigation Behaviors

PROJECT PURPOSECIO

· Population Health

SCIENTIFIC QUESTIONS BEING STUDIED

Answers to COPE survey questions requesting advantage to COVID-19 mitigation recommendations will be used to asswer the following questions:

 De imponent vary by demographic characteristics and identify age, gender inscriptionicity becoming characteristics, employment status, and geographical variables such as urban/numl and state of residence?

2. Are difference in responses by state associated with contemporarious state mandates regarding COVID-18 indigation behavior, controlling for other factors identified in iff above?
3. Do intigation behaviors change over time?

identification of variables associated with entryation behaviors during the current pendemic may help improve further mitigation offorts, sociating for potential future pandemics.

SCIENTIFIC APPROACHES

Using the datasets and fools will be AGLEP Research Workbersch for cohort creation and statistical unaryses (restuding the 4 statistical programs), we will

I Consente descriptive statistics to the sample of participants who answered the CDPL surveys and compare with these of the overall AcURP cahors to ensers generalizability of Indings to the obtain and netronals.

 Compare response re: COVID-BI mitigation between by demographic and geographic characteristics overall and between states, using branate statistics appropriate for the variable types.

3. Examine: responses by level of contemporaneous state mandates regarding mitigation behaviors in machinerable regression models controlling for all other varieties found to be associated with these holywors in Z.

 Perform a longitudinal analysis of changes in mitigation behaviors for individuals answering all 8 COPE surveys.

ANTICIPATED FINDINGS

We expect to that notigation behaviors are associated with many different demographic and group raths and charge over time, identification of the associated weekles will contribute to the understanding of the offsectionness of public health messages and mandates, within demographic, geographic, and temporal carbonics.

DEMOGRAPHIC CATEGORIES OF INTEREST

This study will not conter on sedim-spresented populations.

RESEARCH TEAM

Owner:

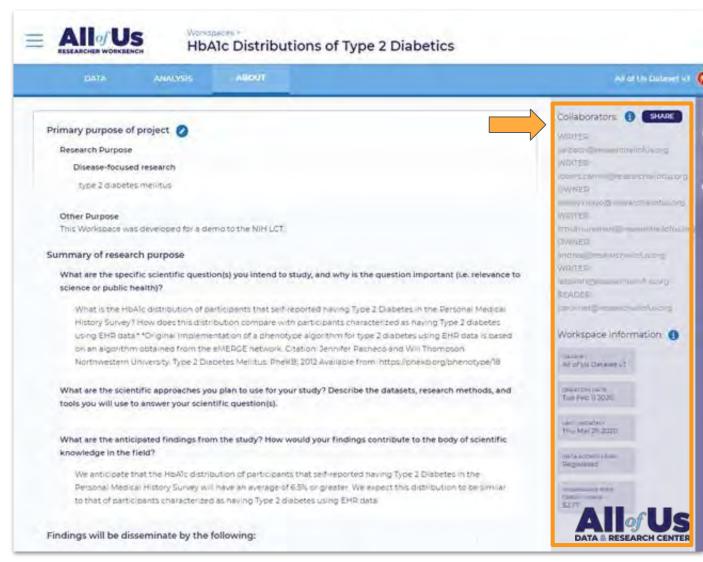
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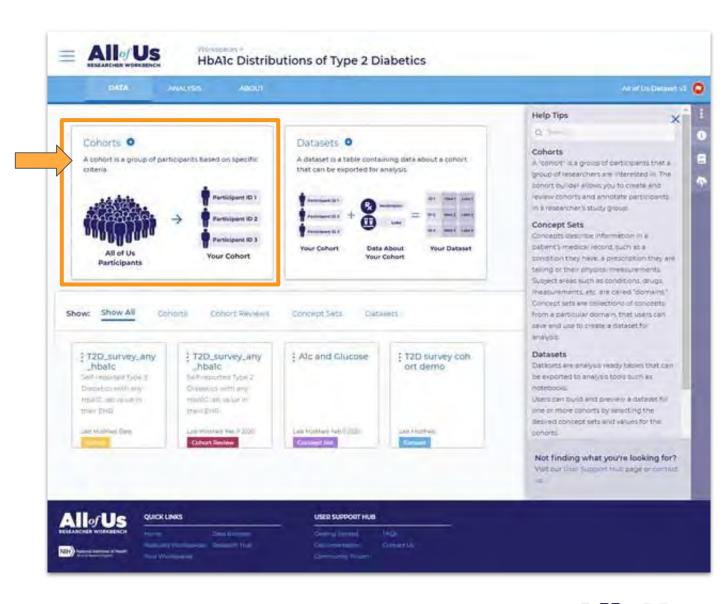






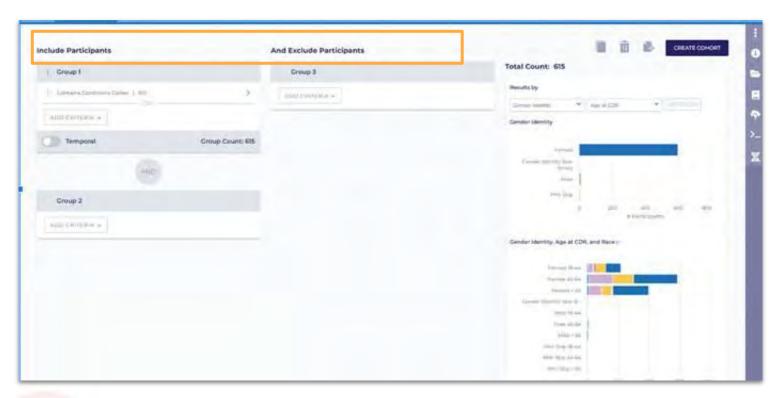














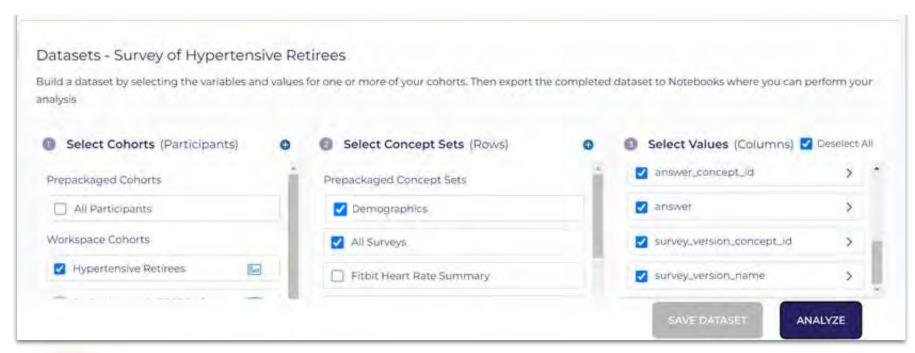
Cohort Builders













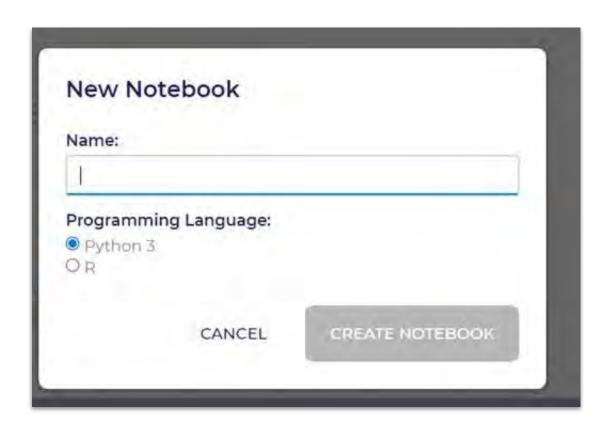
Dataset Builders



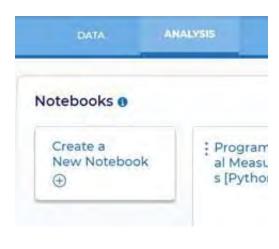




NOTEBOOKS

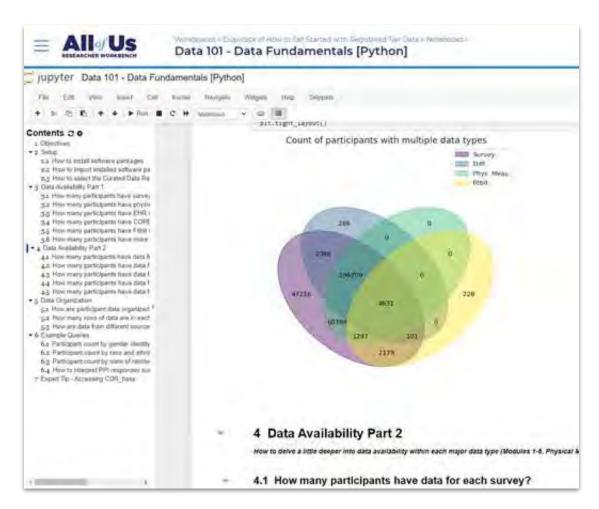






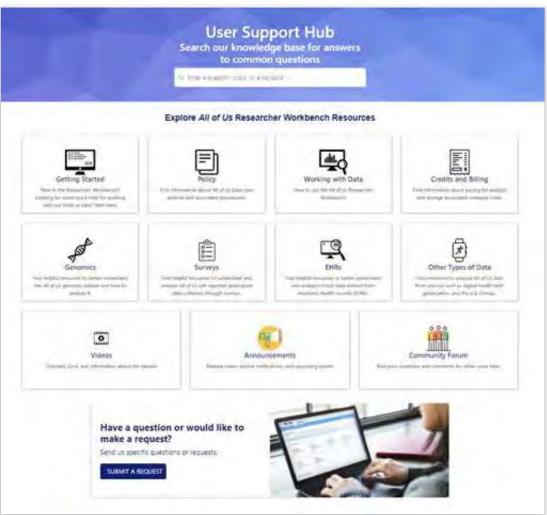


NOTEBOOK











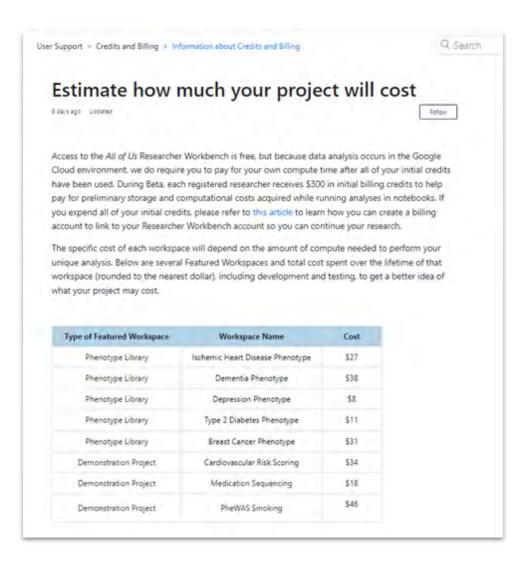


These articles may be useful as you get started (login needed):

- Estimate how much your project will cost
- Exploring concepts and concept relationships within Observational Medical
 Outcomes Partnership (OMOP)
- Selecting participants: using the Cohort Builder tool
- Introduction to All of Us Survey Collection and Data Transformation Methods
- Accessing geolocation data
- All of Us Research Program Policies for Researchers









Virtual User Supports

Support Desk

Send us your questions.

Email us or use our "Help" icon to:

- Resolve technical issues
- Ask questions about our data or the research program
- Give us feedback or make suggestions
- and more...

Response in 1-2 business days. support@researchallofus.org

New User Orientation

Zoom in for a live orientation.

Webinar objectives:

- Understand data & data organization
- Learn how to get started on Researcher Workbench
- Learn how to utilize the User Support Hub

Monthly

link emailed to all registered users

Office Hours

Get live, virtual help with questions.

Ask your questions live:

- Workflow implementation questions
- Data refreshers and updates
- Billing questions
- and more...

Bi-Weekly (Tues., Fri. 1-2pm CST) link emailed to all registered users (recordings are also available)



The DRC (Data and Research Center) also has a <u>YouTube Channel</u> that includes office hours sessions that can be made public

- Office Hours Data Wrangling
- Optimizing Workflow in the Workbench
- Workflows in the All of Us Researcher Workbench: Nextflow and Cromwell
- Using R on the Workbench
- Advancing Cancer Research
- Controlled Tier Introduction
- OMOP Data Structure
- Workspace Tips and Tricks
- Writing a Meaningful Workspace Description

The NIH All of Us Research Program has a YouTube Channel that offers testimonials and lectures

Creating New Knowledge Through the All of Us Researcher
 Workbench to Redress Health Disparities



Opportunities to learn more about All of Us



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Part II Application and Submission Information



Application Information

- Applications must be submitted using: PA-20-272 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)
- To be eligible,
 - This competition is limited to recipients of RCMI U54 awards made under RFA-MD-17-003, RFA-MD-17-006, RFA-MD-18-012, or RFA-MD-20-006
 - The parent award must be active at the time of application
 - Have sufficient time left to complete the project within the parent award's current project period.



Submission Information

- ➤ All Instructions in the SF424 (R&R) Application Guide and PA-20-272 must be followed.
- Within the Research Strategy:
 - This section is limited to 6 pages
 - Should include a summary or abstract of the funded parent award or project
 - Description of the support provided by the parent project program
 - Significance of the pilot project; significant contribution to the field
 - Innovation of the pilot project
 - Approach of the pilot project



Award Information

- NIMHD intends to commit \$200,000 in FY 2022 to fund the award(s)
- An eligible applicant institution may propose one pilot research project
- Applicants may request no more than 1 year of support; the scope of the proposed project should determine the project period



Part III: Review of Applications

Review of Applications

- NIMHD program program staff will assess the applications with the following criteria:
 - Proposed supplement increases or preserves the parent award's overall impact (Is project within scope of the parent grant?)
 - Overall impact and significance of proposed project
 - Advance understanding of minority health and health disparities
 - Enhance the candidate's potential for an independent scientific research career
 - Other Criteria
 - Adequate protection for human subjects; justified inclusion (women, minorities, ages)
 - Justified and reasonable budget, no more than \$200K
 Direct costs



Part IV: Timeline

Timeline

Application Due Date: June 27, 2022

Review of Applications: July 2022

Earliest Start Date: September 2022





Participant Questions





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