

All of Us Research Program- National, State, and Local Engagement Partners FO Informational Webinar

All of Us
RESEARCH PROGRAM



National Institutes
of Health

October 5, 2020

@AllofUsResearch #JoinAllofUs

AGENDA

- Introduction to the *All of Us* Research Program
- Funding opportunity purpose
- Application components and process
- Timeline for the funding announcement
- Review process
- OT award background
- Pre-submitted Q & A
- Next steps

Introduction to the *All of Us* Research Program

All of Us Anthem Video

[15-second version](#)

[30-second version](#)

[90-second version](#)



What is the NIH *All of Us* Research Program?



The *All of Us* Research Program is a historic, longitudinal effort to **gather data from one million or more people** living in the United States to **accelerate research and improve health**. By taking into account individual differences in **lifestyle, socioeconomics, environment, and biology**, researchers will uncover paths toward delivering **precision medicine – or individualized prevention, treatment, and care – for all of us**.



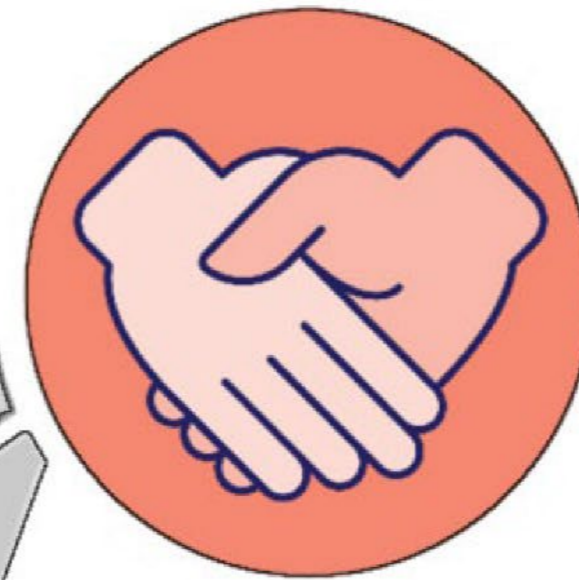
“All of Us is among the most ambitious research efforts that our nation has undertaken!”

NIH Director Francis Collins, M.D., Ph.D.

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

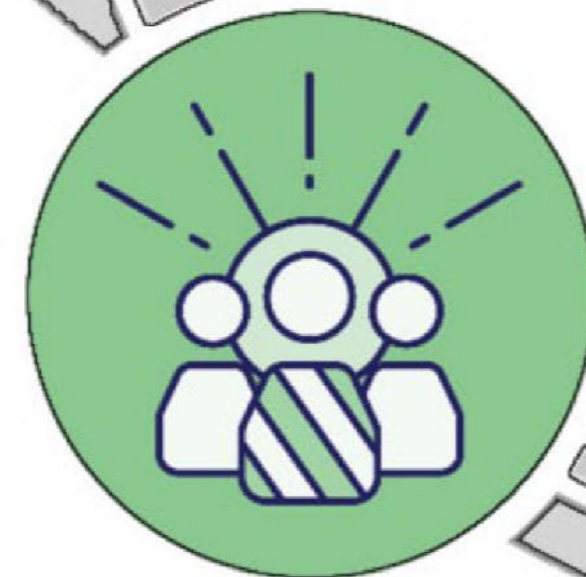
Deliver the largest, richest biomedical data set ever

that is easy, safe, and free to access



Catalyze a robust ecosystem

of researchers and funders hungry to use and support it



Core Values



The *All of Us* Research Program is guided by the following core values:

1. Participation is open to all.
2. Participants reflect the rich diversity of the United States.
3. Participants are partners.
4. Transparency earns trust.
5. Participants have access to their information.
6. Data are broadly accessible for research purposes.
7. Security and privacy are of highest importance.
8. The program will be a catalyst for positive change in research.

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

DATA AND RESEARCH CENTER

Big data capture, cleaning, curation, & sharing in secure environment

BIOBANK

Repository for processing, storing, and sharing biosamples (35+M vials)

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web and phone-based platforms for participants

GENOMICS PARTNERS

Genotyping and whole genome sequencing of biosamples; counseling and educational resources for participants

PARTICIPANT CENTER / DV NETWORK

Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies

HEALTH CARE PROVIDER ORGS NETWORK

HPOs with clinical & scientific expertise, enrollment & retention of participants

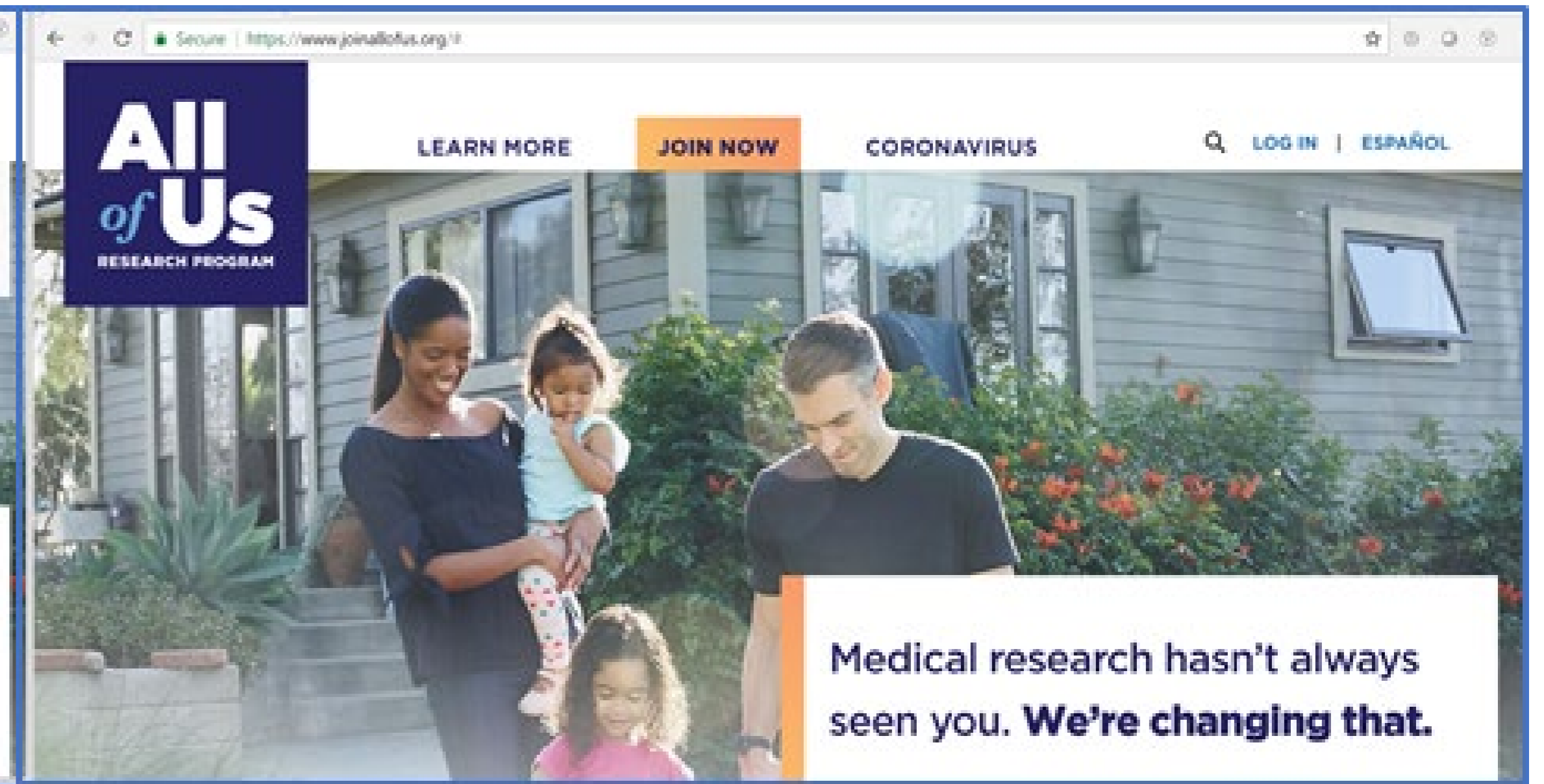
COMMUNICATIONS & COMMUNITY NETWORK

Communications, marketing, and design expertise; engagement coordination and community partners network

Volunteers can enroll in English or Spanish



The screenshot shows the Spanish version of the All of Us website. The top navigation bar includes the logo "All of Us PROGRAMA CENTRICO" on the left, and menu items "APRENDA MÁS", "PARTICIPAR" (highlighted in orange), "CORONAVIRUS", and "ENTRAR | ENGLISH" on the right. A search bar is located below the navigation. The main content area features a photograph of a family (a woman holding a child, a man, and another child) in front of a house. A white text box with an orange border is overlaid on the bottom right of the image, containing the Spanish text: "La investigación médica no siempre se ha enfocado en usted. **Estamos cambiando eso.**"



The screenshot shows the English version of the All of Us website. The top navigation bar includes the logo "All of Us RESEARCH PROGRAM" on the left, and menu items "LEARN MORE", "JOIN NOW" (highlighted in orange), "CORONAVIRUS", and "LOG IN | ESPAÑOL" on the right. A search bar is located below the navigation. The main content area features the same photograph of a family in front of a house. A white text box with an orange border is overlaid on the bottom right of the image, containing the English text: "Medical research hasn't always seen you. **We're changing that.**"

What are the potential activities asked of participants in the current protocol?



Enroll, Consent and Authorize EHR

- Recruiting 18+ years old initially; plan to include children later
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



Answering Surveys

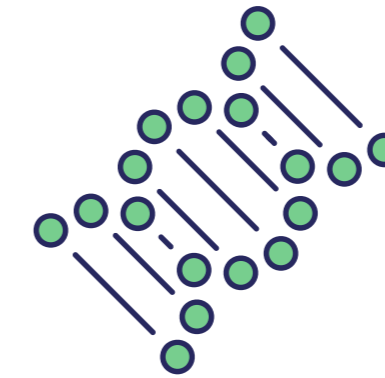
- Six initial surveys: The Basics, Overall Health, Lifestyle, Health Care Access & Utilization, Family Medical History, Personal Health History
- Additional surveys will be released on an ongoing basis.



Physical Measurements *

- Blood pressure
- Heart rate
- Height
- Weight
- BMI
- Hip circumference
- Waist circumference

**Based on diverse sampling and capacity*



Provide Biosamples*

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank

**Based on diverse sampling and capacity*



Wearables and Digital Apps

- Share data from wearable fitness devices, starting with Fitbit
- More integrations under development



To learn more, visit our websites:

- Program overview: <https://allofus.nih.gov>
- Enrollment site: <https://www.joinallofus.org>
<https://www.joinallofus.org/go>
- Research Hub: <https://www.researchallofus.org>

Funding Opportunity Purpose

Funding Opportunity Purpose



This award is designed to fund local, regional, and national engagement partners who will establish strong collaboration with members of the *All of Us* consortium to design, implement, and evaluate strategies and tactics geared toward the following categories:

- Recruiting and retaining one million or more participants who reflect the rich diversity of the United States.
- Engaging researchers from diverse backgrounds to utilize the *All of Us* data resources to advance precision medicine.
- Engaging and collaborating with health care providers who serve UBR communities
- Working with the *All of Us* consortium and communications team
- Contributing to the science of engaging, enrolling, and retaining UBR communities into research.

Each applicant should be an expert and from experienced organizations with a proven track record in some or all tasks and subtasks in this FO.

Underserved Biomedical Research (UBR) Populations



These engagements should also be customizable for many different communities as the *All of Us* is reflective of the rich diversity of those living in the US, including communities historically underrepresented in biomedical research. ***All of Us* considers the following populations historically underrepresented in biomedical (UBR) research:**

- Racial and ethnic minority groups
- Children and older adults
- Sexual and gender minorities
- People living with disabilities
- People with barriers in access to care
- People who have low economic status or low educational attainment
- Rural residents

Funding Opportunity Purpose Cont.

Funds Available

Actual amounts will depend on funds available, but the program expects applicant direct costs to not exceed \$1.5 million per year/awardee.

Anticipated Number of Awards

NIH intends to fund at least 6 awards in FY 2021. Applicants may opt to partner with other organizations on a single application submission. Other applications may be awarded dependent on applications received and funding availability.

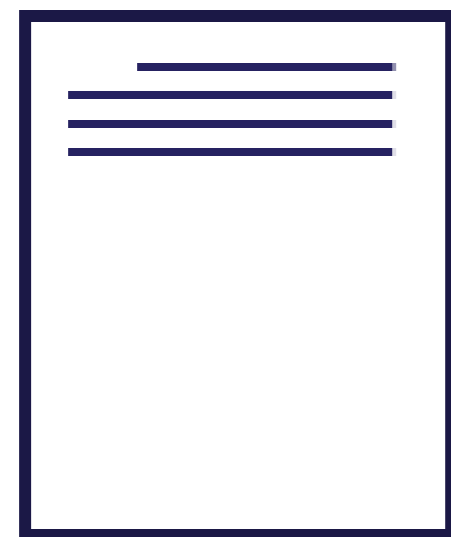


Application Components and Timeline

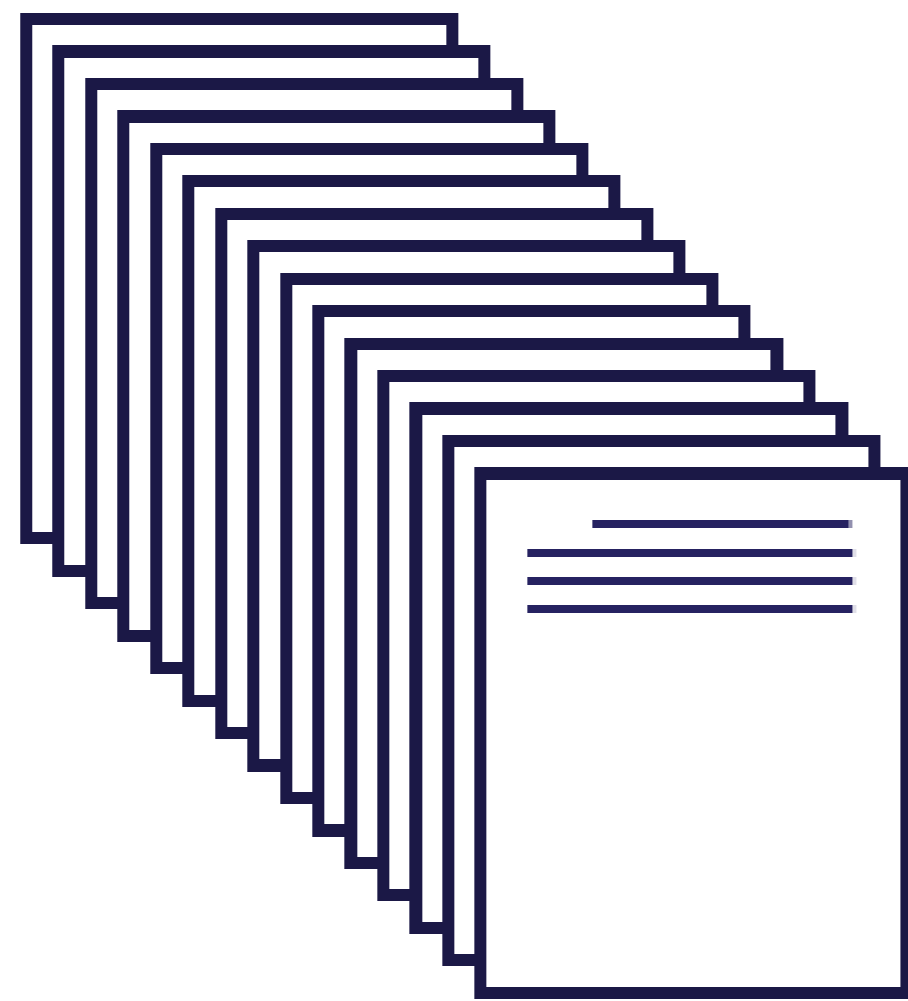
Application components (“Required Application Instructions”)

Page limit = **25** (excluding an optional cover letter)

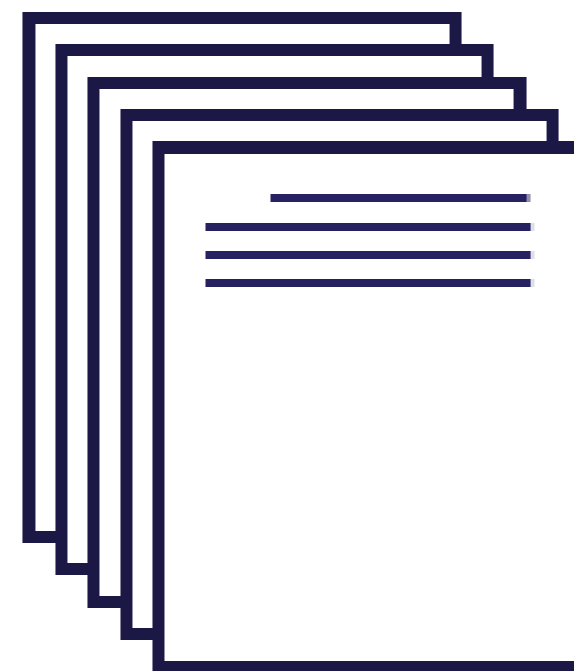
Cover letter
(1 pg,
optional)



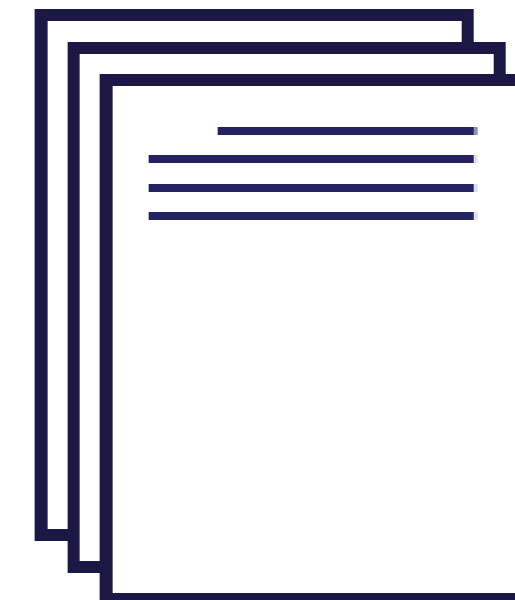
Technical
Approach
(15 pgs max)



Past
Performance
(5 pgs max)



Key
Personnel
(3 pgs max)

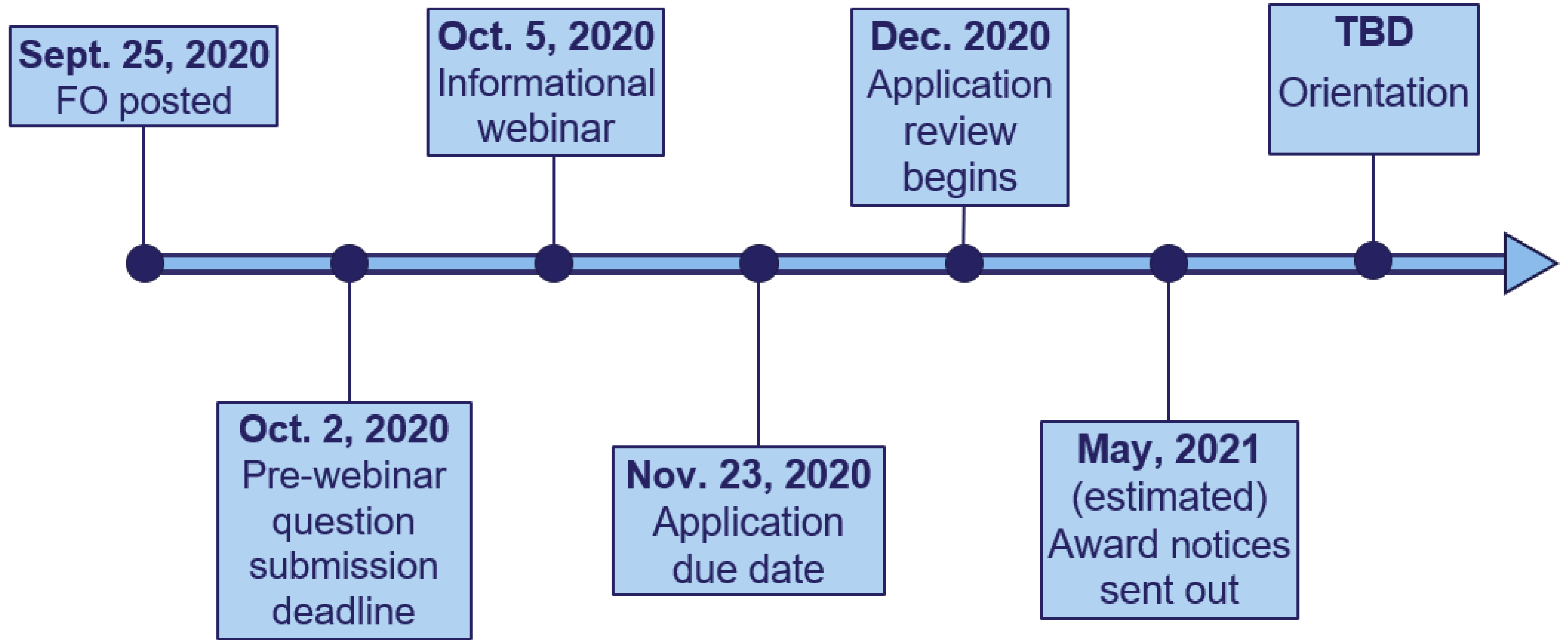


Cost
Proposal
(2 pgs max)



Applicants may opt to partner with other organizations on a single application submission. NIH encourages applicants to partner to provide the best response to the FO.

Important dates



Review Process

Review Process

- Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH.
- An appropriate review group with relevant expertise will be convened.
- Reviewers will evaluate applications based on the following:
 - Completeness of technical elements
 - Quality of submission
 - Past performance and portfolio
 - Key personnel, experience, and proposed commitment to the project
 - Cost proposal
- In addition to technical and scientific merit, applications will be evaluated for programmatic priority Refer to Evaluation Process section of the funding announcement.
- Successful applicants will undergo a negotiation process for award determination.

Other Transactions Authority and Submission Process

Other Transactions Authority

- AoU will be managing and signing the OT awards.
- The Other Transactions (OT) award mechanism is not a grant, cooperative agreement, or contract. Only a few NIH Institutes/Centers have this authority.
- 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 November 23, 2020 by 5pm of applicant's 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!

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

Applications must be submitted via
NIH eRA ASSIST System

The screenshot shows the login interface for the Application Submission System & Interface for Submission Tracking (ASSIST). It includes a 'Login' section with fields for 'User Name' and 'Password', and a 'Federated Institutions/Organizations' section with a dropdown menu for 'Select Login Here'. A 'Forgot Password/Unlock Account?' link is also present. On the right, there is an 'Alert' box and a section titled 'Submit applications electronically to NIH and other Public Health Service Agencies...' with explanatory text.

Applicant must be registered in eRA
Commons

The screenshot displays the 'Online Registration' page on the eRA Commons website. It provides a list of seven steps for institutions to register with the NIH. A 'Register Now' button is located at the bottom right of the registration instructions.

Review to “Instructions for Application Submission” section of FO

- Use **OTA-20-009** in the field requesting Funding Opportunity Announcement

Instructions for Application Submission	Applications must be submitted via the NIH eRA ASSIST System by March 29, 2019. To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (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-19-004 in the field requesting Funding Opportunity Announcement. Here are Instructions for submitting via the NIH eRA ASSIST system . In the future, instructions will also be available in the ASSIST online help (look for the OTA section) . Technical help is available at the eRA Service Desk .
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Pre-submitted Q & A

Next steps

1. Submit additional questions to AllofUsFOAInquiries@nih.gov
2. Release slide deck, questions, and answers
3. Application due date: November 23, 2020 (5 p.m. of applicant's local time)
4. Review applications: December 2020
5. Send out award notices: May 2021 (estimate)
6. Hold orientation event TBD

Q&A

Please send your questions to:

AllofUsFOAInquiries@nih.gov

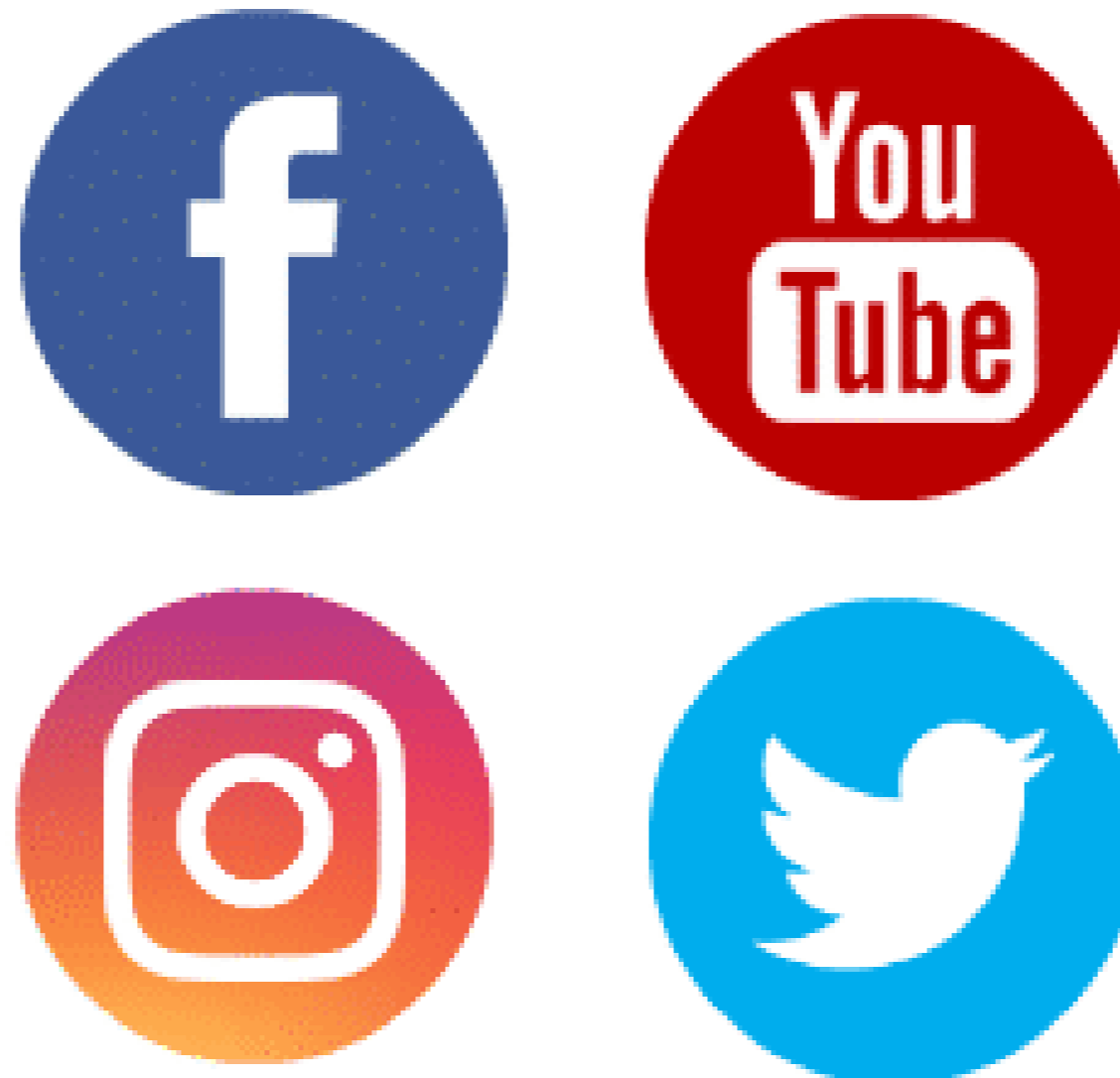
Questions and answers will be posted on the *All of Us* Research Program website at <https://allofus.nih.gov>.



Thank you!



<http://JoinAllofUs.org>
ResearchAllofUs.org



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[#JoinAllofUs](https://twitter.com/AllofUsResearch)



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