

**All of Us**  
RESEARCH PROGRAM

The  
Precision  
Medicine  
Initiative



# FAQs for Health Care Providers

## Program Overview

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

The *All of Us* Research Program, part of the Precision Medicine Initiative, is an ambitious effort to gather data from 1 million or more people living in the United States to accelerate research and improve health. The program will be open to people both healthy and sick, from all communities.

Unlike a single research study focused on a specific disease or population, *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions that affect many different people.

Participants will have opportunities over many years to provide data about themselves that will help researchers learn more about how individual differences in lifestyle, environment, and biological makeup can influence health and disease. By taking part, participants will contribute to an effort to advance the health of generations to come.

### What diseases will be studied?

The *All of Us* Research Program will be a rich resource for researchers and providers exploring a variety of diseases and important health questions. The effort is not focused on any single disease.

### What is precision medicine?

Precision medicine is an innovative approach to disease prevention and treatment that takes into account individual differences in people's environments, lifestyles, and genes. Precision medicine gives clinicians tools to better understand the complex mechanisms underlying a person's health, disease, or condition, and to better predict which treatments will be most effective.

## Why is precision medicine important?

Precision medicine has the potential to dramatically improve the tools available to health care providers. It offers the research and medical community an opportunity to provide patients more individually tailored – and therefore more effective – treatments and prevention strategies.

Early successes of precision medicine include the development of targeted treatments for cancer and cystic fibrosis that were effective in patients who shared an underlying causal genotype, which resulted in improved outcomes for these patients. If we can expand these successes into other diseases, we can improve health outcomes for more patients.

## Patient Experience

### Who is eligible to participate in All of Us?

Enrollment in the study will initially be open to those who live in the United States, are 18 years of age and older, are able to provide consent on their own, and are not currently incarcerated. The program will be open to people both healthy and sick, from all communities. Enrollment will be expanded to include children and other special populations in the future.

### How would an interested volunteer sign up for the All of Us Research Program?

Participants may sign up directly on the program's website at [joinallofus.org](https://joinallofus.org) or through the *All of Us* mobile application. Volunteers will be asked to create an account, provide informed consent, and complete three initial surveys.

Participants may also sign up for the program through participating health care provider organizations (HPOs). A list of HPOs affiliated with the *All of Us* Research Program can be found here: <https://allofus.nih.gov/about/program-components/health-care-provider-organizations>.

### What will be expected of those who participate?

Participants will be asked to complete surveys and share information about their health history, lifestyle habits, and environmental exposures over a number of years. Participants may also be asked to provide access to their electronic health records, and to go to a local enrollment center to have physical measurements taken and to provide blood and urine samples.

### How much time will it take to enroll? To participate over time?

It takes about 20 minutes to join *All of Us*. Once an individual enrolls, he or she will choose when and how much to participate. We are thankful for participant involvement at any level.

Here are some example activities and how long they take:

- **Surveys:** We will ask the participant questions about their health, family, home, and work. Each survey takes about 5 to 10 minutes.
- **Physical Measurements:** We may ask a participant to be measured. This will take about 15 minutes.

- **Samples:** We may ask participants to give blood and urine samples. This will take about 10 minutes.

## Health Care Provider Role

### **If my patient decides to participate in the *All of Us* Research Program, will they be required to change providers?**

No. *All of Us* is a research program and not a clinical care program. Participants will keep their current health care team if they decide to join *All of Us*. To participate, they may be asked to visit one of our affiliated clinics to provide physical measurements and biosamples, but this will not require them to change providers.

### **If my patient decides to participate in the *All of Us* Research Program, will researchers contact them directly or ask them to do things?**

No. Communications with participants will come from the *All of Us* Research Program. From time to time, the program may send participants new surveys or offer other ways for them to share information about their health.

### **Will you continue to enroll participants after you reach the million participant goal?**

*All of Us* hopes to continue enrolling volunteers after reaching a million participants.

### **If my patient decides to participate in the *All of Us* Research Program, will I be responsible for taking their physical measurements and collecting biosamples?**

Unless you are a health care provider in one of the participating health care provider organizations (HPOs), providers are not responsible for taking their patients' physical measurements or collecting biosamples. If a participant is asked to provide measurements and biosamples, they will be directed to a local site for measurements and sample collection.

If you work in one of the health care provider organizations (HPOs) affiliated with the *All of Us* Research Program, your organization may ask you to take the physical measurements, and you may be responsible for ordering the collection of the biosamples at your organization's dedicated *All of Us* collection site. A full list of participating organizations can be found here: <https://allofus.nih.gov/about/program-components/health-care-provider-organizations>

### **Will my patients have access to results and data from the study? Will they share that information with me?**

Participants will have access to their own data along with summarized results from across the *All of Us* Research Program. *All of Us* will not communicate directly with a participant's health care team, but participants may choose to share *All of Us* information with their health care provider.

### **How will the *All of Us* Research Program affect the way I treat and interact with my patients?**

The *All of Us* Research Program should not affect the way you treat and interact with your patients in the short term. However, by launching a study of the size and scope of the

*All of Us* Research Program, we hope to accelerate our overall understanding of disease prevention, onset, progression, treatment response, and health outcomes, which may affect clinical practice in the future.

### **What resources are available to keep me informed about the program and its progress?**

The *All of Us* Research Program is developing materials to help inform providers about precision medicine and the *All of Us* Research Program. These materials include Frequently Asked Questions (FAQs), one-page handouts, and continuing education courses for both physicians and nurses. An online portal will have a number of patient-facing educational materials that can help inform potential volunteers about the *All of Us* Research Program.

### **What happens if by participating in All of Us, my patient finds out they have a previously undetected disease? Is there a treatment plan or resources available for my patient?**

*All of Us* is a research study. We will not provide health care, nor interfere with existing relationships between providers and your patients. We will share educational materials about certain illnesses, and participants will have the opportunity to share information they receive from the program with their health care provider.

### **What opportunities are there for providers to learn more (outside of the materials currently in development, e.g. CME/CNE modules and the provider FAQs)?**

As the provider community is critical to the success of the *All of Us* Research Program, it is our goal to ensure that the community is educated and informed. In addition to making resource materials available and continually updated, *All of Us* staff will be engaging with the provider community through webinars, conferences, and consultation with provider organizations to ensure that educational needs are being met.

### **What do I do if I have more questions that aren't answered by these FAQs?**

If you have additional questions about the *All of Us* Research Program or about the Precision Medicine Initiative more broadly, please visit [joinallofus.org](https://joinallofus.org). You are also welcome to email us at [help@joinallofus.org](mailto:help@joinallofus.org).

## **Data**

### **How will the sharing of health records be facilitated? What is a provider's role in sharing the electronic health data with the NIH?**

Our affiliated health care provider organizations have protocols to securely transfer a participant's medical data to the *All of Us* Research Program. If you are a member of a participating HPO, your patient will simply need to give their consent for the EHR transfer.

Participants who do not enroll through one of our affiliated providers will be able to share their electronic health records with us in the future through the *Sync for Science* program, which is still in development. We anticipate that participants will be able to facilitate this data transfer via our website or app. We will share further details of the *Sync for Science* program as they become available.

## **Who is doing the data analysis and how?**

The *All of Us* Research Program is operated by the National Institutes of Health in collaboration with partner organizations across the country that will help collect and store participant data. Data will be housed in both a public and a scientific database.

The public database will be accessible to all. It will only contain aggregate data about participants; no individual level data will be shared. Everyone can use the public database to engage in research.

The scientific database will contain individual-level data. Researchers, including citizen scientists, may ask for access to the data for a variety of studies. Researchers who seek access to individual level data in the scientific database must adhere to specific policies and principles concerning data security and confidentiality. These researchers may be from anywhere in the world and may work for commercial companies.

## **Will participant information be shared with other parts of the government or used for any purposes beyond the *All of Us* Research Program?**

Information collected by *All of Us* is being gathered only for research purposes. The identifiable health information that we are collecting is private under federal law. It is not our intention to share any identifiable information with other government agencies. Our program has a Certificate of Confidentiality from the U.S. government, which allows us to fight any legal demands to share information about our participants. However, there are certain cases where we have a reporting obligation, including instances where we suspect the participant is being abused or has intent to harm others, and we may need to release participants' personal information to other federal and state agencies in those situations.

It should also be noted that de-identified data will be available to all interested researchers who follow our research access guidelines, so government researchers may access the de-identified data for research purposes.

## **How will you ensure the privacy and security of participants' data?**

Participant privacy and security is a top priority of the *All of Us* Research Program. The program will be protected by rigorous privacy and security safeguards. The PMI Privacy and Trust Principles and the PMI Data Security Policy Principles and Framework were developed at the outset of the program to guide all PMI activities, including the *All of Us* Research Program. The program will engage teams of privacy experts and employ rigorous security testing models, develop participant education regarding privacy and potential re-identification risk, and clearly articulate response plans in the case of a privacy breach.

### **Note**

Precision Medicine Initiative, *All of Us*, the *All of Us* logo, and "The Future of Health Begins with You" are service marks of the U.S. Department of Health and Human Services.