

All of Us
RESEARCH PROGRAM

The
Precision
Medicine
Initiative



Program FAQs

Background

What is research?

Research is the process of finding out new things.

What is health research?

Health research is the process of finding out new things about improving people's health.

Why is health research important?

We all want to live long and healthy lives. People who do health research are identifying better preventive care to keep us healthy. And they are discovering new medicines and treatments for when we do get sick.

Participant Experience

What is the Precision Medicine Initiative?

The Precision Medicine Initiative® (PMI) is an exciting new program. Our goal is to help researchers learn more about what affects people's health. PMI will give new information and tools to people researching health. Their discoveries may lead to more personalized care and treatments.

What is precision medicine?

Precision medicine is health care that is based on you as an individual. It takes into account factors like where you live, what you do, and your family health history. Precision medicine's goal is to be able to tell people the best ways to stay healthy. If someone does get sick, precision medicine may help health care teams find the treatment that will work best.

What is the *All of Us* Research Program?

The *All of Us* Research Program is a large research program. The goal is to help researchers understand more about why people get sick or stay healthy. *All of Us* is part of the Precision Medicine Initiative.

We hope that more than a million people will join *All of Us*. People who join will give us information about their health, habits, and what it's like where they live. By looking for patterns, researchers may learn more about what affects people's health.

The *All of Us* Research Program will last for many years. This will allow us to study health over time.

If you decide to join the *All of Us* Research Program, you will be contributing to an effort to improve the health of generations to come. You also may learn about your own health.

Who runs *All of Us*?

The National Institutes of Health (NIH) runs the *All of Us* Research Program. There are many groups helping the NIH. There is a Data and Research Center that stores the information you contribute. There is a Biobank that stores samples. There is a Participant Technology Systems Center that creates tools for you to connect with us online. There is a Participant Center and several health care organizations that are working with us to help you sign up. Learn more about our partners on our website: <https://www.nih.gov/AllofUs-research-program/program-components>.

Why should I join *All of Us*?

If you join, you will be contributing to research that may improve health for everyone. Our goal is to understand what makes people sick and to develop new treatments. Here are some examples of what researchers might be able to discover from their research:

- Better tests to see if people are sick or are at risk of getting sick
- Better mobile apps to encourage healthy habits
- Better medicine or information about how much of a medicine is right for each person as an individual

Also, you will be able to see your *All of Us* information, which might be interesting to you. You may also learn about your health. If you choose, you will be able to share your *All of Us* information with your doctor.

How will *All of Us* help me?

All of Us is not medical treatment. You will not get direct medical benefit from taking part in the *All of Us* Research Program.

That said, you may indirectly benefit from taking part in *All of Us*. For example, we will give you ways to see the information you share with us and the information we learn about you. This information may be interesting to you. You may learn about your health. If you choose, you will be able to share your *All of Us* information with your health care team. You will have the option to learn about additional research opportunities. Finally, you will

be helping researchers make discoveries that may help future generations.

How do I join *All of Us*?

The *All of Us* Research Program is now in beta testing. Once the program is fully launched, there will be three ways to join:

- Visit the *All of Us* website joinallofus.org.
- Download the *All of Us* app.
- If you get health care at one of our affiliated health care provider organizations, you can join there.

Because *All of Us* is research, you will be asked to complete an informed consent process. This process tells more about what is involved, and the risks and benefits of joining.

What will you ask me to do?

If you decide to join *All of Us*, we will ask you to share different kinds of information. We will ask you basic information like your name and where you live. We will ask you questions about your health, family, home, and work. If you have an electronic health record, we will ask for access. We may ask you to go to a local clinic or drug store for a free appointment with us. At this appointment, we would measure your weight, height, hips, and waist, as well as your blood pressure and heart rate. We might ask you to give samples, like blood or urine, at the appointment.

Do I have to give my Social Security number?

No. We may ask for your Social Security number to help match your information to other information, but you do not have to give it to us.

How will you protect my information?

We will take great care to protect your information. Here are a few of the steps we will take:

- Information we have about you will be stored on protected computers. We will limit and keep track of who sees the information.
- We will remove your name and other direct identifiers (like your date of birth) from your information and replace them with a code. There will be a master list linking the codes to names, but we will keep it separate and secure.
- In order to work with your health information, researchers must promise not to try to find out who you are
- We will tell you if there is a data breach
- The *All of Us* Research Program has Certificates of Confidentiality from the U.S. government. This will help us fight legal demands (such as a court order) to give out information that could identify you.

Can I join *All of Us* if I don't have a computer or internet access?

Some *All of Us* activities happen online. You will need to use a computer, tablet, or smartphone to complete them. If you do not have your own, you can use an *All of Us* kiosk at a participating health clinic or drugstore. You can also visit the *All of Us* website from a computer at your local library.

If you do have a smartphone, you can download the *All of Us* app. It is free and is available for both iOS and Android phones. If you download the app, you can complete some of the research activities right there.

What will you do with my email address or phone number?

We may email you or call you to schedule an appointment. We may send you emails about *All of Us*. We may email or call you to tell you about other opportunities to participate in research. We may reach out to ask you for updates or additional information about your health.

You can tell us if and how often you want to be contacted.

Will you sell my email address or phone number?

No, we will never sell your email address or phone number.

Is there an *All of Us* app?

Yes. It is free and is available for both iOS and Android phones.

Is *All of Us* a one-time activity or long-term activity?

Our plan is that *All of Us* will last for at least 10 years. We hope you will stay involved over time. If you do, researchers may better understand what causes changes in our health and what we can do about it.

If you join, you can withdraw (“quit”) at any time for any reason without penalty.

How often will I hear from *All of Us* program staff?

We will offer regular updates about *All of Us*. You can choose if you would like to get these updates. If you choose to get the updates, you can tell us how often and in what way you would like for us to contact you.

We may contact you to answer surveys from time to time. You can choose to answer the surveys or not. We may contact you to schedule an appointment to provide samples and have measurements taken.

Will you be studying my disease or condition?

Researchers will use *All of Us* to study many different diseases and conditions. It is up to each researcher to decide what they study. You will be able to learn more about the

research being done on our website, joinallofus.org.

How can I enroll in a clinical trial for my specific disease or condition?

A clinical trial is a type of research study. Clinical trials look at specific medical treatments to see if they are safe and effective for humans. *All of Us* is a research program, but it is not a clinical trial.

If you join *All of Us*, we will ask you if you want to hear about chances to take part in other research. If you say yes, we will let you know about other research studies, including clinical trials. You can then decide if you want to join that study. You can say yes or no and still be part of *All of Us*.

You can also search for clinical trials at **ClinicalTrials.gov**.

If I am already enrolled in another study, can I still join *All of Us*?

You can join the *All of Us* Research Program even if you are in other health studies.

If you are already in a clinical trial, you may want to talk with your health care team before joining *All of Us*. *All of Us* is not a clinical trial, so you should still be able to join.

If I am already enrolled in another study, why should I join *All of Us*?

The *All of Us* Research Program is different from other studies. Instead of focusing on just one disease or condition, *All of Us* will help a lot of researchers study many different things about health. *All of Us* is also unique because it may last for many years. It will include participants from lots of different backgrounds.

Does it cost anything to join?

Joining *All of Us* is free. All activities are free. There are no costs to you or your insurance.

If you use the *All of Us* app on your smartphone, it will count against your data on your phone plan. You can set the app only to use wifi to avoid this.

Will I be paid?

If we ask you to have an appointment to be measured and give samples and you decide to do it, we will offer you \$25.

Your information will be used by researchers to make discoveries. If any of their research leads to new tests, drugs, or other commercial products, you will not get any profits. These inventions will be the property of the researchers who develop them.

If I join *All of Us*, will it change my health care?

No. *All of Us* is a research program. It is not medical care. You can keep your current health care team even if you decide to join *All of Us*.

I don't have a doctor. How can I find one?

There are many helpful websites that may help you find a health care provider. A few sites that may be helpful are:

- <https://www.nlm.nih.gov/services/doctor.html>
- <https://www.hhs.gov/programs/providers-and-facilities>

Will *All of Us* communicate directly with my health care team?

No, but you can choose to share your information with your health care team.

Do I need to have health insurance to join *All of Us*?

No. *All of Us* is not medical care. You do not have to have health insurance to join.

Will my insurance know if I join *All of Us*?

We will not let your insurance know if you join unless you are injured. We do not expect you to be injured. Answering surveys, being measured, and giving samples are very safe activities. They are unlikely to cause injury. But if you are injured because of *All of Us* and you have insurance, your insurance may be billed.

Can I sign up my child(ren)?

Right now only people who are 18 or older can join *All of Us*. Children will be able to join in the future.

Do I have to be a U.S. citizen or have permanent resident status to join *All of Us*?

Anyone who lives in the United States can join *All of Us*. You do not need to be a U.S. citizen or permanent resident.

Will you share my residency status with the government?

We will not ask you about your residency status. We cannot share your residency status because we will not know it.

Will you share my citizenship status with the government?

We will not ask you about your citizenship status. We cannot share your citizenship status because we will not know it.

If I plan to move out of the country, can I still participate in *All of Us*?

Only people who currently live in the United States can join. As long as you are not planning to move to another country soon, you are welcome to sign up.

Who can I ask if I have more questions?

If you have more questions you can ask us. You can call the *All of Us* Support Center at (844) 842-2855. You can email us at help@joinallofus.org. Or you can speak with someone in person at one of our affiliated health care provider organizations or direct volunteer sites.

Health Information

If I join, do I have to do all of the activities?

If you decide to join *All of Us*, you get to choose how much you participate. We are thankful for your involvement at any level. We will ask everyone who joins about their health, family, home, and work. We may also invite you to do other activities, but you do not have to do them.

Will researchers contact me directly?

No. The *All of Us* staff will be the only ones contacting you about *All of Us*.

You will be able to choose how frequently we contact you. From time to time, we may send you new surveys or offer other ways for you to share information about your health.

Who can see the information I give *All of Us*?

We will create a public database on the *All of Us* website. The information in the database will be about the group. For example, it might tell the average age of the people who have joined *All of Us*. It will not include information about individual people. It will not include your name or other information that directly identifies you. Everyone can use the public database to make discoveries.

We will also create a scientific database. The scientific database will have individual-level information about people in *All of Us*. Access to this database will be controlled. Researchers will have to get permission from the *All of Us* Resource Access Committee to use this database. These researchers may be from anywhere in the world. They may work for commercial companies, like drug companies. The research may be on many different topics.

What is an electronic health record (EHR)?

Health records are the information collected when you get health care. An electronic health record, or EHR, is when this information is kept in secure electronic systems.

What information is in my EHR?

The information in your EHR depends on what kinds of health care providers you see. Your EHR tells about the health problems for which you have received care. It might have information about the medicines you take. It might have test results. It might have images, like X-rays. If you have had a medical procedure, notes about it will probably be in your EHR.

Is there sensitive information in my EHR?

There might be sensitive information in your EHR, for example, about your use of alcohol or drugs. Your EHR might have information about sexually transmitted infections, like HIV. It might have results from genetic (DNA) tests.

If you have seen counselors or doctors who treat addictions or substance use disorders, information about your care might be part of your EHR. The same goes for if you have seen counselors or doctors who treat mental health, like depression or bipolar disorder. This information would be about your diagnosis and treatment.

Can I do the physical measurement and sample activities from home?

If we ask you to have physical measurements taken and give samples, you will have to go to a place that is participating in *All of Us*. These places are usually health clinics or drugstores. We will give you a list of places close by to where you live where you can go.

In the future, we may offer home visits in limited cases. In general, we will offer home visits only to people who have limited mobility or are too sick to travel.

Will my health information be shared with any insurance companies (health, life, disability, etc.)?

We take your privacy seriously. We will take great care to protect it. But, if you are injured because of *All of Us* and you have insurance, your insurance may be billed.

If there is a data breach, insurance companies could get access to the information we have about you. Even without your name, there is a chance someone could figure out who you are. Your information could be misused. We believe the chance of this is very small, but it is not zero.

What will you do to protect my privacy?

Your privacy is very important and we will take great care to protect it if you join. Here are a few of the steps we will take:

- Information we collect will be stored on protected computers. We will limit and keep track of who sees the information.
- We will remove your name and other direct identifiers (like your date of birth) from your information and replace them with a code. There will be a master list linking the codes to names, but we will keep it separate and secure.
- In order to work with your health information, researchers must promise not to try to find out who you are
- We will tell you if there is a data breach
- The *All of Us* Research Program has Certificates of Confidentiality from the U.S. government. This will help us fight legal demands (such as a court order) to give out information that could identify you.

Still, loss of privacy is a risk of taking part in *All of Us*. Even without your name, there is a chance someone could figure out who you are. Your information could be misused. We believe the chance of this is very small, but it is not zero.

Will you ever give out my name or other information that identifies me to anyone outside of *All of Us*?

If you join, there are a few times when we might need to give out your name or other information about you. For example:

- We may give out information about you to protect your health or the health of others, including:
 - If we learn or suspect that you are being abused
 - If we learn or suspect that you are abusing, are neglecting, or have abandoned someone who depends on you for care, like a child or dependent adult
 - If we learn that you plan to harm someone
 - If we learn that you have certain diseases that could be transmitted to others
- We will give out information to meet U.S. research laws and regulations. One requirement of doing research is that we let officials from the U.S. government review our work. This is to make sure we are doing things the right way.

What are the risks of taking part in *All of Us*?

The main risk of taking part in *All of Us* is to your privacy. If there is a data breach, someone could get access to the information we have about you. Even without your name, there is a chance someone could figure out who you are. Your information could be misused. We believe the chance of this is very small, but it is not zero.

We will gather information from you through the *All of Us* app and/or website. You may be asked to wear a health tracker. There is a risk to your privacy whenever you use an app, website, or health tracker. In general, there is no additional risk to your privacy if you use any of these technologies as part of *All of Us*. However, because the *All of Us* Research Program will be collecting many different types of information from you, there may be additional risk to your privacy in case of a data breach because of the amount of information that the database contains.

Although we will not give researchers your name, we will give them basic facts such as your race, ethnic group, and sex. This information helps researchers learn whether things that affect health are the same in different groups of people. These findings could one day help people of the same race, ethnic group, or sex as you. However, others could misuse the information to support harmful ideas about groups.

If you give a blood sample, the most common risks are brief pain and bruising. Some people may become dizzy or feel faint. There is also a small risk of infection.

Taking part in *All of Us* may have risks that we don't know about yet. We will tell you if we learn anything that might change your decision to take part.

Can I share my information if I want to?

Yes, you can share your *All of Us* information with anyone you choose. For example, you can share your information with your health care team. You can share your information with your family or loved ones. You will be able to access your information online through the *All of Us* Participant Portal.

How long will you keep my information?

Unless you withdraw (quit), there is no limit on how long your health data will be stored and used for research. Your data may be useful in improving health for generations to come.

You can decide to withdraw at any time. If researchers have already used your information in their studies, we cannot get it back. But we will remove your information and destroy your samples so that they cannot be used for new studies.

How do I withdraw from *All of Us*?

You can decide to withdraw (quit) at any time. You can tell us through the app or website. You can call us toll free at (844) 842-2855.

We will stop collecting information and destroy your samples. If researchers already have your information for their studies, we cannot get it back. But your information and samples will not be part of the *All of Us* public or scientific databases going forward.

If you withdraw and want to join again in the future, you will need to give us your information and samples again.

What happens if I withdraw from *All of Us*?

If you decide you want to withdraw (quit) you can tell us through the app or website, joinallofus.org, or by calling us toll free at (844) 842-2855.

Even if you withdraw, we will keep your name and basic contact information in the study records. It will not be used for research of any kind.

If researchers already have your information for their studies, we cannot get it back. But your information and samples will not be part of the *All of Us* public or scientific databases going forward.

If I withdraw from (quit) *All of Us*, can I join again later?

You may join again at any time. However, you will need to give your information again if you rejoin. We may also ask you to give your samples and measurements again. This is because we remove your information and destroy your samples when you withdraw (quit).

Physical Measurements and Samples

What is a sample?

A sample is blood, urine (“pee”), saliva (“spit”), or other material from your body. We may invite you to give samples as part of *All of Us*. You can say yes or no.

What types of samples does *All of Us* collect?

At this time, we are collecting blood and urine (“pee”) samples. We may ask for a saliva (“spit”) sample, too.

Why does *All of Us* want samples?

Samples are a way to understand both health and disease. Researchers will study things in samples like chemicals, biomarkers, and DNA. Chemicals include things like medications or drugs. Biomarkers are signals your body gives off. DNA is your unique genetic information. We will ask for your permission to let researchers study your DNA. You can say yes or no.

Will you test my samples for drugs?

Yes. Your samples may be tested for medications and drugs. We will use this information for health research. We will not use it for criminal prosecution.

Where and how long will my samples be stored?

Your samples will be sent to a secure lab. Currently, the National Institutes of Health has a partnership with the Mayo Clinic, based in Rochester, Minnesota. The Mayo Clinic will be the storage lab for the *All of Us* Research Program.

There is no time limit for how long your samples will be stored.

If I'm not comfortable giving a sample, can I still participate?

You get to choose how much you participate. We are thankful for involvement at any level. We will ask everyone who joins about their health, family, home, and work. We may also invite you to do other activities, but you do not have to do them.

Can I decide which research studies are allowed to use my health information?

No. If you decide to join, your information will be available for many research studies.

Can I give a blood sample if I'm ill?

Probably yes. It depends on the illness you have. If you have a blood disease or have had a transfusion, you may need to check with your health care team before giving a blood sample.

If you have donated blood or had a blood draw earlier in the day, you may need to reschedule your blood sample appointment.

If you find a problem with my blood or urine, will you let me know?

The *All of Us* Research Program is a research effort, so we cannot provide any health care.

Right now, we don't know what tests we may do on your blood and urine samples. We also don't know when we will do the testing. It may be months, or even several years, until we do certain tests on the samples you provided. These tests may not tell you very much about your health currently, but they will be very helpful for research.

We will share the numbers we get back from the tests. We may also provide some educational materials to help you learn more about the tests.

We always recommend that you talk to your doctor about your health care needs and concerns.

Note

Precision Medicine Initiative, PMI, *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.