

# Consent to Join the *All of Us* Research Program

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Sponsor: National Institutes of Health

This form is for people age 18 or older.

This form tells about the *All of Us* Research Program (*All of Us*). It explains what we will ask you to do if you join. Please read this form carefully. If you have questions, there is a list of people you can ask at the end of this form. We will give you a copy of this form if you want one.

## What is *All of Us*?

*All of Us* is a health research program funded by the U.S. government. If you join, we will gather data about you. We will combine it with data from other people who join. Researchers will use this data for lots of studies. By looking for patterns, researchers may learn more about what affects people's health.

We hope that 1 million people or more will join *All of Us*.

## How long will *All of Us* last?

*All of Us* will last for at least ten years. If you decide to join, you can withdraw (quit) at any time.

## What will you ask me to do?

If you decide to join *All of Us*, we will gather data about you. We will gather some of the data from you directly. We will gather some of the data from elsewhere.

## Data that we will gather from you directly:

### 1. Basic data

We will ask you for data like your name and date of birth. Once a year we will ask if you have moved, or changed your phone number or email address. We will ask for the phone number or email address for a friend or family member as a backup in case we need to reach you. We might use social media or public listings to help us keep your contact information up to date.

### 2. Health data

We will ask you questions about your health, family, home, and work. This will take about 30-60 minutes. From time to time, we will ask you follow-up questions about your health. We may ask the same question more than one time, so we can see if there are any changes. You do not have to answer any question you do not want to answer.

### 3. Physical measurements

We may ask you to go to a local clinic to be measured. If you are asked, you can decide yes or no. You can say no and still take part in *All of Us*.

If you say yes to being measured, it will take about 15 minutes. *All of Us* trained research staff will do the measurements. We will measure your height, weight, hips, and waist. We will check your blood pressure and heart rate. We may ask you to have other measurements over time.

### 4. Samples

We may ask you to go to a local clinic to give a blood sample. If you are asked, you can decide yes or no. You can say no and still take part in *All of Us*.

If you say yes to giving a sample, we will use a needle to draw about 3 tablespoons of blood from your arm. We may ask you to give a urine sample (“pee in a cup”). We may ask for other samples, like saliva (“spit”).

Researchers will study your samples. They may measure things that naturally occur within our bodies, for example, cholesterol. They may look for signs of outside factors that affect health. For example, environmental toxins, medications, or drugs.

Researchers may also want to study your DNA. DNA is in your blood and other samples. Genes are made of DNA. Our hair color, eye color, and risk for some diseases depend on our genes.

Genes are passed from parents to kids. Half of your genes came from your mom and half came from your dad. If you have kids, each of them will get half your genes. In this way, your genes also tell about your family.

Researchers will use many methods to study your samples. Because *All of Us* will last for ten or more years, some of the methods may not even be invented yet.

We will store your blood, urine, and saliva samples in the *All of Us* biobank. The biobank is a secure storage place for samples. We will store your samples at the biobank until they are used up by researchers for different studies. If your samples get used up, we may ask you to give more. You can say yes or no.

What researchers learn from studying your samples will be added to the *All of Us* databases.

## 5. Fitness trackers

If you have a fitness tracker (like one to count the steps you take in a day), you might be able to share data from it with *All of Us*. If you don't have a fitness tracker, we may ask you to use one that we give you. You can say no and still take part in *All of Us*.

## Data that we will gather from elsewhere:

### 1. Electronic health records

If you have electronic health records, we may ask for access. If you are asked, you can decide yes or no. You can say no and still take part in *All of Us*, but it might limit what other data we ask to collect from you. For example, if you say no, you might not be asked to give samples.

There will be a separate form called the HIPAA Authorization for you to sign if you decide to give us access. We will see data about your health problems, test results, medical procedures, images (such as X-rays), and medicines you take. Health records can contain sensitive data. For

example, they may tell us about your mental health, genetic conditions, or use of alcohol or drugs. They may contain sexual or infection data, including HIV status.

## 2. Data about your health from other sources

We will add data from other sources to the data you give us. For example, environmental data and pharmacy records. This will give researchers more data about factors that might affect your health.

There are two ways we will add data from other sources to your *All of Us* record:

- *Based on where you live and work*

We will add data about your area based on where you live and work. For example, we may add data about the number of people in your area. We may add pollution data. We may add data like how close you live to the nearest grocery store or park.

- *Based on data that identifies you*

We will use data that identifies you like your name and date of birth to add data that is specific to you. For example, we may add data from pharmacy records or health insurance records. If you have had cancer, we may add data from cancer registries.

If you have a social security number, we may ask you for it to help with adding data. It is optional. Even if we ask, you do not have to give us your social security number. You can say no and still take part in *All of Us*.

These other sources can contain sensitive data. For example, they may tell us about your mental health, or use of alcohol or drugs. They may contain sexual or infection data, including HIV status. Because of this, we will ask the *All of Us* ethics committee to review and approve each data source before we add it.

## What will you do with my data and samples?

We will store your data and samples securely, along with the data and samples from all the other people who take part in *All of Us*. Researchers will use the data and samples to make discoveries.

We will create a public database on the *All of Us* website. The data in the public database will be about the group. It will not include data about individual people. It will not include your name or other data that directly identifies you. Everyone will be able to use the public database to make discoveries.

We will also create a scientific database. The scientific database will have individual-level data and samples. Access to this database will be controlled. Researchers will have to be approved by *All of Us* to use this database. These researchers may be from anywhere in the world. They may work for commercial companies, like drug companies. They may be citizen scientists. Citizen scientists are people who do science in their spare time. Their research may be on nearly any topic. You can learn more about the research being done at [www.joinallofus.org](http://www.joinallofus.org).

Except if you withdraw (“quit”) or there are limits imposed by law, there is no limit on the length of time we will store your samples and data. Researchers will use your samples and data for research long into the future.

## What else will you ask me to do?

We may ask if you want to hear about chances to take part in other studies. You can say yes or no to taking part in other studies. You can say no and still take part in *All of Us*.

## 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. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you

are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

We will gather data from you through the *All of Us* app and/or website. You may be asked to wear a fitness tracker. There is a risk to your privacy whenever you use an app, website, or fitness tracker. In general, there is no additional risk to your privacy if you use any of them as part of *All of Us*. That said, we will be gathering many different types of data in your *All of Us* record. If there is a data breach, there may be additional risk to your privacy because of the amount of data in your *All of Us* record.

Researchers will use basic facts like your race, ethnic group, and sex in their studies. This data helps researchers learn if the things that affect health are the same in different groups of people. These studies could one day help people of the same race, ethnic group, or sex as you. However, there is a risk that others could use this data 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.

## **What will you do to protect my privacy?**

Your privacy is very important to us. We will take great care to protect it. Here are a few of the steps we will take:

- Data we have about you will be stored on protected computers. We will limit and keep track of who can see this data.
- We will limit who is allowed to see information that could directly identify you, like your name or social security number.
- In order to work with your health data researchers must sign a contract stating they will not try to find out who you are.
- We will tell you if there is a data breach.

- *All of Us* has Certificates of Confidentiality from the U.S. government. These will help us fight legal demands (such as a court order or a request from federal, state, or local law enforcement) to give out information that could identify you.

## **Will you ever give out my name or other information that identifies me?**

There are a few times when we might need to give out your name or other information that identifies you.

- We will give out information about you to protect your health or the health of others.
  - If we learn or suspect that you are being abused.
  - If we learn or suspect you are abusing, 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 yourself or someone else.
  - If we learn that you have a disease that is a risk to public health, like measles.
- We will give out any data needed to meet U.S. research laws and regulations. This may include information that identifies you.

Once your information is shared with *All of Us*, it may no longer be protected by patient privacy rules (like HIPAA). However, it will still be protected by other privacy rules. These include the rules that researchers must follow to access the *All of Us* scientific database.

## **Are there any benefits?**

*All of Us* is not medical treatment. It is a research program. You will not get direct medical benefit from taking part in *All of Us*.

That said, you may indirectly benefit from taking part in *All of Us*. For example, we will provide ways for you to get access to all the data you

share with us and some of the results about you. This information may be interesting to you. You may learn about your health. You will be able to share your *All of Us* information with your healthcare provider if you choose. You will have the option to learn about additional study opportunities. Finally, you will be helping researchers make discoveries that may help future generations.

## **Are there any costs?**

There are no direct costs to taking part in the *All of Us* Research Program.

However, we will do various medical tests as part of this study. We will give you the results. You can decide to seek follow up care on your own because of these results. If you receive follow-up care, your doctor will bill you or your insurance company per usual practice. If you do not have insurance, or if your insurance will not pay, you will be responsible for the cost of follow-up care.

## **Are there any payments?**

If we ask you to be physically measured and give samples and you decide to do it, we will offer you a one-time payment of \$25.

Researchers will use your data to make discoveries. If any of their studies lead 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.

## **Will I be able to see my data?**

Yes, you will be able to see some of the data we collect about you. This includes:

- Any data you give us, like your health data.
- Your physical measurements.
- Some measurements from your samples.



You will be able to share this data if you choose. For example, you might want to share your *All of Us* data with your family or your healthcare provider.

## Will I find out the results of the research?

Results explain or interpret data. *All of Us* involves two kinds of results: results about you and results about the group.

### 1. Results about you

We may tell you if there are results about you. You will be able to choose if you want to see these results.

- Results that might change your medical care

These are results that could be used by a healthcare provider to take better care of you. For example, if any of your physical measurements are outside of what we would expect, we will tell you so you can follow-up with your healthcare provider. You will have to pay for the cost of follow-up care with your own healthcare provider.

- Results that would not change your medical care

These results might be interesting to you, but a healthcare provider probably would not use them to take better care of you. For example, these results might come from tests that are still experimental.

### 2. Results about the group

These are reports of what researchers learn about health from studying data from all the different people in the *All of Us* Research Program. You can get these reports, as well as general news and updates about *All of Us* at [www.joinallofus.org](http://www.joinallofus.org).

## What if I get injured?

If you think you have been injured because of taking part in *All of Us*, contact us using the information at the end of this form. If we find that you were injured as a direct result of taking part in *All of Us*:

- You will not have to pay for any immediate medical care to treat your injury.
- Beyond your immediate medical care, we will not pay for your injury.
- If you need follow-up care to treat your injury, you and/or your insurance will have to pay for it.
- If you have any long-term costs to treat your injury, you and/or your insurance will have to pay them.
- You do not give up any of your legal rights if you take part in *All of Us*.

## **Do I have to take part?**

Taking part in *All of Us* is voluntary. You can choose to join or not. No matter what you decide, now or in the future, it will not affect your medical care.

If you decide to join *All of Us*, you can change your mind at any time. If you decide you want to withdraw (quit), you need to tell us. You can tell us through the app or website, or use the contact information at the end of this form to call or write to us.

If you withdraw, your samples will be destroyed. Your data will not be used for new studies. However, if researchers already have your data or samples for their studies, we at *All of Us* cannot get it back. Also, we will let researchers check the results of past studies. If they need your old data to do this work, we will give it to them.

Even if you withdraw, we will keep your name and contact information. We keep this information so we can follow U.S. research laws and regulations.

## Who can answer my questions?

<b><i>If you have questions about:</i></b>	<b><i>Please contact the:</i></b>
The <i>All of Us</i> Research Program.	<p><b><i>All of Us Support Center</i></b> <b>Hours:</b> Mon-Sun, 7am-10pm ET <b>Phone:</b> <a href="tel:1-844-842-2855">1-844-842-2855</a> <b>Email:</b> <a href="mailto:help@joinallofus.org">help@joinallofus.org</a> <b>Chat</b> (website or app): <a href="http://www.joinallofus.org">www.joinallofus.org</a> <b>Languages:</b> English and Spanish</p>
Your rights as a research participant.	<p><b><i>All of Us Institutional Review Board</i></b> <b>Phone:</b> <a href="tel:1-844-200-8990">1-844-200-8990</a> <b>Email:</b> <a href="mailto:AoUIRBContact@emmes.com">AoUIRBContact@emmes.com</a> <b>Address:</b> 401 N. Washington Street, 7<sup>th</sup> Floor Rockville, MD 20850</p>

## **I know and agree that:**

- My data will be stored in the *All of Us* databases.
- If I give a blood, urine, or saliva sample, it will be stored at the *All of Us* biobank. This includes my DNA. Information that researchers learn by studying my samples will be stored in the *All of Us* databases.
- Researchers will do studies using the *All of Us* databases and biobank. Their research may be on nearly any topic.
- If my samples are used up, I may be asked to give more blood, urine, or saliva. I can say yes or no.
- My contact information may be used to tell me about other studies.
- I can withdraw (quit) at any time. There is no penalty if I withdraw.

# **All of Us Research Program HIPAA Authorization for Research EHR/Part 2 Supplement**

Principal Investigator: Joshua Denny, MS, MD  
Vanderbilt University Medical Center  
2525 West End Ave, Suite 1475  
Nashville, TN 37203

Sponsor: National Institutes of Health

This form is for people age 18 or older.

You are a participant in the *All of Us* Research Program (“*All of Us*”).

This form tells about giving *All of Us* access to your EHR (electronic health records). We will only be able to access your EHR if you sign this form.

Please read this form carefully. Take all the time you need to decide if you would like to give us access to your EHR. Ask any questions you have.

You can say yes or no to signing this form. Your choice will not affect your medical care. Your choice will not stop you from taking part in *All of Us*.

## **What is an EHR?**

Health records are the data collected when you get healthcare. Electronic health records, or EHR, are when this data is kept in secure electronic systems.

## **What data is in my EHR?**

The information in your EHR depends on what kinds of healthcare providers you see. Your EHR tells about the health problems and care you have received. It might list 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 data in my EHR?

There might be sensitive data in your EHR. For example, about your use of alcohol or drugs. Your EHR might have data about sexually transmitted infections, like HIV. It might have results from genetic (DNA) tests. We **will** be able to see this data.

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 data would be about your diagnosis and treatment. We **will** be able to see this data.

One exception are any notes from counselors or doctors in specialized clinics who treat addictions or substance use disorders. These notes are usually private and not part of the EHR. We will only be able to see these notes if they are part of your EHR.

## What exactly will you access in my EHR?

We will access your whole EHR. That means we will take a copy of all the tests, results, and images in your EHR. This includes data about your diagnoses, medications, symptoms, allergies, and treatments.

## Why do you want access to my EHR?

Your EHR contains important data about your health. We will add your EHR to your *All of Us* record. Your record will be part of the *All of Us* scientific database. In order to use this database, researchers will have to be approved by *All of Us*. Researchers will use this database to look for patterns. You can learn more about the research being done at [www.joinallofus.org](http://www.joinallofus.org).

## Who will be sending you my EHR?

We will request your EHR from all of your healthcare providers. This includes your regular healthcare providers. It also includes specialists. For example, if you have seen counselors or doctors who treat addictions or

mental health.

We may ask for your EHR from many different places. This may include hospitals where you have gotten care. It also may include addiction rehabilitation or mental health treatment programs where you have gotten care.

## Who will be getting access to my EHR?

If you sign this form, *All of Us* will be getting access to your EHR. We will add your EHR to your *All of Us* record.

The lead researcher of *All of Us* is Dr. Joshua Denny. He oversees the whole Research Program. There are many organizations that work on *All of Us* under Dr. Denny's guidance. Some of them are responsible for processing EHR data for *All of Us*. As they do their part for *All of Us*, they will work with your EHR data. Here is a list of who is involved:

- Broad Institute (Cambridge, Massachusetts)
- Columbia University Medical Center (New York, New York)
- Northwestern University Feinberg School of Medicine (Chicago, Illinois)
- University of Michigan School of Public Health (Ann Arbor, Michigan)
- University of Texas Health Science Center at Houston School of Biomedical Informatics (Houston, Texas)
- Vanderbilt University Medical Center (Nashville, Tennessee)
- Verily (Mountain View, California)

Visit [www.joinallofus.org/EHRdata](http://www.joinallofus.org/EHRdata) if you want to learn more about how your EHR gets to *All of Us*.

## Is there anyone else who will see my EHR?

We will create a public database on the *All of Us* website. The information in the database will be about the group. However, it could have information that comes from your and others' EHR. For example, the database may tell

the average number of times people in *All of Us* visit the doctor in a year. It will not include information about individual people. It will not include your name or other information that directly identifies you. Everyone will be able to 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 be approved by *All of Us* to use this database. These researchers may be from anywhere in the world. They may work for commercial companies, like drug companies. Their research may be on nearly any topic. You can learn more about the research being done at [www.joinallofus.org](http://www.joinallofus.org).

Once your information is shared with *All of Us*, it may no longer be protected by patient privacy rules (like “HIPAA”). However, it will still be protected by other privacy rules and agreements. These include the rules and agreements that researcher must follow to access the *All of Us* scientific database.

## **What if I don’t want to give access to my EHR? What if I change my mind?**

Giving *All of Us* access to your EHR is voluntary. You get to choose. No matter what you decide, now or in the future, it will not affect your medical care.

If you decide to give *All of Us* access to your EHR, you can change your mind at any time. If you decide you want to stop giving us access, you need to tell us. You can tell us through the app or website, or use the contact information at the end of this form to call or write to us.

If you tell us to, we will stop accessing your EHR. Data from your EHR will not be used for new studies. However, if researchers have already accessed data from your EHR for their studies, we at *All of Us* cannot get it back. Also, we will let researchers check the results of past studies. If they need your old data to do this work, we will give it to them.



## **When will my consent expire?**

Unless you tell us to stop, we will access your EHR until December 31, 2099.

## Who can answer my questions?

<b><i>If you have questions about:</i></b>	<b><i>Please contact the:</i></b>
The <i>All of Us</i> Research Program.	<p><b><i>All of Us Support Center</i></b> <b>Hours:</b> Mon-Sun, 7am-10pm ET <b>Phone:</b> <a href="tel:1-844-842-2855">1-844-842-2855</a> <b>Email:</b> <a href="mailto:help@joinallofus.org">help@joinallofus.org</a> <b>Chat</b> (website or app): <a href="http://www.joinallofus.org">www.joinallofus.org</a> <b>Languages:</b> English and Spanish</p>
Your rights as a research participant.	<p><b><i>All of Us Institutional Review Board</i></b> <b>Phone:</b> <a href="tel:1-844-200-8990">1-844-200-8990</a> <b>Email:</b> <a href="mailto:AoUIRBContact@emmes.com">AoUIRBContact@emmes.com</a> <b>Address:</b> 401 N. Washington Street, 7<sup>th</sup> Floor Rockville, MD 20850</p>

**By signing this form, I voluntarily authorize my healthcare providers and organizations to share my EHR with the *All of Us* Research Program, led by Dr. Joshua Denny, and its partner organizations listed above. I know the following information may be gathered from my EHR:**

1. All health information pertaining to my medical history, mental or physical condition, and treatment received
2. Mental health diagnosis or treatment information
3. HIV/AIDS testing information
4. Alcohol/drug abuse, diagnosis or treatment information
5. Genetic testing information
6. Information about domestic violence and sexual assault counseling