

## Sample Consent Document 9: *All of Us*

This consent document was used to recruit participants for a public resource (database) for studying personalized medicine. It includes language about returning individual genetic results.

*Important note: This consent template was developed for the All of Us Research Project. It is not provided as guidance or as a template promoted by NHGRI, but as a reference to inform investigators and IRBs considering these issues. It is important to tailor consent documents for each individual study.*

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

**Principal Investigator:** Paul Harris, Ph.D.  
Vanderbilt University Medical Center  
2525 West End Ave, Suite 1500  
Nashville, TN 37203

**Sponsor:** National Institutes of Health

This form is for people age 18 or older.

This form tells you 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.

## 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 may 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 questions 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”).

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. We may ask you to give more samples in the future. You can say yes or no.

#### 5. Fitness trackers or other devices

We may ask you to share data with us using a product or device made by a company. Products or devices are things like fitness trackers, mobile apps, websites and web apps, or types of computer software. If you don't already have the product or device, we may offer it to you to use for *All of Us*. If we offer you a product or device to use, you must agree to the company's rules before you can use it, just as if you bought the product or service for yourself. You can usually find these rules in the “Terms of Service” or the “End User License Agreement.” *All of Us* does not control these rules. Please read them carefully. These rules may ask you to agree to certain things, like not to sue the company if something goes wrong with the product or device. These rules may also allow the company to get, keep, or give others a copy of your information that comes from the product or device. Although *All of Us* will protect the copy of your information that you give us, we cannot protect or control what the company does with the copy that goes to them. If you do not agree to the company's rules, you do not have to accept the product or device. You can say no and still participate in other parts of *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.

### **1. We will study your samples, including your DNA**

We may measure things that naturally occur in our bodies, like cholesterol. We may look for signs of outside factors that affect health. For example, we may look for environmental toxins, medicines, or drugs.

We will also study your DNA. DNA is in your blood and other samples.

All human beings share more than 99% of their DNA with each other. The tiny bit that is different is part of what makes each of us unique. Things like our hair color and eye color depend on the bits of DNA that are different between human beings. We call these our DNA changes. These DNA changes can also tell you about your health and how your body works. They can tell you about where your ancestors may be from. We are still learning about what role DNA plays in many parts of our lives.

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

We will use many methods to study your samples. For example, we might study your DNA using whole genome sequencing. Whole genome sequencing is a way of studying nearly all of a person's DNA. Every person's whole genome sequence is different. It is unique to them, like a fingerprint.

Because *All of Us* will last for ten or more years, some of the methods we will use may not even be invented yet.

2. 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.

3. We will create a scientific database

The scientific database will have individual-level data and samples. This includes your DNA data. Access to this database will be controlled. Researchers will have to be approved by *All of Us* to use this database. They will have to have special training before they can be approved. Their research may be on nearly any topic. They may look for patterns in DNA. This may help them discover different ways that DNA affects people. These researchers may be from anywhere in the world. They may work for commercial companies, like drug companies. They may be citizen or community scientists. Citizen and community scientists are people who do science in their spare time.

4. Researchers can also ask to study your samples or DNA directly

We may send them a small amount of your samples or DNA so that they can do this. Before we send researchers your samples or DNA, they will have to take special training and sign a contract stating that they will not try to find out who you are. They will have to tell us what they want to study. *All of Us* will have to approve it.

Researchers will use many methods to study your samples and DNA. Because *All of Us* will last for ten or more years, some of the methods may not even be invented yet. The data researchers get from studying your samples and DNA may be added to the *All of Us* scientific database.

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.

## **Are there other risks I should know about?**

Telling people you're part of *All of Us* could be a risk to your privacy. It could make it easier for someone to identify you in the *All of Us* scientific database and learn other information about you. They could misuse your information.

You can help protect your privacy. You may want to be careful about sharing that you are part of *All of Us* on social media or in other public areas. You may also want to be careful about posting your data or results.

## **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 subpoena or a request from federal, state, or local law enforcement) to give out information that could identify you.

*All of Us* will only use information about DNA changes for research. We will

not tell insurance companies about who has DNA changes. We will not tell employers. We will not tell banks. We will not tell any school, college, or university.

## **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. laws and regulations. This may include information that identifies you. For example, there is a regulation that says the U.S. Food and Drug Administration (FDA) may ask to look at the records for the *All of Us* Research Program. The FDA checks how programs like *All of Us* give people DNA results about their health. If the FDA asks to look at these records to do their checks, we will let them.

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 benefits 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 may learn about your DNA changes. You will be able to share your *All of Us* information with your health care 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 can choose to see any of the measurements from studies *All of Us* does on your samples, like your whole genome sequence. You may not be able to see all the measurements from other studies researchers do using 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 health care 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

Over the many years of the *All of Us* Research Program, we will study lots of things about your data and samples. We will tell you if there are results about you from what *All of Us* studies. You will be able to choose if you want to see these results.

Sometimes, we will ask you if you want us to check your data or samples for results that you might find interesting. For example, we may ask you to fill out another form where you can choose if you want us to check your DNA for certain kinds of DNA changes and return your results to you. This form is called the Consent to Get DNA Results. It will tell you about the risks and benefits of having us check your DNA and

about learning your results. We will not check for these kinds of DNA changes until you make a decision.

Some of the results we give you may tell you about your health, and others may not.

- Results that might tell you about your health

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 health care provider.

- Results that would not tell you about your health

These results might be interesting to you, but a health care 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 and samples 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).

While researchers might learn results about you from studying your *All of Us* data and samples, you may not be able to see these results.

## **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>Questions about...</b>	<b>Contact</b>
The <i>All of Us</i> Research Program	<p style="text-align: center;"><b>All of Us Support Center</b></p> <p><b>Hours:</b> Mon.–Sun., 7 a.m.–10 p.m. 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 style="text-align: center;"><b>All of Us Institutional Review Board</b></p> <p><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, 7th 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.
- I may be asked to give more samples in the future. 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.

Please check the box below if you agree to take part:

- I have read this consent form (or someone read it to me). I understand the information in this form. All of my questions have been answered. I freely and willingly choose to take part in the *All of Us* Research Program.**

Sign Your Full Name:

\_\_\_\_\_

Date:

\_\_\_\_\_

Please check the box below if someone from *All of Us* helped you with completing the consent process:

**I received help from *All of Us* to complete the consent process.**

Name of the person who helped you:

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