

All of Us Research Program Consent to Get DNA Results

Person in charge of this study:

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

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This form is for people age 18 or older.

When you joined the program, you signed a form that says you agree to let scientists study your DNA for research. Now we want to know if you want *All of Us* to check your DNA for changes and tell you what we find. These are your DNA results. This form explains the choice you have about learning your DNA results. It explains about different kinds of DNA changes. It explains how we will check for them and how long it will take. It explains how you can learn about your results.

Some people will want to learn about their DNA results. Other people will not. We want you to make the best decision for yourself. No matter what you decide, you can still participate in *All of Us*.

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 are “DNA changes”?

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 our DNA that are different between human beings. We call these our DNA changes. We know what some DNA changes mean, but we still have a lot to learn. For example, we

are still learning what role DNA plays in most health conditions. In fact, that's one of the reasons we are doing the *All of Us* Research Program. But for a small number of things, we already know a lot about the role DNA plays.

We know that certain changes in our DNA can affect our health. For example:

- Certain DNA changes can increase our risk for a few specific health conditions. This could include some cancers and types of heart disease.
- Certain changes in our DNA can increase the risk of passing specific health conditions on to our children, even if we don't have those conditions.
- Certain changes in our DNA can impact how a few specific medicines work.

We also know that other changes in our DNA can tell us about things like:

- Where our ancestors may be from.
- How our bodies work.

The more we study our DNA, the more we will learn what DNA changes mean about us.

How will you check my DNA?

If you say yes, we will check your DNA for certain types of DNA changes. We will do this by having a specially trained scientist look at your DNA.

How long will it take to get my results?

It might take a few months or even a few years for *All of Us* to check your DNA. We may be able to give you results about some types of DNA changes sooner than others. You will be able to follow our progress through your *All of Us* account.

What exactly will you check for?

If you say yes, you are telling us that you want to learn about some or all of your DNA results. When we are ready to check for a specific type of DNA change, we will tell you more about what the results may mean for you. Then you can decide whether you want your results for that type of DNA change. For example, you may want to learn about any health-related DNA changes you have. You might only want to learn results about where your ancestors may be from. Or you might want to learn about all of your DNA results. You get to choose.

The list of DNA changes that we will check for may change as researchers make new discoveries. There will be a link to the most updated list of what we check for in your *All of Us* account.

Over time, we may learn new information that could change your results. We may go back and check your DNA again. We will tell you if we find anything new or if we find anything that changes your results.

What will you tell me?

Health-related DNA results

If we find a change in your DNA that increases your risk of a health condition, we will try to contact you directly. We will help you make an appointment with an *All of Us* genetic counselor. They will tell you your results. They will answer your questions. They will send you a report. They can also send a report to your health care provider. If you want, they will help you find a health care provider in your area.

If we find other types of health-related results, we will send you a note through your *All of Us* account. We will give you a report that you can share with your health care provider.

If we do not find any known health-related changes in your DNA, we will also send you a note through your *All of Us* account.

Remember, ***All of Us* is a research program. It is not medical care.** Do not use *All of Us* as a substitute for medical care.

Results about your health-related DNA changes from *All of Us* are **research results**. Research results are not the same as medical testing. Do not make any changes to your medicines or care until you talk to a health care provider. If you want, we can help you send your *All of Us* DNA results to your health care provider. They will need to confirm your *All of Us* results with medical tests. If you don't have a health care provider, we can help you find one.

Other types of DNA results

DNA can also give you information that is not about your health. DNA can tell you where your ancestors may be from. It can help explain how your body works. You can decide if you want us to check for these kinds of DNA changes. If you say yes, we will send you a note through your *All of Us* account once we have your results. In the note, we will tell you how to see your DNA results using our interactive learning tool.

Do I need to pay to get my DNA results?

You do not need to pay to have us check for DNA changes. You do not need to pay to find out your results. You do not need to pay to talk to an *All of Us* genetic counselor.

How could learning my DNA results help me?

Knowing you have a health-related DNA change may help your health care provider take better care of you. They may be able to prevent or find a health condition early. This could help you get better treatment. They may be able to adjust the type or amount of medicine they give you. You might have fewer side effects.

If you have a health-related DNA change, your blood relatives might have it too. If you tell them about your DNA results, their health care providers might suggest different care for them.

You may think it is interesting to learn information from your DNA that is not about your health. For example, you may want to learn where your ancestors may be from.

Remember, *All of Us* is a research program. It is not medical care. Do not use *All of Us* as a substitute for medical care. Do not make any changes to your medicines or care until you talk to a health care provider. They will need to confirm your *All of Us* results with medical tests.

What are the risks of learning my DNA results?

There are different kinds of risks to learning about your DNA. When we are ready to check for certain types of DNA changes, we will tell you more about the results you would receive. You may have questions. Genetic counselors can help answer any questions you have about what results may mean for you. You may want to talk to a genetic counselor about these questions before signing this consent or after getting your DNA results. You can ask to talk to an *All of Us* genetic counselor at any time through the *All of Us* Support Center. They can also help you find support if you need it.

Health care and Insurance Risks

Changes in health care

A health care provider must confirm your health-related DNA results by medical testing. You or your insurance may be billed for it. Your health care provider may recommend new or different care based on these medical tests. You may want to make some of these changes to your care and not others. You can decide what care is right for you. These changes in your care may cost more than regular care. Some of these changes in your care may not be covered by your insurance. Your health care provider may recommend care that makes you need to take time off of work, like surgery.

Disability, life, and long-term care insurance

In most places, DNA information can be used by disability, life, and long-term care insurers. These insurers can ask you if you have information about your DNA, and you have to tell them what you know. They can use that information to decide if they will cover you and how much they charge. If you find out that you have a health-related DNA change from *All of Us*, it could make it difficult or more expensive to get these types of insurance.

In some places, there are laws that say life, disability, and long-term care insurers can't use DNA information to decide about your coverage. To find

out if you are protected by these kinds of laws, contact the attorney general for your state or territory. You can learn how to contact your attorney general at www.usa.gov/state-attorney-general.

Family Risks

Your blood relatives

Your DNA tells about you and people who are related to you by blood. If you have a certain DNA change, your blood relatives might have it too. They may or may not want to know this information. You may realize you are not related to some family members in the way you thought you were.

Emotional Risks

If you decide to have your DNA checked, you may receive news that worries or scares you. You may be afraid of passing health-related DNA changes on to your children. Remember, you can ask to talk to an *All of Us* genetic counselor at any time. They can answer your questions and help you find support.

What are the risks of sharing my DNA results?

Sharing your DNA results could be a risk to your privacy. It could make it easier for someone to find out who you are in the *All of Us* scientific database and learn other information about you. They could misuse your information.

You can help protect your privacy. Be careful about posting about your DNA results on social media or in other public areas, as you may not be able to control how the information is used. If you decide to find out about your health-related DNA changes, only share those results with people you trust, like your health care provider.

What are the limits of *All of Us* DNA results?

The results you get will not tell you everything about your DNA. This is especially important to remember about health-related DNA results. For

example, we will not check for every health-related DNA change. Even if we do not find a health-related DNA change, you could still have one.

The DNA results you get from *All of Us* are not the same as medical test results. Because DNA results from *All of Us* are research results, there is a chance they could be incorrect. Do not make changes to your medicines or care based on your *All of Us* DNA results.

Are there ways that DNA results cannot be used?

Employment

There are federal laws that say employers can't treat people differently because of their DNA information. These laws do not apply to employers with fewer than 15 people.

Health Insurance

There are federal laws that say health insurers can't use DNA information against people. They can't use it to change your coverage, cancel your coverage, or charge you more.

Will you ever give out my DNA results?

Protecting the privacy of your DNA results is very important to us.

Here are a few of the steps we will take to protect it:

- DNA results we have about you will be stored on protected computers. We will limit and keep track of who can see this information.
- *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.
- We will not tell insurance companies about your DNA results. We will not tell employers. We will not tell banks. We will not tell any school, college, or university.

We will give out any data needed to meet U.S. laws and regulations. This may include information that identifies you. There is a U.S. federal 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.

Do I have to learn my DNA results?

No, learning your DNA results is voluntary. Some people will want to find out. Other people will not. Some people may not be sure right now. It is up to you. No matter what you decide, you can still participate in *All of Us*.

You can change your mind about learning your DNA results at any time. If you change your mind, 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.

When will my consent expire?

Unless you tell us that you have changed your mind, your consent lasts until December 31, 2099.

This form is only for learning about DNA changes. It cannot be used for any other purpose.

Who can answer my questions?

| <i>Questions about...</i> | <i>Contact</i> |
|---------------------------------------|--|
| The <i>All of Us</i> Research Program | <p>All of Us Support Center</p> <p>Hours: Mon.–Sun., 7 a.m.–10 p.m. ET</p> <p>Phone: 1-844-842-2855</p> <p>Email: help@joinallofus.org</p> <p>Chat (website or app): www.joinallofus.org</p> <p>Languages: English and Spanish</p> |
| Your rights as a research participant | <p>All of Us Institutional Review Board</p> <p>Phone: 1-844-200-8990</p> <p>Email: AoUIRBContact@emmes.com</p> <p>Address: 401 N. Washington Street, 7th Floor Rockville, MD 20850</p> |

Would you like to learn any of your DNA results?

- No, I do not want to learn about any DNA results.**
- I know I can change my mind later.
 - I know this means that researchers can still use my DNA to make discoveries unless I withdraw (quit).
- I'm not sure right now.**
- I know that until I decide, I **will not** learn about any of my DNA results.
 - I know I can change my mind later.
 - I know this means that researchers can still use my DNA to make discoveries unless I withdraw (quit).
- Yes, I want to learn some or all of my DNA results.**
- I know *All of Us* will ask me later what specific types of DNA results I want. I get to choose.
 - I know this means *All of Us* will tell me the kinds of results I choose to learn.
 - I know this means I have to keep my contact information in *All of Us* up to date so that you can give me my results.
 - I know this means that researchers can still use my DNA to make discoveries unless I withdraw (quit).

Sign Your
Full Name:

Today's 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:
