All of Us Research Program Authorization to Share My EHRs for Research

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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 you about sharing your EHRs (electronic health records) with *All of Us*. If you agree, we will use this form to ask your health care providers for your EHRs. We will also ask other organizations that have your EHRs (examples below). Signing this form tells your health care providers and other organizations that they can send your EHRs to us.

Please read this form carefully. Take all the time you need to decide if you would like to share your EHRs. Ask any questions you have.

Sharing your EHRs is voluntary. You do not have to share your EHRs. Your choice will not affect your medical care. Your choice will not keep you from taking part in *All of Us*.

What are EHRs?

Health records are the information collected about you when you get health care. They include information about the care you get. Electronic health records, or EHRs, are when this information is kept in secure electronic systems.

What is in my EHRs?

The information in your EHRs depends on what kinds of health care providers you see. Your EHRs tell about any health problems you have seen a health care provider about. They tell about care you have received. They may list the medicines you take. They may have test results. They may have images, like X-rays. If you have had a medical procedure, notes about it will likely be in your EHRs.

Your EHRs may also tell how much you were billed and how much you paid for your care.

Is there sensitive information in my EHRs?

There may be sensitive information in your EHRs. For example, there may be information about your use of alcohol or drugs. Or about tests and treatments for sexually transmitted infections, like HIV. They may have results from genetic (DNA) tests. We **will** be able to see this information.

If you have seen counselors or doctors, information about your diagnosis and treatment may be in your EHRs. For example, if you have seen counselors or doctors who treat

- addictions (also known as substance use disorders);
- mental health conditions, like depression or bipolar disorder; or
- trauma, from things like domestic violence and sexual assault.

We **will** be able to see this information.

Which of my EHRs will you get?

We will get all of your EHRs. This includes records about your health, mental health, dental care, and vision care. That means we will get a copy of all the tests, results, notes, and images in your EHRs. This includes information about your health conditions, medicines, symptoms, allergies, and treatments. We may also get information about how much you were billed and how much you paid for your care.

Why do you want my EHRs?

Your EHRs contain important information about your health. They are a way for researchers to get a picture of your health over a long period of time.

We will add your EHRs to your *All of Us* record. Information from your record will be part of the *All of Us* scientific database. Information that directly identifies you, like your name or address, will not be part of this database. Before researchers will be allowed to see your data, they will have to take special training. They will have to sign a contract agreeing they will not try to find out who you are. This contract also says how they can and cannot use your data. Researchers will use this database to make discoveries about health. You can learn more about the research being done at www.researchallofus.org.

Who will send you my EHRs?

We will ask all of your health care providers for your EHRs. This includes your primary health care provider. It also includes specialists. For example, if you have seen counselors or doctors who treat substance use disorders or mental health conditions. We will also ask your dentist and eye doctor for your EHRs.

We will ask for your EHRs from many different places where this information is kept. These may include health care providers and other organizations, such as:

- hospitals
- substance use disorder treatment programs
- mental health treatment programs
- pharmacies
- dental offices
- vision care offices

- contractors of these health care providers: these are companies that partner with health care providers to help carry out their work
- health information exchange (HIE) networks: these networks allow the types of health care providers and organizations listed above to access and securely share important medical information electronically

Who will get my EHRs?

If you sign this form, *All of Us* will get your EHRs. We will add your EHRs to your *All of Us* record.

The lead researcher of *All of Us* is Dr. Paul Harris. He oversees the whole Research Program. There are many organizations that work with Dr. Harris on *All of Us*. Some of them are responsible for processing EHR data for *All of Us*. 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 if you want to learn more about how your EHRs get to *All of Us.*

Is there anyone else who will see my EHRs?

We will create a public database on the *All of Us* website. The information in the database will be about the group of people in *All of Us*. It will not include information about individual people. It will not include your name or other information that directly identifies you. However, it could have information that comes from your and others' EHRs. For example, the database may tell the average number of times people in *All of Us* visit the doctor in a year. Everyone will be able to use the public database to make discoveries.

We will also create a scientific database. It will have individual-level information about people in *All of Us*. It will include health information from EHRs. It will not include information that directly identifies you, like your name or address. We will control access to this database. Before researchers will be allowed to see your data, they will have to take special training. They will have to sign a contract agreeing they will not try to find out who you are. This contract also says how they can and cannot use your data. 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.researchallofus.org.

Your information may no longer be protected by patient privacy rules (like "HIPAA") once you share it with *All of Us*. This is because *All of Us* does not provide medical care. The patient privacy rules that apply to health care providers do not apply to *All of Us*. The copies of your EHRs that are with your health care providers will still be covered by HIPAA. The copies that are shared with *All of Us* will be protected by other privacy rules and agreements. These include the rules and agreements that researchers must follow to use the *All of Us* scientific database.

What if I don't want *All of Us* to have my EHRs? What if I change my mind?

Sharing your EHRs with *All of Us* is voluntary. You get to choose. No matter what you decide, it will not affect your medical care. It will not affect your treatment, payment, enrollment, or eligibility for any health care benefits.

If you decide to authorize *All of Us* to get your EHRs, you can change your mind at any time. If you decide you want to stop allowing us to get this information, you need to tell us. You can tell us through your *All of Us* account 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 getting your EHRs. Data from your EHRs will not be used for new studies. But, if researchers have already used data from your EHRs for their studies, *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 authorization expire?

Unless you tell us to stop, we will use this form to get your EHRs until December 31, 2099.

Who can answer my questions?

If you have questions:	***Please contact the:***
About the *All of Us* Research Program	***All of Us*** **Support Center** **Hours**: Mon-Sun, 7am-10pm ET **Phone**: 1-844-842-2855 Toll-free TTY-based 711 **Email**: help@joinallofus.org **Chat** (website or app): www.joinallofus.org **Languages**: English and Spanish
About your rights as a research participant	***All of Us*** **Institutional Review Board** **Phone**: 1-844-200-8990 **Email**: AoUIRBContact@emmes.com **Address**: 401 N. Washington Street, 7th Floor, Rockville, MD 20850

I understand that if I sign this form, I authorize my health care providers and other organizations to share my EHRs with the *All of Us* Research Program. This program is led by Dr. Paul Harris and the partner organizations listed above. I know the following information may be gathered from my EHRs:

1. All health information connected to my medical history, mental or physical condition(s), and treatment(s) received. This includes medical, dental, and vision care.
2. How much I was billed and paid for care and medicines.
3. Mental health diagnosis or treatment information.
4. HIV/AIDS testing, status, and treatment information.
5. Substance use disorder (alcohol/drug abuse) diagnosis and treatment information.
6. Genetic (DNA) testing information.
7. Information about domestic violence and sexual assault counseling.

Please sign your name below. You will have access to a signed copy of this form.

Sign Your Full Name:

SAMPLE

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:

SAMPLE