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

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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 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.

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 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.

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 the *All of Us* Research Program ends.

Who can answer my questions?

If you have questions about:	*Please contact the:*
The *All of Us* Research Program.	***All of Us* Support Center** **Hours**: Mon-Sun, 7am-10pm ET **Phone**: 1-844-842-2855 **Email**: help@joinallofus.org **Chat** (website or app): www.joinallofus.org **Languages**: English and Spanish
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

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

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

Sample

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.**

<u>Sample</u>