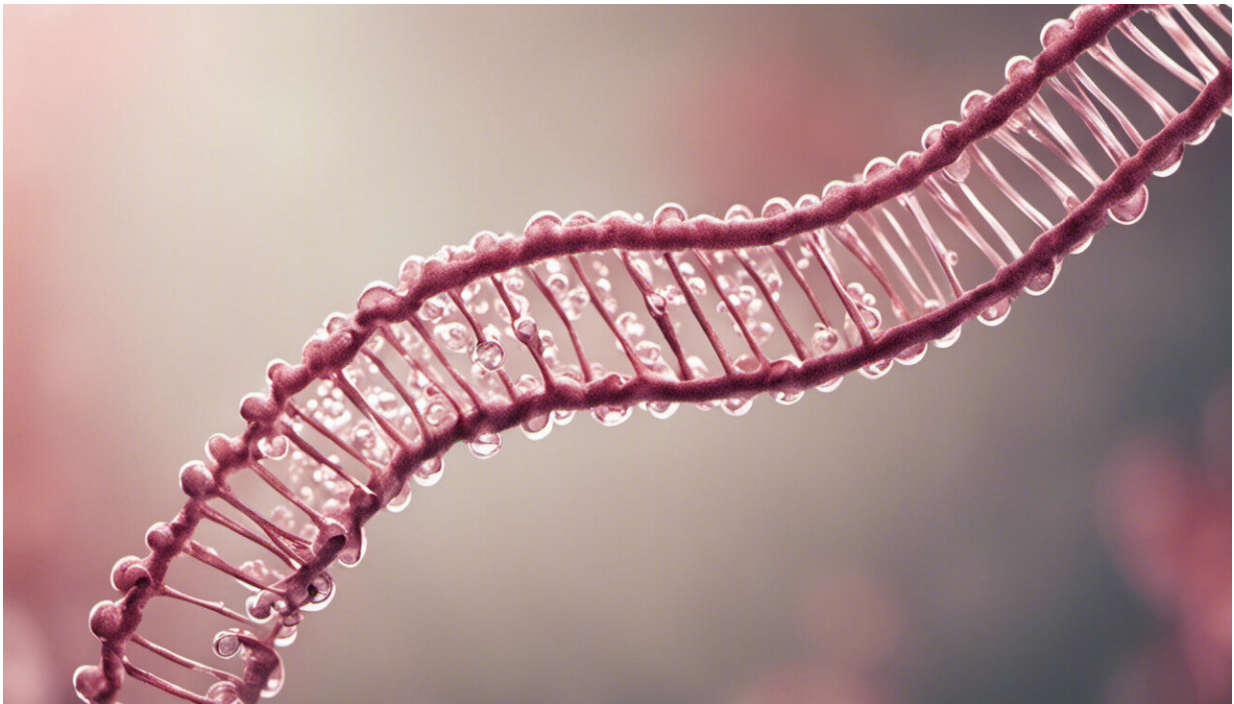


A clinical trial wants your DNA – what should you do?

May 21 2018, by Martin Schiller



Credit: AI-generated image ([disclaimer](#))

On May 6, the ["All of Us" study](#) started enrolling participants. [This national study](#) will be one of the largest ever examining the connection between genetics, behavior and medical outcomes, with a goal of 1 million or more participants. Anyone over the age of 18 in the U.S. can join.

As a researcher who studies personalized medicine, I believe it's important for Americans to be able to make an informed decisions in their quest for cutting-edge health care, but it does raise important questions over privacy. Given modern concerns about data security, I see positives and negatives to participating in [trials](#) like All of Us.

You may question how this will benefit you and potentially compromise your privacy. Your skepticism is warranted and worthy of investigation to help you make the correct decision.

Why do a clinical trial

Clinical trials often offer benefits to their participants. Many offer early access to cutting edge treatment that's not available to others. Another perk may be free or discounted treatment, or some other incentive.

In my view, participating in a clinical trial is also somewhat a personal duty. In the U.S., as of 2013, the Food and Administration has approved [1.453 drugs](#) for use in humans. When you take an approved [drug](#), you benefit from not only the work of scientists and billions of dollars of investment, but the sacrifice of many participants who took a chance on an experimental drug.

In contrast, the All of Us trial is not designed for any direct improved treatment. Instead, it aims to collect data to help researchers understand the connections between genetics, lifestyle and disease. For example, the study could identify novel biomarkers to measure long-term average [blood glucose levels](#).

Despite careful tests on safety and dosage, when some drugs reach market, some individuals have serious adverse reactions, which [in rare cases can be lethal](#). Others see no benefit from the drug.

Why does this happen? The answer in large part comes from genetics. Like a computer program that codes for some task, DNA codes for many traits – including a person's susceptibility to disease and response to drugs.

Each person's DNA sequence encodes millions of variations compared to another person, unless that person has an identical twin. Cost-effective sequencing of all or part of a person's DNA now enables scientists to look at the potential relationship between one or more of these genetic variations and disease diagnosis, prognosis or treatment. In fact, about 8 percent of all approved drugs [now recommend a specific genetic test](#) on their label to identify the right drug and dosage.

The large number of participants in All of Us will give researchers enough data to detect links between treatments, lifestyles and health outcomes.

Risks to your data

One should be aware of the amount of genetic information you are disclosing in a research study, whether it's in a clinical trial or a more generalized study.

Some studies are [genotyping based](#), examining about 1 to 100 genetic variations, often in a specific gene or set of genes, called a panel. Other studies [may use a microarray](#) that has 0.5 to 1 million common genetic variants. This is typically the technology used by recreational genetic companies like 23andMe and Ancestry. Even more data comes from [whole exome sequencing](#). It's not yet clear what type of tests All of Us will use.

What are your risks of giving away your [genetic information](#)? [Research has shown](#) that you and your relatives can likely be identified from your

DNA, so your privacy could potentially be compromised.

In a clinical trial, you will not have ownership or even access to your [genetic data](#). In a company-driven trial, data might be shared with third parties and protections against a data breach are not regulated. If you have used a recreational genetics company, you should review the websites and company policies for the protections afforded.

However, if a dangerous mutation in one of the 59 genes defined by the American College of Medical Genetics is identified in a research study, the participant [will be informed of this incidental finding](#). This screening is an added benefit for the participant.

Weighing the costs

A number of laws protect against the misuse of participant genetic data, especially in a trial sanctioned by the National Institutes of Health, such as All of Us.

Three laws protect Americans against discrimination based on genetics: the [Genetic Information Nondiscrimination Act](#), [Health Insurance Portability and Accountability Act](#) and [Affordable Care Act](#).

Insurance companies cannot access clinical trial results. Nevertheless, there's little [legal protection](#) in many situations, including life insurance, the military and [companies with fewer than 15 employees](#).

As part of a trial, you will be asked to sign an informed consent form, which lets you know the risks and how your information will be used. The trial and consent form must be approved by an Institutional Review Board that monitors human subject research. Read these documents.

The NIH requires that any genetic data resulting from their funding be

shared through secure web systems such that your contribution maximizes impact. That means the use of your genetic data is [strictly controlled and protected](#).

Genetic data can undoubtedly lead to more drugs with more focused targeting and better health care for all. High-quality studies with strong statistical power, like All of Us, may need millions of participants. Clearly, a system that lets scientists comprehensively share genetic and clinical data, yet maintains acceptable privacy, is desperately needed.

By sharing medical records and having the large data set accessible to other scientific researchers, All of Us is a key step in the right direction.

This article was originally published on [The Conversation](#). Read the [original article](#).

Provided by The Conversation

Citation: A clinical trial wants your DNA – what should you do? (2018, May 21) retrieved 27 April 2024 from <https://medicalxpress.com/news/2018-05-clinical-trial-dna.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--