

Information Safety in the Precision Medicine Age

By Barbara Brody

Maybe your doctor has suggested a targeted therapy for your illness. Or you think you might want to join a research study that aims to create new treatments based on differences in people's genes, lifestyle habits, and environmental factors. Either way, you're about to take part in precision medicine (you might also hear it called personalized medicine). And in order to do so, you're going to have to share some very personal information, including your genetic material.

Exactly what information you'll be asked for and what will happen to it depend on whether you need treatment right away for a personal health issue or you just want to share your information to help out with future studies. The type of research program you take part in also matters.

Option 1: You Want Treatment With an Existing Targeted Therapy

Let's say you have cancer. Right now, specific treatments may help you -- but only if you have a certain change in your genes (doctors will call this a mutation) or if your cancer makes too much of a particular protein. Your doctor will need some information about the genes, proteins, and other things about your cancer to help decide if the treatment will work for you.

The first step will probably be for you to have a biopsy. Your doctor will remove a small piece of your tumor and send the material to a lab for analysis.

"That's currently being done routinely to figure out that a patient is most likely to respond to drug X," says Michael J. Donovan, PhD, MD, director of the Biorepository and Pathology Core at Mount Sinai Health System in New York.

After your material is analyzed and your doctor gets the results, she'll store your sample for a set number of years (there are guidelines that tell her how long). The sample -- along with any information that came as a result of the analysis -- becomes part of your medical records. You have a right to access it.

All your records (and material) will mostly be kept private. But they might be shared with other doctors involved in your care, as well as your pharmacy and health insurance company. Your samples will only be used for your care, not for any ongoing or future research, unless you ask for (and choose to sign) a consent form that OKs such use, says Donovan, a professor of experimental pathology.

Sources 

SOURCES:

American Cancer Society: "What Happens to Biopsy and Cytology Specimens?"

American Society of Clinical Oncology: "Understanding Targeted Therapy."

Michael Donovan, MD, PhD, professor of experimental pathology; director, Institutional Biorepository and Pathology Core, Mount Sinai Health System, New York.

Mine Cicek, PhD, director, Biospecimens Accessioning and Processing (BAP) core laboratory, Mayo Clinic, Rochester, MN; co-principal investigator, All of Us program, Biobank, Mayo Clinic in Rochester.

National Cancer Institute: "Targeted Therapy."

National Institutes of Health: "About the Precision Medicine Initiative," "Healthcare Provider Organizations."

U.S. Department of Health and Human Services: "Your Rights Under HIPAA."

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Option 2: You Want to Help Researchers

In this case, you have nothing personal to gain; you just want to advance medical research. At Mount Sinai, for example, you can opt to send so-called waste products from your tests (things you don't need for your own care) to Donovan's laboratory. In other words, your doctor can (with your OK) send your leftover blood, urine, saliva, biopsy tissue, etc. to the biorepository. Doctors there will analyze, store, and use it for a wide range of current and future research projects.

People who agree to send material to the lab tend not to place limits on how the information can be used, Donovan says. That means one day, your sample could help create new treatments for heart disease, autoimmune disorders, cancer, and more. Along the way, doctors take your personal privacy seriously.

"Some patients are worried that their information could get back to health insurance companies," Donovan says. To make sure that doesn't happen, his lab follows strict rules set by groups like the College of American Pathology. Most researchers who come to his lab to get samples for a study never find out who the donors are, he says, unless those people give the OK to share their data.

A National Effort

Donovan's lab at Mount Sinai is one of several around the country that collect, store, and share samples for various research studies. But there is one large-scale effort to advance precision medicine underway. The All of Us research program (formerly called the Precision Medicine Initiative Cohort Program), sponsored by the National Institutes of Health, is a government project with a massive goal: Get a diverse group of at least 1 million Americans to donate blood and urine specimens, answer questions about their diet and lifestyle habits, and allow access to their personal health records to help scientists develop new, more effective treatments for a variety of diseases. Those who take part will also get a baseline checkup to assess their vital signs and review their medical history.

The project will begin to seek volunteers in 2017. Anyone in the U.S. can join. You can sign up at the website

(<https://www.nih.gov/research-training/allofus-research-program>) or through one of many health care provider organizations (major medical groups) around the country, says Mine S. Cicek, PhD, co-principal investigator of the All of Us program Biobank at the Mayo Clinic in Rochester, MN.

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Sources 

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To protect your privacy, Cicek says, your samples and identifying details will be securely stored at different locations: Specimens will be assigned a unique Biobank ID number and shipped to the Biobank at the Mayo Clinic in Minnesota, where they'll be frozen. Your name, demographic details, and personal health information will go to the Data and Research Center at Vanderbilt University in Tennessee.

A researcher who wants to study diabetes might go to Vanderbilt and ask for material on 1,000 people with diabetes, Cicek says. They'll search the database, tell the Biobank at Mayo which samples to pull, and the Biobank will send them to the researcher. The researcher gets limited information on those samples, like age ranges or ethnicity, depending on what's needed for the study. "The goal is for no one to be able to identify that a particular sample belongs to Jane Doe," she says.

As for what can be done with your samples, the sky's the limit. If you join the All of Us program, you'll agree that scientists can use your data for any type of research in the future. The plan is to keep the public informed about new discoveries from the project.

What happens if you sign up but change your mind? You can pull your consent and ask to have your samples and records destroyed at any time. But Cicek and other scientists hope that will be rare. The more people involved, the better chance researchers will have of making major advances, she says. "It might not be something that you personally benefit from, but think about your children and grandchildren. We're in this to help humankind."

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