

Are there any risks?

The physical risks of donating your biospecimens are:



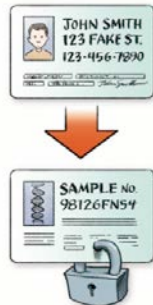
Privacy and Confidentiality Risks

Researchers may publish information about the groups you belong to, like gender, age, or ethnic groups.

Research projects cannot completely guarantee confidentiality. Your personal information could be accidentally released, or someone could illegally use it to try to identify you.

To protect your identity, we will:

- label your biological sample with a code instead of your personal information
- only share your personal information (name, address, Social Security number, or other recognized identifiers) with researchers who are approved to use this information
- use password protection to limit access to authorized users only
- follow all federal and local rules for privacy protection
- review our security procedures regularly to make sure that they are effective and up to date



The CBR has obtained a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. Please review the accompanying document of informed consent for additional details regarding the Certificate of Confidentiality.

Your privacy is important to us. We will take precautions to protect it, but you need to know that no protection system is perfect. If you have reservations, you might not want to contribute to the biorepository.

There are no costs to you or your insurance company for permitting us to use your biospecimens and information.



Each day, nearly 5,000 patients visit the University of Michigan Health System. Their health records and the biospecimens they donate contain valuable information about the biological basis of health and disease.

The University of Michigan is developing biorepositories for collecting, storing, sharing, and using health information and biospecimens for research. Working with researchers here and around the world and with companies, our goal is to turn this information into discoveries that will advance diagnosis, prediction, prevention, and treatment for future patients.

For more information about

Your rights as a human participant, contact IRBMED, 2800 Plymouth Road, Building 520, Room 3214, Ann Arbor, MI 48109-2800
irbmed@umich.edu, 734-763-4768

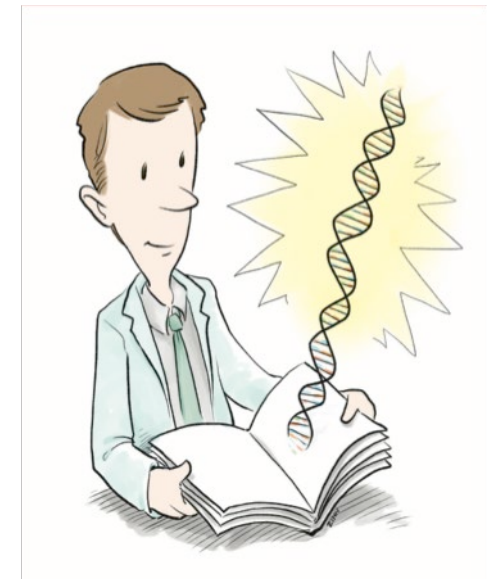
Health information privacy practices (HIPAA), visit <https://www.uofmhealth.org/patient-visitor-guide/protecting-your-privacy-hipaa>
<http://www.hipaa.com/>

Federal law for nondiscrimination (GINA), visit <https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination>

If at any time you want us to stop using your "book," please contact us:

**Dr. Victoria Blanc, Director Central Biorepository
(734) 763-6423**

Donating to the University of Michigan Central Biorepository, as part of



The purpose of a **biorepository** is to store bodily materials (biospecimens) and personal health information for research projects that have not yet been planned. The biorepository combines the biospecimens and health information into "books" that can later be shared with researchers to help advance medicine.

This pamphlet provides information about participating in a biorepository at the University of Michigan by donating your biospecimens and health information.

What happens if you decide to participate?

To collect your biospecimens and health information, we will:

- answer your questions about the biorepository
- ask you to sign a form documenting your choice to participate



Your care at the University of Michigan Health System will not be any different if you do not want to participate or decide to leave the biorepository later.

After that, we will:

Who will use your book?

Your book may be shared as long as the biorepository exists or until you decide to leave it. It may also be shared in public databases.

Your collected information and biospecimens may also be shared with other researchers, both here or around the world, or with companies. Requests for sharing are reviewed by U-M oversight committee(s) and subject to contractual obligations with the sponsor. Identifiable information may be shared with appropriate privacy safeguards in place and regulatory approval.

When you agree to allow your biospecimen(s) and health information to be placed in a biorepository, you should understand that we may remove all details that identify you from your private information or biospecimens, and, after this removal, use them for future research studies or distribute them to other researchers for their studies without your additional informed consent.

What research will your book support?

We don't know in advance what specific projects your book will be used for. So we are asking now for your permission to use your book for any research project that comes up in the future. If you agree now, we generally will not come back and ask your permission for specific projects, unless the nature of the future research project and/or the law at that time requires us to do so. Here are just some examples of possible kinds of projects:

- learning how to target cures to specific diseases, including those unrelated to your condition
- exploring health effects of environment and lifestyle
- creating stem cells that can turn into other cells
- studying how genes contribute to disease and how they affect the way medicines work
- creating cells that live forever
- using your materials in research using animals
- examining your genetic background through analysis of all of your DNA
- **If any of these make you uncomfortable, you might not want to participate in this biorepository.**

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.



The goal of biorepositories is to advance health research in general for all people. **You should not expect to receive information that will benefit you directly.**



You can ask to leave the biorepository at any time by calling or writing to us. See the back panel for contact information.

We will not be able to take your book back from researchers after it has already been shared with them.



The contents of your "book"

- 1 Bodily materials (like blood, tissue, and molecules).** These have information about how your body works.
 - Some bodily materials are like a fingerprint. For example, no one has the same DNA, a kind of molecule that contains genetic information.
 - Your genetic information is protected by a federal law that makes it illegal to use your genetic information to discriminate against you for health insurance coverage and employment (see GINA link, back panel)



Today researchers cannot identify you if they only have your DNA. This could change in the future. Researchers will be asked not to do this, but we cannot promise that this will never happen.

- 2 Personal health information**
 - Health information from your doctor and hospital visit records
 - Information from any surveys you complete for us
 - Results from your x-rays, blood tests, or urine tests
 - Your health history, including any mental health treatment
 - Health information from sources outside of our medical center

DONATE

DISCOVER

USE

Biorepository
information sheet
Version:
11/16/2020