Donating to the University of Michigan Medical School Central Biorepository

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 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.

Are there any risks?

The physical risks of donating your biospecimens are:

- add physical risk
- add physical risk
- add physical risk

No matter which research projects we end up using your “book” for, no research project can completely guarantee confidentiality. Your personal information could be accidentally released, or someone could illegally use it to try to identify you.

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

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

To protect your identity, we will:

- label your biological sample with personal information
- only share your personal information (name, address, social security number, or other recognized identifiers) with researchers who have been 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
- obtain a Certificate of Confidentiality from the National Institutes of Health, so we can keep your information private in a court or other legal proceeding. The Certificate will not allow us to withhold your information from the government if it is necessary for a federal audit or evaluation of federally funded research. Also, if you or a member of your family voluntarily disclose information about yourself or your participation in this repository, the Certificate will not prevent that information from being used in court.

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.

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.

For more information about

Research protections at U-M:
http://www.med.umich.edu/irbmed

Federal health information privacy regulations:
http://www.med.umich.edu/hipaa/npp.htm

Federal genetic nondiscrimination law (GINA):
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf

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

Collector contact: Phone number

Victoria Blanc, PhD, Biorepository Director:
(734) 763-6423

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

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
- ask you to complete a survey about your health
- add collection procedure

After that, we will:
- obtain DNA from your biospecimen and store it in a safe place
- store the rest of your biospecimen in a safe place
- add pre-storage procedure
- link your health and genetic information together to create your “book”

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:
- exploring health effects of environment and lifestyle
- creating stem cells that can turn into other cells
- studying how genes affect the way medicines work
- creating cells that live forever
- learning how to target cures to specific diseases, including those unrelated to your condition
- using your materials in research using animals

If any of these make you uncomfortable, you might not want to participate in this biorepository. Check back to learn what specific projects this biorepository is supporting. Go to: research.med.umich.edu/biorepository

Your book will be used only for research that is approved by the repository’s Oversight Committee made up of medical and scientific experts.

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

CLINICAL RESEARCH: EVERYONE BENEFITS

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)

2. Personal health information
   - Health information from your doctor and hospital visit records
   - Information from our survey
   - 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

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.

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.