

A biorepository contains samples of blood, tissue, and information from many different people. Researchers can take samples and information from the biorepository and use them in their own studies.

You have the option of contributing to a research biorepository called the Michigan Genomics Initiative. This document and a separate information sheet have details that you should consider before you decide to join. When this document is signed, it confirms *our promises to you and gives us your permission for the project team to obtain and use your samples and your protected health information.*

As part of this study, you will also be asked to use a secure third-party study app – MyDataHelps. While participating in the study, you will be asked to set permission to share information from your phone's existing Health App and your Apple Watch (if you have one) with the MyDataHelps app. The MyDataHelps app is compatible with Apple and Android phones. Allowing the sharing of data from your phones existing Health App and/or Apple Watch for the study is optional. You can opt out of this sharing and still participate in the study. Any information that you provide in the MyDataHelps app may be shared with CareEvolution, the company that provides the MyDataHelps app, so you should be sure to review the App's privacy policy and terms to make sure you are comfortable with its data use before signing this consent and authorization. For more information about the MyDataHelps App's privacy policy, please visit <https://rkstudio.careevolution.com/MyDataHelpsPrivacy.html>. If you decide you are not comfortable using the MyDataHelps app, you can still participate in the study and complete the consent form using a study electronic tablet, and complete the questionnaires by email instead. Please let the study staff know if you would prefer to use the study tablet.

Joining the Biorepository. After reading both documents and asking us questions, you should understand that:

- The biorepository is a research project. It is not part of your health care and will not directly help you.
- It is designed to help us learn about health and disease for the benefit of all people.
- Participating in this project is completely up to you.
- If you decide not to participate in this project, it will not affect your health care treatment or payment, enrollment in your health plan, or your eligibility for health care benefits.
- You will not receive payment for participating in this project or receive payments from scientific discoveries made using the information or samples you donate.

Leaving the Biorepository. Even if you decide to take part now, you may end your permission and leave this project at any time without penalty. If you do decide to leave the project, phone Dr. Chad Brummett, 734-232-0320. Keep in mind that we will not be able to get back samples or your information if they have already been shared with other researchers or if we can no longer identify them as coming from you.

Participating in the Biorepository. You should also understand that:

- **Sample donation.** You will be asked to provide a blood sample (DNA, genetics).
- **Data Gathering.** Researchers will be able to use the data that you provide through the study application and activity data from your mobile device and apple watch (if you have one).
- **[Active surveys.** You will be asked to complete surveys before and after your surgery. Prior to surgery, you will be asked to fill out a baseline questionnaire. After surgery, you will be asked to complete additional surveys at the following time points: daily for 21 days, 2 weeks, 1 month, 3 months, and 6 months. These will be completed using the study application or via email. You may choose not to answer certain questions; however, the more information you provide, the more insights we will be able to provide and the more you will help the study.]
- **Passive activity.** You may allow researchers to use other data on your phone to understand activity levels, such as the number of steps you take each day, your distance walking or running, and flights of

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stairs climbed. Collecting and analyzing this data allows researchers to understand how pain, pain medication use, and other health outcomes are affected after surgery.

- **Health records.** You give the biorepository your permission to collect your protected health information from the University of Michigan and **any** other past, present, or future sources and link it to your donated sample. Your permission to let this project team do this has no expiration date. *See the back of this page for examples of what information can be used.*
- **Sharing.** You give the biorepository your permission to share your samples and collected information with researchers **anywhere**, including those in other countries and those working for companies. The biorepository will follow all regulatory standards before releasing samples or information.
- **Research Uses.** You give your permission for researchers to use your samples and health information to study **any** disease or health condition. *The information sheet describes some ways researchers might use your samples and health information.*
- **Recontact.** Researchers may contact you again to ask for more samples or information or to tell you something they have learned about your sample. You can always say no to the researcher.
- **Payment.** If you complete the 6-month survey, you will be entered into an end-of-the-month raffle. This raffle will take place monthly. The odds of winning will depend on the number of subjects who complete the 6-month follow-up survey that month. You have the option not to participate in the raffle if you choose. If you are a winner, we will notify you by email.

Risks and protections for you and your information. You should also understand that:

- There are minor physical risks involved with providing your sample. *See the information sheet.*
- Some people feel uncomfortable when answering questions about pain, mood, pain medication use, sleep, and satisfaction. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you uncomfortable. There is always a risk that you could be identified by your donation and health information.
- The project team will do its best to keep your information confidential, as required by a law called HIPAA. *See the back of this page for important details about privacy and confidentiality.* But once your information has been shared with others, it may no longer be protected by HIPAA.

Privacy and Confidentiality

What will researchers be able to see about me?

If you give them permission by signing this form, they will be able to take your health information from:

- Any health provider's records. This could include information such as:
 - What illnesses and treatments you have had, and how well the treatments have worked.
 - Results from x-rays or lab tests.
 - Mental health records.
 - Alcohol and substance abuse treatment records.
 - Whether you have HIV or AIDS.
 - Billing information.
 - When needed, identifiers like your name, address, or Social Security Number.
 - Activity data from your mobile device and apple watch (if you have one).
- Other health information from sources outside of our medical center with appropriate permissions.
- For more HIPAA information, go to: <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>.

To make sure this project is conducted safely and properly, University, Food and Drug Administration (FDA), government officials, and sponsors of the project might need to see your health information.

How will my privacy be protected?

- Whenever possible, donated samples and your health information will be stored with a code instead of identifiers (such as name, date of birth, medical record number, social security number). However, the more information about you that is combined together, the more likely it is you could be identified.
- All information used by this project will be protected so that it can only be accessed by authorized people. Still, no one can guarantee that computer security will be perfect.
- No published scientific reports will identify you directly.

Can I be discriminated against based on genetic information that people learn about me?

Your biological samples contain genetic information about you. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits certain kinds of discrimination on the basis of genetic information. GINA applies to any genetic information obtained by this project, so you may want to know what protections GINA provides before you decide whether to donate.

- GINA prohibits health insurance companies and health plan administrators from asking for genetic information about you or your family members. It also prohibits them from using genetic information for decisions about coverage, rates, or pre-existing conditions.
- GINA prohibits employers with 15 or more employees from using genetic information for hiring, firing, or promotion decisions, or for any decisions regarding terms of employment.
- GINA does not apply to other kinds of insurance, like life, disability, or long-term care insurance.

For more information about GINA, go to: <http://www.genome.gov/10002328> or ask us for help.

I have read this document and also reviewed the information sheet "Donating to a University of Michigan Biorepository." I have had a chance to ask questions and my questions so far have been answered. If I have questions about my rights as a participant I can contact the Institutional Review Board at: IRBMED, 2800 Plymouth Rd, Bldg 520, Room 3214, Ann Arbor, MI 48109-2800; irbmed@umich.edu; 734-763-4768. By signing below, I agree to participate in the Michigan Genomics Initiative.

Participant Name Printed

Participant Signature

Date

Investigator or Designee Name Printed

Investigator of Designee Signature

Date