Consent to Participate in a University of Michigan Survey and Authorization to Release Protected Health Information

Study Information. Because you have previously enrolled in the Michigan Genomics Initiative (MGI), we are inviting you to participate in a related survey study. This study is called MGI - Epidemiological Questionnaire (MGI EPI-Q). This form has details that you should consider before you decide to join the survey study. When this form is signed, it confirms *our promises to you and gives us your permission for the project team to obtain and use your samples, our survey answers and your protected health information.*

Joining the Survey study. After reading this form and asking questions, you should understand that:

- The survey 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 **voluntary**. 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.
- However, you will not receive payment of money for participating in this project or receive payments from scientific discoveries made using the information or samples you donate.
- If you complete the baseline survey, you can choose to **receive an ancestry report** using DNA that you already provided when you enrolled in the Michigan Genomics Initiative.

Leaving the Study. 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. Bhramar Mukherjee at 734-764-6544. Keep in mind that we will not be able to delete survey answers if they have already been shared with other researchers or if we can no longer identify them as coming from you.

Participating in the Survey. You should also understand that:

- **Establishing an account with CareEvolution**. The preferred way to participate is to download a mobile application called MyDataHelps or to visit a website. You will be asked to provide a username and password and allow linking to your health records. During this process, you will be asked to review and agree to terms related to privacy the application. While it is not the preferred method, you might also be offered a paper survey to complete. If you complete a paper survey, a CareEvolution account will be established under your name by the study team.
- **Answering Survey Questions**. We expect the it to take about 30 minutes to complete the baseline survey. From time to time, you will be offered the opportunity to complete optional modules. Each module will take 1 – 10 minutes to complete.
- **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 survey answers. 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 permission to share your answers and collected information with researchers **anywhere**, including those in other countries and those working for companies.
- **Research Uses**. You give your permission for researchers to use your samples and health information to study **any** disease or health condition. Your permission will also allow researchers to **link** the survey data you provide with other data about you.
- **Recontact**. Researchers may contact you again to ask more questions or to tell you something they have learned about your sample. You can always say no to the researcher.

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

- Some questions might make you uncomfortable or be upsetting.
- 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. But once your information has been shared with others, it may no longer be protected by HIPAA.
- If you choose to receive and view your ancestry results, it is possible that you could discover or suspect non-paternity and/or secret adoption. For example, you could discover that your parents are not your biological parents.

Privacy and Confidentiality

What will researchers be able to see about me?

If you sign this form, researchers will have access to your health information from:

- Genetic information from the sample you provided when you joined the MGI study
- 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.
- Other health information from sources outside of our medical center with appropriate permissions.
- For more HIPAA information, go to: https://www.uofmhealth.org/patient-visitor-guide/protecting-your-privacy-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, survey answers 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.

I have read this document. 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 MGI EPI-Q Study

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Participant Name Printed	Participant Signature	Date