UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Michigan Genomics Initiative Epidemiological Questionnaire (MGI EPI-Q)

Company or agency sponsoring the study:

The study is internally supported by funds from the University of Michigan.

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator:	Bhramar Mukherjee, PhD, Department of Biostatistics, University of Michigan
Study Coordinator:	Maxwell Salvatore, MPH, Department of Biostatistics, University of Michigan

1.1. Key study information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

You are eligible to participate in this study due to your prior enrollment in the Michigan Genomics Initiative (MGI). This research collects health-related information to better understand sociodemographic, lifestyle, behavioral, and other health-related factors associated with a broad range of diseases and conditions. This research will ask you to complete a series of questionnaires who data will be stored at the University of Michigan and may be requested, along with your other data, for researchers with appropriate permissions and approvals. You would be voluntarily participating. If you choose, you can receive an ancestry report for completing the baseline survey.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling uncomfortable with some of the questions you are ask and a breach of confidentiality. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by enabling researchers to investigate factors that may prevent disease and improve treatment. More information will be provided later in this document.

We expect the it to take about 30 minutes to complete the baseline survey. You will be eligible to receive an ancestry report after this is completed. After, we may ask you to complete additional short surveys, but they are optional.

You can decide to not be in this study. Your participation is voluntary. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1. Study purpose

The Michigan Genomics Initiative (MGI) is attempting to gather a large amount of health-related data on a large number of people that will be accessible to approved researchers to identify new risk factors for disease and potential new avenues for treatment. Currently, MGI subjects donate a biospecimen sample (e.g. blood), allow access to their electronic health record, and allow for their data to be linked with other data. This study wants to collect data on these sample subjects on a broad range of health-related topics including alcohol consumption, smoking, physical activity, sleep, and family health history. These data are unavailable anywhere else and will greatly improve the quality of the conclusions that can be made from the research done using these and other linked data.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lost any benefits to which you are otherwise entitled.

3.1. Who can take part in this study?

Adults aged 18 years or older who are also enrolled in the MGI are eligible to participate in this study. Individuals under the age of 18, those who are unable to provide informed consent, and those who cannot complete the survey in English are **not** eligible to participate.

3.2. How many people are expected to take part in this study?

There are over 60,000 individuals enrolled in MGI to date, with the goal of enrolling over 200,000 people. Our aim is to invite all of these individuals to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1. What will happen to me in this study?

If you consent to participate in the study, you will be asked to complete a series of survey either electronically. If you are unable or would prefer not to complete the surveys electronically, you can complete a paper version of the survey.

The identifiable survey data you provide will be stored for unspecified future use.

If you consent to participate, we will use your survey data for future research. Even if you give us permission now, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

Your survey data will be shared with other researchers, so that they can use it in their research. Other researchers can request to link your survey data with other data, including your DNA and electronic health record data you provided in MGI. Once we have shared your survey data with other researchers, we will not be able to get it back.

There is a risk of a breach of confidentiality associated with future research use of the survey data you provide as part of this study. Your data will be securely stored at the University of Michigan and researchers who request your data must demonstrate they have taken efforts to protect your confidentiality before they are approved to access it. Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your survey data. Allowing us to do future research on your survey data will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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.

4.2. How much of my time will be needed to take part in this study?

We ask that subjects complete a baseline survey consisting of several modules that will take approximately **30 minutes** to complete. Completion of the baseline survey makes you eligible to receive the ancestry report. After you complete the baseline survey, we may invite you to complete a couple additional, shorter, optional modules. There is no incentive or compensation for completing these additional modules.

4.3. When will my participation in the study be over?

Your participation will be considered complete when you complete the baseline survey. We ask that you complete this within two weeks of providing consent. However, you will be asked to complete additional optional surveys after you complete the baseline survey. Your survey data will be stored at the University of Michigan indefinitely.

4.4. What will happen with my information and/or biospecimens used in this study?

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1. What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2. What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3. If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase risks to you. You should not take part in more than one study without approval from the researchers involved in each study.

5.4. How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained by the research conducted using the survey data you provide.

5.5. Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1. If I decide not to take part in this study, what other options do I have?

Participation in this study does not involve any medical treatment and does not in any way impact the services that you normally receive and are otherwise entitled to. Your participation in this study is completely **voluntary**.

7. ENDING THE STUDY

7.1. If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study, please tell one of the persons listed in Section 10 “Contact Information”.

7.2. Could there be any harm to me if I decide to leave the study before it is finished?

No. There are no known or expected harms to you if you decide to leave the study. The study team will keep a record that you left the study, as well as your reasons for leaving, should you choose to tell the researchers.

Your data will be destroyed. However, we will not be able to retract data that has already been shared with other researchers before you leave.

7.3. Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1. Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2. Will I be paid or given anything for taking part in this study?

You will be eligible to receive an ancestry analysis for completing the baseline questionnaire. You must indicate in this consent form or at the end of the baseline questionnaire that you want the ancestry analysis to receive it. By consenting, you are giving the researchers access to the DNA you provided through your participation in MGI for the sole purpose of creating this ancestry analysis for you. They will not retain access or perform research using your DNA as part of this study. If you have received an ancestry report from a company or from your participation in other research, you may still request an ancestry analysis; however, there are no alternative incentives for your participation.

8.3. Who could profit or financially benefit from the study results?

There are no known or expected persons or organizations who could profit or financially benefit from the study results.

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.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1. How will researchers protect my information?

Data will be collected securely using CareEvolution's survey software. They have worked on several projects handling protected health information and personally identifiable information across the country and on projects with the University of Michigan. The data will be transferred to the University of Michigan Research Data Warehouse who handle sensitive data and maintain high standards of safety and security. They will be responsible for securely transferring data requested by researchers only after they have received appropriate

permissions and approvals from the Institutional Review Board. Researchers wishing to access the survey data you provide will need to demonstrate the steps they will take to mitigate risks and protect confidentiality and privacy before they can access the survey data.

9.2. What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

Research results using the data collected in this survey could be published in an article but would not include any information that would let others know who you are.

9.3. What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University of government officials make sure that the study was conducted properly

9.4. When does my permission to use my PHI expire?

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1. Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Bhramar Mukherjee
Mailing Address: Biostatistics
M4166 SPH II
1415 Washington Heights
Ann Arbor, MI 48109
Telephone: 734-764-6544

Study Coordinator: Maxwell Salvatore
Mailing Address: Biostatistics
4062 SPH I
1415 Washington Heights
Ann Arbor, MI 48109
Telephone: XXX-XXX-XXXX

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-764-1234
Email: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111. *When you call or write a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

11. RECORD OF INFORMATION PROVIDED

11.1. What documents will be given to me?

If you are completing the consent process electronically, you will be able to download a copy of an unsigned consent form for your records. You may also request an e-signed copy from the study team (specify whether you would like a PDF or a hard copy).

If you are completing the consent process on paper, you may download an electronic copy of an unsigned consent form for your records. You may also request a copy of your signed consent from the study team (specify whether you would like a PDF or a hard copy).

Note: Copies of your signed consent document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information on this form. I have been given the opportunity to discuss this study, its risks and potential benefits, and my other choices by contacting the study team with the contact information provided in Section 10. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I may download this form at any time or request a copy of it from the study team. I understand that this project involves allowing the study team to keep your identifiable data for use in future research. I understand that approved researchers can request my survey data as well as other linkable data for future research. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ **Yes**, I agree and consent to participate in the study

_____ **No**, I disagree and do **not consent** to participate in the study

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to Receive Ancestry Analysis

I understand that I am entitled to request an ancestry analysis upon completion of the baseline survey. I understand that, to do this, the study team will access my DNA that I have provided previously through my involvement with MGI. I understand that I do not need to consent to this now but may at any point inform the study team that I want an ancestry analysis performed, provided that I complete the baseline survey. I understand that I may contact one of the people listed in Section 10 (above) if I have any questions or concerns about how the ancestry analysis is performed or about the implications of the results. I understand that I do not need to consent to this to participate in the study. I understand that I may withdraw my consent to receive an ancestry analysis prior to the completion of the baseline survey if I wish to no longer receive the report.

_____ **Yes**, I agree to give the study team access to my DNA solely for the purpose of creating the ancestry report for me after I have completed the baseline survey.

_____ **No**, I do not give the study team permission to use my DNA for the purpose of creating an ancestry report.

_____ **I do not know**. I am unsure about giving the study team access to my DNA for the purpose of creating an ancestry report at this time. I know the study team will not access my DNA for the purpose of creating an ancestry until I give them permission to do so. I know I will be asked about this again after the completion of the baseline survey.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____