Title of Research Study: - Ten Thousand Families Study (STUDY00000877)

Investigator Team Contact Information: Jenny N. Poynter, PhD, Principal Investigator
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Researcher Name: Jenny N. Poynter, PhD Department of Pediatrics Phone Number: 612-626-2902 Email Address: poynt006@umn.edu	Study Staff (if applicable): Andrea Hickle, MPH Phone Number: 612-301-2726 Email Address: TenKFS@umn.edu Version Date: September 20, 2023

You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is provided later on in this form.

What is health research?

Research consists of making educated guesses called hypotheses about how the world works and testing those hypotheses by collecting data. The goal is to learn new information to help groups of people in the future. Health research is research that focuses on identifying causes of disease, improving the quality of life and extending the life of those with illnesses. To do this, some researchers conduct studies that involve human participants. The top priority of this kind of research is the safety of human subjects. All studies which involve human subjects are reviewed by experts whose goal is to ensure the safety of the participants and prevent other negative outcomes. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being asked to take part in this research study?

You may be eligible to participate in a research study--the 10,000 Families Study--at the University of Minnesota. We are contacting you because you volunteered, or you were randomly selected from lists of people living in Minnesota, or because you have a relative who is already participating in the study. We are inviting you to participate in a large family-based cohort study being done all across Minnesota and including the neighboring states of Iowa, North Dakota, South Dakota, and Wisconsin.

What is a cohort study?

A cohort study is where a large group of individuals is enrolled and then regularly followed for many years to learn about changes in health over time. Using this type of design, researchers can more accurately determine what exposures and lifestyle factors impact health later in life.

At enrollment into a cohort study, participants complete questionnaires and health assessments to

provide information on where people live, what they eat, how much they exercise, whether they smoke, genetic factors, what they are exposed to in their environment, and other factors that may influence disease risks later in life.

What is a family-based study?
A family-based study includes at least two relatives from one or more generations in each participating family. Family-based studies can help us understand how genetics and environment contribute to health and disease. Family-based studies also look at factors that may be important to health across generations.

What should I know about a research study?

- You can ask us to explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are conducting this study because health, diseases and risk factors can run in families. A family study will help us understand how genetics, shared habits and exposures contribute to health and disease.

How long will the research last?

The 10,000 Families Study is an ongoing study and will continue as long as you agree to participate while the study is active.

What will I need to do to participate?

You will be asked to join the study with other members of your family. You will be asked to complete questionnaires about your health and allow us to collect physical and biological measurements from you over time. We will ask you to wear a silicone wristband and may ask you to collect samples from your home. DNA will be extracted from your biological samples for genetic analyses. You will be asked to give us permission to get health-related records about you.

More detailed information about the study procedures can be found under ***"*What happens if I say *'Yes, I want to be in this research'*?"**

Is there any way being in this study could be bad for me?

The procedures and tests used in this study are considered safe, though there are some minor risks to participation, that are described below under **"What are the risks of this study? (Detailed Risks)"**

While we are not planning to give out any results from genetic testing that may be performed on your biological samples, there may be rare situations where we find genetic changes or non-genetic results (e.g., cholesterol) that could significantly impact your medical care or that of your family. At the end of this form we will ask you if you would like these kinds of results.

We will make every effort to protect your identity and privacy, yet we cannot absolutely guarantee that

information about you or your blood relatives will never become known.

Will being in this study help me in any way?

Receiving test results from the Family Health Visit may be of benefit to some participants. You will also have the opportunity to test your home for radon without charge. If you learn that the radon level in your home is high, you will be provided with information and resources on lowering radon levels in your home, if you so choose. Some people like knowing their home radon levels. You may also choose to receive information about other chemical exposures from the study. If you decide to receive information about these chemical exposures, please note that right now we do not know whether these chemicals could cause problems with human health. Current studies suggest that most adults have many of these chemicals in their bodies. In addition, we hope that the information learned from this study will benefit other people in the future.

What happens if I do not want to be in this research study?

Participation is voluntary. If you do not want to participate at any time, just let us know.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

Over time, ten thousand families will be invited to participate in this study.

What happens if I say "*Yes, I want to be in this research*"?

Participants who agree to the study will do the following:

1. Health Questionnaires: You will be asked to complete online health questionnaires that ask questions about your medical history, cognitive factors, medications, and lifestyle questions, such as diet, alcohol and tobacco, physical activity, sleep, family health history, and where you have lived over your life. The initial questionnaires will take about 45 minutes to complete. All information you provide as part of 10,000 Families is confidential.

2. Family members (If you are the FIRST member of your family to join the study): Because this is a family-based study, you will be asked to invite at least one other family member to participate. We are seeking to invite your child or children under age 18, your adult child or children, your parents or grandparents, and/or your siblings or spouse.

3. **Biological Sample Collection:** We may send a biological sample collection kit to your home for simple-to-collect blood and stool samples. We will provide instructions and prepaid postage. The biological sample collection will take you about 15-20 minutes to complete.

4. **Family Health Visit**: You and your family members will be asked to attend a Family Health Visit at a location reasonably convenient to you, such as a clinic, community center or your home. The purpose of the Family Health Visit is to take in-person measurements and collect biological samples. The full list of measurements that may be collected at the Family Health Visit are described below. We will not collect all measurements from all study participants.

- **Height, weight, waist and hip size, percent body fat measurements, pulse, lung function, electrocardiogram and blood pressure**: If you have an implanted device (such as a pacemaker or defibrillator) your weight will be measured using a non-electronic scale.
- **Functional tests such as hearing, grip strength and vision.**
- **Clock drawing:** If you are over 40 years old**,** you may be asked to use a digital pen to draw clock figures. If you have difficulty moving your hands, then you will not be asked to complete the clock test.
- **Blood Sample**: A trained technician will draw samples of your blood (up to 55 milliliters or 3.7 tablespoons) for tests that will include cholesterol and other blood fats, glucose (sugar) level, kidney function and other factors such as common chemicals that come from our environment. With your permission, some of your blood will be stored for future research studies. These samples are not available in the future for your personal use or clinical (diagnostic) purposes. **We will not test for HIV, AIDS or sexually transmitted diseases.**
- **Saliva sample:** We may collect a sample of your saliva using a 'spit' kit.
- **Urine sample**: While you are at the Family Health Visit you will be asked to provide a small amount of urine. Your urine sample will be used only for research studies and your urine sample will be stored for future studies.
- **Hair and finger or toe nail collection:** Your hair and finger or toe nail samples will be used only for research studies and these samples will be stored for future studies.
- **Stool sample**: We may send a kit home with you for stool sample collection, which will be used to measure the types of microorganisms in your gut, and the remaining sample will be used for future research studies.
- **Water sample:** We may send a kit home with you to collect a sample of the tap water in your home. This will be used to measure the level of chemicals in your water.
- **Silicone wristband:** We will send a silicone wristband home with you to be worn for 7 days and returned to the study team. This will be used to measure chemicals that you may be exposed to in your environment. We will store a portion of the wristband for future research studies.
- We may invite you to complete certain interviews or procedures if the information collected during a procedure is incomplete. Or, we may ask you to repeat certain interviews or procedures for quality control purposes. Repeating procedures is optional and will be shorter than the original visit.

5**. Testing of your blood and/or saliva for DNA.**

- We will collect and store genetic material (DNA and RNA) from your blood and/or saliva samples for research studies. DNA is material in our bodies that contains genes. RNA is another material that plays a role in the way genes work.
- In the future, we will examine your DNA to learn whether genes and gene products can help us understand the risk of diseases in adults, particularly cancer, heart disease, stroke, brain function, lung disease, and others. We may look at specific genes and the entire sequence of DNA for their contribution to risk of various diseases. We may also use your samples to make new cells that can be grown in a laboratory and turned into different types of cells. **We will not**

examine your DNA to diagnose diseases, nor to do clinical genetic testing or genetic counseling.

While we are not planning to give out any results of genetic testing, there may be rare situations where we find genetic changes that could significantly impact medical care. At the end of this form we will ask you if you would like to receive these kinds of results.

6. **Radon testing (1/household)**: You (or another study participant in your household) will receive a radon testing kit in the mail to measure the radon levels in your home. This kit will be sent by AirChek, a company that provides radon testing in homes. We will ask you to use a pre-paid envelope to send this kit back to AirChek. You will receive a report back with your radon test results. We will provide your name and mailing address to AirChek so that they can mail you a test kit and return results to you after testing.

7. Medical records: We will ask for your permission to request records from emergency room, urgent care and clinic visits as well as records from admissions to hospitals, long term care facilities or nursing homes. If you have been diagnosed with one of the diseases that we are studying, we will request doctor's office, Medicare and clinic visit records related to the condition. We may request your permission to obtain birth certificate information. For women who have had biological children we may request prenatal and birth records.

8. Link information: We will ask for your permission to link information from state cancer registries or similar systems about diseases you may have had or may develop in the future.

9. **Future contact:** We will contact you by phone, regular mail, text or email to notify you of study events, provide updates and ask you about your health since we last contacted you. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. We may ask you to update this person's name during follow-up.- If in the future we do not have updated information to locate you, we will attempt to obtain that information from your contact(s), internet searches, public directories, social media or a visit to your last known address. If you provide your telephone number and/or e-mail address with your consent, we will use text messages and/or e-mail to send reminders of follow-up questionnaires and other needed information from you. We cannot guarantee the confidentiality of text messages, which means text messages should not include any private information about you or your health.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the study staff so we can remove you from our participant list and stop further contact with you. We will continue to analyze the data you provided prior to your withdrawal *unless* you instruct us in writing to delete all information we have about you. Research already done on data or samples cannot be undone.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to present or future medical care, your academic standing as a student, or your present or future employment.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Specific risks associated with participation in the study are described below:

- **Questionnaires**: You might experience some embarrassment or anxiety from answering sensitive questions. You may refuse to answer any questions that make you uncomfortable.
- **Medical care during the Family Health Visit**: In the unlikely event that during the Family Health Visit you should require medical care, first aid will be available.
- **Fasting:** There is a chance that your blood glucose (sugar) levels drop because you are fasting, especially if you have diabetes. You may feel cold sweats, blurry vision, rapid heart rate, shaking of the hands, dizziness, or fainting. These symptoms can be relieved by some fruit juice, a snack and/or lunch, which can be given after your blood is drawn. Of course, if necessary or requested, juice or a snack can be given earlier than planned.
- **Blood draw**: A skilled technician will draw your blood. Minimal bruising, pain, fainting, temporary bleeding or infection may occur as a result of the blood draw.
- **Blood pressure:** There may be some discomfort from the repeated blood pressure measurements.
- **A new health problem**: You may also learn of a health condition that you did not know you had or that may require you to consult with a physician for further evaluation and treatment. No personal medical results will be released by the research study.
- **Data Sharing:** We will make every effort to protect your identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. **However, researchers are strictly prohibited from attempting to identify you.**
- **Radon testing:** You may find out that the levels of radon in your home are higher than they should be.
    - We will provide information on how to reduce the radon levels in your home, including testing and by a licensed radon professional. The study does not have funds to pay for additional testing or any work to the home that may be necessary to reduce radon levels. If you want to fix your home for high radon, the costs may range from $1,500-$3,000.
    - If you own your home and decide to sell it, Minnesota law requires you to disclose (tell) if you tested your home for radon. This means that if you learn you have a high level of radon in your home and you want to sell your home, you must tell potential buyers about the high radon level.
    - If you are renting your home, you could choose to notify your landlord of the results. If your landlord decides to hire a professional to reduce radon levels in your home, they will incur a financial expense (approximately $1,500-$3,000).
- **Genetic information:** Though there are no plans to perform any genetic analysis at this time, we anticipate that we will perform genetic analysis on the collected samples in the future:
    - Your DNA sequence is like a fingerprint: it is unique to you. All precautions will be taken to protect your privacy and confidentiality. All genetic information will be stored in a secure database that is labeled only with an identification number. Only the study team

and qualified researchers will have access to these data.

- The testing in some cases may reveal information not anticipated. For some DNA testing, this includes information about paternity or blood relationships between the people being tested. We will not tell you this type of information if we find it.
- While there are no plans to perform any genetic analysis at this time, if you decide that you want to receive "medically actionable findings," it is *possible* that we will tell you that you are at high risk for a serious medical condition. In most cases, we do not expect to identify medically actionable results.

  Risks to family members: *If medically actionable genetic results are returned to you, these results may have implications for family members (even if the family members have elected NOT to receive medically actionable genetic results). You can decide whether to share the results of your tests with your family members. Family members can decide to change their option to receive or not receive medically actionable genetic findings at any time during the study.*

  Some non-genetic tests (e.g. cholesterol levels) may indicate risks not only to you but to other family members as well. You can decide whether or not you want to share your individual results with other family members.
- A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
  - Health insurance companies and group health plans may not request your genetic information that we get from this research.
  - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
  - Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

  Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Will it cost me anything to participate in this research study?

We will not charge you for costs associated with the health measurements and biological sampling. We are unable to reimburse you for travel costs to the Family Health Visit (which should be minimal).

What happens to the information collected for this research study?

- **Use of data and samples:**
  - Your biological specimens will be kept until we no longer need them, until they are used up or until you tell us to destroy them.
  - In addition to study information and genetic data, portions of your biological samples and DNA/RNA will be stored by the research study and information about these samples may be

stored on scientific databases at the National Institutes of Health for use by researchers. Any information that is shared in scientific databases will be de-identified and will not be able to be linked to you.

- The study team will allow qualified researchers from the University of Minnesota, other universities, the government, and drug- or health-related companies to use or analyze your samples after your identity has been removed.
- Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to researchers not associated with the research study.

- **Commercial use of data and samples:**
  - Researchers from private companies that develop diagnostic lab tests, or treatments for diseases, may request access to your study information or samples. These researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.
  - Your samples will not be sold to any person, institution, or company, and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).
  - Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.
  - The data you provide may lead to inventions or patents in which private companies, study investigators or their universities may participate and may benefit.
- **Use of data and samples for genetic research:**
  - We may place some of your biologic samples, genetic data and health information in scientific databanks at the National Institutes of Health, along with similar information from people participating in other studies. Information that could directly identify you will never be included. Qualified researchers not associated with this study may request access to it for research. This information and all of your other data will be used by researchers to look for factors that affect the risk of developing diseases and may lead to better methods for prevention and treatment for diseases such as cancer and diabetes.
  - The stored information will not include any identifying information, such as your name, date of birth, address, etc. Access to this stored information will be controlled by the National Institutes of Health.
  - The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws, which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: http://www.nih.gov/icd/od/foia/efoia.htm.
- **Use of medical record information**
  - If you are seen at an emergency room, urgent care or clinic, or admitted to a hospital, long term care facility or nursing home, we will ask that institution for your medical records so that we can learn about your health. We will request your signed permission for our research staff to get a copy of the records from the hospital, clinic, emergency department/urgent care or cancer registry.

- We may ask for records from your doctor for certain office or clinic visits that are related to the health questionnaire and we may request Medicare or Medicaid records to determine if you have been diagnosed with one of the diseases that we are studying.
- To learn more about the health of women who participate in this study, we may request hospital records related to births and also birth certificates.
- We will use your signed medical release to obtain these records. You can cancel this authorization at any time by contacting study staff listed at the top of this form.
- In the event of your death, information about the causes of death or events leading to death will be sought from your relatives or other sources, including the coroner's report, your medical records (if your death takes place in a hospital or long term care facility), and the state health department death record.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. For selected tests from the Family Health Visit, a report will be given or mailed to you. If you have questions about the test results or if a test result is not in the normal range, it is recommended that you discuss the findings with your primary healthcare provider. If you do not have a personal healthcare provider, our staff can provide you information on physicians and clinics in your community. Since this is a research study, any information you receive is not a substitute for care you would receive from your healthcare provider. We do not make a diagnosis, provide treatment, or give medical advice. Your health care provider is responsible for deciding any appropriate medical follow-up, testing, or treatment based on your results. Results from genetic tests will not be reported. Because we are measuring your test results at a research laboratory, obtaining the results may take longer than for a typical medical exam.

You will receive information on your radon test results. If your radon test results show elevated radon levels, it is recommended that you have a certified radon professional conduct follow-up tests of your home. The researchers will provide information on what to do if your radon levels are high and who you can contact for follow-up tests.

You will also have the option to receive information on chemical exposures from your biological samples (blood and urine). If you would like to receive information about the levels of chemicals, we will return the results to you by email and we will compare the levels in your samples to the typical levels found in other study participants. However, because this is a research study, those results can take a long time to process.

If we ask you to provide a water sample from your faucet, you will also have the option to receive the results of any tests. Again, because this is a research study it may take several months for water test results to be available to you. When results are ready, we will send them to you in an email with

information about what the results mean.

Whom do I contact if I have questions, concerns or feedback about my experience?

To reach the research team: Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide feedback about this research.

Will I have a chance to provide feedback about the study?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the **"Investigator Contact Information"** section of this form for study team contact information and **"Whom do I contact if I have questions, concerns or feedback about my experience?"** of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study team know right away.

Will I be compensated for my participation?

You will receive ***compensation for completing parts of this study.*** This includes $15 for completing the online questionnaire, $15 for participation in a Family Health Visit, $5 for returning your silicone bracelet, $5 for returning your home water kit (if requested), and $5 for returning your radon test kit (one per household). The gift cards for completing the questionnaire and the health visit will be sent at the same time after you have completed the health visit. Payment will be made through e-gift cards.

Use of Identifiable Health Information

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information that includes health information in your medical records and information that can identify

you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. As a part of your participation in the study you will be asked to review and sign a HIPAA release form. This will be provided to you at the Health Visit or electronically.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings. No identifying information would be included in the reports.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality (CoC). The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

You can also find the CoC language on our website: https://z.umn.edu/10KFS-CoC.

Ten Thousand Families Study

Final step to consent to be in the study

At this time, we ask that you indicate your willingness to participate in the study activities by checking the agree/do not agree or Yes/No option next to each. There are a total of nine activities for you to consider. **Please note that if you answer "I do not agree" to any of the required items, you are not eligible to participate in the study.**

	Please initial one box per question number.		
1.	☐ I agree	☐ I do not agree	Contact by research staff **(required)**: I agree to allow research staff to contact me periodically in the future to ask questions about my health and where I live.
2.	☐ I agree	☐ I do not agree	Release of my study results to a person I indicate **(optional)**: I (agree/do not agree) to allow research staff to release my findings from participation and **non-genetic** tests to the physician, clinic or person that I designate.
3.	☐ I agree	☐ I do not agree	Use of my biological samples **(required)**: I (agree/do not agree) to allow the **study researchers and other scientists** not associated with the 10,000 Families Study to study my de-identified samples (blood, cells, saliva, urine, stool, nail and hair) in current and future research.
4.	☐ I agree	☐ I do not agree	Use of my de-identified data in scientific databases **(required)**: I (agree/do not agree) to allow the research study staff to deposit my de-identified data in scientific databases maintained by the National Institutes of Health.
5.	☐ I agree	☐ I do not agree	Use of my genetic and non-genetic information by **commercial or for-profit companies (optional)**: I (agree/do not agree) to allow **commercial or for-profit companies that are not part of this research study to use my de-identified stored genetic and non-genetic** information and samples to develop new diagnostic tests and medical treatments that may benefit people.
6.	☐ I agree	☐ I do not agree	Contact about future studies that may interest me **(optional):** I (agree/do not agree) to allow **research** staff to contact me about my interest in participating in future health-related studies.

7.	☐ Yes	☐ No	I would like to receive information about the levels of chemicals found on my wristband and in my urine and/or blood
8.	☐ Yes	☐ No	I would like to receive information about chemicals detected in my home water sample if one is collected for the study
9.	☐ Yes	☐ No	**NOTE: Genetic testing is NOT planned at this time. These results may not be available for a long period of time.** Rarely, the researchers may find that you have a genetic attribute that places you at high risk for a serious medical condition. If we find this type of genetic attribute in your sample *and* there are steps you can take to prevent this condition from happening, we can tell you about this risk for a medical condition. You have the choice of whether or not you want us to tell you about this type of information if it is found in your sample. If our lab identifies medically actionable findings in your sample and you want to receive these findings, we will ask that your healthcare team be contacted by a genetic counselor. The genetic counselor will explain the following: ● What type of medically actionable information was found in your sample. ● If the genetic results we obtain are not found in a clinically certified laboratory, the results cannot be used for healthcare. The genetic counselor will help your healthcare team find a clinical laboratory. The cost of confirming medically actionable findings in a clinical laboratory will not be covered by this study. Any medical care that arises from this finding is part of your regular medical care and will not be paid for by this study. Would you like to receive potentially medically actionable information?

Signature Block

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent