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

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For questions about research appointments, the research study, research results, or other concerns, call
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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.

Supported By: This research is supported by University of Minnesota Masonic Cancer Center, the
Coordinating Centers for Biometric Research, and the University of Minnesota Academic Health Center.

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.

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, 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 at least two different 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 multigenerational 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 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. 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?**
There will be no direct benefit to you or your family. 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 health questionnaires that ask questions about your medical history, cognitive factors, medications, and lifestyle questions, such as diet, alcohol and tobacco, physical activity, and sleep, and family health history. Questionnaires may be completed online or on paper. The initial questionnaires will take about 45 minutes to complete.

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 from a different generation to participate. We are seeking to invite your child or children under age 18, your adult child or children, or your parents. Family members from multiple generations (e.g., parent, child, siblings, grandparents) are welcome to participate.

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

4. **Family Health Fair:** You and your family members will be asked to attend a Family Health Fair at a location reasonably convenient to you, such as a clinic, community center or your home. The purpose of the Family Health Fair is to take in-person measurements and biological samples. These are described below.

   - **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 will 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.

   - **3-dimensional photo:** We will take your picture with a 3D Facial Imaging Camera. The camera creates a three-dimensional image of the participant’s face, including images of facial skeleton, soft tissue, and teeth.
● **Blood Sample**: A trained technician will draw samples of your blood (45 milliliters or approximately 3 tablespoons) for tests that will include cholesterol and other blood fats, glucose (sugar) level, kidney function and other factors. 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 will collect a sample of your saliva using a ‘spit’ kit.

● **Urine sample**: While you are at the Family Health Fair 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 will 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.

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 these kinds of results.

6. **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.

7. **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.

8. **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.

**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 background questions. You may refuse to answer any questions that make you uncomfortable.

- **Medical care during the Family Health Fair**: In the unlikely event that during the Family Health Fair 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.**

- **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 costs related to your time to participate or for travel costs to the Family Health Fair (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.

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 genes 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](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 Fair, 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.

**Whom do I contact if I have questions, concerns or feedback about my experience?**
This research has been reviewed and approved by an Institutional Review Board (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 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach 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 input 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 or your family members will not be compensated for participation in this study. You may receive direct financial benefit if you are selected as a winner in our monthly random drawing for a $250 Amazon giftcard for completion of study procedures.

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 Fair 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.
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.

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<th>Please initial one box per question number.</th>
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<tr>
<td>1.</td>
<td>Contact by research staff <em>(required)</em>:&lt;br&gt;I agree to allow research staff to contact me periodically in the future to ask questions about my health and where I live.</td>
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<td>2.</td>
<td>Release of my study results to a person I indicate <em>(optional)</em>:&lt;br&gt;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.</td>
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<td>3.</td>
<td>Use of my biological samples by research staff <em>(required)</em>:&lt;br&gt;I (agree/do not agree) to allow the study researchers and research team to study my samples (blood, cells, saliva, urine, stool, nail and hair) in current and future research.</td>
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<tr>
<td>4.</td>
<td>Use of my biological samples by other scientists <em>(optional)</em>:&lt;br&gt;I (agree/do not agree) to allow scientists not associated with future research of the 10,000 Families Study.</td>
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<td>5.</td>
<td>Use of my samples of genetic material by research staff <em>(required)</em>:&lt;br&gt;I (agree/do not agree) to allow the research study staff to work with and use my stored genetic material (DNA/RNA) for current and future research.</td>
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<td>6.</td>
<td>Use of my samples of genetic material by other scientists <em>(optional)</em>:&lt;br&gt;I (agree/do not agree) to allow scientists and specialized laboratories not associated with this research study to study my de-identified stored genetic data, information, and samples.</td>
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| 7. |  | 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. |
|---|---|---|
| 8. |  | 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. |
| 9. | Yes | **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 a medically actionable finding 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? | No |
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

______________________________________________________
Printed Name of Person Obtaining Consent