

**Title of Research Study:** PEDS-2017-xxxxx – Ten Thousand Families Study

**Investigator Team:** Logan G. Spector, PhD, Heather Nelson, PhD, DeAnn Lazovich, PhD, Jenny Poynter, PhD, Anna Prizment, PhD, Cavan Reilly, PhD and Bharat Thyagarajan, MD, PhD

**Supported By:** Co-sponsored by University of Minnesota Masonic Cancer Center, the Coordinating Center for Biometric Research, and the University of Minnesota Academic Health Center.

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.

**Who can I talk to?**

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

<p>Researcher Name: Logan G. Spector, PhD          Phone Number: 612-626-2902          Email Address: <a href="mailto:spector@umn.edu">spector@umn.edu</a></p>	<p>Study Staff (if applicable): Michelle Roesler          Phone Number: 1-866-434-9879          Email Address: <a href="mailto:TenKFS@umn.edu">TenKFS@umn.edu</a></p>
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**What is medical 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 about our world. Medical 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 subjects. The top priority of this kind of research is the safety of human subjects. All studies that 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 participating in a research study.

**What should I know about a research study?**

- Someone will 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.
- If you are signing for a child, the word “you” in this consent form refers to that child.

**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 pilot study that will inform 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 pilot study?**

A pilot study is a smaller study done to test feasibility, time, and cost of doing a study and to learn about unexpected results. Pilot studies are important because they allow researchers to improve study procedures and participant experiences before a large cohort study is conducted.

**What is a family-based study?**

A family-based study includes at least two biological relatives from at least two different generations from 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.

**Why is this research being done?**

Studies similar to the 10,000 Families Study have helped our understanding of many conditions, diseases, and risk factors that arise in birth, childhood, and adult years, into old age. We are starting a new Minnesota family-based study because we want to use new, modern tools that will help us understand why some people stay healthy and others develop heart disease, cancer, diabetes, and other related diseases in adulthood. Multigenerational studies are important because some risk factors are experienced by more than one generation in a family due to inheritance or experiences shared by family members.

**How long will the research last?**

10,000 Families is an on-going study and will continue as long as you agree while the study is active.

**How many people will be studied?**

One hundred families will be invited to participate in the pilot of what will eventually become a study of ten thousand families. The pilot will include approximately five hundred people.

**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 asks questions such as your medical history, cognitive factors, medications, lifestyle questions, such as diet, alcohol and tobacco, physical activity, and sleep, and family health history. Questionnaires may be

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completed on-line or on paper before the Family Health Fair or in-person at the Family Health Fair. Completing 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 family members who would be your child under age 18, your adult children, or your parents. Family members from multiple generations (e.g., parent, child, grandparents) are welcome to participate.

**3. Family Health Fair:** You and your family members will be asked to attend a family health fair at a location reasonably convenient to you. 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 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.
- **Hearing test, Grip strength:** You will be asked to complete a hearing test. If you are over 40 years old, you will be asked to use an instrument that will measure your hand strength.
- **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 participants 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.

**4. 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 and long-term storage. 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 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. If you decide you would like these kinds of results and if our laboratory should identify a genetic variant that impacts medical care, called "medically actionable findings", we will confirm these results in a clinically certified laboratory before we return results to you. If you decide to receive potentially medically actionable results, the genetic test results will be given to you and your primary physician by a Genetic Counselor. Costs of follow up tests including confirmation of research findings and medical care would be billed in an ordinary manner to you or your insurance company and you will be responsible for these costs.

- 5. Release your 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 children we may request prenatal and birth records.
- 6. Allow researchers to link information** from state cancer registries or similar systems about disease you may have had or may develop in the future.
- 7. Agree to be contacted in the future:** We will contact you by phone about 6 months after your participation in the Family Health Fair 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 this interview. 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 your annual follow up interview.

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

Participation is voluntary. If you do not want to participate just let us know.

### **What happens if I say “Yes”, but I change my mind later?**

You can leave the research study at any time. Leaving will not be held against you. If you decide to leave the research study, contact the study staff so we can discard your samples and withdraw your information from study databases. If you decide to withdraw from this study after your DNA has been analyzed, your genetic information will be discarded and will not be used in this portion of the study. However, research already done on those samples cannot be undone.

### **What are the risks of being in this study? Is there any way being in this study could be bad for me?**

The procedures and tests done at the Family Health Fair are considered safe and do not involve X rays, or other types of radiation. However, some possible general discomforts may include headaches or feeling hungry, and fatigue or chills.

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.
- **Other risks and sources of discomfort:** In addition to the risks and sources of discomfort mentioned above, and how they can be decreased, there may be other negative effects associated with some of the procedures that are performed during this study that are currently unknown. If you experience any negative effects, it is extremely important that you make us aware of it.
- **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 participants 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.*

### **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 your travel costs to the Family Health Fair.

### **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 to the information collected for this research study?**

A report from the Family Health Fair will be given or mailed to you. It is recommended that you discuss the findings with your primary care physician. If you do not have a personal health provider, our staff will 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 health care 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.

Your specimens will be securely stored with limited access. We will hold them until no longer needed or until you tell us to destroy them. Your blood, urine, saliva, cells, hair, finger or toe nails and DNA samples will be identified only with a numerical code and sent to our laboratory for storage, or for detailed analysis. Some of your samples will be stored for an unlimited time, for future use in studies or in other research projects that have been approved by our research team.

In order for science to progress, researchers exchange scientific resources and information with strict precautions of confidentiality. We are asking for your permission to share your data and samples, in a way that cannot be used to directly identify you, with researchers who are not part of this study.

- **Use of data and samples:**

- In addition to study information and genetic data, portions of samples 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 to 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 to 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, is removed. 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 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.

### **Who 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](tel:612-625-1650) or go to [www.irb.umn.edu/report.html](http://www.irb.umn.edu/report.html). 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 after the study is over?**

At certain points during the study, you might be asked to complete a survey 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 would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the "Who Can I Talk To?" section of this form for study team and HRPP contact information.

### **What else do I need to know?**

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.

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 I be compensated for my participation?**

You or your family members will not be compensated for participation in this study.

### **Use of Identifiable Health Information**

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the 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. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

# Ten Thousand Families Study

Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Please initial one box per question number.			
1.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p>Contact by research staff (required):</p> <p>I agree to allow research staff to contact me in about six months and routinely (not more than once a year) to ask questions about my health and where I live.</p>
2.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Release of my study results to a person I indicate (optional):</p> <p>I (agree/do not agree) to allow research staff to release my findings from participation and <b>non-genetic</b> tests to the physician, clinic or person that I designate.</p>
3.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Use of my biological samples by research staff (required):</p> <p>I (agree/do not agree) to allow the <b>study researchers and research team</b> to study my samples (blood, cells, saliva, urine, stool, nail and hair) in current and future research.</p>
4.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Use of my biological samples by <b>other scientists (optional)</b>:</p> <p>I (agree/do not agree) to allow <b>scientists not associated with</b> future research of the 10,000 Families Study.</p>
5.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Use of my samples of <b>genetic material</b> by research staff <b>(required)</b>:</p> <p>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.</p>
6.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Use of my samples of <b>genetic material</b> by <b>other scientists (optional)</b>:</p> <p>I (agree/do not agree) to allow scientists and specialized laboratories not associated with this research study to study my de-identified stored <b>genetic data, information, and samples</b>.</p>

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