

## 10,000 Families

### **Why am I being contacted?**

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.

### **What can be learned from this kind of study?**

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.

### **If I participate what would I be asked to do?**

You will be asked to: Complete health questionnaires either on paper or on-line; Invite at least one other family member (if you are the FIRST family member to participate in the study) from a different generation to participate; Attend a family health fair where we will take measurements and biological samples (see reverse side for a list). Allow your blood sample to be tested for DNA (and if one or more of your children under age 18 participate, allow their saliva to be tested); Give permission for release of hospital and clinic records related to cancer, heart disease, and any other diseases or surgeries you might have had; Allow researchers to link information from state cancer registries or similar systems about diseases you may have had or may develop in the future; Agree to be contacted on a regular basis (e.g., annually) to obtain updates on your health.

### **What are the benefits of participating in studies like this one?**

There is no direct benefit to you by participating in this pilot study. However, the benefit to participation in this kind of research is that it may help to improve the participant experience in the full-scale study and eventually contribute to the health of all Minnesotans. For participants who would like results, we are able to give back some results from assessments taken at the family health fair. See reverse side for list of results that will be made available to participants.

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## What measurements will be taken at the family health fair?

Measurements	Which participants will complete these?				Return results?	What kind of result is returned?
	Infants and Toddlers	Children	Young adults	Adults		
Height	x	x	x	x	yes	Report of height
Weight	x	x	x	x	yes	Report of weight
Waist		x	x	x	yes	Report of waist circumference
Body composition		x	x	x	yes	Percent body fat
Pulse		x	x	x	yes	Report of beats per minute
Blood pressure		x	x	x	yes	Blood pressure result
Lung function		x	x	x	*no	Research test, results not available for participants
Hearing test		x	x	x	yes	Pass/fail of hearing test
Grip strength				x	*no	Research test, results not available for participants
Digital pen				x	*no	Research test, results not available for participants
3D photos		x	x	x	Yes	Photo

\* The results of grip strength, lung function, and digital pen measurements will not be returned to study participants. These tests are currently available for research purposes only and cannot help in the clinical diagnosis of any disease conditions.

## What samples will be collected at the family health fair?

Biological samples	Infants and Toddlers	Children	Young adults	Adults	Return of results	What kind of result is returned?
Hair	x	x	x	x	*no	
Blood		x	x	x	some	Report for complete blood count, cholesterol, glucose, creatinine
Saliva	x	x	x	x	*no	
Toenails	x	x	x	x	*no	
Urine		x	x	x	*no	
Stool, sent home	x	x	x	x	*no	

\* In this pilot study we do not have the funding to conduct some of the laboratory tests. At this point we will not be able to return these results. However, it is important we ask permission to analyze the samples so we understand participant willingness and will allow us to complete the work in the future.

## What kinds of questions will you ask me and my family members?

We will ask adults to complete health questionnaires about medical history; cognitive factors; medications; lifestyle questions such as diet, alcohol and tobacco, physical activity, and sleep; family health history. If you have a child under age 18 who is in the study, you will be asked to complete health questionnaires on his or her health and development. Adolescents between the ages of 12 and 17 will be asked to complete a standard youth risk behavior survey. \* Questionnaire information will not be returned to participants

## Is my information safe?

Access to the information you provide is restricted to key staff members. When we publicize results from the study, we only report summary information, never names of study members. Privacy laws prohibit release of personal information that could be used to identify participants in research projects such as this. Researchers generally have access only to portions of the data that have been coded in such a way that they cannot tell the identity (name, address, etc.) of participants.

## Who is in charge of the study?

This study is being conducted by researchers from the University of Minnesota. The Principal Investigator, Dr. Logan Spector, can be reached at 1-866-434-9879.