

CONSENT FORM

Gopher Kids Study

*Logan G. Spector, Ph.D. and Ellen W. Demerath, Ph.D – Lead Investigators
University of Minnesota*

The Department of Pediatrics and the Division of Epidemiology and Community Health at the University of Minnesota are conducting a large study of children at the Minnesota State Fair. We would like to gather data from healthy children to better understand the growth, development, and health of Minnesota children.

Logan G. Spector, Ph.D., of the Department of Pediatrics at the University of Minnesota and Ellen W. Demerath, Ph.D., Division of Epidemiology and Community Health, School of Public Health are responsible for this study. We would like your child to participate in our study because he/she is between the ages of 1 and 11 and resides in Minnesota. We would like track the health and development of children these ages and relate it to their genes.

We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Study purpose

The main purpose of this study is to understand how genes contribute to children's normal health and development. During this first phase of the study, we are trying to see if families will participate in research based at the Minnesota State Fair. If it is successful, we will then enroll a much larger group of children. Our goal is to recruit 500 children at the 2010 State Fair and have them visit again for measurement and sample collection at the 2011 and 2012 State Fairs.

Study procedures

If you agree to participate in this study, we would ask you and your child to do the following at the Fair:

- Have your child's height, weight, waist, and blood pressure measured.
- Donate a sample of your and your child's cheek cells. Cheek cells will be obtained by depositing saliva into a plastic Oragene container. Younger children's cheek cells will be obtained by rubbing a soft brush on the inside of his or her mouth.
- Collect nail clippings (OPTIONAL).
- Collect blood spots by a fingerstick from your child (OPTIONAL).
- Complete a short, general survey about your family.

In addition to the parts of the study taking place at the Fair right now, we will ask that you:

- Complete a 45-minute questionnaire that will be mailed to you in the next 4-6 months.
- Return to the Minnesota State Fair in 2011 and 2012 year for additional sample collection.

You may choose to participate in all or some of the procedures. Your participation in this study will last until the final sample collection at the 2012 State Fair. You can stop participating at any time. The study investigators may also decide to take you off this study, if they feel it is in your best interest not to continue.

What will happen with your and your child's DNA samples? The cheek cells and blood spots we collect will be used to study you and your child's DNA. DNA is the genetic material in a person's cells that makes them unique. There are thousands of genes in each cell which are made up of DNA. By studying the DNA, scientists can discover what genes might be involved in normal growth and development. We ask for a parent's DNA sample, although we are studying children, to tell which genes the children inherited.

In this study we will be looking at millions of variations in the collected DNA sample. So little is known about the factors being studied, including your and your baby's DNA, that the results will not provide useful information to your family. This information is for research purposes only and you will not be informed of your individual results. However, if you wish, you will be informed of the overall findings from the study once it is over.

Research that uses your and your child's DNA might be done a long time after they are collected. These samples will be used for research by Logan G. Spector, Ph.D. and his associates for the purposes of learning more about genetics in growth and development. You will not be identified in any publication or reports of this data.

What will happen with your child's blood spot and fingernail samples? These samples may be used to look at hormones or other substances that they body naturally produces, or they may be used to look at chemicals present in the environment. Again, any tests performed on these samples are for research purposed only and you will not be informed of your individual results.

How long will your and your child's DNA and other samples be kept? Your and your child's DNA and other samples will be kept indefinitely, unless you request destruction. We will contact your child when he or she turns 18 to see if we can continue storing his or her samples. You can request that your or your child's samples be destroyed at any time by contacting Dr. Spector or Dr. Demerath at the number provided below.

Risks of Study Participation

The risks of this study are minor. There is a small risk that your or your child's personal information could accidentally be released to someone other than study staff. We would keep all personal information in locked file cabinets or in computer databases protected by passwords. Only study staff would have access to these documents and files.

Also, because we're getting DNA from parents and child, we may be able to tell if someone was adopted or if their father is different than they think. Our policy is to not reveal this information.

Benefits of Study Participation

There is no personal benefit to you or your child for participating. The study may benefit society by discovering genes related to normal growth and development. .

Study Costs/Compensation

There is not cost to you for participating in this study. You will receive a University of Minnesota fair souvenir and \$5 worth of kids' ride tickets at the Fair each year that you participate. In addition, a few weeks before the 2011 and 2012 Fairs we will mail your family one free ticket for each participating child and one for a parent.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by departments at the University with appropriate regulatory oversight. Your participation in this study will not be noted in your medical record. To these extents, confidentiality is not absolute.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Logan G. Spector, Ellen W. Demerath, and their associates at the University of Minnesota. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact Dr. Spector at 612-624-3912 or Dr. Demerath at 612-624-1818.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged to** contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at Fairview University Medical Center - Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study on behalf of myself and my child.

Name of child _____

Signature of Parent _____

Date _____