CONSENT TO PARTICIPATE IN RESEARCH
For parents/guardians of minor subjects (<18 years)
MyTree Study

Logan G. Spector, PhD and Lucie Turcotte, MD, MPH – Lead investigators
Department of Pediatrics and the Masonic Cancer Center
University of Minnesota

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

Our team is working to learn more about immune disorders, known genetic conditions, abnormal growths including cancers and blood disorders. We invite people who have or are suspected to have these types of conditions to help us learn more. We may ask you to invite your family members to participate as well.

Study purpose

The main purpose of this study is to understand how genes might affect people’s chances of developing immune disorders, abnormal growths including cancers, and blood disorders. To do this we will compare the genes of people with immune disorders, known genetic conditions, abnormal growths including cancers, and blood disorders to the genes of people who do not have these conditions.

Study procedures

Summary
If your child participates, we will ask for:

1) Samples of saliva, urine, blood and/or other stored material such as slides or leftover diagnostic material from your child.
2) Questionnaire information completed by parent or guardian, including questions about the young person’s health and family health history.
3) Some people will be asked to release medical record information relating to diagnosis and treatment of infections, immune disorders, known genetic conditions, abnormal growths including cancers, blood disorders, and similar conditions, if applicable. If this step applies to your child then you will be asked to sign a separate form.
4) You may be asked to contact your biological family members to ask them about participating in the study. You will get to decide which family members to invite into the study.
5) You may be contacted in the future if more information becomes available about your child’s genetic analyses or more studies are to be performed. Once your child turns 18 years old we will contact him/her directly. You or your child after he/she turns 18 will be able to decline any future information or studies at any point.
**Genetic material collection**

We will collect saliva, about ¼ cup (50-60ml) of urine, and 2 to 4 teaspoons (10-20 ml) of blood. There will be no cost to you. If we find out that your child’s sample doesn’t have enough cells to be useful, we may call you for an additional sample.

We will collect genetic material (DNA, RNA, and proteins) from your child’s samples. We may also use your child’s samples to make “stem cells.” Stem cells are cells that can be grown in a laboratory and turned into blood cells. By studying genetic material and stem cells, we hope to identify genetic factors that contribute immune disorders, abnormal growths including cancers, blood disorders and similar conditions.

Genetic analysis would include:
- looking for misspellings (mutations) in genes
- looking for the effects of these misspellings (mutations) by analyzing a chemical called “RNA”
- looking at the size of repeat pieces of genes
- analyzing genes in the energy-producing parts of your body called mitochondria.

We may look at all 20,000 genes in the body in order to understand if changes are related to the conditions we are studying. If you would like more specifics about these different types of genetic testing, the investigators would be happy to answer your questions.

**Sample use and storage**

The samples will be used for research by Drs. Logan Spector and Lucie Turcotte and their associates for the purposes of learning more about immune disorders, abnormal growths including cancers, blood disorders and similar conditions. We have some genes that we know right now that we are going to study, but there might be other ones that we only think to study in the future, so we plan to keep the samples indefinitely. In some cases, the samples could be sent to other research groups for analysis. You will not be notified if we send your the sample to another researcher, but any samples we send to another researcher will be labeled with a code (not your child’s name or other identifying information) so that the outside researcher will not be able to trace your child’s sample to him/her. Your child will not be identified in any publication or reports from this study.

You can request that your child’s samples be destroyed at any time by contacting Dr. Spector at 1-866-434-9879 (toll free) or 612-625-3910.

**Results of genetic testing**

Our laboratory is a research laboratory. This means that our studies are being performed to learn about genes that cause early onset diseases. Because this is a research study, we will not give you results of the genetic testing. Participation in this research study does not replace any genetic tests that your child’s healthcare provider may have recommended.

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 your child’s medical care. If our laboratory should identify a genetic variant that impacts your child’s medical care, called
“medically actionable findings,” we will ask your physician to have the result verified in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. We will provide information to the laboratory to allow them to complete the testing. This additional testing in a clinical CLIA laboratory will usually require a new sample and be charged to your child’s insurance as a clinical laboratory test. At the end of this consent form, you may choose whether or not you want to be contacted with any “medically actionable findings.”

**Study Size and Duration**

Initially we will enroll 20-25 individuals and their families. We will enroll more families and unaffected people (to serve as controls) in the future.

Participation in this study will last indefinitely unless you request that your data or samples be destroyed. Research that uses your child’s samples might be done a long time after the sample has been collected. When your child turns 18 years old we will attempt to contact him/her and ask for his/her permission to continue the study. The samples will be used for research by Drs. Spector, Turcotte and their team for the purposes of learning more about immune disorders, abnormal growths including cancers, blood disorders and similar conditions. If you agree to provide a sample for the study, it will be labeled with a number, not your name, and kept indefinitely. Your child’s identity would always remain private and would not be provided with the samples.

**Risks of Study Participation**

**Blood sample.** There are no major risks associated with drawing blood. Having blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, a blood draw can cause fainting. Only trained people will draw your child’s blood.

**Urine.** There are no major risks associated with urine sample collection. However, for a very small number of people (about 2 people in 10,000) we may incidentally find very rapidly growing cells that may be bladder cancer cells.

**Saliva.** There are no major risks associated with saliva sample collection.

**Tumor sample.** If your child has had a biopsy or other diagnostic specimen taken then we would like your permission to collect a portion of the sample. (Only some people in the study will have had a biopsy.) There are no major risks associated with asking the hospital where the tumor was removed to provide a leftover sample of your child’s tumor.

**Personal Information.** There is a risk that 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.

**Genetic information**

- 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 unless it affects your child’s medical care.

• Your child’s DNA sequence is like a fingerprint: it is unique to him/her. All precautions will be taken to protect your child’s privacy and confidentiality. All genetic information will be stored in a secure database that is only labeled with an identification number. Only Drs. Spector, Turcotte, and their study team will have access to these data. Nevertheless, it is possible that someone in the future could identify your child based on this unique genetic information. It is important to note that there is a federal law in place to prevent health insurance and employment discrimination based on genetic information called the Genetic Information Non-Discrimination Act (GINA). See the Confidentiality section on pages 4-5 for the GINA information.

• If you decide that you want to receive “medically actionable findings,” it is possible that we will tell you that your child is at high risk for a serious medical condition. This could be upsetting for you/your child. In most cases, we do not expect to identify medically actionable results.

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

**Benefits of Study Participation**

There will be no direct benefit to you or your family. This research may help us understand more about the genetics of immune disorders, abnormal growths including cancers, blood disorders and similar conditions.

**Study Costs/Compensation**

There is no cost to you/your child for participating in this study.

**Research Related Injury**

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 child’s insurance company. If you think that your child has suffered a research related injury let the study physicians know right away.

**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 your child as a subject. Your child’s record for the study may, however, be reviewed by departments at the University that make sure research is done right. Your child’s participation in this study will not be noted in medical records. To these extents, confidentiality is not absolute.
Organizations that may inspect and/or copy your child’s research records for quality assurance and data analysis include groups such as:

- **Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. and international governmental regulatory agencies involved in keeping research safe for people**
- **The Institutional Review Board of this university.**

We will also ask that you allow us to abstract information from your child’s medical record. All of the information abstracted from the medical records will be secured in accordance with HIPAA regulations. No one other than Drs. Spector, Turcotte or their associates will be able to trace the information used from the medical records back to you or your family.

The risks to you from genetic research are very low. Your child’s samples will be identified only with your study code number. In the event of an unexpected breach of confidentiality, a recent federal law (Genetic Information Non-Discrimination Act, GINA) will help protect your child from health insurance or employment discrimination based on genetic information obtained about you through research such as this. If you have questions about GINA or the risks of research on genetic information, please ask the study staff.

**Protected Health Information (PHI)**

Your child’s PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA.

**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/your child’s current or future relations with the University of Minnesota. If you decide to participate but later change your mind, you can at any time request that the samples be destroyed. However, research already done on those samples cannot be undone.

**Contacts and Questions**

The researchers conducting this study are Dr. Logan Spector and Dr. Lucie Turcotte 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 them at 1-866-434-9879 (toll free) or 612-625-3910.**

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 Research Administration, 2433 Energy Park Drive, St. Paul, MN 55108.

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

Please put a check mark and your initials by your decision for each question below.

1. *Medically actionable information*
   Rarely, the researchers may find that you have a genetic change that places your child at high risk for a serious medical condition. If we find this type of genetic change in your child’s sample and there are steps you can take to prevent this condition from happening, we can tell you about this genetic change. 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 child’s sample.

If our lab identifies a medically actionable finding in your child’s sample and you want to receive these findings, your healthcare team will be contacted by a genetic counselor. The genetic counselor will explain the following:

1. What type of medically actionable information was found in your child’s sample.
2. 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 child’s regular medical care and will not be paid for by this study.

Would you like to receive potentially medically actionable information?

☐ Yes ☐ No

Initials_____  
*Please check one box and initial on line above*

2. *Permission to be contacted in the future*
   The investigators may want to re-contact you in the future to request updated family medical history information or other similar information.

Would you like to be contacted by the researchers in the future?

☐ Yes ☐ No

Initials_____  
*Please check one box and initial on line above*

3. *Banking for future DNA test research*
   When the testing is completed, the DNA sample and its associated genomic data will be retained by our laboratory. Please check the appropriate box below regarding whether or not we may keep your child’s DNA. *Please check one box and initial*
☐ Initials____ You may keep my child’s DNA sample and its associated genomic data.

☐ Initials____ You may not keep my child’s DNA sample and its associated genomic data. Please destroy it upon completion of testing.

In some cases additional tests of value to your child or to a family member can be performed on the saved DNA. We need to know if this is OK with you. Please initial your preference: Please check one box and initial

☐ Initials____ Under no circumstances use my child’s DNA and its associated data again. Please destroy the samples upon completion of testing.

☐ Initials____ Contact me and explain the new study that will involve my child’s DNA and its associated data.

☐ Initials____ Use my child’s DNA and its associated data as desired as long as all identifying information is removed from the sample.

☐ Initials____ Use my child’s DNA and its associated data as desired as long as the test directly relates to testing in my family.

I have read the above information. I have asked questions and have received answers. I consent to my child’s participation in the study.

Name of child:

_______________________________________________________________

Parent/guardian signature:

_______________________________________________________________ Date ________________

Signature of person obtaining consent:

_______________________________________________________________ Date ________________