CONSENT TO PARTICIPATE IN RESEARCH
For unaffected controls
MyTree Study

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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 have invited people who have or are suspected to have these types of conditions to help us learn more. We also need unaffected people to participate as control subjects.

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 you participate, we will ask for:

1) Samples of saliva, urine, blood and/or other stored material such as slides or leftover diagnostic material
2) Questionnaire information, including questions about your 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 you then you will be asked to sign a separate form.
4) You may be contacted in the future if more information becomes available about your genetic analyses or more studies are to be performed. You 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 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 samples. We may also use your 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 your 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**
Your 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 your samples indefinitely. In some cases, your samples could be sent to other research groups for analysis. You will not be notified if we send your sample to another researcher, but any samples we send to another researcher will be labeled with a code (not your name or other identifying information) so that the outside researcher will not be able to trace your sample to you. You will not be identified in any publication or reports from this study.

You can request that your 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 your genetic testing. Participation in this research study does not replace any genetic tests that your 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 medical care. If our laboratory should identify a genetic variant that impacts your 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 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.

Your participation in this study will last indefinitely unless you request that your data or samples be destroyed. Research that uses your samples might be done a long time after the sample has been collected. 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 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 your 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 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.

**Biopsy sample.** If you have 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 biopsy was taken to provide a leftover sample.

**Personal Information.** There is a risk that your 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 medical care.

- 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 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 you 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 you are at high risk for a serious medical condition. This could be upsetting for you. 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 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 insurance company. If you think that you have 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 you as a subject. Your record for the study may, however, be reviewed by departments at the University that make sure research is done right. Your 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 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 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 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 you 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 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 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 you at high risk for a serious medical condition. If we find this type of genetic change in your 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 sample.

   If our lab identifies a medically actionable finding in your 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 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 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 DNA. *Please check one box and initial*

- ☐ Initials_____ You may keep my DNA sample and its associated genomic data.
- ☐ Initials_____ You may not keep my DNA sample and its associated genomic data. Please destroy it upon completion of testing.

In some cases additional tests of value to you 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 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 DNA and its associated data.
- ☐ Initials_____ Use my DNA and its associated data as desired as long as all identifying information is removed from the sample.
- ☐ Initials_____ Use my 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 participate in the study.

Signature ___________________________ Date ________________

Signature of person obtaining consent:

____________________________________ Date ________________