CONSENT FORM

Genes and Phenotype (GAP): A National Resource for Genotype-Phenotype Studies of Immunological and Inflammatory Pathways – The GAP Registry

You are invited to participate in a research study. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Dr. Erik Peterson at the University of Minnesota. It is funded by Autoimmune Arthritis Center Biomarkers Core of the Department of Medicine, University of Minnesota.

This study is part of the Tissue Donation Program at the Feinstein Institute for Medical Research, in the North Shore-LIJ Health System. The Tissue Donation Program (TDP) oversees a data and tissue bank, developed to support research on different diseases and conditions. The TDP collects and stores many types of samples, along with health history information from participants. These samples and data are made available to scientists for use in medical research studies. However, participants' names or other identifying information are not given to the researchers.

Study Purpose:
The purpose of the study is to enroll people who are willing to serve as control subjects in future research studies into the Genotype and Phenotype Research Registry (GAP registry). A control subject is someone who does not have a disease or condition being studied and can serve as a comparison for people with a disease under study. As a participant in the GAP registry, you may be notified about additional studies that you may be able to participate in as a control; however you are under no obligation to join any additional studies. Therefore we will collect information about your age, gender, ethnicity and medical history, as well as a DNA sample. DNA is the genetic material you inherit form your parents. Different studies have different needs; therefore different criteria will be used to select potential controls for each future study.

The GAP registry will allow researchers to increase their understanding of how the immune system functions. The immune system plays a vital role in maintaining health and protects an individual against disease by identifying and destroying foreign substances such as bacteria and tumor cells. With a better understanding of normal range of immune system activity, scientists will be able to compare and learn more about diseases caused by abnormalities in the immune system such as autoimmune disease and cancer.

Study Procedures:
If you agree to participate in this study, we will ask you to sign a consent form, fill out a health history questionnaire, give a small amount (approximately half a tablespoon) of blood and allow us to contact you about additional studies. We may contact you and ask you to provide additional blood samples for follow-up of this study (up to 2.4 tablespoons per visit). You will never be asked to give blood more than once a month. We may also ask you to participate in a different study as a control participant; however, you are under no obligation to participate in any further studies.

Risks of Study Participation:
There is a risk of bleeding in the arm when the needles are placed to draw blood samples. This can result in a bruise occurring at the needle puncture site; severe bleeding in the arm is very rare. There may also be some pain involved in having the needle inserted under the skin. Because we will store your processed blood samples (e.g. DNA), and save your identifiable information so that we may re-contact you to request additional information or invite you to have your blood drawn again, there is a risk to your confidentiality. We will take several steps to protect your confidentiality (see "Confidentiality" below).

The risks to you and your family 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 study staff.

Benefits of Study Participation:
You will not benefit directly from participating in this study. No research results will be given to you or your doctors. The reason you might want to take part is to help researchers make discoveries that may benefit people in the future.

Alternatives to Study Participation:
It is your choice to take part in this research study. You may choose not to participate.

Study Costs/Compensation:
There are no costs to you for participating in this study. At the first visit, you will receive $10. You will be given $25.00 for your time and travel required for participation at each follow-up visit.

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 and completely confidential in locked storage. Your processed blood sample will be marked only with a number in order to protect your identity from anyone not involved in this study. The key that links your study number to your identity will be kept secure, and only the investigator and immediate staff with legitimate need, and the research team at the Feinstein Institute will have access to the key. In any sort of report we might publish, we will not include any information that might make it possible to identify you as a subject. Data will not become part of the subject's medical record, but will be part of the research records of the Principal Investigator and the Feinstein Institute. Data will be kept for an unlimited time period by the University of Minnesota. The data may be shared with the Food and Drug Administration (FDA) and regulatory authorities may examine the research records, including identifying information.

Protected Health Information (PHI):
Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Blood Sample Information:
The DNA and RNA (genetic material), serum (the liquid part of the blood), or cells from the blood will be kept for an unlimited number of years under the ownership of the Feinstein Institute for Medical Research in Manhasset, NY. Samples may also be sent outside the Feinstein Institute for analysis or research collaboration. All identifying information will be removed from the samples so that your confidentiality will be maintained.

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 this relationship.

Contacts and Questions:
We ask that you read this form and have all questions answered to your satisfaction before agreeing to participate. You may ask any questions that you have concerning this study at this time. The researcher conducting this study is Dr. Erik Peterson. If you have questions later, you are encouraged to contact him at 612-625-5634.

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.*

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study. I will be given a copy of this form to keep for my records.

_____
Your Name (please print)

_____ _____
Your Signature Date

_____ _____
Signature of Person Obtaining Consent or Investigator Date