NorthShore
University HealthSystem

Research Institute

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Genomic Health Initiative (GHI)

northshore.org/ghi

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Sponsor: NorthShore University HealthSystem

IRB Approval Date: 12/15/17

This Consent Form gives information to help you decide whether to participate in this research study. If you have any questions, you can ask the research staff or call the GHI telephone number at (224) 364-7470.

Purpose. Our goal is to perform and advance medically relevant genomic research. We are asking you to enroll in this study since you are an adult NorthShore patient. If you decide to participate, we will collect a small sample of blood to isolate your DNA and will access your electronic medical records. Our aims are:

1- Identification of genetic risk factors for common disorders. Such discoveries would enable prediction of risk and enable preventive efforts for these disorders.

2- Development of early new treatment interventions. As the biology of a disease becomes better known, researchers can find potential new treatment targets.

3- Return of clinically actionable genetic data that is highly significant for your health.

We are planning to enroll thousands of participants over the next few years. We hope you will participate.

Nature of the Research. Our research involves comparing DNA variation between groups of participants with and without many conditions to search for genetic risk variants. In addition to studying the DNA directly, we may also conduct studies that examine how genes operate. Our methods will vary over time, as biomedical technology is rapidly changing. We may preserve your blood cells for studies of gene function (such as gene expression, protein synthesis, and metabolism) mentioned above, but we will not use your cells for isolating or generating stem cells.

Procedures. You are asked to donate three small extra tubes of blood, less than one tablespoon in total. The blood sample will be collected at your visit to any of NorthShore's outpatient labs or patient service centers at an already scheduled clinical blood draw, without needing an extra needle stick, or you may instead request a separate research blood draw. Please see www.northshore.org/lab-services/locations for a list of designated laboratories.

You are also asked to allow the donation of clinically unused leftover samples from your laboratory tests that would normally be discarded, such as urine or blood, for research. All samples are stored in locked freezers at NorthShore. The samples will be labeled with a unique research code instead of your name or other identifying information.

We will periodically update the research database with information from your electronic health record. Some of this clinical information could be considered sensitive, such as various diagnoses, behaviors, and conditions. We will make every effort to protect it. Information you provide will be recorded in the research database at NorthShore. All identifiable computer records will be maintained on a protected internal network to which only the study-associated personnel will have access.

We will not give you raw data from research done using your sample. You will be able to get news about general research findings from studies done and publications on the GHI website (northshore.org/ghi).

Other choices. Your participation is voluntary. The alternative is to not participate. Your care at NorthShore will not be affected by your choice.

Benefits. You may or may not receive direct benefits from your participation. Our genetic research may allow doctors to learn more about the genetic influences on various health conditions. We hope such knowledge will contribute to improvements in prevention, diagnosis, and treatment for various diseases. For a small percentage of participants, our study may uncover data directly relevant to your health, such as high risk for some cancers, cardiovascular disorders that are associated with sudden death, or genetic susceptibilities that may predispose to toxic reactions to some drugs. For such clinically actionable findings, if you have any and you have expressed your interest to be recontacted, we may share the information with you and your doctor. This will allow you to get confirmatory genetic tests and consider pursuing medical interventions.

Risks. *Blood draw:* risks include faintness, inflammation (redness and/or warmth) of the vein, pain, bruising, bleeding at the site of puncture, or (rarely) infections. Care will be taken to avoid such side effects.

Information Privacy: During this research, we will collect identifiable personal health information (PHI) from your electronic health record; specifically, your name, addresses, date-of-birth, phone, fax, email, Social Security number, and medical record number. We refer to this information as "PHI identifiers." The PHI identifiers in the research database are limited in this study to information contained in your electronic health record already. We have established systems to protect your PHI. Even with the special precautions there is no absolute guarantee of confidentiality. There is a possible confidentiality risk that someone could access your stored data or trace the de-identified information in a scientific database back to you since your genetic information is unique to you. Federal laws against the misuse of genetic information, most notably the 2008 GINA (Genetic Information Nondiscrimination Act) law, which applies to employment and health insurance. Be aware that this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance; nor does it protect you if you self-disclose any genetic information. Except as required by law, or as detailed in this form, we will not release identifiable information. We will assign a research number to you and your name will not be used. We have obtained a Certificate of Confidentiality from the National Institutes of Health, which allows us to refuse to disclose information that identifies you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (even from a court order or subpoena). Note that this Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself, such as your involvement in this research study.

Some situations legally require mandatory reporting (breaking confidentiality) such as certain communicable diseases or to protect someone from abuse or harm. Most of this research will occur at NorthShore. However, genetic, or other biological data may be shared in scientific databases outside of NorthShore, including the National Institutes of Health (NIH). Any data or biomaterial being shared outside of GHI will only have a unique code number without any identifying information. Information about the code will be kept in a secure location at NorthShore only. We will enter into collaborations only with scientists from institutions that abide by appropriate federal regulations. Researchers who want to study the information in those databases must guarantee they would not attempt to identify you. Scientific publications or research materials will not show your PHI identifiers

Who may see, use, and share your PHI identifiers?: The NorthShore research staff involved in GHI, the NorthShore Institutional Review Board (IRB) that oversees the research, and US agencies that oversee or review research, such as the NIH. By agreeing to participate in this study you are authorizing GHI researchers to use your PHI identifiers. Your PHI identifiers will only be used for the purposes described in this Consent Form.

Costs and Payments: There are no costs to you for being in this study. You will be paid $5 in the form of a gift card e-mailed or postal-mailed to you upon completion of your research blood draw.

How long will the study last? This authorization does not have an expiration date.

How can I withdraw from the study? You can withdraw from this study anytime during your life by contacting the research staff at (224) 364-7470. We will send you a withdrawal form for you to complete. We will then destroy your sample and remove your data from the research database. This will not affect your clinical electronic health record. If your genetic and health information or biosample (such as a DNA sample) were placed in scientific databases or repositories (not managed by NorthShore) or published upon before you withdrew, those may continue to be retained there. However, we would request their removal. Any information already obtained at the time you withdraw may continue to be used if necessary to ensure study integrity. We would still retain your information, biomaterials, and data derived from them for the period required by the policies of the respective scientific journal or funding agency.

What are my rights as a research volunteer? You may get more information about your rights as a research volunteer from the Chairperson or administrators of the IRB at (224) 364-7100. You should contact them about any problems during the research study.

Will the researchers recontact me? Qualified researchers will be able to apply for accessing samples and health information collected in this study. The GHI scientific access committee will review each study data or biomaterial access request, and for any recontacting for future research. You have no obligation to volunteer for future studies. Future studies involving recontact will have their own consent process, which will provide you details to help you decide whether to take part.

This study may yield clinically actionable findings from the analysis of your biological sample. Clinically actionable findings are those for which therapeutic and/or preventive interventions are available. You have an option to receive clinically actionable findings from our research on your samples. We will carefully consider what results should be returned to you and your doctor, if such

sharing is legally permitted at the time. A genetics counselor may recontact you to suggest you obtain additional confirmatory testing in a clinically certified laboratory informed by our research findings. This will then be followed by appropriate specific genetic counseling. Please note that the genetics field is still searching for consensus regarding medical actionability, which will evolve over time. Please visit our study website at northshore.org/ghi to learn more. If you choose to receive clinical follow-up after this recontacting, the actionable genetic data would become part of your clinical records and you (or your insurance) would be responsible for any costs including the confirmatory testing, since such activities would then be out of the scope of this research study. Some samples will be studied earlier than others, and you should not interpret lack of recontact from us as indicating you have no identifiable genetic risks. It is important for you to understand that you should not delay or omit other clinical checks or interventions because you have volunteered for this study. We do not plan to return genetic data for disorders for which there is no treatment or prevention.

Please indicate your willingness for optional recontact by checking the appropriate "yes" or "no" box for each question:

Somebody may contact me with offers to take part in other studies. ☐ **YES** ☐ **NO**

Somebody may contact me with offers to make a clinical referral deemed appropriate for me based on my electronic health record and genetic information. ☐ **YES** ☐ **NO**

CONSENT TO PARTICIPATE: I understand that Dr. Gejman and his research associates and assistants will supervise the study. I have read this consent form or have had it read to me. I understand I may obtain a copy of this consent form from the study website, or request a hardcopy at any time. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I give permission for the research study activities described in this consent form.

Volunteer's Name (Please PRINT)	
Volunteer's Signature	
Date Volunteer Signed	

This consent form is for informational use only. To consent for this study, please come to one of our in-person consenting/enrollment locations such as the Evanston Hospital Outpatient Laboratory, or consent/enroll electronically through NorthShore*Connect* (click on the "Enroll Now" button for GHI after logging onto NorthShore*Connect*).