UNIVERSITY OF WASHINGTON
CONSENT FORM
Medical Genetics Repository and Registry
For adults not currently enrolled in a medical genetics study

206-221-0971

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Researchers’ statement
We are asking you to be in a research study. The purpose of this consent form is to give you the
information you will need to help you decide whether to be in the study or not. Please read the form
carefully. You may ask questions about the purpose of the research, what we would ask you to do, the
possible risks and benefits, your rights as a volunteer, and anything else about the research or this form
that is not clear. When we have answered all your questions, you can decide if you want to be in the
study or not. This process is called “informed consent.” We will give you a copy of this form for your
records.

PURPOSE OF THE STUDY
We want to conduct research, now and in the future, on disorders that run in families and seem to be
hereditary (genetic). We don’t know which genes are involved in causing many diseases, but we hope to
develop better diagnostic tools and treatments by studying genes. The purpose of the Medical Genetics
Repository and Registry is to collect and store blood specimens and information from people who are
patients at the UW Medical Genetics Clinic and other people interested in genetic research, into a bank
(collection of samples and information from a large number of people). Then, information and samples
will be available for future research on how genes can affect health or disease. We will keep your samples
and data indefinitely to use when needed by Dr. Jarvik, or other qualified research partners, for future
research. In addition we want to be able to contact you in the future about possibly joining new research.

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We will create a Registry or list of people to contact for other research projects. If you decide to join a new study, you will be asked to read and sign a separate consent form.

**STUDY PROCEDURES**

We study the genes for these studies from the genetic material (DNA) we get from your blood. We are asking you to donate a blood sample (30 mL, or about 2 tablespoons) and respond to a survey. You may refuse to answer any question. We may need you to fast (not eat) for 12 hours before the blood draw. That means you can only have water and your medications before the draw. We will tell you if you need to fast. It will take about 45 minutes to collect the blood and complete the survey. We will use your blood samples and data for future research studies that are not developed yet. The blood samples and information we collect on you and want to bank into the Repository can include: DNA, serum, plasma, cell lines, RNA, contact and demographic information, survey, medical records including both past and future, clinical notes, imaging studies and clinical test reports. Cells obtained from your blood sample may be kept alive and grown in the laboratory indefinitely in future research projects. Cell lines are necessary for long-term genetic research and also mean we will be probably never have to ask you for another blood sample. The cell lines will be part of future studies and you will be asked to sign separate consent forms for those studies.

If you decide to participate in the Repository study, samples of your blood, DNA, RNA, and possibly cell lines from your blood will be stored in freezers labeled only with coded IDs. All database information on you will be labeled only with coded IDs (never your name). Only coded ID samples and information will be shared with other qualified researchers. Database information is stored in password protected computers in locked offices. We will keep a link between your name and the coded ID in a password protected database. Dr. Jarvik will be the gatekeeper of the link between your coded ID and your name, and will work to keep your information confidential by only allowing authorized research study personnel access to the link. The link will be kept permanently.

If you also agree to be in the registry (list), we will contact you by phone or mail to tell you about a new study when one is available. You can read the consent form, and after all your questions have been answered, can decide if you want to join the new study or not. There are no consequences for declining to join the new study. Your participation is completely voluntary.

**RISKS, STRESS, OR DISCOMFORT**

We will work very hard to keep all information about you private; however there is no way to completely eliminate the risk of loss of confidentiality. Your coded genetic information and data may be shared with other investigators and/or, in the future, with the United States National Institutes of Health database (data bank) for genetic related information, termed dbGaP. You should know that your stored, coded, genetic (genotype) and observable (phenotype; such as blood pressure or cholesterol levels) data may be shared to the National Institutes of Health genetic databank called dbGaP. These data in the databank are used in future research to further knowledge in the interaction of diseases and genes, and will be kept indefinitely. Qualified researchers that receive permission to access and share these data may be from universities or from commercial companies. Your name, address, or any HIPAA identifiers (such as social security number, hospital number, or telephone number) will never be released to the databank. Your privacy will be strictly protected, but we cannot absolutely guarantee there will be no breach of confidentiality. However, because genetic data is considered unique to each individual, it could theoretically identify you. Washington State Law and the University of Washington policy has determined that some types of genetic material are considered identifiable. We need your permission to allow your data to be included in the National genetic database; dbGaP. You can withdraw your consent anytime you don't want your data in the national databank. There will be no consequences for withdrawing consent.

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We will try to combine the research blood draw along with another scheduled blood draw. There is some discomfort when the needle enters your arm. You may get a bruise that should go away in a day or two. We may ask you not to eat breakfast before your blood draw, and you may get hungry.

Rarely, genetic analysis can reveal unexpected results such as a genetic disorder unrelated to your condition. If we find unexpected results, we will NOT disclose them to you unless the information is important for medical management or counseling.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Joining the Medical Genetics Repository and agreeing to be re-contacted about other research is voluntary. You do not have to join if you don’t want. If you join the Repository and later change your mind, you can tell us to remove your name and all information, and destroy any samples we may have banked. If you decide to join another study in the future that developed your cell line, you may request your cell line is destroyed at any time. Please call any of the research staff listed on this consent form to withdraw from this study. Whether you choose to join or decline joining the Repository, will not affect your health care or involvement with other research projects.

BENEFITS OF THE STUDY

You will most likely never benefit personally from participating in this Repository. We are hopeful that future generations may benefit from the knowledge we gain from your participation with better methods to treat or prevent disease.

MEDICAL RECORDS INFORMATION

The Federal Genetics Information Nondiscrimination Act of 2008 offers protection from discrimination by health insurers or employers. Although it is illegal, it is theoretically possible that taking part in any genetic study might hurt your access to health insurance if results of the study become part of your medical record. Therefore, we will keep all research data out of your medical record and completely separate. Because your genetic information is unique to you, it is also theoretically possible that someone could trace the information back to you.

OTHER INFORMATION

All parts of this study will be done without cost to you. Your insurance company will not be billed for any study procedures. You will not receive any money for taking part in this study.

We will keep your participation in this study confidential. Sometimes, government or university staffs review studies to make sure they are being done safely and legally. If a review happens, your records may be examined. The reviewers will protect your privacy. Your name will not be given on any scientific presentation or publication. To further protect your privacy, we have applied for a federal Certificate of Confidentiality that the government issues to researchers to prevent the release of identifiable and sensitive information about subjects who are participating in research projects.

COMPENSATION FOR INJURY:

If you think you have an injury or illness related to this study, contact the study staff [Martha Pyne, 206-221-0971] right away. She will refer you for treatment. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form. The UW will pay up to $10,000 to reimburse for treatment of injury or illness resulting from the study.

Printed name of study staff obtaining consent  Signature  Date

Approved

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UW Human Subjects Review Committee

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject   Signature of subject   Date

Copies: Researchers, subject