Research Consent and HIPAA Authorization Form
Marshfield Clinic Research Institute
A Division of Marshfield Clinic
1000 N Oak Avenue, Marshfield, WI 54449
SP Code: HEB10717 PI: Scott Hebbring, PhD

Title: Effectiveness of Genetic Medicine to Prevent and Treat Human Disease

Why are you being asked to take part in this research study?

You have been asked to participate in this research because you currently receive, or have received, your healthcare at Marshfield Clinic. The goal is to enroll about 2,000 people for this research project.

Taking part in this study is voluntary. Whether you decide to take part in this research is completely up to you. Read the following information carefully before you make a decision. You may also wish to consult with other family members or your healthcare provider before participating in this study. In writing this consent form, some technical words were necessary. Please ask for an explanation of anything you do not understand. Ask the study doctor or staff as many questions as you wish about this consent form and what will happen to you as part of this research.

Why is this research study being done?

Unless you are an identical twin, you have a unique genetic/DNA fingerprint that influences who you are. Genetics defines whether you are a man or woman, affects how tall you are, can help predict how you will respond to common medications, and may influence your risk to serious diseases. This research is being done to better understand how your genetic information can be used to personalize your care.

Your DNA will be evaluated for inherited genetic changes that are linked to diseases where early detection may significantly improve outcomes. This includes cardiovascular diseases, cancer and metabolic diseases. It is expected that three out of every 100 individuals (3%) may carry these disease causing changes. In addition to disease genes, we will also evaluate genetic changes that play an important role in how people respond to specific drugs. In this instance, it is expected that 95 out of 100 individuals (95%) have genetic profiles that may help assist in drug prescribing. Your genetic test results will be returned to you and your healthcare provider. The future hope is for doctors to analyze your genetic profile to customize preventative treatments and prescribe the best available drugs.

What will happen if you agree to be in this research study?

If you agree to be in this research study, you will be asked to do the following:

You will be asked to meet with a research coordinator to discuss the project in depth. This will be in person at Marshfield Clinic or over the phone. We will discuss the Informed Consent/Health Insurance Portability and Accountability Act (HIPAA) Authorization and explain why we are conducting this project, the risks, benefits, alternatives and responsibilities. We will answer all your questions about the project.

You will be asked for a blood sample. A trained Marshfield Clinic employee will draw up to three vials (~2 tablespoons) of blood. The DNA, or genetic part, will be taken from your blood and sent to a clinically certified laboratory for analysis. About 100 genes will be evaluated to identify genetic changes that are believed to be important in disease risk and/or can influence how you may respond to specific medications.

You will be asked to fill out a detailed family history and complete a short questionnaire regarding your personal health and understanding of genetics. You may also be requested to complete a follow-up questionnaire after you have received your genetic report.

We will add this clinically important genetic information into your medical records at Marshfield Clinic. We will work with your Marshfield Clinic provider with the goal of having your doctor use this information to customize your care. This knowledge may be very beneficial to your doctor with regards to evaluating your potential risk for serious diseases and to customize your future medications. For example, tools have already been developed at Marshfield Clinic to use genetic information to help your physician prescribe certain medications. It should be noted that the test will take time to process. It will not be available for your provider to use in your medical records for several months after your enrollment. You will be responsible for sharing results with any non-Marshfield Clinic provider you see.

In the rare instance you carry a genetic change that may put you at risk for a disease, you will be contacted by phone by the Department of Medical Genetics at Marshfield Clinic to discuss test results. Three attempts will be made. Once contacted, and depending on your preference, test results will be offered over the phone, mailed, and/or shared with you during a highly recommended follow-up visit with a Genetic Counselor or Clinical Geneticist Doctor to discuss how your test results may impact you and other family members. You and/or your insurance provider will be responsible for any costs associated with any clinical follow-up visits as it relates to your genetic information. In addition to contacting you directly, we will also share your test results with your most recent Marshfield Clinic primary care provider and incorporate your test result directly into your medical record at Marshfield Clinic. **It is important that you notify study staff and/or your primary care provider if your contact information changes.**

We will store your genetic information for future research and clinical use. Periodically, when new discoveries are made, we may re-evaluate your genetic information and update your medical record accordingly. You will also be notified if these changes could affect your health.

Research staff will have access to your medical record. Selected information from your medical record will be used to learn more about your unique genetic changes. Your medical record will be used to help us understand how your genetic information is being used and how it may have affected your health. This will continue throughout the project.

What are the possible risks or discomforts from being in this study?

Blood Draw Risks: There is always a risk when having blood taken from a vein. This blood draw will not be any different than the blood draw for normal clinical labs. Risks associated with blood draws include the potential for minor pain and slight bruising. There is a very small chance of infection at the site where the blood was drawn. Some people may faint when their blood is drawn.

Genetic Testing Risks: There is a small chance that you may have a genetic change that may increase your risk for a serious disease (approximately 3 out of 100 individuals or 3%). Learning genetic test results may include significant emotional stress and depression and financial costs for yourself and other family members if you have a positive result.

Confidentiality Risk: Your DNA and identifiable personal health information (PHI) will be sent to the clinical laboratory Baylor College of Medicine Human Genome Sequencing Center and will be used by its staff. This laboratory is a CLIA certified laboratory. Your name, birthdate, sex, ethnicity/race, and any health information that may help interpret your genetic results will be sent to the clinical laboratory as dictated by current best practices according to CLIA standards and to ensure the integrity of the result.

When your health information is shared with the external clinical laboratory, we cannot guarantee that your information would not be further shared with others that may not be regulated by HIPAA privacy rules.

Only clinically relevant test results that may benefit you will be put into your medical record. This information will be treated the same as other medical information in your medical record. All records and materials that identify you will be treated as confidential.

As already stated, only those genetic changes that may affect your care will be added to your medical record. Any additional genetic information not incorporated into your medical record will be stored on a secure computer system. A limited number of approved researchers and staff have access to the database. Few individuals will have access to the codes that link your identity to the data and all people working with your data are required by law to protect your privacy.

Although remote, there is a risk that information about your genetic make-up may be accidentally released to others. Researchers will take steps outlined in this consent form to protect your genetic information. It should be noted that there are state and federal laws (for example, Genetic Information Nondiscrimination Act) that can protect you from discrimination by health insurance companies and employers based on genetic information. It should also be noted that these laws are not comprehensive.

This research may also involve risks or discomforts that are now not known.

What are possible benefits from being in this research study?

Genetic information added to your medical record from this research project may help your health care provider evaluate your future disease risks and offer preventative care suggestions. Your genetic data may also identify better drug choices for you when or if you are prescribed them.

Will there be a cost to you to take part in this research study?

Neither you nor your insurance company will get billed for study-related procedures. Any follow-up care you may receive as a result of test results will not be supported by this research study.

Will you be paid for taking part in this research study?

The genetic test will be provided without charge. You will not receive any additional compensation or reimbursement for participation in this project.

How long will you be in this research study?

There is no specific end time since this study will build resources at Marshfield Clinic to incorporate genetic information into clinical care. This information will be placed in your medical records for your doctor and cannot be removed. Therefore, there is no intention to end the study. You are agreeing to be part of ongoing research surrounding genetic and drug related information at Marshfield Clinic.

You will be told of any new findings regarding this research that may affect your willingness to be in this study.

Who will have access to my data?

Your Marshfield Clinic healthcare provider(s) will have access to the clinically important information added to your medical records. The goal is to have your doctor use this information to evaluate disease risk and medication use.

Approved researchers and staff will have access to your research data.

Your coded research data and DNA may be shared with researcher collaborators outside of the Marshfield Clinic. Outside researchers could include other hospitals, medical schools, universities, research institutions and companies that work with Marshfield Clinic. This shared information will have a coded number and will not include your name. Researchers will be able to see selected medical information about you but will not have any way of knowing your name.

We will be required to upload coded data from this study into a public database so other approved researchers may evaluate study results. One example of this type of database is called "dbGaP" (short for "Database of Genotypes and Phenotypes") and has been set up by the National Institutes of Health.

The Marshfield Clinic's Institutional Review Board could review this research project. They may see sections of research records with your name or other identifiers. We may be required to provide summary information to workers or contractors of the United States Government for reviewing or evaluating Federally-funded projects.

Researchers may also present data using combined subject information at scientific meetings and in scientific publications. These results will not identify you.

How will information about you and your participation be kept confidential?

Marshfield Clinic researchers are required by HIPAA, the federal privacy law, to get this written authorization from you, to use and share your identifiable health information for research. HIPAA also provides confidentiality and security protections for your information. Your medical, hospital, or other billing records and research material that would identify you will be held confidential and protected by Marshfield Clinic confidentiality policies. Medical records that identify you and the consent form signed by you, may be inspected by the following agencies:

- National Institutes of Health (NIH)
- Other governmental regulatory (or health) agencies
- Marshfield Clinic's Institutional Review Board
- Medical professionals who need to access your medical record for your continuing care

Because of the need to release pertinent sections of information to these parties, all efforts will be made to maintain confidentiality. These people must keep the information confidential. Your name will not be given to anyone not associated with the study unless required by law.

This research is covered by a Certificate of Confidentiality from the National Institute of Health. This helps us to protect your privacy. Marshfield Clinic researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example. This Certificate will not prevent necessary auditing or evaluation. We would still need to disclose information that is required by law. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Beyond the Certificate of Confidentiality, there are Federal and state laws that provide individuals with a variety of protections against genetic-based discrimination either by employers or by health insurers.

Wisconsin state law was enacted in 1991 and applies to employers, labor unions, employment agencies, licensing agencies, health insurers and self-funded insurance plans sponsored by local government. These groups may not require or even request that you obtain a genetic test; or if a genetic test is obtained, disclose the fact that a test was taken or ask for test results.

The Genetic Information Non-discrimination Act (GINA) applies to health insurance companies and group health plans, and employers with 15 or more employees. Under the terms of the act, these groups may not:

- Request genetic information collected as part of research; or
- Use your genetic information when making decisions regarding your insurance eligibility or premiums; or
- Use genetic information that is obtained from research when making a decision to hire, promote, or fire an individual, or when setting the terms of employment.

Be aware that neither GINA nor the comparable Wisconsin State laws protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. These laws also do not stop employers or health insurers from discriminating against someone on the basis of a pre-existing or apparent genetic disease or disorder.

What happens if you become ill or injured from this study?

If you become ill or injured from this study, medical care is available at Marshfield Clinic or the health care provider of your choice. You or your health insurer would be responsible for this cost. Marshfield Clinic has no plans to compensate you for such illness or injury, financially or otherwise.

What do you do if you want to withdraw from this study?

Taking part in this research is voluntary and you do have the right to stop taking part. If you withdraw and take back your authorization to use your personal health information, your remaining DNA will be destroyed and we will not use your information in future studies. If your samples have already been used in research it would not be possible to remove any of the information that may have been learned prior to your request to withdraw. We will require in writing your wish to take back your authorization to use your health information. We will document your decision on a form and ask you to sign the form. Information placed in your medical records may not be removed. If you wish to withdraw please call us at **715-387-9141** or **1-800-782-8581** ext. **7-9141**.

Who can I contact for more information on this research?

For more information about this research or to report injuries or side effects, you may contact Dr. Scott Hebbring, Marshfield Clinic at **1-800-782-8581** ext. **9-3122**.

What are my rights if I take part in this research?

Being in this study is voluntary. Refusing to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to sign this consent and HIPAA authorization form, your relationship with your doctor and this institution will not change.

You are not giving up any legal rights by signing this consent and HIPAA authorization document and taking part in this research study. Marshfield Clinic cannot condition treatment, payment, enrollment or eligibility for benefits upon signing this form.

If you have any questions about your rights as a research subject, you may contact Marshfield Clinic's Institutional Review Board (IRB) at 1-800-782-8581 ext. 9-3022. The IRB is responsible for helping protect human research subjects.

Collection/Banking of Human Biological Material for Future Research:

As a part of this study, you will have a blood sample collected. DNA, plasma, and/or serum will be extracted from the blood sample and research staff would like to store this material for future research. We may also wish to re-contact you for future research to better understand how your genetic data may have impacted you. When using your banked sample, qualified researchers may use this information to study other diseases you may or may not have.

You will likely gain no personal benefit by allowing your sample to be stored and used for future research. Since any future research with your biobanked samples will be conducted outside of clinical testing, you will not receive any results specific to you. Only society in general may benefit by learning more about the genetics of different diseases and drug response. DNA sampling involves the same risks and protections regarding your genetic information as indicated in the "Confidentiality" section of this form. Before anyone can use your biobanked information, the researcher and the project must be approved by an ethics board (Institutional Review Board).

Participation in this DNA banking is completely voluntary. Your decision will not affect your care. You can participate in the original study without participating in the storage and use of your DNA for future research. You can change your mind at any time about storage and future use of your DNA. Please read the two options below, think about your choice, check "Yes" or "No," and sign and date below.

1) My DNA may be stored for possible use in research about other genetic health problems (for example, diabetes, Alzheimer's, Huntington's, mental illness, etc.). I understand that the investigator will be required to obtain approval from an Institutional Review Board for future use of my DNA and that I will not receive any study results from these future studies.

☐ Yes ☐ No

2) I am willing to be re-contacted in the future to understand how my genetic information acquired during this research study may have impacted my health or for other related research topics.

☐ Yes ☐ No

What does signing the consent and HIPAA authorization form mean?

A signature indicates that:

- You have read this document.
- You have freely decided to take part in the research study as describe above.
- The study's general purposes, details of involvement and possible risks and discomforts have been explained to you.

You will receive a signed copy of this consent and HIPAA authorization form.

Statement of Consent and HIPAA Authorization

I have read the consent and HIPAA authorization form or it has been read to me. I have freely decided to take part in the research study described. The reason(s) for doing the research, procedures, possible risks and benefits, and my non-research options have been explained to me.

_____ _____

Signature of Subject Date of Signature

_____

Printed Name of Subject

_____ _____

Signature of Presenter Date Presented

_____

Printed Name of Presenter

12/14/17; 12/20/17; 01/19/18; 08/02/18
H:\RADM/IN\ORIP\IRB\CONSENT FORMS\A-H\BRI10412.DOC