

***Research* Consent/*Authorization* Form**
Marshfield Clinic Research Foundation
A Division of Marshfield Clinic
1000 N Oak Avenue, Marshfield, WI 54449
SP Code: CAL10102+PM-C PI: Murray H Brilliant, PhD

Title: Personalized Medicine Research Project (PMRP)

Informed consent allows you to choose whether to participate.

The purpose of this consent form is to give you information to help you decide if you want to be a part of this research. We tell you what takes place. We will also tell you the risks or benefits and what choices you have. You can then decide if you want to participate. If you have questions, please ask.

Reasons we asked you to take part in this project.

There are three requirements to be a part of this project:

- 1) You are at least 18 years old.
- 2) You receive your medical care from Marshfield Clinic.
- 3) You either live in one of 19 Zip code areas in central Wisconsin chosen for this project **OR** you have a health problem that is being studied

Research is being done to learn how diseases develop.

Many common diseases may be passed down in families. They may be passed down through our genes. Genes are made up of DNA. DNA is found in all of the cells in your body, including your white blood cells and the cells from your cheek. These are the types of cells we use in our research. DNA is made up of chemicals that are arranged in a specific order, or sequence. Even small differences in genes may play a role in the development of disease and its response to treatment. For example, some people have bad side effects after taking some drugs. Others do not have any side effects. Disease can also be influenced by the environment in which we live or by our personal behaviors, such as diet.

The main goal of this project is to apply genetic science to human health. The project will try to do this by creating a Personalized Medicine Research Database. The purpose of this database will be to store questionnaire, genetic and medical record information. Many researchers will use this database. Some researchers will try to learn what genes cause common diseases and to find out which genes predict reactions to drugs. Other researchers could examine how the environment and genetic factors work together to cause disease. We hope all this information will help us learn to predict the development of disease and responses to drugs. If we can predict disease, we may be better able to prevent or treat disease.

Many subjects will be in this research project.

The goal is to have at least 40,000 people enroll in this project.

We plan to continue this project indefinitely.

We will continue to add to the research database indefinitely. This will allow the researchers to follow the health of a large group of people in Central Wisconsin.

You will not get direct benefit from this project.

You will not receive any direct medical benefit for being in this project. You may feel good being a part of research that could help medical science. A possible gain to you would be if new tests or therapies become part of medical practice and physicians make use of that new knowledge when caring for patients.

You will be paid for taking part in the project.

You will receive twenty dollars (\$20) for being a part of this project. If you return a completed Diet History Questionnaire you will receive an additional ten dollars (\$10).

A number of things will happen if you agree to take part in the project.

We will ask you to fill out a questionnaire. This will give us information about yourself and your environment. The family information you give will be coded to show family relationships among the people taking part in the project.

We will measure your height and weight. We will also measure and record your blood pressure.

A Marshfield Clinic staff member will draw some blood. About 5 tablespoons of blood will be collected. If a blood sample is not possible, a cheek swab or saliva (spit) sample will be used instead. The DNA, or genetic part, will be taken from your sample, and will be stored. The plasma and serum from your blood sample (if available) will be stored separately. We will link information about your DNA, plasma, and serum with selected information from your medical records and other medical samples. Other medical samples could include pathology samples or blood left from lab tests. These samples may have already been collected or may be collected in the future. We will put this information into a research database.

Research staff will have access to your medical record. Selected information from your medical record will be put into the research database. This will continue throughout the project.

You will receive a copy of your signed consent form.

We will protect your privacy and keep your genetic, medical, and other personal information confidential.

We will not put information into your medical record. Your DNA information will not be used for medical care. We will not release it to employers or insurance companies. We will treat all records and materials that identify you as confidential.

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us to protect your privacy. Researchers can not be forced to give out information that could identify you in any court matter. While not likely, government officials could try to use this information. The Certificate has not been tested in courts. This Certificate will not prevent necessary auditing or evaluation. We would still need to disclose information that is required by the Food and Drug Administration (FDA).

We will code all information entered into the database. We will not use your name, date of birth, phone, medical history or social security number as part of this code. Project staff that sees your medical record information will not be able to see genetic information. People we share research data with will see only coded information. They will not be able to identify you.

There is a federal law called the HIPAA Privacy Rule. It requires us to keep your medical information private and confidential. Some researchers we share information with may not be required to follow this federal law. In Wisconsin there is a state law that requires us to keep medical information confidential. We may share information with researchers in states with different state laws. While we work with other researchers that are very professional and are also concerned about confidentiality, we cannot guarantee they are required to follow the same rules.

Another federal law is called The Genetic Information Nondiscrimination Act (GINA) of 2008. This law will protect you against discrimination when you apply for health insurance or employment. GINA will not protect you from discrimination if you apply for other types of insurance. Wisconsin laws also prohibit discrimination based on genetic testing. But the laws do not apply to all types of genetic information. These laws can be hard to enforce. The Marshfield Clinic has a policy that does not allow discrimination in health care based on genetics. If you take part in this research, you would have no genetic information to relay to an employer, insurance company or other inquiring third party.

We will keep the Personalized Medicine Research Database on a secure computer system. It will not connect to any external network, such as the Internet. The computer is in a secure location. A limited number of approved researchers and staff have access to the database. Only a few individuals will have access to the codes that link your identity to the data.

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

Research studies using the database are reviewed. One review is to make sure the studies have scientific value. Another review is done by the Institutional Review Board (IRB). This review makes sure participants are informed and their rights are protected. If deemed necessary, you may be re-contacted for your consent to allow your samples to be used for a specific project.

If you join PMRP, approved Marshfield Clinic research staff will have access to your medical records, in addition to study related data and samples. These data and samples may be shared with trusted research partners outside of the Marshfield Clinic system. In order to minimize the risk of unintended release of information, shared data and samples will be stripped of all identifiers except for a study code to permit tracking.

Databases are being developed to help further medical research. We will share coded data with these types of databases. One example of this type of database is called “dbGaP” (short for “Database Genotype and Phenotype”). This database has been set up by the National Institutes of Health.

The Marshfield Clinic Research Foundation’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. They are required by law to keep the information private.

Researchers may present findings at scientific meetings and in scientific publications. You will never be identified in either of these.

Though unlikely, there are possible risks and discomforts of the project.

Having blood taken from a vein may result in minor pain and slight bruising. There is a small chance of infection at the site where the blood was drawn. Some people might faint when their blood is drawn.

There is a very small chance your personal information could become known to you, your doctor, or others. If research results are released by mistake it may cause you some distress. You could be treated differently. It

may cause psychological or social problems for you. This information could also affect family relationships. These risks are very low because we are careful about protecting research information.

This consent form describes the known risks of research in which DNA samples are used. There may also be risks we have not foreseen.

There is no cost to you for taking part in this project.

Neither you nor your insurance company will get a billed for study- related procedures.

Emergency care and compensation for injury.

If you become ill or injured from this study, medical care is available at Marshfield Clinic, St. Joseph's Hospital or other medical facilities. You or your health insurer would be responsible for this cost. This facility has no plans to compensate you for such illness or injury, financially or otherwise.

Commercial products, patents or licenses may be developed as a result of this project.

All samples, data and research findings will belong to The Marshfield Clinic. However, we may work with other institutions or companies to develop commercial products, patents or licenses. If these are developed, there are no plans to share profits with you. We will put any profits back into the Marshfield Clinic system. We will use the money for healthcare, education and research.

Your relationship with your doctors or this facility remains the same.

If you choose not to participate, your relationship with your doctors or with the Marshfield Clinic will not change. This research project is completely voluntary. You will not lose benefits to which you would otherwise be entitled. The decision will not affect your future medical care at the Marshfield Clinic. The same holds true if you decide to withdraw.

You can withdraw from this project at any time.

You have the right to withdraw from this study at any time. If you withdraw, we will destroy your remaining DNA, plasma and serum. 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 document your decision on a form, and ask you to sign the form. If you wish to withdraw please call us at 715-389-7733 or 1-888-334-2232.

Your relatives will not be contacted because of information you gave us.

Relatives will not be contacted because you gave us their names. They may be contacted if they meet the requirements to be in the project.

Individual results will not be shared with you.

We will not share individual results with you. Research results are often just the first step in answering questions about a disease. They often have not yet been proven. Because of this they cannot help in making decisions about patient care and treatment.

Researchers will send a newsletter up to 4 times a year. The newsletter will not contain individual results. It will have general information about studies. It may provide general information about discoveries from the project. If you wish to get this newsletter by email, please provide your email address here.

We may re-contact you for additional information.

This project will last many years. We will need to update questionnaire information. We may need to re-contact you if we are studying a specific illness or condition that you may happen to have. If you are re-contacted, it would not mean that anything has been learned specifically about you. Everyone in the study should expect to be re-contacted at some point over the life of the project.

Your DNA, plasma and serum will be saved for as long as possible. Over time, samples may be used up or lose quality. Researchers may re-contact you for another blood sample if this occurs. We may need to have samples collected over time to see what changes may be occurring.

There may be future studies.

We may re-contact you about future studies. You can decide at that time if you want to participate in other studies.

_____ Yes, you can contact me about future studies. _____ No, I do not want to be contacted for future studies.

You can contact us if you have questions.

To learn more about this project you can contact the PMRP staff or visit our website. If you have questions or concerns, please contact us. We can be reached at 715-389-7733 or 1-888-334-2232. By email: chg@mcrf.mfldclin.edu or through our website: <http://www.marshfieldclinic.org/pmrp>.

Your rights as a research subject.

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 form, your relationship with your doctor and this institution will not change.

You are not giving up any legal rights by signing this consent document and taking part in this research study.

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

Signing the consent means.

A signature indicates that:

- You have read the above.
- You have freely decided to take part in the research study described 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 form.

Signature of

☐ Subject

☐ Subject's Activated Power of Attorney for Healthcare
(Check appropriate title)

Date of Signature

Printed Name of Subject

Printed Name of Signatory (if other than subject)
(if applicable)

Signature of Presenter

Date Presented

Printed Name of Presenter

06/04/2002; 06/28/2002; 07/19/2002; 07/24/2002; 01/22/2003; 02/07/2003; 04/23/2003; 05/12/2003; 05/17/05; 06/07/05;
09/28/05; 03/08/06; 04/26/06; 12/20/06; 2/1/2010; 3/24/10; 06/21/2011; 11/30/2012; 12/14/2012

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See also:

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