Northwestern University
Center for Genetic Medicine

Consent Form for Research

PROTOCOL TITLE: A Pharmacogenomics Pilot Project in General Internal Medicine

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SUPPORTED BY: National Human Genome Research Institute (NHGRI) and the Northwestern University Center for Genetic Medicine.

Introduction

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you.

What is the reason for doing this study?

This study is being done to help us learn more about how genetic information related to certain medications is used by physicians and how this information may impact patients. We are also interested in learning how to best integrate this information into the electronic health record. You are being asked to participate because you are a physician in the Northwestern Medical Faculty Foundation General Internal Medicine clinic.

What will you do if you choose to be in this study?

A study coordinator will meet with you in the General Internal Medicine clinic to tell you about the study at a time convenient for you. This will take approximately 10 minutes of your time. If you consent to participate, you will be asked to:

- Allow us to recruit eligible patients from your practice on your behalf
- Review the list of eligible patients and let us know if there are any patients you wish for us to not contact/recruit
- Return and/or discuss patients' genetic results (such as ones related to clopidogrel, warfarin, and simvastatin) as you feel are clinically appropriate

- Participate in an approximately 45 minute long phone or in-person interview regarding your experience with the results in the electronic medical record and speaking with your patients about the results

What are some of the possible risks and discomforts?
Your participation in this study does not involve any physical, emotional, or psychological risk to you. If you do not wish to answer a question during the interview, you may skip it and go to the next question.

What are the Possible Benefits for Me or Others?

- You may not benefit from this study.
- Information obtained from this study may benefit your patients. For example, information obtained from this study may help you make choices about which medications to prescribe for your patients to help avoid medication related side effects or complications. By taking part in this study, you may help scientists better understand how genetic information is being used in clinical settings.

What other procedures or courses of treatment might be available to me?
You do not have to take part in this research study. Tests for some of the genes in this study are clinically available; you and your patients may choose to pursue testing separately.

Are there any financial costs to being in this study?
There is no cost to you for participating in this research study. A genetic counselor will be available through the study to answer any questions you or your patient has about the genetic test results. You and your patient can speak to the genetic counselor for free.

Will I receive payment for participation in this study?
You will not be paid for your participation in this study.

If I have questions or concerns about this research study, whom can I call?
Maureen Smith is the person in charge of this research study. You can call her at 312-695-0703 Monday through Friday between 9am and 5pm.You can also call Vivian Pan, the study coordinator, with questions or concerns about this research study. She may be reached via email at PGx@cgm.northwestern.edu or via phone at 312-695-5150 (Mondays and Fridays 8am – 6pm).

What are my rights as a research subject?
If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your present or future employment with either Northwestern University or the Northwestern Medical Faculty Foundation. Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

What about my confidentiality?

Involvement in this research study may result in a loss of privacy, since persons other than the investigator and research team might view your study records. Unless required by law, only the following people can review your study records and they are required to keep your personal information confidential:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
- Office for Human Research Protections (OHRP)

The results of this study may also be used for teaching, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a code number rather than your name or other identifying information.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it

_____ _____

Subject's Name (printed) and Signature Date

_____ _____

Name (printed) and Signature of Person Obtaining Consent Date