Northwestern University Center for Genetic Medicine
Consent Form and HIPAA Authorization for Research

PROTOCOL TITLE: A Pharmacogenomics Pilot Project in General Internal Medicine

PRINCIPAL INVESTIGATORS: Maureen Smith, MS, CGC; Rex Chisholm, PhD

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 about genetic testing related to a person's response to drugs.

- This document has important information about the reason for the study, what you will do if you choose to be in this study, and the way we would like to use information about you and your health.
- You are asked to be in this study because you get your healthcare from a General Internal Medicine doctor at Northwestern Medical Faculty Foundation. You may also be taking certain medications (clopidogrel, warfarin, or simvastatin) right now or possibly in the future. These medications are used for preventing strokes, blood clots, and heart diseases. They have FDA recommendations about genetic testing before prescribing. We will use information from your electronic medical record, such as your age and medical history, to predict if you may be prescribed one of these medications in the future.

Why are we doing this study?

We want to learn more about genetic differences (or variations) that can be involved in a person's response to drugs. We also want to learn how doctors and patients understand and use results from genetic tests that determines a person's response to a medication. Genetic testing is usually a blood test. Your blood will be sent to a laboratory to look at genetic differences in your DNA that are associated with changes in how drugs work in your body. Genes are the biological instructions for your body and are made up of DNA. Genes (and DNA) are passed down from parents to their children. The study of how genetic differences affect a person's response to drugs is called pharmacogenetics. More information about this study can be found in the accompanying pamphlet. To accomplish this study, we are doing two things:

1. You will be tested for a few of the genetic changes that are known to be related to how a person responds to certain medications. The results from this test will be put in your medical record with the goal of having your doctor use the results in your health care. You will learn of your results either by a letter, through your MyChart account, and/or from your physician. Physicians have also agreed to be a part of this study. Both you and your physician will be asked about their experiences with these results to help us learn how patients and doctors understand and use results from these types of genetic tests.

2. You will also donate a blood sample to help researchers learn more about other genetic changes that may be important to a person's response to drugs. Additional testing will be performed on this sample, and unlike the testing above, results from these tests will be shared with other researchers and most likely not be returned to you. No identifying information about you will be shared with outside researchers. However, as we improve our knowledge about genes that affect response to drugs, we may decide to share the additional knowledge about these drugs with you and your doctor. You will have the option to receive results from this additional testing if they become available during the study period (now through 2015).

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

A study coordinator will meet with you at the Northwestern General Internal Medicine Clinic around the time of your regular doctor's appointment. If you prefer, a separate time and location can be arranged. The first visit will be approximately 30-40 minutes long.

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

1. Complete 4 surveys during this study. You will complete the first one at our face-to-face meeting after you sign this form. The other 3 surveys will be mailed or emailed to you at approximately 1, 6 and 12 months after you receive the pharmacogenetics test results. Each survey should take about 20-30 min to complete and will ask about your expectations and experiences with pharmacogenetics testing.
2. Give about 1 tablespoon (20mls) of blood for genetic testing.
3. Let us put results of your genetic testing such as information related to clopidogrel, warfarin and simvastatin into your electronic medical record and follow how that information is used.
4. Let us store your genetic information from the additional genetic testing in a secure research database for future studies related to genes and drug responses.
5. You will be encouraged to sign up for MyChart, if you have not already done so. You will not be required to sign up for MyChart to be in this study.
6. Tell us at the end of this form if you would like to be contacted about results from any additional testing that might be performed.
7. You will receive your pharmacogenomic test results approximately 3 months after giving your blood sample. You will then receive your first follow-up survey 1 month after receiving your results and your final survey 12 months later. This would conclude your participation.

What are some of the possible risks and discomforts?

- The risks of a blood draw may include pain, a bruise at the point where the blood is taken, redness and/or swelling of the vein and infection.
- There is the potential risk for genetic discrimination. Having the genetic test results in your medical record may increase the risk to your privacy. Your insurance company may have access to this information, just like they would any other information that is in your medical record. The federal Genetics Information Nondiscrimination Act (GINA) of 2008 protects you from discrimination by health insurance companies and employers (http://www.genome.gov/10002077), and we are careful to protect your privacy.

However, we cannot guarantee that this information will not be used in an unintended way.
- Learning about your genetic risks may cause you anxiety and other psychological distress.
- As with any research study, there is the possibility for breach of confidentiality and loss of privacy.

What are the possible benefits for you?
- You may not benefit from genetic testing from this study.
- Information from this study may help your doctor make choices about drug options for you. It may also help avoid bad side effects.
- Taking part in this study may help scientists to better understand the role of genes in the way a person responds to certain medications.

What other procedures or courses of treatment might be available to you?
- You do not have to take part in this research study. Clinical genetic tests for the medications included in this study are available. You may choose to pursue testing on your own. If you choose to not participate in this study or do any pharmacogenetic testing, your doctor will make choices for medications based on the current standards of care.

Are there any financial costs to being in this study*?*
- No, you will not be charged for any costs related to the study. This includes the blood draw and the genetic tests. If you wish to speak to a genetic counselor, you may speak to a genetic counselor involved in the study for free.
- The cost of your regular medical care will be billed to you or to your insurance company in the usual way. Any follow-up procedures related to your genetic results that your doctor recommends will be considered part of your regular medical care, and will not be paid for by the research study.

Will you receive payment for participation in this study?
- No, you will not be paid for your participation in this project.
- Allowing for the storage and future testing of your tissue and blood samples will involve no cost to you. Your sample will be used only for research and will not be sold. The research done with your tissue and blood sample may lead to the development of new products in the future. No compensation will be given to you now or in the future for the use of these samples

If you have questions or concerns about this research study, who can you call?
- You can call us with your questions or concerns.
- 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 contact Vivian Pan, the project manager, at 312-695-5150 or PGx@cgm.northwestern.edu with questions about this research study.

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 right to any present or future medical treatment.

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 your confidentiality and privacy rights?

We respect your privacy. We will keep your personal information confidential. All the information we collect will be kept in locked cabinets and secured password-protected computers accessible only by authorized study personnel. We will store any identifying information separately from your subject ID.

If you take part in this study, you give us permission to use your personal health information in your medical records at the Northwestern Medical Faculty Foundation (NMFF). Your medical record may contain information from all current and previous health care providers, including but not limited to Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), and Northwestern Memorial Hospital (NMH).

Personal health information in your medical record identifies you. We may collect and use any and all the information in your medical record for this research including:

- Medical history such as past diagnoses and health concerns
- Records about medication or drugs
- Results of physical examinations, lab tests, wellness diaries, questionnaires, HIV testing, and other information that may be related to a person's response to certain drugs
- Genetic health information including family history related to allergies or reactions to medications

Any research information we share with people outside of Northwestern University will not have any personal information that can identify you unless it is required by law.

We may share some of this information with the following people:

- Northwestern Medical Faculty Foundation (NMFF)'s clinical partners, including but not limited to Northwestern Memorial Hospital (NMH), and Northwestern Memorial Physicians Group (NMPG).
- Other university research centers and university contractors who are also working on the study,

- Study monitors who make sure that the study is being done properly, such as administrative staff and members of the ethical review board who work for Northwestern University,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or research databases such as dbGaP. dbGap is a national genetic database maintained by the National Institutes of Health (a flyer about dbGaP is available for your review).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications or presentations at scientific meetings.

Certificate of Confidentiality

The principal investigator has a Certificate of Confidentiality from the federal government. A Certificate of Confidentiality helps protect the privacy of human research participants enrolled in studies that collect sensitive information. Certificates protect against legal demands, such as court orders and subpoenas, for information that could identify you in this study.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

For additional information about Certificates of Confidentiality see:
http://grants.nih.gov/grants/policy/coc/faqs.htm.

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study.

- If you take back (revoke) this consent, the researcher will also make sure that blood samples you donated are destroyed and will make sure that all information that could identify you is removed from these samples.

- To revoke your consent, you must do so in writing to:
  Maureen Smith
  Northwestern University / Center for Genetic Medicine
  676 N. St. Clair St., Suite 1260, Chicago, IL, 60611
  Email: PGx@cgm.northwestern.edu
  Phone: 312-695-5150
- Unless you revoke your consent, it will not expire.
- If you want to speak with someone who is not directly involved in this research, you can call the Northwestern University Institutional Review Board (IRB) Office at 312-503-9338. You can also call them if you have questions about your rights as a research subject.

Optional Study Elements:

Please initial your preferences below:

	Yes	No
I wish to be contacted with any additional genetic research results that may affect my health if they become available during the study period. I have been told that I may or may not receive any results.		
You may re-contact me regarding other research activities in the future not necessarily related to this study.		

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 the consent form will be provided to me after I sign it.

A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

_____
Subject's Name (printed)

_____ _____
Subject's Signature Date

_____ _____

Name (printed) and Signature of Person Obtaining Consent Date