Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dan M Roden, MD **Revision Date: 10/9/12**
Study Title: eMERGE-PGx
Institution/Hospital: Vanderbilt University

This informed consent applies to: Adults

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to be in this research study to better understand how genetic information may affect medical care of patients.

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment. There are differences in the DNA between people. These differences are called **genetic variants**.

You are being asked to provide a blood sample so Vanderbilt researchers can study your DNA to find out if you have genetic variants that may play a role in how your body responds to certain medications. In this study, we are interested in genetic variants that may:

- affect whether some people need a lower or higher dose of certain medications
- affect whether some people are at an increased risk of side effects from certain medications

By doing this study, we are developing a way to use this information in a person's medical record. We also hope to identify new genetic variants related to how people's bodies respond to certain medications

2. What will happen and how long will you be in the study?

If you agree to be in this study, you will be asked to come to the Vanderbilt Clinic to meet with the research coordinator to discuss the research project. After all of your questions have been answered about the research studyt, if you wish to be in the study, we will ask you to sign this form.

You will be asked for a sample of blood. We will take about 1 teaspoon of blood from a vein in your arm. We will take your DNA from this blood sample. Your DNA and medical information about you from your medical record will be kept for this study and shared with other researchers. We will continue to look at your medical record in the future to review your health.

If you agree to be in this study some of the genetic information we find will be put in your medical record. The genetic information that will go into your medical record are genetic variants that have been approved by Vanderbilt's Pharmacy and Therapeutics Committee as important in choosing medication dose and use. Any genetic information we find that the committee decides is not known to be important to medical treatment will remain in the your research record only and will not be entered into your medical record. **If you do not want your genetic information put in your medical record, you should not agree to be in this study.**

Your blood sample will be processed to get your DNA. The DNA, without any information that will link the DNA to you, will be sent to a central research lab.

Your samples and medical information about you will be made available to others to use for research. To protect your privacy, we will not release your name or any information that could link the samples to you.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

In the future, we also <u>may</u>:

- Ask you to complete questionnaires or be interviewed. You may decide at that time if you want to take part. You can always say no.
- Ask you to check whether any of your family members would like to be in the study. If they agree, we will contact them directly to speak with them about the study. You and your family members can always say no. Your family will not be contacted without their permission.
- Offer you the chance to be in other studies. You can always say no.
- Ask you for additional blood samples. Reasons for a new sample might include that we have used up the first sample you gave or that we want to run new tests. You can always say no.

3. Costs to you if you take part in this study:

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

4. Side effects and risks that you can expect if you take part in this study:

<u>Blood Draw Risks</u>: Drawing blood with a needle in a vein may be painful and may cause bruising, bleeding, or rarely, infection. Some people may feel faint.

<u>Confidentiality Risk</u>: As with all research, there is a chance that some of your medical information could be released. We have methods in place to prevent this from happening.

<u>Genetic Testing</u>: The risks of learning genetic test results may include emotional upset or insurance or job discrimination.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Members of the US military may not have the same protections under this law. More information about GINA can be found at www.ginahelp.org or you can ask a member of the research team to give you additional details about GINA.

5. Risks that are not known:

As with any study there may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study:

We hope that information learned from this study will benefit people with various conditions who take different medications in the future by helping doctors to prescribe the right drug to the right patient. This may help medications people take to be more effective and safer.

b) The benefits you might get from being in this study:

It is not possible to know if you will benefit by taking part in this study.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You may choose not to be in the study.

9. Payments for your time spent taking part in this study or expenses:

You will not be paid for taking part in this study.

10. Reasons why the study doctor may take you out of this study:

You may be removed from this study without your consent if staying in the study would be harmful to you, or you no longer meet the requirements of the study, or if the study is stopped. If you are removed from the study, you will be told the reason.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor.

If you decide to stop being part of the study **before** your genetic information has been added to your medical record:

- no genetic information from this study will be added to your record, and
- you will not be contacted again to provide new information or asked to participate in additional studies related to this project.

If you decide to stop being part of the study **after** some of your genetic information has been added to your medical record:

- your blood sample will be destroyed and no new genetic information will be added to your medical record;
- the genetic information from this study already in your medical record cannot legally be deleted (it will be permanent).
- you will not be contacted again to provide new information or participate in additional studies related to this project.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dan M. Roden, M.D. at 615-322-0067. If you cannot reach the research staff, please page the study doctor at 615-835-7513.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

There are many safeguards in place to prevent the release of information from this study. All research samples obtained for this study will be assigned a code. Personally identifiable information and the key to the code will be kept on secure computers and in a locked file in the research staff's office space. Only the investigator, co-investigators, and research coordinator will have access to the code and information that identifies you as being in this study.

National Human Genome Research Institute (the study sponsor) and Vanderbilt may share your information, without your personal information, with others or use it for other research projects not listed in this form. Vanderbilt, Dr Roden, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Roden and his study team may share the results of your study and/or non-study linked information including your laboratory tests, medical conditions and treatments, medication usage, and demographic information, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, National Human Genome Research Institute, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Roden in writing and let him know that you withdraw your consent. His mailing address is

Dr. Dan Roden
1285 MRB IV
Clinical Pharmacology
Vanderbilt University
Nashville, TN 37205

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment, or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title