Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dan M. Roden, MD
Study Title: eMERGE III
Institution/Hospital: Vanderbilt University

Version Date: 10/18/16

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 take part in this study because you are over 21 and have visited your primary care physician more than 3 times in the past 3 years or some symptoms in your medical record may be related to the purpose of this research.

This study is going to look at many genes in each person who chooses to be in the study. 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. In order to learn more about which genes may be linked with diseases, we will study your genes. We will look for differences that may help us better understand diseases and how to prescribe medication for them.

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

We will ask you to complete a questionnaire about your opinions about this project. This will take about 10-15 minutes of your time. You do not have to complete the questionnaire.
We will then take a blood sample (1 teaspoon) from your arm with a needle the next time you come to Vanderbilt.We will use the DNA in this blood sample for our study. **If you already have DNA saved at Vanderbilt, we will use that sample instead.**

We will be testing your DNA to find if you have any changes in genes that can cause certain diseases or can give information on how your doctor prescribes medicine for you. There is a small chance (less than 10%), that we may find changes in your DNA that could affect your medical care. If this happens, you will be given this result, and this result will be recorded in your electronic health record. If you have an account with MyHealthatVanderbilt, you will be able to see these results on this website as well.

If we find something that is important to your health while we are doing this research, we will tell you about it and put the result in your medical record. For example, we may find a change in a gene that shows you have an increased risk for certain types of cancers. We may find a change in a gene that shows that you have an increased risk of having something wrong with your heart. We may find a change in a gene that could contribute to disease in your child(ren), depending on which genes are passed on to them from you and their other parent. We may also find changes in your genes that would help your doctors pick the right medicines for you. If we find changes in your DNA that affect your health, researchers will help you find the right people to talk with to discuss these findings and for further advice about what, if anything, you should do next.

Being in this study should not keep your doctors from doing any genetic testing that you and your doctors think is needed for your medical care.

We will also ask you questions about your health history and your family's health history. We will review your electronic medical record.

We will contact you in the future when you come to visit your doctor to get additional blood samples (1 teaspoon each) while this study continues (about 4-5 years).

We will be testing your DNA to find if you have any genes that might cause certain other diseases or change how your doctor prescribes medicine for you. If we find an important gene, we will contact you with this information.

Any results you are told are not a substitute for genetic testing and counseling. You would need to contact your regular doctor and discuss these findings with him for further guidance on what, if anything, you should do next.

One to two months after and again one year after your blood is tested for the first time, we will ask you to complete another questionnaire – either online or by telephone. We will ask you about your tests and whether you have changed anything you do because of the results of your tests.

In the future, we also may:
• 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.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

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

Blood draw
Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint.

DNA samples
One risk of giving samples for this research may be the accidental release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

5. Risks that are not known:

None.

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 may learn information that could lead to new tests or treatments for your disease or condition.
b) The benefits you might get from being in this study. None

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

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

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

You will be sent a $25 gift card after you finish the first survey for this study. A $10 gift card will be sent for each additional survey you complete (up to a total of 2 additional surveys.) The total possible for completing the study is $45.

We will ask you for your Social Security number and address before you are compensated for taking part in this study.

You may receive up to $45 for taking part in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS). This information will be stored separately to keep your identity private and separate from your survey responses.

Your samples may be used to make new 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.

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

The doctor may take you out of this study if you ask to be taken out of the study. You may also be taken out of this study for other reasons. You will be told why if this happens.

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.

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 Dr. Dan Roden at 615-343-1333.

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:

All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Information that could identify you will be kept in a locked cabinet or a password-protected computer. Only members of Dr. Roden's study team will have access to this information.

Vanderbilt may share your information, without identifiers, to 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.

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 that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Roden and members of the research team will have access to your name.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

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 blood sample and medical 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. 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 37232

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

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