VICE-MPRINT: Maternal and Pediatric Pharmacogenetics Survey (MPRINT)

NCT05037305

Document Date: 10/26/2022

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: **VICE-MPRINT: Maternal and Pediatric Pharmacogenetics Survey Study**
Version Date: **10/05/2022**
PI: **Digna Velez Edwards, Ph.D., M.S.**

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.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This is a study to help learn about your opinions of genetic (DNA) testing for the purposes of helping doctors learn how to talk about these tests and results with patients. By participating, you will be providing useful information to help us improve how doctors explain the purpose of the testing, and how they talk about the results. You will also get the results of your DNA test and learn what the results mean about how your body works with certain medications. The physical risks to you are about the same as when you have blood drawn for any other test. You may be uncomfortable with some questions in the surveys or by your study results.

If you are eligible, and you choose to participate, you will complete a survey. This will take about 20 minutes. You can call or email the study staff with questions at any time. The questions will ask about your age, background, health, and lifestyle information. After the survey, you will be asked to give some blood for a DNA sample. This may be done at your convenience at a Vanderbilt University Medical Center lab on campus, at the One Hundred Oaks site, or at an upcoming appointment for a blood draw at an on-campus VUMC clinic. The test results will be in the My Health at Vanderbilt patient portal and can sent to you by mail if you want. You will also receive a link to a video on the website to help you learn what the results mean, either at the time you get your results, or a few weeks later. If you have any questions or concerns or just want more information, you can contact the study investigator, Dr. Velez Edwards. About two weeks after you get your study results, you will take another survey and answer more questions online about your medications and what you think about the tests. This will take about 20 minutes to complete. Half of participants will be asked to complete one additional survey.

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because we would like to learn more about what pregnant women think about genetic (DNA) tests that tell you how your body uses and processes different medicines.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. 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 you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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

- The common risks from using a needle to take a blood sample include pain, bruising, feeling lightheaded, and fainting
- A rare risk from a needle-stick is infection where the needle went into the skin
- These risks are the same as for any other blood test
- You may be uncomfortable with some questions in the surveys or by your study results. You don't have to answer survey questions that you don't want to.

Other Risks:
One risk of giving samples for genetic research may be the release of information (for example your name) that could link you to the results of the tests run on your samples. There are many safeguards in place however, to prevent the release of information from this study.

All 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. Velez Edwards and study staff will have access to your name.

Health insurance companies and group health plans may not use your genetic (DNA) 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.

Your sample will be destroyed after it has been tested if you have not consented to allow BioVU to keep your leftover sample from lab tests. This study will not keep or store your sample.

Good effects that might result from this study:
The benefits to you, science and humankind that might result from this study:

- You will learn more about your responses to medications, and which medications may work better for you
- You will help doctors and researchers learn how to better communicate with pregnant women about genetic test results

Procedures to be followed:
After the survey, you will be asked to give some blood for a DNA sample. This may be done at your convenience at a Vanderbilt University Medical Center lab on campus, at the One Hundred Oaks site, or at an upcoming appointment for a blood draw at an on-campus VUMC clinic. The test results will be in the My Health at Vanderbilt patient portal and can be sent to you by mail if you want. You will also receive a link to a video on the website to help you learn what the results mean, either at the time you get your results, or a few weeks later. If you have any questions or concerns or just want more information, you can contact the study investigator, Dr. Velez Edwards. About two weeks after you get your study results, you will take another survey and answer more questions online about your medications and what you think about the tests. This will take about 20 minutes to complete. Half of participants will be asked to complete one additional survey.

The purpose of this study is to look at genes (DNA) and how they affect medication response. 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. The genes we are testing in this study can help us predict how you may respond to certain medicines.

You are being asked to give a blood sample collected for genetic research. What we learn about you from this sample will be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

Payments for your time spent taking part in this study or expenses:
You will receive $25 in gift cards to compensate you for time spent participating in the study. This will include a $20 gift card if you finish the first survey questionnaire and give a DNA sample by blood draw, and a $5 gift card for completing the second survey after you receive your genetic (DNA) test results. One group of participants will be asked to take survey #2 a second time.

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You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

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 any injury caused by the usual care you would normally receive for treating your illness, monitoring your pregnancy, or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

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 study staff and researchers at pgx-survey@vumc.org or (615) 875-4491. The mailing address for the study is:

VICE-MPRINT Study
Department of Pediatrics
2141 Blakemore Avenue
Nashville, TN 37212

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 VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You may be removed from the study if you do not provide a DNA sample.

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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. We will not collect any more information about you, but we cannot delete test results that have been entered into your medical record. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Confidentiality:
This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Information collected about you may be made available to others to use for research. To protect your privacy, we will not release your name or any other information that can be used to identify you.

Study Results:
Results from the study will be shared with other researchers and will be published in a medical journal so outside researchers and doctors can read about it and learn from the results. Your name or other identifiers will never be used. If you would like to be emailed when results are published, please email study staff at pgx-survey@vumc.org.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?

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To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me. 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 _____

Time: _____