

Official Title: A Depression and Opioid Pragmatic Trial in Pharmacogenetics (Depression Trial) (ADOPT PGx)

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**Consent to Participate in a Research Study****DEPRESSION TRIAL- ADULT with Addendum Parental Permission*****A Depression and Opioid Pragmatic Trial in Pharmacogenetics
(ADOPT PGx)*****SUMMARY**

The purpose of this study is to find out if a genetic test can help your provider better manage you or your child's depression. Certain changes in genes can affect whether some commonly used medicines work well or cause side effects.

Not all medicines work the same way for everyone. It can be hard to predict who will benefit from a medicine, who will have a reduced or no response, and who will experience bad side effects. This study wants to find out how inherited differences (what you are born with) in genes affect the body's response to medicines. You or your child will be assigned in a way similar to a toss of a coin to either having your genetic information reported to you or your child's provider at the beginning of the study, or after you or your child finish the study. That information could lead to your provider making changes in your medicine, which may provide better control of your mood symptoms.

In this study, we will ask survey questions and questions about what medicines you are taking. You or your child will be asked to complete surveys at the start of the study, 1 month, 3 months, and 6 months after enrollment. Surveys can be completed in various ways, for example in-person, over the phone, or electronically. The questions about what medicines you or your child are taking will be completed with study staff in person or over the phone. The study team will collect **a blood (1 tablespoon)** sample for genetic testing. You or your child will be in the study 6 months from the time of enrollment.

Risks of the study involve pain, bruising, infection, dizziness, or fainting during or after a blood draw. Results of the genetic test may cause some individuals to feel anxious or distressed. In research, there is always a risk of loss of private information, but we have procedures in place to reduce that risk.

If you or your child are interested in learning more about this study, please continue to read below.

Notation for Parental Permission: throughout this consent document, when text states "you" or "your" it refers to "your child."

We are asking you to take part in this research study because you have been diagnosed with depression. Also, you and your provider have determined you need to take a medication to treat your depression. Research studies are voluntary. Studies only include people who choose to take part. Please read this consent form carefully and take your time making your decision. Ask the study team to explain anything you do not understand. You can speak with your family and friends before you decide to take part.

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This study is funded by a grant from the National Human Genome Research Institute, which is part of the National Institutes of Health (NIH). The NIH is a part of the US Health and Human Services that supports health research. This grant pays parts of the salaries of the researchers and their team.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, **Drs. Josh Peterson** will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

We want to find out if information from a person's genetic makeup (DNA) can help providers better control their patient's depression. DNA determines a person's body traits, like height and eye color. DNA is different in every person and is what you inherit from your mother and father. This is why you may have a different eye color, or are a different height than someone else. By being in this study, we want to find out if your DNA can help your provider choose better medicines for controlling your depression. Your provider may also find out information about other genes that may tell them how you respond to other types of medicines.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 1,500 people will take part in this study at about 50 different hospitals and practices across the United States. About **500**, people will take part where you get your care.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, we will ask you to sign and date this consent form. Being in the study is voluntary.

If you agree to take part, we will ask you to do these things at the start of the study:

- Provide a genetic sample by **blood** at the start of the study
- Complete study surveys when you first enroll. Questions will include things like your depression symptoms, how they affect your life, and about what medicines you are taking.
- We will randomly assign you (like the flip of a coin) to one of two groups:

Group 1: Your genetic test will be done right away and results will be reported to your provider

- Your genetic results will go into your electronic health record and be given to your provider along with a note with medicine recommendations

Group 2: Your genetic test will be done about 6 months after study enrollment

- Your sample will be stored at the lab. We will not do any testing and no one will know the results of the test until after you finish the study.
- After completing the study, in about 6 months, your stored sample will be tested. The results will go into your electronic health record and be given to your provider.

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- Complete the study surveys at the times below after enrollment:
 - 1 month
 - 3 months
 - 6 months
- A trained staff member from the University of Florida College of Pharmacy Call Center or your local study team will call you about your medicines at 3 months and may ask you to complete the 3 month survey over the phone
- The other study surveys can be done in-person, over the phone, or by an email or text message link
- If you choose to complete the other study surveys over the phone, a University of Florida College of Pharmacy Call Center trained staff member or your local study team will contact you.
- After completing the study, in about 6 months, you will get your genetic test results in writing.

As part of this study, we will test for genes that affect medicines used to treat depression. We will share suggestions for depression medicines with you and your provider. These genes may also affect medicines people take for other health problems. These results may help guide some medicines for those problems. If you have questions about the effect on other medicines you are taking now or may take in the future, please ask your provider or pharmacist.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study until about six months after you enroll. We will look at your medical record for information related to this study (like emergency room visits and hospitalizations) up to 12 months after you enroll.

WHAT ARE THE RISKS OF THE STUDY?

Taking part in a research study can include risks. These can include:

Blood Draw: If you give a blood sample, you may have some pain or bruising. Rarely, some people get an infection, bleed a lot, or faint due to a blood draw.

Survey: Some questions may make you feel uncomfortable. You do not have to answer them, and can always take a break if you need to.

Genetic information: There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans, and most employers with over 15 people to show bias against you based on your genetic information. However, it does not protect you against bias by companies who sell life insurance, disability insurance, or long-term care insurance.

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When your genetic information is given to your provider, your provider will receive recommendations of medicines that the genetic tests suggest should be best for you. However, there is a chance that the recommended medicines may not work as well or have more side effects than the medicines your provider would have otherwise prescribed

ARE THERE BENEFITS TO BEING A PART OF THIS STUDY?

You may or may not benefit from being a part of this study. If you are in Group 1, your provider will have your genetic information and you may have better control of your depression during the study period. However, other factors, besides genetics, also play a role in controlling depression. Whichever group you are in, your provider will have your genetic information and this may be helpful with selecting medications or doses in the future. We hope that information from this study will help benefit people with depression in the future.

WHAT ARE OTHER CHOICES THAN TAKING PART IN THIS STUDY?

Your provider can order the genetic test as part of your regular care without you being in the study. You can do this at any time. Discuss this with your provider. You are responsible for the test cost if ordered outside of this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Being in research involves some loss of privacy. We will do our best to keep your information private, but we cannot guarantee total confidentiality. We will do everything we can to reduce the risk. We will share only the smallest amount needed to conduct the research.

We have to connect your information to your samples because your provider will get your test results and put them in your electronic medical record.

Researchers involved in this study, including those funding, and overseeing the study may see your personal healthcare information. We will share only the minimum necessary information in order to conduct the research.

This study may have some support from the government, the National Institutes of Health. 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.

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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.

Research information collected about you might be put in your medical record. It is possible that you will not be able to see the research study information that has become part of your medical record until the entire research study is over.

In the event of any publication or presentation resulting from the research, no personal identifiable information will be shared.

HOW LONG DO YOU KEEP MY DATA?

The study results will be our records for at least 6 years after the study is done. Within 6 years after the end of the study, we will take out all information about you from the study results and keep the de-identified data. Your medical record will keep your genetic results indefinitely.

Some information, like your genetic information, age, sex, ethnic background, diagnosis and disease history may be entered into one or more NIH-designated scientific databases. These databases store medical research information from many studies done at many different places and are available with proper approvals to other researchers. Researchers can then study the combined information to learn even more about health and many different diseases. Your data will only be in databases for which researchers must apply for permission to use the data, and will **not** have any information that can identify you such as your name, address, and telephone number. Because your genetic information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is very small. Researchers will always have a duty to protect your privacy and to keep your information confidential.

If you have Medicare or Medicaid Insurance, or if at any point during your participation in the study you have Medicare or Medicaid Insurance, this section applies to you.

The study also wants to see if having genetic information in your health record helps improve health outcomes without additional costs. We will do this by getting details on the costs and types of related healthcare services that were covered by your insurance if Medicare or Medicaid insures you at any point during the study. The study will collect this information through claims data. Claims are filed to your insurance to cover the costs of your healthcare. We will request claims data for:

- up to 12 months before starting the study
- up to 12 months after you finish the study

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The study team will give your health care system your name, medical record number, date of birth and your unique study ID. Your healthcare system will use this information to retrieve your social security number (SSN) and/or Medicaid or Medicare insurance identification number and securely send an electronic file with this to your insurance provider (Medicare and/or Medicaid). Your insurance provider will use this information to retrieve records about your healthcare visits and cost of care and return this information to the study team. The information returned to the study team will not include your SSN or insurance identification numbers.

Your insurance provider will then link the file sent by your health care system to their records using the provided identifiers and provide all detail on healthcare claims that are submitted for you. The linked data will be de-identified. The de-identified data will be securely sent to the University of Florida with only the unique study ID as the identifier. The claims data of participants in Group 1 will be compared to the claims data of participants in Group 2. This will show us if there were less claims and/or healthcare costs for the participants in one group.

A description of this clinical trial will be available on <https://clinicaltrials.gov/> as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE COSTS TO YOU?

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. 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.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

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If you agree to take part in the study and finish all the surveys, we will pay you up to \$75 for your time and effort (**gift card**). If you take part in the study and do not complete all the surveys, we will pay you a smaller amount of the \$75, based on how many surveys you finish.

**WHAT ABOUT RESEARCH RELATED INJURIES OR OTHER PROBLEMS OR
QUESTIONS I MIGHT HAVE?**

If it is determined by Vanderbilt and the Investigator [with Sponsor input] 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 [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury

If you have any questions about the study or research-related injury, contact Dr. Josh Peterson at (615) 875-1404 during regular business hours and at (615) 322-5000 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to get information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

CAN I REFUSE TO TAKE PART OR WITHDRAW?

You do not have to take part at all. You can stop taking part at any time without losing any benefits. Your decision not to take part or to withdraw will not affect your access to health care at your institution. If you decide to stop taking part in the study, we ask that you tell a study staff member.

If you withdraw from the study, we will not collect any new data about you other than data needed to keep track of your withdrawal. All data already collected for study purposes will be sent to the study sponsor.

If our team feels it is best for your health and safety, we may withdraw you from the study. You may also be withdrawn from the study if you are in Group 2, where your genetic test is delayed until about 6 months after your study enrollment, and you or your study provider want your genetic test results prior to your study completion.

The people, agencies or institutions funding and overseeing this study may stop this study at any time without your consent. This could happen if there are problems with the way the study is being done, if the investigator believes it is in your best interest, or for any other reason. If this happens, we will notify you and discuss other options with you.



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STATEMENT OF CONSENT

"A study member has explained the purpose of this study, what will be done, the risks and benefits. I have been allowed to ask questions, and all my questions have been answered in a way I understand. I was told who to contact if I have questions, problems, concerns, or suggestions about the research. I have read, or someone read me this consent form and I agree to be in this study. I understand I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject _____ Date _____ Time _____

Printed Name of Subject _____ Date _____ Time _____

Signature of Person Obtaining Consent _____ Date _____ Time _____

Printed Name of Person Obtaining Consent _____ Date _____ Time _____

(Optional)

Signature of Principal Investigator _____ Date _____ Time _____

Name of Witness (Print) _____

Signature of Witness _____ Date _____ Time _____

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ADDENDUM FOR PARENT/LEGAL GUARDIAN SIGNATURE SECTION

When the Informed consent document states “you” or “your” that refers to “your child.”

My signature indicates that:

- As his or her parent(s) or legally authorized representative(s), I (we) give my (our) permission for the minor child named below to participate in the research study described in this Parental Permission Form.
- I (We) give the researchers permission to use and / or disclose my (our) child’s individually identifiable health information for this research study as described in this form.

Check Relation to Participant:

Parent

Legal Authorized Representative (Legally Authorized Representatives must have documented authority to give permission for a child’s participation in a research study according to the laws of the State in which the treatment occurs.)

Name of Participant (Print)

Participant Date of Birth

Name of Parent/Legally Authorized Representative (Print)

Signature of Parent/Legally Authorized Representative

Date