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

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DUKE UNIVERSITY HEALTH SYSTEM

University of Florida Consent to Participate in a Research Study

ACUTE PAIN – ADULT and Parental Permission Addendum
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 pain after surgery. Certain changes in our genes can affect if some medicines commonly used for pain control 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 side effects. We want to find out how inherited differences 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 have 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 might lead to better pain control after surgery.

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 within one month before your surgery and about 10 days, 1 month, 3 months, and 6 months after the surgery. 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, cheek swab, or mouthwash sample for genetic testing. You or your child will be in the study 6 months from the time of the surgery.

Risks of the study involve pain, bruising, infection, dizziness, or fainting during or after a blood draw. Results of the genetic test may cause anxiety or distress. 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."

You are asked to take part in this research study because you are planning to have surgery soon. 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 in this consent. You can speak with your family and/or friends before you decide to take part.

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

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, you will continue to see your surgeon like normal. If you are participating at a clinic at UF Health in Gainesville, Dr. Julie Johnson, PharmD and Dr. Larisa Cavallari, PharmD will oversee the study. If you are participating at a clinic at UF Health in Jacksonville, Dr. Alexander Parker, PhD will oversee the study.

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 patients' pain after surgery. 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 providers choose better medicines for controlling your pain after surgery. Your provider may 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 2,000 people will take part in this study at about 50 different hospitals and practices across the United States. About 850 people will take part where you get your care.

WHAT IS INVOLVED IN THE STUDY?

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

If you agree to take part, you will be asked to do the following before surgery:

- Provide a genetic sample by blood, cheek swab, or mouthwash. This will be done at the start of the study.
- Within 1 month before your surgery, a study team member may contact you to complete the study survey.
- The study survey can also be completed by email, text message, or in person.
- The questions will ask about your pain, if and how it affects your everyday life, and other questions about what medicines you are taking.
- At the start of the study, 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 test results will go into your electronic health record and be given to your provider along with a note with medication recommendations.

Group 2: Your genetic test will be done about 6 months after your surgery.

- Your sample will be stored at the lab. We will not do any testing and no one will know the test results 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.

Both Groups: After the surgery

- Complete the study surveys after surgery at the times below:
- The 10-day and 1-month study surveys will ask about what medicines you took for pain after surgery and how many pills are left for those medicines. The study surveys will be asked after surgery at the times below:
  - 10 days
  - 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 10 days and may ask you to complete the 10-day 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. One of the genes affects medicines used to treat pain. We will share suggestions for pain medicines with you and your provider. This gene 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 your surgery. We will review your medical record for information related to this study (like emergency room visits and hospitalizations) up to 12 months after your surgery.

WHAT ARE THE RISKS OF THE STUDY?

Taking part in a research study can involve certain 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 may refuse to answer them or take a break at any time.

Genetic information: 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. Additional information can be obtained at: http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer. Upon your request, your DNA information will be made available to your physician. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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 TAKING PART IN THE STUDY?

You may not get any benefit from taking part. However, if you are assigned to Group 1, your provider will have your genetic result and you may have better pain control after surgery. We hope that the information learned from this study will benefit other people 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. Researchers involved in this study, including those funding and overseeing the study, may see your personal healthcare information. We will only share the smallest amount of information 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.

To protect your privacy, a part of the government, the Department of Health and Human Services (HHS), issued a Certificate of Confidentiality. Study members may not share research information that may identify you to any other person or group unless you have written down that you approve for them to do this. If you decide to share private information with anyone not involved in the study, the law made to protect your privacy may not apply to the things you have shared.

If you need medical help, or we learn that you could harm yourself or harm others, we will share your information to connect you with needed care.

AUTHORIZATION TO COLLECT, USE AND DISCLOSE MEDICAL **INFORMATION**
If you sign this consent form, you give permission for Dr. Julie Johnson, Dr. Larisa Cavallari, Dr. Alexander Parker and their study team to report your study-related test results and medical information, which may contain personally identifiable information to the following people or groups for research:

- National Institutes of Health (NIH)
- Department of Health and Human Services (DHHS)
- United States Food and Drug Administration (FDA)
- University of Florida College of Pharmacy Call Center
- University of Florida
- Duke Clinical Research Institute (DCRI)

Your health information that the people or groups listed above may give to the researchers to use in this research study includes**:**

- Medical History and current medications
- Blood pressure
- Pulse rate
- Height and weight
- Hospitalizations, clinic visits, emergency department visits
- New and existing medical records
- Laboratory results
- Types, dates and results of various tests and procedures

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. The databases 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

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 allow us to compare claims and/or healthcare costs between the groups.

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?
The research team and study sponsor will pay for the DNA sample collection and genetic test. Neither you nor your insurer will be charged or billed for the collection or test. They are free for you. All costs related to your routine medical care and surgery, including copayments and deductibles, will be billed to you or your insurance provider as normal, just as they would if you had not been part of the study.

WILL I BE PAID TO BE IN THIS STUDY?
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. You will be given a gift card and/or a digital payment for $25 after you complete the first study survey and when you complete the 3- and 6-month study surveys after your surgery. 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 you are injured as a direct result of taking part in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists, or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your

insurance company for additional information. The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study are University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Gainesville participants: Please contact Dr. Larisa Cavallari at (352) 273-8245 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

Jacksonville participants: Please contact Dr. Alexander Parker at (904) 244-9478 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

For questions about your rights as a research participant or to discuss problems, concerns or suggestions related to the research; or to obtain 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 and provide the withdrawal verbally, through email, or in writing.

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.

The study team can withdraw you from the study if they feel it is best for your health and safety. The study team can also withdraw you from the study if you do not have surgery within 12 months of enrollment in the study.

The 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 occurs, 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."

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

(Optional)

_____
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