EASTMAN
INSTITUTE FOR ORAL HEALTH

UNIVERSITY of ROCHESTER MEDICAL CENTER
MEDICINE of THE HIGHEST ORDER

CONSENT FORM

Utility of Pharmacogenomic Testing and Postoperative Dental Pain Outcomes

Principal Investigator: Yanfang, Ren, D.D.S, MPH, PhD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you are between the ages of 18-35 and are having at least one impacted lower jaw wisdom teeth removed.

This study is being conducted by Dr. Yanfang Ren at the University of Rochester's Department of General Dentistry and Urgent Care at Eastman Institute for Oral Health

Purpose of Study

- The purpose of this study is to determine whether testing for your genetic make-up can help dentists to select the appropriate pain medications to

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manage dental pain after your wisdom tooth or teeth extraction. If you do not reach a certain level on the dental pain scale 6 hours after the numbness in your mouth wears out, you will be withdrawn from the study and standard of care procedures will be carried out. In addition, saliva samples that were taken from you, will be discarded and will not be stored. If you are withdrawn from the study, you will receive US$50 for your time and participation.

Description of Study Procedures

If you choose to participate and qualify for the study, the following will happen:

Screening visit:

- First, your medical chart will be reviewed to determine if you are eligible to participate in this study.
- If eligible, you will be asked to read a consent form, ask questions about the research. If agree, you will be asked to sign the consent form and a copy will be handed out to you.
- Once you enroll in the study genetic testing will be carried out. This testing consists of spitting approximately 5mL (the equivalent of a tablespoon amount) of saliva into a special laboratory tube. A special kit with supplies to carry out these activities will be used only for you.
- The special laboratory tube with saliva will be sent to a laboratory outside the University of Rochester with only a code that will identify you for this study; no additional personal information will be needed. This laboratory will study your saliva for a specific genetic make-up.
- The genetic testing results, with only a study code with no additional personal information of yours, will be sent to a specialist (examiner) involved in the study at Eastman Institute for Oral Health. Dr. Ren and research investigators involved in your surgery (for this study) will not know which pain medication will be given to you after your surgery.
- You will be asked to answer questions such as your response to pain medications in the past, and how you typically respond to pain.
- You will also be asked about family history of taking pain medications, etc. Then, a complete physical examination will be carried out and intervention will be scheduled.

Surgery and post-surgery visit:

- You will have no food after midnight, except for clear liquids up to 2 hours prior to surgery. You will be reported to the clinic on the morning of your surgery.
- Before the surgery, if you are female we will ask you to take a pregnancy test.
- After your wisdom teeth are removed, you will be monitored in the clinic for pain. This may take up to 6 hours for the numbness to wear off and for you to start feeling pain. You will be asked to rate your pain on a scale of 0-100mm. If your pain is rated more than 50mm you will be assigned 1 of the

two groups in the study. You will be randomly assigned (like the flipping of a coin) to one of the following:

- Control group where you will receive a single dose of a pain medication called Vicodin®(hydrocodone/acetaminophen 5mg/650mg) or
- Experimental group where you may receive a single dose of acetaminophen (Tylenol®) 650 mg or ibuprofen (Motrin®) 400mg, depending on your specific genetic testing.

Neither you nor the study team will know which group you have been assigned to or what medication you are given. To prevent you from recognizing the medication, you will wear a mask over your eyes before you take the medication.

- You will be asked to complete some questions about rating your pain on a scale of 0-100mm. These questions are to be completed 15 minutes, 30 minutes, 1 hour, 1.5 hours, 2 hours, 3 hours, 4 hours, 5 hours, and 6 hours after having taken the study medication. Also, during these times, the study investigators will take vital signs.
- Additionally, three to four (3-4) minutes after you take the study medication, you will be given two stopwatches and asked to stop one when you first feel pain relief. You will also be asked to stop the 2nd stopwatch when you feel much better pain alleviation. At the end of the six hour period, you will be asked to provide an overall evaluation of the study medication.

In the event that the study pain medication is not effective we will give you a non-blinded second medication (rescue medication) named Percocet® (oxycodone/acetaminophen 5/325mg) which is considered also standard of care for pain associated with wisdom teeth removal. We will ask you additional questions about your pain after the medication is given.

You will be dismissed once the investigators determine you are ready to leave the clinic with the following criteria:

1) Your pain is controlled,
2) You are not showing an adverse effect of pain medications, such as excessive sleepiness or drowsiness and
3) You have a companion with you all the time.

You will be given standard home care instructions about wisdom teeth removal including how to contact general dentistry and dental urgent care dentists for any concerns.

Although this is a 12-hour study, you can contact a dental provider any time after your procedure, if you have questions or surgical pain continues. Dental staff

contact information will be provided in the postoperative instructions given to you when you are sent home and ready to leave the dental clinic. Genetic results will not be given to you, but, any incident related to this study will be managed according to guidance stated in the protocol document. Also, if you agree your genetic sample will be stored for future research.

The following information about your study participation will be included in your electronic health record.:

- Documenting you are in this study
- A copy of your signed consent form

Information about Genetic Testing

We are asking your permission to store and share your saliva sample collected during the course of this study for future testing. These future tests are not yet planned, and may or may not be related to this study. These future tests may include testing in relation to your genetic profile.

The purpose of storage and sharing of samples and data for future testing is to make information and samples available to other researchers for use in health research. Collecting, storing and sharing information and making it available for other studies may help people in the future.

The results of future tests performed on stored or shared samples or reports resulting from the analysis of your research samples will not be given to you or your doctor and they will not be put in your dental record. They will not identify you and will not affect your routine dental care.

There is no benefit to you from the storage of samples and information.

If you decide to allow storage, your samples and information may be stored for an unknown length of time. Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your medical information in our databases back to you. There may also be other privacy risks that we have not foreseen. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

Your decision regarding the storage of samples for future testing, or the information resulting from the analysis of your samples will not affect your ability to participate in this study.

☐ Yes, you may store my saliva sample for future genetic research.

☐ No, you cannot store my saliva sample for future genetic research

Number of Subjects
Approximately 238 subjects will take part in this study.

Duration of the Study
Your participation in the study will last about 12 hours, plus the time for consenting and genetic testing that involves approximately, 30 minutes before wisdom teeth extraction(s).

Risks of Participation
Potential risks of participating in this research study are those risks associated with routine wisdom tooth/teeth extraction, side effects of pain medications that include; nausea, allergic reaction, sleepiness, constipation and dizziness.

Also, you can also experience delay in receiving pain medications or ineffective pain control from your participation in this study.

You may be withdrawn from this study after the 6 hours if you do not meet the pain threshold.

Because this study will involve collecting personal information that can identify you, including your genetic profile, there is a possibility for invasion of privacy and loss of confidentiality. To minimize this risk, we will assign a number instead of your name or other personal information we collect about you. All these information will be stored in a secure manner accessible to study personnel only.

A description of this clinical trial will be available on http://www.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 website at any time.

Benefits of Participation
You will not benefit from participating in this study.

Alternatives to Participation
Instead of being in this research study you may choose not to participate and receive standard of care medications for pain management.

Costs
You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

Payments
You will be paid a total of $50 for participation in the study, even if you do not get randomized.

Reimbursement for Travel Expenses
You will be offered a parking voucher to cover any parking expenses.

Compensation for Injury
If you are directly injured by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University,we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose

Confidentiality of Records
Every effort will be made to maintain the confidentiality of your medical and research records related to this study. The monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies) will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representatives are authorizing such access.

The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law. If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present dental records related to the study
- Results of dental X-rays

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Admera Labs

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon

receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort, please contact: Dr. Yanfang Ren, Principal Investigator at 585-273-5588.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation
Taking part in this study is voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____

Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date