Principal Investigator: **Karsten- Bartels, M.D., Ph.D.**

COMIRB No: **18-2098**

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Study Title: **24-hour oral morphine equivalent based opioid prescribing after surgery**

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about more about the use and prescription of opioid pain medications after surgery and the best way to estimate how much medication will be needed for effective pain management. In the future, we would like to better estimate how much medication patients actually use and need.

You are being asked to be in this research study because you recently had surgery at the University of Colorado Hospital.

Other people in this study

Up to 54 people from your area will participate in the study.

What happens if I join this study?

If you join the study, your medical provider will be given a dosing suggestion thru an Electronic Health Record (EHR)-based Prescription Tool to recommend how much pain medication you will need when you are discharged. Final dosing decisions and drug choices will remain at the discretion of your treating provider.

We will ask you to provide contact information so that we can reach you after you are discharged from the hospital. You will be asked to complete a brief online questionnaire asking about your use of prescribed medication and pain management every week for the first four weeks after hospital discharge. Each of the four surveys will take about 10 minutes to complete. You will also complete a short online survey one time to answer some questions about how you are feeling and your pain management. If your pain is not adequately managed we may also contact you by phone and/or email. You can also complete the surveys by filling out a hard copy form or by phone if that is more convenient for you.

We will access your Electronic Medical Record at the University of Colorado Hospital to get demographic data, information on what type of surgery was performed, prescribed and non-prescribed medications, and additional clinical information that may potentially affect how your pain was managed.

How We Decide Which Study Group You Will Be In

This study will have two different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get different versions of the Prescription Tool recommendation. You will not be told which study group you are in.

What are the possible discomforts or risks?

Discomforts you may experience while in this study, and other possible risks include:

Common Risks:

- Tiredness or boredom when completing study assessments.

Uncommon Risks:

- Tension or nervousness may occur from completing the study assessments. You can talk with the researchers about such problems, and can terminate the study if you wish.
- Problems with pain management. The study team will follow-up with you about your pain management and you will also be given a phone number where you can reach a surgical provider 24 hours a day/7 days per week in case pain therapy is inadequate.

Rare But Serious Risks:

- Breaches of confidentiality. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information and keep it confidential, but it cannot be guaranteed.

What are the possible benefits of the study?

This study plans to learn more about more about the use of prescribed opioid pain medications after surgery and how using an EHR-based Prescription Tool may affect the prescription and use of pain medications.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Will I be paid for being in the study?

You will be paid for your time and inconvenience in completing this study. You will receive a $10 gift card or an equivalent money order if so desired ($40 total for all four surveys). If you leave the study early, or if we have to take you out of the study, you will be paid only for the part of the study you have completed.

It is important to know that payments for participation in a study are taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Who is paying for this study?

This research is being paid for by the University of Colorado, Department of Anesthesiology and the National Institutes of Health (NIH), a federal agency.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. We may also contact you in the future to ask if you would be willing to participate in other research studies, but you do not have to participate in any other studies if you don't want to.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Karsten Bartels immediately. His phone number is (303) 724-0166.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Karsten Bartels. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Bartels at (303) 724-0166. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Bartels with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it. The institutions involved in this study include:

- University of Colorado Denver

- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

- Dr. Karsten Bartels, Mail Stop F570, 13001 E. 17th Pl., Aurora CO 80045.

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals or share data that does not identify you with qualified investigators as required by some journals. But we will always keep identifying information of research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Information about you that will be seen, collected, and used in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results, medications
- Research Visit and Research Test records
- Billing or financial information
- Other (please specify): _____

What happens to Data that is collected in this study?

Scientists at the University of Colorado Denver and the hospital involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Some of the data collected by the researchers during the study may be submitted to a research data repository where other scientists, outside of this research team, can utilize data to answer new questions. We will not include any identifiers (e.g., name, date of birth, etc.) with that data.
- If data are in a form that identifies you, UCD or the hospital involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study. I will get a signed and dated copy of this consent form.

Participant Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____