CONSENT FORM
Adult Consent Form

Title of this Research Study
Efficiency And Quality In Post-Surgical Pain Therapy After Discharge EQUIPPED

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

We invite you to take part in this research because you are having or had surgery and have been prescribed opioid pain medication.

The purpose of the study is to learn more about opioid pain medication after surgery. The study will also test how a phone app may affect the use of pain medications. We would like to better estimate how much medication patients actually use and need.

This study is not designed to treat any illness or to improve your health. There may be risks, including discomfort doing the study questionnaires and loss of confidentiality.

You may benefit from the phone app as it may help you manage your pain after discharge.

Instead of being in this research study, you can choose not to take part. If you decide not to participate you will receive routine care.

Why are you being asked to be in this research study?
You are being asked to be in this research study because you recently had surgery or will have surgery at UNMC/Nebraska Medicine. You are 19-89 years old.

Up to 700 people will take part in this study at UNMC/Nebraska Medicine.

What is the reason for doing this research study?
This study plans to learn more about the use of prescribed opioid pain medications after surgery and how using the phone-based app may affect the use of pain medications.

What will be done during this research study?
If you enroll in the study, you will install the *UControlPain* application (app) on your phone. You will be placed in one of two groups by the flip of a coin. You have an equal chance of being randomized to either of the two groups. One group will be using an app with only data collection and one will use the app with educational function.

Using the app, you will be asked to complete a brief questionnaire asking about your pain management every week for the first four weeks after hospital discharge. Each of the four surveys will take about 10 minutes to complete. We will also ask you to complete a weekly walk test and count your steps using the app.

We will access your Electronic Medical Record at UNMC/Nebraska Medicine 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.

We will also contact you by phone after you are discharged to ask you some questions about using technology like this to help manage pain after surgery. If you answer these questions they will be digitally recorded and stored without your name or other identifiers on a secure UNMC server.

At the completion of the study you will be asked to uninstall the application on your smartphone. The study staff will give you specific instructions for your smart phone device.

What are the possible risks of being in this research study?
Discomforts you may experience while in this study, and other possible risks include: tiredness or boredom when completing study assessments, tension or nervousness may occur from completing the study assessments, and 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 to you?
This study is not designed to treat any illness or to improve your health. However, if you are randomized to the educational app, you may benefit from the app, as it may help you better manage your pain after discharge.

If you are randomized into the educational group you may benefit from the summaries of educational materials that may be much more difficult and cumbersome to find independently.

Both subject groups may find the pain diary function helpful to identify triggers and remedies for post-discharge pain.

You may not get any benefit from being in this research study.

What are the possible benefits to other people?
This study plans to learn more about the use of prescribed opioid pain medications after surgery and how using a phone-based app may affect the use of pain medications. This study may benefit society in terms of advancement on the use of prescribed opioid pain medications after surgery.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will be paid for your time and inconvenience in completing this study. You will receive a $10 Visa gift card per week for each of the four weekly surveys completed. 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.

Who is paying for this research?
The Agency for Healthcare Research and Quality (AHRQ) gives us money to do this study.

What should you do if you are injured or have a medical problem during this research study?

Your health and safety is our main concern. If you are injured or have a medical problem or some other kind of problem because of the study call someone listed at the end of this consent form.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible. The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. These groups are NOT required by HIPAA to protect your PHI. If we share your PHI with these other groups they may share it with others who also do not have to protect it under HIPAA.

- Agency for Healthcare Research and Quality (AHRQ), which sponsors this research and may pay the Organization to do this research
- The Data and Safety Monitoring Committee (DSMC)

You are letting us use and share your research data for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?
Information obtained in the course of the research that will not be shared with you is your treatment group. By signing this authorization, you are temporarily giving up your right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical

Center, Omaha, NE 68198-7830

- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____ Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
* Bartels, Karsten
alt #: 402-559-4081
degree: MD PhD MBA

Lead Coordinator
* Hoffman, Julie (Julie)
alt #: 402-559-8299
degree: MSN RN

Other Coordinator

Akwani, Chika
alt #: 402-552-3077
degree: BS

* Harper, Rachel (Rachel)
phone: 402-559-2905
alt #: 402-559-4335
degree: RN

* Sanchez Rodriguez, Emely (Emely)
alt #: 402-552-3077
degree: BS

* Williams, Bailey
alt #: 402-552-3077
degree: BS

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: sirb@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.