To Whom It May Concern,

Attached is the informed consent document, last approved on April 25, 2023 for the grant titled, "Preventing Persistent Post-Surgical Pain and Dysfunction in At-Risk Veterans: Effect of a Brief Behavioral Intervention." (NCT03965897)

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name:

Title of Study: Preoperative Pain and Rehabilitation Education (PrePARE)

Principal Investigator: Barbara Rakel, PHD, RN **VAMC:** Iowa City, Iowa

INFORMED CONSENT DOCUMENT

Project Title: **Preoperative Pain and Rehabilitation Education (PrePARE)**

Principal Investigator: Barbara Rakel, PhD, RN, FAAN

Research Team Contact: **Jennie Embree**
Phone: 319-335-6883
Email: jennie-embree@uiowa.edu

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are a Veteran who is being considered for total knee replacement surgery.

The purpose of this research study is to learn if a group skills workshop with individualized follow-up can lead to less pain and better function after a total knee replacement.

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HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 215 people will take part in this study conducted by investigators at the Iowa City VA Health Care System. A total of 430 people will take part in this study nationwide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last from now to about 6 months following your scheduled surgery date/s. You will first be asked to complete several surveys. Completing these surveys should take 60-90 minutes. If you are eligible to continue participation in the research and your provider determines you should have total knee replacement surgery, you will then be scheduled to attend a 5-hour skills workshop. Approximately 2 weeks after your surgery, you will receive a 20-40 minute follow-up call to review the material covered during the workshop. You may also receive a second follow-up call if the study staff determine it is necessary.

You will also be asked to complete several surveys at 1 week, 6 weeks, 3 months and 6 months after surgery. Completing these assessments and surveys should take 60-90 minutes each time. You may also be asked to complete a daily medication log after surgery. If you are having two knee replacement surgeries, we will ask you to complete these surveys and daily medication logs after each surgery.

WHAT WILL HAPPEN DURING THIS STUDY?

- We will first go over this form and will ask you to sign it if you are interested in participating in this research study.

- We will administer three surveys and one assessment to determine if you are eligible to continue participation. The surveys will ask you about basic demographic and medical history, pain, and symptoms of depression and anxiety. The assessment will measure cognition. Completing these surveys and assessment should take 15-20 minutes. If you are eligible to continue participation, you will also be asked to fill out a second set surveys about your daily pain, function, mood, and quality of life. Completing these

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surveys will take about 1 hour. These surveys may be completed on your own or we can read them to you, depending on what you prefer. We may ask you about your responses if they are unclear and you may skip any question you prefer not to answer. You will then be scheduled to attend a skills workshop sometime before your surgery. If you are scheduled to attend a virtual skills workshop, a team member will contact you by phone to help you get set up.

On the day of the skills workshop, you will also be randomly assigned to receive one of the two study interventions. This means that whichever study intervention you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving any one of the study interventions. Both interventions involve attending a five-hour skills workshop with other patients that will be facilitated by two psychotherapists. The content of the workshop will depend on what group you are assigned to, but will broadly focus on preparing for your surgery and managing pain. Both workshops will include education on pain and pain-control post-surgery and also teach skills for better coping. Breaks will be offered to minimize fatigue. If you attend a virtual workshop, you will be asked to complete and return a short survey about your experience.

- Post-Surgery Follow-ups:

1. Approximately 3 days after surgery, if you are taking any opioid medications, you will receive a packet of daily medication logs to complete and return (in pre-addressed and postage-paid envelopes) weekly.

2. Approximately 2 weeks after surgery, you will receive a 20-40 minute follow-up call to review the material covered during the skills workshop. If you have any complications after surgery, or if the facilitator determines that additional guidance would be helpful for you, you may receive additional 20-40 minute follow-up calls to review the material again.

3. You will also be asked to complete surveys about your daily pain, function, mood and quality of life at approximately 1 week, 6 weeks, 3 months, and 6 months after your surgery. Completing these surveys will take 20-60 minutes. We may contact you by telephone to ask you about your responses if they are unclear and you may skip any question you prefer not to answer.

4. If you report experiencing high pain at 6 months, we will contact you to request permission to notify a case manager in the orthopedics clinic. If you give us this permission, we will contact the case manager

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and provide them with your name, your pain score, and the area/s of worst pain. This will allow the case manager to arrange for a provider to contact you to discuss treatment options.

- If you are having two knee replacement surgeries, and the second surgery is completed before your 6-month post-1st-surgery study follow-up is complete, then the following will happen: after completing the second surgery, you will discontinue the scheduled follow-ups for the first surgery and restart all follow-ups for your second surgery.

- If you do not have surgery after attending the workshop, you may be asked to complete a set of surveys about your daily pain, function, mood, and quality of life. You may skip any question you prefer not to answer.

The following will be collected from your medical record for use in this research: birthday; current medical conditions; medications taken before and after your total knee arthroplasty/ies (TKA/s); dates of your TKA/s, and whether you experience complications associated with your TKA.

Upon enrollment, you will be provided with the phone number of the Iowa City VAMC's Suicide Prevention Coordinator as well as the Veteran crisis hotline. If at any time during study procedures you provide information that leads us to believe that you are at risk for harming yourself or others, we will contact a study psychologist to perform a risk assessment. We may contact your current mental health provider (for example, your psychiatrist) to allow him/her to do what is necessary to help you. If you do not have a mental health provider, we may contact a close friend or family member to ensure your safety. If you would rather we not contact anyone and we still feel you or someone else might be in danger, our study psychologists will determine what else can be done to help you. This may include recommending you go to the emergency room. Also, if you suggest that suicide is imminent, you will be excluded form participation in the study.

Data Storage for Future Use

As part of this study, we are obtaining data from you. The University of Iowa College of Nursing is designated for storage of an identifiable data sample**.** We would like to study your data in the future, after this study is over.

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The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding post-surgical pain, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data,but decide in the future that you would like to have it removed from future research, you should contact Barbara Rakel at 319-335-7036. However, if some research with your data has already been completed, the information from that research may still be used.

Future Studies

We would like to be able to contact you in the future to determine your eligibility for future studies within our lab. If you agree to be contacted, we will add your name, address and telephone number or email address to our callback list. Only members of our research team will have access to the callback list and all other information obtained during the study will be separated from identifying information and stored in a locked room. In addition, agreeing to be in the current study does not obligate you to participate in any of our future studies, and a separate Consent Document would be signed for future studies.

My contact information may be kept for future opportunities to participate in research.

Please initial the appropriate box

_____ Yes _____ No

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Interviews and surveys: You may feel uncomfortable answering questions related to your surgery, personality, emotions, and behaviors. You may also experience some fatigue after answering many questions.

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Workshop: During the workshop, you may feel uncomfortable being in a group setting and you may experience fatigue because you are spending many hours in the workshop. You may also experience emotional discomfort when sensitive issues, such as your problems with pain, pain medications, and function, are addressed.

In order to remedy these potential risks, 1) you will be given the opportunity not to participate, 2) you may stop the study at any time, 3) you may ask questions of the investigator at any time, 4) you do not have to answer any questions that you do not want to answer, 5) you will be given breaks during the workshop, 6) all participants in the group will be encouraged to only use their first names for the purpose of confidentiality, and 7) participants in the group will be asked to keep all personal disclosures of other group members confidential. For the virtual (online) workshop, a secure Zoom platform will be used where attendees will be provided a password to be able to join the workshop. This will protect your privacy by ensuring that only invited participants will be able to join the workshop.

There is also a risk of loss of confidentiality. Measures in place to protect confidentiality of data are indicated in the 'What About Confidentiality' section later in this document.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the study team while you are participating in this study. You also authorize disclosure of the picture and/or voice recording to *Barbara Rakel, 50 Newton Rd, Iowa City, IA 52242.* The said picture, video, and/or voice recording is intended for the following purposes: to ensure quality control of the workshops. Recordings will be destroyed when the study is completed and the needed data is retrieved.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

[ ] Yes [ ] No I give you permission to make audio recordings/ video recordings of me during this study.

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WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of knowledge gained about this treatment for veterans with emotional distress undergoing surgery.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive treatment as usual and/or see a psychologist to address your emotional difficulties. A member of the research team can provide you with referrals if you are interested.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number, address and citizenship status in order for us to pay you. You may choose to participate without being paid if you do not wish to provide this information. Your SSN is obtained for payment purposes only. It will not be retained for research purposes.

If you are having one knee replacement surgery, you will be paid a total of $200 over the course of your participation in the study according to the following schedule:

- Completion of enrollment screening only: $15 (by gift card or check, depending on participant preference)
- Completion of enrollment screening and pre-randomization surveys only: $25
- Completion of enrollment screening, pre-randomization surveys and workshop: $50 (by gift card or check, depending on participant preference)
- Completion of 1-week post-surgery follow-up: $25

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- Completion of 6-week post-surgery follow-up: $25
- Completion of 3-month post-surgery follow-up: $25
- Completion of 6-month post-surgery follow-up: $75

If you are having two knee replacement surgeries, and the second surgery is before completion of your 6-month post 1st surgery study follow-up, then your post-surgery compensation will change based on the number of follow-ups you complete. For each follow-up you complete, you will be paid $25 except for the 6-month post- surgery follow-up, for which you will be paid $75.

If you do not have surgery after attending a workshop, you will be paid $25 to complete a survey about your medications, daily pain, function, mood and quality of life.

You will also receive travel reimbursement at .20/mile (or the equivalent of what the VA provides if you are qualified by the VA to receive travel compensation) for each special trip you make for participating in this study. Finally, if you attend an in-person workshop, you will receive lunch and a parking pass (if necessary) on the day of the workshop.

The University of Iowa will issue compensation checks. If you do not cash a check within 4 months of its issue, you will likely receive a letter from the Accounts Payable department with instructions for receiving the payment by direct deposit. If this happens and you do not wish to utilize direct deposit, please contact us and we will arrange for a replacement check to be mailed to you.

If you are loaned a tablet for attending a virtual workshop, payment will be issued once the tablet is returned.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that the University of Iowa is receiving payments from the National Institutes of Health to support the activities that are required to conduct this study. No one on the research team will receive a direct payment or increase in salary from the National Institutes of Health for conducting this study.

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WHAT ABOUT CONFIDENTIALITY?

It is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- Iowa City VA Health Care System
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will use a code to identify the information we collect from you and save this information in locked filing cabinets and in password-protected computer files. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. Because some of the study activities involve group settings with other subjects, we cannot guarantee that others in the group will keep information disclosed during the group workshop confidential.

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate means that the researchers cannot be forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a Certificate of Confidentiality does not prohibit the researcher from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you request in writing that information about you or your participation in the research be released to an insurance company, the researcher may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the researcher is not prevented from taking steps, including reporting to appropriate authorities, to prevent serious harm to yourself or others. You may receive a copy of the Certificate of Confidentiality upon request.

IS BEING IN THIS STUDY VOLUNTARY?

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Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. Your decision to participate or not will not affect the clinical care you receive.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to describe your reasons for withdrawing and provide feedback on the study. This will be done either in person or by phone. If you were loaned a tablet to attend a virtual workshop, we will also arrange with you to have it returned.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because your condition has become worse or because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or experience a research-related injury, please contact: Jennie Embree at 319-335-6883 or Barbara Rakel at 319-335-7036.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. A copy of the VA brochure 'Volunteering in Research,' (found at http://www.research.va.gov/programs/pride/veterans/Volunteering-in-Research.pdf) has been provided to the prior

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to signing this informed consent document. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

RESEARCH SUBJECT'S RIGHTS

I have read or have had read to me all of the above. Barbara Rakel, PHD, RN (or one of her research team members) has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The Iowa City VA Health Care System is available to provide necessary medical treatment for any injury resulting from participation in this research study. I have been told that I will not be required to pay for care received as a subject in this study except in accordance with federal law (Title 38 United States Code 1710(f) and 1710(g)) and that certain veterans are required to pay co-payments for medical care and services provided by the VA.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Signature Date

STATEMENT OF PERSON WHO OBTAINED CONSENT

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Department of Veterans Affairs

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I have discussed the above points with the subject or, where appropriate, with the subject's authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person Who Obtained Consent) (Date)

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