Participant Name: _____ Date:_____

Title of Study: Veterans' Pain Care Organizational Improvement Comparative Effectiveness (VOICE)

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Erin Krebs MD, MPH; William Becker MD; Karen Seal MD,MPH

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study funded by the Patient Centered Outcomes Research Institute (PCORI). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

This study will compare two pain care delivery methods to determine which one helps more patients achieve improvement in pain.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if anything is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study will compare pain care delivery methods to determine which one helps more patients achieve improvement in pain. Your participation in this research will last one year.

Patients who wish to enter the study will be assigned by chance to receive either "Pharmacist Pain Care" or "Integrated Pain Care" management for pain. Patients in the "Pharmacist Pain Care" group will have their pain managed by a pharmacist and a physician working together, but will have one-on-one appointments with the pharmacist, who has been specially trained in pain management. Patients in the "Integrated Pain Care" group will work with a multi-disciplinary team of clinicians. All patients in the study will get personalized care to figure out what pain treatment plan works best for them as individuals. Also, for patients on high doses of opioid medication who want to cut down on their dose, the study will also test whether offering an extra medication option helps them succeed.

- This research study is being conducted because many people who are treated with daily opioid medications (such as morphine and oxycodone) continue to have serious pain. Individualized treatment can help some people have less pain and/or lower opioid doses. This study is comparing two different ways of delivering individualized pain care.
- This study is for patients who have moderate or severe pain despite treatment with medium or high doses of opioid pain medications.

- By joining this study, you are agreeing to be assigned to receive care from Pharmacist Pain Care or Integrated Pain Care providers. You are not being asked to agree to any specific medication or pain treatment. Your assigned pain care provider(s) may recommend changes to your medications or pain treatments. Recommended treatments will be standard pain treatments, not experimental treatments.
- The study will be conducted at 10 different VA sites, including [NAME OF LOCAL VA].
- The Minneapolis VA Medical Center will operate as the coordinating center for the study.
- The study will enroll approximately 1,000 people in total.
- This study is funded by the Patient Centered Outcomes Research Institute (PCORI), an independent nonprofit, nongovernmental organization.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may benefit from individualized pain care in this study and the information we get from this study may help us treat future patients and Veterans.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may feel stress when responding to interview questions, or committing to minimum number of study appointments and interviews (see below for details). For a complete description of risks, see pages 6-7.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

- The person in charge of the study is *Local Site Investigator name}* at the [*insert name of VA facility*.] If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [local site investigator: [NAME AND PHONE]

Participant Name: _____ Date:_____

Title of Study: Veterans' Pain Care Organizational Improvement Comparative Effectiveness (VOICE)

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Erin Krebs MD, MPH; William Becker MD; Karen Seal MD,MPH

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This study will compare two pain care delivery methods to determine which one helps more patients achieve improvement in pain.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 6 years. Your individual participation in the project will take 1 year.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to take part in this study, this is what will happen:

Randomization: The [local VA facility] study coordinator will randomly assign you to one of two treatment groups, either Pharmacist Pain Care or Integrated Pain Team.

- You will be placed into a group based on computer program (like a flip of a coin, but computerized). Neither you, nor the study coordinator, can choose a specific group.
- Both treatment groups provide active pain care from VA health care providers:
    - If you are assigned to the Pharmacist Pain Care group, you will have an initial appointment (in-person or by video if possible) at the start of the study. You will have telephone follow-up appointments at least every month for the first 2 months then at least every 3 months. You may have more appointments if needed.
    - If you are assigned to the Integrated Pain Care group, you will have at least two appointments (in-person or by video if possible) in the first 3 months of the study. You will have telephone follow-up appointments at least every month for the first 6 months then at least every 2 months.
- You, your primary care team, and the study team at [local VA facility] will know which group you are assigned to.

Pain treatment: You will receive pain care in your assigned treatment group, either the Pharmacist Pain Care or Integrated Pain Care.

- You will have your first appointment with your study health care provider(s) at [local VA facility] as soon as possible after you enroll. This will include discussion of your pain, pain treatment history, and treatment goals and preferences. The appointment will take about one hour.
- You will receive information about pain treatment options. Your pain care provider(s) will work with you to develop a pain care plan.

  - Your pain care plan will be based on your individual needs. It can be adjusted during the study based on how you are doing and how your needs change.
  - Pain care plans will include FDA-approved medications and/or established therapies available in VA. They will not include experimental medications or other experimental treatments.
- You will have regular follow-up appointments by telephone with your pain care provider(s). If you are assigned to the Integrated Pain Care group, you will have at least 2 face-to-face follow-up appointments if possible; telephone may be used for these appointments if needed. These appointments will usually take 20-30 minutes.
- You may have additional face-to-face or telephone appointments depending on your needs and preferences.
- When necessary or at your request, video or telephone appointments may be substituted for in-person visits.
- If you wish to reduce your opioid medication, your pain care provider(s) will discuss options for how to do this. If you agree, they will help you reduce your dose safely and comfortably.
- Your assigned Pharmacist Pain Care or Integrated Pain Care provider(s) will enter progress notes in your electronic medical record and coordinate care with your usual VA primary care team.
- You may decide at any time that you do not wish to continue working with your assigned Pharmacist Pain Care or Integrated Pain Care provider(s). Please tell a research staff member if this is your decision. Your pain care will be transitioned back to your regular primary care provider.

Possible recording of appointments:
There are two instances where you may be audio-recorded for this study (audio recording only, no photographs or video recordings will occur).

1. Monthly telephone coaching sessions will be recorded for Integrated Pain Care participants. As part of the study, the research team wants to ensure clinicians are following a similar protocol for these sessions. Researchers who are experts in counseling techniques listen to the recording of the sessions. If needed, the researchers may give feedback to clinicians to improve their techniques in future sessions. We will record only coaching sessions and not all appointments conducted by telephone. Your clinician will notify you at the beginning of the session if it will be audio-recorded.

2. We will interview only a subset of participants after the 12-month study ends to ask about their experience. This one-time interview is voluntary and is recorded so that we can accurately document what was discussed. If you agree to be interviewed, you will be reminded at the beginning of the interview that you are being audio-recorded.

Additional optional research protocol: Some people in this study will be asked if they want to take part in a second optional research protocol. The purpose of the optional protocol is to help people taking opioid medications reduce their opioid dose by switching to a different medication.

- You may be offered this option if you are treated with a high daily dose of opioid medication AND the computer program selects you by random chance (like a flip of a coin, but computerized).
- If you are offered this option, you will have the choice of whether or not to take part. You will be given time to decide. If you agree, you will be given a separate research consent form. Whether or not you choose to participate in the optional protocol will not affect your participation in the main study.

Research outcome interviews: You will be asked to complete five research interviews by telephone over the course of the 12-month study. The main purpose of these interviews is to compare how effective the treatment groups are at improving pain.

- Research assessments are conducted by study personnel at the Minneapolis VA study coordinating center. These interviewers are "blinded," meaning they do not know which treatment group you are assigned to. It is important that you do not tell "blinded" study personnel which group you are in.
- Interviews include questions about pain, daily activities, medication use, side effects, fatigue and sleep, mental health, and substance use. You may skip any questions you are not comfortable answering.
- Research assessment interviews are conducted for research purposes only. They will not be shared with your [local VA facility] care providers or [local VA facility] pain care provider(s).
- The first interview at the beginning of the study takes about 60 minutes to complete. Follow up interviews will be at 3 months (about 15 minutes), 6 months (up to 45 minutes), 9 months (about 15 minutes), and 12 months (up to 45 minutes).
- You may be asked to participate in a one-time follow up interview to take place approximately three months after completing the study intervention. This interview will ask about your experiences during the study and your opinions about the study. The interview will be audio-recorded, and a transcript will be made of the recording for later review by the research team. Participation in this one-time interview is voluntary.
- At the end of the 12-month interview, we will ask for your permission to re-contact you for other future interviews by the study team.
- It is important for the science of the study to collect information about pain and other outcomes of all enrolled patients, even those who do not continue to get care from the assigned pain treatment group. We will contact you for research interviews and collect data

unless you request to completely withdraw from the study. You are free to withdraw from the study at any time.

Research findings: You will receive a summary of our research findings by mail at the end of this study. This may be a year or more after you complete your part in the study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Ask questions as you think of them. All questions are good questions!
- Keep your study appointments or let us know right away if you need to reschedule.
- Let us know if you move or have a change in your phone number.
- Tell your Pharmacist Pain Care or Integrated Pain Care provider(s) if you might be having a side effect or have any concerns about study medications or treatment.
- Tell your Pharmacist Pain Care or Integrated Pain Care provider(s) if you might be pregnant.
- Keep medications in a safe place for your use only and away from children.
- Tell the research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval. Taking part in another research study at the same time may interfere with study results.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Psychological or Social Risks

- You may feel stress when responding to interview questions. Study staff will conduct interviews in a private setting. You may skip questions that make you uncomfortable.

Risks from medications

- Medication risks are the same as in usual care and are not risks of the research. No experimental drugs are offered in this study. Medications may be recommended by your pain care provider(s). You should discuss risks and benefits of any medication changes with your pain care provider(s). Those risks are not included in this consent form.
- Some medications are not safe in pregnancy or breastfeeding. Let your pain care provider(s) know if you are pregnant, thinking about getting pregnant, or are breastfeeding.
- Medications will be prescribed only if you agree. You may stop taking medications at any time if you have side effects or do not want to continue for any reason. Some medications must be reduced slowly (tapered) before stopping, so let your pain care provider(s) know if you want to stop.

Risks from non-medication treatments

- Pain treatment risks are the same as in usual care and are not risks of the research. No experimental treatments are offered in this study. Pain treatments may be recommended by your pain care provider(s). Risks of these treatments are mostly minor. For example, a new exercise could cause a temporary increase in muscle pain. You should discuss risks and benefits of any treatment changes with your pain care provider(s). Those risks are not included in this consent form.

Unexpected or rare side effects could also occur.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may benefit from individualized pain care in this study. We can't promise that you will get any benefits from taking part in this research study. The information we get from this study may help us treat future patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, you may continue to get care from your current health care providers.

You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will include information about your study participation in your medical record.

The research staff will ensure that measures are taken to maintain your confidentiality. However, participation in research always has a risk of the loss of privacy. Only approved study personnel will have access to the information from the outcome interviews. Information about you that is gathered during the research outcome interviews will be identifiable by a coded study identification number only. The study number will not be based on any information that could be used to identify you (for example, it will not be based on your social security number, initials,

birth date, etc.) A master list matching your personal information with your study number will be kept separate from your personal information.

All information collected about you will be double-locked in secure VA file cabinets and on encrypted VA computers. All research data for this study password-protected and accessible only by authorized study staff. All other research records will be stored in a confidential manner indefinitely in accordance with VHA's record retention schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf).

Your identity will not be revealed in any reports or publications resulting from this study. Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you. Only authorized persons will have access to the information gathered in this study.

If you agree to participate in a one-time follow up interview (within three months of completing the study intervention), it will be audio-recorded and a transcript will be made of the recording so researchers can review it. That recording will be transcribed by the VA's Centralized Transcription Services Program. The recorded audio file will be sent to the them using a secure electronic portal and they will destroy the audio file at the end of the contract.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, the Food and Drug Administration (FDA), the Minneapolis VA Research Office, Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Study health care provider(s) or research personnel may disclose your confidential information without your permission in the event of an emergency or if you indicate imminent danger of hurting yourself or others. Health care provider(s) and research personnel are required to report if you are suicidal or planning to end your life. If this were to occur, we will assist you in contacting your local VA Urgent Care Triage, where you will be referred to appropriate services. If you refuse these services, the researcher will still call the Urgent Care line and relay your contact information for VA staff to follow up with you. You can also contact the Veteran's Crisis Line at 1-800-273-8255 if you are concerned about your mental health or worried that you might hurt yourself.

This is a ten site study. Your information will be shared between [local VA site] and VA study personnel at other sites using the VA secure internal computer network or secure intranet site.

University of Minnesota and their payment contractor will be provided with your name, address, and date of birth to process payments (described below) using secure connections.

Your identity will not be revealed to the study's funder, the Patient Centered Outcomes Research Institute (PCORI).

Your personal Identifiers may be removed from your private information, and that non-identifiable information could be used for future research studies or distributed to another investigator for future research studies without additional consent from you.

A description of this clinical trial is available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Appointments may result in transportation costs and possible wages lost due to time missed from work. If personal devices are used for VA TeleHealth appointments using Video Connect app, data charges may apply.

Payment Offered for Participation:
You will be paid $50 in the form pre-paid debit card after each completed outcome interview at the beginning of the study and at 6 and 12 months.
You will be paid $25 in the form of a pre-paid debit card after each completed outcome interview at 3 and 9 months.

The total payment is up to $200 over the full year for outcome assessment interviews. Additionally, you will be paid up to [LOCAL SITE DOLLAR AMOUNT UP TO $50.00] to offset travel costs to today's appointment if you traveled to a VA facility for this appointment. This travel payment will be paid in the form of the same pre-paid debit card, regardless of your decision to consent to study participation.

IF LOCAL SITE OPTS TO USE TIERED SYSTEM:

Travel payment is based on distance from your current home address to the [LOCAL SITE NAME AND ADDRESS]. If your address is <[LOCAL SITE LOWER MILEAGE TIER] miles, you will receive $[LOCAL SITE DOLLAR AMOUNT BETWEEN $20-25.00] and ≥[LOCAL SITE HIGHER MILEAGE TIER] miles will receive $[LOCAL SITE DOLLAR AMOUNT BETWEEN $40-50.00]. If your visit today is at a VA clinic (not at the main facility address listed above), your travel mileage will be based on the distance from your home address to this VA clinic.

The pre-paid debit card will be given to you today, with no value on the card. Within 7 days after completing the outcome interviews, your card will have the $50 or $25 loaded onto it. Your name, address, and birthdate will be shared with the University of Minnesota and their debit card contractor so they can process your payments. If the debit card is lost, damaged or stolen, the study team can replace it.

If you agree to participate in the one-time follow up interview, you will be paid an additional $50 on your pre-paid debit card.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable safety measure will be used to protect your well-being. If you are injured as result of taking part in this study, VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. If you experience a research-related injury, please contact one of the following:

For non-urgent matters:

- The research coordinator at [local site]: [NAME AND PHONE]
- The principal investigator at [local site]: [NAME AND PHONE]

For urgent matters:

- Your local VA 24-hour care line: (insert local VA number here)
- Veteran Crisis hotline: 800-273-8255 Press 1

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. Choosing not to participate will not affect your current pain care. If you do decide to take part you may withdraw at any time. If you do not wish to be in this study, or if you decide to join and then withdraw, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you choose to withdraw from the study at any point, please notify the study's Principal Investigator in writing at:

Erin Krebs, MD, MPH
Minneapolis VA Medical Center (Code 152)
1 Veterans Drive
Minneapolis, MN 55417

Or you may notify your local site investigator in writing at:

[LOCAL PI NAME AND ADDRESS]
VA Medical Center
Street address
City, STATE ZIP

Any data that has already been collected, up to the point of your withdrawal, will be maintained with the project. However, no information can be collected from you after you choose to withdraw.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, complaints, or concerns about the research or related matters, please contact:

- The research coordinator at [local site]: [NAME AND PHONE]
- The investigator at [local site]: [NAME AND PHONE]
- The patient advocate(s) at [local site]: [PHONE]
  - The study project manager (at the Minneapolis VA): Agnes Jensen 612-629-7456

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). The VA Central IRB is responsible for overseeing the safety of participants in this study. You may call

the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available that might change a person's decision to stay in the study. If this happens, your research coordinator will contact you to discuss with you whether you want to continue in the study. If at that point you decide to withdraw from the study, your pain care provider(s) will arrange for your medical care to continue with your primary care provider. If you decide to continue in the study, you might be asked to sign an updated informed consent form.

FUTURE USE OF DATA AND RE-CONTACT

An important part of this research is to save your data in a secure repository for other research studies in the future. The data will be stored at the study's coordinating center (the Minneapolis VA) on encrypted VA computers. Access to non-identifiable study data will be restricted to authorized uses by VA and the study team. At your final VOICE study research interview, you will be asked if you are willing to be contacted for future research.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The designated research staff member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 10/23/2020

LSI Approval Date: N/A

LSI Verification Date: N/A