CONSENT FORM COVER PAGE

STUDY TITLE:

An Open-Label Randomized Noninferiority Clinical Trial of the Adductor Canal Catheter for Pain Control Post-Total Knee Arthroplasty (The Adductor Canal Catheter Effectiveness and Safety Study (ACCESS))

NCT Identification Number: pending

Date of document: October 6, 2020

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.

San Leandro Medical Center

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: **A randomized noninferiority trial of adductor canal catheters for postoperative pain management among patients undergoing elective unilateral total knee arthroplasty.**

Study Summary

You are being invited to participate in a research study to understand if the potential benefits of using an "Adductor Canal Catheter" (or "ACC") are greater than the risks of using the ACC for patients undergoing a total knee replacement surgery. You are being asked to participate because you are planning to have total knee replacement surgery. Your participation in this study is strictly voluntary and your medical care will not be affected in any way if you decline to participate.

The purpose of this study is to understand whether the benefits of the ACC are greater than the risks of the ACC. Patients undergoing total knee replacement surgery need excellent pain control, which we provide by doing several things, including providing pain medication, injecting long-acting pain-reducing medications (anesthetics) around the knee at the time of surgery, and often by placing an ACC. The ACC is a device that is a long, thin tube (catheter) that is inserted under the skin through the leg near the knee just prior to surgery and is attached to a plastic container filled with an anesthetic; after surgery, this device slowly drips in anesthetic around the knee for two-to-three days, in the hopes of reducing your knee pain. Surprisingly, we don't know how much more benefit the ACC provides over all the other things we do to help reduce your pain. We will try to understand whether the ACC is related to your perception of pain as well as satisfaction. We do know that the ACC can cause problems, such as bleeding and, very rarely, it can lead to infection or damage to a nerve in the leg; it may also fall out early, causing concern for patients (though this is rarely serious). Most orthopedists use ACC's for their knee-replacement surgery patients, but many do not, which reflects the uncertainty about value of the ACC.

In this study, half of the participants will have an ACC inserted and the other half will not. If you decide to participate, the decision about whether you will get an ACC will be randomly determined (by chance, like flipping a coin). All other aspects of your surgery and care will be managed in the usual way.

If you are assigned to the "no-ACC group", you will not bear any risks related to the ACC but you may or may not have more post-surgery pain. If you are assigned to the "ACC

group" you may or may not have better pain control but you will bear the risks of the ACC. As mentioned above, these risks include bleeding, the catheter falling out early and, very rarely, infection or damage to a nerve in the leg. Risks related to the ACC are not likely. A comprehensive list of the risks of participating in this study are listed later on in this consent form on page 5.

If you decide not to participate in this study, you will still be able to receive the ACC. Whether you receive an ACC is generally determined by the preferences of the surgeon who will do your surgery in consultation with you; you may wish to discuss the use of the ACC with your orthopedist.

BEFORE YOU READ THIS CONSENT FORM, YOU SHOULD HAVE READ THE KAISER PERMANENTE MEDICAL CARE PROGRAM RESEARCH PARTICIPANTS' BILL OF RIGHTS. ASK THE STUDY STAFF FOR A COPY OF THIS DOCUMENT IF YOU HAVEN'T ALREADY RECEIVED ONE.

Researchers at Kaiser Permanente in Northern California are conducting a research study. To decide whether or not you want to be part of this research, you should understand the risks and benefits in order to make an informed decision. You have the right to know what the purpose of the study is, how participants are selected, what procedures will be used, what the potential risks and benefits and possible alternative treatments are, what is expected of you as a study participant, and to inform you of how your personal health information may be used or given to others during the study and after the study is finished. This process is called "informed consent." This consent form gives information about the research study, which a study doctor or staff member will discuss with you.

You will also be asked to sign an Authorization Form, which will describe how your personal health information may be used or disclosed by the researchers in the study.

This consent form may contain words or phrases that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may keep the unsigned copy of this consent form to think about or discuss the study with family or friends before making your decision. Once you are satisfied that you understand the study, you will be asked to sign and date this consent if you choose to participate. You will keep the other copy of the consent form.

Who is funding this study?
The research costs of this study are being funded by The Permanente Medical Group (part of Kaiser Permanente, Northern California).

What is the purpose of this study?
The purpose of this study is to understand if the potential benefits of using an "Adductor Canal Catheter" (or "ACC") are greater than the risks of using the catheter for patients undergoing a

total knee replacement surgery.

An ACC is a device that is a long, thin tube (catheter) that is inserted under the skin, through the leg near the knee just prior to surgery and is attached to a plastic container filled with an anesthetic; after surgery, this device slowly drips in anesthetic around the knee for two-to-three days, hoping to reduce your knee pain. Most orthopedic surgeons in Kaiser Permanente recommend ACC's for their patients undergoing total knee replacement, in the belief that the ACC will provide meaningful additional pain relief beyond the other interventions we provide to reduce pain after surgery, such as providing pain-relieving medications and injecting pain medicines (anesthetics) around the knee at the time of surgery. However, many orthopedic surgeons do not recommend using an ACC for patients undergoing total knee replacement, as this device, like all medical devices, has risks and it is not clear if the potential benefits of the ACC outweigh these risks. We hope to resolve this uncertainty for future patients by conducting this study to compare the benefits and risks of the ACC among a group of patients who receive an ACC to a group that does not receive an ACC. This type of research (a "clinical trial") is the best way to determine the best therapy for patients; many of the advances in knee-replacement surgery that you will benefit from with your surgery were discovered through clinical trials conducted in the past.

Why am I being asked to take part in this study?
You are being asked to take part in this research study because you have decided to have a total knee replacement for one knee.

How many participants will take part in this study?
Up to 142 participants at Kaiser Permanente San Leandro undergoing total knee replacement surgery will participate in this study.

How long will I be in this study?
If you decide to participate in this study, you will be actively participating from the time of your surgery until two weeks after your surgery, during which time you will fill out a daily pain-and-medication diary. We will also review your medical chart up to three months following your surgery to look for evidence of problems associated with the use of the ACC.

Your study doctor has the right to end your participation in this study at any time without your consent for any of the following reasons:

- If the Kaiser Permanente Northern California IRB or Data Safety Monitor (DSM) stops the study
- If your doctor feels it is in your best interest (for example, if considering participation may delay your surgery for too long)
- If you develop serious side effects related to the study

If you are withdrawn from the study, we will encourage you to mail back your pain-and-medication diary with whatever information it contains.

What will happen if I take part in this study?
If you agree to take part in this study and sign this consent form, the following things will happen:

First, we will ask you a series of questions to make sure that are eligible to take part in this study. Not everyone who desires to take part in this study will be allowed to do so, as there are specific criteria which must be satisfied by all participants. These criteria are established for your safety and to maintain high scientific standards so that the results of this study are accurate.

If you choose to participate and it is determined that you meet all the eligibility criteria (and sign this consent form and the Authorization Form), there will be no special procedures for you to follow prior to your surgery.

On the day of your knee replacement surgery, you will be taken to the pre-operative area, just as you would if you were not participating in this study. At that time, we will open a special study envelope; in this envelope will be a card which will tell you and your doctors whether you have been assigned to the "ACC group" or the "no-ACC group" (remember that you are being assigned randomly to a group, like flipping a coin). Prior to this point, no one (including your doctors, clinic staff, or study staff) will know to which group you will be assigned.

If you are assigned to the "ACC group," a trained anesthesiologist will then place the ACC in your leg, using the same procedure as for patients who are not enrolled in the study but are to have an ACC placed. If you are assigned to the "no-ACC group," the anesthesiologist will not place the ACC. All other pre-operative procedures, surgery, and post-operative procedures will be the same whether you are participating in the study or not (that is, participating in this study will not affect any other aspect of your surgical care).

After the surgery, you will be given a pain-and-medication diary to fill out each day for two weeks following your surgery. At the end of the two-week period, you will be asked to mail back your diary in the stamped, self-addressed envelope that will be given to you by the study staff. Your active participation in the study will then end. The study investigators and staff will then review your electronic medical record for three months after your surgery to assess any medical events that may have occurred after your surgery.

Will the information collected be used in future research?
Your study information will not be stored or used for future research.

What are my responsibilities while I am in this study?
As a participant in this study, there are certain instructions you must follow during the study. Some are listed below, but there could be others that the study doctor/staff will discuss with you. For this study we ask the following:

1) Please be sure to consider carefully whether you want to commit to participating in this study and read this form carefully. Please be sure all your questions are answered before agreeing to

participate in this study. Your participation requires you to sign and date this form and the Authorization form.

2) Please fill out the "Baseline Questionnaire" included with this consent form and return it to us along with your signed consent form and Authorization Form in the stamped, self-addressed envelope provided to you.

***Please note that if you do not complete the baseline questionnaire, you will not be able to participate in this study.**

3) We ask that you be ready to accept your assignment to a treatment group ("ACC group" or "no-ACC group") prior to surgery. If you have second thoughts about participating at any time prior to your surgery, please inform your surgeon or study staff right away (the phone numbers for contacting the study investigators and staff are shown near the end of this form; you may also send a secure message to your orthopedic surgeon from your kp.org account)

4) We ask that you follow through with your assigned treatment ("ACC" or "no ACC") according to your assignment just before surgery

5) Please fill out your daily pain-and-medication diary for two weeks after surgery, then mail it back to us in the provided stamped, self-addressed envelope.

6) Please let your surgeon or clinic staff know of any problems you have after surgery, just as you would do whether you participate in this study or not.

What are the potential risks, side effects and discomforts of being in this study?
There are risks involved with using any device, including an ACC. It is impossible to predict all of the risks and side effects that might happen if you have an ACC inserted. It is important to report all side effects or changes in your normal health, even those changes you might not consider to be important.

In addition to the risks, side effects and discomforts listed here, there may be other risks that are currently not known.

Risks and side effects related to use of an ACC include those which are:

<u>Likely</u>

- There are no known risks or side effects that are "likely" to occur if you have an ACC

<u>Less Likely</u>

- Among the more common risks of having an ACC implanted are:
  - The possibility of increased bleeding at the insertion site
  - The possibility that the catheter falls out or is accidentally pulled out before you are supposed to remove it (this is generally not serious)

<u>Rare but serious</u>

- Rare but serious risks of having an ACC placed are:
  - Infection of the catheter and/or insertion site
  - Reversible or permanent damage to a nerve in your leg from insertion of the catheter

You may have side effects while taking part in the study. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Note: You are invited to be in this research study because you are scheduled to have a total knee replacement surgery. You have already consented to that procedure. That procedure is not experimental and is not part of this study. The risks of total knee replacement have already been discussed with you by your orthopedic surgeon.

Are there any benefits to being in this study?
It is not possible to predict whether or not you will receive any direct benefit or satisfaction as a result of your participation in this study. You may or may not experience or perceive additional pain relief if you are assigned to the ACC group. However, it is hoped that the results of this study may benefit future patients in helping find the best treatments for patients undergoing knee replacement surgery.

What are my choices if I do not want to be in this study?
The alternative is to not participate and you may still receive the ACC. Whether or not you receive an ACC is dependent on the recommendation of your orthopedist and your preferences. Note that most orthopedists do offer their total-knee-replacement patients an ACC, but many do not, since the balance of risks and benefits of the ACC are not known.

Will there be any costs to me to take part in this study?
There are no costs to you specifically for participating in this study. All costs and co-pays that may be required by your insurance coverage will be your responsibility (including placement and management of an adductor canal catheter).

All aspects of your standard medical care will continue to be provided to you according to the terms of your plan benefits described in your applicable plan Evidence of Coverage or Summary Plan Description, which may include copayments, coinsurance, and deductibles.

Will I be paid to take part in this study?
If you complete all study-related procedures, including filling out the pain-and-medication diary, you will be compensated with a $50 gift card (your choice of an Amazon, Target, or Safeway gift

card). Please note that we are required to collect your Social Security Number and address in order to provide you a gift card. There is no cash compensation for participating in this study.

What will happen if I am injured during the study?
If you participate in this study, you will be exposed to risks of physical injury and/or illness in addition to those related to your condition. If you require medical treatment as a result of participation in this study, medical treatment will be provided.

For all study participants: if you are injured during your participation in this study, you should contact the study doctor as soon as possible in person or at the telephone number listed in this consent form. Medical care may be obtained in the same way you would ordinarily obtain other medical treatment.

If you believe you have been injured or harmed while participating in this research and require treatment, contact Dr. Andrew Avins at 510-891-3596 or Dr. Adrian Hinman at 510-673-5207 If you have an urgent medical problem after hours, please call the Kaiser Permanente Medical Advice telephone line at 510-752-1190.

Further information regarding medical treatment for research-related injuries can be obtained from the study doctor or other authorized personnel.

Any injury or condition experienced by a member of KFHP as a result of being in this study will be treated and covered as described in your plan Evidence of Coverage or Summary Plan Description.

No free medical care or other form of compensation will be offered by Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, The Permanente Medical Group, Inc., or the Kaiser Permanente staff conducting the study.

Your consent to participate in this research study does not take away any legal rights which you may have in the case of negligence or legal fault of anyone who is involved with this study.

Will my information be kept confidential?
Efforts will be made to keep your personal information confidential. However, your personal information may be disclosed if required by law.

To the extent permitted by law and by signing this consent form, you allow access for the following representatives to inspect your research and clinical records without removal of identifying information, such as your name, initials, date of birth, sex, and race, to make sure that the information is correct and to evaluate the conduct of the study.

- The sponsor of this study, The Permanente Medical Group and/or its authorized representatives;

- The U.S. Food and Drug Administration (FDA); the Department of Health and Human Services (DHHS); or other U.S. governmental regulatory agencies involved in keeping research safe for people;
- Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights and welfare of participants)
- Representatives of Kaiser Permanente
- Kaiser Foundation Research Institute and others at Kaiser Permanente responsible for monitoring research

Because of the need to allow access to your information to these parties, absolute confidentiality cannot be guaranteed.

Your personal information, including information about your health, will be collected by study personnel and recorded on study record forms. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified will not be entered on the study record forms. Instead, you will only be identified by a unique study number and your initials. The study doctor will ensure that the link between your name and these study numbers will never be released outside the hospital/study site. All coded records will be kept confidential and stored in a secure area.

If you decide to participate in this study, you will also be giving consent for the medical research investigator or his/her assistants to review your medical records as may be necessary for this study.

A note will be added to your electronic medical record to inform your healthcare providers that you are participating in this study. The study treatment and procedures and details of this study will not be added to your medical record. In case of a medical emergency, your healthcare provider will use this information in your electronic medical record to contact the doctor in charge of this study (the Principal Investigator).

Your identity will not be revealed in any publication or release of study results.

Can I choose to not participate or withdraw from the study?

Participation in this study is completely voluntary. You are free to refuse to participate in this study. Your decision about whether or not to participate in this study will not affect your medical or surgical care. If you decide to participate, you are free to change your mind and discontinue participation at any time without any effect on your medical care or eligibility for future care or membership in KFHP.

If you decide that you no longer wish to continue in this study, you will be requested to return your study two-week pain-and-medication diary to the study investigators with whatever information it contains.

We do not plan to share your research results with you or your primary care provider. However, if we discover information that is important for your health care, either in this study or in the future, we will contact you and ask if you want to know the results. You may learn information about your health that is upsetting.

Will I receive new information about the study while participating?
During the course of the study, you will be informed of any important new findings (either good or bad) such as changes in the risks or benefits resulting from participation in the research or new alternatives that might change your mind about your continued participation in the study. You may be asked to sign a new consent form if additional risks are found.

Where can I get more information?
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 Web site at any time.

What if I have any questions or problems?
In case of study-related questions, problems or injuries, you can call the one of the investigators responsible for the study within Kaiser Permanente in Northern California: Andrew Avins, M.D., at 510-891-3596, or Dr. Adrian Hinman at 510-673-5207

Questions about your rights as a study participant, comments or complaints about the study may be presented to the Kaiser Permanente Northern California Institutional Review Board 1800 Harrison Street, Oakland. CA 94612, or 1-866-241-0690.

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CONSENT TO BE IN THE STUDY:
I have read (or someone has read to me) the above and am satisfied with my understanding of the study, its possible benefits, risks and alternatives. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I will be given a copy of this consent form, and the Authorization to Use and Disclose Protected Health Information.

Please also see the attached "Research Participants' Bill of Rights".

BY SIGNING BELOW, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH STUDY AS DESCRIBED IN THIS FORM.

Participant Signature:		Date:	
Participant Printed Name:			

I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this clinical research study. I have answered any questions that have been raised and have witnessed the above signatures.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date