

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC., San Francisco, CA
And
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, San Francisco, CA

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

FORMAL TITLE: Patient Activation to Address Chronic Pain and Opioid Management in Primary Care

ALTERNATE TITLE: ACTIVATE: Patients Managing Pain

Cynthia Campbell, PhD, from Kaiser Permanente and Constance Weisner, DrPH, from the University of California, San Francisco, are conducting a research study on persistent pain, and you are being invited to participate. 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 are and what is expected of you as a study participant. This process is called "informed consent." This consent form gives information about the research study, which one of the study staff will discuss with you.

Please feel free to ask the Research Assistant if something is unclear during the informed consent process, or if the form contains words or phrases that you do not understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision to participate or not in the study. Once you are satisfied that you understand the study, and have decided to participate, you will be asked to sign and date this consent form. You will then be given a copy of the signed form.

The research costs of this study are being funded by the Patient Centered Outcomes Research Institute, a federally funded organization authorized by Congress to conduct research focused on questions important to patients.

BACKGROUND AND STUDY PURPOSE

This is a research study to learn whether a new behavioral treatment will improve treatment for patients with pain. Through this study, researchers hope to learn what might help patients understand the importance of their overall health care and engage in healthy practices and pain self-management. The study materials have been developed with input from patients with pain.

You are being asked to take part in this study because you take opioid medication for non-cancer pain. The purpose of this study is to examine the effect of a brief, group-based treatment focused on pain management, when provided in addition to usual primary care services.

SCOPE AND LENGTH OF STUDY

There will be about 480 people enrolled in this study. Participation in this study involves up to 8 hours of your time over a period of 12 months.

STUDY PROCEDURES

If you decide to enroll in this study, the following will occur:

The Research Assistant will ask you to answer questions about pain and pain management, including medications, overall health status, alcohol and drug use, medical and psychiatric symptoms, daily activities, and demographic characteristics. It should take about 40 minutes to complete these questions.

You will be randomly assigned to one of two patient groups. Randomization is a process similar to flipping a coin, to decide which group you will be in. One half will be assigned to the behavioral intervention (Group 1), and the other half will be assigned to usual care (Group 2). The following study activities will take place for participants in the two groups:

- Group 1, behavioral intervention: In addition to their usual care, participants in Group 1 will attend four group educational sessions at Kaiser Permanente Santa Clara or Kaiser San Jose. These sessions cover information about pain and pain management including prescription opioids, overall health, how pain interacts with physical and emotional health, communication with clinicians and how to use Kaiser Permanente's resources. These sessions use supportive, patient-centered counseling and education methods to help participants explore these topics. The four group sessions will last about 90 minutes each. If you are not already enrolled in kp.org, we will help you register.
- Group 2: Participants in Group 2 will receive usual care, with no additional treatment procedures associated with the study.

Participants in both Group 1 and 2 will also complete two 40-minute telephone follow-up interviews, which will take place about 6 months, and one year from now. These interviews will include questions about pain, pain management, pain medication, psychiatric symptoms, health problems, alcohol and drug use, daily activities, and demographic characteristics.

All in-person procedures will be done at Kaiser Permanente Santa Clara Medical Center or San Jose Medical Center, in a private room. Follow-up telephone calls will be made to you at your home or another private setting of your choosing.

In addition to these procedures, we need your permission to look at your Kaiser computerized health records for dates of visits, medical conditions, and medication prescriptions received at Kaiser. The researchers will examine your medical records at Kaiser Permanente to determine the quantity and type of services you receive as part of

your usual care services. We will remove your name and all personally identifying information from all study datasets in order to protect confidentiality.

PAYMENT/COSTS

In return for your time, effort and travel expenses, eligible participants will be paid up to \$150 for taking part in this study, which will be paid in the form of Target gift cards. This includes \$50 for the in-person baseline interview, \$50 for the 6-month follow-up telephone interview, and \$50 for the final 12-month follow-up telephone interview. If you do not complete the study, you will receive payment for each interview you have completed. A Target store card will be mailed to you within 3 weeks after you complete each telephone interview.

All study visits and study-related tests and procedures will be provided free of charge while you are participating in this study. Tests and services relating to the health care of KFHP members will continue to be provided as described under your KFHP Evidence of Coverage, which may include co-payments, co-insurance, and deductibles.

RISKS, SIDE EFFECTS AND DISCOMFORTS OF THE STUDY

Answering some of the interview questions (that is, about pain medication, alcohol or drugs) may make you feel uncomfortable or embarrassed. However, you are free to not answer any questions you do not wish to answer or to terminate your participation in the study at any time. Despite taking part in the study, some patients may find that their pain continues or worsens.

POSSIBLE BENEFITS

It is not known if you will receive a direct benefit from participating in this study. The information that you provide may help health professionals learn more about how best to provide services for patients with persistent pain.

ALTERNATIVES

Your other choices include receiving standard primary care treatment without being in a study. If you decide not to take part in this study, there will be no penalty to you. You may choose not to participate in this study, and the decision will not affect your medical care or your relationship with Kaiser Permanente or your care providers in any way.

INJURY

Any injury or condition experienced by a member of Kaiser Permanente, as a result of being in this study, will be covered as described in your Health Plan Evidence of Coverage. 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 in the case of negligence or legal fault of anyone who is involved with this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is completely voluntary. You are free to refuse to participate in parts of or all of this study. Your decision will not affect your medical care. If you decide to participate, you can change your mind at any time without any effect on your medical care or eligibility for future care or membership in Kaiser Permanente.

The researchers can also discontinue your participation in this study at any time without your consent for any of these reasons:

- If you do not follow instructions given to you
- If they feel that it is in your best interest
- If there are administrative reasons to discontinue the study

CONFIDENTIALITY

The researchers will keep information about you, obtained for this study, confidential and will not disclose it without your written permission. However, some personal information may be disclosed. For example, personal information may be disclosed to protect you or someone else from serious harm, or to take steps (including notifying authorities) in cases of child abuse or elder abuse. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. In addition, the Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights and welfare of participants), or other regulatory agencies may look at and/or copy your research records for quality assurance and data analysis. Because of the possible need to release information to these parties, absolute confidentiality cannot be guaranteed. Your other doctors may become aware of your participation. However, hospital regulations require that all health care providers treat information in medical records confidentially.

Study information about you will be identified only by a unique study code. No personally identifiable information such as your name or medical record number will be attached to your study data. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Furthermore, only aggregate data will be published or presented which combines information from all study participants. By signing this consent form, you will also be giving consent for the medical investigator or his/her assistants to review your medical records as may be necessary for this study. Your identity will not be revealed in any publication or release of study results.

CERTIFICATE OF CONFIDENTIALITY

In this study, researchers will ask you about drug use. The researchers will keep your information confidential. To help keep information about you confidential, the research team has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). The Certificate of Confidentiality adds special protection regarding your participation in a research study. It will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. Participation in research may involve a loss of privacy, but information about you will be handled confidentially. Even when a Certificate of Confidentiality is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate of Confidentiality to withhold this information.

QUESTIONS

Any study-related questions, problems or injuries should be directed to the investigators responsible for the study, Dr. Cynthia Campbell at (510) 891-3584, or the Project Manager, Monique Does, at (510) 891-3612. Questions about your rights as a study participant, or comments or complaints about the study also may be presented to the Institutional Review Board for the Protection of Human Subjects, Kaiser Foundation Research Institute, 1800 Harrison St., 16th Floor, Oakland, CA, 94612, telephone toll free (866) 241-0690. If you continue to have questions, you may also contact the Committee on Human Research, University of California, San Francisco, telephone (415) 476-1814.

I have read the above and am satisfied with my understanding of the study, its possible benefits, risks, and alternatives. My questions about the study have been answered. I hereby voluntarily consent to participate in the research study as described. I will be given a signed copy of this seven page consent form, which includes the Authorization to Use and Disclose Protected Health Information and of the attached Research Participants' Bill of Rights.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

STUDY TITLE: ACTIVATE: Patients Managing Pain

Why is this authorization required?

The Privacy Rule is a federal law designed to safeguard your Protected Health Information (PHI). Your PHI is individually identifiable information about you, including your physical or mental health, the receipt of health care, or payment for that care. The Privacy Rule requires that researchers obtain your written authorization to participate in this study.

By signing this authorization, you will permit Kaiser Permanente researchers to use and disclose your PHI for the purpose of the research study named above. Your PHI will only be used and disclosed as described in this authorization, except as otherwise required by law.

Must I agree to this authorization to participate in the research?

Yes, in order to participate in this research study, you must agree to the uses and disclosures of your PHI as described in this authorization.

Who will use or disclose my PHI?

Kaiser Permanente researchers and the research team will use your PHI for the purposes of this study. Your PHI may also be sent to others as required by law.

What is the purpose of the use or disclosure of my PHI?

Kaiser Permanente researchers will use your PHI, including your research and/or medical record, to conduct the study and determine research results. In addition, others at Kaiser Permanente, for example, the Institutional Review Board that approved the study, may also review your research or medical record, or both, to monitor the study.

Information from your research record and medical record used and disclosed for the study may include, for example, laboratory and other tests, and both clinical and research observations relating to your participation in the study, including utilization of chemical dependency and mental health services.

When will this authorization expire?

This authorization will expire at the end of this research study.

Can I withdraw this authorization?

Yes, at any time during this study you may decide that you no longer want to have your PHI used or disclosed as part of this study. If so, you must write a letter stating that you withdraw your authorization and send it to:

Cynthia Campbell, PhD
Kaiser Permanente Division of Research
2000 Broadway
Oakland, CA 94612

If you withdraw your authorization, you may be required to end your participation in the study.

Kaiser Permanente researchers and the study sponsor may continue to use your PHI that was obtained before you withdrew your authorization. Kaiser Permanente researchers will not disclose your PHI after they receive your written request except as required by law. For example, even if you withdraw your authorization, Kaiser Permanente researchers may be required by law to record and report anything that relates to your safety or the safety of others.

What will happen to my PHI after it is disclosed?

The Kaiser Permanente research team will use and disclose your PHI only as described in this authorization. However, if someone receives your PHI from Kaiser Permanente and then discloses it again to someone else, it may no longer be protected by this authorization.

Will I get a copy of this authorization?

The researcher who is obtaining this authorization from you must give you a copy of this form after you sign it.

Authorization signatures

This authorization has been explained to me, and all of my questions have been answered. By signing below, I am giving my permission to allow the use and disclosure of my PHI for the research study as described above.

Signature of Participant
(or Personal Representative,

Date

if Participant is unable to give authorization)

Personal Representative's authority
(e.g., Power of Attorney, parent, spouse)

Date