KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC.

_____DIVISION OF RESEARCH _____

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: FOcus on Reducing dose-limiting toxicities in Colon cancer with resistance Exercise (FORCE) Study

Study Summary

You are being invited to participate in a study conducted by researchers at the Kaiser Permanente Division of Research. You are being asked to participate in this research because you have recently been diagnosed with colon cancer and are receiving adjuvant chemotherapy at a Kaiser Permanente facility. Consent is being sought for research. Participation is completely voluntary. Your involvement in the study is expected to be approximately the duration of your chemotherapy.

The purpose of this study is to determine if a home-based resistance training program can increase muscle and reduce side effects of chemotherapy in patients who participate while undergoing chemotherapy.

Preliminary evidence suggests that patients with increased muscle mass can do better with chemotherapy. It is unknown if improving muscle mass though exercise will help. This research study is being done to learn what effect a resistance training intervention program has on side effects of chemotherapy, dose reductions, and delays.

The following is a list of procedures that will take place if you agree to participate. You will:

1. Attend a 1-hour baseline clinic visit. After this visit, you will be randomly assigned to the resistance training group or the usual care group.
2. Provide two blood samples at a KP laboratory after the baseline and follow-up visits.
3. Complete two whole-body composition dual-energy x-ray absorptiometry (DXA) scans- one after the baseline clinic visit and one around the follow-up clinic visit.
4. Complete a short survey around the time of each chemotherapy session.
5. Attend a 45 minute follow-up clinic visit.
6. If you are assigned to the resistance training group, you will be asked to meet with an exercise professional 4-6 times, exercise 2 times per week at home and take a protein supplement daily. Most meetings will be virtual on an online video conference call.
   Optional:
7. Mail in urine samples after the baseline and follow-up clinic visits.

Reasonably foreseeable risks or discomforts include soreness due to exercise; the potential loss of privacy; and minor local pain or bruising associated with blood draws. Being in this study may or may not help you. The researchers hope that the information learned through this study will help doctors and nurses who care for people with colon cancer in the future.

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 the study doctor 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 take home an 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 be given a copy of the signed and dated consent form.

Who is funding this study?
The research costs of this study are being paid by the study sponsor, the National Cancer Institute. Kaiser Permanente will be reimbursed for the time and resources used in conducting this study on behalf of the sponsor.

What is the purpose of this study?
The purpose of this study is to determine if a home- based strength training program can increase muscle and reduce side effects of chemotherapy in patients who participate while undergoing chemotherapy.

Why am I being asked to take part in this study?
You are being asked to participate in this research study because you have been recently diagnosed with colon cancer and are receiving adjuvant chemotherapy at Kaiser Permanente.

How many participants will take part in this study?
This study will enroll up to 180 women and men. Approximately 138 women and men will participate at Kaiser Permanente in Northern California.

How long will I be in this study?
Your participation in the study is expected to be approximately the duration of your chemotherapy (3-6 months) and after you have completed all visits, and all information has been collected. This includes the Baseline Clinic Visit, activities in the group to which you are assigned and a Follow-up Clinic Visit.

The principal investigator can 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 the principal investigator feels that it is in your best interest
- if there are administrative reasons to discontinue the study
- if you decide to discontinue treatment

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:

We will conduct the Baseline Clinic Visit, which will take about 45 minutes to 1 hour. At this visit the following will occur:

- Conduct a brief physical exam to assess height, weight and measure your waist and hips.
- Have four exercise tests to measure your physical ability (see "Balance", "Sit and Stand", "Grip Strength" & "Gait Speed" below) and answer a "Paffenbarger Physical Activity Questionnaire."
- Be asked to complete additional study questionnaires ("Demographic Information Questionnaire", "Patient Completed Side Effects Questionnaire", "Food & Activity Questionnaire" & "36-item Health Survey (SF-36)") at home online and/or on paper on the same day of the visit.

After we complete the Baseline Clinic Visit:

- You will be randomly assigned to one of the activity groups: Resistance training (RT) group or usual care (U) group.
- Randomization means that the choice of whether you will be in the RT group or the U group will be assigned by a computer program. The program will place women and men in the study group by chance, like a flip of a coin. You will have a 1-in-2 (50/50) chance of being assigned to the RT group or the U group.
- We will let you know your activity group placement.

Following the Baseline Clinic Visit, we will:

- Obtain a blood sample at a KP laboratory. We will draw 3 tubes (approximately two tablespoons) of blood.
- Measure your body composition using the DXA machine. Ask you to provide an optional urine sample. The DXA scan will be administered at a non-KP facility.

- Review a CT scan from your medical record for body composition.

If you are randomized to the RT group, the following will occur:

- Speak to the exercise professional on the phone prior to your first session and schedule your first appointment.
- You will be asked to attend four to six sessions with an exercise professional around the time of your chemotherapy visits approximately every 2-3 weeks. The first visit will be in person scheduled on a day when you already have another appointment at a KP facility. The subsequent sessions will be virtual using online video conference call software.
- The sessions will last from 45 to 60 minutes, based on your individual exercise prescription.
- An exercise professional, who has specialized education and certification, will work with you during your sessions to prescribe training activities on the exercise equipment and to monitor how you are doing.
- You will receive weekly phone calls from a FORCE exercise professional.
- You will be asked to complete the exercise regimen at home two times per week for the duration of your chemotherapy regimen, anywhere between 12 to 24 weeks total.
- At no cost to you, you will be provided with exercise equipment (PowerBlock and an Aerobic Step) to help you perform the exercises.
- You will be instructed to consume your regular diet.
- You will be asked to use one serving (providing approximately 20 grams of protein) of protein supplement twice a day with meals, making an effort to consume it approximately 30 minutes after the initiation of a meal (breakfast, lunch or dinner). The protein supplement will be provided at no cost to you. You will be asked to complete a weekly exercise and brief protein intake log.
- You will be asked to complete the "NCI- PRO-CTCAE™" survey around the time of each chemotherapy visit.

If you are randomized to the U group, the following will occur:

- You will be asked not to change your usual routine during the duration of the study.
- You will be asked to complete the "NCI- PRO-CTCAE™" survey around the time of each chemotherapy visit.
- Upon completion of the follow-up clinic visit, you will be offered: an online resistance training routine; a set of resistance bands; a 30-minute interview with FORCE exercise professional; and a sample of protein powder.

For both groups at your Follow-up Clinic Visit, approximately three to six months after your Baseline visit, which will take about 45 minutes to 1 hour, at this visit the following will occur:

- Conduct a brief physical exam to measure your weight, waist and hips.
- Obtain a blood sample at a KP laboratory. We will draw 3 tubes (approximately two tablespoons) of blood.
- Have four exercise tests to measure your physical ability (see "Balance", "Sit and Stand", "Grip Strength" & "Gait Speed" below) and answer a "Paffenbarger Physical Activity

Questionnaire." If you are in the RT group, complete an intervention follow-up survey.
- Be asked to complete study questionnaires "Patient Completed Side Effects Questionnaire", "Injury History Form", , "Food & Activity Questionnaire" & "36-item Health Survey (SF-36)" at home online and/or on paper on the same day of the visit.
- Measure your body composition using the DXA machine at a non-KP facility.
- Ask you to provide two optional urine samples.

You will be asked if you would be willing to have your photograph taken. These images will be used in research presentations about the study.

Description of study activities and procedures:

Body size measurements: We ask you to remove your shoes to measure your height and weight. You will be asked to lift up your top clothing so that a tape measure can be used to measure your waist and hips.

Balance test: A test to measure your balance will be conducted. An interviewer will ask you to stand in 3 different positions for 10 seconds each.

Sit and stand test: A test of lower extremity muscular strength and exercise endurance, the time required to complete 5 full stands from a seated position will be recorded using a stopwatch.

Grip strength test, right and left hand: To measure upper extremity muscular strength, a Jamar grip dynamometer will be held at the side of the body in a standing position with the elbows slightly bent. The dynamometer will be squeezed with as much force as possible over three trials with 20 seconds rest in between trials.

4-meter walk gait speed test: To measure locomotion, the time in seconds required to walk 4 meters. Participants walk a short distance at their usual pace, completing one practice and two-timed trials.

Questionnaires: The forms in this study are standard, published forms used widely by researchers to measure patient-reported outcomes, quality of life, physical activity, diet behaviors.

Blood collection: After completion of the Baseline and Follow-up Clinic visits, we will collect a blood sample from you, which we will store for future analysis. We will ask you to visit any KP laboratory to have the blood sample drawn.

Dual-energy absorptiometry (DXA) scan: A simple test that measures your total body composition and includes the exact breakdown of bone mass, fat tissue, and muscle in your body. The DXA scan is a painless procedure, which takes less than 2 minutes to complete. You will be asked to lie on the tabletop of the machine while the 'C-arm' takes a picture of your entire skeleton. We will measure your total body composition with a DXA machine 2 times: at Baseline and at Follow-up. Baseline and Follow-up DXA body composition results will be mailed to you at the conclusion of your participation. DXA scans will be administered at a non-KP facility.

Optional urine samples: We will ask you to provide urine samples to assess your skeletal muscle mass. This part of the study is optional. This activity involves about 30 minutes of your time and consists of:

a. Ingesting a pill containing a small amount of a non-radioactively labeled substance called creatine. In skeletal muscle, labeled creatine is converted into labeled creatinine.
b. Three to six days after ingesting the labeled creatine, we will ask you to provide a morning urine sample before you have breakfast, tea or coffee. This can be when you come for your clinic visit, or by mail. The amount of labeled creatinine in the urine is determined. From this value we can find out your total amount of skeletal muscle.
c. At the follow-up visit we will ask you to repeat these procedures and provide two urine samples.

Optional specimen collection/genetic testing procedures

PEMRMISSION TO USE BLOOD SAMPLE FOR FUTURE STUDIES

By signing this consent form and checking the appropriate space (s) below, you are agreeing that:

_____ (initials) I grant permission for researchers to use my blood samples for future research, which may include genetic testing.

_____ (initials) I do not grant permission for researchers to use my blood samples for future research, which may include genetic testing.

PERMISSION TO COLLECT URINE SAMPLES

I have read and understand the section under "Description of study activities and procedures" concerning the fact that urine samples may be collected from me and stored and may be used for determining my total body skeletal muscle mass. My selection below indicates my decision concerning the collection of urine samples for these research purposes.

_____ (initials) I agree to provide urine samples to be used as described in this consent form.

_____ (initials) I do not wish to provide urine samples as described in this consent form

Will the information collected be used in future research?
In the future, your blood may be given to researchers for other research studies. These samples will be stored indefinitely and may be used and shared in the future for research, which may include genetic research. The research that may be done with your samples is not designed to specifically help you. It might help people who have illnesses in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your medical records.

Your samples and data will be labeled only with a code number and will not include any personal or identifying information. In order to use the samples or data for future research studies, Dr. Caan must have the studies approved by the Kaiser Permanente Institutional Review Board, which is responsible for protecting the rights and welfare of all Kaiser Permanente research participants. Your samples may be kept until they are used up, or until Dr. Caan decides to destroy them. You will have no right, title or interest in any inventions or developments created as a result of use of any of your samples.

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, but there could be others that the study staff will discuss with you, including coming to the clinic for your scheduled study visits to have the required tests and evaluations as well as completing surveys around each chemotherapy session.

You must follow the instructions of the study staff, including attending all of your scheduled study visits and participating in the intervention, if randomized to the resistance training group.

It is important that you return to the study clinic for all scheduled visits.

What are the potential risks, side effects and discomforts of being in this study?

Exercise: There are a few risks involved in attending the exercise sessions. You may experience some mild muscle soreness at the beginning of your activity program. Other risks or discomforts may include changes in the strength or sensations in your arms or legs, muscle or ligament strain, or a temporary increase in back pain. These changes are rarely serious. Less common risks associated with physical activity include changes in blood pressure or heart rhythm, dizziness, or fainting. Study staff will monitor all of your sessions to reduce these risks. We also ask you to call us if any of your symptoms become severe.

Questionnaires: The primary risk to participants in the use of these forms may involve a loss of privacy with questions that ask for personal information. All questionnaire data collected will remain totally confidential. During the entire study, you will probably spend a total of about 4 hours filling out forms. You may feel uncomfortable answering questions that seem sensitive and personal. You may skip any question that you don’t want to answer.

Blood draw: There are minor risks when having blood drawn. Local pain, bruising, and, in rare instances, an infection might occur at the site where blood is drawn. There is also the possibility of dizziness or fainting while your blood is being drawn.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for employers, health insurers and group health plans to discriminate against individuals based on their genetic information. GINA limits the way these parties can use genetic information. GINA does not protect individuals against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The genetic information we collect or obtain through research will not affect your eligibility for future medical care, membership in Kaiser Foundation Health Plan, or cost of your premiums or benefits.

DXA scan: In this study, you will be exposed to radiation during the DXA scan. The additional amount of radiation that you will receive as a result of participating in this study will be equivalent to one-tenth the radiation received by a chest x-ray or less than a round trip plane flight from San Francisco to New York. If you have any questions regarding the use of radiation or the risks involved, please consult the investigator conducting the study. While we cannot be sure any dose of radiation is entirely safe, the amount you will be exposed to in this study is not known to cause health problems. The DXA scan will not be taken if you are pregnant.

Urine sample with labeled creatine: There are no known risks to the non-radioactively labeled creatine. Labeled creatine is a stable isotope. Creatine is a normal component of animal protein; the average person consumes 1 gram of creatine per day, which is several times greater than the dose (30 mg) you will receive for this study. The labeled creatine pill has not been approved by the Food and Drug Administration (FDA) because it is not a drug. Non-labeled creatine is available over the counter as a nutritional supplement.

Risks related to loss of privacy: There is a small chance that being in this study may involve a loss of privacy. State and federal laws require Kaiser Permanente to keep your health information private and safe. In this study, your de-identifiable information is going outside Kaiser Permanente to another company, research organization, or person. Although Kaiser Permanente requires these outside researchers to keep your information private and safe, the laws that protect your information may not apply. Therefore, Kaiser Permanente cannot guarantee that your information will be protected once it is sent outside of Kaiser Permanente.

The storage and analysis of your blood and urine samples will be done in laboratories that are both inside and outside of Kaiser Permanente. Kaiser Permanente research staff at the RPGEH Biorepository in Berkeley, CA will separate the blood sample taken at the lab into smaller amounts for storage and analysis, Samples will be stored at a facility under the control of Division of Research Scientists, such as at the RPGEH Biorepository, and some of these blood samples will then be shipped to facilities that are controlled by research colleagues at the Boston Children's Hospital, Boston, MA. Urine samples will be shipped to a laboratory at the University of California, Berkeley, where analysis will take place. Use of your blood and urine

sample will remain under the control of the study principal investigators. Any samples that are stored outside Kaiser Permanente will not have identifying information such as your name or medical record number and will be linked only to a study-specific ID number.

You will be asked to have the DXA scan completed by a facility outside of Kaiser Permanente. You will supply them with your first name, year of birth, gender and race/ethnicity, for purposes of comparison of your body composition with that of other people of your age, gender, and race/ethnicity. The facility will return your DXA results to Kaiser Permanente and will be linked only to a study-specific ID number.

Unknown Risks: In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

Are there any benefits to being in this study?
Being in this study may or may not help you. There is no guarantee that you will see improvement. The researchers hope that the information learned through this study will help doctors and nurses who care for people with colon cancer in the future.

What are my choices if I do not want to be in this study?
Your alternative is not to participate in this study.

Will there be any costs to me to take part in this study?
No. All tests and physical examinations required as part of this study and parking at the research site will be provided at no cost to you while you are participating in this study. For those assigned to the RT study group, the exercise sessions, personal exercise counseling, and exercise equipment are free of charge.

As a member of Kaiser Foundation Health Plan, Inc. (KFHP) 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?
As a token of thanks for your time and efforts for participating, you will be given gift cards totaling $50 for study completion; $25 after completing the baseline visit and $25 after the follow-up visit.

What will happen if I am injured during the study?
In the event of a research-related injury, please contact the Study Principal Investigator, Bette Caan, DrPH, (510-891-3719) or the Research Project Manager, Michelle Ross, (510-891-3205).

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 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 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, or otherwise indicated in this consent form.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Under California law, the researchers must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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 National Cancer Institute, and/or its authorized representatives;
- Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights and welfare of participants); or the IRB that reviewed this research
- The study Data Safety Monitoring Board
- 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.

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 that is sent outside of Kaiser Permanente.

By signing this consent form, you will also be giving consent for the principal 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.

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 whether to participate in the study will not affect your medical 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 write a letter stating that you would like to withdraw from the study and send it to: Bette Caan, DrPH, Division of Research, Kaiser Permanente, 2000 Broadway, 5th Floor, Oakland, CA 94612.

Will I receive results from the DXA scans in this study?
We will mail you your baseline and follow-up body composition DXA results at the conclusion of your participation in the study. These results will not be placed in your medical record.

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 investigator responsible for the study within Kaiser Permanente in Northern California Bette Caan, DrPH, of the Division of Research, Kaiser Permanente at (510) 891-3719 or the Project Manager, Michelle Ross, at (510) 891-3205.

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.

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, which includes 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.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

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

Legally Authorized Representative (if applicable):

_____ _____
Legally Authorized Representative's Signature Date

_____
Legally Authorized Representative's Printed Name

_____
Legally Authorized Representative's Relation to Participant

AUTHORIZATION TO USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

STUDY TITLE: FOcus on Reducing dose-limiting toxicities in Colon cancer with resistance Exercise (FORCE) Study

SPONSOR: The National Cancer Institute

PRINCIPAL INVESTIGATOR: Dr. Bette Caan

STUDY CONTACT PHONE NUMBER: 510-891-3205

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, some of which includes your physical or mental health, the receipt or provision of health care, or payment for that care. The Privacy Rule requires that researchers obtain your written authorization (approval) for us to use and disclose (release) your PHI. A disclosure of PHI means communicating that information to a person or research facility/company outside of Kaiser Permanente Northern California.

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.

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, monitor your health status, measure effects of drugs, and determine research results. In addition, others at Kaiser Permanente may also review your research or medical record, or both, to monitor the study. For example, the Institutional Review Board that approved the study, may also review your research or medical record, or both, to monitor the study.

What information will be used or disclosed?

To do this study, we will look at or collect information about you and your health, which may include, for example, laboratory and other tests, and both clinical and research observations relating to your participation in the study. We will use and disclose your information electronically and via paper.

The following identifiable private information about you will be used and disclosed:

- Name
- Address
- Dates, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Electronic mail addresses
- Medical record number

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 as described in the consent form.

Kaiser Permanente researchers will not disclose your PHI unless required by law.

How will the confidentiality of my information be protected?

Kaiser Permanente is committed to protecting your personal health information. State and federal law also require Kaiser Permanente to maintain privacy and security of your information in this study. To protect the confidentiality of your information, we will create a unique study code to identify all study information about you. No personally identifiable information such as your name or medical record number will be attached to your study data that is sent outside of Kaiser

Permanente.

When will this authorization expire?

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

Can I withdraw this authorization?

If at any time you want to withdraw from this agreement, you must notify us in writing:

Bette Caan, DrPH
Kaiser Permanente
Division of Research
2000 Broadway, 5th floor
Oakland, CA 94612

After we receive your notification, we will continue to use only data that we have already looked at or disclosed, unless we need to monitor your data for your safety.

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.

Can I see the information collected about me in this study?

You may not be allowed to review the information collected about you for this clinical trial. Individual level information will not be provided.

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.			
Participant Signature:		Date:	
Participant Printed Name:			
Legally **A**uthorized **R**epresentative **(LAR) (if applicable):**			
LAR Signature:		Date:	
LAR Printed Name:		Relationship to Participant:	
Signature of Person Explaining the Authorization			
I attest that I discussed this authorization with the participant named above, and the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.			
Person Explaining Signature		Date:	
Person Explaining Printed Name			

---------- **Use this witness section only if applicable** ----------

Note: If this authorization form is read to the research study participant because they are unable to read the form, an impartial witness not affiliated with the research or investigator must be present and sign the following statement*:*

As an impartial third party, I witnessed the entire authorization discussion and the signature of the participant on this form.

Witness Signature:		Date:	
Witness Printed Name:			