Version Date: 08.31.2020	R&D Stamp: VA R&D	COMIRB Approval Stamp/Date:

Subject Name: _____ **Date:** _____

Title of Study: Optimizing Physical Activity Outcomes after Total Knee Arthroplasty

Principal Investigator: Cory Christiansen PT, PhD **VAMC:** 554

VA Investigator: Cory Christiansen PT, PhD **COMIRB# 17-0079**

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about physical activity behavior intervention as part of physical rehabilitation after total knee arthroplasty (TKA).

You are being asked to be in this research study because you are scheduled to have a total knee arthroplasty surgery.

Other people in this study

Up to 100 people from your area will participate in the study.

Up to 100 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will have a total of 24 rehabilitation visits. Fourteen of these visits will be inpatient or outpatient visits and 10 of these visits will be telerehabilitation visits. The telerehabilitation visits will be 30-minute, video-based visits using a computer tablet provided to you by the VA.

You will be randomly selected (like the flip of a coin) to be in the group receiving physical activity behavior change intervention or to be in the control group. If you are randomly selected to be in the physical activity behavior change intervention you will wear an activity sensor. If you are in the physical activity behavior change intervention you may also be asked to participate in two semi-structured interviews.

Tests and questionnaires will be given to you either at your home, via phone or video call, and/or through a website at four time points: 1) 2 weeks prior to TKA (PREOP), 2)

midway through intervention (8 weeks after TKA), 3) at the end intervention (14 weeks after TKA), and 4) at a long-term follow-up (38 weeks after TKA). At each session you will be asked to complete physical function testing and questionnaires that assess your physical health, functional ability, symptoms, physical activity, and quality of life. In addition, after each test session you will be given an activity monitor to wear for 1 week. The monitor will be wrapped around your thigh with a non-allergenic, water-proof wrap and TegaDerm patch and will measure your physical activity for that week. You are free to skip any tests and questions that you prefer not to perform or answer. Each test session will last approximately 1 ½ hours.

If you are participating in the semi-structured interviews, one will take place after your random selection and one will take place at the end of the intervention. The researcher will ask a series of open-ended questions about your perceptions of the rehabilitation process after total knee replacement. You have the choice to disclose as much or as little as you desire during this portion of the testing session. This portion of the testing session will be digitally recorded for analysis.

We may ask to audio record some telerehabilitation sessions so that we can check the researcher's consistency in the sessions. You are free to choose to allow this recording or not to allow it.

This research study is expected to take approximately 39 months. Your individual participation in the project will take 38 weeks.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Discomforts you may experience while in this study include delayed onset muscle soreness, fatigue, minor sprains, or strains (rare).

Distress caused by health-related questioning is also a risk (rare). If you experience distress, please discuss this with a member of the research team. All members of the research team are trained in methods to promote patient comfort and empathy. Should stressful moments arise during the interview, a member of the research team will provide you with a list of local mental health providers.

Other possible risks include:

- falls related to the intervention or testing
- negative cardiovascular response
- skin rash in response to activity monitor wrap and TegaDerm patch

We anticipate a negative cardiovascular response to the intervention to be rare, but serious. We do not anticipate the risk of such a response to be higher than regular daily physical activity. In the rare case of a negative cardiovascular response to physical activity, they may manifest in symptoms such as excess fatigue, chest pain and shortness of breath. In such incidence, you should immediately seek medical attention.

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

Risks of the usual care you receive are not risks of the research and 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 the study?

This study is designed for the researcher to learn more about physical activity behavior intervention as part of physical rehabilitation after total knee arthroplasty (TKA). However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

Are there alternative treatments?

There may be other ways of treating your knee post-TKA. These other ways include standard of care rehabilitation. You can receive standard of care rehabilitation outside of participating in this research study. You could also choose to get no treatment at all. You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored for by the VA.

Will I be paid for being in the study?

You will be paid $50.00 for each test visit (4 test visits total) in this study. The total amount possible to be paid to you is $200.00 if you complete all of the visits. If you leave the study early or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study are taxable income.

Your SSN will be collected and used to report this taxable income to the IRS.

Will I have to pay for anything?

There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you don't take part or leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get the same kind of medical care outside of the study. Ask your study doctor.

For data already collected prior to withdrawal from the study, the investigator may continue to review the data already collected for the study, but cannot collect further information, except from public records.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans, in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not

required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call Dr. Cory Christiansen at 303.724.9101 at any time.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Cory Christiansen.
You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call Dr. Christiansen at 303.724.9101. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303.724.1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at 720.857.5092

How will my private information be protected?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information confidential to the extent allowed by law. Records about you will be kept in a locked filing cabinet in a locked room and on password protected computers only accessible by authorized study team members.

Your social security number will be collected to report study participation payments. You can withhold your social security number and still participate in the study; however, you will not be able to receive payments.

Identifiers might be removed from the identifiable private information data that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

A description of this clinical trial will be available on http: 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.

Audio Recordings

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating in this study. You also authorize disclosure of the voice recording to Transcription Outsourcing Denver, an approved transcription service. The said voice recording is intended for the following purposes: Data analysis.

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

While this study is being conducted, you will have access to your research related health records.
This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, and lab results.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- Federal agencies such as the Food and Drug Administration (FDA), the

General Accountability Office (GAO), the Office of the Inspector General, Office for
Human Research Protections (OHRP), and the VA Office of Research Oversight (ORO)
that protect research subjects like you, may also copy portions of records about you.

- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor, the VA, study monitors, or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- Colorado Clinical and Translational Science Institute (CCTSI), REDCap Database (Research Electronic Database)

I understand that by signing this consent form, a copy of limited data about me, all research data that is collected as part of this specific VA research study will be stored in the REDCap database (or Data Storage System) at the University of Colorado Denver's (UCD's) Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed on the CCTSI REDCap Database will not be accessed or used for any other study or purposes and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Database is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado Denver.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Christiansen and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

Agreement to be in this study

I have read this form, or it has been read to me. A member of the research team has explained the study to me. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____.

Witness Signature: _____ Date: _____

Print name: _____

Witness of Signature ☐

Witness of consent process ☐