Participant Name: _____ Date:_____

Title of Study: Staying Positive with Arthritis: A Program to Improve Quality of Life

Principal Investigator: [Local Site Investigator] VA Facility: [Local Site]

Principal Investigator for Multisite Study: Leslie R.M. Hausmann, PhD

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

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

BACKGROUND AND PURPOSE

Why is this study being done? Arthritis of the knee is a painful and disabling condition. Existing arthritis treatments are not appropriate or effective for all patients. This study tests whether Veterans with arthritis benefit from a new treatment approach that is focused on staying positive. With this research we hope to learn whether a behavioral program that teaches people how to be positive will improve pain and overall well-being of Veterans with knee arthritis. We also hope to learn whether this new program works equally well for African American and white Veterans with arthritis.

Why are you being asked to participate? You are being asked to participate in this research study because you receive health care at *[enter VA facility name]* and have chronic and frequent knee pain due to arthritis.

How many people will participate in the study? Approximately 360 people will be enrolled in the study. About half (180) will be patients from *[enter VA facility name]*. The other half will be from other participating VA Medical Centers. As resources allow, up to approximately 240 additional people beyond the initial target (up to 120 from each participating site, including *[enter VA facility name]*) will be enrolled to support additional analyses.

Who is conducting the study? Dr. Leslie R.M. Hausmann is the Principal Investigator leading this study. Dr. Hausmann is an investigator at the Center for Health Equity Research and Promotion at the VA Pittsburgh Healthcare Center. Investigators from multiple VA Medical Centers are working with Dr. Hausmann on the study. Study activities at *[enter VA facility name]* are being led by *[enter LSI name]*.

Who is sponsoring the study? The study is sponsored by the Department of Veterans Affairs.

SUBJECT'S IDENTIFICATION

DURATION OF THE RESEARCH

This research study will be conducted over the course of about 3 years. Your individual participation in this study will include an initial survey, followed by completion of a 6-week program, followed by telephone surveys 1, 3, and 6 months after the program ends. From start to finish, your participation will last approximately 7 to 8 months.

STUDY PROCEDURES

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

Initial Survey: First, you will meet with a research staff member to complete an initial survey. The survey will include questions about your pain, mood, functional abilities, coping strategies, life experiences, health conditions, and demographics. You are free to skip any questions that you would prefer not to answer. The survey will take approximately 45 to 60 minutes and will take place at [*enter VA facility name(s)*]. If possible, you will complete the survey immediately following this consent process.

Randomization to 1 of 2 Programs: Following the initial survey, you will be randomly assigned (like by a flip of a coin) into one of two 6-week programs. The programs are similar in format and duration. The only difference between the programs is the specific activities they include. One program includes activities that will ask you to do things such as keep track of important things that happen to you over the course of a day, think about ways you would like to change your life circumstances, and think about your early memories. The other program will ask you to do things such as express thanks to someone, reflect on positive moments, or be pro-active about planning what you will do over the course of a week. You will be given a workbook for your assigned program. The workbook will contain instructions for a series of simple activities that may or may not help you stay positive. You will be asked to complete one activity per week for a total of 6 weeks. The activities are designed to be brief, but you can spend as much or as little time completing activities as you want. You will be asked to record your completion of activities each day in the workbook.

During the 6-week program, a research staff member will call you once each week to check in on your progress and answer any questions you have about the next week's activity. You are free to skip any questions that you would prefer not to answer. Each telephone call will take about 10 to 15 minutes.

Post-Program Follow-Up Surveys (1-Month, 3-Month, and 6-Month): At the end of the 6-week program, you will begin a 6-month follow-up period. You may continue to use activities from your assigned program, or not, as you prefer. A research staff member will contact you by telephone to complete follow-up surveys 1 month, 3 months, and 6 months after the 6-week program has ended. These surveys will include a subset of the questions from the initial survey. You are free to skip any questions that you would prefer not to answer. Each survey will take about 30 to 45 minutes.

Summary of Your Responsibilities If You Participate: If you decide to participate in the study, it is important that you fulfill the following responsibilities:

- Keep your study appointments. If you need to reschedule an appointment, contact the research staff to reschedule as soon as you know you will miss the appointment.
- Fill out your workbook as instructed.
- Complete the surveys with research staff as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators.

POSSIBLE RISKS OR DISCOMFORTS

There are minimal medical risks to you in this study.

There is a small risk that you may feel uncomfortable answering some of the questions asked on the surveys or completing some of the activities. You do not have to answer any questions or complete any activities that make you feel uncomfortable.

Because there may be risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

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

POTENTIAL BENEFITS

You may directly benefit from participating in this study. Research has shown that doing activities to be positive can reduce pain and increase overall well-being for some people. However, since we are testing new activity programs in this study, we cannot guarantee that you will benefit directly by participating in this study.

This study may also help others and society in general by adding to the scientific knowledge available about methods to reduce pain and increase well-being.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to participate in this study. If this is your decision, you may find information about activities that reduce pain and/or improve well-being through self-help books and the internet.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Only project staff will have access to electronic and paper data collected about you for this study.
- Electronic data will be stored on computer systems within a VA computing network that is protected by a VA firewall. Access to electronic data will be restricted only to authorized study personnel through the use of VA login and password permissions.
- Paper files will be locked in filing cabinets accessible only to approved project staff.
- Any information that could be used to identify you (such as your name, address, date of birth, etc.) will be stored separately from any information that does not contain identifiers.
- We will collect the last 4 digits of your social security number for this study. This information is necessary to process your payment and is recorded on your HIPAA Authorization form.

Information about you will be combined with information from other people taking part in the study. We will write and talk about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. We will include information about your study participation in your medical record. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

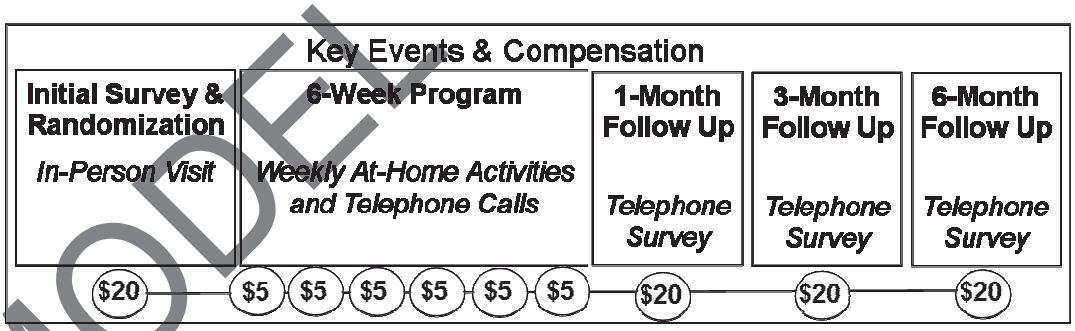
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COSTS TO PARTICIPANTS AND PAYMENT

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

This study requires 1 in-person visit at [*Enter VA facility name*]. You will be responsible for covering the cost of transportation to and from that visit. We will make every effort to schedule your study appointments at times that do not require you to miss work. You will not be reimbursed for wages lost due to your participation in this study.

Payment Offered for Participation: You will be compensated up to $110 for participating in the study. Payments will be issued as you complete key study events:



[Note: Payments can be in the form of cash, mailed checks, or direct deposit, per local payment policies at participating sites. Sites can edit the following suggested language as needed to reflect their local payment policies.]

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 07/28/2014

LSI Approval Date: N/A

LSI Verification Date: N/A

Payments will be delivered in the form of cash, checks delivered to you by mail, or direct deposits into your bank account. Cash payments will be made using payment vouchers that can be taken to an agent cashier. For payments made by check or direct deposit, study personnel at [*Enter VA facility name*] will submit forms to initiate payments after the completion of each study event. Payments will then be processed and disbursed by the national VA Austin Financial Services Center. Due to requirements in how participant payments are made, processing your payments will result in you receiving an Internal Revenue Service Form 1099 and will require the use of your SSN.

Checks that are mailed will take about 4 weeks to arrive. Direct deposits will take about 2 weeks to be posted to your account.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

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

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call **[insert LSI or designated local contact person]** at **[insert daytime phone number]** during business hours.

If you experience a medical emergency, please call 911, contact your local emergency medical service, or go to your local emergency room.

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

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. To withdraw from the study, tell the Principal Investigator or a study team member that you no longer wish to participate.

If you do not wish to be in this study or choose to leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you choose not to complete the 6-week program portion of the study, we will ask if you are still willing to be contacted to complete all follow up surveys. There will be no penalty to you if you

decide not to complete these surveys. If you choose to leave the study entirely, data already collected about you may continue to be reviewed for the study, but no further information will be collected.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigator(s) may stop your participation in this study without your consent for reasons such as it will be in your best interest, you do not follow the study plan, or you experience a study-related injury.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have general questions, concerns, or complaints about this research study, you may call **[insert name of local contact person], [insert role on study], at (xxx) xxx-xxxx.** [*If the person named is someone other than the LSI, add the following text:* You may also contact the **Principal Investigator, [insert LSI], at (xxx) xxx-xxxx** with questions about the study.]

You may also call your **local Patient Advocate** with any questions, complaints, or concerns about this research study at (xxx) xxx-xxxx.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Title of Study: Staying Positive with Arthritis: A Program to Improve Quality of Life

Principal Investigator: [Local Site Investigator] VA Facility: [Local Site]

Principal Investigator for Multisite Study: Leslie R.M. Hausmann, PhD

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

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

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. *[INCLUDE THE FOLLOWING ONLY IF APPLICABLE AT YOUR SITE:* A copy of this signed consent will also be put in your medical record.*]*

I agree to participate in this research study as has been explained in this document.

_____	_____	_____
Participant's Name	Participant's Signature	Date
_____	_____	_____
Name of person obtaining consent	Signature of person obtaining consent	Date

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