Participant Name:	**Date:**
Study Title: STepped Exercise Program for Knee OsteoArthritis (STEP-KOA)	
Principal Investigator: Kelli D. Allen, PhD	**VAMC:** Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to examine whether a stepped approach to improving physical activity will improve outcomes such as pain severity, physical function, and exercise abilities for veterans with osteoarthritis. The stepped approach allows the physical activity program to be customized for different people.

A total of 345 veterans from the Durham VA Medical Center (Durham VAMC) and the Greenville Health Care Center will participate in this study.

You are being asked to participate in this research study because you are a veteran that has been identified as a patient with knee osteoarthritis and have self-reported knee symptoms.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The study examines a 9 month program of access to either (1) a stepped physical activity program for people with knee osteoarthritis (STEP-KOA) or (2) an arthritis education program.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study the total time for your participation today will be 1 ½ - 2 hours. You will first complete baseline questionnaires and physical function tests like walking and standing up from a chair. We will also take your blood pressure. During these assessments it is possible that we may identify some health concerns that could make it unsafe for you to begin a new exercise program. If that happens, we would ask you to follow up with a health care provider first, to see if it would be safe for you to continue in the study.

Within about a week after today's visit, a study team member will call you to give you your group assignment. You will be randomly assigned (using a procedure like flipping a coin), to one of two (2) groups as explained below. You will have a 2 in 3 chance of being in the STEP-KOA Group or a 1 in 3

chance of being in the Arthritis Education Group. The table below is an overview of your participation based on the group you are assigned.

	STEP-KOA GROUP	ARTHRITIS EDUCATION GROUP
Baseline assessments	Complete questionnaires today.	Complete questionnaires today
	Phone call to receive instructions to access and use the STEP-KOA program.	
	(Step 1 of STEP-KOA) Access to the internet-based exercise training program	Receive arthritis education materials by mail every 2 weeks
3-month assessments	Complete questionnaires by telephone (30 minutes)	Complete questionnaires by telephone (30 minutes)
	(Step 1) Continue access to the internet-based exercise training program only **OR** **(Step 2)** Access to the internet-based training program + telephone-based exercise counseling (15-20 minutes every other week)	Receive arthritis education materials by mail every 2 weeks
6-month assessments	Complete questionnaires by telephone (30 minutes)	Complete questionnaires by telephone (30 minutes)
	(Step 1) Continue access to the internet-based exercise training program only **OR** **(Step 3)** Access to internet-based training program + in-person physical therapy visits (3-7 visits, 30-60 minutes each)	Receive arthritis education materials by mail every 2 weeks
9-month assessments	Complete questionnaires in-person at the site where you first enrolled in the study - Durham VAMC or Greenville Health Care Center (30 -60 minutes)	Complete questionnaires in-person at the site where you first enrolled in the study - Durham VAMC or Greenville Health Care Center (30-60 minutes)
		(Step 1) Access to the internet-based exercise training program **AND** **(Step 2)** telephone-based exercise counseling (15-20 minutes every other week)
15-month assessments	Complete questionnaires by telephone (30 minutes)	NONE

STEP-KOA Group

The STEP-KOA program involves 3 different Steps (described below). All participants in this group will start with Step 1. Participants who experience clinically meaningful improvements in pain and function (based on surveys) after three months of the Step 1 program will continue with that step. Participants who do not experience clinically meaningful improvements will add Step 2 for the next three months. After six months in the program, participants who have experienced clinically meaningful improvements in pain and function will continue with their current program. Those who have not experienced clinically meaningful improvement will go on to Step 3.

Step 1:

Step 1 is an internet-based exercise training program. It was developed by a team of patients, physicians, and physical therapists to provide personalized exercise recommendations for people with knee osteoarthritis. The program includes different levels of difficulty. Each exercise level includes recommendations for specific strengthening and stretching exercises, along with videos to show how to do each exercise. The program also recommends aerobic exercise appropriate for each level. Participants in the study will be asked to record their exercises and pain level each time they use the internet-based exercise training program. The program will make recommendations for increasing exercise levels, based on this information.

Participants will not be asked to enter their name or any other personal identifying information into the website. You will be provided with a unique ID number to use when accessing the website. We will provide instructions for using the program. Participants can also contact a study team member for help or questions about using the program. A study team member may also call you with reminders or other information related to the web-based exercise program.

Participants will use their own computers or tablets to access the internet-based exercise training program. However, participants who do not have access to a home computer with internet access will be loaned an appropriate device to run the program. This will be loaned only for the time period when participants are in the STEP-KOA program. If you are loaned a device you will need to sign forms agreeing to appropriate use and care of the device.

Step 2:

Step 2 of the program involves telephone calls from an exercise counselor, every other week. These calls will usually be about 15-20 minutes long. The first call may be longer to help get you started with these sessions. The exercise counselor will help participants to address any barriers or difficulties with exercise. The exercise counselor will also help participants to develop personal goals and action plans for their exercise.

Step 3:
Step 3 involves 3-7 visits with a study physical therapist. The first visit will be about an hour, and the rest of the visits will be about 30 minutes. These visits will occur at the Durham VAMC or Greenville Health Care Center. These visits will include assessments of physical function and the need for any assistive devices. Physical therapists will also make recommendations about participants' home exercise program.

Arthritis Education Group
Participants in this group will receive educational information via mail, about every two weeks for 9 months. These materials will include a variety of topics about osteoarthritis and how it can be managed, including physical activity, weight management, and different medical therapies. After completing nine-month study measures, participants in this group will be given access to the Step 1 program (as described above) and will receive the exercise counseling phone calls described above for Step 2.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?
Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

WHAT OTHER OPTIONS DO I HAVE?
Taking part in this study is your choice. You have the option not to participate. If you decide not to take part in the study, or if you withdraw from the study, you will continue with your usual medical care through the Durham VAMC without participating in this study. The only alternative to participating in the study is choosing not to participate.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?
Your participation in this study will be 9-15 months, depending on the study group you are assigned to.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?
- All risks associated with participating in this study cannot be predicted. As part of this study you will receive education about exercises that are appropriate for people who have had knee osteoarthritis. These exercises follow guidelines recommended by physicians and physical

therapists. However, exercise programs may be associated with muscle soreness, or joint pain. If you do experience increased pain, we will provide recommendations on how you may be able to reduce the pain.

- As part of this study you will be providing us with information about you and your health. There is a risk of loss of confidentiality of this information. However, we will take every precaution to protect your personal information, using procedures required by the VA.

- Information shared with Visual Health Information on their website may no longer be protected under federal law. Once information is entered into the website, Visual Health Information will be responsible for maintaining its security.

- If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. You may experience improvements in pain, function, or other symptoms by taking part in this study.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

Participants will be paid up to $140 for completing the study. Please note that this is not considered travel pay. You will receive $40 for each in-person visit to the Durham VAMC or Greenville Health Care Center. These in-person visits are at baseline and 9 month follow-up. You will receive $20 for each telephone-based assessment you complete at 3 month, 6 month, and 15 month follow up. Exercise coach phone calls are considered part of the intervention and will not be compensated. You are responsible for travel costs to study visits.

Patients who require study Step 3: Physical therapy sessions will be paid $10 for each physical therapy visit, plus an additional amount that varies by distance traveled for the 3-7 sessions.

Distance (miles)	Additional allowance
0-25	$8
25-50	$15
50-100	$30
100-150	$45
150-200	$60
> 200	$75

HOW WILL I BE COMPENSATED?

The way you receive this money will be according to VA procedures during the time you are in the study. A study team member will explain these options to you. The VA preferred method of payment is through electronic funds transfer (direct deposit into your bank account). This takes approximately 1-3 business days. Payment through electronic funds requires you to give the VA your bank account number. If you choose to receive your payment by check it will take approximately 4-6 weeks. Payments will be processed immediately after each in-person visit or each telephone-based assessment.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Kelli D. Allen may take you out of the study without your consent for one or more of the following reasons:

- She decides that continuing your participation could be harmful to you,
- You fail to follow instructions of the investigator and/or study staff, or
- You need treatment that is not allowed on the study.
- You develop a health condition or have a procedure that would influence study outcomes

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

While we do not plan to provide results of individual tests to participants in this study, we plan to send a letter to all participants, after the study is completed, to report on the overall results of the study.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

The study is sponsored by the Department of Veterans Affairs, Health Services Research and Development. Dr. Kelli D. Allen will not financially benefit from the study, but the Department of Veterans Affairs will support the salary of the research team.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

There are VA rules (called records control requirements) about how long your research records are kept. Your medical records will be maintained according to this medical center's requirements.

Your paper files and questionnaires will be stored and locked in locations managed by the Durham VAMC and will only be available to Dr. Allen and her research team to protect your privacy. Study databases will be stored on a secure VA server in locations only accessible to study personnel. Key study personnel include the principal investigator, co-investigators, physical therapists, exercise scientist/counselor, project coordinator, research assistant, and statisticians. Once the study data are no longer needed, paper files will be shredded in accordance with VA requirements for destruction of sensitive information. Information in electronic format, including videos, will be deleted or purged from data files in accordance with VA records control requirements.

Your research records will be maintained and destroyed according to VHA records retention requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Visual Health Information (VHI) is the company that maintains the exercise website. VHI will have access to your responses to questions asked on the website.

Your name and address may be shared with a courier like UPS or FedEx for the purposes of receiving study equipment.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Allen at (919) 286-0411 x7090 during the day or at (919) 641-2052 at night. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

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AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

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Participant's Signature **Date**

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Signature of Person Obtaining Consent **Date**