RUTGERS
Robert Wood Johnson
Medical School

Department of Orthopaedic Surgery

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: The Impact of Two Different Physical Therapy Programs in the Rehabilitation of Patients Undergoing Anterior Approach Hip Replacement Surgery.

Principal Investigator: Stephen Kayiaros, MD

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor Stephen Kayiaros will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Stephen Kayiaros is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Kayiaros may be reached at (732) 537-0909, or at the University Orthopaedic Associates office:

- UOA Somerset: 2 Worlds Fair Drive, Somerset, NJ 08873

The study doctor will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

The study's purpose is to investigate two types of physical therapy programs in the rehabilitation of patients who undergo a minimally invasive hip replacement surgery (anterior approach). This special type of surgery uses the top portion of the thigh for the incision rather than the back of the thigh (posterior approach). Multiple studies have shown that patients undergoing this specific type of hip replacement surgery (minimally invasive) require less intense rehabilitation because their muscles are damaged less by surgery. This study wants to compare physical therapist directed physical therapy with a self-directed physical therapy protocol to demonstrate that both types of therapy will equally return people to normal function after surgery.

Why have you been asked to take part in this study?

You are a patient of Dr. Kayiaros' and are interested in having anterior hip replacement surgery. Since you will undergo your surgery and post-operative care at with Dr. Kayiaros, you may be eligible for this study.

Who may take part in this study? And who may not?

Patients between the ages of 18 to 80, who walk without help (canes, walkers), and those that will be going home directly from the hospital after surgery are eligible for this study.

You may not enter the study if you meet any of the following:

- If you recently (<1 year) had a heart attack, stroke, or lung clots
- If you had previous invasive surgery on the hip undergoing replacement
- If you have dementia, Parkinson's, or similar problems because that makes it more difficult to follow physical therapy programs and require special treatment/rehabilitation
- If you don't walk. This study is looking at your ability to walk after hip replacement surgery.
- If you don't have the ability to consent, whether because of mental illness or otherwise.
- If you are being discharged to a rehabilitation center. We won't be able to monitor your post-operative therapy if you go to a rehab center.
- If you experience any complications during the surgery, such as a fracture of the leg bone. These complications change the postop therapy.

How long will the study take and how many subjects will participate?

Your study participation will last from your pre-admission visit with your surgeon and will continue for 12 months following your hip surgery.

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150 people will participate in this study. There will be 75 people in each study group.

What will you be asked to do if you take part in this research study?
You will be randomly assigned to one of two physical therapy groups by chance. Neither you nor your doctor can choose the group you will be in. The two groups are: 1) self-directed physical therapy or 2) formal physical therapy.

The self-directed physical therapy group concentrates on a self-directed home therapy program, which will be supervised by Dr. Kayiaros and his physician assistant. This self-directed physical therapy group will perform daily exercises at home. You will be given instructions on how to perform these exercises at your pre-op visit as well as in the hospital after surgery. To assure that you are advancing appropriately, you will follow up week 2 after surgery. At this week 2 visit, Dr. Kayiaros or his physician assistant will evaluate your progress. If there is concern you are not progressing appropriately, Dr. Kayiaros will discuss with you the option of switching to formal therapy. This self-directed physical therapy group will continue to perform self-directed home therapy for the duration of the study.

The second group will undergo standard outpatient physical therapy (formal physical therapy) for the duration of the study. Thus, if you are in the formal group, your process will be monitored by a trained physical therapist.

Regardless of your group, you will be continuously monitored by clinical staff and/or physical therapists at all times.

Participants in both groups will have an office visit at 1 month, 3 months, 6 months and 12 months after surgery, which is normal after hip replacement surgery. If more postoperative visits are deemed necessary depending on individual progress, these will be arranged. Upon each visit to the office you will be asked to complete self-administered questionnaires that address how you are functioning. These forms and scales are standardized tests used in research. The completion of these forms will take roughly 5-10 minutes.

You will also complete a Timed Up and Go Test (TUG Test). The TUG test consists of timing you getting up from a chair, walking 10 feet, and then returning back to the chair.

Your office visit will last as long as necessary for Dr. Kayiaros and his clinical staff to properly evaluate you, which is generally 10-20 minutes.

What are the risks and/or discomforts you might experience if you take part in this study?

There are minimal risks to you in this study since the study takes place after your hip surgery. You may experience pain after participating in physical therapy after surgery. Pain is the main risk and discomfort that you may experience in both groups of this study. Pain can be relieved with both ice and/or pain medications. You may take over-the-counter medicines, prescription pain medications, herbal products, vitamins or food supplements while taking part in this study.

The additional risk in the Self-Directed Physical Therapy group is that you may not improve as quickly after surgery as the formal therapy group. However, it is believed by Dr. Kayiaros, and demonstrated in medical research studies, that various forms of physical therapy have equal effect on postoperative recovery following hip replacement surgery. To assure that you progress appropriately, you will have an extra post-op visit at 2 weeks if you are in the self-directed group. At this visit, Dr. Kayiaros will evaluate you and determine your progress. If you or Dr. Kayiaros believes that you are not progressing appropriately, you will be switched to the traditional therapy group. There is no harm to switching groups.

Are there any benefits for you if you choose to take part in this research study?

You may benefit from forgone PT, which allows you to have more free time, allowing you to return to your normal life quicker when compared to patients undergoing PT.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

If you don't want to take part in this study, you will receive medical care that Dr. Kayiaros uses commonly for his patients after the operation.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There will be no additional costs to you by participating in this study.

Will you be paid to take part in this study?

There is no compensation for participating in this study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All study data will be either stored on the secured network at Robert Wood Johnson University Hospital on a locked computer located in the locked orthopedic office, or in a locked filing cabinet. Only Dr. Kayiaros and the study staff (Drs.

Preston and Bateman) will have access to your information. No one else in the hospital will have access to you information.

What will happen if you are injured during this study?

It is highly unlikely you will be injured during this study. There are less than minimal risks to you when participating in this study since it takes place during your surgical recovery.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Dr. Kayiaros - (732) 537-0909, or at the University Orthopaedic Associates offices:

- UOA Somerset: 2 Worlds Fair Drive, Somerset, NJ 08873

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor Stephen Kayiaros' office at (732) 537-0909.

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Protected Health Information (PHI) under HIPAA means any information that identifies an individual and relates to at least one of the following:

- The individual's past, present or future physical or mental health.
- The provision of health care to the individual.
- The past, present or future payment for health care)

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- *All information in your medical record*
- *Hospital discharge summaries*
- *Medical history or treatment*
- *Medications*
- *Diagnostic tests or imaging*
- *Operative reports (about a surgery)*

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

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Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others.

If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Kayiaros - (732) 537-0909, or at University Orthopaedic Associates - 2 Worlds Fair Drive, Somerset, NJ 08873

How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____