

Title:

Informed Decisions and Patient Outcomes: An Interdisciplinary Approach to Chronic Hip Pain.

NCT03519087

Document dates:

2017.11.06	Approved by Institutional Review Board(IRB)
2018.02.14	IRB approved amendment to add qualitative interviews
2018.03.30	IRB approved amendment to add observational arm for laboratory testing and enrollment reasons
2019.03.06	IRB approved amendment to include patients with bilateral hip pain and add exit survey

## The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

**Study Title:** Informed Decisions and Patient Outcomes: An  
Interdisciplinary Approach to Chronic Hip Pain.

**Principal Investigator:** Stephanie Di Stasi Roewer, PT, PhD

**Sponsors:** Foundation for Physical Therapy, Ohio Physical  
Therapy Association, The Ohio State University  
School of Health and Rehabilitation Sciences, and The  
Ohio State University Graduate School

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

### 1. Why is this study being done?

This study is being done to collect information on people who have hip pain that is not associated with osteoarthritis (ie. degeneration of the joint). The overall goal of this study is to better understand whether or not interdisciplinary care can impact treatment decisions and outcomes for patients with non-arthritic hip pain. By collecting this information, we can determine whether a physical therapy evaluation and treatment focused on posture and movement training can provide additional benefits for patients seeking treatment for hip pain from an orthopaedic physician.

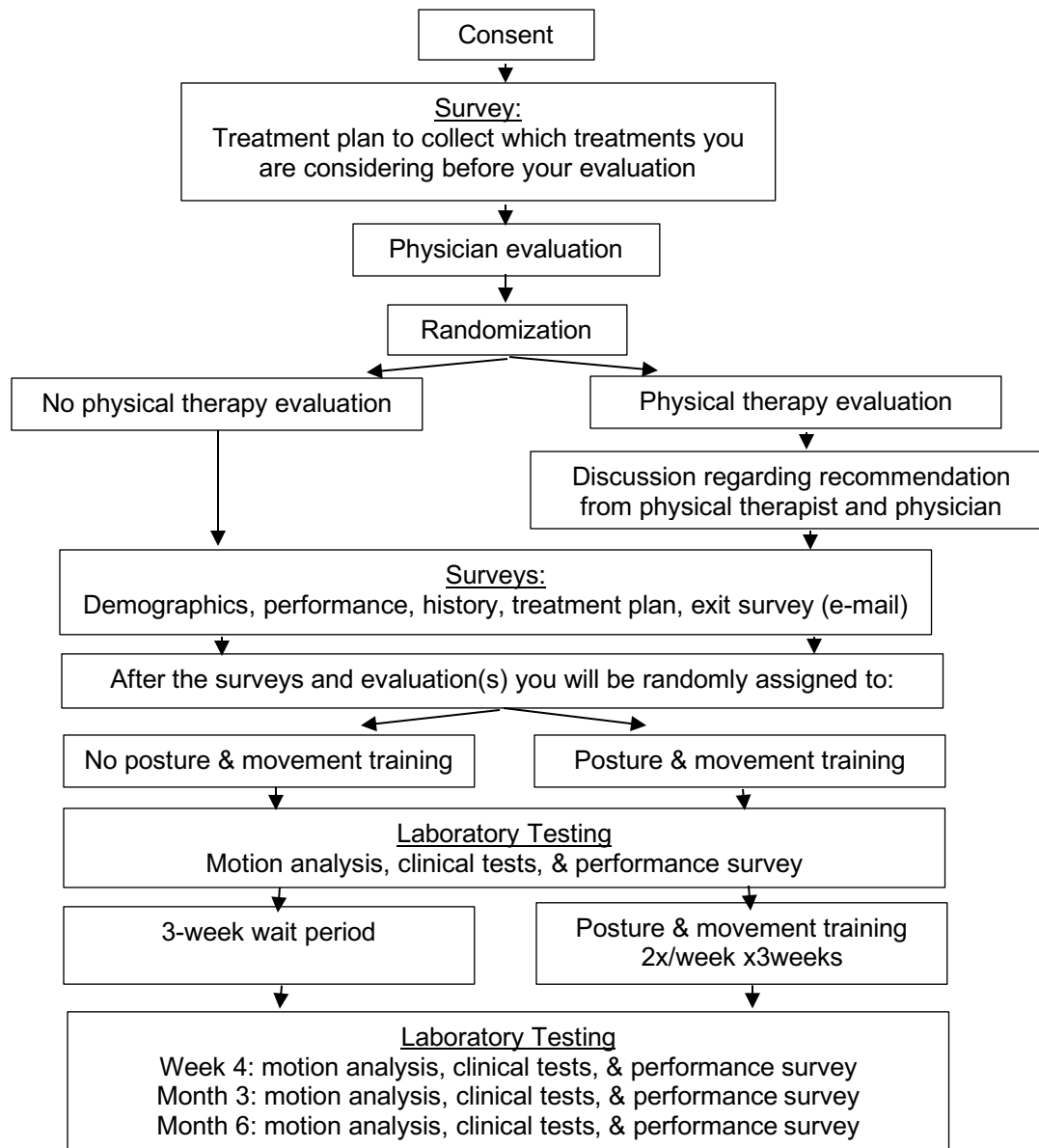
You are being asked to participate in this study because you are a new patient at the Hip Preservation Clinic at The Ohio State University Wexner Medical Center (OSUWMC). All patients who consent to participate will be enrolled in this study and will proceed with their scheduled evaluation with the physician. The physician will confirm participants have non-arthritic hip pain in only one hip, are not pregnant, and do not have a spine or lower extremity injury or health condition that negatively affect your function.

**2. How many people will take part in this study?**

We expect to enroll a total of 640 participants; of these enrolled participants, we expect 96 to meet inclusion/exclusion criteria.

**3. What will happen if I take part in this study?**

To best understand how this study works, you should understand what randomization is. Randomization is a process of randomly assigning participants to different groups. Consider for each participant, if the investigators flip a coin to determine which of the 2 groups each participant will be assigned. This is an example of how randomization is performed. We will not flip a coin to assign groups, a computer program will randomly select which evaluation you should be assigned.



If you agree to be in this study, after the survey and physician evaluation you will be randomly assigned to either receive or not receive a same-day physical therapy evaluation (10 min) immediately following your evaluation with your physician.

If you are NOT randomized to receive the Physical Therapy Evaluation:

You will complete a survey regarding your treatment plan (5 min). This survey will collect information regarding which treatments you are considering before your evaluation. You will then proceed with the physician evaluation that you have

scheduled for today. After your evaluation you will complete surveys (10-15 min) to collect information about your:

- Demographics (ie. Your age, ethnicity, type of work you do, etc.),
- Performance (ie. How does your hip affect you during your normal data activities),
- History of your hip pain or injury, and
- Treatment plan.

An exit survey (3min) will be emailed to you an hour after leaving the physician office to provide you the opportunity to give our study team feedback about your experience.

If you are randomized to receive the Physical Therapy Evaluation:

You will complete a survey regarding your treatment plan (5 min). This survey will collect information regarding which treatments you are considering before your evaluations. You will then proceed with the physician evaluation that you have scheduled for today. After your evaluation with the physician, if he confirms you have hip pain not due to arthritis, a physical therapist will conduct an evaluation.

The physical therapist will use the information documented in your medical record by the physician in order to streamline his or her evaluation. He or she will focus on evaluating your strength, posture, movement, and balance. This appointment will happen today, in this clinic, immediately following your visit with your physician and will last approximately 10 minutes.

Both the physician and physical therapist will return to discuss treatment recommendations with you, then you will complete surveys (10-15 min) to collect information about your:

- Demographics (ie. Your age, ethnicity, type of work you do, etc.),
- Performance (ie. How does your hip affect you during your normal data activities),
- History of your hip pain or injury, and
- Treatment plan.

An exit survey (3min) will be emailed to you an hour after leaving the physician office to provide you the opportunity to give our study team feedback about your experience.

Regardless of which evaluation you receive:

You may be asked to discuss how you felt about your evaluation (with the physician or with the physician and physical therapist) with a research investigator. This

discussion would be audio-recorded, but will not contain any personal information about you.

After you discuss your treatment options, you will then be randomly assigned to receive posture and movement training or undergo a 3-week wait period. Regardless of group, you will be asked to complete laboratory testing (1.5hr) to collect information on how you move during functional tasks and clinical measures of your movement and strength. If you receive the posture and movement training you will be scheduled twice weekly for 3 weeks; each session lasts 30 minutes. If you receive the 3-week wait period we will ask you withhold any treatment (e.g. surgery, injections, physical therapy) for those 3 weeks. After the 3-week intervention or wait period, you will be asked to come in at week 4 to complete the same laboratory testing you did at the entry to this study. You may then proceed with any treatment you desire. At 3 months and 6 months from the time of entry into the study we will contact you to schedule follow-up laboratory testing.

#### Laboratory Testing:

Laboratory testing will occur in the Motion Analysis and Performance Laboratory at the Jameson Crane Sports Medicine Institute at 2835 Fred Taylor Drive, Columbus OH 43202. Your first testing will occur within the next few days based on your availability; we will work with you to identify a time in which you can come for testing. If you are assigned to receive posture and movement training, it must be completed before you begin treatment. Testing includes 3 components:

##### 1. Motion Analysis:

This will take about 45 minutes. Motion analysis testing uses special 2- and 3-dimensional cameras with synchronized force platforms to record how you move and the forces acting upon your body during common daily activities, like walking and standing up from a seated position. Reflective markers will be attached to your feet, legs, pelvis, trunk, and arms with adhesive spray and double-sided tape – this allows the specialized cameras to see your limbs moving during all of the testing activities.

First, you will perform several trials of standing up and sitting down from a standard chair height. Next, you will perform several trials of stepping down from a standard step height. Then, you will be asked to perform several walking trials at a controlled and consistent pace.

##### 2. Clinical Testing:

This will take about 45 minutes and will be completed by a licensed physical therapist. Your height and weight will be recorded and body mass index (BMI) will be calculated. The strength of your hip muscles will also be measured. You will be asked

to sustain your maximum force against the strength measuring device. These tests will be performed on each leg. You will be allowed several practice trials before we record your performance

3. Self-reported performance:

We will ask you to complete surveys to capture how you reported you are performing during activities of daily living. These surveys should take approximately 15 minutes.

Physical Therapy Treatment (Posture and Movement Training):

If you are randomized to receive posture and movement training, your appointments will be scheduled twice weekly for 3 weeks at an OSUWMC Sports Medicine location most convenient for you. Your first appointment will last approximately 60 minutes, with following appointments generally lasting 30 minutes. Each appointment will focus on posture and movement training specific to your needs from the physical therapist. This will include exercises and education to improve your posture and movement.

4. How long will I be in the study?

You will be in the study for six (6) months. Your time commitment may vary depending on what groups you are randomized to participate in (Table 1-2).

**Table 1. Time commitment for same-day clinic evaluations**

	Physician evaluation	Physician evaluation + Physical Therapy evaluation
Baseline surveys	5min	5min
Physician evaluation	10min	10min
Physical Therapist evaluation	--	10min
Discussion with physician and physical therapist	--	5-10min
Follow-up surveys	10-15min	10-15min
<i>Recorded discussion with research personnel (not all participants will complete)</i>	<i>10-20min</i>	<i>10-20min</i>
Exit e-mail survey	3min	3min
<b>Total time estimate</b>	<b>38-53min</b>	<b>53-73min</b>

**Table 2. Time commitment for 3-week intervention or wait period**

	3-week wait period	Posture and movement training PMT)
Baseline testing	1.5hrs	1.5hrs
Week 1	--	1.5hr
Week 2	--	1hr
Week 3	--	1hr
Follow-up testing	1.5hrs	1.5hrs
3mo testing	1.5hrs	1.5hrs
6mo testing	1.5hrs	1.5hrs
<b>Total time estimate</b>	<b>6hrs</b>	<b>9.5hrs</b>

## **5. Can I stop being in the study?**

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or your relationship with any of your health care providers.

You may choose to withdraw from the study at any time by notifying the clinician monitoring your hip pain or any member of the research team. If you wish, you may also request your data, including all protected health information (PHI), be removed (deleted) from the database. While the study is ongoing, we can withdraw your information from the database. Once the study ends, the information that identifies you will be removed from your study records and the study team will keep these records for as long as they wish. After that, we can no longer tell which information is yours, so there will be no way to remove your information from the database.

### Additional options to participate:

- You can choose to participate in the full study, including randomization to posture and movement training and the accompanying lab testing and follow-up surveys;
- You can choose to participate in the lab testing and follow-up surveys, but not randomization to posture and movement training;
- Or, you can choose to participate in follow-up surveys, but not lab testing or randomization to posture and movement training.

## **6. What risks, side effects or discomforts can I expect from being in the study?**



The risk of breach of your confidentiality is minimal. Your data will be maintained in a security-protected and encrypted database only accessible to the research team. Any identifying information about you will only be shared with the personnel involved in this research study.

The physician and physical therapist will record their recommendations for your treatment in their evaluation notes; this information will be used for research purposes. Physical therapy treatment notes as part of this study will be used for research purposes to evaluate what interventions you underwent.

The risk of physical injury or muscle fatigue discomfort to you during the clinical and motion analysis testing is minimal. This risk is no greater than the risk you assume during daily living.

We will aim to schedule your first laboratory visit within a few days of your evaluation with the physician. If you are randomized to receive the 3-week wait period, you may undergo 4 weeks without treatment. This wait period is consistent with the standard 3-4 week wait period from physician evaluation to surgery date at Ohio State. This wait period may be longer than your standard 2 week wait period from physician evaluation to first day of physical therapy treatment at Ohio State.

**7. What benefits can I expect from being in the study?**

There are no direct benefits from participating in this study.

**8. What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

**9. Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;

- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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 the website at any time.

#### **10. What are the costs of taking part in this study?**

This physical therapy evaluation and any subsequent treatment (ie. posture and movement training) is within the standard-of-care for individuals with non-arthritis hip pain. **If you are randomized to receive posture and movement training**, your insurance will be billed for these services as it would if you saw a physical therapist at any other clinic.

**I have read the above statement and understand that physical therapy treatment as part of this study will be billed as such to my insurance company (initial and date below).**

\_\_\_\_\_ **I consent to this physical therapy treatment and understand that if my insurance does not cover it, I am responsible for the costs of treatment.**

\_\_\_\_\_ **I do not consent to this physical therapy treatment (withdrawn from study).**

You may incur cost of travel to physical therapy treatment sessions for posture and movement training; however, parking is provided without cost to participants.

There are no costs for the testing sessions, other than you may incur cost of travel. Parking is provided without cost to participants.

#### **10. Will I be paid for taking part in this study?**

To compensate you for your time, you will be provided one \$10 gift card after completing all surveys today. If you participate in the additional interview process you will receive a second \$10 gift card for your time.

To offset costs associated with participation you will be given (1) a \$20 check for each laboratory testing session you complete and (2) a \$20 check for each physical therapy treatment session you complete (if you participate in randomization for posture and movement training). By law, payments to participants are considered taxable income.

### **11. What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should notify the researcher, your physician, or your physical therapist immediately. They will help determine whether you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

### **12. What are my rights if I take part in this study?**

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

### **13. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

#### **I. What information may be used and given to others?**

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;

- Information that includes personal identifiers, such as your name, or a number associated with you as an individual; and
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires.

## **II. Who may use and give out information about you?**

Researchers and study staff.

## **III. Who might get this information?**

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- Those who oversee the study will have access to your information, including:
  - Members and staff of the Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
  - The Office for Responsible Research Practices
  - University data safety monitoring committees
  - The Ohio State University Research Foundation
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;
- Others: Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study.

## **IV. Your information may be given to:**

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and

- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

**V. Why will this information be used and/or given to others?**

- To do the research;
- To study the results; and
- To make sure that the research was done right.

**VI. When will my permission end?**

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

**VII. May I withdraw or revoke (cancel) my permission?**

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

**VIII. What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study. However, if you are being treated as a patient here, you will still be able to receive care.

**IX. Is my health information protected after it has been given to others?**

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

**X. May I review or copy my information?**

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

## 15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the principal investigator, Dr. Stephanie Di Stasi at 614-685-9779 or [Stephanie.distasi@osumc.edu](mailto:Stephanie.distasi@osumc.edu).

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **the HIPAA Privacy Officer: Address: Suite E2140, 600 Ackerman Road, Columbus, OH 43210; Phone: (614) 293-4477.**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, please contact Dr. Stephanie Di Stasi at 614-685-9779.

## Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form.

---

**Printed name of subject**

---

**Signature of subject**

---

**Date and time**

**AM/PM**

---

**Printed name of person authorized to consent for subject (when applicable)**

---

**Signature of person authorized to consent for subject (when applicable)**

---

**Date and time**

**AM/PM**

---

**Relationship to the subject**

\_\_\_\_\_ By placing my initials here, **I do agree** to participate this study, including the randomization to the Posture and Movement Training.

\_\_\_\_\_ By placing my initial here, I agree to participate in the study EXCEPT, **I do not agree** to the randomization to the Posture and Movement Training.

\_\_\_\_\_ By placing my initials here, I agree to participate in the study EXCEPT, **I do not agree** to the randomization to the Posture and Movement Training OR the laboratory testing.

**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

\_\_\_\_\_  
**Printed name of person obtaining consent**

\_\_\_\_\_  
**Signature of person obtaining consent**

\_\_\_\_\_  
**Date and time**

**AM/PM**

**Witness(es) - May be left blank if not required by the IRB**

\_\_\_\_\_  
**Printed name of witness**

\_\_\_\_\_  
**Signature of witness**

\_\_\_\_\_  
**Date and time**

**AM/PM**

\_\_\_\_\_  
**Printed name of witness**

\_\_\_\_\_  
**Signature of witness**

**AM/PM**