COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE ORTHO – YPB
YALE ORTHO – MILFORD
YALE MEDICINE - MULTISPECIALTY

Study Title: Investigating the Impact of a Shared Decision-Making Tool on Patient Attitudes and Behaviors Regarding Treatment for Knee Osteoarthritis

Principal Investigator (the person who is responsible for this research): Daniel Wiznia, M.D. Orthopaedic & Rehabilitation Yale University School of Medicine, 800 Howard Avenue New Haven, CT 06520

Phone Number: 203-785-3714
24-Hour Phone Number: N/A

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to learn more about how the use of a Shared Decision-Making Tool (SDMT) will impact a patient's decision-making to pursue treatment for knee osteoarthritis.
- Study procedures will include: As a patient, you will be randomly assigned to either have your provider utilize the SDMT during your visit or not. Regardless, you will receive standard of care counseling with your orthopaedic surgeon as well as an opportunity to ask questions following the visit. You will also be asked to complete pre- and post-visit surveys designed to measure the severity of your knee osteoarthritis and your willingness to proceed with different treatment modalities.
- **At least one** visit is required, which will take approximately **thirty minutes** total.
- There are some risks from participating in this study**,** including the potential risk of breach in confidentiality to your stored health information.
- The study may also benefit you since it provides additional information about knee pain and osteoarthritis. The knowledge gained can help you better understand the role of lifestyle and treatment on your prognosis.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will provide consent to participate in the study.

Why is this study being offered to me?

We are asking you to take part in a research study because we are seeking patients between the ages of 45-65, who have knee pain. We are looking for approximately 200 participants who are already scheduled for appointments at Yale Orthopaedics clinic sites (800 Howard Ave, 48 Wellington Rd, 800 Boston Post Rd) to be part of this research study.

Who is paying for the study?
There is no funding support for this study.

Who is providing other support for the study?
There is no additional support to disclose.

What is the study about?
The purpose of this study is to determine the impact of a Shared Decision-Making Tool (SDMT), which provides information about osteoarthritis disease progression, on a patient's decision to pursue treatment for knee osteoarthritis.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:

Overview
We anticipate an initial patient visit that would take 30-45 minutes including an explanation of the study and obtaining consent, pre-study survey, PROMIS survey, short video, clinical exam, Shared Decision-Making Tool discussion, and any additional questions you may have.

Survey Clarification
The pre-study survey will ask questions to assess your willingness to pursue different treatments for osteoarthritis.

The PROMIS survey is a short survey that changes the questions asked based on the responses you enter. This will assess both your function and pain levels, prior to moving forward with the remainder of the study.

Patients will be given a unique alphanumeric code that will be used for the randomization process and to protect patient confidentiality.

Procedure
After the standard of care appointment with the physician, study participants will have the opportunity to discuss the recommended treatment options and ask questions. After one month, the study participants will receive a request to complete a follow-up survey. There are no additional appointments needed to participate in the study.

What are the risks and discomforts of participating?
How will I know about new risks or important information about the study?

There is a risk of breach in confidentiality to a subject's stored health information. We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
The study and the use of the SDMT can help provide additional information about your prognosis, as well as help you better understand the role of lifestyle and treatment on your prognosis.

How can the study possibly benefit other people?
The benefits to science and other people may include a better understanding of how utilizing a shared decision-making tool during patient appointments can help improve patient understanding of their prognosis and the treatment paths available to them.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?
You will not be paid for taking part in this study.

What are my choices if I decide not to take part in this study?
The alternative is to not participate and continue with the standard of care patient visit.

How will you keep my data safe and private?
We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?
The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes: name, date of visit, gender, age, MRN (medical record number), height, weight, telephone number, race, ethnicity, living arrangement, marital status, education attainment, insurance type, past medical history of diabetes or hypertension, treatment recommendations, and survey responses

How will you use and share my information?
We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies

- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By providing verbal consent, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to *Daniel Wiznia* at 800 Howard Yale University, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.
To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?

If you choose to terminate participation in the study, then we will not collect additional information, but we will use the information already collected to ensure the integrity of the study. data will be kept coded for one year then identifiers will be destroyed, and anonymized data kept for 5 years.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Dr. Daniel Wiznia, at **203-785-3714.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.