

Protocol Title:	Factors influencing patient expectations in joint replacement surgery
Principal Investigator: (Study Doctor)	Charles L. Nelson, MD Penn Orthopaedics Penn Presbyterian Medical Center 51 N.39th Street 1 Cupp Pavilion Philadelphia, PA 19104 (215) 349-8862

Why am I being asked to volunteer?

You are being invited to participate in a research study because you are receiving treatment at PennOrthopaedics for osteoarthritis and need either a knee or a hip replacement. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to investigate how expectations about joint replacement may impact satisfaction about the procedure.

How long will I be in the study? How many other people will be in the study?

If you decide to participate, you will be in the study from the time that you sign this consent form until 9 to 14 months after your surgery. The actual time may vary from person to person depending on each person's follow up visit schedule. We are planning to enroll about 250 people at Penn. About 500 people will be enrolled in total between Penn and New York University.

What am I being asked to do?

All participants are being asked to complete several surveys before joint replacement and at follow up care visits after total joint replacement surgery. We are also asking permission to access and use the information in your medical records and healthcare billing and financial information as part of this study. It will take about 15 – 20 minutes to complete all the surveys. The surveys will ask you about pain and function in your affected joint (hip or knee), your social support, your activities of daily living, your quality of life, your work life, and your expectations about your surgery. If it is not possible to complete the surveys during your follow-up clinic visits, a member of the study team may call you and ask you the survey questions over the phone.

What are the possible risks or discomforts?

This study poses risks to your confidentiality and/or privacy. The study team is trained and experienced in the conduct of clinical trials, in HIPAA legislation, and in ethical principals. Subject confidentiality and privacy is of the utmost importance to our team. All the standard processes of supplying a unique study identifier to each subject, the use of password protected/limited access

electronic files, and other standard procedures to ensure the confidentiality and privacy of research subjects will be used. Nevertheless, it is possible that subject confidentiality and/or privacy may be compromised.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available. If you wish to be added to a mailing list to receive a copy of any publications that result from this study, please provide your preferred contact information to the coordinator.

What are the possible benefits of the study?

You will not get any direct benefit from participating in the study. We hope knowledge that will result from the study may benefit patients undergoing knee or hip replacement surgery in the future.

What other choices do I have if I do not participate?

You can freely decline participation in this study.

Will I be paid for being in this study?

You will not be paid for your participation in this study.

Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. You will not be billed for any study specific activity.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent, because the Principal Investigator or regulatory oversight committee has decided to stop the study. If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What information about me may be collected, used or shared with others?

If you agree to participate in this study, the following information will be collected for study purposes.

- Name, address, telephone number, email or other electronic contact method if preferred by participants, date of birth
- Your medical record number, and other identifiers or codes (i.e. insurance info or invoice numbers)
- Your social security number (which may be required to access healthcare utilization or billing information)
- Personal and family medical history
- Results from a physical examinations, tests or procedures, including, implant device identifiers and serial numbers
- Information in the medical record

- Self-reported racial/ethnic background
- Your answers to survey questions

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

Since you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- See if the research was done right.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn (including the following):
 - The University of Pennsylvania Institutional Review Board (IRB)
 - The University of Pennsylvania Office of Clinical Research (OCR)

Who, outside of the School of Medicine, might receive my information?

Investigators at other sites:

- New York University, Langone Medical Center, New York, New York 10003
- New York University, Hospital for Joint Diseases, New York, New York 10003

Oversight organizations

- The Office of Human Research Protections (OHRP)
- Study funders (i.e., foundations or the NIH, if appropriate)

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Yes. 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 investigator for the study. If you withdraw your permission, you will not be able to stay in this study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's IRB grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. 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 investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

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. By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print Clearly)

Name of Subject
(Please Print)

Signature of Subject

Date

Name of Person Obtaining Consent
(Please Print)

Signature of Staff

Date