**An Examination of the Effects of Pre-operative Education on Patient Expectations in Total Knee Arthroplasties**

Participant Consent Form for 2009C6252

**Disclosure**

You are invited to participate in research conducted by Natasha D. Ray. ***Your participation in this study is entirely voluntary*.** Data you provide will be assigned an anonymous Participant Code. ***You can discontinue your participation at any time*.** Furthermore, your decision *not* to participate will have *no* adverse effects on your medical care at Texas Hill Country Orthopaedics, P.A. Please read all the information below and ask questions about anything you do not understand before deciding whether to participate. When all of your questions have been answered to your satisfaction, you may then, if you so choose, sign the attached consent forms to volunteer and participate in various aspects of this research study.

**Purpose of the Study**

The primary purpose of this study is to determine if the use of a pre-surgical patient education class with an additional educational module which addresses recovery during the first 12 months is more effective in modifying participant’s pre-operative expectations than participants receiving the standard pre-operative educational class alone. The primary investigator of this research study will be Natasha Ray at Texas Hill Country Orthopaedics, P.A. Mrs. Ray does have ownership in Texas Hill Country Orthopaedics, P.A. stock and is a practicing clinician in this clinic. This research study is being conducted to assist with the fulfillment of a Doctorate of Philosophy degree in Adult, Professional, and Community Education at Texas State University – San Marcos.

You have been invited to participate because you have met the criteria set for study participants. Criteria set for participants to be included in this study are as follows:

* Between the ages of 55 and 85
* You have been diagnosed with Osteoarthritis of the knee(s)
* You are having your first total joint replacement
* The joint being replaced is your knee
* You do not have a diagnosis of dementia or other cognitive disorders
* You retain the right to make your medical decisions and you have not delegated authority to a third party while you are still able to make those decisions indepently
* Your primary language is English

You will be one of 60 individuals that will be invited to participate in this research study. You will be asked to complete a total of 4 surveys, three before your educational class and one after your pre-surgical education course. The process of data collection will be as follows:

* Completion of the Western Ontario McMasters University Osteoarthritis Index 3.1 (WOMAC, 3.1). This questionnaire has been specifically developed for patients with hip and knee arthritis. It has 24 items that ask about your pain, function, and joint stiffness.
* Completion of the Short Form -36 (SF-36). This questionnaire has 36 questions

that ask you about your general physical functioning, role – physical, bodily pain, general health, vitality, social functioning, role – emotional, and your mental health.

* Completion of the Hospital of Special Surgery Total Knee Replacement Expectations Survey©. This survey has 17 questions that ask about your symptoms, activities of daily living, walking distance, employment, and psychological well-being.

Each of these questionnaires/surveys will be given to you after your office visit with the doctor and before you attend the pre-surgical education course at Christus Santa Rosa Hospital of – New Braunfels. Completing these surveys will take you between 15 and 20 minutes to complete. After you attend the pre-operative course at the hospital, you will be asked to complete the following survey:

* Hospital of Special Surgery: Total Knee Replacement Expectations Survey©.

This survey alone should take 5 -7 minutes to complete.

**Procedures used in collecting data**

Psychometric data. These data are acquired in the standard form of questionnaires.

Time commitment: approximately +/- 20 minutes

**Risks and Benefits**

The risks that are associated with this study are minimal. Risks include mild fatigue while completing the required surveys. No other risks have been identified in association with this study.

Continued compliance with Texas Hill Country Orthopaedics’, P.A. HIPAA policies and procedures is of the utmost importance. In addition to this clinic’s HIPAA policy and procedures and consent form, all data gathered will be handled with the utmost care and confidentiality. Participant codes will be assigned on all data collected; therefore no identifying information will appear on any of the data collection forms or digital files. Furthermore, all data will be scanned and stored in your electronic medical records at Texas Hill Country Orthopaedics, P.A. The paper copies that you will complete will be scanned into your electronic medical record that then immediately destroyed. Back-up data will be obtained on a secure server. In addition to the data collected, all study related documents will also be stored in your electronic medical record.

All data obtained in this study will be treated as confidential and will not be released without your written consent. Any publications as a result of this study will not include your name or any identifying information will be used in any reports or publications that may result from this study.

There will be no direct benefits to you as a result of this research. However, you will be an important vehicle in the future of developing patient education programs that assist with helping individuals generate realistic expectations of total joint replacements. The significance of this research is imperative to future individuals that this clinic serves.

**Participant’s Rights**

Your participation in this study is entirely and strictly voluntary. If you have read, understood all of the above information and have decided to participate in this study, you have the right to withdraw your consent and discontinue participation at any time.

If you have any questions or need additional information, please direct them to Natasha D. Ray. Any pertinent questions about the research, research participants\' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413 – [lasser@txstate.edu](mailto:lasser@txstate.edu)), or to Ms. Becky Northcut, Compliance Specialist (512-245-2102). Please reference application number: 2009C6252.

You will be provided a copy of this signed consent form for your personal records. At the completion of this study, you have the right to access the findings and results of the research. Please contact Natasha D. Ray by phone at 830.625.5252 and a copy of the results will be provided to participants if requested.

**Consent to Participate in Minimal Risk Research**

**Statement of Comprehension and Voluntary Agreement**

I am being asked to participate in a patient education research study. By this signing this document accordingly, I acknowledge that I have read and understand the information provided above, that I have been given an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I attest that the information provided is both accurate and complete.

I further attest that am at least 18 years of age or older. I understand that the data I provide will be anonymously maintained, analyzed, presented, and published. By signing below I am providing my consent to participate in the following research titled **“An Examination of the Effects of Pre-operative Education on Patient Expectations in Total Knee Arthroplasties”.** By signing this informed consent, I willingly agree, free of coercion and undue influence, to participate in this (minimal risk) research study.

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Name of Participant Signature of Participant Date

I have explained the research to the participant, and answered all of his/her questions. I believe that he/she understands the information described in this document and, with that understanding, freely and willingly consents to participate:

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Natasha D. Ray, M.A., CCC-SLP Date

(or authorized designate)

**Withdrawal of Consent**

**Study Title:** An Examination of the Effects of Pre-operative Education on Patient Expectations in Total Knee Arthroplasties

This is to inform you that I am **withdrawing** my previously given consent to participate in this study. I understand that my right to withdraw this consent pertains only to data I have provided that has not already been used in an unidentifiable manner as part of a greater aggregate of data. I also understand this right will be waived for any permission that I have provided for the anonymous presentation or publication of my likeness that have already been submitted to an academic venue or that have already been submitted to an academic publication.

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Participant’s Name and Signature Date

You will be offered a copy of this form to keep.

Primary Researchers contact:

**Natasha D. Ray 830.625.5252**

Faculty Sponsor Contact:

**Steve Furney, PhD 512.245.2939**