RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

Department of Orthopaedic Surgery
Rutgers, The State University of New Jersey
Medical Education Building, Room 422
51 French Street, New Brunswick, NJ 08901
p. 732-235-7859 ; f. 732-235-6002
rwjms.rutgers.edu/departments_institutes/orthopaedic

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Utilization of Video as Preoperative Education for Meniscectomy Surgery Patients
Principal Investigator: Charles Gatt, MD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to determine if the use of digital media, specifically an educational video, can increase patient comprehension of pre- and post-operative instructions for patients undergoing meniscectomy procedures. A meniscectomy is a surgical procedure that is used to treat a damaged meniscus. A meniscus is a structure in your knee that is made of cartilage and acts as a shock absorber to help your knee work properly. The secondary objective is to evaluate whether the utilization of video instructions versus a patient handout will lead to lower post-operative use of opioid medications.

Possible harms or burdens - Participation in the study requires completing a questionnaire to determine level of comprehension of pre- and post-operative instructions regarding your upcoming meniscectomy. As with participation in any study, there is a small chance of loss of confidentiality, though every effort is taken to keep your information private.

An alternative to taking part in the research study - If you decide not to take part, you will not receive the additional paper handout or video, but you will receive all of the same medical care, and your interactions with the physician will not be altered.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Charles Gatt, MD 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. Charles Gatt, MD may be reached at 732-537-0909 at 2 Worlds Fair Drive, Somerset, NJ 08873.

The study doctor Dr. Charles Gatt, MD or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

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Why is this study being done?
The primary objective is to compare the effectiveness of video instructions versus a patient handout as method for patient comprehension of pre- and post-operative instructions regarding meniscectomy procedures. Concept areas such as how to care for the incision, how to safely manage pain with and without opioids, and the side effects of opioids will be highlighted. The secondary objective is to evaluate whether the utilization of video instructions versus a patient handout will lead to lower post-operative use of opioid medications.

Who may take part in this study and who may not?
You may participate in the study if you are over the age of 18, English-speaking, and undergoing a meniscectomy procedure, have intact decision-making capacity and have access to the required technology to participate in this study (cell phone to receive text messages and view the instructional video). Patients who do not speak English and those with documented cognitive impairment or neurological disorder affecting word processing or memory may not participate.

Why have I been asked to take part in this study?
You have been asked to participate in this study as you are undergoing a meniscectomy procedure.

How long will the study take and how many subjects will take part?
We will enroll 80-160 patients to participate in this study. The study will last until your first post-operative visit at 10-14 days after the day of your surgery. Once the final survey is completed on day 10-14, your participation in the study will be complete. The total study duration is estimated to be 1 year, or however long is required for the recruitment of the appropriate number of patients to complete the full study.

What will I be asked to do if I take part in this study?
You will be randomized to one of two groups that will each go through the timetable below. You will receive operative instructions at the first preoperative clinic visit when you book your procedure. If you are in the control group, you will be given a physical copy of the handout of operative guidelines at the time you book your surgery in the office, and again in the post-anesthesia care unit (PACU) after surgery. If you are in the study group, you will receive a link at the same time-points by email or text message, when you book your surgery in the office and again in the PACU after surgery. This email or text message will provide you access to a video on YouTube outlining the same operative instructions. At the first postoperative visit, 10 to 14 days after surgery, you will be given a questionnaire to evaluate your comprehension of concepts which were outlined in the video or the handout.

What are the risks of harm or discomforts I might experience if I take part in this study?
Participation in the study requires completion of a survey. As with participation in any study, there is a small chance of loss of confidentiality, though every effort is taken to keep your information private.

Are there any benefits to me if I choose to take part in this study?
You may not personally benefit from taking part in this research, but other people may be helped by what is learned.

What are my alternatives if I do not want to take part in this study?
If you decide not to take part, you will not receive the additional paper handout or video, but you will receive all of the same medical care, and your interactions with the physician will not be altered.

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How will I know if new information is learned that may affect whether I am willing to stay in the 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 me to take Part in this study?
There is no additional cost to you.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. All data will be stored on a password protected document and stored on the Rutgers approved Office Cloud - OneDrive. Only the research team will have access to this information. All members of the research team are CITI-trained. But the information collected about you can never be 100% secure.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Responses to questionnaires

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board, Compliance Boards and other research administrators
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this study 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 this website at any time.

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What will happen to my information collected for this research after the study is over?
The information collected from you for this research will not be used by or distributed to investigators for other research.

What will happen if I am injured during this study?
The University will make appropriate referrals for medical and/or dental treatment for you if you were to sustain personal injuries or illnesses as a direct consequence of participation in the research. Your health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I 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. Charles Gatt at University Orthopaedics Associates, LLC outpatient surgery center located at 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 I contact if I have 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:

Dr. Charles Gatt
Rutgers-RWJUH Department of Orthopaedic Surgery
732-537-0909

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent 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 and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____