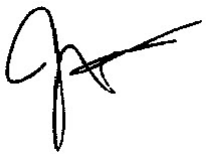
Surgical Outcomes System

In efforts to collect our patient outcomes over time and provide remote monitoring of patient data, we ask each of our patients to participate in our web-based outcome collection tool. This system automatically emails you pre and post-treatment surveys that ask questions such as your level of pain, how you feel, and your ability to perform certain activities in your daily life. Survey results allow us to review your treatment progress in real-time. You may be asked to fill out electronic surveys during your office visit on a computer or tablet and/or from your home computer (if possible). The following consent form explains this process in greater detail. Feel free to ask any of our office staff if you have any questions.

Thank you for your participation,



John A. Schlechter, DO

Primary Email Address: _____

Secondary Email Address: _____

RESEARCH PARTICIPANT HIPAA AUTHORIZATION

Surgical Outcomes System (SOS)

Federal privacy laws protect the use and release of your identifiable health information, which is called protected health information (PHI). Under these laws, you must give permission before your health care providers may use or release your protected health information for the registry research study titled "Orthopaedic sports medicine, arthroscopy, and related surgery registry using the web-based Surgical Outcomes System (SOS)". You are not required to sign this form. However, if you decide to participate in this research study, you must sign this form in addition to reviewing the accompanying Research Participant Information Sheet that details the procedures and risks and benefits of the study. This form will describe the ways that your protected health information will be used and released if you decide to participate in the study.

I. Who is being authorized to release my protected health information and what protected health information will be used and released?

If you give permission and sign this form, you are allowing your study site,

_____

and your doctor and staff to use and release certain kinds of protected health information about you. This includes all health information in your medical and billing records that is related to the research study. For example, your medical record number, email address, date of birth, medical history, diagnosis and medical procedures, medical device(s), other medical data collected by the doctor and study staff and other healthcare providers as part of your normal clinical care, financial charges, and any survey data.

II. Who will use my protected health information and to whom will it be released?

Your protected health information may be used by and released to the following:
The research study staff and affiliated clinic/hospital/ambulatory surgery center employees, the research sponsor Arthrex, Inc., other companies that work for or with Arthrex, such as database administrators; other researchers and scientists; government employees or contractors that perform studies or draft reports; federal and foreign government health agencies, including, but not limited to, the United States Food and Drug Administration and the European Medicines Agency, and Institutional Review Boards, and local ethics committees.

III. What are the purposes for the use and release of my protected health information?

Your protected health information may be used and/or released for the following purposes:

To conduct the research and establish a registry called the Surgical Outcomes System (SOS); (2) To host and provide technical support for the SOS database or other databases that contain the collected data; (3) To review the quality and security of the research; (4) To carry out statistical analyses, and prepare reports which may be provided to your doctor; (5) To help other researchers and scientists carry out other studies or to draft reports for scientific publications relating to these outcomes; (6) To prepare analyses for governments and health insurers or for marketing purposes about surgical and non-operative benefits, cost-effectiveness and patient outcomes, (7) To make reports to government agencies that oversee Arthrex and the other people involved with the studies, (8) To remove from your health information any information that could be used to identify you, (9) To support future product development and improvements to products and surgical procedures, and (10) for other uses/disclosures required by laws or regulations.

Protected health information, if released outside of your study site, may not be protected by federal privacy laws.

IV. Does my permission expire?

Your authorization for use of your personal health information for this specific study does not expire.

V. Can I cancel my permission?

You can cancel your permission at any time. If you want to cancel your permission, please notify your doctor. If you cancel your permission, you may no longer be in the research study. If you cancel your permission, information that was collected and released before your cancellation may continue to be used and released as needed to maintain the reliability of the registry data. If you refuse to sign this form or cancel your permission during the research study, your health care treatment will not be terminated, withdrawn, changed or otherwise affected in any way.

VI. Signature

If you agree to the use and release of your protected health information, please sign below. You will be given a signed copy of this form.

_____ _____

Signature of Research Participant Date

_____

Print Name of Research Participant

For Personal Representative of the Research Participant *(if applicable)*

_____ _____

Signature of Personal Representative Date

_____

Print Name of Personal Representative

_____

Personal Representative Relationship or Authority

RESEARCH PARTICIPANT INFORMATION SHEET

Orthopaedic sports medicine, arthroscopy, and related surgery registry using the web-based Surgical Outcomes System (SOS).

INTRODUCTION AND PURPOSE

You are being asked to participate in a global registry for orthopedics and sports medicine using the web based Surgical Outcomes System (SOS). The purpose of this research study is to create a large clinical database to collect information on patients undergoing orthopaedic and sports medicine related surgery and treatment, and to look at the outcomes and cost-effectiveness associated with treatment procedures.

Your participation in this study will involve that you complete outcome surveys that ask questions such as your level of pain, how you feel, and your ability to perform certain activities in your daily life. Through your completion of these surveys, your doctor has the opportunity to monitor your progress after treatment, even when you may not be scheduled to see him/her. Your doctor is also able to compare your outcomes to the average de-identified global data.

Your participation in the SOS study is voluntary and will not change your treatment in any way. Please read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

PROCEDURES

Your participation will involve completing surveys on your level of pain, function and well- being before and after treatment for at least two years on a web based secure site. Data collection time points are before treatment, multiple times after treatment during the first 6 months, 6 months, and 1 and 2 years after treatment. Depending upon your type of surgery or treatment, you may be requested to complete these same surveys up to 15 years. Completion of these surveys will take approximately 15 minutes or less to complete.

You will be asked to complete these surveys by providing your email address. An email reminder that has a secure link to the survey will be sent to you. If you do not complete the surveys online, you will be emailed another reminder. Your information will be kept secure and confidential, and your name will not be used in the database. If you do not have access to a computer or internet, or do not have an email address, your doctor or designated study staff has the option to collect the survey information over the phone or at the office and enter it into SOS on your behalf.

Before and after your treatment or surgery your doctor will enter your medical information (for example, your medical record number, age, date of birth, medical history, diagnosis and procedures, financial charges) and email address into the registry. Your email address and medical record number will be the only information that directly identifies you and these will be stored encrypted.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating. You may withdraw from this study at any time by contacting your doctor. When you withdraw your permission, no new health information will be entered into SOS after that date. Information that has already been gathered may still be used and given to others. If you leave

the study before the planned final survey, you may be asked by your doctor to consider completion of a final survey. Your part in this study may be stopped at any time by your doctor or the sponsor without your permission.

POTENTIAL RISKS AND DISCOMFORTS

There are no known physical risks associated with being in this study; however the privacy of your health information cannot be guaranteed. You will be told about anything new that might change your decision to be in this study, such as how the data will be collected and used.

ANTICIPATED BENEFITS

You may not receive a direct benefit if you agree to participate; however participation gives your doctor the opportunity to remotely monitor your health progress and outcomes. Future patients may benefit from the information obtained from this study.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not participate.

PRIVACY AND SECURITY

The SOS registry is maintained by the study sponsor, Arthrex, Inc. or another qualified company working with Arthrex. Arthrex manufactures orthopedic medical products that may be used in your treatment; however, Arthrex does not participate in your doctor's selection of medical device or provision of treatment to you. Both your doctor and the study sponsor have taken precautions to protect the data collected for this research. These precautions include for example developing and using unique user ids and passwords to access the registry, not sharing that information with other people, special security clearance for your email address in the database, and using an electronic data storage system that is designed to ensure the security of patient health information according to HIPAA regulations. The information collected about you for this research may be shared with others such as the study staff, sponsor, other researchers, and federal and foreign government agencies as fully described in the accompanying HIPAA Research Participant Authorization. This information is shared for monitoring the quality of the research data, performing clinical and scientific research, medical product development and marketing analysis. Publications or presentations that result from this study will not contain personal information that may identify you.

FINANCIAL OBLIGATION

Responsibility for treatment payment is in no way different from responsibility for payment for patients who do not participate in the study. You will not be paid for your participation.

QUESTIONS AND CONCERNS

Contact your doctor at _____for questions about the study or if you think you have been harmed as a result of joining this study. Contact Research Consulting Review Committee (RCRC) IRB if you have questions about your rights as a research subject: 1-800-562-4789. RCRC IRB is a group of people who perform independent review of research.

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