CAPITAL REGION ORTHOPAEDICS
BONE & JOINT
CENTER
Orthopaedic Excellence. Exceptional Care.

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,
The Bone and Joint Center/ Capital Region Orthopaedics
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;, and the Institutional Review Board that approved this study..

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 remove from your health information any information that could be used to identify you, and (6) for other uses/disclosures required by laws or regulations.

Your de-identified data may additionally be used by your doctor and designated study staff, other doctors and study staff participating in the registry and Arthrex to (1) help other researchers and scientists carry out other studies or to draft reports for scientific publications relating to these outcomes; (2) to prepare analyses for governments and health insurers; (3) or for marketing purposes about surgical and non-operative benefits, cost-effectiveness and patient outcomes; (4) to make reports to government agencies that oversee Arthrex and the other people involved with the studies; and (5) to support future product development and improvements to products and surgical procedures.

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

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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 Email

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

_____ _____
Signature of Personal Representative Date

_____
Print Name of Personal Representative

_____
Personal Representative Relationship or Authority