Consent Form

Title: Evaluating the Implementation, Utility, and Clinical Importance of the Patient-Reported Outcome Measure Information System (PROMIS) in Sarcoma Patients: A Multi-Centered Prospective Cohort Study

Version: 1.0 **Date**: November 3, 2025

NCT Number: ***

Primary Investigator: Dr. Joe Kendal

Co-Investigators:
Dr. Michael Monument
Dr. Shannon Puloski
Dr. Jay Wunder
Dr. Aaron Gazendam
Dr. Kim Tsoi
Dr. Peter Ferguson
Dr. Matthew Houdek
Dr. Krista Goulding

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title	Mobility and Patient-Reported Outcomes Evaluation in Musculoskeletal Oncology Patients
Investigator	Dr. Joseph Kendal
Co-Investigators:	Dr. Michael Monument Dr. Shannon Puloski Dr. Jay Wunder Dr. Aaron Gazendam Dr. Kim Tsoi Dr. Peter Ferguson Dr. Matthew Houdek Dr. Krista Goulding

Sponsors: American Academy of Orthopaedic Sugeons, Musculoskeletal Tumor Society, Sarcoma Strong, Orthopaedic Surgery Catalyst Grant, Calgary Surgical Research Development Fund

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

You are being invited to participate in a research study because you are undergoing surgical management for a tumour located in your muscuoskeletal system, including extremities (arm or leg) and pelvis. The purpose of this study is to help us understand the feasibility of collecting mobility data following surgery and detecting long-term changes in health perceptions using smart devices. To date, this sort of investigation has not been performed in patients with musculoskeletal tumours.

Participating in this study will help us better understand the course of patient recovery following their surgery, facilitating future research and improving future clinical management and health outcomes.

This consent form provides information about the study to assist you with making an informed decision. The researcher will discuss this study with you and will answer any questions you may have. You are encouraged to ask questions. When all your questions have been answered to your satisfaction, you can decide if you want to be in the study or not.

Taking part in this study is voluntary. You may choose whether or not you take part. If you choose to participate, you may leave the study at any time without giving reason or without penalty. Deciding not to take part or deciding to leave the study early will not result in any penalty or effect current or future care or employment.

If you decide to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

Study Design

This study is a multi-centre study involving patients treated surgically for a musculoskeletal tumour at Mount Sinai Hospital, Foothills Medical Center in Calgary, and Mayo Clinic in Rochester, Minnesota and Phoenix, Arizona. There will be approximately 600 participants involved across the four centres. You will be enrolled in this study for about one year.

The normal standard of care for patients with a musculoskeletal tumour involves clinic visits at regular intervals after surgery including every 3 months for the first 2 years for a physical exam and chest x-ray, then every 6 months between years 2 and 5, then yearly between years 5 and 10.

If you choose to participate in this study, you will first be asked to download our research app onto your smart phone. This app was designed by the musculoskeletal oncology team at the University of Calgary. Your mobility data will be collected autonomously and remotely, requiring no interaction from the user. You will be prompted to fill out short questionnaires via the smartphone app pre-operatively and at 6 weeks, 3 months, 6 months, and 1 year post-operatively. At the end of your study participation, you will be asked to complete two short surveys assessing your phone carrying habits and the function of the app.

Study Visits and Procedures

Screening/baseline visit: The first study visit will be a screening/baseline visit. This visit is where we will explain details about the study and how the app works, and any questions you may have will be answered. If you consent to participate in the study, you will be asked to download the app onto your smartphone and the app will prompt you to answer two short questionnaires (Toronto Extremity Salvage Score (TESS) and Patient-Reported Outcome Measure Information System (PROMIS)). For the duration of the study, the app will passively collect data on how active you are, much like a step counter.

6 week postoperative visit: During this appointment, the app will prompt you to complete the two questionnaires. This can be done at home and is considered an extra visit for the purpose of the study.

3 month and 6 month postoperative visits: These are part of your normal visits to the clinic, where you will have a physical exam and chest x-ray**.** You will also be prompted by the app to

complete the two questionnaires. If you are not seen at this time in clinic, the questionnaires can be completed at home.

1 year postoperative visit: This is also part of the normal visits to clinic, where you will have a physical exam and chest x-ray**.** You will be prompted by the app to complete the two questionnaires. If you are not seen at this time in clinic, the questionnaires can be completed at home. Additionally, you will be asked to complete two short surveys assessing your phone carrying habits and the function of the app.

Calendar of Visits

Boxes marked with an X show what will happen at each visit:

Visit	Location	Questionnaire	Time
Screening/baseline	Clinic	X	30 minutes
6 week visit	At home	X	10 min
3 month visit	Clinic	X	10 min
6 month visit	Clinic	X	10 min
1 year visit	Clinic	X	15 min

Reminders

It is important to remember the following things during this study:

- Ask your study team about anything that worries you.
- Tell study staff anything about your health that has changed.
- Tell your study team if you change your mind about being in this study.

Risks Related to Being in the Study

As an observational study with no intervention other than the administration of questionnaire assessments, this study represents only minimal risk or discomfort to participant. There is a small amount of time required to fill out the questionairres.

Inherent to data collection and storage, there is a risk of loss of confidentiality. This is minimized by maintaining the information in a university-compliant database and removing personally identifiable information.

As this is a multi-center study, all sites will be requested to store their data for their patients in a similar manner following their own institutional review board and HIPAA guidelines and that

no identifiable data will be shared between the institutions including disclosure to the University of Calgary, the data hub.

Benefits to Being in the Study

You may or may not receive any direct benefit from being in this study. However, based on the results of this study, we hope to improve future patient care.

Incidental Findings

Questinnaires and information used for the study are not for the purpose of diagnosis, and results will not be reviewed by a doctor or recorded in your medical history. However, during the study, the research team may learn something about you that they didn't expect. For example, the researchers may discover a trend in your questionnaire responses that could potentially be indicative of a health-related event. You will be given the opportunity to decide if you wish to be made aware of this information. If warranted, a physician will meet with you to discuss the findings. They may provide you with a letter to take to your family physician describing the circumstances of the findings and a recommended course of action. Your family physician may, in turn, recommend further diagnostic tests, which may then have an impact on your health and insurance.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying "pass".

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- New information shows that the research is no longer in your best interest
- The research team decides to stop the study
- The Research Ethics Board withdraw permission for this study to continue
- You are unable to complete all required study procedures

If you are removed from this study, the study doctor will discuss the reasons with you.

Alternatives to Being in the Study

You do not have to join this study to receive treatment for your condition.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- Name,
- Address,
- Date of birth
- New or existing medical records including types, dates, and results of medical tests or procedures

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years after completion of the study. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee
- Mount Sinai Hospital Research Ethics Board

Authorized representatives of the above organizations and the organizations listed below may **receive** information related to the study from your medical/clinical study records that will be kept confidential in a secure location and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided (i.e., the information will be de-identified). The records received by these organizations will be coded with a number. The key that indicates what number you have been assigned will be kept secure by the researchers directly involved with your study and will not be released.

The following organizations may receive study data:

- Cumming School of Medicine, University of Calgary (parent institution of this multicenter study)

De-identified copies of the relevant medical information collected in this study including your demographic information, medical comorbidities, and disease- and treatment-specific data will be collected as part of this study. This is required for complete statistical analysis of your post-operative functional recovery.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Data collected using the PROMIS questionnaire system resides on the National Institute of Health servers and no assurance can be made about its confidentiality or that it will only be used for research purposes. Likewise, data collected using the ACTIVATION app resides on on your smartphone manufacturer's servers and no assurance can be made about its confidentiality or that it will only be used for research purposes.

Your coded study data may be used or shared with other researchers (inside and outside of Canada) for future studies. "Coded" means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the study data. This may include storing the coded study data in controlled-access databases for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database. The goal of sharing is to make more research possible. However, the code matching your study data with your name and other directly identifying study data will not be shared.

You will not be asked if you agree to take part in future research studies using your study data. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your study data.

Clinical Trial Registration

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Research Results

You have the right to be informed of the results of this study once the entire study is complete.

If you would like to be informed of the results of this study, please let the study doctor know.

The results of this study will be also be available on the clinical trial registry (see the "Clinical Trial Registration" section for more details).

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the procedures involved with this study. You will not be reimbursed.

Commercialization

It is possible that the research conducted using your study data may eventually lead to the development of new diagnostic tests, new drugs or devices, or other commercial products. If this happens, there are no plans to provide payment to you.

Conflict of Interest

The American Academy of Orthopaedic Surgeons (AAOS), the granting agency funding this study, will pay the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. Jay Wunder at (416) 586-4800 x6341 or the study staff (Raghda AlAtia, Study Coordinator at (416) 586-4800 x1583 or Anthony Griffin, Clinical Research Manager at (416) 586-4800 x5975).

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics Office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies.These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to take part in this study and to the use of my personal health information as described above.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator	Signature	Date

Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant