Official Title	Improving Advance Care Planning Around Mobility Needs Among Patients With Sarcoma
NCT Number	NCT05835154
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Patient Informed Consent

Please carefully read and sign the informed consent below.

Thank you!

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Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

Improving advance care planning around mobility needs among patients with sarcoma Aim 2 - Patient

Principal Investigator: Megan Shen PhD. Fred Hutchinson Cancer Center.
Telephone: 206-667-4172

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to assess the helpfulness and acceptability of a new mobility checklist designed to help people with sarcoma engage in advance care planning related to mobility needs. We are seeking to examine how feasible and acceptable this intervention is among people with sarcoma as part of a research study.

People who agree to join the study will be asked to complete a brief survey, a questionnaire checklist designed to help sarcoma patients, a clinical appointment with a rehabilitation clinician (to assess possible impairments or supportive care needs), and another brief survey and interview (after completing the checklist) that will ask you questions to get your feedback on the checklist. Each survey and interview will be administered in person or over telephone or videoconferencing. All surveys and interviews combined will take approximately 45-60 minutes to complete.

You do not have to join this study. Although the study will not benefit participants directly, we hope the information we learn will help people with sarcoma in the future. There are minimal risks associated with participation in this study. These risks include: possible distress related to answering personal questions related to your cancer, health, mobility needs, and treatment planning.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to improve a mobility checklist designed to help people with sarcoma engage in advance care planning related to mobility needs. We want to obtain

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feedback from people with sarcoma as part of a research study. The feedback will help us optimize the checklist to meet patient's needs.

Since you have been diagnosed with sarcoma, we would like you to join this study.

If you agree to be in this study,

- We will examine your medical records.
- We will ask you to complete a questionnaire checklist related to your mobility needs.
- We will ask you to attend a one-time appointment with a rehabilitation clinician to assess possible impairments and/or supportive care needs or referrals. This visit will be a standard mobility assessment that includes a physical examination of balance, range of motion, and functional evaluations such as a sit-to-stand test.
- We will ask you to complete two sets of questionnaires about your demographics, cancer, health, treatment preferences, and knowledge about mobility needs as well as a brief interview to provide feedback on this content to the study team. Combined, the survey and interview will take 45-60 minutes to complete.
- Your interview with study team members during which you will be asked to provide feedback on the checklist will be audio recorded. All recordings will be confidential and will be destroyed after the study is completed. If you do not give us permission to audio record our interview with you, you are not eligible to participate in the study.
    - Do you give us permission to audio record our interview (record patient response):

      ☐ Yes ☐ No

If you agree to be in this study, may we contact you via text messaging to schedule surveys and interview session?

☐ Yes ☐ No

Do you give us permission to share your survey responses and results with your care team?

☐ Yes ☐ No

If you agree to join this study, your participation will last up to eight weeks and your time devoted to study procedures will be approximately 2 hours.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

If you leave the study, your research record and information cannot be removed from the study records.

What are the risks?

- Possible distress related to answering personal questions related to your cancer, health, mobility needs, and treatment planning.
    - If you experience extreme distress due to study procedures, please contact the researcher on this project, Dr. Megan Shen at 206-667-4172. She can refer you to a psychiatrist or another mental health service provider.
- There is a slight risk of loss of confidentiality.
- The rehabilitation visit may or may not represent standard of care for participants, but the risks to this are low as it just includes an assessment around potential mobility challenges or needs. Risks include possible discomfort (e.g., dizziness) at completing physical assessments. However, patients will be provided the opportunity to accommodate this assessment as needed.

What are the benefits?

Although the study will not benefit you directly, we hope the information we learn will help people with sarcoma and their caregivers in the future.

Protecting your privacy as an individual and the confidentiality of your personal information

If you join this study, some people and organizations might need to look at your medical or research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Center.
- University of Washington.
- Office of Human Research Protections (OHRP).

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you

about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

Will you pay me to be in this study?

You will receive compensation for participating in this study. You will receive $25 for completing each set of surveys (for a total of $50). This will be paid to you in the form of pre-printed checks. The pre-printed checks will be either mailed to you or given to you in person.

How much will this study cost me?

There are no costs for being in this study.

What will my information be used for?

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. There is also a risk of loss of private information. This risk always exists, but, there are procedures in place to minimize the risk.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

In addition to the planned uses described above, we might remove all identifiers and codes from your information. We could then use or share them with other researchers for future research. If you do not want your anonymous information used for other projects, you should not participate in this study.

If we do share your information with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information back to you. We will not contact you or otherwise inform you before we share your information for future research.

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.

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HIPAA Authorization for the Use of Patient Information for Research

By signing this consent form, you permit your patient information to be shared with Fred Hutchinson Cancer Center, its staff, and others who work with them. In this section of the consent form, the term for all these people is "Researchers." Their individual names appear in this consent form.

Federal and state laws require that you give your permission for the Researchers to see and use patient information. A federal law known as the Health Insurance Portability and Accountability Act (also called "HIPAA") protects the confidentiality of patient information created and used by your health care providers. Once patient information is disclosed to the Researchers, it will no longer be protected by HIPAA and could be re-disclosed. However, other laws do apply to the Researchers that require them to protect the confidentiality of your information.

The Researchers will use the patient information only for the purposes named in this form.

1. The patient information to be obtained and used includes:

- All patient information in your medical records needed by the Researchers for the Study. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birth date, and medical record number.

- The specific patient information that will be obtained and used for the Research is described below:
    - Hospital discharge summary
    - Radiology records
    - Medical history/treatment
    - Consultation
    - Radiology films (like X-rays or CT scans)
    - Laboratory/diagnostic test
    - EKG report
    - EEG report
    - Psychological testing
    - Pathology reports
    - Operative report (about an operation)
    - Pathology specimen(s) and/or slide(s)
    - Diagnostic imaging report
    - Dental records
    - Cancer diagnosis

2. What the Researchers may do with patient information.

The Researchers will use your patient information only in the ways described in this consent form. They may also share your patient information with certain people and groups. These may include:

- The sponsor of the study. A sponsor provides support for research studies. The sponsor reviews the study. By law, Researchers share some information with the sponsor.
- Government agencies, review boards, and others who watch over the safety, effectiveness and conduct of the research
- Others, if the law requires.

This consent form describes who will have access to your patient information. It also describes how your information will be protected. By law, the Researchers are required to protect the confidentiality of your information. You may ask questions about what the Researchers will do with your information and how they will protect it.

3. How long the permission will last?

The permission for the Researchers to obtain and use your patient information will end when the Researchers complete the research study AND any review of the research study is completed.

4. Canceling your permission.

You may change your mind and take back your permission anytime. To take back your permission, write to: Dr. Megan Shen at mshen2@fredhutch.org. If you do this, you may no longer be allowed to be in the study. The Researchers may still keep and use any patient information they already have. But they can't obtain more patient information about you for the study unless it is required by a federal agency that reviews the study.

5. Giving permission

You give your permission for the use of your patient information by signing this consent form.

In addition to signing this consent form, federal and state laws require that you provide specific permission for certain types of information to be shared with the Researchers. These types of information include any diagnosis or treatment of HIV/AIDS, sexually transmitted diseases, drug and alcohol abuse, mental illness or psychiatric conditions. Please note that federal law prevents the use of this type of information to criminally investigate or prosecute alcohol or drug abuse patients.

I give my specific authorization for this information to be released:
Yes ___ No ___

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Your rights

- You do not have to join this study. You are free to say "yes" or "no".
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

For more information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-4172 (Dr. Megan Shen) 206-667-5507 (Trevor Bender – Research Coordinator)
If you get sick or hurt in this study	206-667-4172 (Dr. Megan Shen)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

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Signature

Please sign below if you:

- Have read this form (or had it read to you);
- Had the opportunity to ask any questions you have;
- Had the opportunity to discuss the research with the person obtaining consent; and
- Agree to participate in this study.

Participant:

Printed Name	Signature	Date

Protocol: RG1123026
Current version date : 03/10/2025
Previous version date: 10/23/2024
Copies to:

Permissions

Do you give us permission to audio record our interview with you?	◯ Yes ◯ No
If you agree to be in this study, may we contact you via text messaging to schedule surveys and interview session?	◯ Yes ◯ No
Do you give us permission to share your survey responses and results with your care team?	◯ Yes ◯ No

I give my specific authorization for this information to be released:

◯ Yes
◯ No

Patient Signature

Subject first name:

_____

Subject last name:

_____

Subject signature:

_____

Date:

_____