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Fred Hutchinson Cancer Center
Confluence Health
UT Southwestern/Parkland Health and Hospital Systems

Consent to take part in a research study:

Planning For Your Advance Care Needs (PLAN)

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 a new tool (booklet and coaching sessions) designed to help people with cancer plan for and talk about the future of their cancer care with their loved ones/family members and doctors.

People who agree to join the study will be asked to complete two sets of surveys that will be administered in person or over the telephone by a member of our team. These surveys will take approximately 30 minutes to complete. All participants will complete the surveys. However, in our study, we have two groups. One group gets to use the booklet and work with a health coach on the telephone to help them talk about their cancer care wishes. This is Group #1. The other group does not use the booklet or work with a health coach and is Group #2. To decide who goes into which group, we use a method called randomization, which is kind of like flipping a coin. It's a fair way to make sure everyone has the same chance to be in either group.

If you agree to participate in this study, your interviews with study team members during which you complete study surveys and your intervention sessions with the health coach 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 interviews and intervention sessions with you? (Please record your response and sign your initials in the space provided):

  ☐Yes ☐No _____ _____
  Initials Date

If you agree to participate in the study, may we contact you via text messaging to schedule surveys and intervention sessions? (Please record your response)

- ☐Yes ☐No

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 cancer 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, 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 assess a tool (booklet and coaching sessions) designed to help people with cancer plan for and talk about the future of their cancer care with their loved ones/family members and doctors.

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

If you agree to be in this study,

- We will look at your medical records.
- We will ask you to complete a series of surveys about yourself and your health, cancer, health, treatment preferences, and knowledge about making future medical care plans. These surveys will take approximately 30 minutes to complete.
- If you are picked at random to participate in the group with the booklet and health coach (Group #1, called the "intervention group"), you will complete three coaching sessions with a health coach. Each session lasts 45-60 minutes. You will be asked to complete exercises and answer questions during and in between sessions related to the information you discuss with your health coach. These exercises may take an additional 10-15 minutes to complete each week. After you finish the final session, a study team member will contact you in person or over the telephone to complete another set of surveys. These surveys will take approximately 30 minutes to complete and will ask you questions about yourself and your health, cancer, health, treatment preferences, and knowledge about making future medical care plans as well as your views of the booklet and health coach.
- If you are picked at random to participate in the group without the booklet or health coach (Group #2, called the "control condition"), you will complete the first set of surveys as well as a second set of surveys four weeks after you completed the first survey but without receiving the coaching sessons in between. Each set of surveys will take approximately 30 minutes to complete.

If you agree to join this study, your participation will last four to six weeks.

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, and treatment planning. If you experience extreme distress due to study procedures, please contact the lead 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.

What are the benefits?

Although the study will not benefit you directly, we hope the information we learn will help people with cancer 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.
- National Cancer Institute (NCI).
- 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, Confluence Health (Wenatchee Valley Hospital and Clinics, Moses Lake Clinic, Omak Clinic), and UT Southwestern/Parkland Health and Hospital Systems.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law.

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

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.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we are asked to by a court of law. We would use the Certificate to resist any demands for identifying information. Talk to the study researcher if you have questions about this.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others. https://extranet.fredhutch.org/en/u/irb/hipaa-compliance.html

Will you pay me to be in this study?

You will receive compensation for participating in this study. You will receive $25 for completing the first set of surveys and $25 for completing the second set of surveys. This will be paid to you in the form of a gift card.

How much will this study cost me?

There are no costs for being in this study

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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**.**

Your information (even if made anonymous) will not be used for any research other than this study.

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) 206-667-1565 (Claudia De Los Santos – 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)

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

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

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Copies to: