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Fred Hutchinson Cancer Center

Consent to take part in a research study:

Testing the Utility of a Novel Website to Help Cancer Patients Plan for their Future

Patient Consent Form

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 examine the potential impact of a new intervention to help people with cancer engage in advance care planning and other future arrangements. This study is expected to result in a commercial website, in collaboration with the company Peacefully, Inc., to help serve patients and their families in planning for financial, social, and emotional spiritual tasks. As such, results from this study will be utilized to help optimize the website. All information shared, however, will be confidential and kept private.

People who agree to join the study will be asked to complete surveys that will be administered via an online survey, in person, or over the telephone or videoconferencing by a member of our study team. These surveys will take approximately 30-45 minutes to complete. You will then be randomly selected to either participate in the intervention or control condition. If you are randomly selected to participate in the intervention condition, you will utilize the website intervention for four weeks as well as have an introductory session and two "check in" sessions with our intervenionist, who is a trained health coach. After using the website for four weeks, you will complete three post-intervention or follow-up study surveys at 4-, 12-, and 24-weeks after being assigned a study condition.

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 or future 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 examine the potential impact of a new intervention to help people with cancer engage in advance care planning (the care they would want if they were unable to communicate) and other types of future arrangements (financial, emotional spiritual, social). We are seeking to examine the impact of the intervention on patients' engagement in various future planning tasks such as advance care planning, financial planning, and social and emotional support as part of a research study.

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 examine your medical records.
- We will ask you to complete a series of questionnaires about your demographics, cancer, health, treatment preferences, knowledge of advance care planning, and engagement in financial, social, and emotional spiritual. These questionnaires will take approximately 40-45 minutes to complete.
- You will be randomly selected to either participate in the intervention or control condition.
    - If you are randomly selected to participate in the intervention condition, you will utilize the website intervention for four weeks as well as have an introductory session and two "check in" sessions with our interventionist, who is a trained health coach. The introductory session will last approximately 30-45 minutes and the check-in sessions will last approximately 15 minutes. After using the website for four weeks, you will be asked to complete another set of surveys. You will be given these same surveys 12-weeks and 24-weeks after joining the study. These surveys will take approximately 30-45 minutes to complete and will ask you about your demographics, cancer, health, treatment preferences, and knowledge of advance care planning.

      If you are randomly selected to participate in the control condition, you will complete the first set of surveys as well surveys 4, 12, and 24 weeks after you complete the first survey but without receiving the intervention in between. Each set of surveys will take approximately 30-45 minutes to complete.

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

□ Yes □ No

If you agree to participate in this study, we would like to audio-record the check-in sessions with the interventionist. All recordings will be confidential and will be destroyed after the study is completed.

- Do you give us permission to audio record our check-in sessions with you? (record patient response):

  □ Yes □ No

If you agree to join this study, your participation will last 24 weeks (6 months).

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 test results 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 researcher on this project, Dr. Megan Shen. She can connect you with a mental health 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.

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 additional surveys (for a total of $100). 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.

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 Institute for Nursing Research (NINR).
- 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
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.
- Peacefully, Inc., a collaborative investigator with Fred Hutchinson Cancer Center.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your 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. 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.

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.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This 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. The Certificate may not last the duration of the research. 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 the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe 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.

What will my information be used for?

Your information will be used for the purposes of this study. Your information will be utilized to help optimize the intervention website which aims to help people with cancer engage in advance care planning and other future arrangements.

Your information might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your information.

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.

Will my information ever be use for future research?

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

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 ___

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 or email at mshen2@fredhutch.org (Dr. Megan Shen) 206-667-6844 or email at tbender@fredhutch.org (Trevor Binder – 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)

Signatures

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 and authorize your doctors and other health care providers to disclose patient information that identifies you with the researchers.

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: