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Fred Hutchinson Cancer Center

Consent to take part in a research study:

IMPACT Study

Improving Access to Cancer Survivorship via Telehealth

Principal Investigator: Eric Chow, MD, MPH, University of Washington
For more information contact The IMPACT Study at Fred Hutchinson Cancer Center, 1-888-626-0922.

Important things to know about this study

You are invited to participate in this research study. *The purpose of this research is to determine if helping cancer survivors develop their own survivorship care plan, with and without receiving an education session on cancer survivorship, can improve their ability to manage their health and well-being.*

We will enroll up to 150 people. Only adult cancer survivors who have completed their primary (main) treatment will be eligible to participate.

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.

The 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 decide to join this study, we will give you a copy of this form to keep for future reference.

What research tests and procedures are part of this study? / What will happen in this study?

People who agree to join the study will be asked to complete two questionnaires, one at the beginning and one at the end of the study, either on paper, on-line, or over the phone with study staff, depending on your preference. The questionnaires will ask you about the treatment that you received during your care and about how you manage your health. You will also be asked to give researchers at the Fred Hutchinson Cancer Center permission to access your medical records. They will keep your records confidential.

We will use information from the questionnaire and your medical records to create a document called a ‘Survivorship Care Plan’. This document contains a summary of your cancer diagnosis and treatment that you received, as well as recommendations for your future care. We will send you this document and will also share it with your primary care provider.

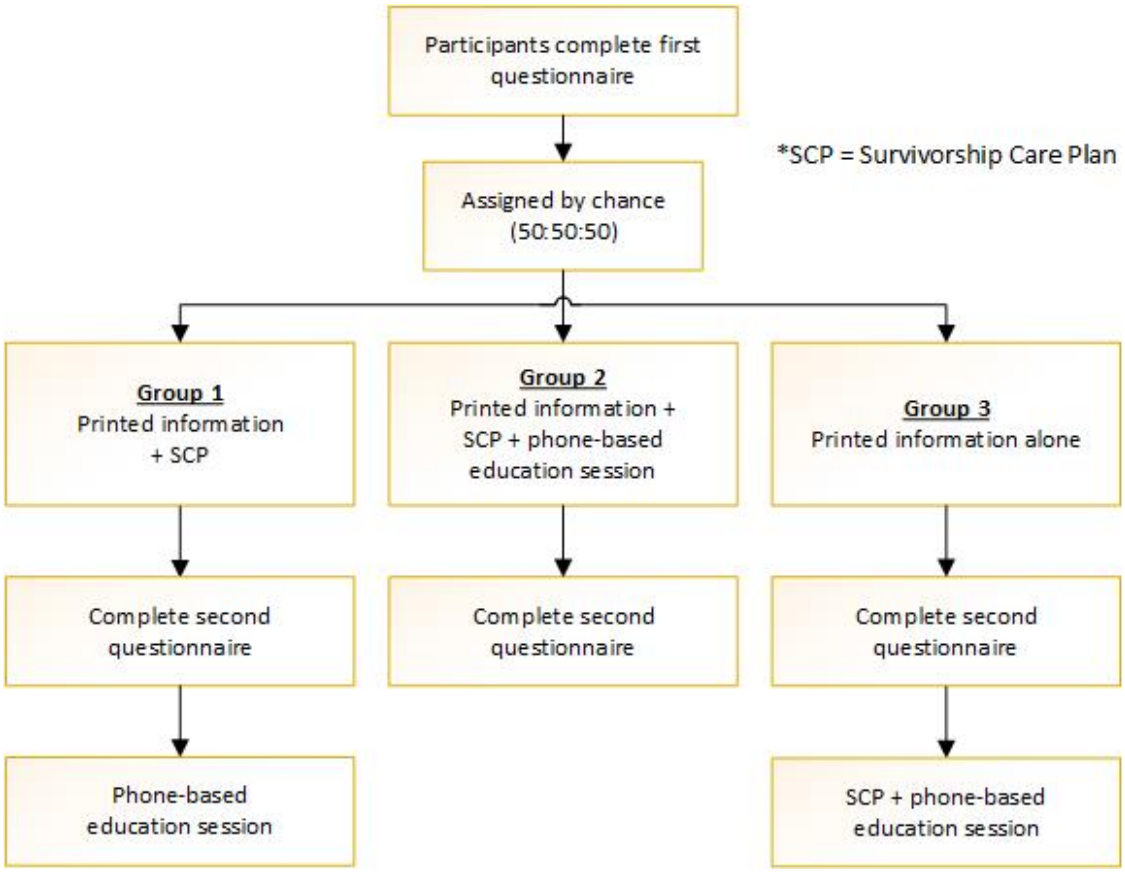
If you do not already have a copy of your survivorship care plan, this will give you a history of your cancer treatment and care, and some recommendations for your future health care.

You will also receive a phone-based education session from trained health educators at the National Cancer Institute's Cancer Information Service, who are trained to provide confidential responses to specific questions about cancer. This is a free program provided to the public by the U.S. National Institutes of Health to provide personalized, confidential responses to specific questions about cancer.

There are three groups of participants in this study. Each group will receive the same material about adjusting to life after cancer but will receive the information in a different order. We will use a computer program to decide by chance which study group you would be assigned to. About 50 people will be assigned by chance to each group.

- Group 1 will receive their Survivorship Care Plan within one month of enrolling onto the study. Participants will then complete a follow-up questionnaire 2-3 months later. Once complete, they can then access the education session if they want.
- Group 2 will also receive their Survivorship Care Plan within one month of enrolling onto the study. Participants will then be asked to schedule an education session at the same time. They will then be asked to complete a follow-up questionnaire 2-3 months later.
- Group 3 will be asked to complete the follow-up questionnaire a few months after enrollment onto the study, and afterwards, will receive their Survivorship Care Plan and can then access the education session if they want.

This figure summarizes the different parts of the study:



IRB Approval: 10/26/2023

How long will I be in this study?

We think you will be in this study for about 4 months. The total time includes the time required to collect your medical records, develop your personal survivorship care plan, and complete the 2 study questionnaires. If you are scheduled for a phone-based education session, the session itself will take approximately 30 minutes.

Risks and benefits to being in the study

What are the risks?

- While unlikely, the education session may discuss long-term health problems which could cause you to feel upset or worried.
- Loss of confidentiality or privacy. This would mean that someone other the research team may find out that you were in the research or see your answers or medical information.
- There could be other risks that we are not aware of. If we find out about new risks, we will tell you.

What are the benefits?

Although the study will not benefit participants directly, we hope the information we learn will help people in the future.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

We will do our best to keep the personal information in your medical record confidential. When analyzing your data, it will be **de-identified**. That is, we will remove your name, address, or telephone number from the records. We will not share your data with other researchers or use it for any other reason outside of this study. However, some people or organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study at the Fred Hutchinson Cancer Center.
- 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.
- The National Institutes of Health (NIH) a government agency who funded this study
- Office for Human Research Protections, and other agencies as required.

We will do our best to keep the personal information in your medical record confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, a court may order study information to 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.

Certificate of Confidentiality

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 were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold your research information if you give your 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 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.

Will you pay me to be in this study?

We will pay you $25 at the beginning of the study and another $25 when you complete the entire study.

How much will this study cost me?

There are no extra costs for being in this study.

What if you get sick or hurt after you join this study?

There are no anticipated risks to your health from being in this study. However, you may become ill while enrolled in this study for other reasons.

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

If you do become ill, immediately contact your primary healthcare provider. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.
You will not lose any legal right to seek payment for treatment if you sign this form. If you feel you have been hurt by this study, please call Dr. Chow at 206.667.4630 or toll free at 1.888-626-0922.

Your rights

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change. However, if you leave the study, your information cannot be removed from the study records.
- 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 may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information

If you have questions or concerns about this study, you may talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	1-888-626-0922
If you get sick or hurt in this study	1-888-626-0922
Your rights as a research participant	206.667.5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

What will my information and samples be used for?

Your information will be used for the purposes of this study.

Do you agree to participate in the IMPACT Study?

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 including about risks of taking part in the study;
- had the opportunity to discuss the research with the person obtaining consent;
- agree to participate in this study.

Participant:

Printed Name	Signature	Date