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Fred Hutchinson Cancer Center
Dana Farber Cancer Institute
University of California Los Angeles
Memorial Sloan-Kettering Cancer Center
University of Pennsylvania Abramson Cancer Center.

Consent to take part in a research study:

INSPIRE–AYA: A Multicenter INteractive Survivorship Program to Improve Healthcare REsources for Adolescent and Young Adult (AYA) Cancer Survivors

Principal Investigator: K. Scott Baker, MD. Fred Hutchinson Cancer Center, University of Washington. 206-667-5594

Co-Investigators:

Multi-Center Performance Sites:		
Investigator	Role	Phone Number
Jean Yi, PhD	Investigator, Fred Hutchinson Cancer Center	(206) 667-3435
Wendy Leisenring, ScD	Biostatistician, Fred Hutchinson Cancer Center	(206) 667-4374
Ann Partridge, MD, MPH	Site PI, Dana Farber Cancer Institute	(617) 632-3800
Patricia Ganz, MD	Site PI, University of California Los Angeles	(310) 206-1404
Danielle Novetsky Friedman, MD, MS	Site PI, Memorial Sloan-Kettering Cancer Center	(212) 639-7376
Linda Jacobs, PhD, RN	Site PI, University of Pennsylvania Abramson Cancer Center	(215) 615-3371

Emergency (24-hour) phone: (888) 344-5678 **Fax:** 206-667-4356

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We would like you to join this research study.

Since you had treatment for cancer as an adolescent or young adult (AYA) between 1 and 5 years ago, we would like to ask you to join this research study. We will enroll about 140 paticipants from Fred Hutchinson Cancer Center (Fred Hutch, formerly Seattle Cancer Care Alliance) and about 700 people nation-wide.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

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, the medical care you receive from your health care providers will not change.

Why are we doing this study?

We are doing this study to examine ways to improve the health of AYA cancer survivors. After treatment many survivors may feel stressed or may be unsure of what health care they need as a cancer survivor. We want to know if an online program called 'INSPIRE–AYA' can improve stress and health care for AYA cancer survivors.

In this study, we want to compare the online INSPIRE–AYA program to the standard care of available online sites for cancer survivors to learn which is better at meeting the health resource needs for AYA survivors.

You will be assigned to a study group.

There are 2 groups of patients in this study based on your scores on the first survey. We will give different treatments to different groups and compare the results. This is how we hope to find out if the INSPIRE–AYA program is effective.

If you agree to be in this study, you will be randomly assigned by a computer to receive options that can include:

1. Immediate access to the INSPIRE–AYA program which includes a mobile application for smartphones, a website, and a phone call after two weeks to answer any questions you have. You can still be in the study if you do not have a smartphone. In addition:
    - We will mail you copies of your personal survivorship care plan that you can take to your health care providers and discuss with them.
    - You will have the option to join the INSPIRE–AYA private Facebook and/or Instagram groups and/or secret Twitter INSPIRE–AYA group just for AYA survivors on the INSPIRE–AYA study. You can still be in the study if you do not join them. The sites are moderated by one of the INSPIRE–AYA study staff. We will note whether you join the private social media sites, but we will not identify or record who makes any specific comments on the sites.
    - You will have an option for up to four phone calls after six weeks to help you use the program.
2. Immediate access to an online site that has descriptions and links to many different types of survivorship resources that existed before the INSPIRE–AYA program. You also will have delayed access to the INSPIRE–AYA online program after 12

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months, including the mailed copies of your personal survivorship care plan that you can take to your health care providers and discuss with them.

Neither you nor your doctor can choose the group you will be in. You will have a 1-in-2 chance of being placed in a given group.

What research tests, procedures, and treatments are part of this study?

If you decide to join this study, we will ask you to tell us how you are doing three times: at the beginning of the study, after 3 months, and after 12 months. At those times, we will contact you by phone or email to tell you how to access and complete the survey. Some of the questions on the survey may be sensitive. If a question makes you feel uncomfortable, you may choose not to answer.

If you are assigned to the immediate INSPIRE–AYA program, you will have open access to the INSPIRE–AYA program mobile app, website, and social media options. After two weeks we will contact you for a phone call to address any questions you may have about using the INSPIRE–AYA program. That call is optional. After six weeks, we will ask you a few questions about how you are doing with the INSPIRE–AYA program. You will then have an option to receive up to four phone calls to assist you in using the online program.

If you participate in the optional phone calls, we would like to record these calls only to confirm that the study staff calling you is following the call guidelines for the study. Before we record the calls we would ask your permission. We would use only your first name on the audiotape and put no other identifying information on the audiotape. You can say no to us recording these calls and still participate in the study.

If you are assigned to delayed access to the online site, you will have full access to the online site after you complete the 12-month survey. We also will mail you copies of your personal survivorship care plan that you can take to your health care providers and discuss with them.

The INSPIRE–AYA study provides no medical treatment or medical advice. The study provides you with resources to make informed choices with your health care providers and tools to track the health care you receive, as well as information on reducing stress.

How long will I be in this study?

You will be in this study for one year. After that, you are free to continue visiting the online site until the study closes, but you have no obligation to do so. We may contact you in the future for studies related to this study. If contacted, you would have the choice to say yes or no.

The study doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

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If you are thinking about dropping out of this study, please tell the study investigator. You can decide to drop out of the study at any time. If you leave the study, your study information that has already been collected cannot be removed from the study records.

What are the risks?

The following are rare and limited risks expected with this study:

- You may experience distress from providing information on the surveys.
- Some of the questions may be sensitive. If a question makes you feel uncomfortable, you may choose not to answer.
- You may experience unwanted intrusions into your privacy through calls or emails from study staff. You can let us know that you would like only emails or only phone calls.

What are the benefits?

We do not know if this study will benefit participants. We hope that you will find it easier to meet your health care needs and track your exams and test results after your participation in the study. You may have reducedstress or worry after your participation in the study. We hope the information we learn will help AYA adults in the future who have cancer.

You have other choices besides this study.

You do not have to join 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. Saying no will not change your other contacts with your treatment center in any way. Whatever you decide, your regular medical care will not change. You would not lose any legal right to seek payment for treatment if you sign this form.

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

If you join this study, specific health information about you will be shared with Fred Hutch study staff, and others who work with them who are described below, and their local teams participating in this study. This is necessary so that we can personalize your Survivorship Care Plan and other study materials and for quality assurance and data analysis. If you do not agree to allow your health information needed for the study to be shared with the study staff or the people and organizations listed below, you cannot participate in this study.

In this form, all these people together are called “Researchers.” Their names appear at the beginning of this Research Consent form. A federal law known as the Health Insurance Portability and Accountability Act or “HIPAA,” protects the confidentiality of your health information. Your doctors and other health care providers generally won’t share this “protected health information” with the Researchers without your permission. By signing this form, you are explicitly agreeing to allow the Researchers to see all of your protected health information for use in this study. This includes sensitive health information that is subject to additional legal protection such as information about alcohol and substance abuse or mental health counseling. This sensitive information also includes health information about sexually transmitted disease (including HIV) diagnosis and treatment. Once the Researchers get your protected health information, the HIPAA

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protections no longer apply but the Researchers are required by other laws to protect the confidentiality of this information. The Researchers may redisclose your protected heatlh information for other research purposes as approved by an Institutional Review Board (IRB). An IRB is a group that reviews research studies to protect your rights as a research participant. After your information has been given to others, there is a risk that it could be shared without your permission.

The Researchers may remove your name (and other information that could identify you from your protected health information). No one would know the information was yours. If your name is removed, the information may be used, created, and shared by the Researchers as the law allows. (This includes other research purposes.) This form would no longer limit the way the Researchers use, create, and share the information. The information you provide, and the protected health information we receive from your health care providers will become part of the study database or data repository. Unless you take back your permission, the permission you provide by signing this form will end when the study ends or the database or data repository is destroyed, whichever is later.

Some people or organizations may need to look at your research records for quality assurance, data analysis or investigations. We want you to know who may use this information and how they may use it. They include:

- Researchers, doctors or healthcare professionals involved with this study, including those at the Fred Hutchinson Cancer Center.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB.
- People at your treatment center and its related institutions participating in the study. This could be at one of the following: Dana Farber Cancer Institute, University of California Los Angeles, Memorial Sloan-Kettering Cancer Center, University of Pennsylvania Abramson Cancer Center, Fred Hutchinson Cancer Center (formerly Seattle Cancer Care Alliance). People at the treatment centers where you were not treated would not have access to your identifiable research records.
- US National Institutes of Health, National Cancer Institute, and Office for Human Research Protections.

These people are interested in study data, not your personal information. Personal information is information that can identify you. It may include your name, date of birth, social security number, phone number, address, medical information or other information.

Medical information that can identify you will be created if you take part in this study. This may include information about your participation in this study, information used to find out whether you are eligible to take part in this study, medical history (including exams, tests, treatments, responses, labs and other procedures or tests) and any other information that you may release to us.

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. For example, workplace safety rules may require health workers to contact you. Or a court may order study information to be disclosed. Such cases are rare.

The Researchers and NIH (the federal agency supporting the study) will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.

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

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.

You may change your mind and take back your permission at any time. To take back your permission, write to: Dr. Scott Baker
1100 Fairview Avenue N, D5-280
Seattle, WA 98108

If you do this, you will no longer be allowed to be in the Study. If we have your protected health information by then, it will stay in the Study record.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by U.S. Law. This online site will not include information that can identify you.

At most, the online site will include a summary of the results. You can search this online site at any time.

By law, we must protect the privacy of health information about you. We may use, create, or share your health information for research **only if you let us**. This form describes what we would do. Please read it carefully. You can print a copy of this form at any time.

Will you pay me to be in this study?

We will give you a $25 gift card after you complete the initial study survey and after you complete the 1 year follow-up survey.

It is possible that a commercial product could result from this study. You will not receive compensation or profit from any such product.

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How much will this study cost me?

There are no costs for being in this study.

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

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. You would not lose any legal right to seek payment for treatment if you sign this form.

For all other medical problems or illness related to this research, immediately contact Dr. K. Scott Baker at 206-667-5594 or the doctor from your treatment center who is listed on the first page of this form. 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.

Your rights

- You do not have to join this study. You are free to say yes or no.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). Your regular medical care will not change. There is no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- 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. 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):	206-667-5566 (Dr. Scott Baker) 888-344-5678 (study toll free number)
If you get sick or hurt in this study:	206-667-5566 (Dr. K. Scott Baker) 888-344-5678 (study toll free number)
Your rights as a research participant:	206-667-5900, IRO@fredhutch.org, Director of Institutional Review Office, Fred Hutchinson Cancer Center

Emergency number (24 hours): 888-344-5678

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Agreeing to participate

If you have read this form (or had it read to you), asked any questions, and agree to participate, please select “I Agree”.

If you do not want to participate, please select 'I Disagree'

If you participate in the phone call component of the study, is it ok if we use text messaging to contact you to schedule? ☐ Yes ☐ No

If you agree to be contacted for future studies, please select “Yes, it’s ok to contact me for future studies”.

You can save or print a copy of this form on the next page.