IRB Approved
Consent Release Date: 05/06/2015
Consent Expiration Date: 05/22/2016

Fred Hutchinson Cancer Research Center
H. Lee Moffitt Cancer Center and Research Institute
University of Nebraska
University of Pennsylvania

Consent to take part in a research study:

INSPIRE for Survivorship after Transplant: A Multicenter Randomized Controlled Trial of an Internet and Social-media Program for Long-term Hematopoietic Cell Transplantation Survivors

Principal Investigator: Karen Syrjala, PhD, Member, FHCRC and Professor of Psychiatry and Behavioral Sciences, UW, 206-667-4579;

Co-Investigators:

Fred Hutchinson Cancer Research Center:		
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Emergency number (24 hours): 888-344-5678 **Fax:** 206-667-4356

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We would like you to join this research study.

Since you have had a bone marrow or blood stem cell transplant between 2 and 10 years ago, we would like to ask you to join this research study. We will enroll up to 1600 people.

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, your regular medical care will not change.

Why are we doing this study?

We are doing this study to examine ways to improve the health of long-term survivors of bone marrow or blood stem cell transplant. We want to know if a survivorship-focused internet program can improve mood, stress, and preventive health care, and provide useful health resources for transplant survivors.

In this study, we want to compare a survivorship internet program to the standard treatment of currently available internet sites for transplant survivors to learn which works better for people who have received bone marrow or blood stem cell transplants.

Patients in this study will either receive immediate access to the survivorship internet program that includes links to existing resources, or will receive links to existing resources and delayed access to the full internet program. All participants will eventually receive access to the survivorship internet program.

You will be assigned to a study group.

There are 2 groups of patients in this study. We will give different treatments to different groups, and compare the results. This is how we hope to find out if the internet 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 survivorship internet program
2. immediate access to an internet site that has descriptions and links to other online resources, and delayed access to the survivorship internet program after 12 months

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.

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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, email, or text messages to tell you how to access the internet site and complete the online survey. You can tell us by which method you prefer to be contacted. If you are in the delayed access to the internet site group, you will have full access to the internet site after you complete the 12 month survey. Some of the questions may be sensitive. If a question makes you feel uncomfortable, you may choose not to answer.

This is a study of an education and behavior-based treatment. No medical treatment is provided, although you will receive medical guidelines you can take to your doctor for individualizing to your own needs.

How long will I be in this study?

We think you will be in this study for at least one year. After that, you are free to continue visiting the internet site until the study closes, but you have no obligation to do so.

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.

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 survey information cannot be removed from the study records.

What are the risks?

Limited risks are expected with this study:

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

You can use as much or as little of the internet site information as you like.

What are the benefits?

We do not know if this study will benefit participants. You may have improved mood or find that you manage your health needs better after your participation in the study. We hope the information we learn will help people after transplant in the future.

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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. Saying no will not change your other contacts with your treatment center in any way. Your regular medical care will not change.

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

If you agree to join this study, health information about you will be shared with Fred Hutchinson Cancer Research Center, its staff, and others who work with them. 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 agreeing to allow the Researchers to see all of your protected health information for use in this study. Once the Researchers get your protected health information, the HIPAA protections no longer apply but the Researchers are required by other laws to protect the confidentiality of this information.

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. 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. Unless you take back your permission, this form does not have an ending date.

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.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children's, and Seattle Cancer Care Alliance.
- H. Lee Moffitt Cancer Center and Research Institute, University of Nebraska Medical Center, and University of Pennsylvania.
- 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, or other information.

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

You do not have to agree to give permission ("authorization"). If you do not, you will not be allowed to join the Study.

You may change your mind and take back your permission at any time. To take back your permission, write to: Dr. Karen Syrjala
1100 Fairview Avenue N, D5-220
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.

You can print a copy of this form at any time.

The Researchers and NIH 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. 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 internet site will not include information that can identify you. At most, the internet site will include a summary of the results. You can search this internet 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?

There is no payment for being in this study.

How much will this study cost me?

There are no extra costs for being in this study.

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.

- 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)	206-667-4579 (Dr. Karen Syrjala) 888-344-5678 (toll free number)
If you get sick or hurt in this study	206-667-4579 (Dr. Karen Syrjala) 888-344-5678 (toll free number)
Your rights as a research participant	206-667-4867 (Karen Hansen, Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

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

Agreeing to participate

If you have read this form (or had it read to you), asked any questions, and agree to participate, please click the “I accept” button to indicate that you agree to this consent. A copy of the consent form is available at all times on the INSPIRE internet site.

Protocol: 2605.00
Current version date: 09/25/14
Previous version date: 08/20/14
Copies to: Patient, Research File, Data Management: Mail Stop LF-229